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Research article

Statistical models and implant customization in hip arthroplasty: Seeking patient satisfaction through design

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ABSTRACT

Objectives: This study conducts a systematic literature review to explore the role of statistical models and methods in the design of orthopedic implants, with a specific focus on hip arthroplasty. Through a comprehensive analysis of the scientific literature, it aims to understand the relevance and applicability of these models in implant development and research trends in the field of design.

Methods: Data analysis and co-occurrence mapping techniques were employed to investigate the statistical models used as predictors of satisfaction in hip arthroplasty and in implant design. This approach facilitated a detailed and objective assessment of existing literature, revealing key trends and identifying gaps in current knowledge.

Key findings: The review's findings underscore a burgeoning interest in implant customization, with a significant emphