Global Clinical Engineering Journal

Vol.8 Issue 1

Publisher International Medical Sciences Group, LLC

GlobalCE

open access

ISSN: 2578-2762

GlobalCE

Editor's Corner

Clinical Engineering in the Age of Intelligent Systems

Why AI Literacy, Governance, and Ethical Competence Are No Longer Optional

We are living in the midst of a technological inflection point. For the first time in history, we possess computational systems capable of performing tasks that, in many domains, rival aspects of human cognitive performance. Artificial Intelligence is no longer experimental; it is embedded in diagnostics, imaging, predictive analytics, decision support, workflow optimization, and resource management across healthcare systems worldwide.

Yet precisely at this moment of unprecedented capability, the profession risks making one of two fundamental mistakes.

On one side are those who view AI as the solution to all systemic inefficiencies and clinical challenges. On the other are those who see it as an existential threat—an opaque force that may erode professional autonomy, accountability, or patient safety. As with most transformative technologies, the truth lies between these extremes.

Artificial Intelligence is neither savior nor destroyer. It is a collection of tools—powerful tools—that can enhance human resolutory capacity if, and only if, two essential conditions are met.

First, the human in the loop must possess the cognitive and professional maturity to properly interpret, validate, challenge, and contextualize AI-generated outputs. The role of the clinical engineer is not to passively deploy intelligent systems, but to critically assess them—understanding when to accept their conclusions, when to question them, and when to override them.

Second, the technology itself must be developed, trained, and deployed within a framework of context awareness, accountability, traceability, and governance. AI systems do not operate in isolation. They depend on data quality, ontologies, interoperability standards, lifecycle management, cybersecurity safeguards, and ethical oversight. When components are assembled without structured integration—without guardrails, interoperability layers, or standards alignment—we do not create solutions. We amplify complexity and risk.

Healthcare systems are sociotechnical ecosystems. Introducing AI into these environments without governance does not simplify them; it can fragment them further.

Clinical engineers therefore face a critical transition. Historically, the profession has been the steward of medical devices, infrastructure, and safety systems. Today, we are becoming stewards of intelligent systems. This shift demands more than operational familiarity. It demands conceptual literacy.

We must understand not merely how to use AI tools, but why they function as they do.

- How are solutions generated?
- What data structures shape outputs?
- What forms of bias or drift may influence performance?
- Are errors random anomalies, or systemic consequences of training limitations?
- How do we ensure traceability and accountability?
- What governance structures activate when systems fail—and they will fail?

Without the ability to answer these questions, we risk surrendering professional agency to black-box systems we neither fully understand nor adequately supervise.

Technology can empower clinical engineering—or it can become a hindrance. The difference lies in literacy, governance, and intentional design.

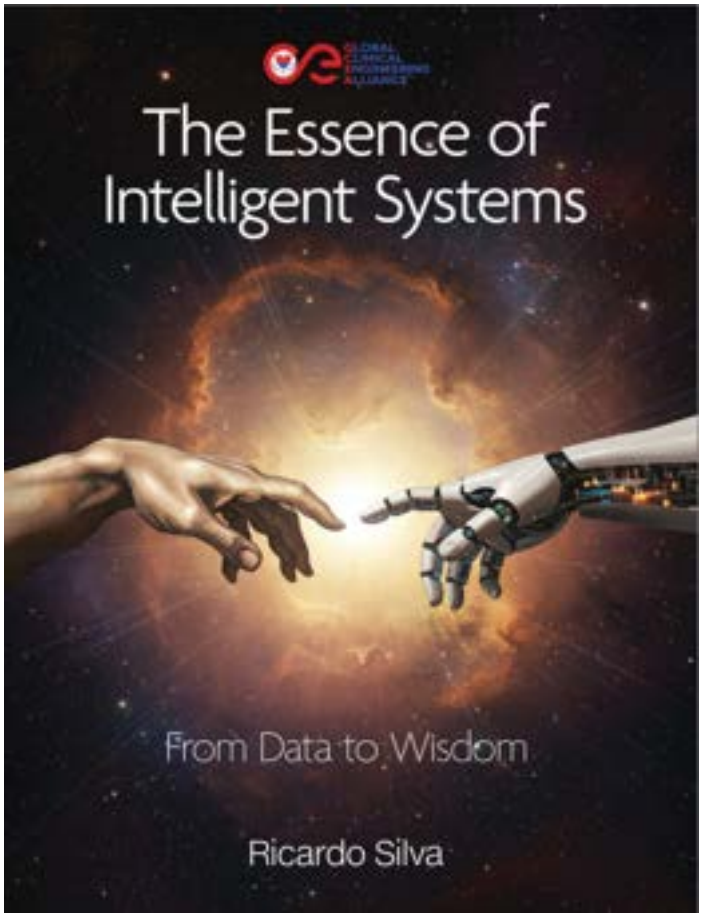
In *The Essence of Intelligent Systems*, I argue that intelligence—artificial or biological—must be understood as structured information operating within constraints. Without ethical boundaries, contextual awareness, and accountability mechanisms, intelligent systems become unstable. When integrated responsibly, however, they can extend human capability, improve decision quality, and strengthen healthcare delivery.

The future of clinical engineering will not be defined by how rapidly we adopt AI tools, but by how rigorously we govern them.

To support this transition, GCEA, through the Health Technology Foundation and its collaborators, is developing technical, academic, and educational initiatives designed to upskill clinical engineers for the age of intelligent systems. These efforts aim to cultivate not just technical competency, but ethical discernment and systems-level thinking.

The question before us is not whether AI will shape healthcare. It already does. The question is whether clinical engineers will shape how AI is governed, integrated, and held accountable.

If we rise to this responsibility, we will not be displaced by intelligent systems. We will become their architects.



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CONTENTS

Editor's Corner 1

Original Research Article: Is It Possible to Detect Effects of the COVID-19 Pandemic on the Prevalence of Malnutrition-Anorexia Using Big Data Tools in a Pediatric Population? 5
Ignacio Diez Lopez, Sandra Maeso Mendez, Gaspar Sanchez Merino, Iñaki Zorrilla Martinez, Ana Gonzalez-Pinto

Original Research Article: Variation in Phototherapy Treatment in Some Selected Hospitals in Ghana 15
David Ebo Anderson, Van Wellington Elloh, Srinivason Shanker Balapangu, Isaac Arhin, Daniel Abbeyquaye, Seyram Perpetual, Anderson Mon

Original Research Article: Facilitating Tongue Length and Mobility Using a Novel Loop Device for Dysphagia in Stroke Survivors: Efficacy in a Quasi-Randomized Study 25
Deeksha Vishwakarma, Mayank Shukla

Original Research Article: Functional Significance of the Curve of Spee: Electromyographic Analysis of Young Adults—A Preliminary Study 36
Enzo Maria Cumbo, Ilde Bertolino, Pietro Messina, Giuseppe Gallina, Giuseppa Bilello, Luigi Caradonna, Mohmed Isaqali Karobari, Anand Marya, Giuseppe Alessandro Scardina

Original Research Article: Predicting Patient Satisfaction in Indian Healthcare Using Artificial Intelligence: A Data-Driven Approach to Patient Relationship Management 45
Varun Kumar Sahu, Sumita Dave, Vedang Dave

Original Research Article: Genitourinary System Imaging with Low-Cost Portable Ultrasound Device in the Context of Telemedicine Implementation 52
Afroza Naznin, Muhammad Abdul Kadir, Fatima Begum, Khondkar Siddique-e Rabbani

CONTENTS

Original Research Article: Accuracy of Control of Infusion Pumps in the Post-Market: A Practical Approach Based on IEC 60601-2-24: 2012 66
Diego Rosa, Edison Silva, Miguel Nunes, Danilo Nascimento, Paulo Zanuzzio, Henrique Moriya

Original Research Article: Artificial Intelligence and the Future in Knee Surgery: Challenges and Opportunities for Personalized Care 73
Luca Andriollo, Corrado Ciatti, Stefano Marco Paolo Rossi, Francesco Benazzo

Original Research Article: Adhesion Characteristics of HAp Functional Coatings onto 3D-Printed Ti-6Al-4V and PEEK IPCs for Enhanced Bioactivity 79
Sahil Mehta, Abhineet Saini

Engineering Report: Role of a Biomedical Engineer in Latin America as a Supplier of Medical Devices and Services for an Asian Transnational Company 87
Daniel Ricardo Argumedo

Review: Biomedical Implants and Applications: Current Innovative Materials and Regenerative Solutions 95
Prachi Palta, Aastha Palta, Virinder Kumar

Original Research Article: The Role of Clinical Engineering in Management and Decision-Making in Brazilian Hospitals 114
Marcello Dias Bonfim, Ana Maria Malik

This paper is part of the Special Issue on Transformation of Medical Technologies for Improving Patient Care Outcomes.
Guest Editor: Prof. Ignacio Díez López, Hospital Universitario Araba, Vitoria-Gasteiz, Spain.

Received September 12, 2024, accepted June 11, 2025, publication date for online-first January 21, 2026.

Original Research Article

Is It Possible to Detect Effects of the COVID-19 Pandemic on the Prevalence of Malnutrition-Anorexia Using Big Data Tools in a Pediatric Population?

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ABSTRACT

This research investigates the consequences of the COVID-19 lockdown on pediatric health, with a specific focus on nutritional deficiencies potentially linked to disordered eating. Contemporary Big Data analytical techniques provide a powerful framework for detecting such population-level shifts and exploring their underlying drivers.

Primary Aim: To determine if significant changes occurred in the prevalence of malnutrition, identified by a low body mass index (BMI), among children following confinement during COVID-19. **Methodology:** We conducted a cross-sectional analysis of anonymized data from digital health records. Key metrics—gender, age, weight, and height—were analyzed for a cohort of young people, comparing a pre-pandemic baseline (early 2020) with a post-confinement period (early 2022). Advanced computational models were applied to process these extensive datasets. The analytical strategy utilized the Cole-Green LMS algorithm with penalized likelihood, implemented via RefCurv 0.4.2 software, chosen for its efficacy with large-scale information. Selection of hyperparameters was guided by the Bayesian Information Criterion (BIC). Our specialists in mathematics endorsed this methodological pathway as the most robust for our objectives. Nutritional status was assessed by identifying individuals whose BMI fell more than 2.0 standard deviations below the age-adjusted population mean. **Findings:** The study included 66,975 clinical records from individuals under 16 years, analyzing over 1.2 million distinct data points. Results and comparative visualizations across different geographical districts are presented. A notable rise of 60 instances per 100,000 residents was observed following the pandemic. This increase was not uniform, showing distinct patterns: it was more marked in boys than girls, affected females more in rural settings, and males more in urban centers. **Interpretation:** Leveraging Big Data allows for highly efficient public health surveillance, pinpointing demographic groups that would most benefit from targeted support, thus ensuring optimal use of limited medical resources. Based on these results, proactive screening programs in specific urban zones should concentrate on male adolescents, while in certain rural areas, the focus should shift to female adolescents, who may constitute an under-identified at-risk group.

Keywords—*Big data analytics, Pediatric malnutrition, Nutritional status, COVID-19 impact.*

INTRODUCTION

The body mass index (BMI) serves as a key indicator for evaluating nutritional health in pediatric populations.[1–3] Tracking BMI trajectories is vital for the effective oversight and health promotion of children.[3,4] While scientific literature often emphasizes the escalating issue of childhood obesity[2], another critical dimension of nutritional status—underweight, indicated by a low BMI—demands equal attention.[3] Globally, the predominant reason for a low BMI is undernourishment resulting from food insecurity and poverty[2,3] or chronic illness.

A BMI reading under 2.0 SDS (Standard DeviationS) is generally considered clinically relevant, possibly indicating a pathological condition or at least necessitating a professional evaluation, as it signifies a weight significantly lower than that expected for a child's stature and sex.[2,3]

In affluent societies, however, another significant etiology must be considered: malnutrition secondary to psychological conditions. Therefore, when a child in a developed context presents with low weight-for-height, clinicians must differentiate between organic disease, constitutional lean body habitus, socio-familial nutritional challenges, or psychiatric conditions leading to weight loss, such as anorexia nervosa or restrictive-type bulimia.[2,3]

Anorexia nervosa ranks among the most lethal psychiatric diagnoses.[5] It is characterized by a pervasive fear of weight gain and a profoundly distorted body image, driving intense dietary restriction and weight loss.[5]

Adult prevalence of anorexia nervosa is around 0.6%, with a rising incidence noted in teenage cohorts.[6] This disorder typically emerges in females during early-to-mid adolescence, with higher incidence rates observed in Caucasian demographics and those from higher socioeconomic strata.[7,8]

The mean age of onset is approximately 12.3 years.[7] Epidemiological data from our national context are consistent with these global trends. A consistent finding across multiple investigations is that the public health measures enacted during the COVID-19 crisis[8]—including social distancing, school shutdowns, and increased digital device usage—correlated with a deterioration in youth mental health.

The magnitude of this effect is substantial; reports suggest a 25% to 27% surge in the prevalence of anxiety and depressive disorders post-pandemic.[9] Furthermore, the post-COVID era has witnessed a rise in case numbers, hospital admissions, and a trend toward younger age at presentation for anorexia nervosa, with current prevalence estimates reaching 4% for females and 0.3% for males.[9]

Compounding these issues, the pandemic has intensified systemic weaknesses in healthcare and widened economic disparities, disproportionately impacting teenagers and young adults.[8–10]

Beyond being a potential sign of organic pathology or a nonpathological variant, a lean physique can also indicate a susceptibility to developing an eating disorder. Risk factors associated with these conditions include high academic achievement, familial history of eating disorders, an excessive focus on muscularity (vigorexia), domestic conflict, and difficulties associated with pubertal development.[8–10] Crucially, being underweight can also be a marker of a family's experience of social or financial marginalization.

According to a UNICEF analysis[11], Spain faces a child poverty and social exclusion risk rate as high as 28%. This statistic has profound potential implications for the dietary well-being of affected minors.

Modern healthcare systems' digital archives accumulate a multitude of clinical variables during standard care, encompassing both anthropometric and sociodemographic information.

Sophisticated analytical approaches, like machine learning, allow researchers to harness these data from enormous sample sizes in a largely automated manner, generating insights with considerable statistical validity.

Although international research and cross-national analyses on this topic exist[10], a gap remains: no studies have specifically examined the landscape of under-nutrition in the child and adolescent demographic within our local and regional context. Moreover, the application of innovative Big Data methodologies for such an inquiry has not been previously documented.

GOALS

Primary Goal: To characterize the prevalence of malnutrition, operationalized as a low BMI, within a pediatric population in Álava, Spain, by employing a Big Data framework at two separate time points: prior to and following the revocation of COVID-19 social restriction policies.

Secondary Aims: To investigate potential associations between malnutrition prevalence and geographic location, district-level average income, and the proportion of immigrant residents.

MATERIAL AND METHODS

Study Design: A cross-sectional, population-level analysis was performed.

Cohort: All patients under 18 years of age enrolled in the OSAKIDETZA public health service of the Basque Country, who had both weight and height measurements documented in the centralized OSABIDE GLOBAL electronic health record system for the Álava region.

Eligibility:

- Male and female individuals
- Age range: 0 to 18 years
- Official registration or declared residence within the catchment area

Exclusion:

- Missing or incomplete essential data in the GLOBAL database

Contextual Data:

Official and reliable statistics on district-level median income, unemployment, and immigration prevalence were sourced from the Basque Statistics Institute (EUSTAT). Accessible via: https://www.eustat.eus/bankupx/pxweb/es/DB/-/PX_010154_cepv1_ep06b.px/table/tableViewLayout1/ (Accessed 08/29/2022).

Enrolling the complete registered pediatric cohort rendered a preliminary sample size calculation redundant. Initial data capture occurred from January 1 to March 30, 2020. A subsequent identical data extraction was conducted from January 1 to March 30, 2022.

Measured Parameters

- Primary measures:
- Body weight (Kilograms)
- Stature (Centimeters)
- Sex (Male, Female)
- Chronological age (Years and months)
- Date of clinical assessment
- Residential location—coded by district/neighborhood
- Local unemployment rate and per capita income

Analytical Approach

Our procedure was grounded in the Dirichlet process (DP) theory. This project embraced a Bayesian nonparametric strategy to construct Gaussian mixture models (GMM). Specifically, we employed DP Gaussian mixture models (DPGMM). For population-level inferences, we utilized hierarchical DP Gaussian mixture models (HDP-GMM).[12] This generated clustering outcomes that reveal somatometric commonalities and divergences within the population, based on physical metrics and residential district[13], integrating recent computational advances tailored for databases with profiles akin to ours.[14–16] BMI was computed as weight in kilograms divided by height in meters squared (kg/m^2). These values were benchmarked against established Spanish reference means and SDS.[4] The case definition for low weight was set at below 2.0 SDS compared to age- and sex-specific normative data.[4]

Our consortium of data scientists evaluated multiple analytical frameworks, ultimately selecting the HDPGMM because of the dataset's magnitude and the team's proven proficiency with such techniques (see the team's prior high-impact work), deeming it the superior instrument for this investigation.

The analysis involved comparative assessments using a paradigm previously validated by Diez et al.[17]: the hierarchical DPGMM, applied to contrast our sample against national reference curves from the 2010 Spanish growth study.

Statistical significance was determined at $p < 0.05$. In line with the model's constraints, only clusters containing

a minimum of 20 subjects with full data were included in the comparative analysis.

RESULTS

The final dataset comprised information from 67,270 young individuals. The aggregate count of examined parameters (some disclosed in this report, others withheld) totals 1,749,020 data cells. Subsequent tables detail findings categorized by sex, age bracket, and BMI, alongside other relevant factors.

Official demographic statistics (National Institute of Statistics, EUSTAT) reported a population of 338,765 individuals in the province of Álava during the analysis timeframe.

The region is administratively partitioned into seven major districts, incorporating the city of Vitoria-Gasteiz. As the Basque capital and primary urban hub, Vitoria-Gasteiz accounts for over 255,000 residents.

The financial well-being of children is intrinsically tied to household earnings. The median household income for the Basque Country stood at €47,005 in 2021. Figure 1 represents the combined gross income of all cohabiting family members, including children. Pronounced economic gradients exist across different districts (EUSTAT source), with several municipalities in Álava registering the most modest average incomes regionally.

Regional unemployment was recorded at 7.5%, significantly lower than the national Spanish average. Disparities are evident across districts (EUSTAT source), with certain localities in Álava and Vizcaya experiencing the highest joblessness levels.

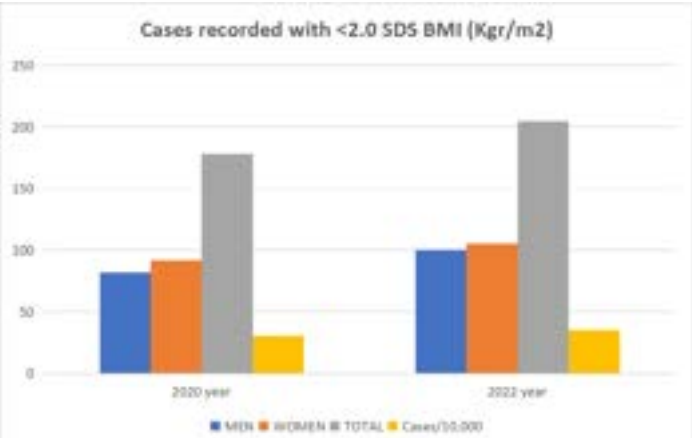

FIGURE 1. Cases with < 2 SDS BMI recorded between 2020 to 2022. Sex differences.

Concerning foreign-born residents, the average for the Basque Country is 13%. However, Vitoria-Gasteiz stands out with one of the highest proportions nationally, at 15%. Specific city districts exceed 18%, and some towns surpass 20%.

Accessible at: https://www.vitoria-gasteiz.org/http/wb021/contenidosEstaticos/adjuntos/es/36/18/3618.pdf. Dec. 2024, and the EUSTAT portal https://www.eustat.eus/estadisticas/tema_131/opt_0/tipo_1/ti_actividad-ocupacion-y-paro/temas.html and https://www.eustat.eus/elementos/ele0000200/migraciones-de-la-ca-de-euskadi-por-ambitos-territoriales-segun-clase-de-migracion-y-sexo/tbl0000255_c.html Dec. 2024.

During the initial 2020 quarter (pre-pandemic), 178 minors under 16 (83 males, 92 females) were identified with a BMI below the 2.0 SDS threshold. This count corresponds to 0.26% of the analyzed sample.

This incidence translated to 30 cases per 100,000 population in 2020.

In the first quarter of 2022 (post-confinement), 205 individuals under 16 (100 males, 105 females) met the same low BMI criterion. Figure 2 represents 0.30% of the total studied cohort.

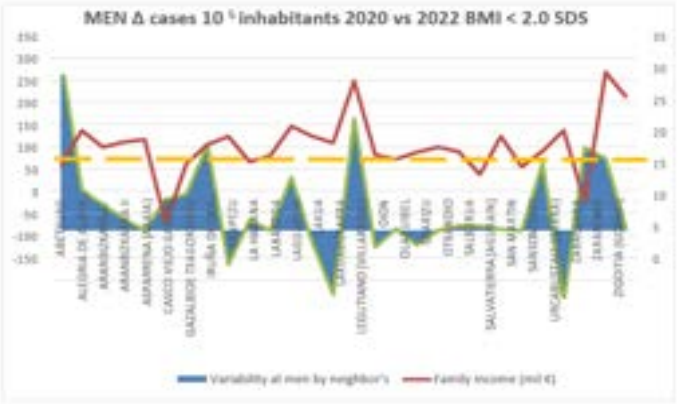

FIGURE 2. Relationship in MEN between changes number of cases and family incomes in different neighbors.

This incidence translated to 35 cases per 100,000 population in 2022.

Statistical analysis confirmed significant differences between the two time intervals and between genders ($p < 0.05$), reflecting a net increase of 27 children, or an additional five cases per 100,000 inhabitants.

Visual 1. Data presentation for BMI (kg/m^2) stratified by sex. The reference population is the normative median (P50) from the Carrascosa study. The graph displays the proportion of the cohort with a BMI falling more than 2.0 standard deviations below their age-specific mean for both observational windows, 2020 versus 2022.

Numerical outcomes are itemized in Tables 1 and 2. Consistent with the clustering protocol, districts reporting fewer than 20 valid cases during the analysis were excluded from the final district-level breakdown.

TABLE 1. Data for men, showing district-level data for 2020 and 2022, percentage values, and the variation between periods.

Men 2020 DISTRICT	Men 2022		DIFFERENCES
	%		% variation
ABETXUKO	0.00	3.90	3.90
ALEGRIA OF ALAVA (DULANTZI)	1.32	2.22	0.91
ARABIZKARRA I	5.34	5.92	0.58
ARABIZKARRA II	1.30	1.56	0.26
ASPARRENA (ARAIA)	4.00	4.00	0.00
OLD TOWN GASTEIZ	1.58	2.27	0.69
GAZALBIDE TXAGORRITXU	1.73	2.54	0.81
IRUÑA DE OCA (NANCLARES)	2.63	4.55	1.91
KANPEZU	4.76	4.00	−0.76
HABANA	2.48	2.70	0.22
LABASTIDA	0.00	0.00	0.00
LAGUARDIA	0.00	1.19	1.19
LAKUA	1.59	1.33	−0.26
LAKUABIZKARRA	2.67	1.23	−1.44
LEGUTIANO (VILLARREAL)	0.00	2.50	2.50
OION	0.99	0.62	−0.37
OLAGUIBEL	1.47	1.50	0.03
OLARIZU	1.49	1.16	−0.33
OTXANDIO	0.00	0.00	0.00
SALBURUA	1.28	1.38	0.10
SALVATIERRA (AGURAIN)	3.75	3.85	0.10
Saint Martin	1.49	1.52	0.03
SANSOMENDI	0.00	0.00	0.00
Urcabustaiz (Izarra)	0.00	1.50	1.50
ZABALGANA	2.89	1.26	−1.63
ZARAMAGA	1.27	3.13	1.86
ZIGOITIA (GOPEGI)	0.00	1.61	1.61
Zuya (Murgia)	0.00	0.00	0.00
TOTAL	**1.57**	**2.05**	0.48

Note: Red numbers indicate negative variation.

TABLE 2. Data for women, showing district-level data for 2020 and 2022, percentage values, and the variation between periods.

DISTRICT	%	%	% variation
ABETXUKO	1.45	1.23	−0.21
ALEGRIA OF ALAVA (DULANTZI)	2.86	2.50	−0.36
ARABIZKARRA I	0.80	2.01	1.21
ARABIZKARRA II	0.76	1.95	1.19
ASPARRENA (ARAIA)	5.00	5.50	0.50
OLD TOWN GASTEIZ	3.90	1.82	−2.07
GAZALBIDE TXAGORRITXU	2.40	2.80	0.40
IRUÑA DE OCA (NANCLARES)	0.00	0.54	0.54
HAVANA	1.04	1.00	−0.04
LABASTIDA	1.28	1.20	−0.08
LAGUARDIA	0.00	1.52	1.52
LAKUA	2.81	1.37	−1.44
LAKUABIZKARRA	2.23	2.20	−0.03
LEGUTIANO (VILLARREAL)	0.00	0.10	0.10
OION	2.25	2.03	−0.22
OLAGUIBEL	3.18	1.37	−1.81
OLARIZU	2.59	3.57	0.98
OTXANDIO	2.35	4.35	2.00
SALBURUA	1.45	1.32	−0.13
SALVATIERRA (AGURAIN)	3.85	3.55	−0.30
Saint Martin	1.64	1.29	−0.35
SANSOMENDI	4.55	4.80	0.25
Urcabustaiz (Izarra)	0.00	0.10	0.10
ZABALGANA	1.77	1.59	−0.19
ZARAMAGA	2.25	1.93	−0.32
ZIGOITIA (GOPEGI)	1.00	2.78	1.78
Zuya (Murgia)	2.17	2.20	0.03

Note: Red numbers indicate negative variation.

Tables 1 and 2 for men and women would be inserted here, showing district-level data for 2020 and 2022, percentage values, and the variation between periods.

Reviewing case distribution reveals an overall upward trend, largely attributable to the male demographic (4 extra cases/100,000). The female cohort contributed a smaller increment (1 additional case/100,000).

Distinct geographical patterns emerged. A widespread increase was evident among boys across most districts,

while girls exhibited a more variable and less uniform distribution.

After independent examination of BMI and income data for each district, we identified those geographical units demonstrating the most substantial relative change in low BMI case numbers between 2020 and 2022, using national reference standards.[4]

Figures 2 and 3, show the relationship in man and woman between changes in case numbers with < 2 SDS BMI and family incomes in different neighbors in our territory.

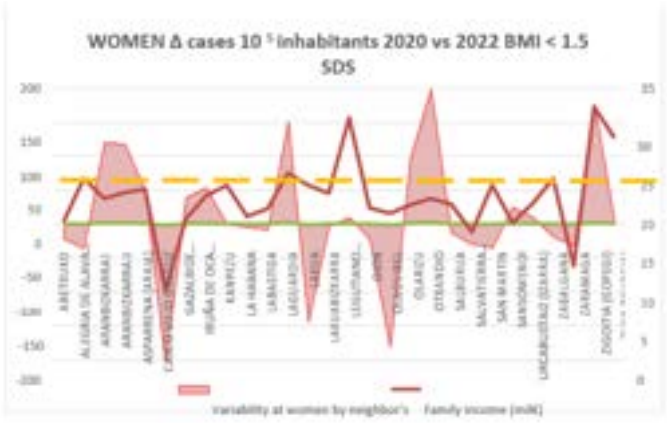

FIGURE 3. Relationship in WOMEN between changes number of cases and family incomes in different neighbors.

For the male population, 2022 witnessed 17 more total cases than 2020. This elevates the proportion from 1.57% to 2.02% of the male sample, denoting a 0.48% absolute and a 28.66% relative surge. This rise was not geographically uniform. Districts such as Abetxuko, Alegria, Gazalbide, Legutiano, Zaramaga, and Zigoitia reported increases markedly above the mean. Most, though not all (e.g., Zaramaga, Abetxuko), are situated in zones with above-average income. Conversely, other areas like Kanpezu, Lakua, and Zabalgana saw a reduction in identified cases. These interdistrict variations are statistically significant ($p < 0.05$).

The female cohort displayed a disparate geographical pattern. A total of 12 new cases appeared in 2022 compared to 2020. This shifted the prevalence from 1.98% to 2.10%, a minor 0.12% absolute and a 6.06% relative growth. This subtle overall increase masks considerable local variation. Significant upticks were recorded in districts including Aramizkarra I and II, La Guardia, Olarizu, Otxandio, Zigoitia, and Zuya. These are largely rural localities with incomes near the regional median, except for Zigoitia, which is a high-income area. Meanwhile, districts like Casco Viejo, Olaguibel, and Lakua experienced declining numbers; the first two are low-income zones. These territorial discrepancies are significant ($p < 0.05$).

DISCUSSION AND CONCLUSION

The capacity for epidemiological inquiry using Big Data is growing exponentially, creating new avenues for health intervention strategies. Machine learning, validated across diverse fields[14–16] for interpreting complex real-world data, is positioned as a transformative asset.

Pediatric physical development metrics[17], as a barometer of general health, and the specific challenge of eating pathologies represent ideal candidates for investigation via these sophisticated computational tools.[18–19]

Prior scholarship has detailed the multifaceted impact of the COVID-19 crisis[20,21], frequently citing the effects of lockdowns, diminished social contact, and increased screen time.

The pandemic period correlated not only with a higher incidence of eating disorders[21] but also with greater acuity, including elevated risks for medical instability, self-harm, and hospital admission.[22]

Other implicated factors encompass family socioeconomic position, household income[23], and the psychological strain of parental job loss.[8,9,11]

UNICEF's metric for child poverty risk uses a threshold of 60% of the national median equivalized household income, adjusted for family structure.[11]

Our investigation incorporated these elements, analyzing accessible district-level variables like average income and immigrant concentration in relation to low BMI. Immigration rate often correlates with larger family size, lower mean income, and higher unemployment.

This study confirms a post-pandemic rise in low BMI cases among youth in both sexes. The methodological design does not permit differentiation between cases stemming from clinical eating disorders, other medical conditions, or socioeconomic deprivation.

Evidence suggests that urban youth may be more vulnerable to mental health difficulties[24,25], potentially because of heightened exposure to pandemic-related biopsychosocial stressors like financial hardship, reduced service access, and limited social interaction, fostering anxiety and depression[26–28], alongside increased risks of familial conflict and violence.[29–32]

Initially, pediatric presentations were dominated by anxiety disorders[33–35], likely fueled by fears of infection and bereavement. Prolonged isolation, however, is strongly linked to the subsequent emergence of depression, social anxiety, self-injurious behaviors, suicidal thoughts, and eating disorders.[24,36–39]

Our research, covering both urban and rural settings, indicates that the male increase was more frequent in urban, often more affluent areas. For females, the rise was most prominent in rural communities and one affluent urban zone. This aligns with literature suggesting boys were more affected in urban, sometimes lower-income neighborhoods, whereas girls were more impacted in rural settings.[26,28,30–32] This divergence may reflect gendered social dynamics and support structures within different environmental contexts.

Healthcare budgets are constrained, complicating decisions about where to direct intervention programs or active screening for nutritional risk. Big Data provides a rapid, cost-efficient mechanism to gain a realistic overview of population health, informing strategic resource investment.[15–17]

Our analysis confirms tangible malnutrition risk within our community, with certain areas showing nearly 4% of all children affected.

This necessitates serious consideration of both the methodological framework[39] and the social determinants of health in our region.

The results further suggest that a child's residential environment influences nutritional status.[8,9,19,20] The interplay of income, food quality/access, opportunities for extracurricular and physical activities[22], and the general milieu of development appears to affect vulnerability to malnutrition critically.

In economically disadvantaged areas[11], child poverty becomes a tangible threat. Children from vulnerable households are more reliant on external support like school meals, charitable aid, and social services.[11] They also typically have less access to enriching recreational, athletic, and cultural pursuits, all factors that can compromise nutritional health.

Child poverty in Spain unequivocally impacts multiple life domains, from educational attainment and health outcomes to overall welfare.

Our analysis enables specific targeting: for boys, screening should emphasize urban neighborhoods with lower incomes and specific higher-income rural towns. The focus for girls is different. The data also reveal an asymmetrical increase, with males experiencing a more pronounced rise than females from 2020 to 2022.

We suggest that public health authorities enhance monitoring of these variables and their sociodemographic correlates, as a low BMI can be a common endpoint of diverse pathways: true food poverty, organic illness, or an eating disorder; but understanding how to intervene effectively against malnutrition risk[23] not only reduces associated mortality but also curtails resource-intensive hospital and emergency care. Big Data utilization is, and will remain, a cornerstone of modern public health[29] for evidence-based policy, offering a tangible opportunity to refine everyday clinical practice.

Finally, we notice as biases and limitations of the study that, a key limitation involves the use of routine clinical data, not originally collected for research. As noted in literature, this can introduce measurement or recording inaccuracies.[3] The study's design permits its regular repetition, facilitating ongoing monitoring of progress within various population subgroups.

AUTHOR CONTRIBUTIONS

Conceptualization, I.D.L. and S.M.M.; Methodology, I.D.L.; Software, I.D.L. and G.S.M.; Validation, all; Formal Analysis, G.S.M.; Investigation, I.D.L.; Resources, G.S.M.; Writing–Original Draft Preparation, all.; Writing–Review & Editing, all; Visualization, all; Supervision, I.D.L.; Project Administration, I.D.L.; Funding Acquisition, I.Z.M. and A.G.

ACKNOWLEDGEMENTS

We express our gratitude to the collaborating researchers from the Basque Center of Applied Mathematics (BCAM), Bilbao, Spain, for their invaluable contributions.

• Jose A. Lozano, Basque Center for Applied Mathematics BCAM

• Ioar Casado Tellechea, Basque Center for Applied Mathematics BCAM

• Aritz Pérez, Postdoctoral Fellow BCAM, Basque Center for Applied Mathematics

FUNDING

This research received no external funding.

DATA AVAILABILITY STATEMENT

Official and reliable statistics on district-level median income, unemployment, and immigration prevalence were sourced from the Basque Statistics Institute (EUSTAT). Accessible via: https://www.eustat.eus/bankupx/pxweb/es/DB/-/PX_010154_cepv1_ep06b.px/table/tableViewLayout1/ (Accessed 08/29/2022).

Complete registered pediatric are from official clinical datas -electronic clinical history.

CONFLICTS OF INTEREST

The authors declare they have no competing interests.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

This research adhered to the ethical principles of the Declaration of Helsinki (2013, Fortaleza), the Council of Europe's Oviedo Convention (1997), and national regulations on biomedical research and data protection (Law 14/2007). Ethical approval was granted by the Ethics Committee of OSI Araba (CEIC) on 03/24/2023 (Registration Number: 2022-058). Informed consent was not required as only anonymized, aggregated epidemiological data were used.

CONSENT FOR PUBLICATION

Not applicable.

FURTHER DISCLOSURE

Not applicable.

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Received November 14, 2024, accepted July 12, 2025, publication date for online-first January 22, 2026.

Original Research Article

Variation in Phototherapy Treatment in Some Selected Hospitals in Ghana

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ABSTRACT

Background: Neonatal jaundice (NNJ), one of the major diseases among neonates, could lead to Kernicterus (brain damage) if not treated well and early. The most significant treatment modality in the management of NNJ is phototherapy (PT). Providing PT by using clinical standards can enhance its effectiveness and safety and minimize PT-related complications. However, research shows that PT has not always been utilized in healthcare settings with low resources, and there is an incomplete understanding of NNJ and the use of PT for its management among trained community health workers (CHWs) and local communities. **Objectives:** The study aims to provide a basis for standardizing the use of PT to improve practice in Ghana. This was achieved by visiting selected hospitals in Ghana to acquire information on the use of PT and assessing the approach by which PT is administered by health professionals. **Methods:** The research utilized a descriptive cross-sectional design. Data were gathered using a Likert scale structured questionnaire. In addition, the Chi-square test of independence was used to establish the correlation between sociodemographic characteristics and health care workers' perspectives on PT treatment. Data analysis was performed using SPSS, and a p-value of 0.05 or less indicates a significant relationship. **Results:** The study revealed that over half of the participants had a good attitude toward clinical presentation, emphasizing the importance of always testing for bilirubin levels before administering PT treatment. The majority of respondents also demonstrated a good understanding of the importance of calibrating and maintaining PT devices. Lastly, most participants had good knowledge of standard protocols and held a positive attitude toward PT treatment. **Conclusions:** NNJ is prevalent, and PT has become the gold standard method for treating both full-term and preterm infants affected by it. Therefore, we recommend that other health care facilities assess the effectiveness of their PT devices and follow standard procedures to enhance the efficacy of this treatment.

Keywords—*Neonatal jaundice, Hyperbilirubinemia, Health care professionals, American Academy of Pediatrics.*

INTRODUCTION

Neonatal jaundice (NNJ), also known as hyperbilirubinemia (HB), is a prevalent condition that affects at least 60% of term and preterm neonates worldwide, including those born between 35 and 38 weeks of pregnancy.[1] Severe HB is expected to impact at least 481,000 newborns worldwide each year. More than 63,000 of these babies survive with moderate to severe long-term disabilities[2], such as hearing loss, choreoathetoid cerebral palsy, developmental delay, and other neurological problems. The greatest burden of severe HB is commonly reported in low- to middle-income countries than in developed countries because of the large disparity in health care access and resources[3,4], with only 31.6/100,000 live births with HB reported in high-income countries.[5,6] As there has been concern about a possible re-emergence of bilirubin encephalopathy in the United States and other parts of the world, severe HB has been gaining recognition among the world's leaders in health policy research as an important clinical and public health issue that requires further attention in these resource-constrained settings.[7]

Understanding NNJ is critical for developing a strong and safe rationale for the use of phototherapy (PT). PT was first used to treat neonatal HB in the late 1950s and was mostly used to avoid exchange transfusions.[8] Its use has gradually become more widely suggested for the prevention of "acute bilirubin encephalopathy", a reversible symptom of bilirubin toxicity, and "kernicterus", a chronic and permanent clinical sequela of bilirubin toxicity.[9] The American Academy of Pediatrics (AAP) has published a clinical practice guideline on the "Management of Hyperbilirubinemia in the Newborn Infant 35 or More Weeks of Gestation", which will hopefully provide greater uniformity and consistency in the application of PT in this newborn population.

The AAP recommends a clinical pathway that uses suitable nomograms to guide the use of PT and/or exchange transfusion for the management of a newborn infant who has been diagnosed with jaundice.[10]

The most effective treatment for HB is light, which has a wavelength range of 430 to 490 nm with a peak at 460 ± 10 nm.[11] The fundamental laws of photobiology and photochemistry determine the efficacy of PT. The interaction of blue light with bilirubin creates a therapeutically effective photochemical shift, which allows for a decline in the levels of bilirubin in the neonate. PT causes bilirubin to undergo fast oxidative reactions and intermolecular rearrangements, resulting in mutant bilirubin isomers, which are more polar and thus excretable without conjugation in bile and urine.[12] Despite this knowledge, pediatricians still occasionally use heliotherapy or PT with visible light in homeopathic quantities.[13]

PT devices with intensive irradiance are quite expensive in Ghana.[14] Since intense PT equipment is so much more expensive, most clinical services have no choice but to purchase the far less expensive, but inferior, traditional devices, which lack appropriate irradiance if they have any resources at all.[15] As a result, most neonatal clinical facilities are unable to treat severe HB in a timely and effective manner to avoid serious consequences.

A survey is undertaken in this study to assess variations in PT treatment in terms of clinical presentation, calibration of equipment, procedure for treatment, and knowledge assessment of caregivers among selected health facilities in Ghana.

METHODS

Study Setting and Period

The investigation was carried out in 15 medical facilities that treat NNJ with PT equipment. Six regions of the nation—Ashanti, Central, Eastern, Greater Accra, Volta, and Western—were home to these specific facilities. Health care facilities in Ghana that provide comprehensive neonatal care across emergency, outpatient, and inpatient settings were selected. Between May and June 2023, a prospective cohort study was conducted at these facilities, enrolling two key stakeholder groups: Caregivers and health care professionals (HCPs).

Study Design and Population

A cross-sectional study with an institutional focus was carried out. A cross-sectional study design was suitable because it allowed information to be gathered on participant characteristics at the time of the study, together with data on the outcome and any associations between

participant characteristics and the desired outcome. Nurses, midwives, doctors, and engineers/technicians who worked in neonatal intensive care units at various chosen facilities during the study periods were the study's target demographics. The study excluded staff who declined or did not want to participate.

Sampling Technique and Sample Size

Purposive sampling was utilized in this investigation. This technique allows units to be chosen because they share specific attributes or characteristics that will allow the researcher to gain a better understanding of the topic under investigation. It was important to select HCPs who belong to units involved in the use of PT. This is to obtain precise and correct information in order to satisfy study objectives. The sample size was 82 HCPs from 15 selected facilities who volunteered to participate in the study.

Outcome Measures

In this survey, participants' attitudes were assessed by the extent of agreement or disagreement with corresponding statements under each section. Response was rated as strongly agreeing, agreeing, neutral, disagreeing, and strongly disagreeing on a five-point Likert scale. The "strongly agree" responses received a score of 5, "agree" responses received 4, "neutral" a score of 3, "disagree" a score of 2, and "strongly disagree" a score of 1. An inverted score was made for statements whose correct response was disagreement (the strongly disagree score becomes 5 and the strongly agree score becomes 1).

Attitude toward clinical presentation was assessed using seven statements. The maximum possible attitude score was 35. The median attitude score was calculated for each respondent, on the basis of which their attitude was categorized as positive or negative. Attitude toward calibration of equipment was assessed using three statements. The maximum possible attitude score was 15. The median attitude score was calculated for each respondent, on the basis of which their attitude was categorized as positive or negative. Attitude toward the procedure for treatment was assessed using six statements. The maximum possible attitude score was 30. The median attitude score was calculated for each respondent, on the basis of which their attitude was categorized as positive or negative.

General knowledge on PT was assessed using four statements. The maximum possible attitude score was 20. The median attitude score was calculated for each respondent, on the basis of which their attitude was categorized as good or poor.

Data Collection

The data collection tool is a structured questionnaire using a Likert scale measurement. The questionnaire was administered as an online survey. The questionnaire had five main sections, with each section having a set number of items. The main sections included the following variables: demographic data, assessment of attitude toward clinical presentation, calibration of equipment, procedure for treatment, and general knowledge assessment. A reminder was provided to nonrespondents twice a month. If the survey was not received by the last week of the second month, the participant was considered a nonrespondent.

Statistical Methods

After data collection, the data were edited, coded, transcribed, and then cleaned. Data was grouped in measures such as ordinal, nominal, and scalar.

The data were then coded by attaching numerical value to every qualitative data. Before any statistical analysis was done, a pretest statistical measure called a normality test was conducted to validate the authenticity of the numerical data collated. Statistical Package for Social Science (SPSS) was used to analyze data using both inferential and descriptive statistics. Inferential statistics performed included chi-square test of independence to evaluate relationship between two categorical variables.

Limitation

Relatively low sample size can be attributed to the fact that even though there are many health facilities in these regions, few of them offered PT treatment on account of the nonavailability of PT devices. In addition, most neonatal units have limited staff (HCPs).

RESULTS

Demographic Characteristics

In the current study, an online questionnaire was distributed through a focal person from the selected facilities. In total, 82 responses were received to proceed with analysis. The majority of respondents were nurses, reaching 66 (80.5%), 7 (8.5%) were midwives, 4 (4.9%) were nursing students, 3 (3.7%) were engineers/technicians, and 2 (2.4%) were medical doctors. Almost half of the respondents were from the Ashanti region, about 39 (47.6%), and 16 (19.5%) were from Greater Accra (Table 1).

TABLE 1. Sociodemographic characteristics of respondents.

Variables	Category	Frequency (%)
Sex	Male	18 (22.0)
	Female	64 (78.0)
Region	Ashanti	39 (47.6)
	Central	8 (9.8)
	Eastern	12 (14.6)
	Greater Accra	16 (19.5)
	Volta	6 (7.3)
	Western	1 (1.2)
Age (Years)	18–24	13 (15.9)
	25–34	63 (76.8)
	35–44	6 (7.3)
Position	Student	4 (4.9)
	Nurse	66 (80.5)
	Midwife	7 (8.5)
	Engineer/Technician	3 (3.7)
	Medical Doctor	2 (2.4)

Attitude of HCPs Toward Clinical Presentation

Regarding attitudes of HCPs toward clinical presentation, the majority (70.7%) of respondents agreed that it is always necessary to test for bilirubin levels before administering PT, while a few (26.8%) admitted that PT is administered simply because the baby's skin appears yellowish, and with a neutral (2.4%) response. Overall, more than half of respondents (53.7%) had a positive attitude toward clinical presentation, while 46.3% had a negative attitude (Table 2).

TABLE 2. Attitude of health care professionals toward clinical presentation.

Items	Responses				
	Strongly Disagree, N (%)	Disagree, N (%)	Neutral, N (%)	Agree, N (%)	Strongly Agree,N (%)
It is not always necessary to test for bilirubin levels before administering phototherapy.	30 (36.6%)	28 (34.1%)	2 (2.5%)	11 (13.4%)	11 (13.4%)
I administer phototherapy simply because the baby's skin appears yellowish.	2 (2.4%)	16 (19.5%)	4 (4.9%)	39 (47.6%)	21 (25.6%)
I am familiar with some bilirubin testing methods.	2 (2.4%)	2 (2.4%)	17(20.7%)	48 (58.5%)	13 (15.9%)
It is necessary to check the bilirubin level after some time of exposure to **phototherapy light.**	0 (0%)	0 (0%)	2 (2.4%)	24 (29.3%)	56 (68.3%)
The level of bilirubin is determined using a laboratory method.	0 (0%)	3 (3.7%)	3 (3.7%)	42 (51.2%)	34 (41.5%)
A point-of-care (POC) device, such as the Bilistick, is used to determine bilirubin levels in real time.	0 (0%)	3 (3.7%)	16 (19.5%)	50 (61.0%)	13 (15.9%)
It is important to check the total serum bilirubin level before discharge.	0 (0%)	1 (1.2%)	1 (1.2%)	17 (20.7%)	63 (76.8%)
Overall Level of Attitude					
Positive	44 (53.7%)				
Negative	38 (46.3%)				

Attitude of Health Professionals Toward Calibration of Equipment

Regarding attitudes of HCPs toward maintenance of equipment, overall, the majority (72.0%) of respondents had a positive attitude, while a few (28.0%) had a negative attitude (Table 3).

TABLE 3. Attitude of health care professionals toward maintenance of equipment.

Items	Responses				
	Strongly Disagree, N (%)	Disagree, N (%)	Neutral, N (%)	Agree, N (%)	Strongly Agree, N (%)
It is critical that the equipment be standardized on a regular basis.	0 (0%)	0 (0%)	6 (7.3%)	22 (26.8%)	54 (65.9%)
The clinical engineer is in charge of maintenance and repair.	0 (0%)	0 (0%)	3 (3.7%)	22 (26.8%)	57 (69.5%)
For treatment, I used irradiance-based protocols.	0 (0%)	3 (3.7%)	20 (24.4%)	31 (37.8%)	28 (34.1%)
Overall Level of Attitude					
Positive	59 (72.0%)				
Negative	23 (28.0%)				

Attitude of Health Professionals Toward Treatment Procedures

Regarding attitudes of HCPs toward treatment procedures, overall, the majority (62.2%) of respondents had a positive attitude, while a few (37.8%) had a negative attitude (Table 4).

TABLE 4. Attitude of health professionals toward treatment procedures.

Items	Responses				
	Strongly Disagree, N (%)	Disagree, N (%)	Neutral, N (%)	Agree, N (%)	Strongly Agree, N (%)
Before treatment, I consider the baby's exposed body surface area (BSA).	0 (0%)	0 (0%)	2 (2.4%)	25 (30.5%)	55 (67.1%)
I document treatment duration.	1 (1.2%)	3 (3.7%)	11 (13.4%)	39 (47.6%)	28 (34.1%)
Before treatment, I cover the baby's eyes.	1 (1.2%)	5 (6.1%)	3 (3.7%)	9 (11.0%)	64 (78.0%)
I consider the irradiance level before treatment.	0 (0%)	3 (3.7%)	9 (11.0%)	33 (40.2%)	37 (45.1%)
Phototherapy is admitted while the preterm baby is in the infant incubator.	0 (0%)	3 (3.7%)	5 (6.1%)	46 (56.1%)	28 (34.1%)
Between the baby and the phototherapy source, there is a standard measurement.	0 (0%)	4 (4.9%)	10 (12.2%)	45 (54.9%)	23 (28.0%)
Overall Level of Attitude					
Positive	51 (62.2%)				
Negative	31 (37.8%)				

HCPs' Knowledge Assessment of PT

Regarding HCPs' knowledge assessment of PT, overall, the majority (64.6%) of respondents had a good knowledge, while a few (35.4%) had a poor knowledge (Table 5).

TABLE 5. Health care professionals' knowledge assessment of phototherapy.

Items	Responses				
	Strongly Disagree, N (%)	Disagree, N (%)	Neutral, N(%)	Agree, N (%)	Strongly Agree, N (%)
I am aware of some standard treatment operation protocols.	0 (0%)	0 (0%)	3 (3.7%)	23 (28.0%)	56 (68.3%)
We have a standard protocol in my facility.	0 (0%)	2 (2.4%)	2 (2.4%)	19 (23.2%)	59 (72.0%)
After purchasing phototherapy equipment, users must be trained.	0 (0%)	0 (0%)	0 (0%)	13 (15.9%)	69 (84.1%)
We have another form of treatment procedure for neonatal jaundice.	1 (1.2%)	5 (6.1%)	41 (50.0%)	18 (22.0%)	17 (20.7%)
Overall Level of Knowledge					
Good	53 (64.6%)				
Poor	29 (35.4%)				

Association Between Demographic Features and Key Indicators

The chi-square test of independence was conducted to determine the significant relationship between any two categorical variables or parameters, or attributes of interest. The null hypothesis (H_o) of this study states that there is no significant relationship between sociodemographic factors and attitudes and knowledge about PT treatment, while the alternate hypothesis (H_a) also states that there is a relationship between the paired categorical variables, as shown in Table 6.

Apart from the region of respondents, the remaining demographic features did not show any significant relationship with clinical presentation ($p > 0.05$). There was a statistically significant relationship between region and clinical presentation ($\chi^2 = 16.141$, $p = 0.006$). Positive attitude toward clinical presentation was seen to be the highest in respondents who work in facilities located in the Ashanti region.

TABLE 6. Association between sociodemographic features and attitude of health professionals toward clinical presentation.

	Attitude		Total (N = 82)	Chi-square (χ^2)	*p*-value
	Negative (%)	Positive (%)			
Sex					
Male	8 (44.4%)	10 (55.6%)	18	0.033	0.855
Female	30 (46.9%)	34 (53.1%)	64		
Region					
Ashanti	11(28.2%)	28 (71.8%)	39	16.141	**0.006**
Central	5 (62.5%)	3 (37.5%)	8		
Eastern	8 (66.7%)	4 (33.3)	12		
Greater Accra	7 (43.8%)	9 (56.2)	16		
Volta	6 (100.0%)	0 (0.0%)	6		
Western	1 (100.0%)	0 (0.0%)	1		
Age (yrs.)					
18–24	8 (61.5%)	5 (38.5%)	13	1.547	0.461
25–34	27 (42.9%)	36 (57.1%)	63		
35–44	3 (50.0%)	3 (50.0%)	6		
Position					
Student	3 (75.0%)	1 (25.0%)	4	1.591	0.810
Nurse	30 (45.5%)	36 (54.5%)	66		
Midwife	3 (42.9%)	4 (57.1%)	7		
Engineer/Technician	1 (33.3%)	2 (66.7%)	3		
Medical Doctor	1 (50.0%)	1 (50.0%)	2		

TABLE 7. Association between sociodemographic features and attitude of health professionals toward maintenance of equipment.

	Attitude		Total (N = 82)	Chi-square (χ^2)	*p*-value
	Negative (%)	Positive (%)			
Sex					
Male	2 (11.1%)	16 (88.9%)	18	3.278	0.070
Female	21 (32.8%)	43 (67.2%)	64		
Region					
Ashanti	4 (10.2%)	35 (89.8%)	39	14.352	**0.014**
Central	5 (62.5%)	3 (37.5%)	8		
Eastern	5 (41.7%)	7 (58.3%)	12		
Greater Accra	7 (43.8%)	9 (56.2%)	16		
Volta	2 (33.3%)	4 (66.7%)	6		
Western	0 (0.0%)	1 (100.0%)	1		
Age (yrs)					
18–24	5 (38.5%)	8 (61.5%)	13	1.001	0.606
25–34	16 (25.4%)	47 (74.6%)	63		
35–44	2 (33.3%)	4 (66.7%)	6		
Position					
Student	4 (100.0%)	0 (0.0%)	4	13.069	**0.011**
Nurse	14 (21.2%)	52 (78.8%)	66		
Midwife	3 (42.9%)	4 (57.1%)	7		
Engineer/Technician	1 (33.3%)	2 (66.7%)	3		
Medical Doctor	1 (50.0%)	1 (50.0%)	2		

Demographic features like the region and position of respondents showed a statistically significant relationship with attitude toward maintenance of equipment ($p < 0.05$). Positive attitude toward maintenance of equipment was seen to be higher in respondents who work in facilities located in the Ashanti and western regions when compared to those in the other regions. Also, a positive attitude toward maintenance of equipment was determined to be the highest among nurses as compared to the other professionals (Table 8).

TABLE 8. Association between sociodemographic features and attitude of health professionals toward treatment procedures.

	Attitude		Total (N = 82)	Chi-square (χ^2)	*p*-value
	Negative (%)	Positive (%)			
Sex					
Male	4 (22.2%)	14 (77.8%)	18	2.382	0.123
Female	27 (42.2%)	37 (57.8%)	64		
Region					
Ashanti	12 (30.8%)	27 (69.2%)	39	2.631	0.757
Central	4 (50.0%)	4 (50.0%)	8		
Eastern	5 (41.7%)	7 (58.2%)	12		
Greater Accra	7 (43.8%)	9 (56.2%)	16		
Volta	3 (50.0%)	3 (50.0%)	6		
Western	0 (0.0%)	1 (100.0%)	1		
Age (yrs.)					
18–24	7 (53.8%)	6 (46.2%)	13	5.072	0.079
25–34	24 (38.1%)	39 (61.9%)	63		
35–44	0 (0.0%)	6 (100.0%)	6		
Position					
Student	4 (100.0%)	0 (0.0%)	4	8.852	0.065
Nurse	21 (31.8%)	45 (68.2%)	66		
Midwife	3 (42.9%)	4 (57.1%)	7		
Engineer/Technician	2 (66.7%)	1 (33.3%)	3		
Medical Doctor	1 (50.0%)	1 (50.0%)	2		

There was no statistically significant association between demographic features and attitude toward treatment procedures ($p > 0.05$).

TABLE 9. Association between sociodemographic features and knowledge assessment of phototherapy.

	Knowledge		Total (N = 82)	Chi-square (χ^2)	*p*-value
	Poor (%)	Good (%)			
Sex					
Male	2 (11.1%)	16 (88.9%)	18	5.935	**0.015**
Female	27 (42.2%)	37 (57.8%)	64		
Region					
Ashanti	5 (12.8%)	34 (87.2%)	39	23.284	**0.000**
Central	7 (87.5%)	1 (12.5%)	8		
Eastern	5 (41.7%)	7 (58.2%)	12		
Greater Accra	9 (56.3%)	7 (43.7%)	16		
Volta	2 (33.3%)	4 (67.7%)	6		
Western	1 (100.0%)	0 (0.0%)	1		
Age (yrs.)					
18–24	7 (53.8%)	6 (46.2%)	13		
25–34	19 (30.2%)	44 (69.8%)	63		
35–44	3 (50.0%)	3 (50.0%)	6	3.252	0.197
Position					
Student	4 (100.0%)	0 (0.0%)	4	17.231	**0.002**
Nurse	18 (27.3%)	48 (72.7%)	66		
Midwife	4 (57.1%)	3 (42.9%)	7		
Engineer/Technician	3 (100.0%)	0 (0.0%)	3		
Medical Doctor	0 (0.0%)	2 (100.0%)	2		

As shown in Table 9, the demographic features, sex, region, and position of respondents showed a statistically significant association with knowledge on PT ($p < 0.05$). Good knowledge about PT was seen to be higher in males compared to females. In addition, good knowledge about PT was seen to be higher among respondents who work in facilities located in the Ashanti region, as compared to those in the other regions. Also, good knowledge about PT was seen to be higher in nurses and medical doctors when compared to other professionals.

DISCUSSION

The discussion summarizes and interprets the key findings of the study in relation to the research objectives: to examine how clinical presentation guides neonatal jaundice (NNJ) treatment decisions, assess the calibration processes of phototherapy equipment, analyze the procedures involved in NNJ treatment, and evaluate the knowledge applied by health professionals in managing NNJ.

Attitude of HCPs Toward Clinical Presentation

The overall positive attitude of respondents (53.7%) toward clinical presentation suggests that the majority of the HCPs are aware of the principles of clinical assessment of treating NNJ using PT. Notwithstanding, 46.3% of the respondents who exhibited a negative attitude toward clinical presentations point out the presence of varying levels of knowledge and experience among HCPs regarding the assessment of NNJ prior to treatment. Significantly, the study findings revealed a noticeable number of respondents' (70.7%) test bilirubin levels before administering PT, indicating that HCPs understand the importance of appropriate diagnostic procedures prior to treating NNJ. This aligns with the established clinical guidelines, which advocate for a thorough assessment of bilirubin levels before commencing treatment.[16] However, 26.8% of the findings indicate that respondents administered PT based on only the visual assessment of the level of bilirubin. Reliance on only visual assessment might not only result in insufficient or inappropriate treatment but also ineffective treatment of NNJ. Emerging concerns about the risks of unnecessary PT highlight the need for strict bilirubin checks or testing before starting treatment and monitoring (4–6 hour intervals during therapy to prevent overuse, following the recommendations of the 2022 AAP guidelines).

Attitude of Health Professionals Toward the Maintenance of Equipment

Generally, the study indicates a predominantly positive attitude among HCPs toward the maintenance of equipment, with 72% of respondents favorably validating this perspective. This affirms the importance of appropriately maintaining equipment for safe and effective delivery of PT.[8] Table 3 highlights several key parameters related to the attitude of HCPs toward maintenance. Notably, the majority of the respondents (65.9%) agreed that it is crucial to regularly maintain equipment, which aligns with existing literature that emphasizes the necessity of

regular maintenance to uphold the quality of health care services and improve PT.[17] Besides, the majority of the respondents (69.5%) also agreed that clinical engineers are responsible for maintaining equipment. This suggests that there is adequate collaboration between the health-care givers and the specialized professionals to ensure the safety and functionality of the equipment. Interestingly, the responses on the use of irradiance-based protocols for treatment varied. Although a substantial number of the respondents (37.8%) agreed with the statement, 24.4% remained neutral, while 3.7% disagreed. This result indicates differing levels of knowledge and familiarity with irradiance protocols among HCPs.

Attitude of HCPs Toward Treatment Procedures

The overall positive attitude (62.2%) toward treatment procedures among the respondents is encouraging, suggesting a high level of knowledge on treatment procedures. However, 37.8% of respondents expressing a negative attitude indicate the underlying concerns in knowledge about treatment procedures that need to be addressed. A significant majority of the respondents (67.1%) consider the baby's exposed body surface area (BSA) before treatment, which reflects the understanding of the basic principles of PT, where the surface area exposed to light directly correlates with treatment outcomes, which is crucial for optimizing effective treatment and minimizing potential risks. This emphasizes the importance of health-care givers to be well-versed in the physiological aspects of treating NNJ, ensuring that treatments are tailored to the individual needs of each infant. Moreover, a notable 78.0% of the respondents practiced covering the baby's eyes before administering treatment. This aligns with the established recommendation of protecting the eyes from potentially harmful light exposure during PT.[18] In addition, the findings also reveal a similar level of agreement among respondents on the statements; consideration of specific treatment duration and irradiance levels with 47.6% and 45.1% responses, respectively. Even though the majority of the respondents demonstrated awareness of these factors, a noticeable proportion of respondents who disagreed and took a neutral stance suggests that this is an area that requires potential improvement in practice. Notably, a substantial portion of the respondents (56.1%) treat infants while they are in incubators, which is a common practice in neonatal care. This approach not only provides a controlled environment for the infant but also facilitates the administration of treatments without compromising the infant's safety or stability. However, 54.9% of the respondents agreed that there is a standard measurement between the baby and the PT source. This indicates a recognition of the need for standardized protocols in NNJ treatment delivery, which affirms the existing literature on achieving effective treatment of NNJ by improving upon standardization.[4]

HCPs' Knowledge Assessment of PT

Generally, 64.4% of the respondents had good knowledge of PT, while 35.4% who had poor knowledge cannot be overlooked. This finding indicates that there is a need for HCPs to be well-informed about the knowledge regarding PT and its clinical applications. The results reveal that a notable 68.3% of respondents agreed with the statement regarding the awareness of standard treatment operation protocols. While 72.0% of respondents agreed that their facility has a standard protocol for PT, the small percentage (2.4%) who disagreed or remained neutral raises questions about the consistency and uniformity of practices across different health care facilities. This suggests that some facilities do not adopt the universal or standardized protocols, resulting in variations in treatment approaches, thereby potentially affecting the quality of treatment provided. The study findings also reveal that a substantial 84.1% of HCPs agreed on the necessity of training for users of PT devices. This indicates a strong acknowledgment of the critical role that adequate training plays in ensuring an effective and safe use of PT devices.[19] Without proper training, there's a risk of misuse, potentially leading to inadequate treatment or harm to neonates. Moreover, the responses about alternative treatment options for NNJ revealed a divided opinion. While half of the respondents (50.0%) were neutral, only 20.7% agreed that their facility utilizes different treatment methods. This uncertainty suggests a possible lack of knowledge or awareness regarding alternative therapies that could be beneficial in certain cases. It indicates the need for HCPs to stay informed about all treatment options for NNJ to provide optimal care.

CONCLUSION

This study aimed to identify the variations in treatment procedures using PT by assessing the approach in the treatment administered by HCPs, focusing on the use of clinical presentation in the treatment of NNJ, the calibration process of the PT equipment, the procedure involved in the treatment of NNJ, and the knowledge used by health professionals in the treatment of NNJ. Generally, the majority of the HCPs had good knowledge of the treatment of NNJ and also demonstrated a positive attitude toward clinical presentation, maintenance process of the PT equipment, and procedures involved in the treatment of NNJ. However, the low sample size can be attributed to the fact that most of the neonatal units in the selected facilities have limited staff. On the other hand, further research can focus more on exploring how adequately educating HCPs on clinical presentation, maintenance process of the PT equipment, and standardized treatment procedures can improve the overall positive attitude toward these factors necessary for the effective treatment of NNJ.

AUTHOR CONTRIBUTIONS

Conceptualization, D.E.A., S.S.B. and A.M.; Methodology, V.W.E.; Formal Analysis, D.A. and S.D.P.; Investigation, D.E.A. and S.D.P.; Data Curation, D.E.A. and I.A.; Writing–Original Draft Preparation, D.E.A. and S.S.B.; Writing–Review & Editing, D.E.A.; Supervision, A.M.

ACKNOWLEDGMENTS

Not applicable.

FUNDING

No external funding was received. The research was supported through institutional resources.

DATA AVAILABILITY STATEMENT

Raw institutional data are not publicly available due to hospital confidentiality agreements. Anonymized summary data may be made available upon reasonable request and subject to ethics committee approval.

CONFLICTS OF INTEREST

The author declares no conflicts of interest, including no affiliations with phototherapy equipment manufacturers.

ETHICS APPROVAL

Ethical approval was obtained from the Institutional Review Board and the ethics committees of all participating hospitals. Institutional consent was secured from each facility prior to data collection.

CONSENT FOR PUBLICATION

Written consent for publication was obtained from all participating healthcare facilities. Hospital-specific findings are presented anonymously.

FURTHER DISCLOSURE

This study forms part of a doctoral thesis at the University of Ghana. It aims to inform policy and support the standardization of phototherapy practices across healthcare facilities in Ghana.

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Received January 2, 2025, accepted December 10, 2025, publication date for online-first January 27, 2026.

Original Research Article

Facilitating Tongue Length and Mobility Using a Novel Loop Device for Dysphagia in Stroke Survivors: Efficacy in a Quasi-Randomized Study

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ABSTRACT

Background: Dysphagia in stroke patients is primarily attributed to motor weakness and decreased voluntary motor control, leading to delayed swallowing reflexes and pharyngeal contractions. There are limited technical aids available for the rehabilitation of the tongue. This study presents an option in the form of a loop device. **Objective:** To investigate the use of a loop device for dysphagia in stroke survivors using a quasi-randomized study. **Methods:** This quasi-randomized study was conducted at a hospital on post-stroke dysphagia for 1 year. The sample was divided into either Group A (n = 6) or Group B (n = 6). Group A received tongue stretching and strengthening using the loop device. Group B received tongue stretching (manually) and strengthening intervention (tongue depressor) without using a loop device. Eating Assessment Tool (EAT10), M.D. Anderson Dysphagia Inventory (MDADI), and tongue length change measure or tongue protrusion change (TLCM) were used to check the outcome using the significant difference of means at a p-value of 0.05, considering a normal distribution and SD. Paired and independent t-tests were used for analysis. **Results:** Group A: the mean TLCM score increased from 1.56 (SD = 0.91) to 2.0 (SD = 0.82) from the pretest to the posttest (p = 0.007). The mean EAT10 score decreased from 24 (SD = 5.21) to 19.33 (SD = 6.80), (p = 0.011). In addition, the mean MDADI score increased from 53.80 (SD = 7.71) to 62.97 (SD = 12.37), (p = 0.021). The p-value was found to be significant at < 0.05. Group B: In Group B, the mean TLCM score increased from 2.23 (SD = 0.34) to 2.50 (SD = 0.41), (p = 0.014). However, the mean EAT10 score decreased notably from 19.16 (SD = 2.48) to 13.5 (SD = 3.27), (p = 0.001). Similarly, the mean MDADI score increased from 51.7383 (SD = 6.16) to 58.3967 (SD = 6.16), (p = 0.001). The p-value was found to be significant at < 0.05. In intergroup comparison, no significant difference is seen. **Conclusions:** Improvements have been observed in dysphagia using TLCM, EAT-10 scores, and MDADI after the interventions. No significant improvement of the novel device use over the traditional methods is seen in the studied measures, and both are comparable to each other. The loop device provided the intervention in an effective, hygienic, and clinically appropriate manner. The manual stretching of the tongue was not preferred by patients.

Keywords—*Oral rehabilitation, Swallowing function, Tongue mobility, Tongue strength.*

INTRODUCTION

Stroke is a medical condition characterized by decreased cerebral perfusion, which is caused by insufficient blood flow to the brain.[1] More than 50% of stroke patients experience dysphagia. However, the majority of patients regain their ability to swallow within 7 days, but after 6 months, 11–13% of them still have dysphagia.[2] Dysphagia is associated with decreases in tongue pressure, which is a measure of tongue muscle strength.[3,4] The mobility of the tongue with actual tongue protrusion, a reflection of functional tongue length, is also a factor responsible for swallowing dysfunction. The primary purposes of the tongue, in the oral phase of swallowing, are to facilitate the creation of boluses, chewing, and the passage of boluses to the throat. The tongue, being a mobile muscular structure, must have enough power and mobility to perform these tasks during the oral phase. Consequently, finding therapeutically useful interventional techniques to enhance tongue function in dysphagia individuals is desirable.[5] In clinical practice, manual tongue stretching and strengthening exercises are frequently utilized to improve oromotor performance overall by decreasing tongue shortening and enhancing tongue motility.[6]

The consequences of dysphagia impact various aspects of life satisfaction and health outcomes—mealtime anxiety, reduced enjoyment of eating, and social isolation, with approximately one-third avoiding eating with others; this requires early screening.[7] It may contribute to aspiration, prolonged hospital stays, breathing problems, dehydration, malnutrition, weight loss, and ultimately, a lower quality of life and increased mortality risk.[8] It also leads to general muscle weakness and muscle loss[9], requiring comprehensive rehabilitation with therapeutic modalities.[10] Commonly reported modalities are strengthening.[11,12] However, electrical stimulation[13] has also been reported. Devices for dysphagia rehabilitation are available[14–16], but are not commonly prescribed in a developing setting and are of higher cost.[17]

Oral rehabilitation includes assessment, early detection, and management of dysfunctions in the tongue[18] and buccal physiology, along with restoration of dentation, and is not limited to prosthetic dentures. It is a comprehensive approach including a combination of therapies.[19] Rehabilitative interventions with *dysphagia as a focus have been seen as effective*.[20]

This study aimed to explore the significance of tongue-strengthening exercises, tongue stretching, and tongue motility in dysphagia management post-stroke. A simple, self-collapsible loop device for providing the exercises hygienically and stretching the tongue gradually from the base to the tip of the tongue (Figure 1) has been studied. We elucidate the potential benefits of these interventions in enhancing swallowing function and overall quality of life for stroke survivors with dysphagia. The device in the form of a loop with a handle is simple yet novel as it not only stretches and mobilizes the tongue from its very root in a circular and gradual fashion which not only elongated the tongue but also facilitates its motility and thereby is a unique rehabilitative perspective for dysphagia. It is nonobvious because the tongue muscles' *external group*, Genioglossus, Hyoglossus, Styloglossus, and Palatoglossus, and *internal group*, Superior longitudinalis, Inferior longitudinalis, Verticalis, and Transversalis, have a diverse role and distinct direction of movement, which can be re-trained by the loop device. The external and internal tongue muscles move the tongue in anterioposterior, superior–inferior, and oblique directions in a 360-degree fashion. It has an impact on the biomechanics of swallowing, the oral phase, and the chewing mechanism for bolus formation.

Objective: To investigate the use of the above loop device for oral functions in dysphagia patients using a quasi-experimental design. Specifically, the stretching and strengthening exercises are performed in a clinically precise manner, and we elucidate the potential benefits in enhancing swallowing and quality of life. Previous studies have discussed manual stretching, and the gradual fascia stretching from the base to the tip of the tongue in a circular manner is not mentioned. Specific muscle groups are strengthened in different directions of motion using the circular loop by us in the present study, as opposed to only the inferior pressure or using a wooden compressor.

MATERIALS AND METHODS

We have developed a simple loop device (a prototype) for providing the exercises hygienically and stretching the

tongue gradually from the base to the tip of the tongue (Figure 1). Intellectual property right patent no. 504718 in the Indian patent office has been registered. This is named as oral rehabilitation frame (ORF).[21] (all details related to this patent registered with the Indian patent office can be accessed online: https://iprsearch.ipindia.gov.in/PublicSearch/PublicationSearch/Eregister).

Materials

Food-grade stainless steel (as the outer core of the prototype), which can be cleaned and boiled for sterilization and re-used by the same patient, and sterile copper looped wire covered in a silicone sleeve as use and throw loop has been used. A silicone rubber stopper with spring for producing a self-collapsible loop is part of the design.

FIGURE 1. Loop device for tongue exercises. Patented device prototype. IPR (patent no—504718). This device provides tongue stretching from base till the tip of the tongue in a gradual and hygienic way, where the tongue is not pulled by hands but gradually elongated with circular compression of the fascia. Strengthening is performed from various directions by encircling the loop on the tip and asking to move the tongue. The prototype handle is made of food-grade stainless steel and is of low cost. It can be boiled/autoclaved for repeated use. The loop is a non-slippery copper wire in a rubber coating, which is one-time use and throw. There is a silicone rubber stopper. The loop in the prototype is controlled manually.[21]

The looped tongue attachment in the device is a circular attachment getting tied/gripped lightly over the tongue, as seen in Figure 2, which elongates the tongue from the base to the tip; it is non-obvious and has stepped forward tongue mobilization to the facial level. The tongue elongation itself is a distinct physiological variable for oral function, and the looped attachment has specifically catered to it. The same may have a circular constrictive ring; however, we have tested a looped one, and it completely encircled the tongue as seen in Figure 3.

Assembly

The device prototype was developed using a hollow-bend steel console, and a loop was passed through it. The loop was made up of copper wire and covered by a nonslippery silicone rubber coat. The frame holder was adapted from an earbud, and assembly was done (Figure 1).

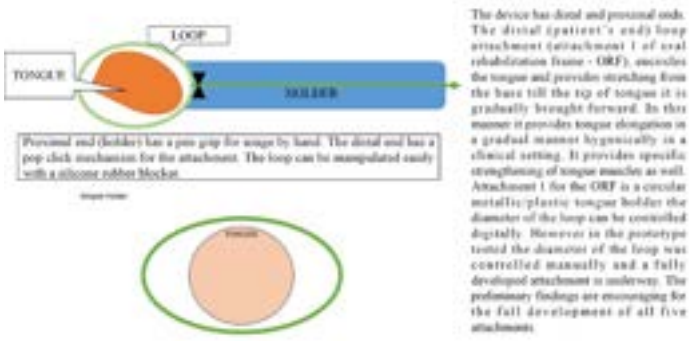

FIGURE 2. The novel ORF attachment 1 has two ends—distal and proximal. The distal (patient's end) loop attachment (in the case of attachment 1 of ORF) encircles the tongue and provides stretching from the base till the tip of the tongue, and it is gradually brought forward. It does not require the manual tongue stretching, which is a crude method and provides excessive pinching force for the tip of the tongue, and is uncomfortable for the patients.

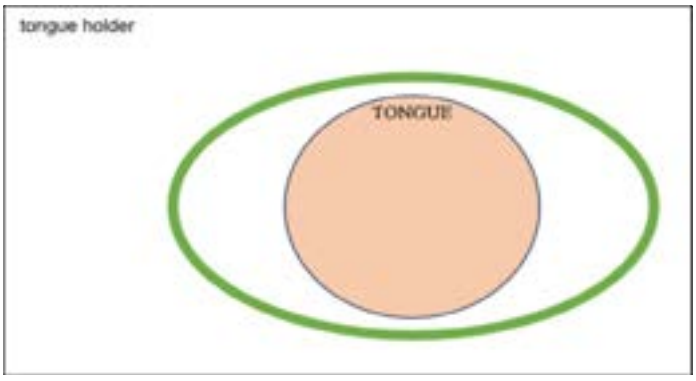

FIGURE 3. The position of the tongue in the cross-sectional view, as enclosed from the base to the tip. The loop elongates the tongue from the base till the tip, and it leads to gradual stretching of the tongue.

The prior art in this area is found but is limited in scope and specificity. For tongue examination, we find prior use of disposable wooden depressors and their modifications like in patent US5897492A * 1998-08-21 1999-04-27 Feller; Mitchell Dean Candy tongue depressor.[22] Few specific devices at the case study level[18] are available at the high end for tongue physiotherapy, but a simple solution is lacking. Devices for oral hygiene are available, but for oral physiotherapy and rehabilitation of tongue and oral function, there are restricted options like To To (a type of device)[14]; nevertheless, it lacks the simplicity for clinical inpatient applications. There is a forceps that is used to hold the tongue during surgeries, CN206080478U, China.[23] However, there are no strengthening, mobilization, manipulation, or stimulation devices with a variety of attachments for different oral functions. It forms the rationale for the development of ORF.[21]

The prototype is human safe, that is, only those materials that are intended for human use are used, as seen in Figure 1. The material involves food-grade stainless steel, a copper loop covered with non-slippery silicone, which is one-time use and throw. The risk assessment of the device has been mentioned.

The stainless steel part is angulated, meaning it is intended to go inside the mouth like a straw. Copper is known for its medicinal properties. It is strong enough to withstand human force, and the coat or outer jacket is of silicone rubber. It is nonslippery, and silicone rubber is nonreactive even at very high temperatures.

Risk Assessment of the Device

The device was used by the author, and it did not induce any choking. The patient is placed in a comfortable sitting position, and the therapist is standing in front of the patient. The therapist is wearing gloves and is using a mask during the therapy, as seen in Figure 1. Two ends of the device are of such a design that they can reach the tongue easily, as seen in Figure 2.

Protocol

Ethical Considerations

Ethical considerations were presented to the Institutional Ethics Committee of The School of Medical Science and Research & Sharda Hospital. The human issues were approved in the committee meeting dated 08/01/2024. Ref No- SU/SMS&R/76-A/2024/31. Informed consent has been received from all participants. This work conforms with the Code of Ethics of the World Medical Association (Declaration of Helsinki).

Study Design and Setting

Study design: randomized study. Study setting: Sharda Hospital. Study subjects: poststroke dysphagia. Study duration: 1 year. Instrumentation: tongue rehabilitation frame prototype, wooden compressor, transparent ruler, cotton gauge, and gloves. Independent variables: (1) tongue stretching and (2) tongue strengthening. Dependent variables: (1) tongue length, (2) swallowing abilities, and (3) tongue strength. Sample selection: criteria-based.

Participants

Sample size: N = 12. Inclusion criteria: all types of stroke patients with dysphagia, both male and female, age group: 60–75 years, score of less than 90 in M.D. Anderson Dysphagia Inventory (MDADI). Exclusion criteria: duration of stroke more than 1 year; GCS below 13; uncontrolled diabetes mellitus; uncontrolled hypertension; and previous history of chewing tobacco. Random group allocation by the chit method. The flow of the participants' recruitment is seen in Figure 4.

Data Collection

Data were obtained by the researcher using tools assessment at the baseline before starting the therapy. The tongue length was measured with the help of a transparent flexible ruler by placing it at the base of the incisors. Swallowing was assessed using the EAT-10 tool and the MDADI, which includes a questionnaire regarding swallowing ability for assessing tongue functions.

Data Analysis

Analyses were carried out using SPSS. A p-value of 0.05 was considered significant. Paired and independent t-tests were used for data analysis.

FIGURE 4. Flow chart of study procedure as per the CONSORT criteria of the randomized controlled trials.

Procedure

A total of 12 patients were divided into either Group A (n = 6) or Group B (n = 6). The distribution was based on the chit method. Group A received tongue stretching and strengthening using the novel device. Group B received tongue stretching and strengthening intervention without using a loop device. During the therapy, firstly, we placed the patient in a comfortable sitting position. For stretching, the patients were instructed to protrude their tongue and insert it into the loop of the device. The therapist pushed the loop to the base of the tongue and tightened it to grasp the tongue securely. Then, while maintaining the force according to the patient's comfort level, the therapist stretched the tongue and gently moved it toward the tip, providing intermittent stretches in between. Stretching was also applied in medial, lateral, superior, and inferior directions. Both dynamic and static stretching techniques were employed. For dynamic stretching, the tongue was held for 2–3 seconds, and for static stretching, it was held for about 20 seconds before guiding it back into the mouth. Stretching was performed in each direction with five repetitions per day, five times a week, for 4 weeks. For strengthening, during the therapy sessions, a wooden compressor was used to provide resistance alongside the novel device. The patients were instructed to protrude their tongue, and the therapist held the wooden compressor against it, applying resistance in forward, lateral (both right and left), and vertical (up and down) directions. The training was divided into 10 sets, each comprising 5 repetitions in each direction, with obligatory rest periods of 60 seconds between sets. This regimen was followed for 3 days a week over the course of 4 weeks.

RESULTS

Participants

Based on the methodology employed by Buscemi et al. (2022)[24], tongue motility has been measured as the distance between the lower lip and the tongue's greatest protrusion point during an active movement. In this study, 12 patients were randomly divided into two groups using the chit method. Group A (n = 6) received tongue stretching and strengthening intervention using a loop device. Group B (n = 6) received tongue stretching and strengthening intervention without using a loop device.

Loop Device Versus Conventional Use

The loop device provided tongue exercises clinically and effectively, and the pressure was applied from the base to the tip. Manually, more force and pulp-to-pulp grip give a less clean experience to the therapist and the patient. Table 1 summarizes the pre- and post-intervention measures for the tongue length change measure (TLCM), eating assessment tool (EAT-10) (Belafsky et al., 2008)[25], and MDADI (Alsubai et al., 2022)[26] for Groups A and B. The t-values and significance level (level of sig. < 0.05) indicate the statistical comparison between the groups for each measure. Figure 5 indicates the results graphically with actual p and t values.

TABLE 1. Summary of group comparison between Group A and Group B. The statistical significance has not been witnessed; the clinical acceptance of the novel device was better. [*Tongue Length Change Measure (TLCM), Eating Assessment Tool* (*EAT-10), and M.D. Anderson Dysphagia Inventory (MDADI).*]

Measures	Gr A Mean ± SD	Gr B Mean ± SD	*t*-value	Sig. (two-tailed)
Pre TLCM	1.6 ± 0.9	2 ± 0.34	–1.676	0.125
Post TLCM	2 ± 0.8	2.5 ± 0.4	–1.321	0.216
Pre EAT 10	24 ± 5.21	19.16 ± 2.48	2.05	0.086
Post EAT10	19.3 ± 6.8	13.5 ± 3.27	1.893	0.088
Pre MDADI	53.80 ± 7.71	51.73 ± 6.16	0.513	0.619
Post MDADI	62.97 ± 12.37	58.39 ± 6.16	0.812	0.436

Note: Gr means Group. Sig. means significance.

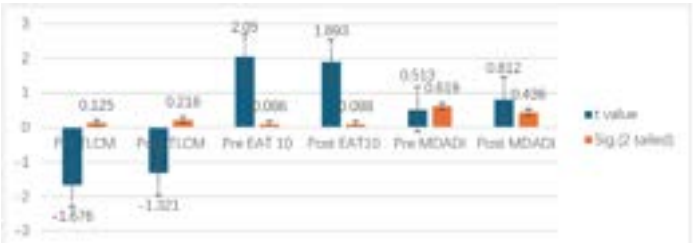

FIGURE 5. The bar graph shows the comparison of pre- and post-intervention measures between Groups A and B for tongue length change measure (TLCM), eating assessment tool (EAT-10), and M.D. Anderson dysphagia inventory (MDADI). The *t* values and actual *p* values are used.

Factors Associated with Loop Device

A two-tailed significance analysis has been used. The patient's position is comfortable, and the tongue is being elongated and assisted by the device. It is an active assisted/resisted movement of the tongue muscle and therefore can increase the functionality of the tongue, as seen in Figure 6.

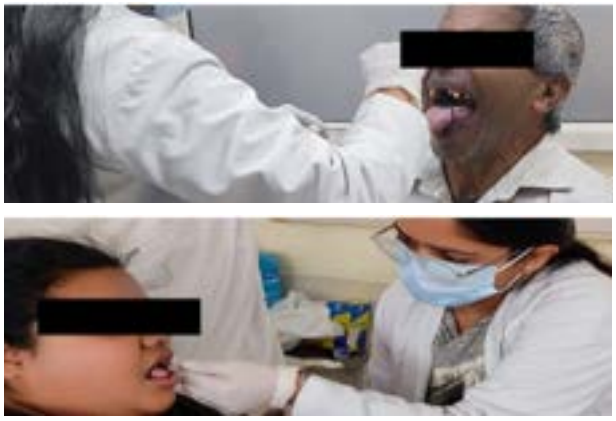

FIGURE 6. Tongue stretching and strengthening—a loop device is being used for tongue exercises. It allows stretching and strengthening exercises from the base to the tip of the tongue, affecting the intrinsic and extrinsic muscles of the tongue. It comprises a collapsible loop and a holder that is designed to enter the mouth. Written informed consent was obtained from all participants in the study.

TABLE 2. Cohen's d (effect size) for the tongue length change measure (TLCM), eating assessment tool (EAT-10), and M.D. Anderson dysphagia inventory (MDADI) scores for the groups after the intervention were given. Cohen's d = M1–M2/s pooled where s pooled =√[(s 12+ s 22) / 2] and rYl = d/√(d2 + 4). Note: d and rYl are positive if the mean difference is in the predicted direction.

S. No.	Measure	*r* (Effect Size)
1.	TLCM Group A	–0.22
2.	TLCM Group B	–0.55
3.	EAT10 Group A	0.36
4.	EAT 10 Group B	0.69
5.	MD Anderson Score Group A	–0.40
6.	MD Anderson Score Group B	–0.47

The paired sample *t*-tests revealed significant differences between pretest and posttest scores for both Group A and Group B in measures of TLCM, EAT10, and MDADI (all *p*-values < 0.05). Specifically, for Group A, TLCM scores increased significantly, while EAT10 scores decreased, indicating improvement in swallowing function and reduction in dysphagia severity. Similarly, MDADI scores significantly improved, suggesting an overall enhancement in swallowing-related quality of life.

In contrast, Group B also demonstrated significant improvements in TLCM and MDADI scores. However, the decrease in EAT10 scores was greater compared to Group A, indicating a potentially greater reduction in the severity of dysphagia. These findings suggest that interventions in both groups were effective in improving the swallowing function and quality of life. The study shows that, between groups, no significant results were found for Group A and Group B in tongue length ($p > 0.05$), Table 1, and within groups, significant results were found for Groups A and B in tongue length ($p < 0.05$), Table 3.

TABLE 3. Paired *t*-test for Group A and Group B for all variables, namely, Tongue Length Change Measure (TLCM), Eating Assessment Tool (EAT-10), and M.D. Anderson Dysphagia Inventory (MDADI).

Paired Comparison of the Groups												
Groups A & B paired analysis	TLCM				EAT 10				MDADI			
	m ± σ	SE	*t*	*p*	m ± σ	SE	*t*	*p*	m ± σ	SE	*t*	*p*
Group A Pre- and post-paired	−0.43 ± 0.24	0.98	−4.3	0.007	4.66 ± 2.87	1.17	3.9	0.11	−9.17 ± 6.79	2.77	−3.3	0.02
Group B Pre- and post-paired	−0.26 ± 0.17	0.07	−3.73	0.01	5.66 ± 1.36	0.55	10.15	0.01	−6.65 ±1.97	0.80	−8.27	0.01

DISCUSSION

To our knowledge, this study is the first to use a simple, low-cost loop device that offers a practical solution for delivering targeted therapy to dysphagic individuals by stretching and strengthening the tongue muscles. By gradually stretching the tongue from the base to the tip, the device aims to enhance tongue strength and mobility, thereby improving the swallowing function.

The study employed a quasi-experimental design to evaluate the effectiveness of the device in comparison to traditional manual exercises. However, both groups showed significant enhancements in tongue length and swallowing functions.

Tongue protrusion was studied by Cho et al. (2021)[27], who found a correlation between decreased maximal tongue protrusion length and poststroke dysphagia, highlighting the importance of assessing tongue function in dysphagic patients. Shimizu et al. (2021)[28] observed that low tongue pressure was associated with poor swallowing function in sarcopenic dysphagia patients, emphasizing the significance of tongue strength in swallowing physiology. Buscemi et al. (2021)[24] introduced a tongue muscle normalizing technique focusing on resetting deep tongue receptors, which led to improvements in tongue relaxation and tension reduction. This technique, although different from the intervention in our study, underscores the potential benefits of addressing tongue muscle function in dysphagia management. Hwang et al. (2019)[5,29] demonstrated the efficacy of tongue stretching exercises in improving oromotor function and tongue motility in dysphagic patients poststroke, aligning with our intervention's emphasis on tongue stretching and strengthening. Van den Steen et al. (2020)[30] investigated the effectiveness of tongue-strengthening exercises in patients with chronic radiation dysphagia, reporting improvements in tongue strength and swallowing parameters. While their focus was on a different patient population, the positive outcomes support the notion that targeted exercises can enhance tongue function and swallowing ability, as seen by others.[31,32]

Sakai et al. (2019)[33] explored the diagnostic accuracy of tongue strength and lip force for sarcopenic dysphagia in older inpatients. Their findings suggested a relationship between increased tongue strength and improved swallowing function, corroborating the importance of tongue muscle strength in dysphagia management. The findings of this study provide valuable insights into the effectiveness of tongue stretching and strengthening interventions using a novel device in improving swallowing function and reducing dysphagia severity among stroke patients. Both Group A and Group B demonstrated significant improvements in various outcome measures, including TLCM, EAT-10 scores, and MDADI scores, as seen in Table 1 and Figure 5. However, the clinically acceptable method of device-based stretching is more acceptable and hygienic in nature than manual stretching.

The significant increase in TLCM scores in both groups indicates an improvement in tongue muscle length by the loop device and manual stretching, which is essential for proper bolus formation and propulsion during swallowing. This improvement suggests that the tongue stretching and strengthening exercises, facilitated by the novel

device, effectively targeted the tongue muscles, leading to enhanced tongue mobility and function. The effect size as seen in Table 2 indicates a greater effect by manual stretching because it applies more force to the tongue.

Furthermore, the significant decrease in EAT-10 scores observed in both groups reflects a reduction in dysphagia severity following the intervention. Dysphagia can significantly impact a stroke patient's quality of life and nutritional status, and the improvement in EAT-10 scores suggests that the intervention successfully addressed swallowing difficulties, leading to enhanced eating ability and overall well-being. The effect sizes (*r*) as seen in Table-2 are in the medium to moderate category and the groups are compared.

Similarly, the significant increase in MDADI scores indicates an improvement in swallowing-related quality of life among participants. Dysphagia can have profound psychosocial implications, affecting an individual's confidence, social interactions, and emotional well-being. The improvement in MDADI scores suggests that the intervention not only improved the physiological aspects of swallowing but also had a positive impact on the participant's overall quality of life. The effect sizes as seen in Table 2 are of a comparable nature, and both interventions are equally effective.

The findings of this study are consistent with prior research on tongue rehabilitation in dysphagic individuals.[18–20] Studies by Steele et al. (2016)[34] and Kang et al. (2012)[35] have reported similar benefits of targeted tongue exercises in improving swallowing function and tongue strength. These findings underscore the importance of incorporating tongue stretching and strengthening exercises into dysphagia rehabilitation programs to optimize outcomes for patients.

Future Research

While this study provides promising results regarding the efficacy of tongue stretching and strengthening interventions, there are several avenues for future research to explore. Firstly, longitudinal studies with larger sample sizes and longer follow-up periods are warranted to assess the long-term effects of the intervention on swallowing function and dysphagia severity among stroke patients.

In addition, future research could investigate the optimal frequency, duration, and intensity of tongue stretching and strengthening exercises to maximize therapeutic outcomes. Furthermore, exploring the potential synergistic effects of combining tongue exercises with other rehabilitative interventions, such as neuromuscular electrical stimulation or traditional swallowing therapy, could enhance the efficacy of dysphagia management strategies. This may require the holder to be fixed with different attachments, as seen in Figure 7. Moreover, investigating the underlying mechanisms of how tongue stretching and strengthening exercises contribute to improved swallowing function could provide valuable insights into the pathophysiology of dysphagia and inform the development of targeted interventions.

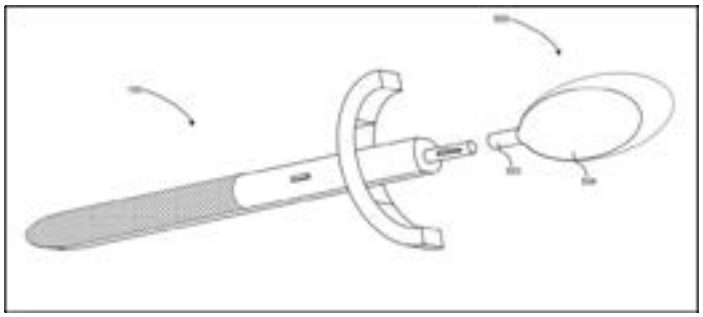

FIGURE 7. The conceived holder with the looped device is seen as an automatic control with a bite block in place. It is proposed as a digitally controlled platform for the attachment of all five distinctly functional heads of the ORF.

Relevance to Clinical Practice

The findings of this study have significant implications for clinical practice in the management of dysphagia among stroke patients. Tongue stretching and strengthening exercises using the novel device offer a safe, noninvasive, and cost-effective approach to improving swallowing function and reducing dysphagia severity. Health care professionals, including speech-language pathologists and rehabilitation therapists, can incorporate these exercises into their treatment protocols for stroke patients with dysphagia. The use of the device provides a hygienic and standardized method for delivering tongue exercises, ensuring consistency and reproducibility in clinical practice.

The observed improvements in swallowing-related quality of life underscore the importance of addressing dysphagia beyond physiological outcomes. Integrating patient-centered approaches that focus on enhancing overall well-being and functional outcomes can optimize dysphagia management and promote holistic patient care in any setting without significant financial burden.

Limitations

There may be limitations in the study, such as (1) The study's sample size of 12 patients may limit the generalizability of the findings. A larger and more diverse sample would enhance the robustness and external validity of the study results. (2) The study's follow-up period of only 5 weeks, including a 4-week therapy session and a 1-week follow-up, provides limited insight into the long-term effectiveness and sustainability of the intervention. Longer-term follow-up assessments would better elucidate the durability of the observed improvements in swallowing function and dysphagia severity. (3) While the study assessed various outcome measures, such as TLCM, EAT-10 scores, and MDADI scores, additional objective measures, such as instrumental assessments like video-fluoroscopy or fiber-optic endoscopic evaluation of swallowing (FEES), could provide more comprehensive insights into the swallowing function. (4) The study was conducted at a single center, which may limit the generalizability of the findings to other clinical settings with different patient populations, resources, and health care practices. Multicenter studies involving diverse patient cohorts would enhance the external validity of the study findings. Blinding of the patients is undertaken, but therapists were aware of the intervention as it is obvious and cannot be concealed.

Generalizability

Patients with dysphagia may enhance their dietary intake and quality of life through improvements in tongue strength and mobility and swallowing, as described by Abe et al., 2020.[36] Therefore, the novel device can be used for tongue exercises in stroke patients suffering from dysphagia, for improvement of functioning and quality of life.

CONCLUSIONS

The study underscores the clinical efficacy of tongue stretching and strengthening interventions using the loop device, among stroke patients with dysphagia. The significant improvements observed in TLCM, EAT-10 scores, and MDADI scores highlight the multifaceted benefits of the interventions in both groups.

AUTHOR CONTRIBUTIONS

D.V. and M.S. designed the work; D.V. acquired and analyzed data; D.V. and M.S. drafted, revised, and approved the manuscript. All authors agree to be accountable for all aspects of the work.

ACKNOWLEDGMENTS

No specific funding was obtained for this project.

FUNDING

This research received no external funding.

DATA AVAILABILITY STATEMENT

Data supporting reported results can be found at https://doi.org/10.6084/m9.figshare.26816143.

CONFLICTS OF INTEREST

The authors have no conflict of interest to report. The loop device is a patent, IPR patent no. 504718.

FURTHER DISCLOSURE

A related preprint can be found at https://papers.ssrn.com/sol3/papers.cfm?abstract_id=5558069.

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This paper is part of the Special Issue on Electron Microscopy in Dentistry: Clinical and Research Applications.
Guest Editor: Enzo Maria G. Cumbo, Giuseppe Alessandro Scardina, Pietro Messina, Università degli Studi di Palermo, Palermo, Italy

Received August 5, 2024, accepted December 9, 2025, publication date for online-first February 4,2026.

Original Research Article

Functional Significance of the Curve of Spee: Electromyographic Analysis of Young Adults—A Preliminary Study

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ABSTRACT

Background: The curve of Spee is a fundamental anatomic feature of dental occlusion that influences mandibular movement, muscle coordination, and masticatory efficiency. In contemporary orthodontics, standardized leveling and flattening of this curve are frequently adopted, as originally proposed by Andrews. However, in prosthetic and restorative dentistry, the management of the curve of Spee often requires a more individualized approach. Given the high prevalence of fixed orthodontic treatment, understanding the functional consequences of altering this occlusal curvature is clinically relevant. **Objective:** This pilot study aimed to investigate the effects of leveling the antero-posterior occlusal curve on muscular activity and functional harmony of the stomatognathic system in young adults previously treated with fixed orthodontic appliances. **Materials and Methods:** Sixteen young adult subjects with a history of fixed orthodontic treatment were enrolled. Muscular activity was assessed by surface electromyography using a four-channel Kinelock electromyographic device wirelessly connected to a dedicated personal computer. Electromyographic recordings were used to evaluate masticatory muscle function in relation to the occlusal configuration and the characteristics of the curve of Spee. **Results:** Electromyographic analysis revealed variations in muscular activity associated with modifications of the curve of Spee. The findings suggest that standardized flattening of the occlusal curve may influence neuromuscular balance and masticatory function, highlighting interindividual differences in functional adaptation. **Conclusion:** Within the limitations of this pilot study, the curve of Spee appears to be a parameter requiring individualized consideration to optimize functional harmony of the stomatognathic apparatus. Standardized leveling procedures may have unavoidable functional consequences, supporting the need for personalized occlusal management in orthodontic, prosthetic, and restorative treatments.

Keywords—*Curve of spee, Electromyographic analysis, Young adults.*

INTRODUCTION

The curve of Spee is an anatomical curve described by German anatomist Ferdinand Graf Von Spee in 1890, after whom it is named. It is a curve that is described as "an ideal line connecting the cusps, that is, the top of the natural teeth, starting from the canines and passing through the premolars to the molars of the same half of the mouth."[1] Spee realized how this curved line could optimize tooth contact between elements on antagonistic arches. The curve of Spee is defined as a dental parameter determined by the mesiodistal inclinations of the latero-posterior elements of the mandibular dental arch.[2] As Osborn demonstrated, this arrangement allows a more efficient distribution of forces and masseter action.[2] Osborn also noted that the inclination of the masseter was parallel to the long axis of the lower first molars.[2–10] The normal functions of the stomatognathic apparatus (chewing, swallowing, and phonation) result in contacts between antagonistic arches, and the consequent distribution of forces along the bone structure differs between patients because of several variable parameters, including the Spee curve. A similar sagittal arrangement of dental elements maximizes muscle efficiency during chewing.[2] These different muscle forces and the direction of the fibers could contribute to the mandibular shape and, consequently, could influence the inclination of the occlusal plane.[11] The curve of Spee is thus a dental parameter, which is probably affected and, in turn, influences both hard and soft tissues.[12] A similar curve in the sagittal plane is found in several mammalian taxa, including modern humans and fossil hominids. It went from a totally flat curve with a wide retromolar space, found in Neanderthals and Australopithecus, to the progressive change in the hominid craniofacial structure, which also included the appearance and variation of the curve in sapiens.[13] The presence/absence of this feature may be related to the functional variation of the masticatory apparatus and also to broader dentognathic spatial dynamics. It can be argued that this morphological relationship is probably due to the developmental and functional integration between the maxillary and mandibular dental arches.[13] Pathological situations, ethnicity, genetic components, and age may be part of the factors influencing the curve of Spee. This anatomical curve not only varies in relation to evolution but also varies interpersonally and even within the same individual, depending on age. Studies show that it varies according to the subject's stage of dentition. Marshall et al. noted how the occlusal plane is flat in full deciduous dentition.[14] Similar results were reported by Ash et al.[15], who suggested that deciduous dentition exhibits a curve of Spee that ranges from flat to slight, whereas dentition in adulthood exhibits a more pronounced Spee curve, which is stabilized and maintained. Thus, if in deciduous dentition the flattened curve is physiological, the same cannot be said for the curve in adulthood. Often, however, there is a tendency to alter this curve to reduce its depth or level it off, especially in the orthodontic school that follows Andrews, who believed that this curve should be reduced or eliminated to improve occlusal contact.[4]

While that is true in static structures, it must nevertheless be remembered that the mandible is an organ that performs its functions primarily in movement. When designing dental treatment that is aimed at maintaining or restoring ideal functional harmony, not only must the centric movements of the mandible be taken into account but also the eccentric and excursive components of mandibular movements. In fact, this curve favors the posterior disocclusion in protrusive movements.[16] As proof of this, a clinical examination that can be carried out is to ask patients to perform a protrusive movement by bringing the upper incisal margins into a head-to-head position with the lower ones. Subsequently, the amount of posterior disocclusion should be noted, as well as the presence of any precontact or contact that obstructs the movement. Dental extrusions can pathologically alter this curve and lead to a similarly altered occlusal plane[17], with the presence of posterior protrusive interference, which can cause abnormal activity—hyperactivity—in mandibular elevator muscles, particularly the masseter and temporalis muscles[18], whose activity was examined in this study using electromyographic tracings. Excessive interference can also cause wear and tear, the fracture of restorations, and temporomandibular joint dysfunction. In confirmation of this, it has been observed that problems such as temporomandibular disorders are more prevalent in patients in whom the curve of Spee has been altered following orthodontic treatment.[19] Such complications can be avoided by reconstructing a curve of Spee that is

in harmony with the subject's stomatognathic apparatus, and in particular with the structure of the mandibular condyle.[18] The purpose of this study is to investigate the curve of Spee in relation to muscle activity, assessed by electromyographic analysis, in a group of 16 young adults with previous fixed orthodontic treatment.

MATERIALS AND METHODS

Digital imprints and electromyographic tracings of the anterior masseter and temporalis muscles were taken in a group of 16 subjects. The age of the subjects examined ranged from 20 to 25 years. All the subjects had Angle Class I occlusal relationships and had undergone previous fixed orthodontic treatment.

The study consists of three phases: 1. Measurement of the curve of Spee on digital imprints and assessment of the extent of occlusal contact, using the Cerec software, version 5.2.4 (Dental CAD/CAM software; Dentsply Sirona Inc., Charlotte, NC, USA, 2022); 2. Analysis of the electromyographic tracings obtained from the same subjects, study of the indices obtained from the electromyographic recordings, and evaluation of the fit bite system of the Kinelock electromyograph software (4T srl Cisnago Italy); 3. Correlation of the data obtained.

Materials

Fingerprints were taken using the Primescan Connect intraoral scanner. For the evaluation of the occlusal contacts, the obtained digital surveys were studied using the Cerec 5.2.4 software. Data measurements of the maximum depth of the curve of Spee were made on digital models, with the Blender computer graphics computer-aided design (CAD) software (version 2023). In order to detect information about the muscular activity of the same subjects, the 4-channel Kinelock electromyographic device was used, wirelessly connected to a dedicated personal computer (PC). The readings were carried out using disposable bipolar Ag/AgCl electrodes. Before placing these electrodes, cotton swabs with an alcoholic solution were used to cleanse the skin. For the neutralization of occlusal contacts, cotton rolls with a diameter of 10 mm were used. Latex gloves were used to conduct the study. The data obtained from the present study were recorded using the Panasonic Lumix GH4 camera.

Methods

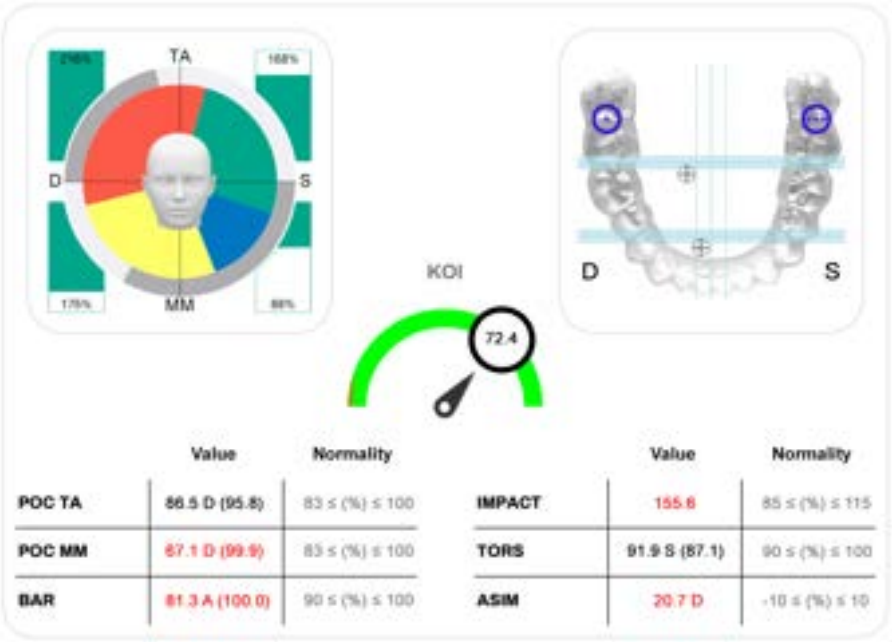
The fingerprints of upper and lower dental arches and of the position of maximum intercuspidation (bite) of each of the 16 examined subjects were considered. With the Cerec 5.2.4 software, it was possible to visualize the colorimetric evaluations of the extent of the occlusal contacts (generated by the articulation of the opposing dental arches in maximum intercuspidation). On these fingerprints, the curves of Spee were evaluated, both in the right and left side of the mandibular arch.

The maximum depth of the curve of Spee was measured in the mandibular arch as the greatest perpendicular distance between the tips of the buccal cusps of the mandibular teeth and a plane of measurement that went from the canines to the tip of the distal cusp of the most posterior ipsilateral tooth of the same dental arch. The maximum depth was studied by plotting several segments with the software, starting from the cusps of the latero-posterior elements perpendicular to the curve, and selecting the one having the greatest value corresponding to the point of maximum depth of the curve. The same subjects underwent electromyographic studies to assess activity of the masticatory muscles: both anterior temporalis and masseter.

The Kinelock electromyograph, equipped with eight channels, connected wirelessly to a dedicated PC, was used for the study. Bipolar Ag/AgCl electrodes, with 10-mm diameter and 1-mm inter-electrode distance, were used for all the subjects and muscle surfaces, using a gelled surface treated with conductive paste and a reference electrode placed at the center of the forehead on a silent area. Before placing the electrodes on the skin, it was necessary to clean it with a cotton swab soaked in methylated spirit. Electrodes were placed parallel to the muscle fibers. For the anterior temporalis, they were placed vertically along the anterior margin of the muscle, just above the coronal suture, while for the masseter, they were placed parallel to the muscle fibers with the upper pole at the height of the intersection of the plane between the tragus and the angle of the lips and the plane between the gonion and the outer canthus of the eye. For each subject, five acquisitions lasting for 5 seconds each were performed in the position of maximum voluntary contraction (MVC). During these tests, the subjects were

verbally urged to clench as hard as possible. They were not shown the tracings during the test to avoid alterations because of visual biofeedback. In order to simulate the subjects' muscular activities as closely as possible to reality, the assessments were made with visual correction means usually used by the subjects examined. For the first three recordings, the subjects were made to sit on a wooden chair, assuming a straight posture, with their feet resting on the ground and their hands resting on their knees, their gaze directed toward the horizon plane. The additional two acquisitions, on the other hand, were taken by asking the subjects to acquire an orthostatic posture, with their gaze toward the horizon and their arms along their sides. In the first survey, a neutralization of the occlusal contact through "cotton clenching" was performed: in subjects seated according to the arrangements described above, with their eyes open and looking straight at the horizon, two cotton rolls, 10 mm in diameter, were interposed between the arches, symmetrically in the left and right premolar areas. After cotton clenching, the cotton rollers were removed, and the additional four recordings were made. The second recording was made with the subject sitting and eyes open. The third recording was made with the subject sitting and eyes closed. The fourth and fifth recordings, on the other hand, were made in the orthostatic position, with eyes open and then eyes closed, respectively. Thus, the electromyographic activity of the masseter muscles and the anterior temporalis muscles on both sides was recorded in different positions with eyes open and closed, to study the possible influence of postural and visual proprioceptive inputs. From electromyographic recordings, it was possible to evaluate raw and root mean square–derived standardized electromyographic signals (RDS) tracings to study the percentage of overlapping coefficient for masseter muscles (POC MM), percentage of overlapping coefficient for the temporalis anterior muscles (POC TA), IMPACT index (overall muscle work), BAR index (occlusal barycenter), and TORS index (muscle activity torsion).

The POC indices (masseters/anterior temporals) indicate the level of contraction symmetry of the individual pairs of muscles—masseters or anterior temporals. In case of perfectly symmetrical contraction, that is, if two muscles contract with perfect symmetry, we obtain a POC = 100%. A malocclusion condition that reduces this symmetry is highlighted by a lower value at 83%. The BAR index refers to the overlap percentage between the clenching activity of the pair of anterior temporals, compared to the pair of masseters. When there is a prevalence of posterior contacts, the masseters do contract more than the anterior thunderstorms. Conversely, if the contacts are concentrated anteriorly, the occlusal barycentre will be anterior and the temporal contracts more. The lower limit of normal for the BAR value is 90%. The IMPACT index represents the electrical activity that each single muscle expresses during the test, compared to the cotton calibration values, expressed as a percentage; evaluate the intensity of the muscle work during maximum intercuspidation. The normal range is 85–115%. The TORS index measures the torsional attitude of the mandible (in the transversal plane) when this articulates in occlusion with the maxilla. Compare pairs "right anterior temporal to left masseter" and "left anterior temporal to masseter right." Normality varies between 90% and 100%. The presence of occlusal fulcrums can cause the prevalence of one couple over the other, resulting in a torsion of the jaw. The ASIM (asymmetry) index evaluates the symmetry of muscle contraction, of occlusal condition, between left and right-side muscles. In normal ranges, the index can vary between −10% and +10% (assuming positive values in case of occlusal prevalence in the right hemiarch and negative values in case of occlusal prevalence in muscles on the left). Over the evaluation of such electromyographic indices, it is possible to visualize the graphical representation of the occlusal condition of each individual subject with the fit bite algorithm of the software, which shows the areas in which the occlusion should be modified, suggesting possible modifications of the thickness necessary to obtain a better muscular activity (Figure 1).



	Value	Normality		Value	Normality
POC TA	86.5 D (95.8)	83 ≤ (%) ≤ 100	IMPACT	155.6	85 ≤ (%) ≤ 115
POC MM	67.1 D (99.9)	83 ≤ (%) ≤ 100	TORS	91.9 S (87.1)	90 ≤ (%) ≤ 100
BAR	81.3 A (100.0)	90 ≤ (%) ≤ 100	ASIM	20.7 D	-10 ≤ (%) ≤ 10

FIGURE 1. Indices obtained from an electromyographic recording, with muscle activity graph and fit bite algorithm (Kinelock electromyograph).

RESULTS

This study evaluated the influence of the arrangement of dental elements in the sagittal view on the contractile activity of the masticatory muscles.

The subjects examined presented curves of Spee with mild depth, zero depth, and in some cases, had a negative curve (inverted concavity), probably caused by previous orthodontic treatment. The study shows that in the arches where the curve of Spee is more flattened and leveled, the maximum depths of the curve are often reached at the level of the distal buccal cusp of the first molar.

A further observation pertains to the differences in the depth of the curves in two hemiarches, left and right, in the same subject.

It was noted that the curvatures of the two hemiarches are different, in a variably marked manner, and that the hemiarches in which the third molar is present have a greater curvature. In fact, the presence of the third molar in the arch causes a significant increase in the curve of Spee. The results show that the hemiarch in which the curvature is deepest is the hemiarch of the subject in which the occlusal contacts in maximum intercuspation are greater, as observed by colorimetric evaluations (Figure 2), and in which the stress resulting from occlusion in maximum intercuspation appears as more distributed at the molar level and less localized at the premolar, canine and incisor levels. In contrast, in the arches or hemiarches in which the curve of Spee is flatter and almost level, stress appears to be more evenly distributed over anterior, lateral, and posterior elements.

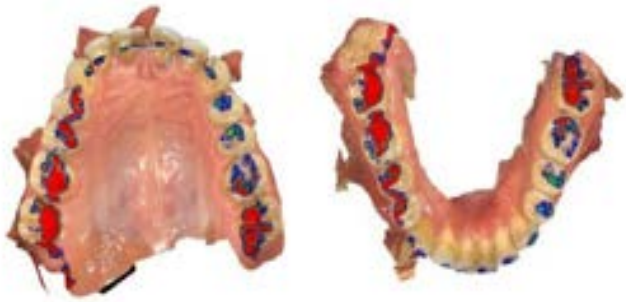


FIGURE 2. Colorimetric analysis of occlusal contacts (Cerec 5.2.4 software).

With these curve depth values (reduced, zero, or reversed), an increased activity was noted in the anterior temporalis. The BAR index (occlusal centre of gravity) was found to vary in all subjects and be delocalized anteriorly (Figure 3). In addition to the BAR index, the

electromyographic evaluations showed that IMPACT was another parameter which was often found to be lower than the normal range (Figure 4).

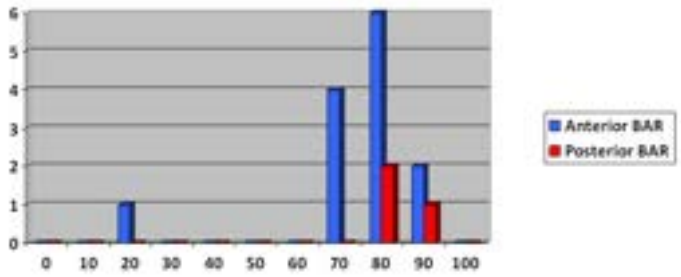


FIGURE 3. Histogram of the distribution of BAR index values in the studied subjects. The abscissa axis represents BAR values (%), and the ordinate axis represents the number of subjects. Red bars indicate posterior occlusal center of gravity, whereas blue bars indicate anterior occlusal center of gravity. Columns with values >90% indicate a good occlusal center of gravity. Most subjects showed BAR values <90%, with a predominance of anterior localization (blue bars), indicating an occlusal center of gravity frequently outside the normal range and shifted anteriorly.

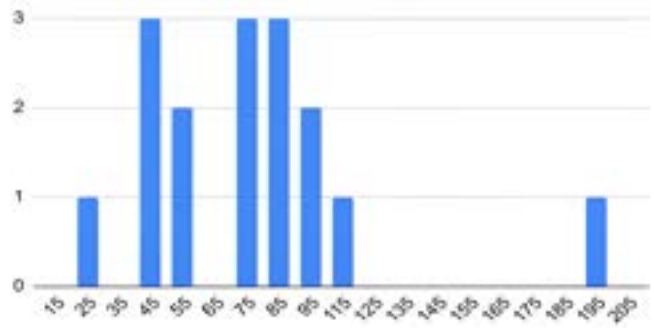


FIGURE 4. Histogram of the distribution of IMPACT index values in the studied subjects. On the abscissa axis is the IMPACT index value, and on the ordinate axis is the number of subjects. Columns between 85 and 115 indicate the IMPACT index. Values are found within the normal range. The prevalence of columns for values < 85 is noted; this indicates that most of the subjects have an IMPACT index altered beyond the normal range, often reduced.

In these cases, the system's fit bite algorithm indicated the need for shim additions in posterior sectors (Figure 1). Changes in MVC activity recorded in the muscle activity while seated, and the activity measured in orthostatism, presented no significant differences; both tracings and indices were found to be similar, slight differences presented were related to interpersonal variations. Visual inputs were found to be irrelevant in the muscle activity of the examined masticatory muscles. Slight differences in developed contractile activity (along the vertical y-axis of the ordinates of electromyographic tracing, measured in microvolts) reoccurred and were reflected in slight, non-significant differences at the level of the indices evaluated.

For this reason, in this study, the results of electromyographic recordings obtained while sitting and eyes opened were considered, as shown in the results (Table 1).

TABLE 1. Values obtained from measurements of the maximum depth of the curve of Spee and indices obtained by electromyographic examination.

Case	Maximum Depth of the Left Hemiarch Spee Curve	Maximum Depth of the Right Hemiarch Spee Curve	Bar 90 < (%) < 100	Impact 85 < (%) < 115	POC MM 83 < (%) < 100	POC TA 83 < (%) < 100	TORS 90 < (%) < 100	ASIM −10 < (%) < 10
1	2,219 mm	2,183 mm	89.6P	47.6	86.6L	82.3L	92.1L	−10.5L
2	2,779 mm	2,834 mm	76.8A	50.4	82.8R	91.6R	93.9L	9.8R
3	3,491 mm	1,663 mm	88.4A	64.0	89.4L	92.0R	92.2L	−1.4L
4	2,029 mm	1,842 mm	78.4A	27.0	86.3L	91.1L	92.8L	−5.0L
5	1,778 mm	4,154 mm	88.0A	81.1	93.5R	91.9R	94.5L	1.9R
6	1,474 mm	1,043 mm	87.6A	89.3	86.3R	84.7R	91.1L	11.0R
7	2,624 mm	2,159 mm	94.0A	98.3	89.7L	89.8L	94.1L	−5.8L
8	−1,257 mm	−1,403 mm	91.0A	119.2	91.4L	92.9L	95.3L	−3.3L
9	2,092 mm	2,302 mm	91.2P	112.9	88.3L	87.3L	92.2L	−3.7L
10	1,810 mm	2,927 mm	29.3A	52.2	62.5R	76.9R	84.7L	21.7R
11	4,281 mm	5,214 mm	88.7A	87.1	80.8L	88.8R	88.8R	−7.1L
12	2,784 mm	1,224 mm	80.8A	83.5	89.5R	82.5L	87.9L	−6.4R
13	1,412 mm	1,560 mm	89.0A	76.2	81.8L	89.0A	90.4L	0.1R
14	1,271 mm	1,035 mm	81.9P	198.7	62.6R	82.5L	71.1L	15.0R
15	4,214 mm	−1,082 mm	78.3A	59.7	74.3L	56.4L	82.9L	−36.2L
16	2,695 mm	3,783 mm	86.9P	90.2	93.9L	81.3L	93.1L	−10.5L

Footnote: Electromyographic recordings obtained while sitting and eyes opened were considered. Abbreviations: P, posterior; A, anterior; L, left; R, right.

DISCUSSION

The curve of Spee is in harmony with other factors that include the condylar guidance angle, the incisal guidance angle (overbite and overjet), and the occlusal plane angle. This harmony involves not only the dentoskeletal tissues but also the soft tissues.

The reduced, zero, or negative depth values of the curve of Spee assessed in the examined subjects imply a prevalence of anterior contacts (as visible in the colorimetric assessments) and correspond to an increased activity in the anterior temporalis, probably as a result of the reduced depth of the curve of Spee.

This finding is confirmed by the BAR index (occlusal center of gravity), which varied in all the subjects and was anteriorly delocalized in at least one of the five electromyographic recordings made in each subject.

This observation can be correlated with the images of the colorimetric evaluations of occlusal contacts carried out by the intraoral scanner software. Above all, in cases of leveled curves of Spee, occlusal contacts in maximum intercuspation are observed as well distributed along the arch, in a homogeneous manner, even at the level of the anterior incisal region, where, however, there should be a "grazing" contact and instead this contact is very much present, for guidance, during the protrusive excursive movements. Alteration in the BAR index can be correlated with the change in the IMPACT index. The latter index corresponds to the distal vessel occlusion (DVO) of the subject: an increase in DVO correlatively produces an increase in IMPACT index, which can be read as an index of chewing effectiveness.[20] The IMPACT index was found to be altered in almost all subjects: in most cases it was lower. In these cases, the system's fit bite algorithm indicated the need for the addition of shims in the posterior sectors to restore an ideal curve of Spee, increasing its depth.

Information from the colorimetric analysis of occlusal contacts and from the fit bite software of the Kinelock electromyograph confirms the need for the addition of thickness at the posterior level.

If in a study it is observed that a mild and flattened curve of Spee is correlated (when the other values were normal) to low IMPACT, with a need for increased posterior DVO and an increase in the Spee curve, it is assumed that leveling has resulted in a reduced biological vertical dimension of occlusion in the individual and a consequent reduced effectiveness of the masticatory muscle activity.

On the other hand, it is also possible that leveling alters the DVO by increasing its values.

The IMPACT index increases in subjects with increased DVO, for example because of leveling caused by excessive extrusion in the premolar/molar area: the curve of Spee should no longer be restored by adding thickness and height to increase posterior DVO, by adding hard tissue, or by extruding teeth and tilting them mesially, but rather by decreasing this DVO through selective intrusion or grinding.

Therefore, in the leveling of the curve of Spee, one of the issues that can arise is how to maintain a DVO in the ideal biological range for the subject and for the correct and the most effective muscular and postural functioning. Leveling the curve of Spee could in fact cause an alteration in DVO, which may increase or decrease.

When the mandibular curve is convex with negative depth values, DVO is increased, as is the IMPACT index. On the other hand, the leveling of the curve of Spee in the other cases result in reduced DVO, with low IMPACT index, and the consequent need, as indicated by the fit bite algorithm, to add shims at the posterior level, increasing DVO at the molar level, along with IMPACT, thus achieving a restoration of the curve of Spee. In addition, the fact that the maximum depth of the curve is often reached at the level of the distal buccal cusp of the first molar highlights how the mesiodistal inclination of these elements is different from normal, where the maximum depth is generally reached at the level of the buccal cusp of the second molar or at the mesiobuccal cusp of the first molar, because of their mesiodistal inclination. In the hemiarch in which the curve is deeper, the mesiodistal inclinations of the posterior elements are greater. In these cases, the occlusal stress is distributed more on these lateral-posterior dental elements and is less localized anteriorly. Moreover, the occlusal contact in the maximum intercuspation is greater. This arrangement of contacts and stress in the maximal intercuspation benefits both lateral and anterior elements, which are the ones assigned to bearing high occlusal loads, especially in movements with a greater vertical component (unlike the anterior and

lateral elements, which are usually used more in movements in which the horizontal component predominates: the antero-posterior and the latero-lateral, respectively).

Conversely, in the arches or hemiarches in which the curve of Spee appears to be shallower, stress appears to be more evenly distributed on anterior, lateral, and posterior elements, thus making both anterior and lateral elements susceptible to stress arising from the centric component of mandibular movements, and the posterior ones susceptible to stress from the eccentric and excursive components of the same mandibular movements during chewing.

In confirmation to this, it is observed from the electromyographic tracings that a deeper arch curve does not only correspond, as mentioned, to the arch in which the stronger occlusal contact occurs and is more localized at the molar level in maximum intercuspation but it is observed that it is also the arch in which a greater ipsilateral masseter activity occurs (within normal ranges). This is observed by analyzing both tracings and indices of the respective electromyographic evaluations.

Limitations of the Study

To better assess muscle function as a function of occlusion, it is proposed that dynamic electromyographic evaluations be made in future studies, especially for protrusive movements, with the relative muscles involved, in which the curve of Spee has been observed to play an important role.

The present study focuses its attention on the curve of Spee. It would be interesting if the evaluation was also applied to the curve of Wilson for a complete three-dimensional analysis of the occlusal plane.

An additional limitation of the study is the reduced size of the group of young adults on whom the test was performed, from which Angle class II and III subjects were excluded.

In addition, since many of the subjects evaluated had had previous orthodontic treatment, it would have been interesting to evaluate not only the post-treatment data but the pre-treatment data as well.

CONCLUSIONS

The curve of Spee represents a variable in dentistry treatments, in both orthodontic field and conservative prosthetic one, and it must be taken into account to achieve maximum masticatory efficiency and muscular balance in the stomatognathic apparatus.

In the orthodontic field, the flattening of the curve of Spee is expected in both restorative and prosthetic fields. Such a compensatory curve plays an indispensable role in positive outcomes, success, stability, and long-term prognosis of the element. Its alteration or the production of a curve that is not in harmony with the balance, both static and dynamic, of the neuro-musculo-skeletal (NMS) apparatus of the subject may lead to various difficulties. Proposing a treatment with an alteration of such a curve should raise questions, not only about the stability of the treatment but also about the occlusal and overall harmony of the stomatognathic system.

INSTITUTIONAL REVIEW BOARD STATEMENT

The study was conducted in accordance with the Declaration of Helsinki and approved by the Institutional Review Board (or Ethics Committee) of University of Palermo-Policlinico Paolo Giaccone n. 04/2023 (19/04/2023).

AUTHOR CONTRIBUTIONS

Conceptualization, G.A.S., and I.B.; Methodology, G.A.S., I.B., and E.M.C.; Validation, M.I.K., A.M., G.G., and G.B.; Formal analysis, I.B.; Investigation, I.B. and G.A.S.; Data curation, I.B.; Writing—original draft preparation, G.A.S.; Writing—review and editing, P.M.; Visualization, A.M., M.I.K., and L.C.; Supervision, P.M.

ACKNOWLEDGMENTS

No specific funding was obtained for this project.

CONFLICTS OF INTEREST

The authors declared no conflict of interest.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

Informed consent was obtained from all the subjects involved in the study.

FUNDING

This research received no external funding.

FURTHER DISCLOSURE

Not applicable.

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Received August 5, 2024, accepted December 21, 2025, publication date for online-first February 10, 2026.

Original Research Article

Predicting Patient Satisfaction in Indian Healthcare Using Artificial Intelligence: A Data-Driven Approach to Patient Relationship Management

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ABSTRACT

Background: Patient satisfaction serves as a vital measure of healthcare quality, especially in regions with limited resources, such as Chhattisgarh, India—a state characterized by its tribal populations and underdeveloped medical infrastructure. This research employs Artificial Intelligence (AI) to forecast patient satisfaction levels, specifically the overall satisfaction, with the goal of improving patient relationship management (PRM) in a public hospital setting in Chhattisgarh. **Methods:** Data from 107 patient surveys were examined, encompassing demographic factors (e.g., age group, gender, income level, and frequency of visits), service quality aspects (e.g., timeliness, accessibility, communication, system efficiency), and views on technology (e.g., technology quality and usability). An XGBoost regression model was developed to predict the overall satisfaction, complemented by SHapley Additive exPlanations (SHAP) for model interpretability. Additional analyses involved Pearson correlations, multiple linear regression, and *t*-tests. Missing values (under 5%) were handled through *k*-Nearest Neighbors (*k*-NN) imputation. The study did not involve preregistration or animal testing. **Results:** The XGBoost model yielded a root mean squared error (RMSE) of 0.39 and a coefficient of determination, R^2 of 0.90. SHAP highlighted communication (mean SHAP value = 0.72, $p < 0.001$), system efficiency (0.48, $p < 0.01$), and technology usability (0.35, $p < 0.05$) as primary influencers. Correlations revealed strong links, such as between communication and the overall satisfaction (correlation coefficient, r = 0.82, $p < 0.001$). Regression analysis supported the significance of communication ($\beta = 0.70$, $p < 0.001$) and system efficiency ($\beta = 0.45$, $p < 0.01$). Patients with very frequent visits showed reduced satisfaction (mean = 3.5 vs. 4.0 for occasional visitors, $p < 0.001$). **Conclusions:** Artificial Intelligence demonstrates strong potential for predicting patient satisfaction, emphasizing the roles of communication and operational efficiency. These insights could guide targeted PRM interventions in Chhattisgarh to better serve tribal and low-income groups. However, given the modest sample size from a single site, results should be viewed as preliminary, warranting larger-scale validation.

Keywords—*Patient satisfaction, Artificial intelligence, Predictive analytics, Healthcare technology, SHAP, Patient relationship management.*

INTRODUCTION

Patient satisfaction, defined here as the overall satisfaction (OS), captures how well healthcare services meet patient expectations, influencing treatment adherence, trust in providers, and long-term health results.[1] In India, with its population surpassing 1.4 billion, public health systems grapple with resource shortages and varied patient demands.[2] This challenge is amplified in Chhattisgarh, a central state home to 29.4 million people, including 30.6% from tribal groups in remote areas.[3] The state's healthcare faces constraints, with just 1.8 beds per 1000 residents (below India's average of 2.9 beds) and a doctor–patient ratio of 1:2000, falling short of the World Health Organization's 1:1000 standard.[4] Effective patient relationship management (PRM) is essential to elevate patient experiences and streamline care in such environments.[5]

Conventional methods for gauging satisfaction, such as paper surveys, are typically conducted after the fact, leading to issues such as recall inaccuracies and delayed insights. For instance, research in Indian public hospitals indicates that 60% of surveys occur post-discharge, limiting their use for immediate improvements.[6] Artificial intelligence (AI) presents a forward-looking alternative by forecasting OS in real time using diverse data sources, enabling timely PRM adjustments.[7] In Chhattisgarh, where 70% of surveyed patients were women and 40% earn Indian rupees (Rs.) 10,000–20,000 monthly, AI can tailor solutions to address needs such as accessible communication and user-friendly technology for tribal and economically disadvantaged communities.[8]

This investigation draws on 107 patient surveys collected in April 2025 from a Chhattisgarh public hospital. OS averaged 3.85 (standard deviation [SD] = 0.92) on a 5-point Likert scale (1 = strongly disagree, 5 = strongly agree). [9] The data covered the following:

- **Demographics:** Age group (60% aged 25–34 years), gender, income level, and visit frequency (35% occasional).[10]
- **Service quality:** Timeliness (mean = 3.75, SD = 0.95), accessibility (3.80, 0.90), communication (4.15, 0.75), and system efficiency (4.05, 0.80).[11]
- **Satisfaction metrics:** OS, expectations met, feeling valued, and communication satisfaction.[12]
- **Technology aspects:** Technology quality, usability (3.90, 0.85), communication via technology, and efficiency.[13]
- **Additional factors:** Admission efficiency, care quality, discharge smoothness, and intent for continued use.[14]

An XGBoost regression model was developed to predict the overall satisfaction, complemented by SHapley Additive exPlanations (SHAP) for model interpretability. Employing this XGBoost model with SHAP for transparency, we predicted OS and located key factors such as communication, system efficiency, and technology usability.[15] Research questions include the following: (1) Can AI reliably forecast OS using elements, such as communication and efficiency?[16] (2) What drives OS in Chhattisgarh, and how does visit frequency affect it?[17] (3) How does SHAP boost AI's value for PRM?[18] This aligns with India's 2017 National Health Policy for fair healthcare access, aiming to enhance outcomes for Chhattisgarh's tribal populations.[19]

MATERIALS AND METHODS

Materials

The dataset includes responses from 107 patients gathered through a digital survey at a public hospital in Chhattisgarh, India. The questionnaire, created with Google Forms (Google LLC, Mountain View, CA, USA), featured demographic items and 5-point Likert-scale questions (1 = strongly disagree, 5 = strongly agree).[20] No animals or physical specimens were used in the study. Analysis occurred in Python 3.8 (Python Software Foundation, Wilmington, DE, USA), utilizing libraries such as pandas (2.2.2), XGboost (2.1.1), SHAP (0.46.0), matplotlib (3.9.2), and seaborn (0.13.2).

Data Preprocessing

Survey data were imported from an Excel file (Microsoft Corporation, Redmond, WA, USA). Variables encompassed age group, gender, income level, visit frequency, timeliness, accessibility, communication, system efficiency, OS, expectations met, feeling valued, communication satisfaction, technology quality, usability, communication, efficiency, admission efficiency, care quality, discharge smoothness,

and continued use. To prepare for analysis—particularly for nonexperts, note that preprocessing ensures data cleanliness and model compatibility—categorical variables (e.g., age group, gender, and visit frequency) were converted to numerical form via one-hot encoding, creating binary indicators for each category. Numerical variables (e.g., timeliness and communication) were standardized to a mean of 0 and an SD of 1 to prevent scale biases in modeling. Missing entries, affecting less than 5% per variable, were filled using *k*-Nearest Neighbors (*k*-NN) imputation ($k = 5$), which estimates values based on similar observations. Outliers beyond three SDs were capped at that threshold to minimize their undue influence without removal.

Machine Learning Model

We used an XGBoost regressor—a popular AI algorithm for regression tasks that builds sequential decision trees to minimize prediction errors—to estimate OS from predictors: timeliness, accessibility, communication, system efficiency, and technology usability. The data were divided into 70% training and 30% testing sets. Hyperparameters were optimized through grid search, a systematic trial of combinations:

- **Learning rate:** 0.1 (controls update size per iteration).
- **Maximum depth:** 5 (limits tree complexity to avoid overfitting).
- **Number of estimators:** 100 (total trees built).

Performance metrics included a root mean squared error (RMSE; measures average prediction error) and a coefficient of determination, R^2 (indicates variance explained). Stability was assessed with five-fold cross-validation, splitting data into five parts for repeated training/testing. For interpretability, SHAP values were calculated using a tree explainer. SHAP, grounded in game theory, assigns contribution scores to each feature for individual predictions, as per the following formula:

$$\phi_i = \sum_{S \subseteq N \setminus \{i\}} \frac{|S|!(|N| - |S| - 1)!}{|N|!} [f(S \cup \{i\}) - f(S)] \quad (1)$$

where φ_i is the SHAP for feature i, N all features, S a subset without i, f the prediction function, and $|S|$ the subset size.

Correlation analysis

Pearson's correlation coefficients, which quantify linear relationships between variables (ranging from −1 to 1), were computed for OS and predictors, with p values testing significance.

Regression analysis

Multiple linear regression modeled OS as a linear combination of timeliness, accessibility, communication, system efficiency, and technology usability, yielding standardized coefficients (β), standard errors, and p values to identify influential factors.

Statistical Analysis

Using Python's scipy (1.11.1) and statsmodels (0.14.0), we performed *t*-tests to compare OS by visit frequency groups (e.g., very frequent vs. occasional). Significance threshold was $p < 0.05$. Descriptive statistics (means, SDs, min./max.) were calculated, with visualizations via matplotlib and seaborn for better comprehension.

RESULTS

Descriptive Statistics

Table 1 summarizes key variables. OS mean was 3.85 (SD = 0.92), suggesting generally positive but room-for-improvement satisfaction. Communication rated highest (mean = 4.15, SD = 0.75), then system efficiency (mean = 4.05, SD = 0.80), with timeliness lowest (mean = 3.75, SD = 0.95). Demographically, 60% patients were aged 25–34 years, 70% were females, 40% were in the Rs. 10,000–20,000 income bracket, and 35% were occasional visitors.

TABLE 1. Descriptive statistics of key variables.

Variables	Mean	SD	Min.	Max.
OS	3.85	0.92	1	5
T	3.75	0.95	1	5
A	3.80	0.90	1	5
C	4.15	0.75	1	5
SE	4.05	0.80	1	5
TU	3.90	0.85	1	5
CQ	4.00	0.80	1	5
CU	3.95	0.85	1	5

Note: OS: overall satisfaction; T: timeliness; A: accessibility; C: communication; SE: system efficiency; TU: technology usability;

CQ: care quality; CU: continued use. All on 5-point Likert scale (1 = strongly disagree, and 5 = strongly agree).

Correlation Analysis

Table 2 displays Pearson's correlations. OS strongly correlated with communication (correlation coefficient, $r = 0.82$, $p < 0.001$), system efficiency ($r = 0.78$, $p < 0.001$), and technology usability ($r = 0.65$, $p < 0.001$). Care quality and continued use showed moderate ties ($r \approx 0.70$, $p < 0.001$). Figure 1, a heatmap, uses blue shades for positive correlations (darker for stronger, e.g., communication–OS at 0.82).

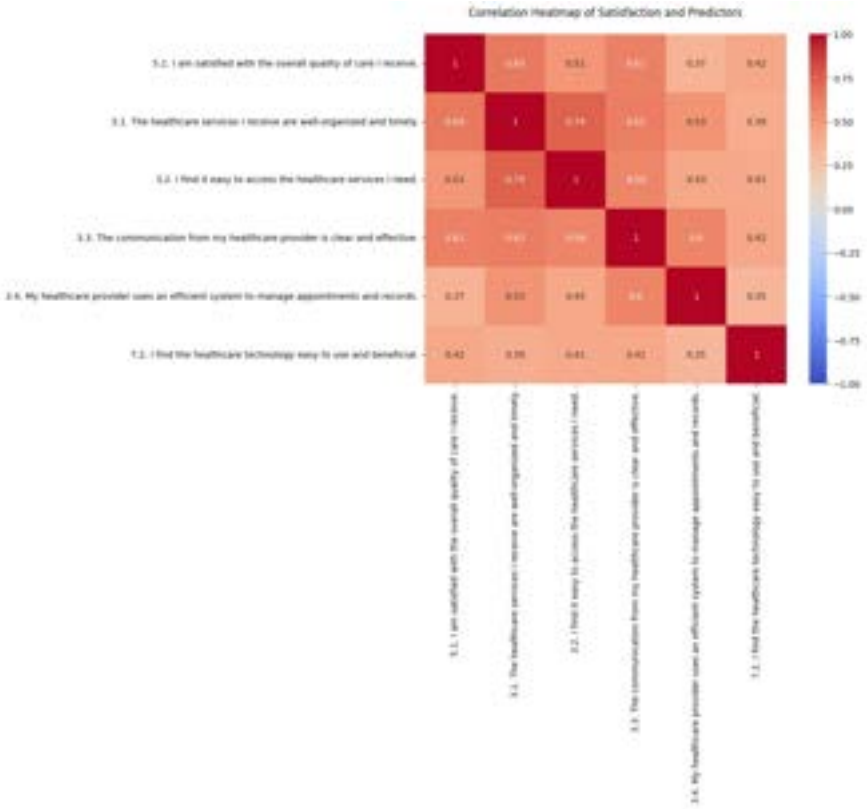

FIGURE 1. Correlation heatmap of satisfaction and predictors. Note: A square matrix showing Pearson's correlations among OS, T, A, C, SE, and TU. Colors from red (−1) to blue (1), with values annotated (e.g., $r = 0.82$ for C–OS). Strong links are in dark blue.

TABLE 2. Correlation matrix of key variables.

Variables	OS	T	A	C	SE	TU
OS	1.00	0.68*	0.70*	0.82*	0.78*	0.65*
T	-	1.00	0.72*	0.65*	0.60*	0.55*
A	-	-	1.00	0.68*	0.62*	0.58*
C	-	-	-	1.00	0.75*	0.70*
SE	-	-	-	-	1.00	0.68*
TU	-	-	-	-	-	1.00

Note: OS: overall satisfaction; T: timeliness; A: accessibility; C: communication; SE: system efficiency; TU: technology usability. *$p < 0.001$.

Regression Analysis

The model accounted for 85% of OS variance ($R^2 = 0.85$, $F(5, 101) = 114.2$, $p < 0.001$; Table 3). Key predictors were communication ($\beta = 0.70$, $p < 0.001$), system efficiency ($\beta = 0.45$, $p < 0.01$), and technology usability ($\beta = 0.30$, $p < 0.05$). Timeliness and accessibility were nonsignificant ($p > 0.10$).

TABLE 3. Regression results for the overall satisfaction (OS).

Predictor	β	SE	p value
C	0.70	0.08	< 0.001
SE	0.45	0.09	< 0.01
TU	0.30	0.10	< 0.05
T	0.15	0.11	0.18
A	0.12	0.10	0.23
Constant	0.90	0.25	< 0.01

Note: C: communication; SE: system efficiency; TU: technology usability; T: timeliness; A: accessibility. β, standardized coefficient; SE, standard error. $R^2 = 0.85$, and $p < 0.001$.

Machine Learning Model

Trained on timeliness, accessibility, communication, system efficiency, and technology usability, the XGBoost achieved RMSE = 0.39 and $R^2 = 0.90$ on test data. Cross-validation: mean RMSE = 0.40 (SD = 0.02). SHAP values prioritized communication (0.72), system efficiency (0.48), and technology usability (0.35).

Feature Importance

Figure 2 shows XGBoost gain scores: communication (0.38), system efficiency (0.25), and technology usability (0.18), confirming SHAP.

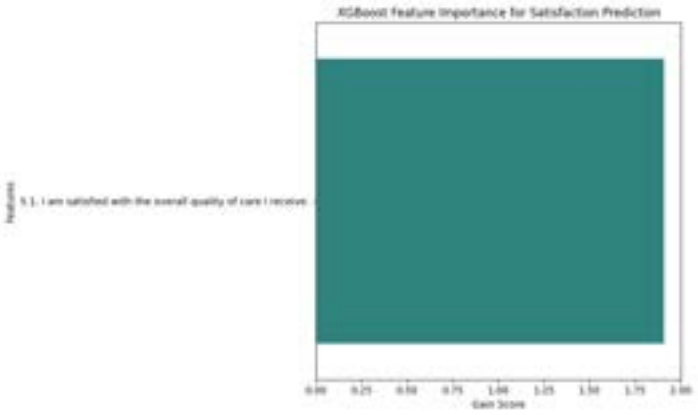

FIGURE 2. Feature importance chart for XGBoost model. Note: Horizontal bar chart showing gain score on the x-axis and the top predictor (5.1. I am satisfied with the overall quality of care I receive) on the y-axis. The bar represents the gain score of this feature in the XGBoost model for satisfaction prediction.

Demographic Analysis

Very frequent visitors had lower OS (mean = 3.5, SD = 1.0) than occasional visitors (mean = 4.0, SD = 0.8; t(105) = 4.1, $p < 0.001$). No notable differences by age or gender ($p > 0.10$; Figure 3 depicts this).

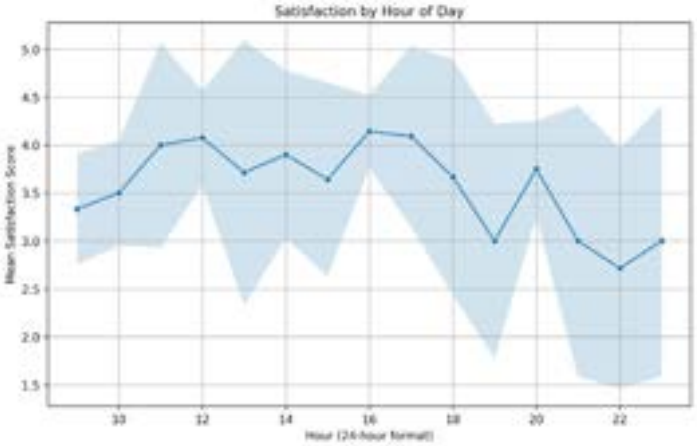

FIGURE 3. Overall satisfaction (OS) by visit frequency. Note. Bar plot of mean OS (1–5) across categories (first visit, occasional, frequent, and very frequent). Very frequent lowest (3.5), blue error bars (± 1 SD).

Secondary Variables

Care quality ($r = 0.70$, $p < 0.001$) and continued use ($r = 0.72$, $p < 0.001$) were moderately linked to OS; admission efficiency and discharge smoothness were weaker variables ($r < 0.60$, $P < 0.01$).

DISCUSSION

The XGBoost's robust performance ($R^2 = 0.90$, RMSE = 0.39) exceeds common benchmarks in healthcare prediction, underscoring AI's promise for PRM in resource-limited areas, such as Chhattisgarh. Communication's prominence ($r = 0.82$, $\beta = 0.70$, and SHAP = 0.72) echoes worldwide findings that strong provider–patient dialogue boosts trust and satisfaction by up to 25%. In Chhattisgarh's tribal context (30.6% of population), overcoming language barriers—known to cut satisfaction by 30%—is crucial. System efficiency ($\beta = 0.45$, SHAP = 0.48) highlights the need for smooth processes in busy facilities, where average waiting period of 45 minutes in Indian hospitals correlate with 20% satisfaction decline. Technology usability ($\beta = 0.30$, SHAP = 0.35) points to digital tools' value, although only 15% of Chhattisgarh hospitals are fully digitized. Lower OS in very frequent visitors (mean = 3.5) may indicate "care fatigue," aligning with global drop of 10% in chronic cases.Comparing to similar AI studies, our work parallels Penn State research using machine learning on historical data to derive patient satisfaction insights,

although they focused on text analysis, rather than surveys. A 2024 Sage study on AI's role in patient satisfaction modeled factors similar to ours, finding communication central but in urban Indian settings with larger samples. Internationally, a Nature article on AI-integrated care emphasized patient experience, reporting improved outcomes via predictive tools but noting ethical concerns such as bias, addressed by our SHAP. Another PMC review on AI analytics for outcomes highlighted predictive accuracy similar to ours ($R^2 > 0.85$) in diverse contexts, reinforcing XGBoost's scalability. These comparisons suggest that our approach is viable but would benefit by incorporating natural language processing for richer feedback, as in a 2021 sentiment analysis review.SHAP's transparency mitigates AI "black box" issues, with 70% of clinicians seeking explainability. Moderate ties of care quality and continued use ($r \approx 0.70$) imply that satisfaction fosters loyalty, key to PRM. Our study has limitations, such as a small, single-site sample limits broad applicability; and possibility of Likert biases (e.g., high communication mean = 4.15). Future efforts should expand to multi-site Indian studies, integrate objective data (e.g., actual wait times), and apply advanced AI such as deep learning.

CONCLUSION

This research illustrates AI's capability to forecast OS accurately ($R^2 = 0.90$, RMSE = 0.39) in a Chhattisgarh public hospital, locating communication, system efficiency, and technology usability as main drivers. Communication's strong link ($r = 0.82$) and reduced satisfaction in very frequent visitors (mean = 3.5) stress the importance of clear interactions and tailored support. SHAP enhances practical use by providing transparency.

While these results are encouraging for AI-enhanced PRM to advance care for tribal and low-income patients—aligning with India's healthcare equity intentions—the small sample from one location tempers conclusions. Potential survey biases exist. Larger and multi-center studies are recommended to confirm and extend findings.

AUTHOR CONTRIBUTIONS

Conceptualization, S.D. and V.K.S.; Methodology, S.D. and V.K.S.; Software, V.K.S. and V.D.; Validation, S.D., V.K.S., and V.D.; Formal Analysis, V.K.S.; Investigation, S.D.; Resources, S.D. and V.K.S.; Data Curation, V.S.; Writing–Original Draft Preparation, V.K.S., S.D., and V.D.; Writing–Review & Editing, S.D., V.S., and V.D.; Visualization, V.S. and V.D.; Supervision, S.D.; Project Administration, S.D.

ACKNOWLEDGMENTS

Not applicable. No individuals or institutions provided non-financial support or assistance beyond the listed authors.

FUNDING

This research received no external funding.

DATA AVAILABILITY STATEMENT

The data supporting the reported results are available from the corresponding author (Varun Kumar Sahu, varunsahu1992@gmail.com) upon reasonable request, subject to ethical and privacy restrictions. The dataset is not publicly archived due to patient confidentiality requirements.

CONFLICTS OF INTEREST

The authors declare they have no competing interests.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

The appropriate approval was taken for the study. informed consent was obtained from all participants prior to their participation in the survey, with participants informed of the study's purpose, voluntary nature, and data anonymization procedures.

CONSENT FOR PUBLICATION

Informed consent for publication was obtained from all participants, permitting the use of anonymized survey data in this manuscript for study purpose during data collection process. No identifying information (e.g., names, images) is included, and data were aggregated to ensure patient confidentiality.

FURTHER DISCLOSURE

Not applicable. The findings have not been presented at conferences, academic meetings, or congresses, nor has the manuscript been uploaded to a preprint server.

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Received July 8, 2025, accepted January 6, 2026, publication date for online-first March 2, 2026.

Original Research Article

Genitourinary System Imaging with Low-Cost Portable Ultrasound Device in the Context of Telemedicine Implementation

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ABSTRACT

Background: The integration of digital diagnostic tools is essential for strengthening telemedicine infrastructure, particularly in remote and resource-limited settings. Ultrasound is a promising imaging modality because of its noninvasive disposition, absence of ionizing radiation, and ability to provide rapid, real-time diagnostic information. Among the wide range of ultrasound systems, cost-effective and portable devices with acceptable diagnostic performance are needed to improve accessibility. This study aimed to evaluate the performance of a commercially available low-cost portable ultrasound device, with a specific focus on imaging the genitourinary (GU) system. **Methods:** This cross-sectional study was conducted between December 2022 and July 2023 and included 169 participants. Each participant underwent ultrasound examinations using both a low-cost portable ultrasound device and a conventional ultrasound machine, which served as the reference (gold) standard. The assessment included measurement of organ sizes and detecting pathological conditions in the kidneys, urinary bladder, uterus, ovaries, and prostate. **Results:** The portable ultrasound device demonstrated high diagnostic accuracy for detecting renal cysts (98.7%), uterine masses (97.2%), polycystic ovaries (98.7%), and adnexal cystic lesions (96.3%). Relatively lower accuracy was observed for the detection of renal parenchymal disease (93.7%) and ovarian enlargement (91.5%). Agreement between the portable and conventional devices for organ size measurements showed moderate to strong correlations. The coefficients of determination (r^2) for bipolar lengths of the right and left kidneys, uterine length, and uterine anteroposterior diameter were 0.5907, 0.6345, 0.8637, and 0.8444, respectively. **Conclusion:** These findings suggest that low-cost portable ultrasound devices can provide acceptable performance for imaging of the GU system. Their integration into telemedicine and tele-ultrasound services could enhance diagnostic capabilities and improve access to essential imaging in resource-limited and underserved populations.

Keywords—*Telemedicine, Tele-ultrasound, Portable ultrasound, Genitourinary system, Low-cost device, Low resource settings.*

INTRODUCTION

Telemedicine enables patients to receive timely consultations, diagnoses, and treatments from healthcare professionals without the need to travel, reducing both costs and barriers to care. Telemedicine has become an integral part of modern healthcare, especially in the wake of the COVID-19 pandemic[1–3], bridging gaps in healthcare access in both urban and rural settings, particularly in low-resource environments.[4] A critical component of telemedicine infrastructure is the integration of diagnostic tools that allow for remote evaluation and monitoring. Among available imaging modalities, ultrasound is especially well-suited for telemedicine because of its real-time capability, portability, relative affordability, and minimal infrastructure requirements, compared to computed tomography (CT) or magnetic resonance imaging (MRI). The concept of tele-ultrasound, wherein ultrasound images and videos are transmitted for remote interpretation, has been successfully deployed in diverse settings, including emergency medical services[5,6], conflict zones[7,8], and remote expeditions[9], demonstrating its broad applicability and clinical value. Even the International Space Station has implemented tele-ultrasound as a cost-effective tool for onboard medical diagnostics, underscoring its versatility and global utility.[10]

In low-resource settings, indigenous innovations, such as tele-stethoscopes and tele-electrocardiograms (ECG), have already improved the quality of telemedicine consultations by enabling real-time transmission of basic diagnostic data.[11] Building on this progress, incorporating tele-ultrasound systems into telemedicine could be a pivotal step forward in enhancing remote healthcare. While high-end ultrasound machines provide exceptional detail, their high costs and need for skilled technicians limit accessibility, especially in rural and underserved areas. As a result, there has been a growing interest in the use of low-cost portable ultrasound devices to address these limitations. However, concerns remain regarding the trade-off between cost and diagnostic performance in low-cost portable ultrasound systems. Previous studies have explored the accuracy of low-cost portable ultrasound scanners, compared to more sophisticated standard devices in various applications, including pregnancy profiling[12], detection of pneumothorax, abdominal pathologies, and imaging of knee structures. These findings suggest that portable ultrasound technology holds potential to strengthen telemedicine in multiple areas.

Genitourinary (GU) conditions, including kidney stones, bladder abnormalities, and prostate disorders, are common and require timely and accurate diagnosis to prevent complications and improve patient outcomes. The use of portable ultrasound devices for GU imaging has been explored in various studies, with promising results for their diagnostic accuracy and practicality. Lavi et al. evaluated kidney length measurements using a portable ultrasound scanner and reported a difference of approximately 0.8 mm, compared to conventional ultrasound systems.[13] This is a very small difference when considering the full length of the kidney, which is about 110 mm. Stock et al. demonstrated that a pocket-size ultrasound device achieved a sensitivity of 79% and specificity of 100% for detecting renal cysts.[14] Portable ultrasound devices are also investigated for urinary bladder (UB) imaging. Multiple studies have concluded that these devices provide sufficient accuracy to enhance clinical decision-making.[13,15,16] Prostatic evaluation with portable ultrasound remains underexplored, although Lavi et al. demonstrated no significant difference (p = 0.46) in prostate volume measurements between portable and standard devices in a small prospective observational study involving 25 urology patients.[13] For uterine and ovarian imaging, portable devices have shown good agreement with high-end systems in detecting pathologies, such as uterine mass lesions and adnexal abnormalities. Toscano et al. conducted a pilot study on 40 subjects, finding substantial agreement (Cohen's Kappa > 0.7) in evaluating uterine position, the presence of myomas, and adnexal pathologies.[17] A recent study reported good to excellent agreement (Cohen's Kappa = 0.68 – 0.84) for measurements, such as uterine length, volume, endometrial thickness, and the diameter of uterine myomas as well as ovarian volume.[18] Toscano et al. also quantified the diagnostic performance of handheld ultrasound devices for uterine mass lesions, reporting sensitivity of 80%, specificity of 93.1%, positive predictive value (PPV) of 80%, and negative predictive value (NPV) of 93.1%.[7] For intracavitary content detection, Araujo et al. reported a sensitivity of

12.5%, specificity of 99.3%, accuracy of 90.3%, PPV of 66.7%, and NPV of 90.8% using a handheld device.[18]

Despite these encouraging findings, many of the studies to date have been pilot in nature, involved limited sample sizes, and a narrow focus on specific GU pathologies. Importantly, most of these studies relied on portable devices with 128-element arrays, typically costing around US$5,000. Although such devices are less expensive than conventional high-end ultrasound systems, their cost remains prohibitive for large-scale deployment in low- and middle-income countries, where thousands of units are required to serve widespread populations. Moreover, little evidence exists regarding the clinical performance of ultra-low-cost portable ultrasound probes with fewer elements and reduced bandwidth, which are increasingly marketed for use in resource-limited settings. The diagnostic reliability of these devices is not studied to a sufficient degree. The present study aims to address these issues by evaluating the performance of a low-cost portable ultrasound device with only 80 elements, resulting in lower image resolution, lower bandwidth, and costing less than US$1,000. The device was assessed across a broad range of GU conditions, including the kidneys, UB, uterus, ovaries, and prostate. Given the high prevalence of GU disorders and the frequent presentation of GU symptoms in telemedicine consultations, a dependable and affordable portable ultrasound solution could bridge critical healthcare gaps and improve patient outcomes, particularly in underserved populations.

MATERIALS AND METHODS

Study Design

This cross-sectional study was conducted from 01 December 2022 to 30 July 2023 to assess the diagnostic accuracy of a low-cost portable ultrasound device with 80 elements (Sunbright SUN-P1, costing approximately US$900; Sunbright, Shanghai, China; more information is provided in Table 1) for imaging the GU system. Participants were selected randomly from patients who presented to the hospital with symptoms suggestive of kidney, UB, prostate, uterine, ovarian, or adnexal abnormalities. Additionally, the study included apparently healthy individuals who were referred for GU ultrasonography as part of a routine health check-up. A total of 169 patients, aged 15–76 years (mean ± SD: 34.5 ± 13.7 years), were included in this study. The cohort consisted of 63 males and 106 females. Inclusion criteria required that patients had non-emergency stable conditions to ensure that imaging could be performed safely and systematically. Individuals presenting with any urgent or life-threatening conditions were excluded to maintain consistency in the study's non-emergent focus and to avoid compromising patient safety. Each selected patient underwent imaging using the portable ultrasound device. The findings were then compared with measurements performed on the same patients using a standard, high-end ultrasound machine (Samsung Medison Accuvix A30, 192 elements; Samsung Medison, South Korea, more information is provided in Table 1), which served as the reference standard. This comparison allowed for evaluation of the portable device's accuracy, sensitivity, and specificity in detecting various GU pathologies.

Specifications of Ultrasound Machines

The portable handheld ultrasound device (Sunbright Sun-P1, Shanghai, China) features a wired convex probe that connects to a smartphone, tablet, or personal computer (PC).[19] This device was chosen for its affordability (about US$900), commercial availability, Conformité Européenne (CE) marking indicating conformity with applicable European Union regulatory requirements as declared by the manufacturer, and its ability to transfer data to both PCs and smartphones. For the present study, a tablet or PC was used to acquire and display ultrasound images. Data obtained from the portable device were compared with the results from a high-end conventional ultrasound machine (Samsung Medison Accuvix A30), which is widely used in hospital settings.[20] Technical specifications of the two devices are summarized in Table 1.

TABLE 1. Comparison of the technical specifications of both conventional and portable devices.

Feature	Conventional Device	Portable Device
Model	Accuvix A30	SUN-P1
Manufacturer	Samsung Medison, South Korea	Sunbright, Shanghai, China
Number of elements	192	80
Frequency	2–6 MHz	2.5–4.5 MHz
Fractional bandwidth	100%	57%
Maximum scanning depth	35 cm	24 cm
Maximum frame rate	30	20
Gray scale level	256	256
Display resolution	1920 × 1080	1024 × 768
Power supply	100–220 V, 50/60 Hz, 1100 VA	5 V USB powered, 1 W
Price	US$30,000	US$900

Most previous studies evaluating portable or handheld ultrasound devices[13–15, 21] for point-of-care or telemedicine applications relied on probes with at least 128 transducer elements and wide fractional bandwidths, typically exceeding 80%. The technical parameters of representative probes used in such studies are summarized in Table 2. These hardware configurations provide improved beam-forming capability, shorter pulse lengths, and better axial and lateral resolution. In contrast, the low-cost device evaluated in this study employs an 80-element convex probe with a narrower fractional bandwidth. From a physical standpoint, the reduced element count limits spatial sampling and beam-steering flexibility, while the narrower bandwidth increases spatial pulse length, both of which are expected to degrade image resolution and contrast, compared to higher-end portable systems. The aim of this study is to assess whether such a low-cost probe can nevertheless provide clinically relevant diagnostic information for common GU conditions with acceptable accuracy.

TABLE 2. Technical specifications of portable ultrasound probes previously evaluated for point-of-care applications.

Device / Probe	No. of Elements	Frequency Range (MHz)	Fractional Bandwidth (%)
GE Vscan Air (convex)	128	2–5	90
Siemens Acuson P10	64	2–4	67
Philips Lumify™ C5	128	2–5	75
Sunbright SUN-P1 (present study)	80	2.5–4.5	57

Data Collection

After obtaining informed consent, each subject underwent two ultrasound scans: the first using a low-cost, tablet/PC-based portable, and handheld device, and the second using a high-end, sophisticated scanner operated by the same sonologist. To minimize bias, a sufficient time interval (minimum 1 h) was maintained between the two scans so that the sonologist forgets the measured values in the previous scan. The scans focused on evaluating the size, structural characteristics, and pathological changes in the kidneys, UB, uterus, ovaries, and prostate. Specific measurements and observations were made for each organ system as follows:

Kidney Assessment

For each kidney, length was measured as the longest longitudinal diameter along the bipolar axis. Parenchymal echotexture was categorized as normal, echogenic, or hypoechoic, and corticomedullary differentiation was classified as intact, reduced, or poor. The pelvicalyceal system was evaluated for dilation, and the presence or absence of focal lesions, including cysts, masses, or stones, was recorded.

Urinary Bladder Assessment

The urinary bladder wall thickness was classified as normal or increased, and wall regularity was noted as either regular or irregular. The presence or absence of any intraluminal structures was documented.

Uterus Assessment

Uterine size was documented as normal, smaller, or enlarged. The presence or absence of any mass lesion within the myometrium was recorded, and the endometrial

cavity was assessed for the presence of material, with endometrial thickness measured where applicable.

Ovary Assessment

Each ovary was evaluated for size and classified as normal or enlarged. The presence or absence of focal lesions, such as cysts or masses, was documented.

Prostate Assessment

The prostate gland was assessed for size, categorized as normal or enlarged, and echotexture was noted as homogeneous or heterogeneous.

Measurements of organ diameters and lengths were taken using electronic calipers integrated into each device, with each measurement repeated thrice. The arithmetic mean of these measurements was calculated and recorded for final analysis. Statistical analysis was performed to evaluate concordance between the two devices, focusing on parameters such as organ measurements and the detection of pathologies. Sensitivity, specificity, PPV, and NPV were calculated to determine the diagnostic performance of the portable device relative to the conventional system.

Analysis and Presentation

Statistical analyses were conducted using the SPSS software and Microsoft Excel to evaluate accuracy and agreement between portable and standard ultrasound devices. Scatter plots were initially constructed to visually assess the overall correlation between the measurements from both devices. Agreement on categorical variables, such as parenchymal echotexture and the presence or absence of specific pathologies, was assessed using Cohen's Kappa statistics[22], which measure the degree of agreement beyond chance. For continuous variables, including organ measurements such as kidney length and endometrial thickness, a Bland–Altman plot was used to evaluate agreement by illustrating mean differences and limits of agreement between the two devices. Additionally, a paired *t*-test was applied to identify any statistically significant differences between measurements from portable and standard devices, with a significance level set at $p < 0.05$.[23]

RESULTS

Ultrasound scans were performed according to the referral request. The patients' age ranged from 15 to 76 years (mean ± SD: 34.5 ± 13.7 years). The number of scanned organs and the gender distribution of the subjects are summarized in Table 3.

TABLE 3. Number and distribution of study subjects.

Scanned Organ	Number of Patients	Male	Female
Kidney	80	57	23
Urinary bladder	125	30	95
Uterus and adnexa	83	-	83
Prostate	7	7	-

Some representative ultrasound sonography (USG) images of different organs are shown in Figures 1–3, which demonstrate both normal and pathological states of organs as captured with both devices in this study. Figure 1 illustrates two distinct renal pathologies captured by both standard and portable ultrasound devices. In the upper row, a cystic lesion is visible in the lower pole of the kidney, while the lower row displays a renal stone casting a characteristic distal acoustic shadow, effectively detected by both devices.

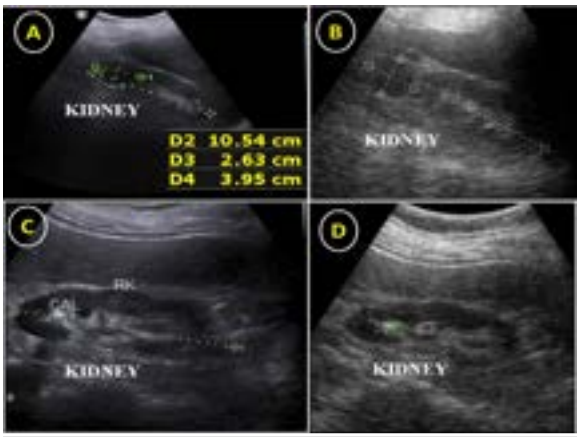

FIGURE 1. Ultrasound scan images of the kidneys captured with both devices. (A) and (C) are from the standard USG unit, while (B) and (D) are the corresponding images from the low-cost device. The upper row demonstrates a cystic lesion in the lower pole of the kidney, while the lower row shows a renal stone casting distal acoustic shadow, detectable in scans from both devices.

Figure 2 presents comparative images of UB and prostate obtained using the standard ultrasound device (left) and the portable device (right). Both scans demonstrate comparable structural details, highlighting the devices' capability to identify key anatomical features of these organs.

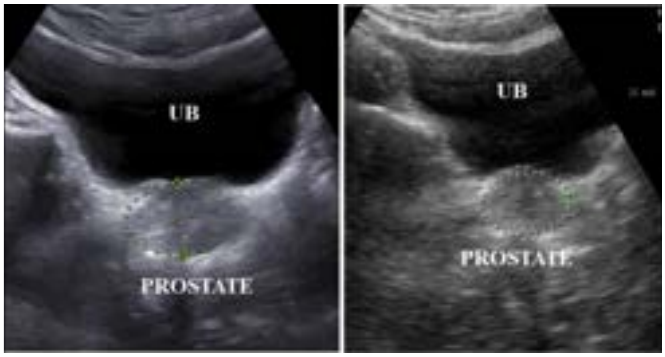

FIGURE 2. Ultrasound scan images of the urinary bladder and prostate captured with the standard device (left) and the portable device (right).

Figure 3 showcases ultrasound images of the uterus and ovary captured with both the standard and portable devices. Images 3A and 3C correspond to scans from the standard device, while images 3B and 3D are their counterparts from the portable device. The upper row images depict a normal anteverted uterus with clear delineation in both devices. In contrast, the lower row focuses on the right ovary. While the standard device provides a well-defined image, the ovary is less distinct in the portable device scan, as indicated by the white arrow, reflecting a limitation in its resolution for small or less echogenic structures.

Kidney Evaluation

Bipolar length of the right kidney, as measured by portable and conventional machines show moderate positive correlation as plotted in Figure 4. The squared correlation coefficient (r^2) is 0.5907. Bland–Altman plot in Figure 5 shows that overall, the mean value given by the portable device was only 0.1 cm greater than that obtained using the conventional device. The plot also shows that 95% of the measurements using the portable device remained within +1.8 cm and −1.5 cm range of the actual values.

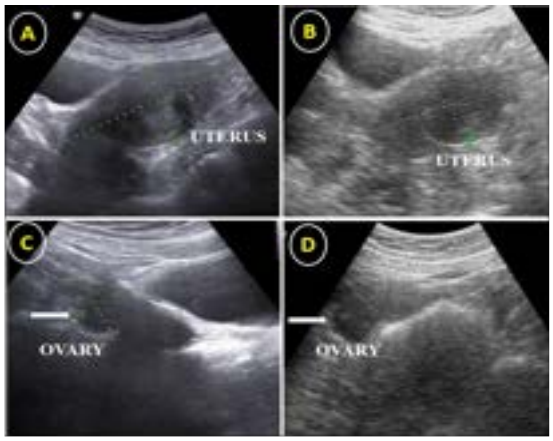

FIGURE 3. Ultrasound scan images of uterus and ovary captured with both devices. (A) and (C) are images from the standard USG unit, while (B) and (D) are the corresponding scans from the low-cost device. The upper row shows a normal anteverted uterus, while the lower row depicts a right ovary, which is difficult to delineate in the portable device scan (white arrow).

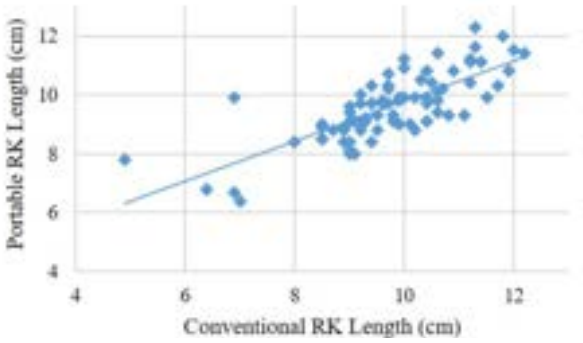

FIGURE 4. Scatter plot showing correlation between right kidney bipolar length measurements taken with the two devices. The squared correlation coefficient (r^2) = 0.5907.

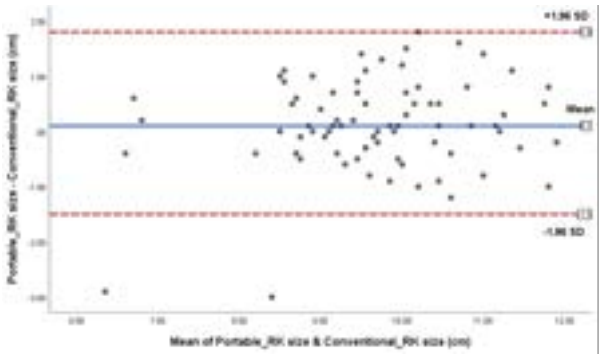

FIGURE 5. Bland–Altman plot showing the difference of the two paired right kidney (RK) length measurements plotted against the mean of the two measurements. There is no remarkable tendency toward under- or overestimation by the portable device.

Performance of the low-cost device in evaluating different pathologies involving the right renal parenchyma is summarized in Figure 6. The portable device could detect normal parenchymal echogenicity accurately, but about 33.3% of echogenic kidneys and 66.6% of hypoechoic kidneys were perceived as normal. The overall agreement between the portable and standard devices was substantial, with a Cohen's Kappa value of 0.715.

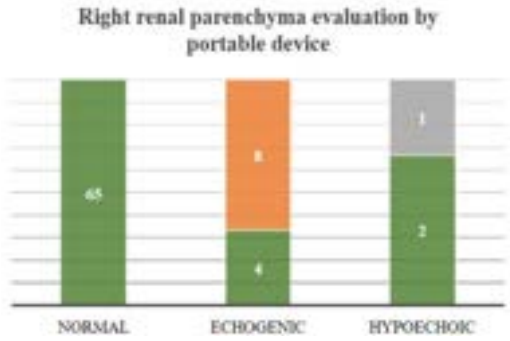

FIGURE 6. Distribution of right renal parenchymal change detection with the portable device plotted against the conventional USG unit. The Kappa value was 0.715, indicating substantial association.

Performance of the low-cost device in evaluating right renal lesions is summarized in Figure 7. It is observed that, except for one case of cortical cyst, the portable device performed accurately. Kappa value was 0.852, indicating a very good association.

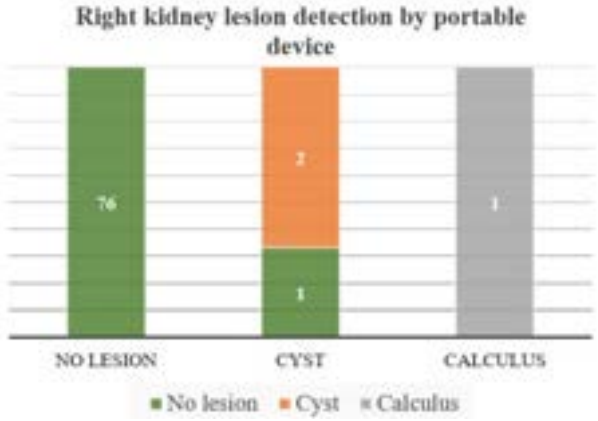

FIGURE 7. Distribution of right renal lesion detection with the portable device plotted against the conventional USG unit. The Kappa value was 0.852, indicating a very good association.

The bipolar length of the left kidney, as measured by both portable and conventional ultrasound devices, demonstrated a moderate positive correlation, as depicted in Figure 8.

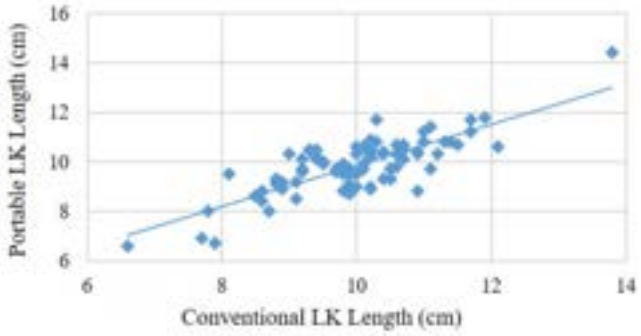

FIGURE 8. Scatter plot showing the correlation between left kidney bipolar length measurements taken with two devices. The squared correlation coefficient (r^2) = 0.6345.

The squared correlation coefficient (r^2) was 0.6345. The Bland–Altman plot in Figure 9 further illustrates the agreement between the two devices, showing that the mean measurement obtained with the portable device was only 0.14 cm greater than that obtained from the conventional device. Additionally, 95% of the measurements using the portable device were within a range of +1.55 cm-1.27 cm, compared to the gold standard.

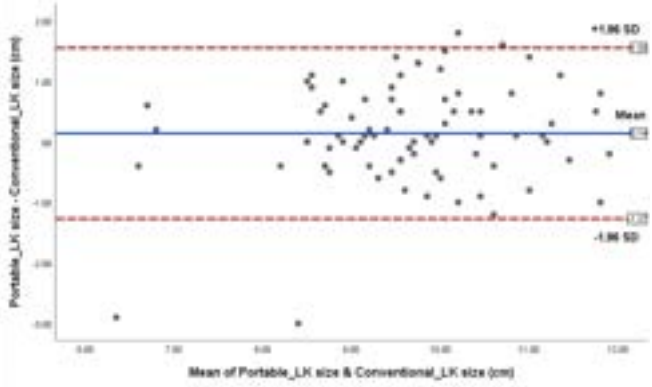

FIGURE 9. The Bland–Altman plot shows the difference of the two paired left kidney (LK) length measurements plotted against the mean of the two measurements. No remarkable tendency toward under- or overestimation by the portable device.

The performance of the portable device in detecting various pathologies affecting the left renal parenchyma is summarized in Figure 10. While the portable device accurately identified normal parenchymal echogenicity,

50% of cases with increased echogenicity and approximately 66.6% of cases with hypoechoic kidneys were misclassified as normal. The Cohen's Kappa value for agreement between the two devices was 0.595, indicating a moderate level of association.

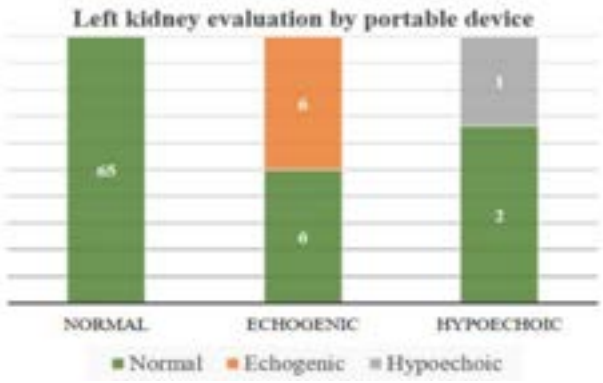

FIGURE 10. Distribution of left renal parenchymal changes detected by the portable device compared to the standard USG unit. A Cohen's Kappa value of 0.595 indicates moderate agreement.

Performance of the low-cost device in evaluating left renal lesions is summarized in Figure 11. Except for one case of cortical cyst, the portable device performed accurately. Kappa value was 0.662, indicating a substantial association.

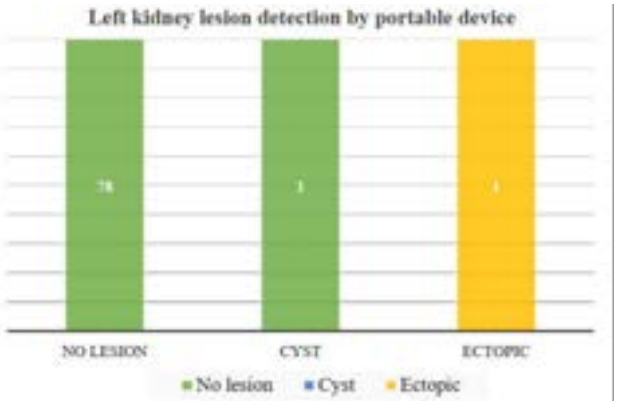

FIGURE 11. Distribution of left renal lesion detection by the portable device compared to the conventional USG unit. A Cohen's Kappa value of 0.662 indicates substantial agreement.

Urinary Bladder Evaluation

A total of 126 patients underwent UB examinations. Among these, 82.5% of UB cases were optimally filled, 13.5% were partially filled, and approximately 4% were empty. Regarding wall thickness, 82.5% of the examined UB cases exhibited normal thickness, while the remaining showed abnormal thickening. Both portable and conventional ultrasound devices demonstrated perfect agreement in assessing the level of UB filling and wall thickness, with a Cohen's Kappa value of 1. This indicates complete concordance between the two devices for these parameters.

The uterine length and anteroposterior (AP) diameter measurements obtained using the portable and conventional ultrasound devices demonstrated good positive correlations, with correlation coefficients of 0.8637 and 0.8444, respectively, as shown in Figures 12 and 13. Bland–Altman plots in Figures 14 and 15 show that there is no remarkable tendency toward under- or overestimation by the portable device in case of uterine size measurements.

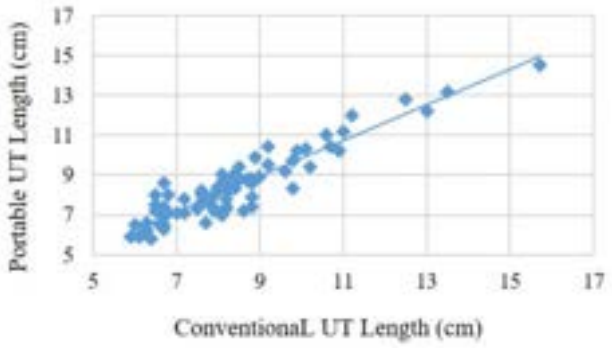

FIGURE 12. Scatter plot showing correlation between uterine length measurements obtained by using both portable and conventional ultrasound devices. The squared correlation coefficient (r^2) is 0.8637.

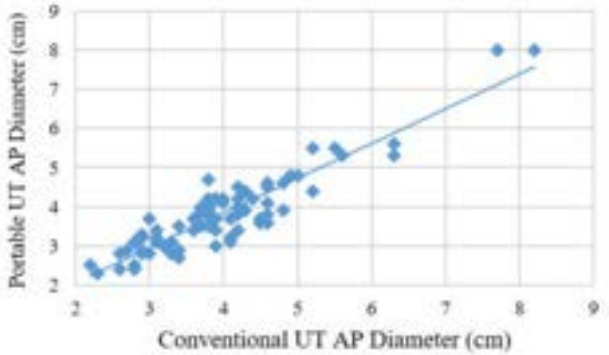

FIGURE 13. Scatter plot showing correlation between uterine A/P diameter measurements obtained using the portable and conventional ultrasound devices. The squared correlation coefficient (r^2) = 0.8444.

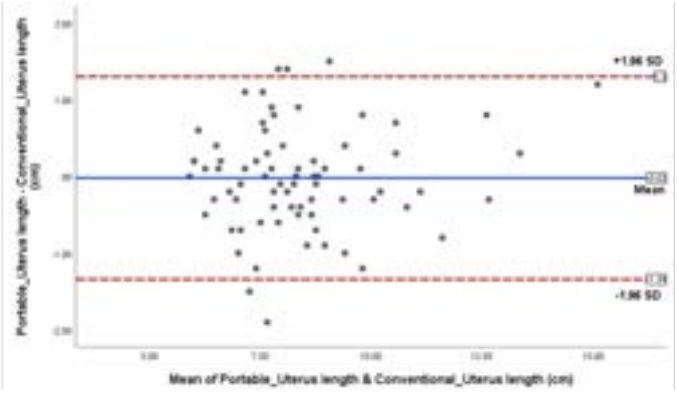

FIGURE 14. The Bland–Altman plot for the two paired uterine length measurements. The mean value from the portable device was only 0.02 cm lower than that of the standard device. Additionally, 95% of the values from the portable device were within the range of +1.30 cm–−1.34 cm, compared to the reference.

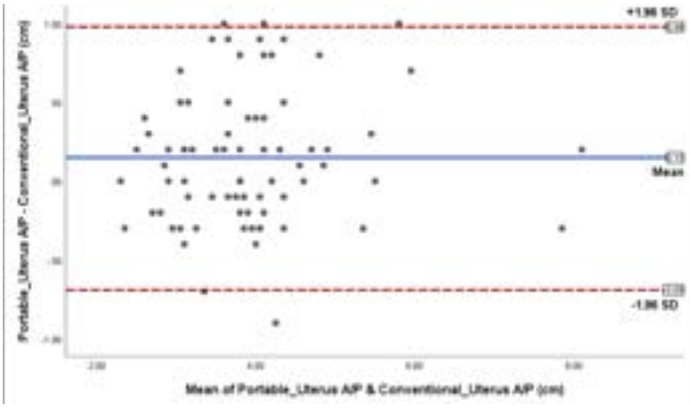

FIGURE 15. The Bland–Altman plot for the two paired uterine A/P diameter measurements. The mean value from the portable device was only 0.15 cm higher than that of the standard device. Additionally, 95% of the values from the portable device were within the range of +0.98–−0.69 cm, compared to the reference.

Performance of the low-cost device in evaluating the myometrium is summarized in Figure 16. The portable device had difficulty in differentiating solid lesions, inhomogeneous texture, and myometrial calcification from a normal myometrium, resulting in a Cohen's Kappa value of 0.710. The portable device could accurately identify normal myometrium. However, about 25% of the solid lesions, 66.7% of the inhomogeneous texture, and myometrial calcification could not be distinguished.

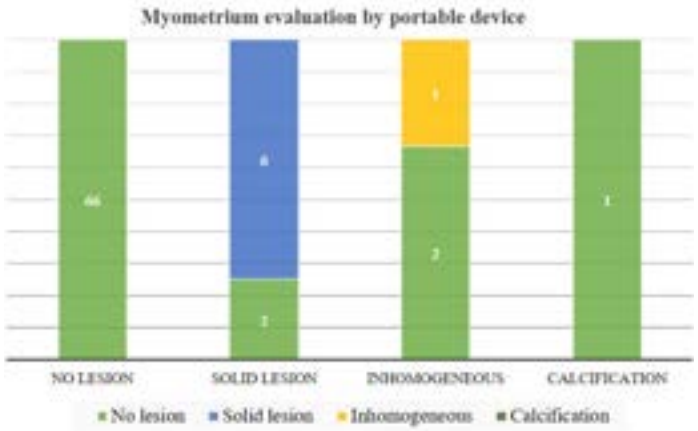

FIGURE 16. Bar chart showing the distribution of myometrial pathology detection using the portable device, compared to the standard USG unit. The portable device accurately identified normal myometrium but failed to detect 25% of solid lesions and 66.7% of cases with inhomogeneous texture and myometrial calcifications.

Performance of the low-cost device in evaluating the endometrium is summarized in Figure 17. Inhomogeneous endometrium and most endometrial collections were misdiagnosed with the portable device. Cohen's Kappa value was 0.696, indicating a substantial association.

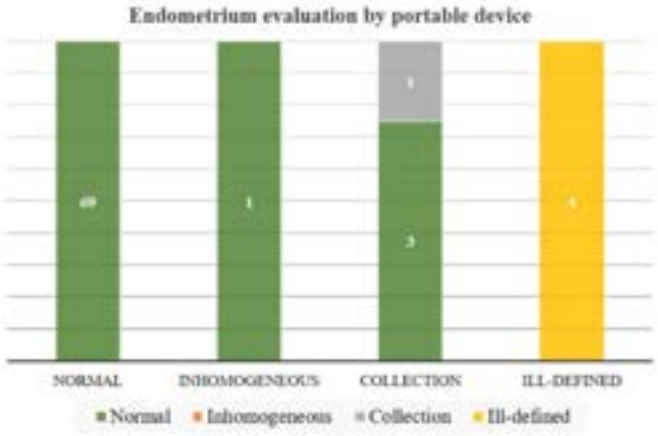

FIGURE 17. Bar chart showing the distribution of endometrial pathology detection using the portable device, compared to the standard USG unit. The Kappa value was 0.696, indicating a substantial agreement.

Ovary Evaluation

The performance of the low-cost portable device in evaluating ovarian size is summarized in Figure 18. While

the device accurately identified normal-size ovaries, approximately 53.8% of enlarged ovaries were misclassified as normal. Cohen's Kappa value for agreement with the conventional device was 0.740, indicating substantial association. Notably, among the subjects, six had no ovaries because of surgical removal, and the portable device detected this in all cases. Figure 19 illustrates the device's performance in detecting ovarian and adnexal lesions. The portable device accurately identified non-pathological ovaries; however, it misclassified 14.2% of polycystic ovaries and 27.2% of adnexal cysts as normal. Despite these limitations, the device showed good agreement with the standard system, with a Cohen's Kappa value of 0.854.

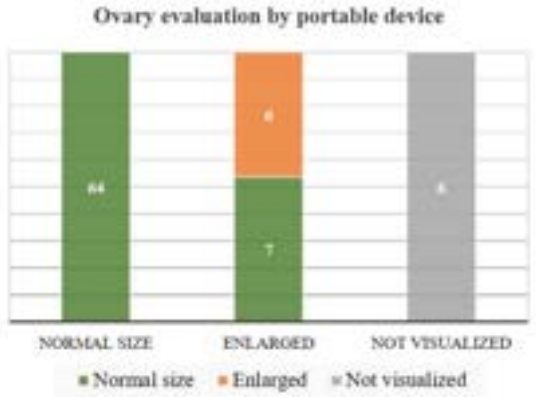

FIGURE 18. Bar chart showing ovarian size assessment findings using the portable device, compared to the standard USG unit. The portable device accurately identified normal-sized ovaries. The Kappa value was 0.740, indicating a substantial agreement.

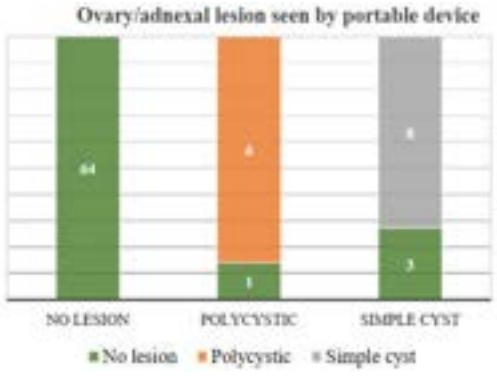

FIGURE 19. Bar chart showing findings from ovarian/adnexal lesion assessment using the portable device, compared to the standard USG unit. The Kappa value was 0.854, indicating a good association.

Prostate Evaluation

Figure 20 shows the performance of the low-cost device in evaluating the prostate. Except for one case of a small prostatic cyst, the test device was accurate. Cohen's Kappa value was 0.611, indicating a substantial association.

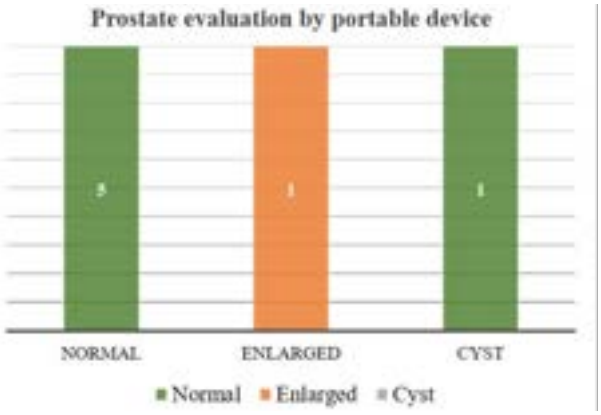

FIGURE 20. Bar chart showing findings from prostate assessment using the portable device, compared to the standard USG unit. The Kappa value was 0.611, indicating a substantial association.

Diagnostic performance of a method/device to detect a pathology is usually described in terms of sensitivity, specificity, accuracy, PPV, and NPV. Table 4 summarizes these findings for the portable device in case of some commonly found pathologies of GU system.

TABLE 4. Diagnostic performance of portable device in statistical terms.

Pathology	Number of subjects	Sensitivity (%)	Specificity (%)	Accuracy (%)	Positive predictive value (PPV) (%)	Negative predictive value (NPV) (%)
Chronic kidney disease	80	58.3	100	93.7	100	93.1
Acute kidney injury	80	33.3	100	97.5	100	97.4
Renal cyst	80	50	100	98.7	81.2	98.5
Bulky uterus	78	92.8	95.3	94.8	100	97.1
Uterine mass	78	75	100	97.2	100	97.3
Inhomogeneous myometrium	78	33.3	100	97.2	100	96.0
Endometrial collection	78	25	100	95.8	100	90.9
Enlarged ovaries	83	46.1	100	91.5	100	98.6
Polycystic ovaries	83	85.7	100	98.7	100	95.9
Adnexal cyst	83	72.7	100	96.3	100	98.9

DISCUSSION

This study evaluated the accuracy and agreement of a low-cost portable ultrasound device (80 elements, US$900) with a high-end conventional system (192 elements, US$30,000) for imaging the GU system. The evaluation focused on organ size measurements and the detection of pathological changes in the kidneys, UB, uterus, ovaries, and prostate. While the portable device demonstrated satisfactory performance for basic measurements, its lower resolution limited its ability to detect fine anatomical details and subtle textural changes, as illustrated in Figures 1–3.

Ultrasound is a valuable tool for kidney evaluation, leveraging the distinct echogenicity of the renal parenchyma, and the ability to detect architectural distortions caused by pathology.[24] In this study, the portable device provided renal bipolar length measurements within 1 mm of the conventional device, corroborating the findings of Lavi et al. in a comparison study, who reported a 0.8 mm difference.[13] However, the portable device exhibited reduced sensitivity for detecting parenchymal diseases, misclassifying 33.3% of echogenic kidneys and 66.6% of hypoechoic kidneys as normal for the right kidney, with a Cohen's Kappa value of 0.715 (Figure 6). Similar limitations were observed for the left kidney, yielding a Cohen's Kappa value of 0.595 (Figure 10). These findings appear to match those obtained by Zúñiga et al., who reported challenges in the left kidney evaluation because of its posterior position despite using a device with more elements (128) and higher price in a prospective observational study.[25] Despite these issues, the low cost portable device performed well in detecting renal cysts and stones, achieving Cohen's Kappa values exceeding 0.8 for the right kidney and 0.6 for the left kidney (Figures 7 and 11). The device's sensitivity (50%) and specificity (100%) for cyst detection were partially comparable to Stock et al., who reported a sensitivity of 79% and specificity of 100% in another comparison study using a pocket-size device[14], again with a greater number of elements.

For UB evaluation, the portable device achieved perfect agreement with the conventional device in assessing bladder filling and wall thickness, with a Cohen's Kappa value of 1. This aligns with previous studies demonstrating the accuracy of portable devices for UB evaluation, supporting their integration into clinical workflows.[13,15,16] Uterine size measurements showed a very strong correlation ($r^2 > 0.8$ for both longitudinal and anteroposterior diameters), with mean differences of only 0.02 cm and 0.15 cm, respectively (Figures 12–15). The portable device effectively identified normal myometrium but struggled to detect inhomogeneous textures and calcifications, yielding a Cohen's Kappa value of 0.710 (Figure 16). The sensitivity, specificity, PPV, and NPV values for detecting uterine mass lesions were 75%, 100%, 100%, and 97.3%, respectively, exceeding the results reported in a pilot study conducted by Toscano et al.[17]

For endometrial evaluation, the portable device demonstrated a Cohen's Kappa value of 0.696, indicating a substantial agreement with the conventional device (Figure 17). However, misdiagnoses occurred for inhomogeneous endometrium and some endometrial collections. Sensitivity was 25%, while specificity, PPV, and NPV were 100%, 100%, and 90.9%, respectively, the results that were consistent with the findings reported by Araujo et al. in a prospective accuracy study.[18]

Ovarian size evaluation showed substantial agreement, with a Cohen's Kappa value of 0.740 (Figure 18). However, 53.8% of enlarged ovaries were misclassified as normal. For adnexal lesions, sensitivity ranged between 72% and 85%, with specificity and PPV at 100% (Figure 19). The portable device performed well in identifying cystic adnexal lesions but had limitations in detecting subtle ovarian enlargements. Prostate assessments demonstrated excellent agreement with the standard device, highlighting the portable device's potential for evaluating this organ (Figure 20). However, the sample size for prostate evaluations was limited.

Overall, the portable device was comparable to similar devices tested in previous studies, as it also showed higher specificity and lower sensitivity (Table 3), indicating its ability to report fewer false negatives than false positives. The ease of use and accessibility of portable diagnostic tools often come with such trade-off between sensitivity and specificity, which, in turn, affects their accuracy. However, for large-scale screening programs, or to avoid

unnecessary intervention, a tool with higher specificity is worth considering.

The high cost of sophisticated ultrasound machines (US$20,000–50,000) limits their use in telemedicine for rural areas of LMICs. Even portable models from reputed brands (about US$5,000) remain expensive for such settings. This study focuses on an even lower-cost device (about US$900) with only 80 elements probe and a narrower fractional bandwidth. Despite these inherent technical constraints, our results demonstrated that clinically relevant diagnostic information for common GU conditions could still be obtained with acceptable accuracy. This finding suggests that, although image quality is compromised relative to higher-element, wider-bandwidth devices, the performance of an ultra-low-cost ultrasound system may remain sufficient for targeted diagnostic tasks in telemedicine. While a smartphone or tablet/PC (around US$200) is needed to operate the device, the existing personal devices may suffice. Portable units are far more power-efficient (1 W vs. 1000 W for conventional systems), can be recharged via solar power, and require minimal maintenance, because most controls are software-based. Although repairs may be challenging, the low price makes replacement feasible, enhancing affordability, scalability, and suitability for rural healthcare delivery.

Limitations

The inclusion of patients with routine or nonurgent complaints resulted in a low prevalence of abnormal findings. In addition, emergency cases were excluded due to their inability to stay for prolonged evaluations, meaning the device's performance in critical care settings was not assessed. Scans were performed by the same person using both devices; therefore, inter-observer agreement could not be evaluated. Involving multiple observers and a larger patient pool would help to address these limitations in future studies. Furthermore, as a single-center study, the findings may not be generalizable. Future multicenter trials are recommended to validate these results and assess the device's performance in diverse clinical settings, including critical care.

Historically, several factors have hindered the widespread adoption of tele-ultrasound, including the complex challenges of transducer positioning, patient body posture, device settings, and image quality and clarity. Additionally, the process requires sophisticated medical software and secure transmission protocols to ensure patient privacy. However, advances in wireless network technology and increased cell phone accessibility are making tele-ultrasound an increasingly viable option. Challenges such as probe handling, orientation, and machine settings can be mitigated through adequate training of remote operators. Beyond traditional teaching methods, approaches such as tele-learning, augmented reality tools, and tele-guided ultrasound can further enhance operator proficiency.[26]

CONCLUSION

This study evaluated the diagnostic accuracy of a low-cost portable ultrasound device for GU system imaging and found it effective for detecting renal cysts, uterine masses, polycystic ovaries, and adnexal cystic lesions. However, its accuracy was lower for diagnosing renal parenchymal diseases and ovarian enlargement. Pathologies affecting the parenchymal echotexture of solid organs should be interpreted with caution. The portable device exhibited high specificity but comparatively lower sensitivity, a common characteristic of such devices. For size measurements, it demonstrated reliable accuracy across most organs, reinforcing its utility in routine clinical settings. While the portable ultrasound device shows promise as a point-of-care diagnostic tool and holds potential for integration into telemedicine services, particularly in resource-limited areas, its limitations must be clearly understood. Adequate user training is essential to ensure safe and effective use. Additionally, efficient data transfer mechanisms are crucial to maximize its utility, especially in remote settings, such as refugee camps, hilly regions, and islands.

AUTHOR CONTRIBUTIONS

Conceptualization, K.S.R. and M.A.K; Methodology, A.N.; Validation, A.N.; Formal Analysis, A.N.; Investigation, A.N.; Writing–Original Draft Preparation, A.N.; Writing–Review & Editing, M.A.K., F.B. and K.S.R.; Supervision, M.A.K., F.B. and K.S.R; Funding Acquisition, M.A.K and K.S.R.

ACKNOWLEDGMENTS

Not applicable.

FUNDING

The authors acknowledge the International Science Programme (ISP) of Uppsala University in Sweden for financial support as a research grant (IPPS BAN:04). The funders had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript.

DATA AVAILABILITY STATEMENT

The data supporting the results are available online in Harvard Dataverse: https://dataverse.harvard.edu/dataset.xhtml?persistentId=doi:10.7910/DVN/I1FGPG

CONFLICTS OF INTEREST

The authors declared they had no competing interests.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

This study was conducted under the principles embodied in the Declaration of Helsinki and in accordance with local statutory requirements. Ethical approval was obtained from the National Research Ethics Committee, Bangladesh Medical Research Council (Registration No.: 457 13 12 2021, dated: 09/06/2022) for this study. The objectives and procedures were explained in details to the patients and their attendants. Written informed consent was taken from each subject preserving their rights, privileges and freedom. Written informed consent was obtained from the parent/guardian of each participant aged < 18 years.

CONSENT FOR PUBLICATION

Data and images were anonymized, and all analyses were conducted thereafter. Informed consent was obtained from the subjects to publish their anonymized data.

FURTHER DISCLOSURE

Not applicable.

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Received July 4, 2025, accepted December 21, 2025, publication date for online-first March 4, 2026.

Original Research Article

Accuracy of Control of Infusion Pumps in the Post-Market: A Practical Approach Based on IEC 60601-2-24: 2012

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ABSTRACT

Background: Infusion pumps are critical medical devices widely used in clinical practice, particularly in intensive care units, where precise delivery of fluids and medications is essential for patient safety. Deviations in flow rate accuracy may lead to underinfusion or overinfusion, potentially compromising therapeutic outcomes. Post-market surveillance of infusion pump performance is therefore a key component of clinical engineering strategies, especially under real-use hospital conditions. **Objective:** This study aimed to evaluate the post-market flow rate accuracy of volumetric infusion pumps used at the University Hospital of the University of São Paulo (HU-USP), Brazil, in accordance with the requirements of the IEC 60601-2-24:2012 standard. **Material and Methods:** Three volumetric infusion pumps of the same model, allocated in the Pediatric Intensive Care Unit (PICU), were evaluated. Flow rate accuracy tests were conducted using a measurement system composed of an analytical balance and dedicated software developed for automated data acquisition and processing. The pumps were tested at a low flow rate of 1 $mL \cdot h^{-1}$ over 24 hours under ambient pressure conditions, and at a nominal flow rate of 25 $mL \cdot h^{-1}$ over 2 h under three conditions: ambient pressure, overpressure (+100 mmHg), and vacuum (−100 mmHg). The measured flow rates were compared with the accuracy limits specified by the manufacturer. **Results:** At the flow rate of 1 $mL \cdot h^{-1}$, two of the three infusion pumps did not comply with the manufacturer's specified accuracy limit (±5%), exhibiting underinfusion. At 25 $mL \cdot h^{-1}$, all evaluated pumps demonstrated deviations exceeding the expected tolerance, particularly when subjected to pressure variations. In addition, all devices exhibited a consistent delay of approximately 11 min in completing the 24 h infusion period, despite being newly acquired and previously unopened. These findings indicate performance deviations under post-market conditions that may not be identified through routine acceptance testing alone. **Conclusion:** The results highlight the importance of implementing systematic post-market performance evaluation of infusion pumps as part of clinical engineering management practices. Even newly acquired devices may present deviations that pose potential risks to patient safety, especially in pediatric intensive care environments. The study supports the expansion of this evaluation methodology to the entire infusion pump inventory of the University Hospital, currently comprising 221 devices, and to testing scenarios involving clinically relevant medications and operating conditions. Such an approach contributes to evidence-based decision-making in medical technology management and to the continuous improvement of healthcare quality and safety.

Keywords—*Infusion pump, Accuracy, Post-market, Clinical engineering.*

INTRODUCTION

Medication errors can occur throughout the medication use process, encompassing the phases of prescription, preparation, and administration.[1] Although evidence suggests that the use of infusion pumps can reduce errors in medication administration[2,3], these devices inherently exhibit measurement deviations that must be considered. The effective use of such medical equipment by healthcare professionals is therefore essential to ensure delivery of accurate medication[4]; moreover, regular verification, maintenance, and calibration are crucial to guarantee optimal device performance.[5]

Studies have demonstrated that errors in medication administration involving infusion pumps occur across different countries, with such events reported and associated with clinical impact in different scenarios, particularly in neonatology.[6] Variability in proportion of infusion during neonatal therapies poses a significant risk to patient safety, as it may lead to underinfusion or overinfusion and consequently compromise the newborn's fluid, hemodynamic, and metabolic balance.[7]

Low-risk patients can generally tolerate ±30% variability in infusion accuracy. However, in critical situations, such as in case of patients with heart failure, liver cirrhosis, or chronic kidney disease, both underinfusion and overinfusion therapy can compromise the patient. For example, post coronary artery bypass graft patients commonly receive sodium nitroprusside to manage arterial blood pressure. Hypertension associated with underinfusion places greater stress on graft sutures, increasing the risk of internal bleeding. Conversely, hypotension resulting from overinfusion may compromise cardiovascular stability.[8]

In Brazil, recent studies have examined reports of failures associated with the use of infusion pumps. The authors identified events primarily related to operational errors and misinterpretation of alarms.[9,10] Even though such investigations contribute to strengthening research on infusion pump safety in the country, it is important to emphasize that numerous issues are also related solely to the device itself, including lack of accuracy, software malfunctioning, and recurrent alarm failures.

In 2017, Bottaro et al. presented the findings of a study conducted between 2009 and 2015 across 38 hospitals in Brazil.[11] The investigation included accuracy testing of 245 infusion pumps and revealed the poorest performance indicators, with failure proportion exceeding 40%.[11]

Although the regulatory framework governing the pre-market phase of medical devices in Brazil is well established with emphasis on verifying compliance with basic safety and essential performance requirements[12], failures continue to be reported in the post-market context, when devices are already in active use in healthcare institutions.[13]

Data from Brazil's National Notification Health Surveillance System (NOTIVISA), the national health technology surveillance platform, indicate that more than 260,000 notifications related to health products were reported between December 2006 (from the time the platform was established) and October 2025.[14] Notifications refer to reports submitted to Brazilian Health Regulatory Agency (ANVISA) regarding issues associated with products and services subject to health surveillance.[13]

Despite the considerable number of formally registered notifications, it should not be interpreted as a complete representation of reality, as underreporting remains a systemic limitation acknowledged in the country.[15]

Within this context, the present study aimed to assess the flow rate accuracy of infusion pumps in clinical use at the University Hospital, based on the technical criteria prescribed by the International Electrotechnical Commission (IEC) 60601-2-24:2012 standard[16] as well as the uncertainty assessment[17] and acceptance criteria.[18]

By presenting the results and critical analysis of the performance tests, this study seeks to contribute to the strategic planning and decision-making processes of the clinical engineering sector, supporting evidence-based actions to improve safety, optimize maintenance practices, and enhance the quality of care delivered in the institution.

MATERIALS AND METHODS

Materials

To perform the experimental procedures, the infrastructure of the Biomedical Engineering Laboratory/ Laboratório de Engenharia Biomédica (LEB) was utilized. The laboratory is equipped with an analytical balance

(BP221S, Sartorius, Göttingen, Germany); needle 18G (Descarpack, Sao Paulo, Brazil); Becker (Laborglass, Sao Paulo, Brazil); vacuum gauge (63 mm, Wika, Klingenberg am Main, Germany); pressure gauge (IDP-2000, Connect JCO, Sao Paulo, Brazil); air compressor (Schulz S.A., Joinville, Brazil); vacuum pump (Schulz S.A.); environmental conditions meter (Davis Instruments, Hayward, CA, USA); and standard mass 100 g class E2 (Knwaagen, Sao Paulo, Brazil). All measurement instruments used complied with the specifications established by the IEC 60601-2-24:2012 standard and were duly calibrated and traceable to recognized metrological standards, ensuring the reliability and accuracy of the tests performed.

Method

The methodology adopted in this study was based on the technical standard IEC 60601-2-24:2012, which prescribes the criteria for evaluating the flow rate accuracy of infusion pumps. Specifically, the procedures were carried out under items 201.12.1.101 and 201.12.1.102 of the standard, entitled Accuracy of Controls and Instruments, and followed the test configuration illustrated in Figure 1.

All tests were performed using an infusion set and recommended height (h_1 in Figure 1) specified by the manufacturer to ensure compliance with operational declarations.

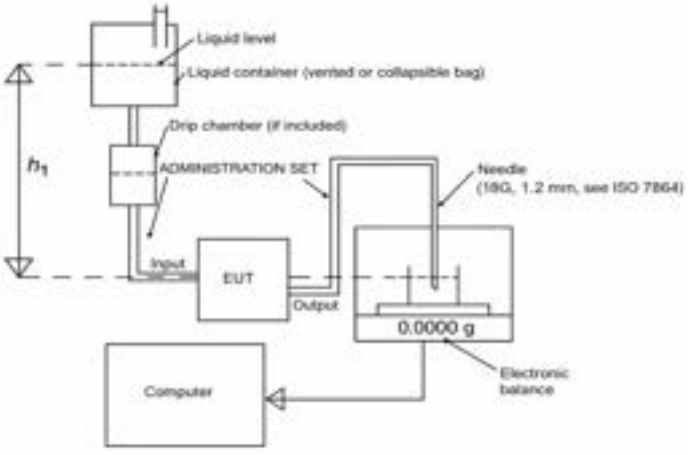

FIGURE 1. Test apparatus for volumetric infusion pumps. EUT: equipment under test.

Description

Three volumetric infusion pumps with linear peristaltic mechanisms, along with their respective dedicated infusion sets and water for medical use (test solution of ISO Class 3)[19], were supplied by the Pediatric Intensive Care Unit (PICU). All three devices under evaluation were of the same model, for which the manufacturer specified an overall mean percentage flow error of ±5% in technical documentation. For this study, the infusion pumps were anonymized and identified numerically as Infusion Pump 1, Infusion Pump 2, and Infusion Pump 3.

The experimental procedures were performed at the Biomedical Engineering Laboratory (LEB), which offered a controlled environment maintained at 23 °C ± 2 °C temperature and 65% ± 15% relative humidity (RH). The analytical balance was interfaced with a computer via RS232 communication for real-time data acquisition. The computer-operated custom software was developed in the graphical programming environment (LabVIEW, National Instruments, Austin, TX, USA), which guided the step-by-step execution of tests and performed automated data processing.

The infusion pumps were evaluated at two flow rates: 1 $mL \cdot h^{-1}$ for 24 h under ambient pressure, and 25 $mL \cdot h^{-1}$ for 2 h. At the 25 $mL \cdot h^{-1}$ flow rate, tests were initially performed under ambient pressure and subsequently repeated under controlled overpressure (+100 mmHg) and vacuum (−100 mmHg) conditions. To guarantee pressure application, an acrylic chamber of appropriate dimensions was built to enclose the analytical balance. Pressure conditions were actively monitored throughout the experiments using a pressure gauge and a vacuum gauge.

Before initiating the test, a layer of oil was carefully added to the water for medical use contained in a Becker placed on the analytical balance. This oil layer served to minimize evaporation during long-duration tests, thereby preserving the integrity and accuracy of the mass measurements over time. Furthermore, a preliminary study was conducted by the laboratory to quantify the mass loss of sodium chloride solution because of evaporation throughout the test, even with the protective oil layer in place. The measured mass loss was subsequently used to correct final measurements.

All formulas employed in this study were prescribed by the IEC 60601-2-24:2012 standard, which defines the technical criteria.

RESULTS

The results of the tests performed on the infusion pumps are presented in Table 1, which summarizes the overall mean percentage flow error corresponding to the trumpet curve analyses at time points T1 and T2, performed at 1 mL·h^{-1} for 24 h.

TABLE 1. Accuracy results based on trumpet curves at T1 and T2 for the flow rate of 1 mL·h^{-1}.

Medical Devices	T1	T2
Pump 1	−3.78%	3.46%
Pump 2	−11.36%	−1.64%
Pump 3	−8.75%	0.94%

Note: T1 is designated as the second hour of the test period, while T2 corresponds to the last hour.

Figure 2 shows T1 and T2 trumpet curves for Infusion Pump 1 operating at a flow rate of 1 mL·h^{-1}.

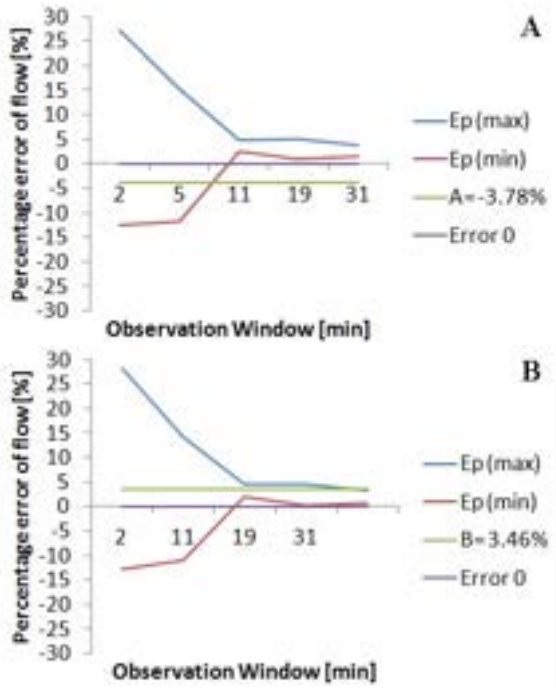

FIGURE 2. Trumpet curves of Infusion Pump 1 at a flow rate of 1 mL·h^{-1}.
Note: Ep(max): maximum measured error in observation window; Ep(min): minimum measured error in observation window; A: the overall mean percentage flow error measured over the analysis period T1; and B: the overall mean percentage flow error measured over the analysis period T2.

Table 2 shows the overall mean percentage flow error based on the T2 trumpet curve analysis for the infusion pumps operating at a flow rate of 25 mL·h^{-1} under ambient pressure as well as under overpressure and vacuum variations.

TABLE 2. Accuracy results based on trumpet curves at T2 for a flow rate of 25 mL·h^{-1}.

Medical Devices	Ambient pressure (T2)	Overpressure(T2)	Vacuum(T2)
Pump 1	−6.04%	−4.29%	−7.84%
Pump 2	−6.49%	−5.81%	−12.57%
Pump 3	−6.83%	−6.79%	−6.73%

Note: T2: the last hour of the test period.

Figure 3 shows the T2 trumpet curves of Infusion Pump 1 operating at a flow rate of 25 mL·h^{-1} under ambient pressure, overpressure (+100 mmHg), and vacuum conditions (−100 mmHg).

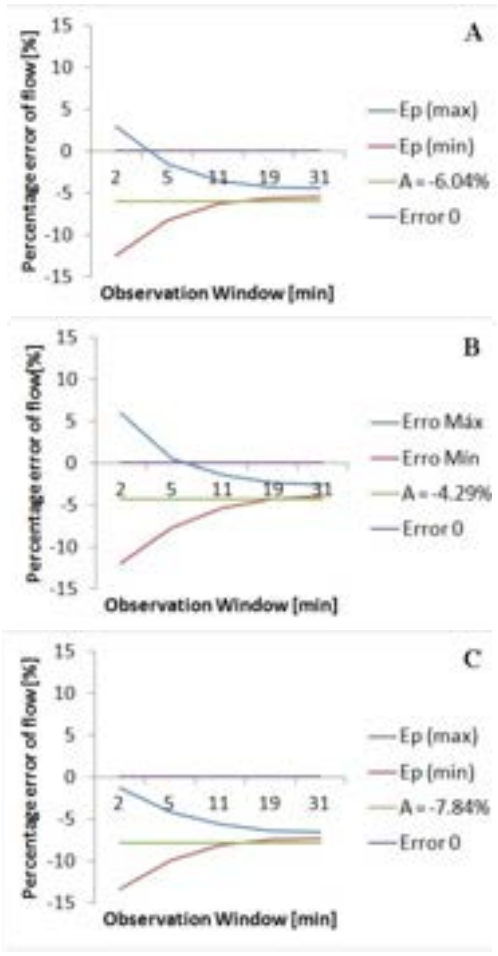

FIGURE 3. Trumpet curves of Infusion Pump 1 at 25 mL·h^{-1}. (A) Refers to ambient pressure. (B) Corresponds to overpressure. (C) Corresponds to the vacuum condition. Notes. Ep(max): maximum measured error in observation window; Ep(min): minimum measured error in observation window; A: the overall mean percentage flow error measured over the analysis period T2.

DISCUSSION

The primary objective of this study was to assess the flow rate accuracy of infusion pumps currently in use at the University Hospital of University of São Paulo (HU-USP), Brazil, comparing their performance against the accuracy specifications declared by the manufacturer. The findings revealed that the tested equipments delivered infusion outside the acceptable tolerance limits. The infusion pumps consistently administered less than the programmed amount, and such deviations may result in underinfusion, potentially compromising the efficacy of clinical treatments.

Bottaro M et al.[11] did not disclose the involved manufacturers in their findings, as this information was anonymized, which precludes a direct comparison of specific devices. Despite this limitation, a broader comparison was established: post-market data indicate that numerous infusion pumps are currently displaying significant issues concerning infusion accuracy.

During the tests, it was observed that all three infusion pumps, when set to a flow rate of 1 mL·h^{-1} over 24 h, exhibited a uniform delay of 11 min in completing the programmed volume. Even with this extended duration, the total volume infused remained below the intended target. As shown in Table 1, infusion pumps 2 and 3 failed the T1 test. Furthermore, according to the data presented in Table 2, these same pumps failed under all tested conditions at a flow rate of 25 mL·h^{-1}. In contrast, Infusion Pump 1 met the accuracy criteria in both T1 and T2 evaluations at 1 mL·h^{-1}, and in the T2 test at 25 mL·h^{-1} under overpressure conditions.

Infusion Pump 1, at a flow rate of 1 mL·h^{-1}, exhibited an overall mean percentage flow error within the tolerance limits specified by the manufacturer. However, a detailed analysis of the trumpet curves, as shown in Figure 2, reveals significant amplitude variability in flow, which may compromise its suitability for use in newborn patients, where high accuracy and stability are critical for safe and effective therapy.

Unfortunately, LEB is not authorized to conduct technical investigations aimed at determining the root causes of the device issues. The infusion pumps used at HU-USP were obtained through a leasing contract. According to this method, while the manufacturer supplies the devices, the hospital is responsible for purchasing infusion sets, maintenance, and calibration directly from the manufacturer.

Although many infusion pumps operate across a wide range of flow rates, for example, from 0.1 mL·h^{-1} to 999 mL·h^{-1}, the tests conducted in this study did not encompass the device's full operating range; however, they provide an important indicator of its performance quality. The study is still in progress and follows a three-stage timeline, advancing from standardized accuracy tests prescribed by IEC 60601-2-24 to evaluations at clinically used flow rates and, ultimately, to simulations of real PICU conditions using medications of varying viscosities.

The results obtained highlight the importance of implementing systematic and standardized performance verification protocols as part of routine clinical engineering practice. Additionally, it is important to emphasize the need for continuous monitoring and quality assurance, even for new devices that are unused and sealed in original packaging. The underperformance of brand-new pumps underscores the critical role of post-market evaluations before clinical deployment.

CONCLUSION

The study supports the proposed objective and reinforces the relevance of structured accuracy evaluation for infusion pumps in clinical scenarios. The consistent deviations observed, particularly in devices that had not yet been placed into clinical service, demonstrate the importance of testing protocols that go beyond the minimum regulatory requirements.

This work, however, is part of an ongoing initiative. The initiative will be expanded to include the entire inventory of infusion pumps in the hospital, which currently comprises 221 devices. Future assessments are not limited to flow rates and fluid prescribed by the IEC 60601-2-24:2012 but incorporate input from clinical teams regarding commonly

used medications and clinically relevant infusion profiles, thereby ensuring that testing protocols are aligned with real-world usage and institutional needs.

SUPPLEMENTARY MATERIALS

Not applicable.

AUTHOR CONTRIBUTIONS

Conceptualization, D.R., E.S. and H.M.; Methodology, D.R., E.S., and H.M.; Formal analysis, D.R.; Investigation, D.R., D.N, and P.Z.; Data curation, D.R.; Writing original draft, D.R. and E.S.; Writing, review and editing, D.R., E.S., M.N. and H.M.; Visualization, D.R.; Supervision, H.M.

ACKNOWLEDGMENTS

This study was carried out within the framework of a partnership between the Escola Politécnica and the University Hospital of the University of São Paulo. The authors gratefully acknowledge the support of the Superintendent of the University Hospital, Prof. Dr. José Pinhata Otoch, and the Director of the Escola Politécnica, Prof. Dr. Reinaldo Giudici. The authors also acknowledge the support provided by endowment fund of University of São Paulo Engineering School (Amigos da Poli).

FUNDING

This research received no external funding.

DATA AVAILABILITY STATEMENT

Not applicable.

CONFLICTS OF INTEREST

The authors declare that they have no conflict of interest.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

Not applicable.

CONSENT FOR PUBLICATION

Not applicable.

FURTHER DISCLOSURE

Part of the findings reported in this manuscript was previously presented at the Third Latin American Seminar on Clinical Engineering, held on May 20–21, 2025, São Paulo, Brazil.

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This paper is part of the Special Issue on The Advancement of Technology and Surgical Procedures in the Fields of Traumatology and Orthopedics: How Far Along Are We Now?

Guest Editor: Prof. Pietro Maniscalco, Ospedale Guglielmo da Saliceto, Piacenza, Italy. Dr. Corrado Ciatti, Università di Parma, Parma, Italy. Dr. Fabrizio Quattrini, Ospedale Guglielmo da Saliceto, Piacenza, Italy.

Received September 27, 2024, accepted January 5, 2026, publication date for online-first March 16, 2026.

Original Research Article

Artificial Intelligence and the Future in Knee Surgery: Challenges and Opportunities for Personalized Care

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ABSTRACT

Artificial Intelligence (AI) is revolutionizing the field of orthopedics and trauma surgery, offering new possibilities for improving diagnostic accuracy, enhancing surgical precision, and optimizing patient care. Through machine learning and deep learning algorithms, AI can analyze vast datasets, including medical images and patient histories, to recognize patterns that may be undetectable to the human eye. In orthopedics, AI is increasingly being integrated into preoperative planning, surgical navigation, and robotic-assisted procedures, providing surgeons with tools to perform more accurate interventions while reducing medical errors and physician fatigue. Despite the many benefits, challenges such as ethical considerations, patient privacy concerns, and regulatory requirements need to be addressed to ensure the reliable and safe use of AI in clinical practice. This study highlights AI's current applications in knee osteoarthritis diagnosis and treatment, its growing role in surgical decision-making, and the potential for machine learning models to personalize treatment plans. Additionally, it discusses the future of AI in healthcare, including the ethical dilemmas posed by autonomous systems and the importance of maintaining human empathy and judgment in patient care. Ultimately, while AI holds immense promise in transforming orthopedics and surgery, its full potential will only be realized through thoughtful integration and responsible use.

Keywords—*Artificial intelligence, Knee arthroplasty, Robotics, Robotic surgery, Cutting-edge arthroplasty.*

INTRODUCTION OF ARTIFICIAL INTELLIGENCE IN JOINT ARTHROPLASTY AND TRAUMA SURGERY

Artificial Intelligence (AI) is rapidly transforming the medical field, with particularly significant advancements in orthopedics and trauma surgery. By leveraging machine learning and deep learning techniques, AI algorithms can process vast amounts of data, including medical images, clinical records, and patient histories, to enhance decision-making and diagnostic accuracy. One of the key advantages of AI lies in its ability to analyze large datasets and recognize patterns that might not be immediately obvious to the human eye. For example, AI can assist in interpreting radiological images, predicting patient outcomes, and personalizing treatment plans based on individual patient data.[1]

In the realm of orthopedics, AI is becoming increasingly valuable in preoperative planning, surgical navigation, and even robotic-assisted surgeries, aiding surgeons in performing more precise interventions. AI-driven systems can analyze radiographic images to detect fractures, joint abnormalities, and other pathologies with accuracy often comparable to that of human radiologists. Furthermore, AI has the potential to reduce medical errors and alleviate physician burnout by automating repetitive tasks and offering decision support.[2,3]

Despite these promising benefits, there are still notable challenges to address. Ensuring the ethical use of AI, maintaining privacy of patient data, and establishing clear regulatory frameworks are crucial considerations. Additionally, proving the clinical superiority of AI over traditional methods requires rigorous validation through ongoing research. Nevertheless, the potential of AI to reshape orthopedic surgery is immense, from improving patient outcomes to enhancing healthcare efficiency. Orthopedic surgeons must embrace these emerging technologies to fully leverage their benefits in clinical practice.[4]

ARTIFICIAL INTELLIGENCE IN ORTHOPEDIC DIAGNOSIS AND IMAGING

Knee pain and injuries are common in clinical practice, and diagnosing such conditions often involves complex musculoskeletal (MSK) imaging. However, interpreting these images can be time-consuming and subject to variability, even among specialized MSK radiologists, because of the sheer volume of data and the details required for accurate assessments. Integrating AI into MSK radiology workflows presents a potential solution, offering improvements in diagnostic accuracy, expediting cases with urgent findings, reducing radiologist fatigue, and providing decision support in regions with limited access to expert radiology.[5]

Artificial Intelligence algorithms designed to assess knee pathology have shown great potential. Experimental models can now evaluate the severity of knee osteoarthritis (OA) using radiographs, detect and classify cartilage lesions, and identify meniscal and ligament tears on magnetic resonance imaging (MRI) scans. They can also provide automatic quantitative assessments of tendon healing and fracture detection, as well as predict the likelihood of recurrent bone tumors, offering powerful tools for both diagnosis and prognosis.[5]

One such algorithm, the You Only Look Once version 3 (YOLOv3), assists radiologists and orthopedists in detecting and classifying knee OA, following the Kellgren–Lawrence (KL) grading system. This model has demonstrated high accuracy, particularly in identifying early-stage OA from simple anteroposterior radiographs (YOLOv3; Creator: Joseph Redmon and Ali Farhadi; Version 3; real-time object detection neural network; open-source software; Online repository, 2018)[6].

Another development, the Knee Osteoarthritis Labelling Assistant (KOALA), has proven that AI can significantly enhance diagnostic consistency. Studies have shown that when physicians are supported by this system, their agreement proportions on assessing KL grades, sclerosis, and osteophyte formation improve, compared to when they work unaided. This highlights the potential of automated software to improve the accuracy of OA diagnoses.[7]

Additionally, the quantitative double-echo steady-state (qDESS) method, enhanced by deep learning, offers a rapid, 5-min three-dimensional (3D) knee MRI scan with automatic T2 mapping, improving sensitivity for detecting cartilage abnormalities. Its diagnostic performance rivals that of conventional MRI, with high inter-reader agreement.[8]

ETHICAL CHALLENGES AND LIMITATIONS OF ARTIFICIAL INTELLIGENCE IN ORTHOPEDIC SURGERY

The origins of AI in the mid-20th century were centered on replicating human cognitive functions. Today, advancements in machine learning have enabled systems to collect, analyze, and solve complex problems. Within medicine, AI has increasingly influenced clinical decision-making and enhanced surgical precision through sophisticated algorithms and robotics. However, the integration of AI into healthcare brings ethical concerns, including safeguarding patient privacy, mitigating algorithmic biases, and ensuring cybersecurity.[9]

In orthopedics, AI holds transformative potential by improving patient care, risk assessments, diagnostics, and surgical techniques. Yet, the rapid pace of development introduces challenges that demand the establishment of robust regulatory frameworks. Key ethical issues include preventing discrimination, addressing bias within AI training datasets, maintaining patient confidentiality, and securing informed consent. Automation also raises concerns about deskilling clinicians and over-reliance on AI systems, which could lead to significant risks in the event of system failures. Additionally, cybersecurity threats and questions of accountability further underline the need for ongoing monitoring and regulatory updates.[9]

Although fully autonomous medical practice remains a distant possibility, the field of AI in orthopedics is advancing rapidly. Current applications rely on augmented intelligence, where human oversight is essential for monitoring data inputs and outputs. The early developmental stage of AI in this field sparks debates that are likely to evolve into more complex ethical dilemmas as technology continues to progress.[10]

Artificial Intelligence in healthcare, powered by machine learning and deep neural networks, also presents significant concerns about privacy and bias. For instance, the 2015 partnership between DeepMind and the UK National Health Service, later found to breach data protection laws, highlighted critical privacy issues. Algorithmic bias, often arising from skewed training datasets, can result in systematic errors, disproportionately affecting underrepresented populations. Furthermore, adversarial attacks pose a serious risk, potentially impacting medical diagnoses, insurance processes, and drug approvals.

While regulating AI may help mitigate risks, it could also slow innovation. Proposed solutions include revising regulatory frameworks, but challenges such as the deskilling of healthcare professionals, over-reliance on data without context, and underestimating the complexity of medical decision-making persist. Addressing these issues is vital to ensure the safe and ethical integration of AI into healthcare systems.[4]

THE FUTURE OF ARTIFICIAL INTELLIGENCE IN ORTHOPEDIC SURGERY

As AI and robotics continue to advance, the role of surgeons and healthcare providers is evolving. Stephen Hawking once warned that fully developed AI could surpass human intelligence, potentially replacing us in many tasks. In the surgical field, this raises questions about whether intelligent machines could eventually replace human surgeons, whose skills and decision-making abilities have long been integral to patient care.[11]

While surgical robots have already improved precision and reduced human error, they still rely on human guidance, especially for complex ethical decisions. However, as these technologies evolve, there is a growing possibility that robots could become more autonomous, leading to concerns about job displacement and the erosion of the human element in patient care.

Despite these concerns, AI could ultimately empower surgeons, rather than replace them. By automating technical aspects of surgery, AI may free up surgeons to focus more on the human side of patient care, building stronger therapeutic relationships and enhancing the emotional and moral dimensions of treatment.

The future of surgery lies not in resisting AI but in mastering it. By integrating AI into their practice, surgeons can continue to play a vital role in healthcare while leveraging AI as a powerful tool to improve patient outcomes and enhance the overall quality of care.

The Evolving Role of Artificial Intelligence

Artificial Intelligence has become a transformative force across multiple fields, including robotics and surgery. As

an informatic discipline, AI focuses on developing software that can perform tasks traditionally requiring human intelligence, such as decision-making and problem-solving, through advanced algorithms and methodologies.

In robotics, AI enables machines—especially advanced robotic arms and industrial robots—to learn from their environment and optimize their movement despite challenges such as friction and mechanical slippage. These machines continuously map their surroundings, improving their efficiency over time.[12–14]

Robot-assisted knee surgeries, including single-compartment knee arthroplasty and total knee arthroplasty (TKA), are becoming increasingly common.[15] Compared to traditional navigation methods, robotic-assisted TKA offers several advantages, such as providing real-time haptic feedback during bone cutting, achieving more precise alignment, evaluating the soft-tissue envelope, and enhancing early functional outcomes. A comparative analysis of postoperative images from conventional and robotic-assisted TKA procedures found that the robotic approach resulted in reduced bone damage and less injury to soft tissue.[16] These findings highlight the significant improvements that robotics and AI have brought to knee surgeries, particularly in enhancing accuracy, surgical planning, and the overall patient outcomes.

However, in robotic surgery, today's machines are not fully autonomous or "intelligent" as AI might eventually allow. Surgical robots still rely heavily on surgeons for guidance, particularly in ethical and moral decision-making. AI enhances the precision of tasks, but the human surgeon remains responsible for critical decisions. This partnership highlights a limitation of current surgical robots: they enhance human capability, rather than make patient-specific decisions independently.

Nonetheless, AI's future in surgery is promising. In knee arthroplasty, for instance, robotic systems now allow for highly customized prosthetic implantation, with AI providing real-time data on ligament compliance. This enables surgeons to plan and execute resections and alignments more accurately. As AI evolves, we may see robots capable of analyzing vast amounts of patient data to predict optimal surgical strategies, offering tailored solutions based on individual anatomy and biomechanics.

While this potential is exciting, it raises important questions about the future role of surgeons. As AI-driven systems become more autonomous, surgeons' decision-making freedom may face new constraints. Balancing AI's precision with human experience and intuition is a key to achieve the best patient outcomes.

Where Are We Going?

Artificial Intelligence is making significant strides in the management of knee OA, with machine learning models showing great promise in automating radiographic grading and predicting the need for TKA. These models also show potential in forecasting postoperative outcomes, such as patient satisfaction, recovery time, and the risk of complications. However, challenges remain, particularly the lack of external validation for current AI algorithms, biases inherent in clinical data, and the need for larger and more representative datasets. Additionally, there are gaps in the literature regarding the generalizability and reliability of these models across diverse populations.[17]

Hip and knee OA are highly prevalent conditions globally, especially among the aging population. Joint replacements are becoming increasingly common, and the backlog of elective surgeries because of the COVID-19 pandemic has only exacerbated this demand. With limited resources and rising patient numbers, AI could offer a solution by streamlining the patient care pathway, particularly in selecting suitable candidates for arthroplasty. Projects such as "AI to Revolutionize the Patient Care Pathway in Hip and Knee Arthroplasty" (ARCHERY) aim to develop predictive models using machine learning, combining patient demographics, medical history, and radiological data to improve surgical selection processes.[18]

The ability of AI to learn from data makes it a valuable tool throughout the arthroplasty process, from diagnosis to surgical planning and postoperative monitoring. AI algorithms can assist surgeons in making patient-specific decisions, optimizing preoperative health, and allocating resources more efficiently. This level of personalization has the potential to revolutionize patient care. However, concerns about algorithmic bias—where non-representative data could lead to inaccurate recommendations for minority groups—must be addressed. Ensuring the

privacy and protection of patient data is also critical to the widespread adoption of AI in healthcare.[19]

One of AI's more promising applications is in implant identification during revision surgery. Accurate identification of knee arthroplasty implants is crucial for successful revisions, where delays in identifying the manufacturer and model can lead to complications and increased healthcare costs. Deep learning models have shown the ability to distinguish between different knee implants with near-perfect accuracy, facilitating more efficient preoperative planning and reducing revision surgery costs.[20]

While AI has the potential to transform knee and hip arthroplasty, addressing algorithmic biases, ensuring clinical validation, and protecting patient privacy remain critical.[21] As AI research continues to evolve, its integration into routine care could improve patient outcomes and streamline surgical processes, delivering more personalized and cost-effective solutions.

AUTHOR CONTRIBUTIONS

Conceptualization, L.A. and C.C.; Methodology, L.A. and C.C.; Writing—Original Draft Preparation, L.A. and C.C.; Writing—Review & Editing, F.B. and S.M.P.R.

ACKNOWLEDGMENTS

Not applicable.

FUNDING

This research received no external funding.

DATA AVAILABILITY STATEMENT

Not applicable.

CONFLICTS OF INTEREST

Not applicable.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

Not applicable.

CONSENT FOR PUBLICATION

Not applicable.

FURTHER DISCLOSURE

Not applicable.

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This paper is part of the Special Issue on Design and Manufacturing in Biomedical Engineering.
Guest Editor: Dr. Jashanpreet Singh, University Center for Research and Development, Chandigarh University, Punjab, India. Prof. Dr. Chander Prakash, University Center for Research and Development, Chandigarh University, Punjab, India.

Received October 28, 2025, accepted January 28, 2026, publication date for online-first March 17, 2026.

Original Research Article

Adhesion Characteristics of HAp Functional Coatings onto 3D-Printed Ti-6Al-4V and PEEK IPCs for Enhanced Bioactivity

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ABSTRACT

The current study probes the growth and characterization of composite hydroxyapatite (HAp) coatings on titanium alloy (Ti-6Al-4V, Grade 5 titanium) + polyetheretherketone (PEEK) substrates by a biomimetic deposition technique. HAp coatings were deposited on three titanium-based substrates: solid Ti-6Al-4V, three-dimensional printed porous Ti-6Al-4V, and interpenetrating composites (IPCs) Ti-6Al-4V + PEEK utilizing 10× concentrated simulated body fluid (SBF) buffered in tris (hydroxymethyl) aminomethane (TRIS or tromethamine) solution at physiological temperature (37 °C). Analysis of adhesion strength was carried out for assessing the mechanical bonding behavior of HAp coating with various substrate configurations. Surface analysis methods, such as scanning electron microscopy and energy dispersive spectrometry, established the growth of crystalline HAp with morphology similar to bone with all substrates. The findings proved that porous Ti-6Al-4V substrates had better adhesion strength through increased mechanical interlocking, and composite Ti-6Al-4V + PEEK substrates had a better stress distribution and a lower interface mismatch. The values of adhesion strength were from 16.6 ± 2.0 megapascal (MPa) for non-treated coatings to 30.0 ± 2.0 MPa for optimized composite coatings, greatly surpassing the minimum clinical requirements of ≥ 10 MPa. The displaced biomimetic HAp coatings enhanced wettability, better corrosion resistance, and increased apatite formation in SBF, relative to uncoated substrates. These results indicate that composite HAp coatings on Ti-6Al-4V + PEEK IPCs are a potential method for fabricating superior bioactive implant surfaces with outstanding mechanical and biological performance for orthopedic and dental applications.

Keywords—*Biomedical implants, HAp coating, PEEK, Ti-6Al-4V, Biomimetic deposition, Osteointegration.*

INTRODUCTION

Titanium alloys, particularly Ti-6Al-4V (Grade 5 titanium), are the gold standard for medical implants because of their excellent mechanical properties, corrosion resistance, and biocompatibility. However, in spite of these favorable characteristics, Ti-6Al-4V suffers from inherent biological inertness and susceptibility to stress shielding effect, both of which are detrimental to long-term implant success and osseointegration.[1,2] The moduli mismatch between titanium alloys (110 gigapascal [GPa]) and natural bone (15–30 GPa) have a tendency to lead to stress concentration and consequent bone resorption at sites of implants.[3–5] To overcome these drawbacks, researchers have tried to investigate numerous surface modification techniques, with composite hydroxyapatite (HAp) coating being a highly promising method. Hydroxyapatite, $Ca_{10}(PO_4)_6(OH)_2$, the principal mineral component of natural human bone, is a highly osteoconductive and biocompatible material that can be an ideal candidate for enhancing the bioactivity of the implant.[6–8] HAp coatings can potentially significantly improve the bone–implant integration by providing a bioactive surface for rapid osseointegration and reduced healing time.

The latest advances in biomaterials have encountered the creation of composite systems where titanium alloys are mixed with polyetheretherketone (PEEK), a high-performance thermoplastic that is popularly known due to its desirable properties. PEEK has a number of positive characteristics, such as excellent chemical resistance, radiolucidity, and an elastic modulus (3.5–4 GPa) that is nearly identical to that of cortical bone, thus reducing the stress-shielding effect. PEEK is used with Ti-6Al-4V to create composite structures that form an attractive pool of mechanical strength and elasticity with native bone tissue.[9–11] Conventional approaches to the deposition of HAp surface, such as sol–gel processing, plasma spraying, and electrophoretic deposition, generally result in crystalline pores with poor adhesion and constrained biological functionality. As an alternative, biomimetic deposition has the advantage of mimicking the process of bone mineralization in nature. In this test, substrates are put into super-saturated simulated body fluid (SBF), which is similar to the ionic composition of human plasma and favors the growth of bone like apatite with enhanced biological functionality.[12] In order to speed up coating formation at physiological conditions, 5×–10× concentrated solutions of SBF are usually used, whereas tris (hydroxymethyl) aminomethane (TRIS or tromethamine) buffer is necessary to keep a constant pH of approximately 7.4 during the coating process. Consequently, nanoscale morphology carbonated HAp, similar to natural bone mineral, is obtained, with greater bioactivity than synthetic HAp coatings.[13–16]

Some of the most important parameters that define the long-term success of coated implants include the adhesion strength between titanium substrate and HAp layer. Lack of proper adhesiveness can lead to delamination of coating and ultimate failure of implant. Crystallinity, coating thickness, surface pretreatment, and interfacial chemistry are some of the factors that are decisive in defining adhesion. It is thus critical to investigate these mechanisms in a variety of substrate geometries, such as solid Ti-6Al-4V, porous three-dimensional (3D)-printed Ti-6Al-4V, and Ti-6Al-4V + PEEK interpenetrating composites (IPCs), to optimize coating performance and clinical applicability.[17–19]

Titanium porous architectures are especially investigated due to their capability to strengthen bone growth as well as to reduce stress shielding. The networks of their pores are interconnected, which enhances surface area, hence resulting in mechanical interlocking and greater adhesion of HAp. Complicated geometries of porous structures are however a challenge in the uniformity of coating deposition as well as in a consistent quantification of adhesion strength.[20,21] Although titanium implants have been extensively studied with respect to HAp coatings, there is still a lack of data on the behavior of biomimetic HAp coatings on Ti-6Al-4V + PEEK IPCs, there is a dearth of data on the behavior of biomimetic HAp coverings on Ti-6Al-4V + PEEK IPCs. The interfacial relationships between the layers of HAp and PEEK composites have been poorly studied, particularly in relation to the effect of polymer phase on adhesion and mechanical stability. The current work fills these gaps in knowledge by conducting systematic research, exploring biomimetic HAp coatings on three substrate materials, such as bulk Ti-6Al-4V, porous Ti-6Al-4V and Ti-6Al-4V + PEEK composites. With the help of SBF 10× buffered with TRIS, the paper aims

at streamlining the coating procedure and conducting in-depth characterization of coating structure, composition, and adhesion strength.[22–24] These results are probably to provide important understanding of how to develop next-generation bioactive implant surface with improved mechanical reliability and biological integration to be used in clinical practice.

MATERIALS AND METHODOLOGY

The quality of HAp coatings onto pure Ti-6Al-4V alloy was compared to that on 3D-printed porous Ti-6Al-4V alloy and Ti-6Al-4V + PEEK composite. This section presents the material configuration of various substrates along with HAp coating preparation.

Sample Fabrication

Ti-6Al-4V alloy (99.5% purity) annealed round bar was purchased and cut to three substrates of varying configurations: solid Ti-6Al-4V discs (10-mm diameter × 5-mm thickness). Selective laser melting (SLM) technique, additive manufacturing technique, was used to fabricate porous Ti-6Al-4V scaffolds, in which a high-energy laser selectively melts successive layers of Ti-6Al-4V powder to fabricate fully dense, near-net shape components. The process enables precise control over microstructure, mechanical properties, and complex geometries. A porous Ti-6Al-4V scaffold with 65% porosity and 200–400-µm pore size, and composite 3D printed Ti-6Al-4V + PEEK samples, was fabricated by injection moulding of PEEK into Ti-6Al-4V scaffolds. All substrates were successively polished using silicon carbide (SiC) papers (400–1,200 grit size) and subsequently cleaned in acetone, distilled water, and ethanol for 10 min.

Solution Preparation

TRIS Buffer Solution Preparation

Chemicals of analytical grade (99.9% purity) used to prepare solutions were as follows: sodium chloride (NaCl), calcium chloride dihydrate ($CaCl_2 \cdot 2H_2O$), potassium chloride (KCl), sodium hydrogen phosphate (Na_2HPO_4), sodium hydrogen carbonate ($NaHCO_3$), magnesium chloride hexahydrate ($MgCl_2 \cdot 6H_2O$), and TRIS (Sigma-Aldrich, St. Louis, MO, USA). A solution of 2 mg $(mL)^{-1}$ dopamine hydrochloride (Sigma-Aldrich), in 10-mM TRIS buffer at pH 8.5, was used to create a thin layer of polydopamine (PDA). The PDA layer served solely as an adhesion-promoting interfacial layer to facilitate uniform HAp deposition. TRIS buffer was prepared in laboratory by dissolving 1.21 g Trizma® base (Loba-Chemie Pvt. Ltd., Mumbai, India) in deionized water, and diluted to 1-L final volume. The pH was set at 7.4 by a gradual addition of about 6–7 mL of concentrated HCl, cooling the solution prior to final pH reading, and any further adjustments.[25–28]

Preparation of 10× SBF Solution

In laboratory, 10× SBF solution was prepared according to the chemical composition listed in Table 1. All chemicals used were obtained from Loba-Chemie. Therefore, to make 2 L of SBF solution, chemicals were added sequentially to 1,000 mL of deionized water. An 800-rpm constant-speed magnetic stirrer was used to stir chemicals until they were dissolved. More deionized water was added to make a total volume of 2 L, and the pH was set at 7.4 by slow addition of $NaHCO_3$.[29,30]

TABLE 1. Composition of chemicals used to prepare 10× SBF solution.

S. No.	Chemical	Formula	Amount (g)	Concentration (mM)
1.	Sodium chloride	NaCl	115.76	10^3
2.	Potassium chloride	KCl	0.7456	5^1
3.	Calcium chloride dehydrate	$CaCl_2(2H_2O)$	6.3508	5^2
4.	Magnesium chloride hexahydrate	$MgCl_2(6H_2O)$	4.0330	5^1
5.	Sodium dihydrogen phosphate	(NaH_2PO_4)	2.3996	10

All Ti-6Al-4V substrates were pretreated in alkaline conditions to enhance surface reactivity toward biomimetic coating. The samples were immersed in 5 M NaOH solution at 50 °C for 24 h, rinsed thoroughly with water, and air-dried at 40 °C. The treatment introduces surface hydroxyl moieties that serve as nucleation regions for HAp crystallization. In the case of Ti-6Al-4V porous samples, the alkaline treatment was performed in vacuum to ensure complete infiltration of NaOH solution within pore structure. Pretreated composite Ti-6Al-4V + PEEK IPCs were subjected to modified conditions with 2 M NaOH for 40 °C for 12 h to prevent PEEK degradation.

Biomimetic Coating Process

Biomimetic HAp coating was performed through 10× SBF immersion process. Pretreated substrates were placed in a freshly prepared 10× SBF solution (TRIS-buffered to pH 7.4) at 37 °C ± 1 °C in a temperature-controlled incubator. The solution was slowly agitated at 70 rpm by an orbital shaker for even distribution of ions. The coating process continued for 7 days for a solution–substrate volume ratio of 100:1 to prevent depletion with daily solution renewal during the first 3 days and then at every 48 hs. Samples were taken out gently and cleaned in distilled water after coating and air-dried at 27 °C.

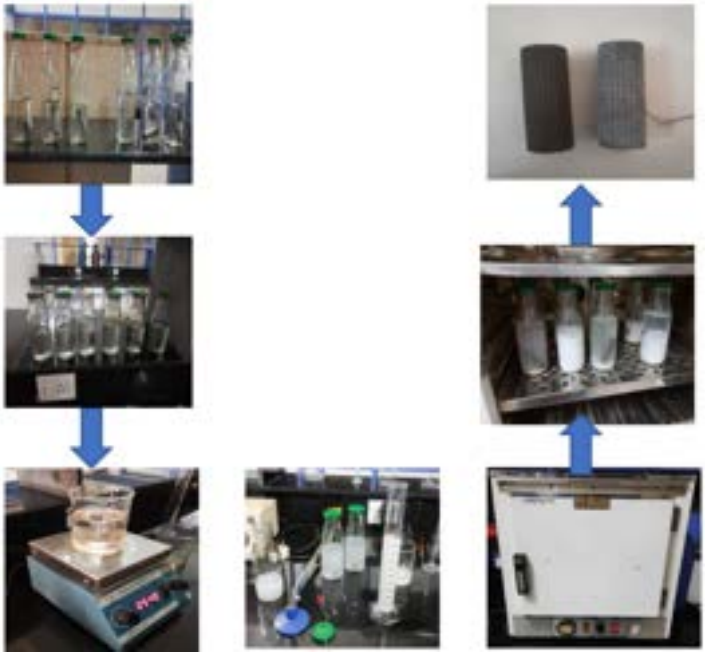

FIGURE 1. Biomimetic coating process.

RESULTS AND DISCUSSION

Morphological and Structural Characterization of Coatings

Surface topography of HAp coatings of three different substrate configurations' was determined by scanning electron microscopy (SEM), and elemental analysis was verified using energy dispersive spectrometry (EDS).

As reflected in the representative SEM micrographs in Figure 2, dense and homogeneous coating was actually deposited on all substrates following immersion in 10× SBF solution for 24 h. On solid Ti-6Al-4V substrate (Figure 2a), the coating consisted of rounded discrete crystallites that had aggregated to form a continuous "cauliflower-like" morphology. This type of morphology is a characteristic of biomimetically precipitated apatite and is said to be favorable for cell adhesion and proliferation.

In case of porous Ti-6Al-4V substrate (Figure 2b), not only was the outer surface covered by HAp coating but it penetrated deeply into the porous structure, encapsulating internal struts. This complete infiltration is critical for inducing bone growth throughout the scaffold. Morphology within pores was equal, compared to that on the solid surface.

The coating formed on Ti-6Al-4V + PEEK composite substrate (Figure 2c) was checked to cover both titanium and polymeric areas and was equal, which indicated that alkaline pretreatment successfully conditioned the surfaces to enable the growth of apatite. The interface between coated and uncoated regions was found to be continuous and did not appear to have any apparent discontinuity, and this demonstrated high levels of interfacial integration.

Energy-dispersive spectroscopy of a typical coated specimen (Figure 2d) showed that the coating was mostly composed of calcium (Ca) and phosphorus (P). The final Ca–P atomic ratio was about 1.65, which was quite near the stoichiometric ratio of 1.67 of crystalline HAp ($Ca_{10}(PO_4)_6(OH)_2$). Besides, traces of magnesium (Mg) and sodium (Na) were also discovered. Their occurrence was due to the incorporation of SBF ions, which usually replaces into apatite lattice, creating a carbonated HAp that is much more similar to the mineral composition of the bone of natural origin.

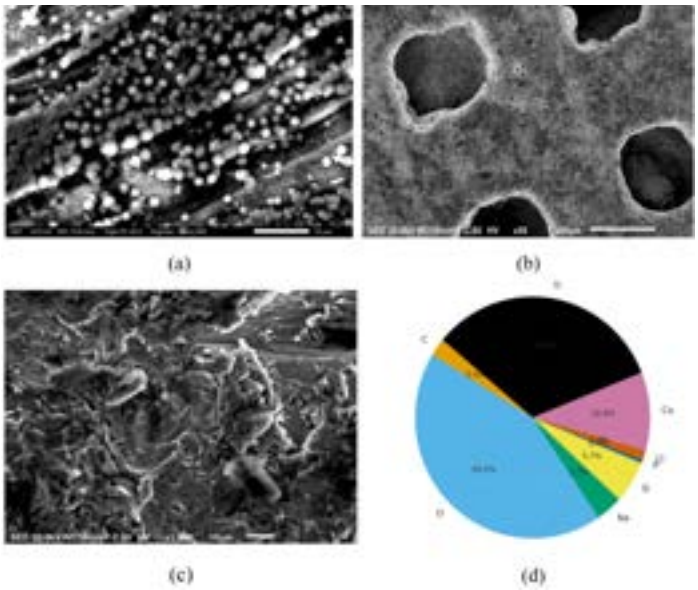

FIGURE 2. (a) SEM image of HAp coating on solid Ti-6Al-4V. (b) SEM image of HAp coating on porous Ti-6Al-4V. (c) SEM image of HAp coating on Ti-6Al-4V + PEEK IPC. (d) Representative EDS spectrum of HAp coating.

The elemental composition of HAp coatings formed on different samples is listed in Table 2. The coating trend demonstrated that thickness was comparatively more in porous and composite samples, compared to traditional solid samples.

The calculated Ca–P atomic ratios were approximately 2.35, 1.64, and 1.62 for 12, 24, and 48 h of immersion, respectively. The Ca–P ratios for 24 and 48 h were close to the stoichiometric value of HAp (1.67), suggesting improved apatite formation and maturation with longer duration of immersion. These results confirmed the successful formation of a calcium phosphate ($Ca_3(PO_4)_2$)-rich HAp coating on substrate surface as shown in Table 3.

TABLE 2. Mass and thickness of HAp coating on different samples.

Sample	Initial Mass (mg)	Final Mass (mg)	Mass Gained (mg)	Coating Thickness (µm)
HAp (solid Ti6Al4V)	3,779.4	3,838.8	59.4	39.78
HAp (porous Ti6Al4V)	2,718.6	2,816.3	97.7	65.32
HAp (Ti6Al4V + PEEK)	2,730.2	2,832.8	102.6	54.16

TABLE 3. HAp coating constituents using EDS technique for Ca–P ratios.

Elements	HAp (12 h)	HAp (12 h)	HAp (24 h)	HAp (24 h)	HAp (48 h)	HAp (48 h)
	Wt%	At%	Wt%	At%	Wt%	At%
Ti	59.83	37.38	37.89	22.69	36.22	20.62
O	27.97	52.32	43.62	64.77	44.94	66.79
Ca	7.88	5.89	10.55	6.39	10.84	6.51
P	2.61	2.51	5.35	3.89	5.58	4.01
Al	1.71	1.9	2.59	2.26	2.42	2.07
Total	100	100	100	100	100	100
Ca–P ratio		2.35		1.64		1.62

Coating Adhesion Strength

The mechanical integrity of biomimetic HAp coatings was quantitatively assessed using pull-off adhesion and scratch tests. The results, summarized in Figure 3, revealed significant differences in adhesion strength among the three substrate configurations.

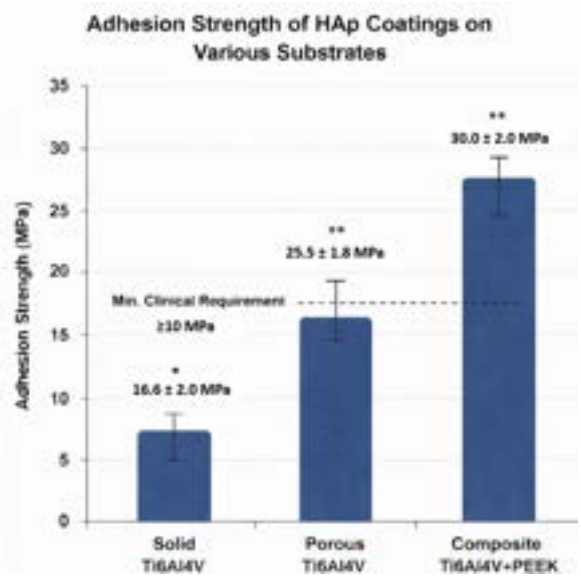

FIGURE 3. Adhesion strength comparison graph (*$p < 0.05$; **$p < 0.01$).

The pull-off test revealed that the solid Ti-6Al-4V substrate had the lowest adhesion strength of 16.6 ± 2.0 megapascal (MPa). The porous Ti-6Al-4V scaffolds had a remarkable improvement, with an adhesion strength of 25.4 ± 1.8 MPa. The maximum adhesion value was for the

Ti-6Al-4V + PEEK IPC, which had an adhesion strength of 30.0 ± 2.0 MPa. Its graphical illustration is shown in Figure 3.

The scratch tests were performed according to ASTM C1624-05 using a Rockwell diamond indenter (200-µm tip), with a load range of 0–80 N, a loading rate of 10 N min^{-1}, and a scratch speed of 10 mm min^{-1}. The results of scratch tests confirmed the trends of pull-off tests. The dense Ti-6Al-4V coatings fractured at the lowest critical loads, with the initial cohesive cracks (Lc_1) at 18.5 ± 1.2 N and a full coating delamination (Lc_2) at 35.2 ± 2.5 N. The porous and composite substrates showed increasingly higher critical loads. The highest scratch resistance was shown by Ti-6Al-4V + PEEK IPC with Lc_1 and Lc_2 at 32.4 ± 2.1 N and 55.1 ± 2.8 N, respectively. These results are shown in Figure 4.

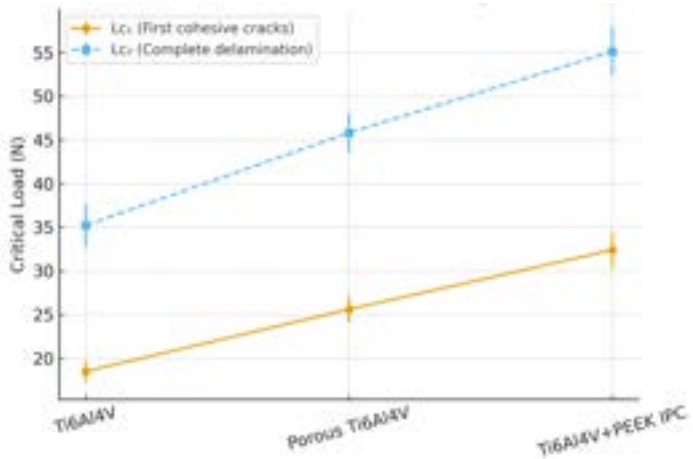

FIGURE 4. Graph showing scratch test results.

CONCLUSION

This research effectively illustrates the biomimetic deposition of a crystalline, uniform, and bone-like HAp coating onto solid Ti-6Al-4V, porous Ti-6Al-4V, and new Ti-6Al-4V + PEEK composite substrates.

The findings clearly indicate that substrate architecture significantly influences the coating's mechanical performance. The highest adhesion strength was shown by Ti-6Al-4V + PEEK composite, which exceeded both porous and solid Ti-6Al-4V in a significant manner. This higher performance was due to lower elastic modulus of the PEEK component, which reduces stress at the coating–substrate interface. In addition, porosity increased adhesion by mechanical interlocking. All coated substrates considerably exceeded the minimum requirements of clinical adhesion strength, establishing their mechanical stability. Finally, HAp-coated Ti-6Al-4V + PEEK IPCs are very promising material for next-generation dental and orthopedic implants, with an ideal blend of bioactivity and improved mechanical stability.

AUTHOR CONTRIBUTIONS

Conceptualization, S.M. and A.S.; Methodology, S.M. and A.S.; Software, S.M.; Hardware, S.M., Validation, S.M.; Formal Analysis, S.M.; Investigation, S.M. and A.S.; Writing–Original Draft Preparation, S.M.; Writing–Review & Editing, S.M. and A.S.; Visualization, S.M. and A.S.; Supervision, A.S.

ACKNOWLEDGEMENTS

Not applicable.

FUNDING

This research received no external funding.

DATA AVAILABILITY STATEMENT

Not applicable.

CONFLICT OF INTEREST

The authors declared no conflict of interest.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

Not applicable.

CONSENT FOR PUBLICATION

Not applicable.

FURTHER DISCLOSURE

Not applicable.

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Received November 5, 2025, accepted January 16, 2026, publication date for online-first March 18, 2026.

Engineering Report

Role of a Biomedical Engineer in Latin America as a Supplier of Medical Devices and Services for an Asian Transnational Company

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ABSTRACT

The hiring of biomedical engineers by an Asian multinational in Latin America is increasing. Chinese companies are expanding, and this professional profile is the most sought-after saliency by these companies. Biomedical engineers have multidisciplinary training to support multinationals in planning, finding potential distributors, and performing pre-sales and post-sales operations, thereby involving biomedical engineer in all company departments. Biomedical engineers are key and highly valuable employees for the business growth of companies in Latin America. This paper provides biomedical engineers an overview of the activities performed by a Chinese multinational, the challenges, important peculiarities of Latin American countries, and the skills and capabilities that a biomedical engineer must have to work for a Chinese multinational.

Keywords—*Biomedical engineer, Multinational, Technical service, Marketing, Business.*

SCENARIO

The Latin American (LA) market is of great interest for global multinational companies, especially for Asian companies that provide goods and services related to medical devices (MD) because of constant economic and technological development and day-to-day expansion of LA.[1,2]

To develop robust and lasting business and commercial partnerships in LA, multinationals hire for the region professionals with a multidisciplinary background, such as biomedical engineering. Biomedical engineering has multidisciplinary educational foundation, making it a profession with great emerging potential. It includes training in medical devices, hospital areas, and technical support, training, and advice on software development and programming, and commercial development, among other subjects, which make it attractive for multinationals.[3]

Hence, the role of a biomedical engineer has become fundamental in multinationals because of commercial globalization of medical devices between Asia (China) and LA.

Chinese multinationals are increasing the number of biomedical engineers in the region to expand their businesses. These professionals are the targets of recruitment,

with attractive and well-paid job offers that provide economic stability and best salaries.[4]

AREAS OF PRACTICE OF A BIOMEDICAL ENGINEER

A biomedical engineer has many areas of action, as described, when working in an Asian multinational (Figure 1).

***Technical Support*:** A biomedical engineer is responsible for providing support, advice, and technical training on medical devices to distributors of Asian multinationals (Figure 1).

A biomedical engineer, formally and in person, introduces the Chinese multinational to the companies they visit, explaining the multinational's history, certifications, potential clients, medical devices it manufactures, and its competitors, among other things. They also disseminate technological trends and their positioning in the international market regarding medical devices.

Training: Biomedical engineer provides training of medical devices manufactured by Asian multinationals to interested distributors. A training plan is developed to cover topics such as operations, functioning, installation, equipment start-up, technical issues, troubleshooting, applications, technical differences with competitors, and queries.

Marketing: Multinational companies have a marketing department, which also includes biomedical engineers. They constantly support and assist distributors in LA as well as staffs of hospitals and clinics public and private sectors.

Market Research: A biomedical engineer assists in acquiring new businesses in LA. This activity requires conducting a market study, which analyzes the portfolios, products, and devices distributed by companies in LA. This allows companies to identify whether they lack devices manufactured by Asian multinationals in their portfolios.

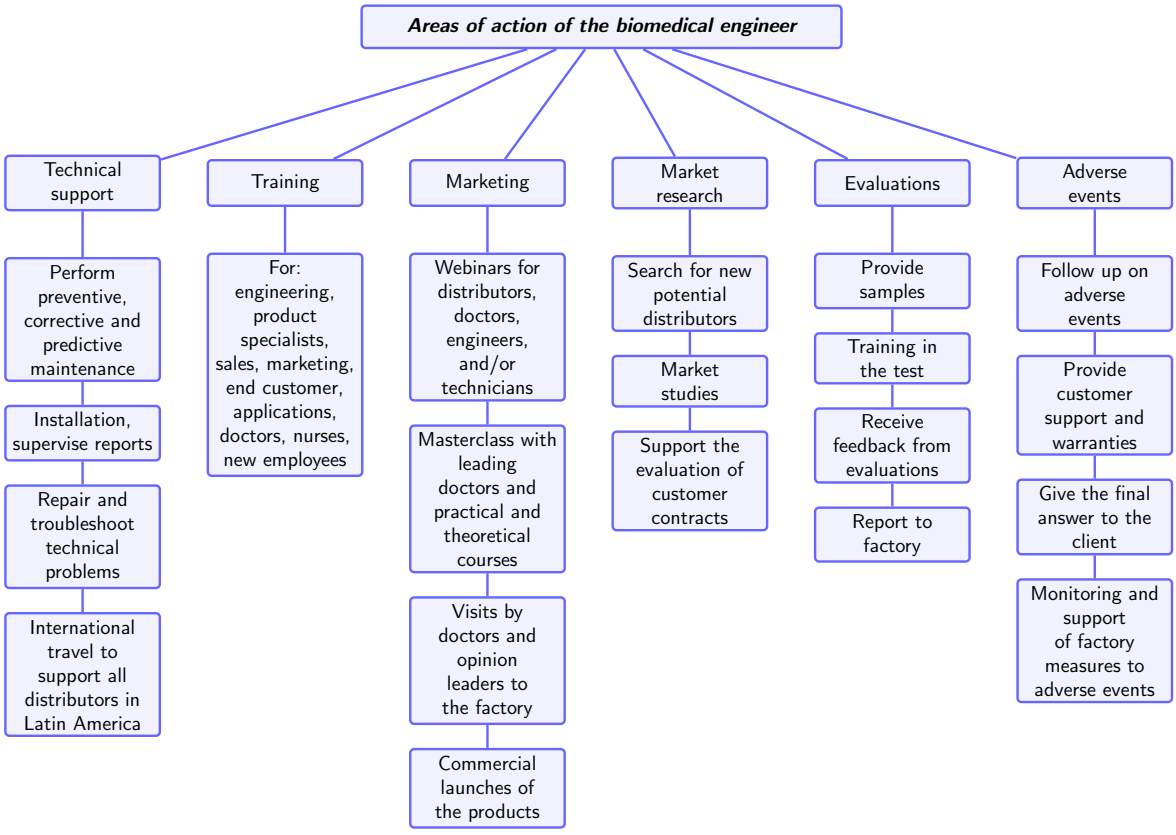

FIGURE 1. Areas of action of a biomedical engineer.

It is essential to conduct an in-depth and comprehensive market study of medical devices that have arrived in each country, including brands, models, prices, competitors, and other factors. LA companies must not have conflict of interest; a commercial strategy is developed to convince and justify the need to include the products offered in their portfolio.

Advantages over competitors must be demonstrated along with price comparisons in both public and private sectors as well as the market size in absolute numbers. Biomedical engineers assist and support this research so that Asian multinationals can identify their best distributors in each LA country.

Support for Potential Distributors: Biomedical engineers provide demonstrations of the medical devices manufactured by Asian multinationals. They provide all necessary support, so that the potential distributors can evaluate the medical devices and decide whether to distribute products in their country. Biomedical engineers provide samples, accompany them to the facility, provide training, and support and assist a physician or healthcare professional conducting the evaluation.

Adverse Event Management: Adverse events are the situations that compromise or affect life or health of the patients using the medical device.[5] In case users inform about an adverse event, then biomedical engineer provides the distributor a detailed report of adverse events, attaching photos, videos, and related information of the medical device, such as model, serial number, or lot. With this information, the manufacturer identifies the lot number and requests that the medical device be sent to China for evaluation, and gives a response to the distributor and/or hospital where the adverse event occurred.

BIOMEDICAL ENGINEER AS A PRODUCT SPECIALIST

To become a product specialist in an Asian multinational, a biomedical engineer must have a professional degree, a professional card, and the necessary country-specific permit to work with medical devices in hospitals and/or clinics.[6] They must also be qualified and possess the skills described below:

Experience with Medical Devices: A biomedical engineer must have experience in the operation and technical support of medical devices as well as experience of working in a hospital environment.

Authorization by the Manufacturer: A biomedical engineer must receive training at a manufacturer's location.[7] This multidisciplinary training involves several departments, such as service, technical support, marketing, product specialists, sales, vendors, commercial support, and human resources, among others.

Knowledge of Different Languages: Most Chinese multinationals have English-speaking staff in their international teams, so biomedical engineers must speak at least English. Knowledge and speaking of more languages expands job opportunities and enhances global management skills.

Speaking Spanish and Portuguese is a plus point to work in LA markets.

This allows for a direct communication between companies in LA and manufacturers in China.

Business and Negotiation skills: Biomedical engineers possess and develop commercial skills to promote medical devices manufactured by multinationals. Being professionals, they obtain information on market behavior from distributors. They must provide credibility to companies and gain the trust of investors.

Troubleshooting: Biomedical engineers must have quick and practical problem-solving skills. They maintain direct communication with factories in China for support, to provide information and support to distributors in a quick and professional manner.

Independent Work: Complete knowledge must be acquired promptly. Learn to work independently, develop quickly job responsibilities, schedule daily activities, and show the Chinese company significant results within a short term. All this to provide technical support required by distributors.

COMMERCIAL DIFFERENCES BETWEEN LA COUNTRIES

As observed in Tables 1 and 2, markets are very diverse in LA. They vary in area, population, GDP per capita, number of hospitals and beds, trade relations with China, and diverse economies. This diversity is LA's greatest asset that attracts the attention of multinationals globally.

TABLE 1. Differences in territorial extension, population, GDP per capita, and number of beds and hospitals in the countries of LA.[7–10]

Country	Territorial Extension (km^2)	Population 2023 (Millions)	GDP per Capita 2023 (USD)	Number of Hospitals (Beds)
Brazil	8,510,417,771	211.1	10,294,87	7,191 (427,097)
Argentina	2,780,000	46.65	14,187,48	5,012 (166,943)
Chile	756,626	19.66	17,067,81	425 (44,700)
Colombia	1,142,000	52.32	6,947,36	2,500 (79,000)
Perú	1,285,000	33.85	7,906,59	1,078 (35,981)
Ecuador	283,561	17.98	6,609,80	900 (24,802)
Venezuela	916,445	28.3	5,213	757 (16,300)
Uruguay	176,215	3.388	22,797,81	105 (9,505)
Bolivia	1,098,581	12.24	3,686,28	469 (17,000)
Paraguay	406,752	6.844	6,276,35	1,107 (10,200)

TABLE 2. Differences between markets in LA countries.[11–14]

Country	Health Registry	Trade Relations with China	Reuse of Disposable Medical Devices	National Tax (Average 2025)
Brazil	Yes	Yes	No	22.25%
Argentina	Yes	Yes	Yes	21%
Chile	No	Yes	No	9%
Colombia	Yes	Yes	Yes	19%
Perú	Yes	Yes	Yes	18%
Ecuador	Yes	Yes	Yes	12%
Venezuela	Yes	Yes	Yes	16%
Uruguay	Yes	Yes	No	10%
Bolivia	Yes	Yes	Yes	13%
Paraguay	Yes	No	Yes	10%

In terms of territory/land area, Brazil is the largest country in LA, followed by Argentina, with Paraguay being the smallest country.

In terms of population, Brazil is the most populated country among all representative countries of LA. Curiously, Colombia, which in territorial extension is number four, becomes the second most populated country in LA.

The country with the highest GDP per capita (USD) in 2023 was Chile, followed by Argentina and Brazil. These three are the richest countries in LA.

Regarding the number of hospitals and beds in LA countries, Brazil is at number one, followed by Argentina and Colombia.

To do medical business in LA countries, it's necessary to know whether health registration is required, what documents are needed, expenses, and the processing period. Chile is one of the countries where business can be started promptly because health registration is not required. However, Chile is a very demanding country with high quality standards, and any product is not accepted easily.

For disposable medical devices, it is important to know whether these countries reuse these devices or not because the sales volume depends on the volume of reuse. Brazil, Chile, and Uruguay are the only countries in LA that do not reuse disposable medical devices, so sales volume in these countries is high.

National tax in each country of LA is very important and must be taken into account when calculating the final price of manufactured products. High taxes impact the final price of products reaching the consumer. The strategy adopted by Chinese multinationals is to lower prices for importers in the countries with higher taxes in order to maintain competitive prices in the market. Table 2 shows that Brazil has the highest taxes. However, owing to a large population, all multinationals vie for market share and high sales volumes in Brazil. Many Chinese brands often fail to enter the Brazilian market because high taxes make product prices uncompetitive. Other countries with high taxes are Argentina and Colombia. Countries with the lowest taxes are Chile, Paraguay, and Uruguay.

Below-mentioned countries have a significant impact in medical devices market of LA.

Brazil: In Brazil, National Health Surveillance Agency (Agência Nacional de Vigilância Sanitária, ANVISA) supervises and controls the marketing of medical devices. It is responsible for issuing health registrations and authorizing the distribution of medical devices.

In the case of Class III medical devices[15], ANVISA officials travel to China to thoroughly inspect the factories and warehouses of medical devices. In Brazil, manufacturers have to obtain the certificate of good practices to process the health registration of their medical devices.[16]

Brazil's market for disposables and consumables is 100% effective; there is no reuse because ANVISA imposes rigorous sanctions on healthcare institutions that do not use products as described in the instructions for use of medical devices. The Brazilian market is receptive and open to distribute medical devices from Asian companies. Trade agreements between Brazil and China facilitate this trade between the countries.[17]

Chile: Chile is a country that does not require health registration to import medical devices.[13] A free trade agreement between Chile and China facilitates trade between the countries.[18] The Chilean market does not reuse disposable consumables; clinics and hospitals have strict policies, do not accept reuse, and fully comply with manufacturers' recommendations.

Argentina: The government entity responsible for granting health registrations is the National Administration of Drugs, Food, and Medical Technology (Administración Nacional de Medicamentos, Alimentos y Tecnología Médica, ANMAT).[19] Asian multinationals must provide local companies in Argentina with a free sale certificate (for their protection) issued by a country with high health surveillance in medical technology, such as the European Union, the United States, Canada, Australia, Japan, and Israel.[20]

Paraguay and Bolivia: In both countries, documents are required to register medical devices and obtain health records to market medical devices. Paraguay has no commercial relationship with China[21], which makes the procedures longer. In Paraguay, the government entity in charge of carrying out health records is the National Directorate of Health Surveillance (Dirección Nacional de Vigilancia Sanitaria, DINAVISA)[22], while in Bolivia it is the State Agency for Medicines and Health Technologies (Agencia Estatal de Medicamentos y Tecnologías en Salud, AGEMED).[13]

Uruguay: The health registration of medical devices must be processed at the Information Transfer Platform for the registration of medical products (PIRM), which is controlled by the Ministry of Public Health (Ministerio de Salud Pública, MSP).[13] In this case, there is a market leak from Uruguay because of its proximity to Argentina, because many people travel to Argentina to undergo medical procedures because of affordability.

Peru and Colombia: The government entity that accomplishes health registrations of medical devices in Colombia is the National Institute for Drug and Food Surveillance (Instituto Nacional de Vigilancia de Medicamentos y Alimentos, INVIMA)[23], while in Peru it is the General Directorate of Medicines, Supplies and Drugs (Dirección General de Medicamentos, Insumos y Drogas, DIGEMID).[13] New manufacturers are constantly entering the markets of these countries because of considerable potential to develop new distributors.

Ecuador: The health registration of medical devices is accomplished by the National Agency for Health Regulation, Control and Surveillance (Agencia Nacional de Regulación, Control y Vigilancia Sanitaria, ARCSA).[13] The official currency is US dollar, and Ecuadorian businesspeople can conduct commercial transactions with China using their currency.

The LA countries are experiencing constant economic growth and have enormous potential to develop new businesses and markets for Chinese multinationals. China boasts cutting-edge technology with competitive prices. LA has a significant market for Asian medical technologies.

CHALLENGES OF WORKING IN A CHINESE MULTINATIONAL

A biomedical engineer confronts many job challenges for working in an Asian multinational, which are as follows.

Cultural Differences: Asian culture and anticipations are quite different from LA culture. It is advisable to maintain good communication with Chinese employees, and share everything and listen to their perspective.

Working Hours: In China, employees are expected to work 24 hours daily. They must always be willing and able to work directly in factories. Owing to the time difference, they must be willing to have work meetings at night.

Documentation: Asian manufacturers have high standards for the services and documents they issue to clients. Therefore, it is important to have proficiency in English writing and presentation of reports (weekly, biweekly, monthly, quarterly, semiannual, and annual).

Language: Language is often a limitation. Asian multinationals always hire English-speaking employees, but

it is a Chinese-based English that employees of these multinationals must adapt to and become familiar with.

Most countries in LA speak Spanish, so it's important to speak and write Spanish. Portuguese is spoken in Brazil. Having knowledge of these three languages allows to work effectively in LA, including several Caribbean islands that have their own dialects but understand English.

Departmental Interrelations Within the Company: One must interact frequently with many departments, so learning to work in multidisciplinary teams is important. Therefore, a biomedical engineer must achieve this professional profile.

Business Trips: International travel is ongoing. A US visa is required because most medical device exhibitions are international, and LA businesspeople often attend to close deals and do business with multinational companies. A Chinese visa is also required for factory training, certification, and in-person meetings at the end of the year.

AUTHOR'S WORK EXPERIENCE IN CHINESE MULTINATIONALS

Specialist Engineer (2018–2020): The author represented the entire product line of Medcaptain Medical Technology (www.medcaptain.com) located in Shenzhen, Guangdong, China.

The author was responsible for the southern LA countries (Brazil, Chile, Argentina, Uruguay, Bolivia, and Paraguay). The following products were covered:

- Infusion workstation
- Infusion pump
- Enteral infusion pump
- MRI infusion pump console
- Video laryngoscope
- Portable oxygen
- Vein viewer
- Immunoassays
- Thromboelastography (TEG)
- Real-time PCR (RT-PCR)
- RT-PCR kits
- Blood typing

International Sales Manager (2020–2022): The author worked with in vitro diagnostic (IVD) products at Medcaptain Medical Technology. He developed business throughout LA in the company's IVD clinical laboratory line.

LatAm Regional Manager (2023–2024): The author expanded business in LA for Fulbright Medical Inc. (https://www.fulbrightmed.com). He was responsible for Chile, Peru, Argentina, Bolivia, Uruguay, and Paraguay markets. Fulbright Medical Inc. specializes in manual and motorized surgical staplers, with a wide range of staplers on different platforms.

Regional Manager Latin America (2025–Present): At Hocer (Tianjin) Medical Technologies Co. (http://en.hocermed.com/), located in Tianjin, China, the author is responsible for opening business avenues throughout LA and Central America. Hocer Medical Technologies specializes in high-tech ultrasonic scalpels used for surgical procedures.

CONCLUSIONS

The hiring of biomedical engineers by Asian multinationals is constantly growing in LA markets; hence, it is important to be prepared and have necessary skills to fill these positions. Biomedical engineers are fundamental employees for these companies, providing LA professionals with job stability and the opportunity to work globally.

Chinese have arrived to revolutionize the field of medical technology and are here to stay because of competitive prices, cutting-edge competition, high-quality technology, easy operation, and many other applications that make daily life easier for healthcare professionals.

Biomedical engineers are valuable to LA businesspeople who want to do business with Chinese multinationals. Because biomedical engineers are the intermediaries between LA businesses and China, LA businesspeople greatly value being served by a Spanish speaker from their region.

Biomedical engineers need a well-rounded education, with fluency in spoken and written languages; a coursework in marketing and business is essential. LA is looking for leaders and professionals in this rapidly growing field.

ACKNOWLEDGMENTS

The author thanks for help and support to Dr. Martha R. Ortiz-Posadas, Dr. Antonio Alvaro Ranha Neves, Tita Liu, and Mandy Tao.

AUTHOR CONTRIBUTIONS

Conceptualization, Methodology, Investigation, Resources, Data Curation, Writing – Original Draft, Writing – Review & Editing, Project administration, Funding acquisition: D.R.A. The author read and approved the final manuscript.

FUNDING

Not applicable.

DATA AVAILABILITY STATEMENT

Not applicable.

CONFLICTS OF INTEREST

Not applicable.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

Not applicable.

CONSENT FOR PUBLICATION

Not applicable.

FURTHER DISCLOSURE

Not applicable.

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This paper is part of the Special Issue on Design and Manufacturing in Biomedical Engineering.
Guest Editor: Dr. Jashanpreet Singh, University Center for Research and Development, Chandigarh University, Punjab, India. Prof. Dr. Chander Prakash, University Center for Research and Development, Chandigarh University, Punjab, India.

Received August 13, 2025, accepted December 10, 2025, publication date for online-first March 19, 2026.

Review

Biomedical Implants and Applications: Current Innovative Materials and Regenerative Solutions

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ABSTRACT

Background: The orthopedic biomedical implants industry is undergoing a surge in demand all over the world due to the growing ageing population, the growing life expectancy, and the growing number of high-impact traumatic injuries. Although the present-day implants used in joint replacement, spinal fixation, and bone regeneration are very effective in enhancing mobility and the quality of life of the patients, biological and mechanical complications tend to reduce the success of implants in the long-term. Stress shielding, osteolysis associated with wear, and biofilm-related infections are still some of the main factors that lead to revision surgeries. **Objectives:** This paper seeks to offer an extensive assessment of the present situation regarding orthopedic implants. It is dedicated to the interaction of material science, biomechanical needs, and high-end surface engineering to respond to current failure modes and suggest a structure of the next-generation regenerative devices. **Material and Methods:** The systematic review and analysis were done on four main types of materials namely metals, polymers, ceramics, and composites. The paper proposes the analysis of the contemporary manufacturing and design technologies integration (AI-driven CAD/CAM systems, additive manufacturing (3D printing) to create patient-tailored geometries, and nanostructured coating deposition). As criteria of evaluation, such factors as the potential of the bio-integration of the material and wear resistance and the biomechanical compatibility between biodegradable metallic alloys and the stimuli-responsible materials as the smart ones was taken into consideration. **Results:** It is demonstrated in the analysis that the developments in additive manufacturing can enable the production of porous, biomimetic, structures that can reduce the stress shielding greatly because of its comparable elastic modulus to natural bone. Moreover, nanostructured surface layers and the creation of biodegradable alloys (e.g., made of magnesium) has a considerable amount of potential in the stimulation of bone cell adhesion and the minimization of foreign body retention when present over extended periods. It was concluded that the AI implant design phase enhanced the optimization of the implant geometry, thereby decreasing the rate of mechanical failure. Nonetheless, regardless of such technical advances, the key challenges of long-term stability are control of immune response and avoidance of microbial colonization (biofilms). **Conclusion:** Active regeneration is the future of orthopedics due to the fact that it succeeds the passive fixation. Integration of the multi-scale innovations - nano-engineering to real time monitoring with intelligent systems creates a strategic framework of next-generation implants. The research finds that a combined method of predictive design and infection-resistant materials is the only

way to decrease the revision rates and attain high-quality and dynamic clinical results.

Keywords—*Orthopedic implants, Biomaterials, Osseointegration, Titanium alloys, UHMWPE, Ceramics, Surface engineering, Additive manufacturing, Nanomaterials, Bioactive coatings, Biodegradable alloys, Patient-specific design, Smart implants.*

INTRODUCTION

Orthopedic implants represent one of the most significant achievements in modern medicine, fundamentally transforming the management of musculoskeletal disorders, trauma, and degenerative joint diseases. Through the integration of advances in materials science, biomechanics, and surgical technique, biomedical implants have enabled millions of patients worldwide to regain mobility, relieve pain, and experience a dramatic improvement in quality of life.[1] The scale of their impact is reflected in the dominance of orthopedic devices in the global biomaterials market, with joint replacements and fracture fixation systems accounting for billions in annual healthcare expenditures. This remarkable progress is driven not only by demographic changes such as an aging population and the rising prevalence of chronic bone and joint conditions, but also by relentless scientific innovation and clinical need.[2] Historically, the development of orthopedic implants has paralleled the evolution of biomaterials (Figure 1). Demographic data confirm a substantial rise in orthopedic implant procedures globally, driven by aging populations, rising proportions of arthritis and osteoporosis, and improved access to healthcare. For instance, annual knee replacements in the United States are expected to surpass 1.2 million by 2030, reflecting nearly a two-fold increase over the past two decades.

Early efforts relied on rudimentary materials, but it was not until the 20th century, with the introduction of advanced metallic alloys, that reliable and effective orthopedic devices became possible. The discovery of

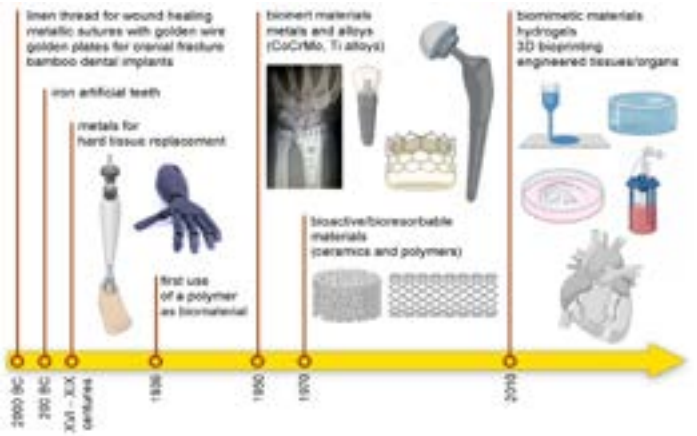

FIGURE 1. Development of orthopedic implants has paralleled the evolution of biomaterials.[3] (CC by 4.0)

osseointegration by Dr. Per-Ingvar Brånemark and the subsequent development of titanium (Ti) as a premier implant material marked a turning point in implantology.[4] Osseointegration, the direct, functional connection between a living bone and surface of an implant, has fixed a new standard for the biological and mechanical stability required for permanent prostheses (Figure 2).[5,6]

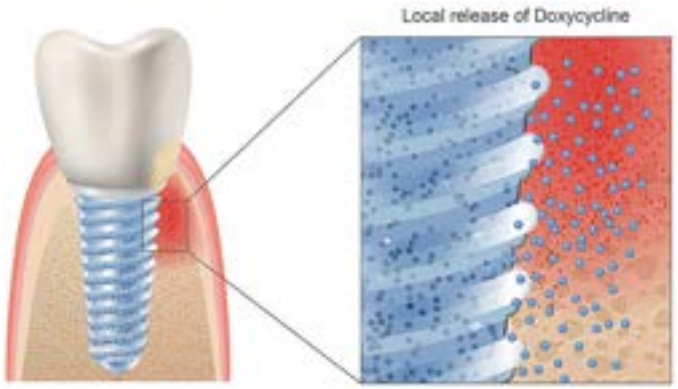

FIGURE 2. Osseointegration between a living bone and surface of an implant.[7] (CC by 4.0)

The ability of titanium and its alloys to combine high strength, corrosion resistance, biocompatibility, and promotion of bone integration has firmly established them as the gold standard in load-bearing applications. Meanwhile, cobalt (Co)–chromium (Cr) alloys offer exceptional hardness and wear resistance for articulating surfaces, while stainless steel, although less resistant to corrosion, is valued for its cost-effectiveness and ease of

fabrication, especially in temporary fixation devices.[8,9] The functional diversity of orthopedic implants is vast, ranging from permanent joint replacements, such as hips, knees, and shoulders, to temporary devices for fracture stabilization, as well as specialized constructs for spinal fixation and reconstructive surgery (Figure 3). Each application brings its own biomechanical and biological requirements and challenges.

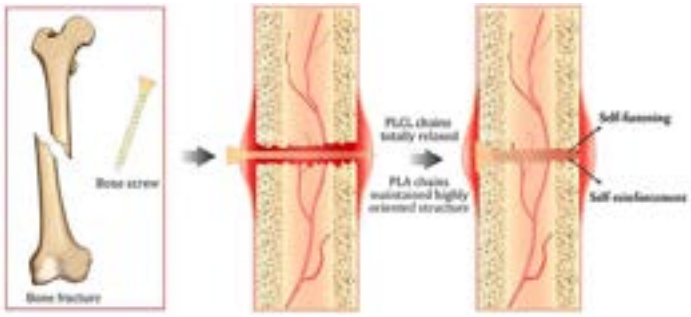

FIGURE 3. Structural stability of osseointegration connection.[10] (CC by 4.0)

Permanent implants demand not only strength and durability but also a high degree of biocompatibility and resistance to long-term corrosion and wear. Temporary devices, designed to support bone healing, must strike a balance between mechanical support and the potential for controlled degradation, thereby reducing the need for secondary removal surgeries. The application of materials and engineering principles is, therefore, paramount to ensure clinical success and patient safety. Three principal classes of biomaterials, such as metals, polymers, and ceramics, dominate the orthopedic landscape. Metals, particularly titanium alloys, are celebrated for their excellent mechanical performance and ability to osseointegrate with bones.[11,12] However, they are not without challenges: stress shielding, caused by a mismatch in stiffness between bone and implant, can lead to bone resorption and loosening of implant, while release of metal ion and wear debris are implicated in adverse local and systemic tissue responses (Figure 4).[13,14]

Polymers, notably ultra-high molecular weight polyethylene (UHMWPE), are widely used as low-friction articulating surfaces in joint prostheses (Figure 5). Despite their

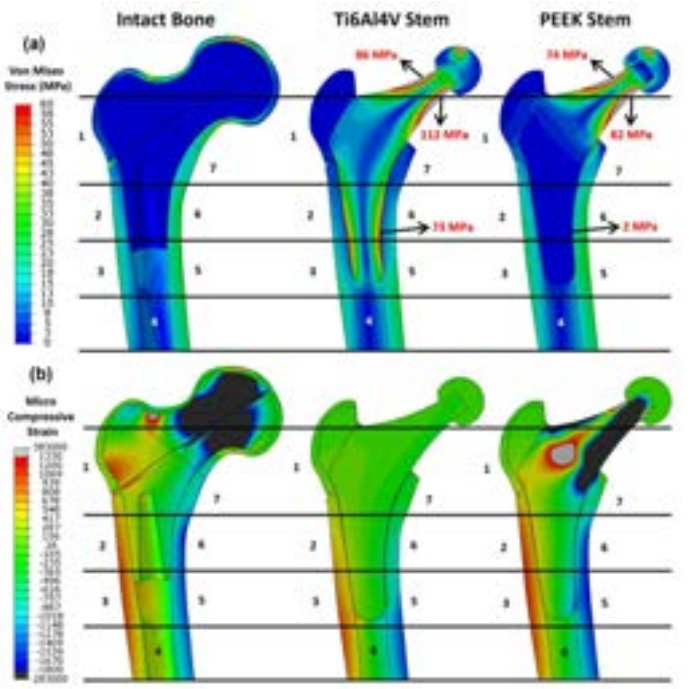

FIGURE 4. Stress shielding caused by a mismatch in stiffness.[13] (CC by 4.0)

success, the generation of wear particles remains a leading cause of inflammatory osteolysis, which subsequently leads to failure of an implant. Polymethylmethacrylate (PMMA) is the cement of choice for securing implants, yet its exothermic setting reaction can damage local bone tissues, and it is recognized as a potential sensitizer. Ceramics, such as alumina and zirconia, offer exceptional wear resistance and biocompatibility, making them ideal for use in bearing surfaces. In contrast, bioactive ceramics, such as hydroxyapatite, facilitate direct bonding with a bone, thereby mimicking the natural tissue interfaces. Despite their exceptional wear resistance and bioactivity, ceramics are limited by brittleness, risk of fracture, and challenges in manufacturing, which limit their use to select implant applications where moderate load demands are present and precise surface properties are critical.

The biological response to implants is complex and multifactorial, shaped by material composition, surface characteristics, mechanical properties, and the dynamic interplay with host tissues. Osseointegration remains the ideal outcome for permanent load-bearing devices, promoting stability and physiological load transfer.[15,16]

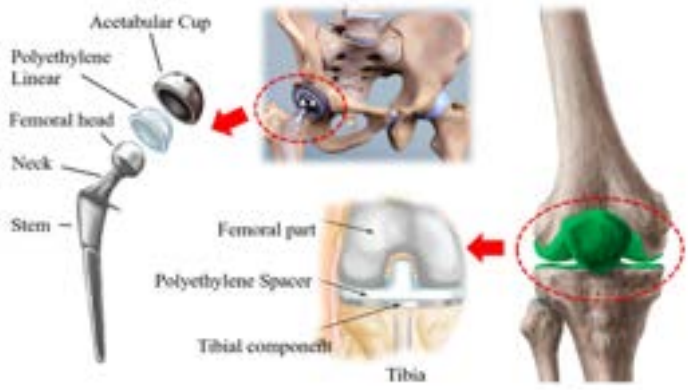

FIGURE 5. Ultra-high molecular weight polyethylene's (UHMWPE) low-friction articulation.[17] (CC by 4.0)

Nonetheless, all biomaterials elicit some degree of host response, ranging from benign fibrous encapsulation to chronic inflammation, which can lead to loosening, failure, or the need for revision surgery. Wear particles and corrosion products are particularly problematic, triggering inflammatory cascades that result in bone loss around the implant. Infection, although less common, presents significant management challenges because of biofilm formation and antibiotic resistance.[18,19] Table 1 presents an overview of orthopedic implant materials, highlighting their functions and the challenges linked to their usage.

In response to these challenges, the present research continues to refine material formulations, develop advanced surface modifications, and incorporate emerging technologies such as nanostructuring and additive manufacturing (AM). The future of orthopedic implants lies in the development of smarter, more adaptive, and regenerative devices that not only restore function but also integrate seamlessly with the body's own healing processes. Through interdisciplinary collaboration and a commitment to innovation, orthopedic biomaterials continue to evolve, offering ever-greater hope for improved patient outcomes and long-term clinical success. The following literature review of the latest advances in implant technology provides a comprehensive classification of biomedical implants based on both material composition and their functional or anatomical deployment. The literature reviewed in this article was systematically selected to provide a thorough and current overview of biomedical implant materials and technologies. Studies addressing both fundamental properties and translational applications were considered to offer balanced insights bridging science and clinical relevance. The selected literature was critically appraised for scientific rigor, relevance, and impact, forming the basis for synthesis and thematic analysis throughout this review. This structured approach ensures the manuscript reflects a rigorous evidence-based perspective on current challenges and emerging trends in biomedical implant research.

TABLE 1. Summary of orthopedic implant materials, functions, and challenges.

Material/Aspect	Functions	Advantages	Limitations/ Challenges
Titanium and alloys	Permanent load-bearing implants	High strength, corrosion resistance, and osseointegration	Stress shielding and metal ion release.[13–18]
Cobalt–chromium alloys	Articulating surfaces	Exceptional hardness, wear resistance	Ion release and stiffness mismatch.[8,9]
Stainless steel	Temporary fixation devices	Cost-effective and easy fabrication	Lower corrosion resistance.[4–6]
UHMWPE (polymer)	Low-friction articulating surfaces	Good wear properties	Wear particles → osteolysis.[1–3]
PMMA cement	Fixation of implants	Strong anchorage	Exothermic reaction, and sensitization.[7,12]
Alumina/ zirconia (ceramics)	Bearing surfaces	High wear resistance, biocompatibility	Brittleness and fracture risk.[11–14]
Hydroxyapatite (bioactive ceramic)	Bone bonding	Direct osseointegration	Coating degradation over time.[6,9]
Biological response	Tissue integration	Stability, physiological load transfer	Inflammation, loosening, and infection.[17,18]

Note: PMMA: polymethylmethacrylate; UHMWPE: ultra-high-molecular-weight polyethene.

CLASSIFICATION OF BIOMEDICAL IMPLANTS

Biomedical implants are essential components of contemporary medical practice, providing structural support, restoring lost function, and significantly enhancing patient quality of life across a wide range of clinical disciplines.[20,21] The performance, safety, and longevity of these devices are determined not only by their anatomical or functional application but also by the careful selection of constituent materials.

Classification Based on Material

Metallic implants have long served as a structural foundation of implantable medical devices because of their excellent mechanical properties, including high strength, fracture toughness, and fatigue resistance. Among these, titanium and its alloys, particularly Ti-6Al-4V, a Grade 5 alloy, have become the gold standard in orthopedics and dentistry, attributable to their unique combination of strength, corrosion resistance, and biocompatibility. The spontaneous formation of a titanium oxide (TiO_2) layer on the implant surface occurs rapidly in vivo following exposure to body fluids, providing essential corrosion resistance and promoting biocompatibility. Cobalt–chromium–molybdenum (Mo) alloys are primarily used in joint surfaces that are exposed to high wear, taking advantage of their superior hardness and resistance to abrasion. Stainless steel, especially the 316L grade, is widely used for temporary fixation devices, such as plates, screws, and nails, thanks to its ductility and cost-effectiveness. However, its susceptibility to corrosion and ion release limits its use in permanent implants. In recent years, magnesium (Mg) and other novel biodegradable metals have emerged for temporary implants, offering the advantage of gradual degradation and absorption, thereby eliminating the need for removal surgeries.[22,23]

Ceramic implants are notable for their high wear resistance, chemical inertness, and excellent biocompatibility. Materials such as alumina and zirconia are extensively used in orthopedic joint prostheses, where low friction and hardness are paramount for bearing surfaces. Furthermore, bioactive ceramics, such as hydroxyapatite and bioglass, possess a unique ability to bond directly with bone tissues, making them invaluable as coatings or components of composite structures to promote osseointegration and enhance the longevity of orthopedic and dental implants.[24] Polymeric implants have become indispensable due to their versatility and ability to emulate the mechanical properties of soft tissues or form flexible interfaces. UHMWPE is widely utilized in joint replacements as a low-friction, wear-resistant bearing material, particularly between metal or ceramic components. PMMA is used as a bone cement for anchoring implants, especially in elderly patients. However, its use may be limited by risks, such as thermal injury during polymerization and allergenic potential. Advances in biomaterials have introduced high-performance polymers, such as polyetheretherketone (PEEK), for permanent devices and bioresorbable polymers, such as polylactic acid, for temporary scaffolds and fixation systems.[25,26]

Composite implants integrate the advantages of metals, ceramics, and polymers, yielding devices with optimized mechanical properties and biological interactions. Notable examples include hydroxyapatite-coated titanium implants, which combine the strength of titanium with the bone-bonding capabilities of hydroxyapatite. Additionally, carbon fiber-reinforced polymers offer both structural support and radiolucency, making them particularly beneficial in orthopedic fixation plates and spinal devices. The continuous evolution of composite materials is focused on maximizing implant performance, biocompatibility, and imaging compatibility (Figure 6).[27,28]

Classification Based on Function and Location

Orthopedic implants are principally designed for the repair, replacement, or stabilization of bones and joints. This diverse category encompasses permanent prosthetic joints, such as hip, knee, shoulder, elbow, ankle, wrist, and finger replacements as well as temporary fixation hardware, including plates, screws, pins, wires, and intramedullary nails, used in fracture management. Selection of appropriate implant material is governed by the specific mechanical demands, the need for osseointegration, and the expected service life. Dental implants predominantly utilize titanium alloys for the fabrication of root replacements, abutments, and orthodontic anchorage devices (Figure 7). The oral environment presents unique challenges,

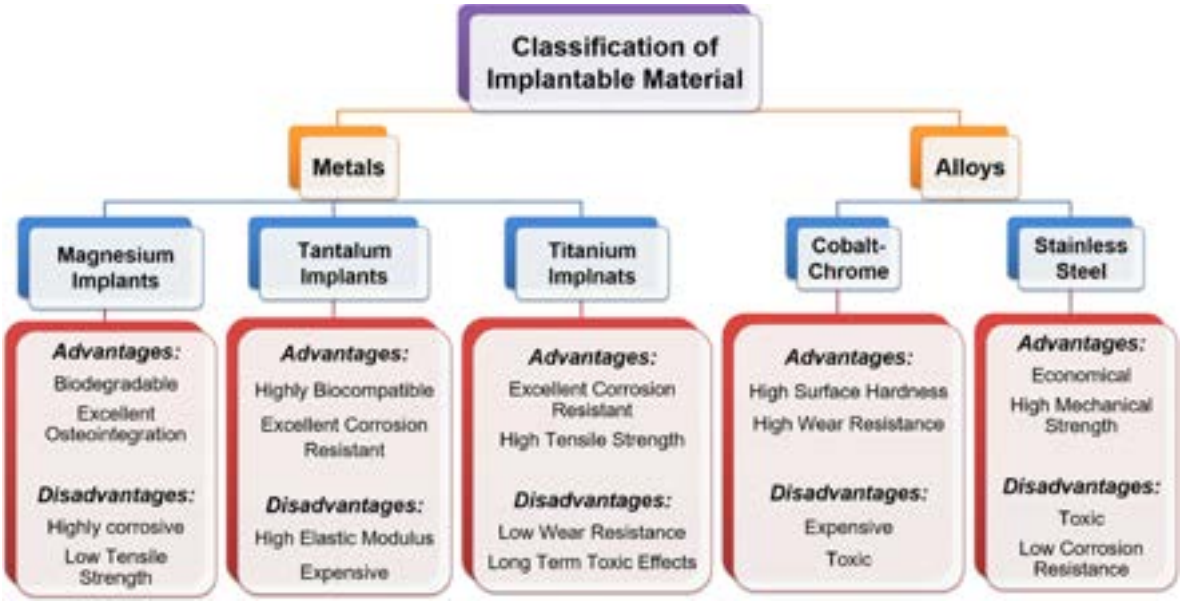

FIGURE 6. Classification of implants based on material.[29] (CC by 4.0)

such as fluctuations in pH, presence of microorganisms, and significant mechanical loading. Titanium's ability to resist corrosion and integrate with bone ensures its superiority for dental applications, where longevity and biointegration are crucial.[30,31]

Cardiovascular implants encompass a broad spectrum of devices, including stents, heart valves, vascular grafts, and enclosures for pacemakers or defibrillators. The materials used in these devices must demonstrate exceptional biocompatibility, corrosion resistance, and mechanical endurance under dynamic physiological conditions. Titanium alloys and nitinol, a nickel–titanium shape memory alloy, are frequently chosen for their fatigue resistance, elasticity, and low thrombogenicity, thereby reducing the risk of device failure in the circulatory system.[35,36] Neurological implants are represented by devices such as cochlear implants, deep-brain stimulators, and neural electrodes, all of which aim to restore or enhance neural functioning. These implants require precise electrical conductivity, mechanical flexibility, and biocompatibility to ensure stable performance with minimal immune or inflammatory response in the sensitive environment of the central or peripheral nervous system. The materials of choice often include specialized polymers and selected

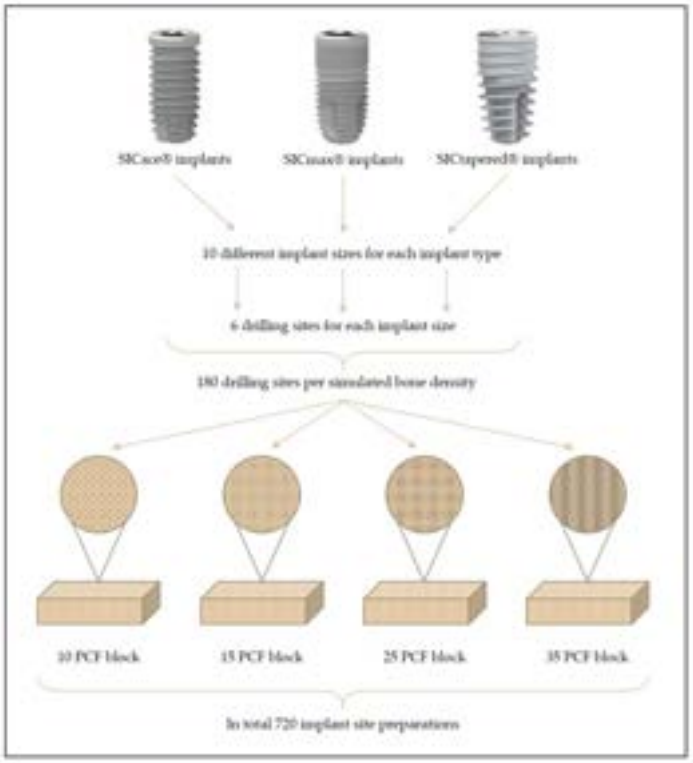

FIGURE 7. Classification of implants based on function and location.[32] (CC by 4.0)

metals that interact favorably with neural tissues.[35,36] Ocular and maxillofacial implants address the reconstruction or replacement of anatomical structures in the eye and facial region, including orbital floor implants and prosthetic devices for the maxilla, mandible, or jaw. These devices demand materials that provide high biocompatibility, corrosion resistance, and mechanical compatibility with native tissues. Titanium, advanced ceramics, and advanced composites are commonly used due to the anatomical complexity and functional demands of these applications.[37,38]

MATERIALS USED IN BIOMEDICAL IMPLANTS

The development of biomedical implants relies fundamentally on the selection of materials that combine both biocompatibility and biofunctionality. Biocompatibility refers to a material's ability to function in physiological environment without provoking harmful local or systemic effects. This property is assessed through rigorous *in vitro* (cell-based) and *in vivo* (animal or clinical) studies to ensure that the material does not elicit inflammation, immune rejection, cytotoxicity, or other adverse reactions. However, biocompatibility alone is not sufficient; biofunctionality, which describes the material's ability to perform its intended physiological or therapeutic role, must complement it. Successful implants must not only avoid negative tissue responses but also facilitate specific clinical outcomes, such as promoting osseointegration in orthopedic devices, supporting tissue regeneration, or maintaining functional stability as in cardiac stents.[21,30,40]

The performance of an implant within the body is profoundly influenced by its surface characteristics. Unmodified surfaces can lead to suboptimal cell attachment, bacterial colonization, or the formation of fibrous capsules, all of which can compromise integration and longevity of device. As a result, extensive research has focused on surface modifications and coatings to optimize the interface between implant and tissues.[41] Physical modifications, including polishing, grit blasting, and plasma spraying, are commonly used to tailor the topography and roughness of implant surfaces, enhancing cellular adhesion and proliferation. Chemical treatments, such as salinization and plasma activation, introduce reactive groups that increase hydrophilicity and enable the immobilization of bioactive molecules.[42–44] The application of specialized coatings such as hydroxyapatite on bone implants, polymeric layers on vascular stents, or antimicrobial films further enhances the implant's performance by improving bone bonding, reducing thrombogenicity, or minimizing the risk of infection. Cutting-edge approaches in surface engineering, including nanostructured coatings and layer-by-layer self-assembly, now enable highly tunable and multifunctional surfaces that facilitate controlled therapeutic release or dynamic adaptation to the biological environment.[45–47] Therapeutic release from implant materials is crucial as it enables localized delivery of drugs, such as antibiotics or growth factors, directly at the implant site, which helps to prevent infection, enhances tissue regeneration, and improves the overall success of implant. Dynamic adaptation refers to the implant's ability to respond and adjust its properties in response to changes in the surrounding tissue environment, thereby enhancing biocompatibility, therapeutic efficacy, and resistance to infection. Table 2 summarizes the classification of biomedical implant materials along with their key features.

TABLE 2. Classification and key features of materials used in implants.

Material/Aspect	Functions	Advantages
Biocompatibility	-	Safe in body; no harmful reactions.[48]
Biofunctionality	Orthopedic devices, stents	Performs intended clinical role.[49]
Surface modifications	Polishing, plasma spraying	Improves cell adhesion and integration.[50]
Chemical treatments	Silanization, plasma activation	Adds bioactivity, hydrophilicity.[51]
Coatings	Hydroxyapatite and antimicrobial films	Enhances bonding and prevents infection.[52]
Biodegradable	PLA, PGA, Mg alloys	Temporary use; resorbs naturally.[53]
Nonbiodegradable	Titanium and stainless steel	Long-term durability.[54]
Smart materials	Nitinol and hydrogels	Respond to stimuli; adaptable.[55]
Nanomaterials	Nanotubes, graphene	Tunable properties; advanced functions.[56]

Note: PLA: polylactic acid; PGA: polyglycolic acid; Mg: magnesium.

A critical consideration in biomedical implant design is the distinction between biodegradable and nonbiodegradable materials, a decision largely driven by clinical application. Biodegradable materials, such as polylactic acid (PLA), polyglycolic acid (PGA), and magnesium alloys, are designed to degrade and be absorbed or excreted by the body once their primary function is fulfilled. This property is particularly advantageous in temporary applications such as sutures, scaffolds for tissue engineering, and specific drug delivery devices, where material resorption eliminates the need for removal and can facilitate tissue regeneration by providing a temporary matrix that is gradually replaced by natural tissue. In contrast, nonbiodegradable materials, including titanium, stainless steel, and various ceramics, are used for long-term or permanent implantation because of their superior mechanical strength, durability, and stability within the physiological environment. These materials are preferred for load-bearing applications, such as orthopedic joint replacements, dental implants, and cardiac valves. Nevertheless, their long-term presence may, in some cases, trigger chronic inflammation or device-related infection, underscoring the ongoing importance of advancements in biocompatibility and surface engineering.[57–59]

The landscape of biomaterials is rapidly evolving with the emergence of smart materials and nanomaterials, which offer novel functionalities and enhanced performance. Smart materials possess the ability to sense and respond to environmental changes, such as pH, temperature, mechanical stress, or electrical signals. Shape memory alloys, such as nitinol, can recover their original shape following deformation and are widely utilized in minimally invasive surgical devices and vascular stents. Stimuli-responsive hydrogels, capable of reversible swelling or contraction, are finding increasing use in controlled drug delivery and soft tissue engineering. Meanwhile, nanomaterials, including nanoparticles, nanofibers, and carbon-based structures, such as nanotubes and graphene, enable the precise manipulation of surface properties, mechanical characteristics, and biological interactions at the molecular scale. These materials are being integrated into a broad array of biomedical applications, from antimicrobial wound dressings and targeted drug delivery systems to neural interfaces that benefit from high electrical conductivity and flexibility. The incorporation of nanomaterials into implant design also enhances the prospects for next-generation tissue engineering scaffolds and diagnostic platforms.[60–63]

DESIGN AND FABRICATION TECHNIQUES

The successful development and clinical implementation of biomedical implants rely heavily on sophisticated design methodologies, precise fabrication processes, and the integration of advanced technologies. Contemporary approaches to implant design and fabrication emphasize customization, improved biocompatibility, enhanced functionality, and optimized structural integrity. Key techniques include computer-aided design and computer-aided manufacturing (CAD–CAM), additive manufacturing (3D printing), advanced surface engineering, nano-fabrication, and integration of biomechanics and bioinformatics.

CAD–CAM and 3D Printing

Computer-aided design and CAM technologies have revolutionized implant design by enabling precise modeling, rapid prototyping, and efficient manufacturing (Figure 8). CAD facilitates detailed visualization and simulation of implants explicitly tailored to individual patient's anatomy, significantly improving clinical outcomes. These technologies allow clinicians and engineers to analyze anatomical complexities digitally, optimize implant shapes, anticipate biomechanical performance, and streamline production processes.[64,65]

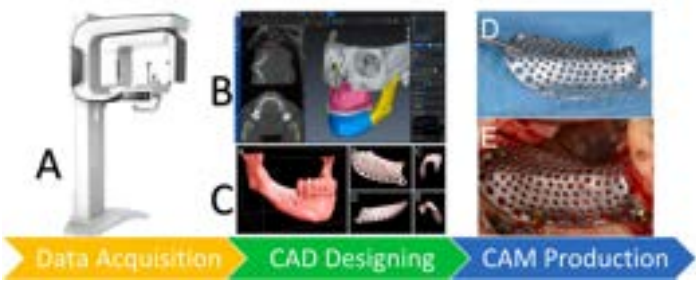

FIGURE 8. Integration of CAD–CAM for seamless design, planning, and manufacturing control.[66] (CC by 4.0)

Additive manufacturing, that is, 3D printing, further advances implant fabrication by allowing the direct construction of complex structures layer by layer from digital models. This approach has drastically enhanced customization possibilities in medical implants, facilitating patient-specific solutions for complex clinical challenges (Figure 9). Techniques such as selective laser melting (SLM), electron beam melting (EBM), and fused deposition modeling (FDM) enable the production of implants with intricate internal geometries and graded porosities that precisely match the mechanical properties of native tissues. For example, porous titanium scaffolds produced via SLM and EBM closely replicate the architecture of bone, promoting superior osseointegration, compared to traditional implants. Moreover, 3D printing enables the rapid prototyping and manufacturing of implants at reduced costs and shorter lead period, greatly benefiting complex clinical scenarios, such as cranial, maxillofacial, or orthopedic reconstructions.[67,68] Table 3 provides an overview of CAD–CAM and 3D-printing approaches used in biomedical implant fabrication.

FIGURE 9. Applications and properties of 3D-printed carbon materials in mechanical, thermal, and structural components.[69] (CC by 4.0)

Additionally, 3D printing supports the creation of multi-material implants, which combine metals, ceramics, and polymers into a single device, thus expanding the functional versatility of biomedical implants. Emerging techniques such as bioprinting leverage additive manufacturing technologies to fabricate implants embedded with living cells or bioactive agents, demonstrating immense potential in regenerative medicine and tissue engineering.

TABLE 3. CAD–CAM and 3D printing in biomedical implants.

Material/Aspect	Functions	Advantages	Limitations/ Challenges
CAD–CAM	Digital modeling, simulation, and optimization of implants	Patient-specific design, improved fit, biomechanical optimization	Orthopedic, dental, craniofacial implants
3D printing (SLM, EBM, FDM)	Layer-by-layer fabrication from digital models	Complex geometries, graded porosity, and rapid prototyping	Porous titanium scaffolds, cranial plates
Multi-material printing	Combines metals, ceramics, and polymers	Enhanced functionality, tailored mechanical/ biological properties	Hybrid Orthopedic devices
Bioprinting	Printing with living cells/ bioactive agents	Regenerative potential, tissue integration	Tissue engineering, regenerative implants

Note: SLM: selective laser melting; EBM: electron beam melting; FDM: fused deposition modeling; CAD: computer-aided design; CAM: computer-aided manufacturing.

Surface Engineering, Nano-fabrication, Biomechanics, and Bioinformatics in Implant Design

The success of biomedical implants depends heavily on the implant–tissue interface, which influences integration, durability, and long-term performance. Advanced surface engineering tailors surface chemistry, roughness, wettability, and topography to improve protein adsorption, cell adhesion, and tissue integration. Physical methods, such as grit-blasting, plasma spraying, and laser texturing, modify surface roughness to facilitate better osseointegration. Meanwhile, chemical treatments, such as silanization, anodization, and plasma activation, enhance hydrophilicity and bioactivity (Figure 10). Nano-fabrication offers nanometer-scale precision, with techniques such as anodic oxidation and electrochemical etching producing controlled nano-topographies to enhance osteoconductivity. Nanoscale coatings also deliver drugs, prevent infection, and promote tissue regeneration.[70–73]

FIGURE 10. Surface engineering features enhancing implant integration and performance.[74] (CC by 4.0)

ORTHOPEDIC APPLICATIONS

Orthopedic implants play a vital role in restoring musculoskeletal functioning compromised by trauma, degenerative diseases, or congenital conditions. Designed to withstand substantial biomechanical loads, these implants must integrate seamlessly with host bone tissue to ensure long-term stability and function. Key applications include hip and knee replacements, spinal implants, and bone scaffolds for regeneration (Figure 11). Hip implants, particularly in total hip arthroplasty (THA), replace damaged joint surfaces with prosthetic components typically composed of titanium alloys or cobalt–chromium alloys for femoral stems and heads, combined with UHMWPE, ceramics, or metal acetabular cups, to reduce friction and wear. Innovations such as hydroxyapatite coatings, porous titanium, and nanostructured surfaces improve osseointegration and longevity, while patient-specific designs enabled by CAD–CAM and 3D printing optimize fit and performance.[75–77] Knee implants, used in total knee arthroplasty (TKA), often feature titanium or cobalt–chromium alloy femoral and tibial components paired with polyethylene bearing surfaces. Cross-linked UHMWPE enhances wear resistance, advances designs, such as mobile-bearing platforms, patient-specific implants, and gender-specific implants, and improves kinematics, stability, and comfort. Bioactive coatings and nanostructured surfaces further enhance bone–implant integration and reduce the risk of infection.[78–80] Spinal implants address conditions such as degenerative disc disease, deformities,

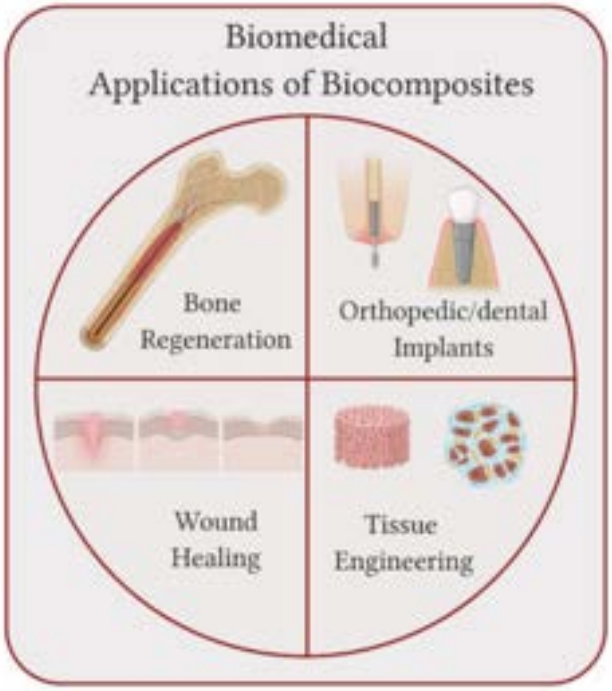

FIGURE 11. Applications of implants.[86] (CC by 4.0)

and fractures. Common devices include rods, screws, plates, and interbody fusion cages, typically fabricated from titanium alloys or PEEK for their mechanical compatibility and radiolucency. Radiolucency, the ability of a material to permit the transmission of X-rays, is crucial in implant applications, as it enables unobstructed imaging of bone and surrounding tissues during postoperative assessment. Porous titanium-coated PEEK enhances bone bonding, while additive manufacturing enables the creation of patient-specific geometries. Motion-preserving alternatives, such as artificial discs, help to maintain natural spinal biomechanics.[81,82] Bone scaffolds provide structural support for bone regeneration in complex fractures, significant defects, and post-tumour resections. They are made from bioactive ceramics (hydroxyapatite and tricalcium phosphate), biodegradable polymers (PLA, PGA, and polycaprolactone [PCL]), or composites, and are often enhanced through 3D printing to achieve precise pore architecture. Incorporation of growth factors, bone morphogenetic proteins (BMPs), and mesenchymal stem cells significantly improves osteogenesis. Emerging bioprinting methods integrate living cells and bioactive agents directly into scaffold structures, while nanostructured

surface modifications further accelerate regeneration.[83–85] Table 4 summarizes the significant applications of orthopedic implants.

TABLE 4. Summary of orthopedic implant applications.

Application	Common Materials	Key Functional Requirements	Recent Advancements
Hip implants	Ti alloys, Co–Cr, UHMWPE, ceramics	High strength, wear resistance, and biocompatibility	Hydroxyapatite coatings, porous/nano surfaces, patient-specific 3D-printed designs
Knee implants	Ti alloys, Co–Cr, cross-linked UHMWPE	Load bearing, smooth articulation, longevity	Mobile/gender-specific implants, nanocoatings, customized TKA
Spinal implants	Ti alloys, PEEK	Stability, fusion promotion, biomechanical compatibility	Porous titanium-coated PEEK, additive manufacturing, motion-preserving devices
Bone scaffolds	Hydroxyapatite, TCP, PLA, PGA, PCL, composites	Osteoconductivity, biodegradability, and structural support	3D printing, growth factor/stem cell integration, bioprinting with living cells
Emerging technologies	Smart alloys, responsive polymers, and nanomaterials	Adaptive response, infection control, and personalization	Nanostructures, FEA optimization, bioinformatics-driven design

Note: FEA: finite element analysis; TCP: tricalcium phosphate; PLA: polylactic acid; PGA: polyglycolic acid; PCL: polycaprolactone; PEEK: polyetheretherketone; UHMWPE: ultra-high molecular weight polyethylene.

CHALLENGES AND LIMITATIONS OF BIOMEDICAL IMPLANTS

Biomedical implants have revolutionized clinical management of degenerative diseases, trauma, and organ dysfunctioning, markedly improving patient mobility, functionality, and quality of life. Despite significant advancements in the engineering of biomaterials, computational design, and surgical methodologies, several unresolved limitations hinder optimal performance and longevity.

Tribology and Mechanical Longevity

Mechanical degradation in biomedical implants is caused by cyclic loading, material fatigue, corrosion, and inadequate biomechanical compatibility. Load-bearing devices, such as hip and knee prostheses, are particularly prone to fatigue fracture, stress shielding, and interface loosening (Figure 12). Articulating surfaces generate polyethylene, ceramic, or metallic wear debris that can initiate pro-inflammatory cascades, osteolysis, and bone resorption.[19,87,88] Although advancements such as cross-linked UHMWPE, ceramic-on-ceramic bearings, and hard-coating technologies have reduced wear, tribological degradation remains a concern, especially in younger or more active patients. Long-term reliability is challenged by variable biochemical conditions, fluctuating mechanical loads, and the ongoing bone remodeling, causing even corrosion-resistant alloys and high-performance polymers to gradually lose structural integrity and biocompatibility over decades.[89,90]

Infection and Immune Response

Implant-associated infections remain a primary cause of post-surgical morbidity and implant failure. Pathogenesis is often biofilm-mediated, with organisms such as *Staphylococcus aureus* and *Staphylococcus epidermidis* producing extracellular polymeric matrices that confer resistance to phagocytosis and conventional antibiotic regimens.[92,93]. Biofilms strongly adhere to implant surfaces, creating a microenvironment shielded from systemic immune responses (Figure 13). Concurrently, foreign body reactions, involving persistent macrophage activation and giant cell formation, may induce fibrous encapsulation, impairing osseointegration. Metal ion release (e.g., Ni^{2+}, Co^{2+}, Cr^{3+}) from corrosion or wear debris can provoke hypersensitivity reactions, compounding inflammatory pathology. Advanced strategies include surface functionalization with bactericidal nanocoatings, biofilm-resistant polymers, and immunomodulatory biomolecular layers.[94]

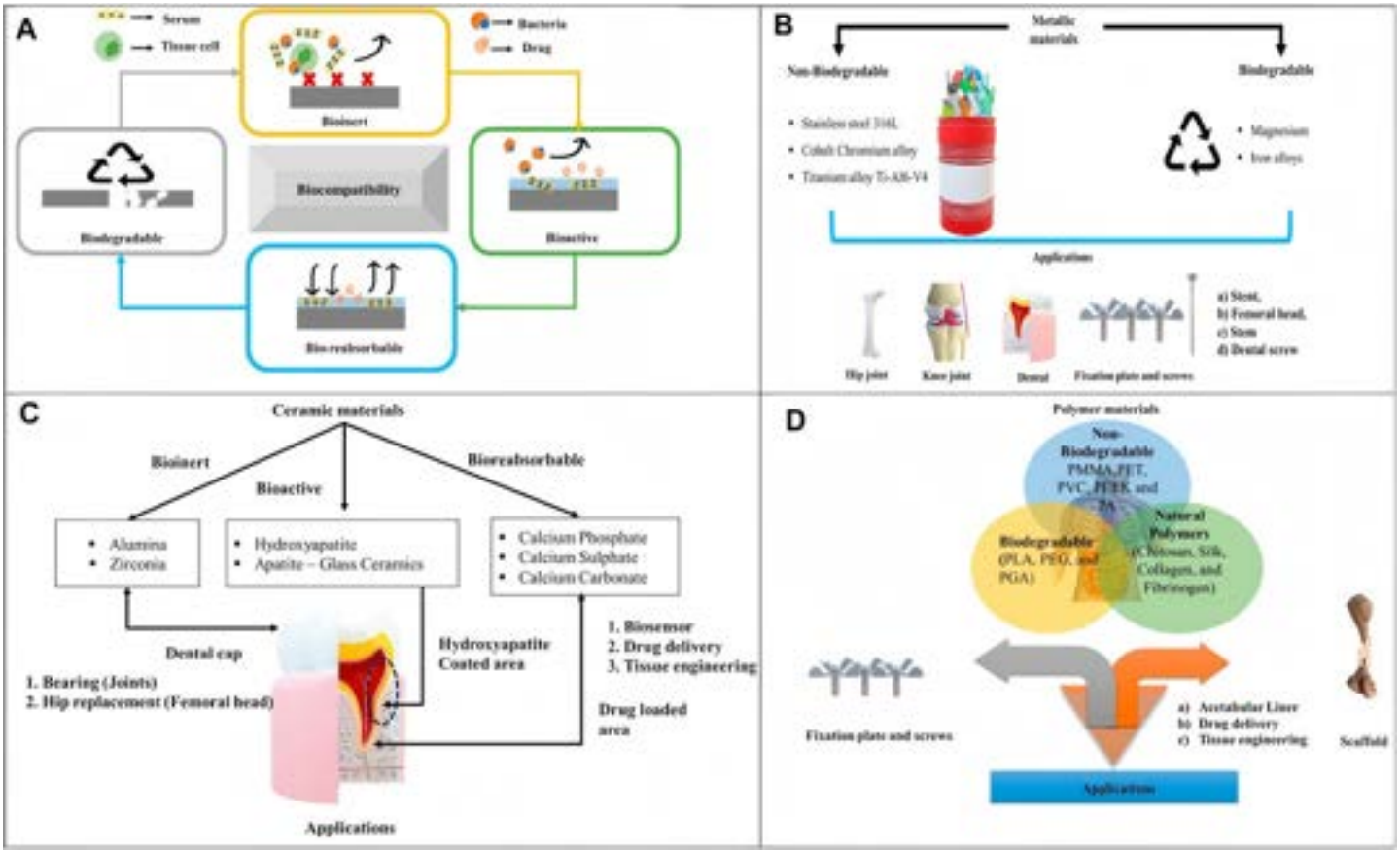

FIGURE 12. Classification of metallic, ceramic, and polymer biomaterials for implants with properties and applications.[91] (CC by 4.0)

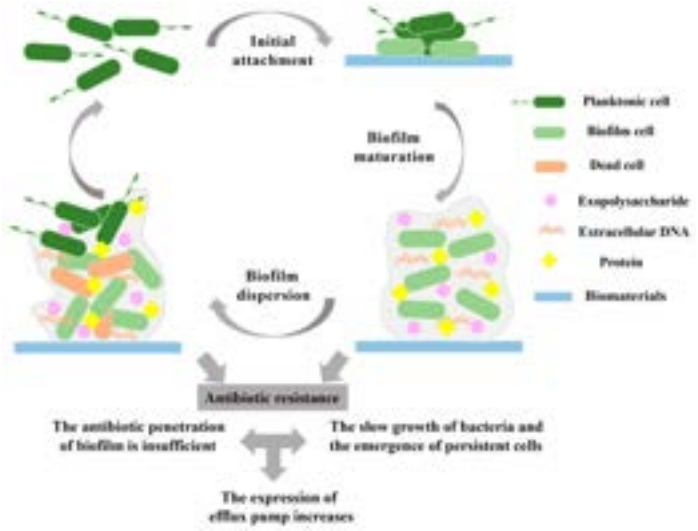

FIGURE 13. Biofilm formation pathways and anti-biofilm strategies.[88] (CC by 4.0)

Regulatory Challenges in Biomedical Implants

To address this, predictive assessment methods, such as finite element analysis (FEA), accelerated fatigue testing, and multi-scale degradation modeling, are employed to forecast performance and failure risks. Regulatory oversight from agencies such as the US Food and Drug Administration (FDA) and the European Medicines Agency (EMA) ensures rigorous preclinical validation, clinical trials, and post-market surveillance, which safeguard patient safety but prolong development timelines and increase costs.[95,96] Ethical considerations ranging from equitable access and patient data security in personalized implants to the uncertain long-term effects of advanced materials such as nanostructured surfaces and biohybrid constructs necessitate transparent communication, robust cybersecurity measures, and globally harmonized regulatory frameworks to ensure both innovation and safety.

RECENT ADVANCES AND FUTURE TRENDS

Recent advances in biomedical implants increasingly focus on the development of "smart" implant technologies capable of dynamic interaction with physiological environment to enhance therapeutic outcomes. Additive manufacturing, popularly known as 3D printing, has emerged as a transformative technology enabling the fabrication of highly personalized implants precisely matching the patient's unique anatomical geometry. Unlike conventional standardized implants, additive manufacturing supports design complexity and rapid prototyping, allowing incorporation of tailored porosity and biomimetic structures that promote osseointegration and mechanical compatibility. This patient-specific customization reduces the proportion of implant failure and improves recovery period.[97,98] Integration with AI further optimizes implant design by enabling rapid simulation and generative modeling of implant geometry, materials, and internal architectures. AI-driven design enhances predictive performance evaluations and personalized load distribution, addressing individual biomechanical demands.[99] Furthermore, implantable sensors are being incorporated to enable real-time monitoring of implant status and early detection of complications, such as infection or mechanical degradation.

Emerging biofabrication approaches utilize bioprinting techniques to produce living tissue scaffolds that incorporate cells and bioactive agents, paving way for the future of regenerative implants that not only replace damaged tissues but also actively promote their restoration.[100,101] These multifunctional implants, with controlled therapeutic release and adaptive surface properties, mark a significant stride toward personalized and precision medicine in orthopedics and dentistry. Such technological innovations promise to increase implant longevity, decrease the need for revision surgeries, and offer improved quality of life for patients through tailored therapeutic interventions. The synergy across materials science, biotechnology, and digital manufacturing is essential to fully realize the potential of next-generation implants, positioning the field toward smarter, safer, and more effective clinical solutions.[102,103]

CURRENT STATE AND FUTURE DIRECTIONS OF BIOMEDICAL IMPLANTS

Biomedical implants occupy a pivotal position at the intersection of technological innovation and growing clinical demand, driven by an aging population and rising cases of chronic diseases, degenerative disorders, and traumatic injuries. They have transformed modern medicine by restoring form and functioning where conventional treatments have fallen short, thereby significantly improving mobility, independence, and quality of life. Today's implants span orthopedics, cardiovascular devices, dental prostheses, neural interfaces, and craniofacial reconstruction, with designs heavily dependent on material selection—metals, ceramics, polymers, and composites—optimized through advances in materials science, CAD–CAM, 3D printing, and surface engineering. Clinically, implants such as hip and knee replacements have delivered exceptional outcomes, yet challenges, such as infection, immune reactions, mechanical wear, and long-term degradation, persist, often necessitating expensive revision surgeries.

Opportunities for innovation are emerging through the convergence of materials science, regenerative medicine, AI, and digital health. Smart and responsive implants integrate sensors, actuators, and adaptive materials to monitor performance, detect complications, and deliver targeted therapy in real time. Bioactive and bioresorbable materials, including hydroxyapatite coatings, bioactive glass, degradable polymers, and magnesium alloys, promote tissue integration, prevent infection, and safely degrade after use, thereby reducing the risks associated with permanent implants. Integration with tissue engineering and 3D bioprinting enables the creation of patient-specific scaffolds containing living cells and bioactive cues, thereby advancing the regeneration of bone, cartilage, vascular structures, and neural tissues. Personalized, AI-driven designs leverage imaging, computational modeling, and machine learning to optimize anatomical fit, biomechanical performance, and long-term safety while predicting complications and accelerating regulatory pathways.

Clinical translation requires rigorous evaluation of safety, efficacy, and cost-effectiveness, supported by collaborative networks that link researchers, clinicians, industry, and regulators. Ethical considerations, including

patient consent, data privacy, equitable access, and long-term monitoring, must guide innovation. The future holds biomimetic, interactive, and patient-tailored implants integrated with closed-loop control systems, adaptive therapeutic delivery, and remote monitoring, all enabled by additive manufacturing, cellular engineering, and digital technologies. These advances promise shorter development cycles, broader accessibility, and more durable personalised solutions that redefine implantable medicine.

AUTHOR CONTRIBUTIONS

Conceptualization, P.P. and V.K.; Methodology, A.P. and V.K; Validation, P.P., A.P. and V.K.; Formal Analysis, P.P. and V.K.; Investigation, P.P., A.P. and V.K.; Resources, P.P. and V.K.; Data Curation, A.P.; Writing–Original Draft Preparation, P.P.and A.P.; Writing–Review & Editing, V.K.; Visualization, P.P. and V.K.; Supervision, V.K.; Project Administration, V.K.

ACKNOWLEDGMENTS

Not applicable.

FUNDING

This research received no external funding.

DATA AVAILABILITY STATEMENT

All data that support the findings of this study are included within the article.

CONFLICTS OF INTEREST

The authors declare they have no competing interests.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

Not applicable.

CONSENT FOR PUBLICATION

Not applicable.

FURTHER DISCLOSURE

Not applicable.

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Received September 11, 2024, accepted December 11, 2025, publication date for online-first March 25, 2026.

Original Research Article

The Role of Clinical Engineering in Management and Decision-Making in Brazilian Hospitals

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ABSTRACT

In an ever-changing hospital landscape, where technology intertwines with health care, clinical engineering emerges as a beacon to guide medical equipment management. But how do managers perceive the role of this crucial area? This study aims to unravel this question by exploring the views of 25 public and private hospitals across Brazil. Equipped with a carefully crafted online questionnaire, we embarked on an exploratory expedition, using Google Forms® as our map. Through the responses of 25 hospitals, we unraveled the structure and performance of clinical engineering, seeking to understand its relevance in hospital management. Following Donabedian's footsteps, we evaluated quality through three lenses: structure, processes, and outcomes. The responses revealed that clinical engineering plays a pivotal role in equipment management, the pursuit of accreditation seals, and strategic planning, proving its growing importance. In spite of the limited scope (only 25 out of over 7,100 Brazilian hospitals), the responses provided a glimpse into the evolution of clinical engineering. More than that, they revealed gaps that call for more in-depth research, opening up a range of possibilities for future studies. This study serves as a beacon for hospital managers, illuminating the path to structuring a robust and effective clinical engineering department. Clinical engineering is not limited to mere operation but rather stands as a strategic ally in the pursuit of excellence in health care. The results of this study indicate that, although clinical engineering is still largely viewed as an operational function, its role in the surveyed hospitals shows a clear movement toward greater strategic relevance. Managers increasingly recognize its value in cost management, investment decision-making, contract oversight, participation in institutional projects, and contributions to organizational strategy. When interpreted through the Donabedian model, the findings suggest that more structured departments—particularly those aligned with Health Technology Assessment HTA committees—tend to produce stronger organizational outcomes. In spite of variations in structure, hierarchy, and employment models, evidence shows that clinical engineering plays an expanding role in enhancing care effectiveness, optimizing the technology fleet, and promoting the sustainability of health care services. Overall, the study points to a gradual maturation of the field, in which strengthening its technical and managerial leadership becomes essential for continuous hospital improvement. Through continuous and in-depth research, we can further unlock the potential of this crucial area for the future of health.

Keywords—*Clinical engineering, Biomedical engineering, Hospital management, Hospital administration, Health technology.*

INTRODUCTION

Clinical engineering arises from the application of engineering principles to efficiently address clinical challenges, grounded in knowledge from various disciplines such as electrical engineering, mechanical engineering, and physiology. Its origins trace back to the need to enhance communication among health care professionals, hospital managers, and engineers. In addition to creating job opportunities for engineers, this field plays a crucial role in optimizing patient care, developing technological solutions for diagnosis and treatment, and creating research opportunities.[1] According to Porto and Marques, in the 1940s, the first maintenance course for military medical equipment emerged in the United States, coinciding with the development of various types of medical devices.[2] Taghipour emphasizes that the increase in the number of medical devices requires the implementation of a medical equipment management program in hospitals.[3] Not only did costs increase, whether related or not to these devices, but there was still concern about safety aspects in the use of these medical devices, following reports of serious patient events related to equipment maintenance issues or improper handling. This led the Food and Drug Administration (FDA) to establish stringent processes for evaluating the design and manufacturing of medical equipment. In the 1970s, the term "clinical engineer" was defined as the engineer who manages the installed base of medical equipment in a hospital.[2] Since the early 21st century, the image of the clinical engineer has remained the same, characterized by a stereotypical view:

What is the first image that comes to mind with the term "clinical engineer"? For many, it is that of a middle-aged man with higher education and advanced training who manages a department of technicians and support staff, with the primary role of repairing medical equipment. Typically, this department is in some basement of the hospital, near infrastructure equipment, or even the morgue. There is no apparent reason for this, but this is often the case.[1]

After more than 20 years, such a scenario persists. A similar setup is implemented in our clinical engineering department, with equivalent examples found in other hospitals. In Brazil, during the 1980s, there were hospitals with much deactivated equipment, beyond repair. As a result, hospitals created their own maintenance teams because of the difficulty in accessing training, manuals, and spare parts.[4] A significant milestone in the country was the founding of ABEClin in 2003 (Associação Brasileira de Engenharia Clínica, in Portuguese), the Brazilian Association of Clinical Engineering. It promotes courses and scientific events and raises awareness about the role of the clinical engineer in equipment management. Since the early 2000s, numerous specialization courses in clinical engineering have emerged, aimed at professionals working in hospitals managing the installed base of medical equipment. Currently, there are over 70 active courses available in either in-person or distance formats.[5] In which clinical engineering is considered a specialization, derived from a biomedical engineering undergraduate degree. Considering that clinical engineering operates differently across various hospitals, with diverse hierarchical structures and responsibilities, there is still no consensus on how its activities should be developed. Given this context, there remains a question of whether hospital managers are aware of the role of the clinical engineer and recognize the field as potentially capable of supporting them in the management of the installed range of medical equipment. Thus, the guiding question of this applied work is: What is the role of clinical engineering, according to the perception of hospital management leadership?

The scope of the bibliographic research was defined as the period from 2003 to 2023, based on the founding date of ABEClin on October 16, 2003, as noted on its website.

ABEClin was established as a nonprofit private legal entity with an unlimited duration. Its goals include encouraging, consolidating, integrating, and qualifying professionals working in the field of clinical engineering. Its founding marked a formal milestone for those working in clinical engineering.

The field research was exploratory, involving the distribution of a questionnaire to 127 private hospitals associated with ANAHP, the Brazilian National Association of Private Hospitals. In addition, 10 invited hospitals, both public and private, were included in the study.

The study was conducted over a 30-day period, from March 8 to April 8, 2024, with the aim of analyzing the

understanding of managers from various public and private hospitals about the role of clinical engineering in management and decision-making within high-complexity hospitals, ranging from medium to large size, across the country.

LITERATURE REVIEW

The History of Clinical Engineering

The origins of clinical engineering trace back to the 1940s in St. Louis, USA, when the armed forces initiated training programs for the maintenance of military medical equipment. The subsequent proliferation of medical technologies—such as ultrasound and computed tomography—triggered a significant increase in health care costs, directly and indirectly related to medical devices. In response, the U.S. FDA extended its regulatory scope to include medical equipment, initially applying the same approval protocols used for pharmaceuticals, which later proved inadequate.[4] The enactment of Public Law 94-295 in 1976 formally subjected medical devices to FDA approval, imposing obligations on manufacturers such as facility registration, product listing, compliance with good manufacturing practices, and reporting of adverse events.[6] Brazil followed a similar path with the establishment of the National Health Surveillance Agency (Anvisa) in 1999, adopting analogous regulatory principles.[7] This regulatory evolution fostered the emergence of a new professional field—biomedical and clinical engineering—dedicated to ensuring the safety, efficacy, and performance of medical technologies within health care environments. The 1970s introduced the term clinical engineer to describe engineers responsible for managing hospital equipment.[2] In Brazil, institutional recognition of the discipline began in the 1980s. According to clinical engineering in Brazil[8], a 1982 task force led by the National Council for Scientific and Technological Development (CNPq) identified major deficiencies in equipment acquisition, maintenance, training, and cost management. The evaluation and perspectives project further emphasized the need for specialized training to support technology management in health care services. A milestone of this period was the creation of the Biomedical Engineering Center at the State University of Campinas (Unicamp), which combined research, training, and technical advisory functions. However, until the early 1990s, clinical engineering services remained rare in Brazilian hospitals. The Ministry of Health's PROEQUIPO program addressed this gap by establishing nationwide training courses, which effectively defined the professional profile and competencies of clinical engineers. The creation of the ABEClin in 2003 represented the consolidation of the field, marking its maturity within the national health care context.[8] Further advancement occurred with the establishment of the Brazilian Hospital Services Company in 2011 (Law No. 12,550), aligned with the National Program for the Restructuring of Federal University Hospitals (REHUF).[9] EBSERH's standardized management framework, refined through pilot projects in six hospitals, culminated in the *Clinical Engineering Processes and Practices Handbook*, setting national benchmarks for equipment management and quality outcomes.[10]

Distinction Between Biomedical and Clinical Engineering

Although closely related, biomedical engineering and clinical engineering perform distinct roles. Biomedical engineering focuses on developing new materials, modeling physiological processes, and creating devices for diagnosis or rehabilitation. Clinical engineering, conversely, concentrates on managing the life cycle and operational performance of medical technologies through maintenance programs, risk management, contract control, forensic engineering, health technology assessment (HTA), human factors engineering, and point-of-care operations.[11] As Zhang defines, human factors engineering aims to design systems that adapt to human capabilities and limitations, ensuring usability and safety in health care technology applications.[12]

Education and Professional Training in Clinical Engineering

Biomedical engineering education, typically offered at the undergraduate level, integrates engineering principles with medical sciences to design and optimize health care technologies.[13] Training is regulated by the Ministry of Education (MEC) and the Regional Council of Engineering and Agronomy (CREA), with professional representation through the Brazilian Society of Biomedical Engineering, founded in 1975. Clinical engineering specialization, in

contrast, emphasizes the operational management of medical devices. While biomedical curricula prioritize technical and mathematical foundations, clinical engineering programs highlight managerial competencies alongside technical proficiency. For instance, an undergraduate curriculum (Federal University of São Paulo - UNIFESP) distributes its 64 courses across technical (71.9%), mathematical (14.1%), biological (6.3%), and administrative (7.8%) domains. A clinical engineering specialization (Einstein) allocates 53 courses as technical (50.9%), biological (9.4%), and administrative (39.6%), reflecting a stronger management orientation. As of April 2024, Brazil offers 71 clinical engineering specialization programs—93% in private institutions, 19.7% of which are nonprofit—and only 7% in public universities.[5] The oldest program was established in 2005 at the Federal University of Health Sciences of Porto Alegre. As can be observed in Figure 1, these programs are present in 19 states, with concentrations in Minas Gerais, São Paulo, Goiás, Santa Catarina, Paraná, Rio Grande do Sul, Rio de Janeiro, and Bahia, which together host 63% of the total. Course formats include 36.6% in-person and 63.4% distance learning, expanding access to qualified training nationwide. The evolution of clinical engineering, both globally and in Brazil, underscores its vital role in bridging technology and patient safety. Its trajectory reveals a continuous alignment between regulatory rigor, educational development, and the growing complexity of health care systems.

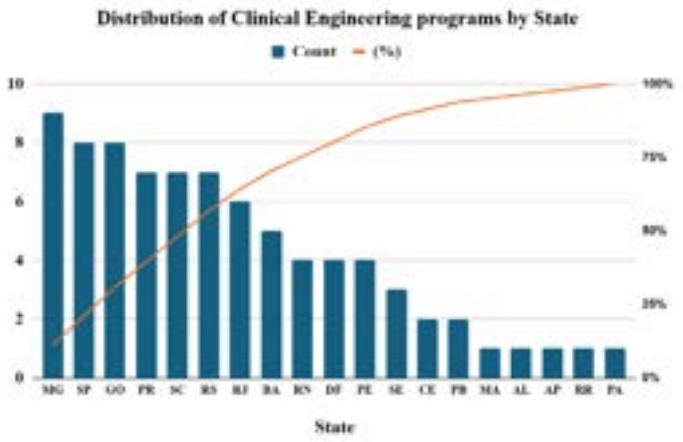

FIGURE 1. Specialization courses in clinical engineering in Brazil. Note: Elaborated by the author based on the National Registry of Courses and Higher Education Institutions—e-MEC.[5]

Health Care Organization Accreditation Bodies

A study conducted in Canada revealed that pursuing accreditation can enhance hospital performance, although there is insufficient evidence to confirm that it directly improves care delivery or health outcomes. The main benefits identified include fostering teamwork, promoting continuous improvement programs, encouraging new leadership, strengthening professional relationships, and enhancing interaction among health care organizations. These initiatives demand continuous learning and investment, producing results over time; however, after about a decade, new strategies are often required to sustain motivation for ongoing improvement.[14] To ensure the quality and safety of health care services, accreditation plays a fundamental role, structured upon internationally recognized standards. Two leading global organizations in this field are the Joint Commission International (JCI) and Accreditation Canada International (ACI). JCI, a nonprofit institution, identifies and disseminates best practices in patient safety and quality, supporting health care organizations to enhance performance and outcomes. ACI operates through the Qmentum accreditation program, with a similar focus on quality advancement. In Brazil, the National Accreditation Organization(ONA) defines and manages national quality and safety standards for health care institutions.[15] ONA offers three accreditation levels (ONA 1, ONA 2, and ONA 3), and over 80% of accredited hospitals in the country hold ONA certification. This recognition extends internationally through its membership in the International Society for Quality in Health Care (ISQua), a nonprofit organization present in more than 70 countries across 6 continents National Accreditation Organization(ONA).[16] The JCI specifies in its Hospital Accreditation Standards manual that hospitals must "develop and implement a medical equipment management program throughout the organization".[17] This reinforces the need for structured and comprehensive equipment management, both as a quality requirement and an accreditation condition. Similarly, National Accreditation Organization(ONA), Accreditation manual details in Section 4.1 the entire technology management process, covering planning, operation, and deactivation of medical equipment—including that of third parties—to

ensure safe use.[15] Item 8 of Subsection 4.1 emphasizes the management of medical and hospital technology and mandates the implementation of technical training programs for clinical engineering teams, aligned with clinical applications and continuously evaluated for effectiveness. ONA currently recognizes nine qualification seals for clinical engineering services in Brazil, all held by private companies. As a result of these accreditation initiatives, health care institutions are required to establish comprehensive medical technology and facility management policies. These have expanded to include activities such as technology assessment, asset management, professional training, financial management, technical and managerial reporting, contract control, project development, technovigilance, quality tool application, root cause analysis, and participation in committees related to standardization, radiological protection, HTA, and patient safety. According to a JCI accreditation consultant, external certification for a 300–500-bed hospital costs approximately US$300,000, covering preparation, organization, and audit expenses, excluding structural adaptations. Each recertification, required every 3 years, costs about US$75,000. Since accreditation standards mandate the implementation of medical equipment management plans, it becomes essential to investigate whether hospitals without accreditation still maintain such programs. This raises an important question: Is there a correlation between the presence of clinical engineering departments and the absence of hospital accreditation?

The Relationship with the Hospital's Technology Park

In the complex environment of hospital management, the administration of medical equipment is crucial, as hospitals constantly seek innovation and new services to remain competitive. Within this context, clinical engineering applies structured management methods to medical devices, creating historical records and performance indicators that classify equipment according to clinical use.[18] Considering the life cycle of medical devices, acquisition cost alone provides a misleading basis for decision-making. The total cost of ownership (TCO) model offers a more comprehensive assessment, encompassing expenses such as acquisition, installation, energy consumption, maintenance, repairs, upgrades, and training. Frequently, the TCO far exceeds the initial purchase price, reinforcing its adequacy as an evaluation method.[19] According to Moraes et al.[20], the use of medical technologies can be optimized through multi-criteria decision aid (MCDA) tools, which identify process stakeholders, capture their contributions, and organize results into structured decision-making frameworks—highlighting the importance of multidisciplinary collaboration.

As established by Donabedian[21], the quality of care is defined by three dimensions:

- Structure, referring to the material, human, and organizational resources;
- Process, representing what occurs during care delivery; and
- Outcome, reflecting the effects of care on individuals or populations.

The relationship between care improvement and associated costs is not linear: after a certain point, process enhancement no longer translates into better clinical outcomes, even as costs continue to rise. Thus, the expansion of a hospital's technological park may increase expenses without proportionate clinical benefit. In this context, just as patient information is essential to assess care quality, historical data on medical equipment—spanning its entire lifecycle—are critical to evaluating the performance and efficiency of the installed technological park.

Resolutions and Norms Guiding Clinical Engineering Services

Resolution No. 473/2022 of the Federal Council of Engineering and Agronomy (CONFEA/CREA) establishes professional titles such as Biomedical Engineer (code 121-12-00), Health and Safety Engineer (421-02-00), and Occupational Safety Engineer (424-01-00). No specific title exists for the clinical engineer. According to Anvisa RDC 02, professionals responsible for medical technology management must possess higher education and registration with their professional council when applicable, though no further requirements are defined. In Brazil, clinical engineering training occurs mainly through postgraduate programs, open even to nonengineering professionals, and focused on management and administration rather than technical certification. Thus, CREA registration is not

required. The most common professional designations are specialist, master, or doctor in clinical engineering.[22] The regulation of the clinical engineering profession remains under discussion, with CONFEA/CREA currently recognizing only biomedical engineers. The literature attributes the responsibility for medical technology management to biomedical engineers[1,23], while laws and resolutions assign this function to clinical engineering services within health care institutions.

MATERIALS AND METHODS

This study was developed through a bibliographic review of academic publications and institutional reports from databases and organizations such as EBSCO, SciELO, Google Scholar, WHO, ANAHP, MEC, CNES, and SBEB, covering the period 2003–2023. The search terms included: "Clinical Engineering", "Tecnologias Médicas", "Health Technology", "Medical Technology", "Dispositivos Médicos", "Medical Devices", "Gestão Hospitalar", "Hospital Management", "Gestão Econômica", "Economic Management", "Tomada de Decisão", "Decision Making", "Orçamento Hospitalar", "Hospital Budget", "Gestão Baseada em Evidências", "Evidence-Based Management", "Administração Hospitalar", "Hospital Administration", "Resultado Financeiro", "Financial Results", "Engenharia Biomédica", "Biomedical Engineering", and "Engenharia Clínica".

Within EBSCO's Business Source Complete, Boolean searches produced:

- (ti:("health technology") AND TX:("management" AND "clinical engineering")) → 22 results;
- (ti:("hospital management") AND TX:("clinical engineering")) → 28 results;
- (ti:("evidence-based management") AND TX:("clinical engineering")) → 6 results.

Complementing the literature review, exploratory field research was conducted with hospitals affiliated with ANAHP, as well as comparable public and private institutions, to broaden representativeness. The ANAHP secretariat authorized and distributed the research invitation, including the Invitation Letter, Informed Consent Form, Microsoft Forms survey link, and Ethics Committee approval (document P.057.2024, CEPH/FGV). In addition to ANAHP's 127 member hospitals, other institutions were invited, including Charitable hospitals (Santas Casas), a military hospital, and philanthropic and public hospitals serving both SUS and private patients, ensuring diverse perspectives. The study followed exploratory research methodology, designed to provide familiarity with the investigated phenomenon and identify the most relevant analytical dimensions.[24] As Babbie[25] emphasizes, exploratory studies deepen understanding, test methodological feasibility, and guide future research focus. The field data, collected via Microsoft Forms, employed categorical and open-ended responses ("yes", "no", or keywords with commentary). The questionnaire was based on seminal works such as *Health & Citizenship: Hospital Equipment Maintenance Management (Saúde & Cidadania: Gerenciamento de Manutenção de Equipamentos Hospitalares)*[26], *Quality in Local Management of Health Services and Actions (Qualidade na Gestão Local de Serviços e Ações de Saúde)*[27], *Clinical Engineering Handbook*[1], and *Clinical Engineering*.[28] In spite of the robust design, technical issues prevented some hospitals from receiving the survey. The ANAHP secretariat reported that IT filters categorized the emails as spam, reducing response rates. The limited yet rich dataset revealed fragmented internal information systems, underscoring the absence of standardized mechanisms for managing and retrieving clinical engineering data across hospitals.

Preparation

For the hospitals associated with ANAHP, an initial contact was made through the association's secretariat, and research materials were sent to be distributed to the hospitals and their associated leaders via email. For the other invited hospitals, contact was first made through telephone calls and subsequently via email, attaching a request for authorization to conduct the research and sending the link to access the instrument.

Survey Implementation

For all respondents, an explanation of the project, the research objectives, and the confidentiality of the work were provided. Authorization documentation, the file containing the research questions, and the online response link were sent as attachments in each recipient's email. Responses were organized in an Excel spreadsheet, with data sorted

by theme and question. Typographical errors were corrected, and graphs were created. Responses with free text were analyzed, and data were categorized according to the theme addressed. The collected data were examined, grouping responses and checking relationships between the data and the research theme. Using Excel spreadsheets and calculation tools, the percentage of participation in constructing each response was calculated, and tables and graphs of the results were generated.

RESULTS

In the following section, in Figure 2 we present the aggregation of responses obtained through the field survey, compiled in an Excel spreadsheet. Based on the collected data, graphs were created for each research theme. Here are some key topics that emerged from the study:

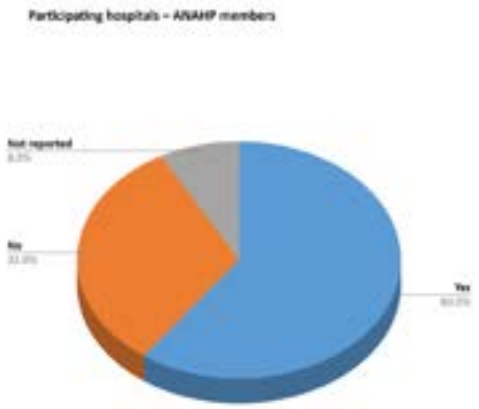

FIGURE 2. Hospitals that responded to the survey according to ANAHP affiliation.

The survey was designed to gather responses from professionals in leadership positions, consistent with the objectives of the study. As shown in Figure 3, participants reported a variety of roles. When considering both "director" and "superintendent" as executive-level positions, 14 hospitals—representing 56% of all respondents—provided answers from individuals in directive roles within their institutions. It is also noteworthy that two respondents chose not to disclose their positions.

The next analysis presents the distribution of participating hospitals across seven different states, with one hospital choosing not to report its location, as shown in Figure 4. Among the respondents, hospitals from São Paulo, Minas Gerais, and Paraná predominated, accounting for 80% of the sample, or 20 hospitals in total.

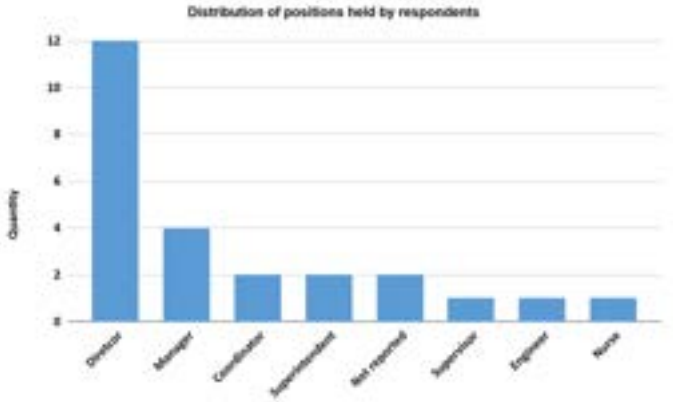

FIGURE 3. Positions of survey participants.

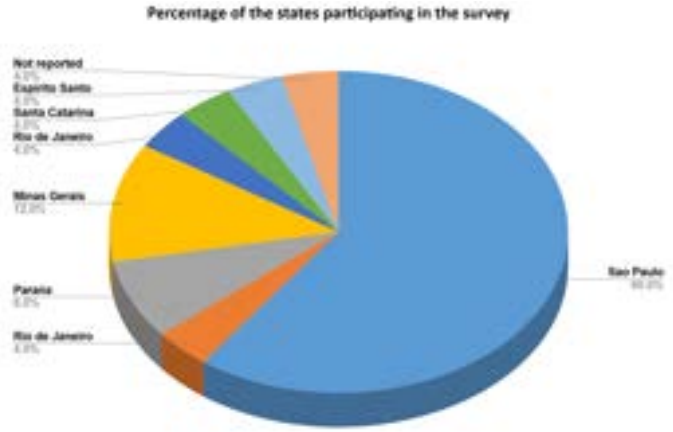

FIGURE 4. Distribution of survey participants by state.

Considering the national distribution of hospitals based on the National Registry of Health Establishments[29], 62.1% of listed hospitals are private and 37.9% are public. In our survey, 19 private hospitals participated, representing 76% of the total. This proportion is, to some extent, aligned with the public–private distribution reported by CNES. However, it is important to note that our sample does not possess sufficient statistical representativeness to confirm this correspondence conclusively, as shown in Figure 5.

Hospitals with more than 5,000 employees have bed capacities ranging from 340 to 2,950, as shown in Figure 6. Notably, one hospital in the sample, with nearly 3,000 beds, stands out significantly in size compared with the others.

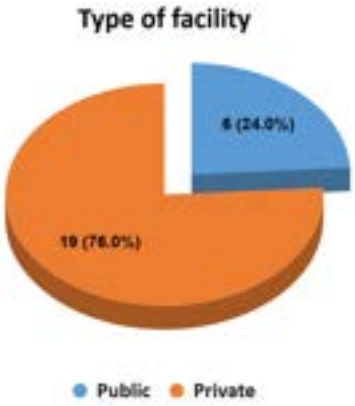

FIGURE 5. Hospitals that responded to the field survey, by type of facility.

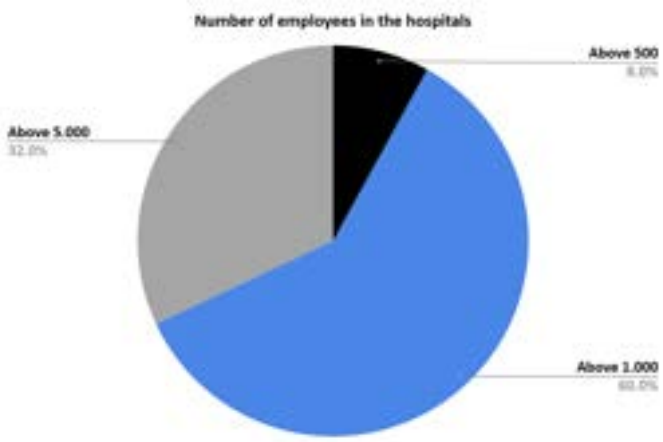

FIGURE 6. Number of employees reported by the hospitals in the survey.

The initial classification of hospitals by bed capacity was based on the combined total of general and critical-care beds reported by each institution. These totals were then grouped into three major categories, with medium- and large-sized hospitals predominating. Together, these two categories accounted for 72% of the sample, corresponding to 18 hospitals, as shown in Figure 7.

To classify hospitals according to the literature, the categorization based on hospital size proves to be the most effective. Chaves et al.[30] define hospital size by the number of beds as follows: small hospitals have up to 49 beds; medium hospitals range from 50 to 150 beds; and large hospitals have 151 to 500 beds.

An additional classification is provided by the Federal Council of Medicine (CFM)[31] in its 2023 *Manual de Procedimentos Administrativos para Pessoa Jurídica*, which

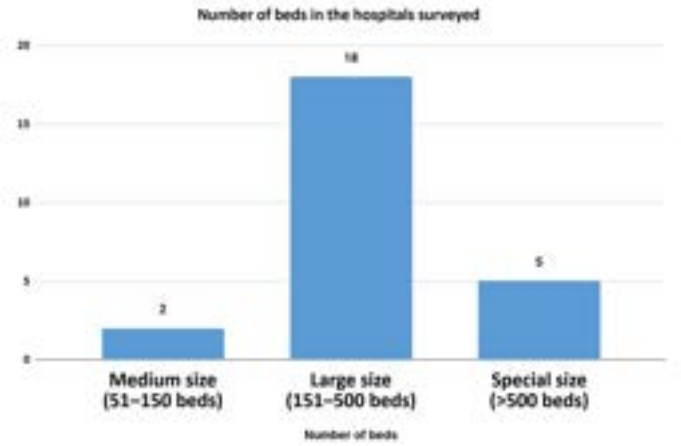

FIGURE 7. Number of beds reported by the hospitals in the survey.

categorizes hospitals as: Size 1, small hospitals with 5 to 50 beds; Size 2, hospitals with 51 to 150 beds; and Size 3, hospitals with more than 151 beds, noting that institutions with fewer than 5 beds are not registered as hospitals.

As shown in Figure 8, the survey sample was predominantly composed of large hospitals, which accounted for 88% of participants, or 22 institutions.

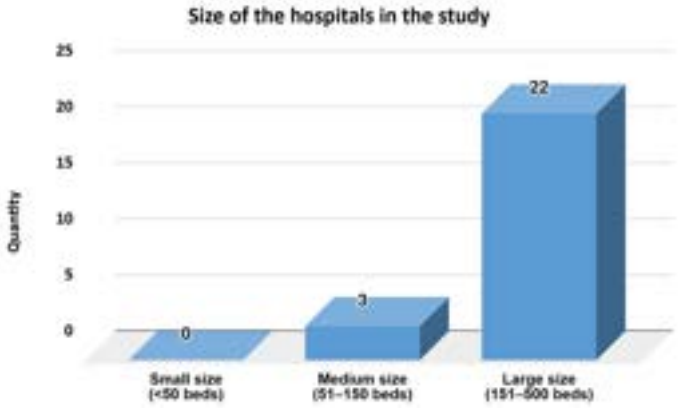

FIGURE 8. Distribution of hospitals by size.

Based on the data collected through the questionnaires, there is a clear predominance of hospitals operating with in-house clinical engineering teams, as illustrated in Figure 9. This distribution may reflect a sampling bias, given the participation of ANAHP-affiliated hospitals, as well as the limited number of survey responses.

When grouping responses that reported either fully in-house or mixed clinical engineering models, 23

hospitals—representing 92% of the sample—adopt these approaches. The mixed model allows for two interpretations: it may indicate the presence of professionals formally employed under the Brazilian Consolidation of Labor Laws (CLT), alongside externally contracted personnel by specialized service providers through technical support agreements.

FIGURE 9. Types of clinical engineering composition in the research hospitals.

In addition, two hospitals reported fully outsourcing their clinical engineering services. This indicates that some institutions choose not to maintain an internal team, although no explanatory comments were provided to clarify the rationale behind this decision.

The following comments refer to the respondents' answers regarding the availability of in-house clinical engineering teams in their hospitals. Some statements suggest that, from the perspective of hospital managers, maintaining an internal team fosters greater engagement among clinical engineering staff. This perception is supported by remarks highlighting the team's participation and support in hospital operations. In contrast, comments about outsourced teams indicate a lower level of managerial involvement with contracted clinical engineering services.

Below are the verbatim comments gathered in the survey:

For in-house teams:

• "We provide 24/7 support and replace some activities on equipment that are usually performed by external service providers."

• "The team is highly participative in equipment maintenance processes and in identifying opportunities for process improvement."

• "The team truly embraces the institution's mission and strongly identifies with its purpose."

For outsourced teams:

• "The clinical engineering contract provides advisory support to the hospital in order to improve the service delivered by maintenance contractors."

• "We contract corrective and preventive maintenance services."

For mixed-model teams:

• "Management is handled by the hospital's team, and the technicians belong to a contracted company."

The participation of women in the workforce has increased significantly, particularly in the service sector.[32] In the hospitals surveyed—in spite of the small sample—the composition of clinical engineering teams remains predominantly male, as shown in Figure 10.

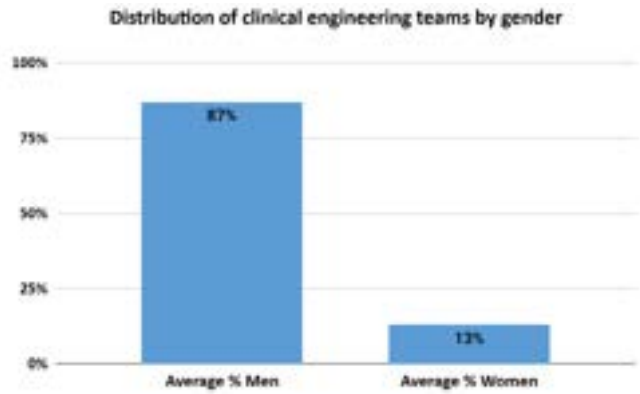

FIGURE 10. Distribution of clinical engineering teams by gender.

Chesler et al.[33] offer a contrasting view by showing a decline in the number of women graduating in biomedical engineering, even though it is the engineering field with the highest proportion of female students. The authors attribute this to challenges faced in male-dominated environments, influenced by "unconscious biases," as well as greater difficulty obtaining promotions, lower evaluations of their work, and the disproportionate burden of family-care responsibilities. They emphasize that "we simply need people with the best minds and skills, and many of them are women."

In this study, examining gender distribution in clinical engineering teams serves to better understand the context of participating hospitals. The analysis is exploratory and does not aim to define an ideal gender balance, but rather to complement the broader goals of the research.

Figure 11 shows a wide variety of positions cited as part of clinical engineering teams, totaling 138 roles. When grouped, the data reveal the main functions that compose these teams, with the mention of a purchaser as part of the department standing out as an unusual detail.

Another relevant observation is the presence of differing job titles for similar functions, such as "electronic technician" and "medical equipment technician." Among management roles, multiple hierarchical levels were identified, including leader, head, supervisor, coordinator, manager, executive manager, and director. Notably, two hospitals reported having only an engineer responsible for leading the clinical engineering department.

In Figure 12, we observe several hierarchical configurations within clinical engineering teams, based on the positions reported by each hospital. Leaner structures predominate, with one or two management levels, accounting for 16 hospitals that indicated this configuration.

An area of interest in the study was identifying the hospital directorate to which clinical engineering reports. The responses revealed a diverse set of reporting structures, with a predominance of administrative directorates—such as general administration, administrative, administrative and financial, operations, and financial—totaling 16 responses.

FIGURE 12. Grouping of hierarchical management levels of clinical engineering in the surveyed hospitals.

In addition, nine hospitals indicated reporting lines linked to technical directorates, including Infrastructure, Technical, Clinical Care, and Information Technology, as shown in Figure 13.

The placement of clinical engineering under the information technology directorate may be explained by the increasing integration of medical equipment into hospital networks, involving the transmission of images, data, and device-generated signals, as well as the growing

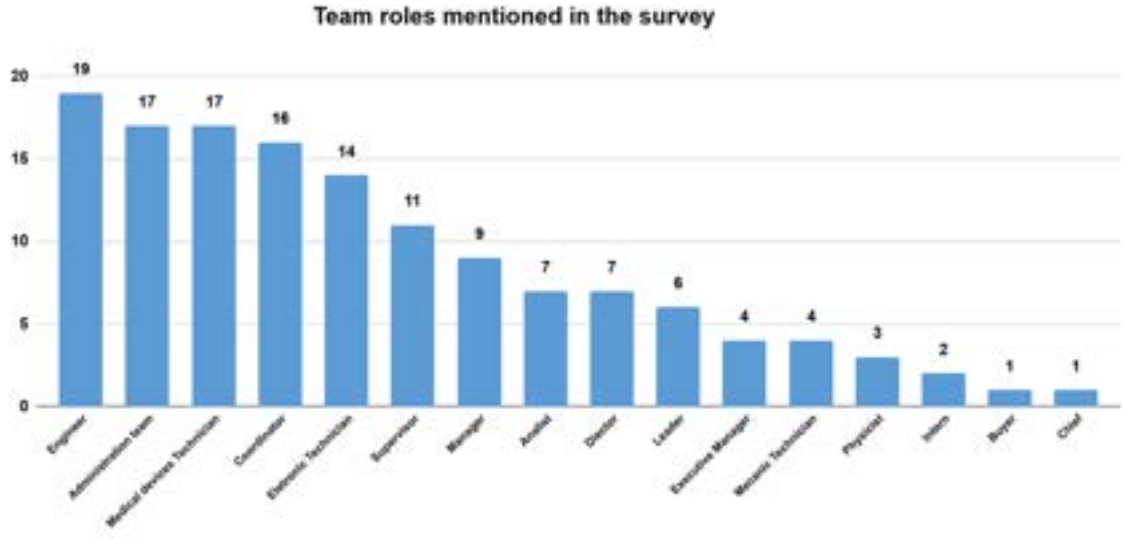

FIGURE 11. Types of positions cited that make up the clinical engineering team in the surveyed hospitals.

challenges related to safeguarding patient data. The presence of clinical engineering under the clinical care directorate also suggests a strong integration with care teams, aligning with Dyro's[1] interaction diagram, which identifies nursing as one of the key areas interfacing with clinical engineering.

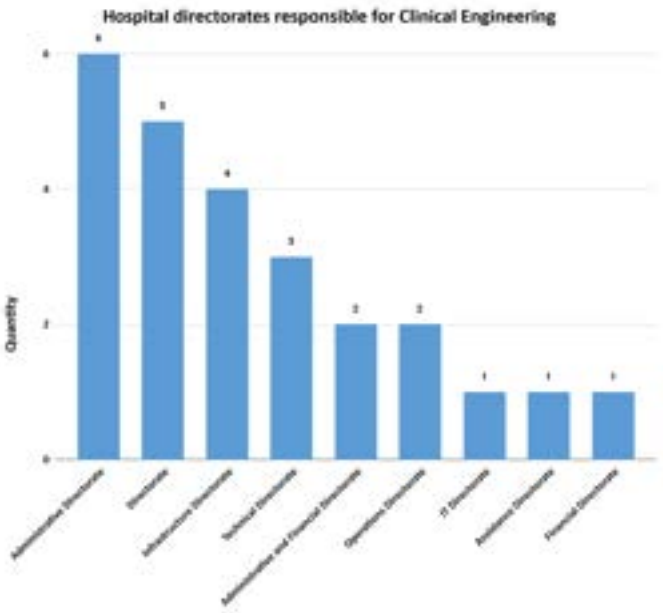

FIGURE 13. Directorates responsible for clinical engineering.

This study clearly demonstrates the diversity of areas to which clinical engineering reports within hospitals, as can be seen in Figure 14.

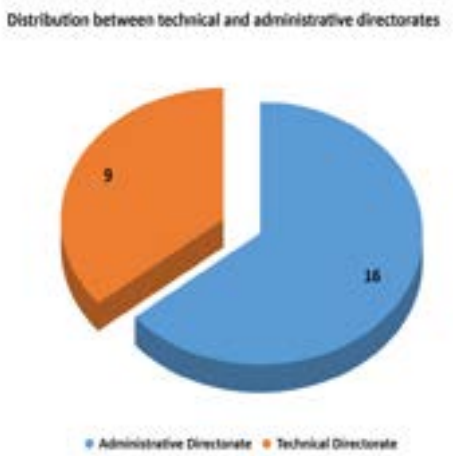

FIGURE 14. Grouping between technical and administrative directorates.

Among the open responses, several comments illustrate the diversity of reporting structures for clinical engineering, ranging from direct linkage to the corporate superintendency to matrix reporting through areas such as real estate or operational management.

The survey also examined the presence of HTA processes. HTA is essential for supporting evidence-based decisions regarding the incorporation and rational use of technologies.[27,34] In our sample, 15 hospitals reported having an HTA committee, as shown in Figure 15, a finding aligned with Francisco and Malik[27], who noted the limited influence of NATS on hospital decision-making. Likewise, Novaes and Soárez[35] observed low adherence to economic evaluation in national HTA bodies, with only a small proportion of CITEC and CONITEC studies incorporating such analyses.

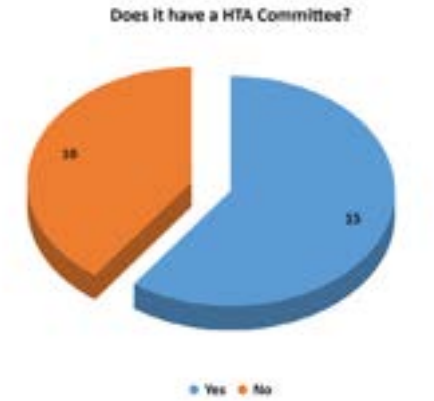

FIGURE 15. Hospitals and the HTA committee.

In spite of greater reported participation in HTA among the hospitals surveyed, these results do not confirm full institutional consolidation of HTA practices. As highlighted by Francisco and Malik[27], most hospitals still rely on simplified assessments rather than complete economic evaluations.

Open comments further illustrate this variability, referencing:

- alternative nomenclatures (e.g., "CITES");
- absence of formal committees, with decisions driven by internal prioritization and corporate budget review;
- committees still under development;

• collegial structures composed of clinical and administrative directors.

The open-ended responses suggest that HTA is still in a process of consolidation within hospitals, indicating that the full scope of HTA procedures is not yet clearly established or understood by many institutions. Among the 10 hospitals in our survey that reported not having HTA activities, 8 are private, as shown in Figure 16. These findings indicate that, regardless of whether hospitals are public or private, the presence of a formal HTA Committee is not yet a widespread reality.

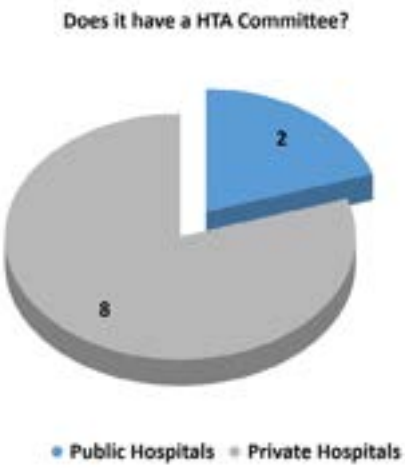

FIGURE 16. Hospitals without HTA Committee by type of facility.

One of the core responsibilities of clinical engineering is the maintenance of the installed fleet of medical equipment. Beyond maintenance activities, monitoring maintenance-related expenditures is essential to ensure alignment with the institution's budget. In some hospitals, however, the management of these expenses is assigned to other departments, which may indicate the absence of a dedicated clinical engineering manager or suggest a fully outsourced service model. In such cases, clinical engineering may focus solely on executing and documenting maintenance activities, while financial oversight is handled elsewhere.

Figure 17 shows that Clinical engineering predominates as the area responsible for managing maintenance expenses, with 20 hospitals reporting this arrangement. In five hospitals, this responsibility lies with other sectors—such as directors or superintendents—thereby positioning the clinical engineering team primarily as an operational executor rather than a financial manager.

FIGURE 17. Areas that manage maintenance expenses.

Open-ended responses indicate that, in several hospitals, clinical engineering collaborates closely with finance in managing maintenance expenses. Examples include financial oversight by the infrastructure directorate, joint management with operations, support from financial units linked to the superintendency, and prioritization led by infrastructure.

In terms of contract management, responsibilities fall predominantly to technical areas—clinical engineering and the infrastructure directorate—which together account for 24 hospitals (see Figure 18). One hospital reported that contracts are managed by the contract directorate, consistent with its fully outsourced clinical engineering model.

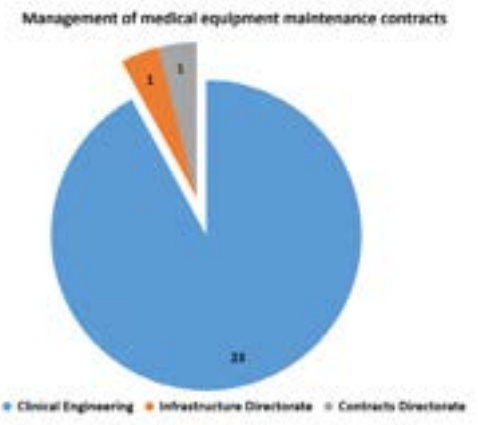

FIGURE 18. Management of maintenance contracts.

The open-ended responses suggest that clinical engineering often plays a supportive role in managing maintenance contracts, as illustrated in the comments below:

• "Responsibility lies with the hospital's infrastructure directorate, with support from clinical engineering."

• "Most contracts are corporate, with joint management for unit-specific needs. Contract execution, however, is primarily local."

• "Some contracts are managed corporately by the central unit."

One hospital reported not performing investment management. This institution is a public hospital with 612 beds, without an HTA department and with outsourced clinical engineering services. In such cases, investment decisions are typically led by the executive directorate, with clinical engineering acting as a supporting area (see Figure 19).

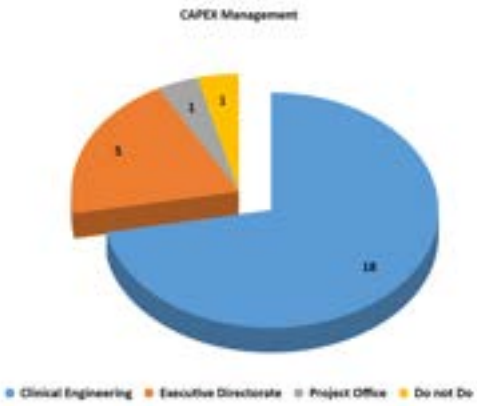

FIGURE 19. Areas that manage CAPEX (capital expenditure–capital expenses).

The open-ended responses for this question reinforce the perception that clinical engineering supports hospital leadership in evaluating and deciding on medical equipment acquisitions. Examples include:

• "Indicates replacement due to obsolescence and provides input on equipment purchases."

• "Responsibility lies with the infrastructure directorate, supported by clinical engineering and other hospital sectors."

• "Clinical engineering serves as an advisory body to the executive directorate for investment decisions in medical technologies."

Regarding budgeting, the responses show that clinical engineering plays a central role in preparing the budget for managing the hospital's medical equipment fleet. One hospital, however, reported that budget preparation is not the responsibility of clinical engineering because of its outsourced service model; in this case, financial planning is handled by a manager appointed by the hospital leadership (see Figure 20).

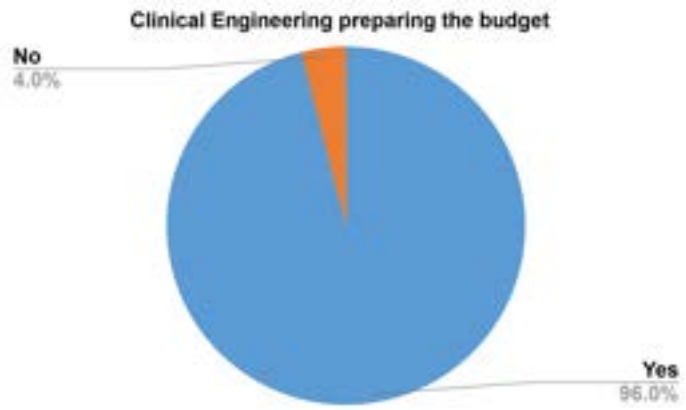

FIGURE 20. Clinical engineering and budget planning.

The open-ended responses reveal different degrees of involvement of clinical engineering in the budgeting process, as illustrated by the following remarks:

• "Through the infrastructure directorate."

• "Not only clinical engineering but also other business units through matrix management."

• "Yes. The total OPEX budget comes predetermined by the corporate office. It is then allocated across areas in agreement with the directorate and finance, with active participation in identifying needs and forecasting expenses. CAPEX also involves this participation."

• "Somewhat… clinical engineering prepares projections, but financial responsibility lies with finance."

• "Cost projections for general maintenance and fixed contracts are prepared."

Importantly, clinical engineering has a guaranteed seat in strategic meetings in 13 responses, suggesting that participation in strategic planning is considered essential in most hospitals. This finding aligns with the research question and indicates a relevant area for further exploration.

In Figure 21 we observed that in 12 responses, the participation of clinical engineering is occasional or occurs only when the need arises, indicating that it is not a permanent participant in strategic meetings.

FIGURE 21. Participation of CE in strategic meetings.

Among the many open-ended responses, several deserve emphasis, as illustrated below:

• "There is participation in weekly meetings with the board, where results and strategic actions are reviewed. The area is represented by the Operations Manager, who requests direct involvement whenever decisions require Clinical Engineering support."

• "Participation in discussions is carried out by the Director of Engineering."

• "This process is led by the Maintenance and Construction Management, which encompasses areas beyond Clinical Engineering."

The findings also show strong involvement of clinical engineering in project committees (see Figure 22). As a technical specialty, the area contributes to the implementation of new health care services by integrating medical equipment specifications with hospital infrastructure planning. Accordingly, 24 hospitals in the survey recognize the importance of including clinical engineering in project committees.

The study by Treib et al.[36], based on accreditation programs such as ONA, JCI, Accreditation Canada International (ACI) and Qmentum, shows that in spite of the growth in the number of certified hospitals, only 6.1% of the 6,424 hospitals registered in the CNES had accreditation as of

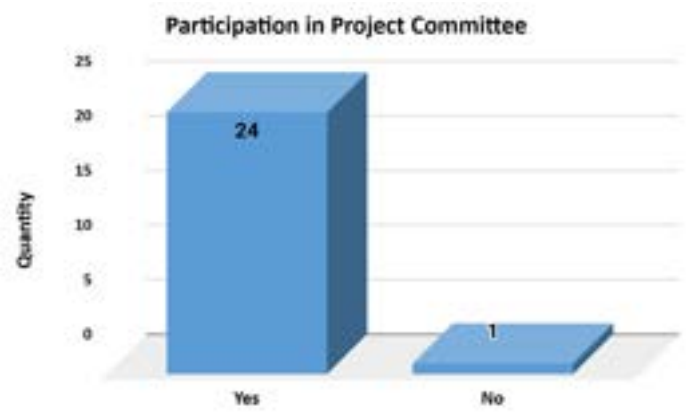

FIGURE 22. Participation in project committees.

September 2021. The authors conclude that accreditation in Brazil still exhibits an incipient level of adherence.

In our survey, three hospitals reported not having accreditation. Although most respondents indicated possessing some type of certification, the sample does not reflect the national scenario. The three hospitals without accreditation also reported not being ANAHP members; two of them are public institutions (one medium-sized and one large), and only one has a HTA committee (see Figure 23).

FIGURE 23. External evaluations.

The medium-sized hospital stated that clinical engineering does not participate in institutional strategy or budget planning, and that the service is outsourced. The analysis also identified one large private hospital without an HTA committee, suggesting that although accreditation is not necessarily linked to the type of management (public or private), some relationship may exist.

The absence of accreditation may indicate a lack of interest or insufficient resources to establish a clinical engineering team, a lower prioritization of technology assessment, or constraints related to human resources that hinder the formation of an HTA committee.

Of the 22 hospitals in the survey that reported having accreditation, many hold multiple certifications. We identified 42 mentions of different accreditation seals among these institutions, which may indicate that a quality-oriented culture fosters continuous improvement, or that obtaining multiple accreditations is being used as a marketing strategy to enhance competitiveness in the health care market (see Figure 24).

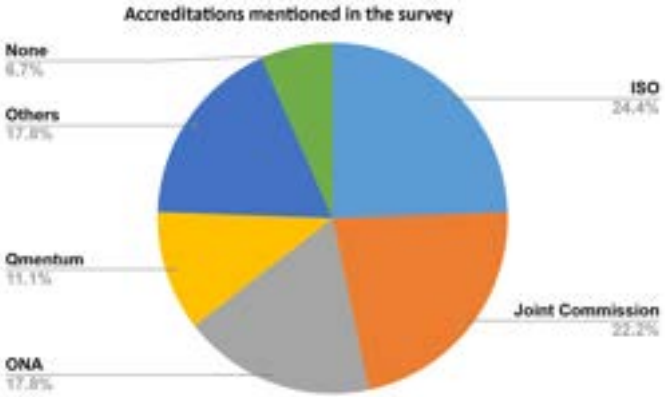

FIGURE 24. Mentions of accreditations.

Treib et al.[36] note that accreditation should promote a culture of quality and safety, driving positive changes in processes and the continuous improvement of health systems and services.

Finally, the perception of how clinical engineering is characterized shows overwhelmingly (see Figure 25) that it operates predominantly in an operational capacity, providing technical support for medical equipment. Moreover, as indicated by other responses in the survey, its involvement in strategic activities is less frequent and often occurs only when specifically requested.

FIGURE 25. Qualification of clinical engineering.

DISCUSSION

Quality in Health Care in Clinical Engineering: An Approach Based on Donabedian

Donabedian[21] argues that the quality of technical performance is judged in comparison to the best practice, and that effectiveness is the extent to which expected outcomes are achieved. Therefore, the quality of technical care is proportional to its effectiveness, and it is necessary to have information on the cause-and-effect relationship between the attributes of structure, process, and outcome of care. To relate the research in this study to Donabedian's framework, we organized the responses according to the attributes mentioned: structure, process, and outcome. We highlighted the items with the absolute number of hospitals that responded to the categorical questions. We observed that most of the hospitals with accreditations have their own clinical engineering services, which predominantly include technology assessment processes (ATS). However, the depth of these assessments was not detailed. All the questions classified under the process attribute indicated a prevalence of clinical engineering in responses that converged on the understanding that, although clinical engineering is also cited as responsible for maintaining medical equipment, it is perceived as a department actively involved in managing expenses, maintenance contracts,

supporting investment decision-making, and participating in strategic discussions. Notably, its participation in the latter is often demand-driven rather than compulsory. Therefore, the study suggests that the role and actions of clinical engineering have gained significant traction within hospital management, aligning with the research question (Appendices 1 and 2).

Firstly, the number of hospitals that responded to the survey was small, with only 15 hospitals associated with ANAHP participating, representing 11.8% of the 127 hospitals in that group. The remaining 9 hospitals were from non-associated, public, and private institutions that accepted the invitation to participate. Thus, a total of 25 hospitals completed the survey.

The data collection period lasted 30 days, which limited the response time for the hospitals. Many managers missed the deadline and did not participate in the survey.

Many contacts with ANAHP hospitals were initiated by us through personal networks to raise awareness about the importance of the survey and ensure the delivery of the invitation emails, as there were reports that some hospitals did not receive the invitations because they were directed to spam folders.

Regarding the hospitals that received our invitation, some declined to participate because of various reasons, including concerns about compliance with the General Data Protection Law (LGPD), Law No. 13.709/2018 (https://www.gov.br/mds/pt-br/acesso-a-informacao/privacidade-e-protecao-de-dados/lgpd), or because the required information was stored in a central office with no access to specific data from the invited hospital. In addition, internal bureaucracy at some hospitals led to missed deadlines for response submission.

The survey yielded 28 responses within the 30-day period, from March 8 to April 8, 2024. However, 3 responses were duplicates from the same hospital, reducing the total to 25 hospitals, which is the basis for this study.

Two participants did not provide their name, job title, or the hospital's identification. Nevertheless, we considered all other responses from these hospitals in the survey because of their significant contribution to the study.

Two participants did not provide their name, job title, or the hospital's identification. Nevertheless, we considered all other responses from these hospitals in the survey because of their significant contribution to the study.

Despite the small sample size in this exploratory field research (25 participating hospitals), the recognition of clinical engineering by hospital managers was evident. Although the role and functions of clinical engineering were better understood, there were still discrepancies in the responses, indicating that gaps remain in the understanding of clinical engineering's role. This suggests that clinical engineering is recognized as a key player in managing medical equipment services and that it has a substantial role in hospital management. The sample provided valuable information for our research objective, revealing various organizational structures and the involvement of women in both management and technical roles, highlighting areas for further exploration and advancement. Despite the results, the research presents a significant field for study.

FINAL CONSIDERATIONS

The research met its objectives, revealing a rich landscape of information about clinical engineering's role in supporting hospital managers. However, significant differences in the perception of this area's role suggest that a broader analysis could consolidate the data. There are still gaps in clinical engineering's operations, possibly because of a lack of awareness, resources, or qualified professionals. Therefore, it is necessary to expand the study to include more hospitals to better understand these disparities and strengthen clinical engineering in the country.

In Appendix 1, a key finding of this study is the strong indication that clinical engineering has significant potential to contribute to hospital management, working across multiple areas and reporting structures. This suggests that senior leadership is still developing a full understanding of how clinical engineering can support decision-making and operational performance. Professional organizations such as ABEClin and SBEB, along with scientific events and specialized training programs, play an essential role in strengthening and promoting the field in Brazil. Although the results show a generally positive trend, they are not unanimous, indicating that opportunities remain—particularly regarding the optimal placement of

clinical engineering within organizational structures. The analysis based on the Donabedian model shows that having a qualified team supported by structured processes leads to more strategic management of the medical equipment fleet. This contributes to reduced operational disruptions, cost efficiency, rapid repairs, precise technical support, critical analysis of expense-reduction opportunities, and evidence-based technology assessment. According to Donabedian, outcomes do not necessarily improve proportionally with higher investments, reinforcing that efficiency arises from best practices rather than elevated spending alone. Overall, these results highlight that effective clinical engineering enhances organizational performance and strengthens the department's credibility in achieving accreditation from recognized auditing bodies.

The work proved to be quite complex and challenging, given the country's dimensions. Even in a small-scale study, we encountered several difficulties, indicating that such tasks are neither simple nor quick. Hence, a good strategy would be to start with small niches of hospitals and then expand gradually to include more participants. While our research has already provided valuable information for analysis, a more detailed mapping could offer a clearer understanding of which management models in clinical engineering are prevalent in these institutions. By exploring how hospital managers perceive the role of clinical engineering and obtaining various perspectives according to the nature of the hospitals—whether public or private, small, medium, or large—we could achieve a more profound and refined understanding of the subject.

AUTHOR CONTRIBUTIONS

Conceptualization, M.D.B.; Methodology, M.D.B. and A.M.M.; Validation, M.D.B. and A.M.M.; Formal Analysis, M.D.B.; Investigation, M.D.B.; Resources, M.D.B.; Data Curation, M.D.B.; Writing—Original Draft Preparation, M.D.B.; Writing—Review & Editing, M.D.B. and A.M.M.; Visualization, M.D.B.; Supervision, A.M.M.; Project Administration, M.D.B.

All authors have read and agreed to the published version of the manuscript.

ACKNOWLEDGMENTS

We would like to express our sincere appreciation to Fundação Getulio Vargas for challenging and encouraging us to undertake the development of this study. We are especially grateful to the hospitals affiliated with ANAHP, as well as to military hospitals and other public and private institutions that agreed to participate in our research. Their openness and generosity in providing rich and valuable information were fundamental to the conduct and robustness of this work.

FUNDING

This research received no external funding.

DATA AVAILABILITY STATEMENT

Not applicable.

CONFLICTS OF INTEREST

The authors declare they have no competing interests.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

Not applicable.

CONSENT FOR PUBLICATION

Not applicable.

FURTHER DISCLOSURE

Not applicable.

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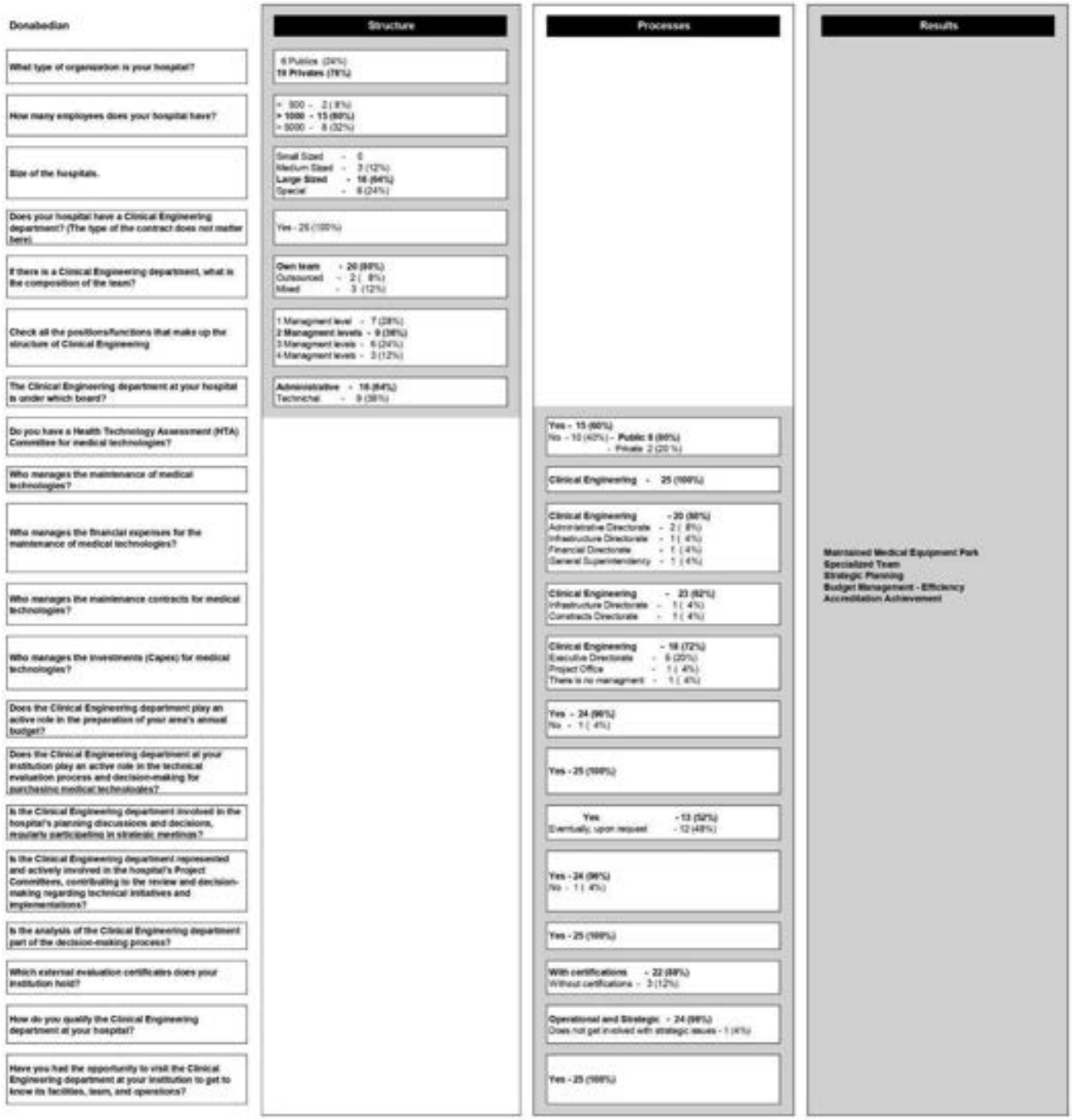
APPENDICES

Appendix 1. Distribution of questions in the Donabedian model.



Appendix 2. Questionnaire–survey.

FGV

Name:		**Position:**	
Institution:		**City/State**	
Questionnaire – Survey			
1	How many general (non-critical care) beds does your hospital have?		
2	How many critical-care beds (ICU, step-down, UCG, UCO, cardiac units) does your hospital have?		
			Mark with an "x"
3	How many employees does your hospital have?	Fewer than 200	( )
		More than 200	( )
		More than 500	( )
		More than 1000	( )
		More than 5000	( )
4	How is your hospital classified in terms of organizational type?	Public	( )
		Private	( )
		Philanthropic	( )
		Other (specify):	Text:
5	Does your hospital have a Clinical Engineering service (regardless of the type of employment arrangement)?	Yes	( )
		No	( )
6	If your hospital has a Clinical Engineering service, what is the composition of the team?	In-house	( )
		Outsourced	( )
		Hybrid	( )
7	Which roles make up the structure of the Clinical Engineering department?	Director	( )
		Superintendent	( )
		Executive Manager	( )
		Manager	( )
		Coordinator	( )
		Supervisor	( )
		Team Leader	( )
		Engineer	( )
		Analyst	( )
		Physicist	( )
		Eletronics Technician	( )
		Mechanical Technician	( )
		Medical Equipment Technician	( )
		Administrative Staff	( )
		Others	Text:
8	Do you have an HTA Committee for medical technologies?	Yes	( )
		No	( )
9	Who is responsible for managing maintenance activities?	Clinical Engineering	Yes ( )
			No ( )
		Another area? Which one?	Text:
10	Who is responsible for financial management?	Clinical Engineering	Yes ( )
			No ( )
		Another area? Which one?	Text:
11	Who is responsible for managing medical technology contracts?	Clinical Engineering	Yes ( )
			No ( )
		Another area? Which one?	Text:
12	Who is responsible for managing capital investments (CAPEX) in medical technologies?	Clinical Engineering	Yes ( )
			No ( )
		Another area? Which one?	Text:
13	Is Clinical Engineering responsible for preparing the department's annual budget?	Yes	( )
		No	( )
14	Does Clinical Engineering participate in the processes of evaluating and purchasing technologies?	Yes	( )
		No	( )

15	Does Clinical Engineering participate in strategic meetings?	Yes	( )
		No	( )
16	Does Clinical Engineering participate in project committees?	Yes	( )
		No	( )
17	Is Clinical Engineering analysis part of the decision-making process?	Yes	( )
		No	( )
18	What is the gender distribution (%) in the Clinical Engineering department?	Men	( )
		Women	( )
		Others	( )
19	Which external evaluation certifications does your institution hold?	Joint Commission	( )
		ONA	( )
		PADI	( )
		CARF	( )
		ACR	( )
		Others	Text:
20	How do you perceive the Clinical Engineering department in your hospital?	It is purely operational	( )
		It is operational and strategic	( )
		It is solely strategic	( )
		It is not involved in strategic matters	( )
		I cannot say	( )
21	Have you visited your institution's Clinical Engineering department?	Yes	( )
		No	( )

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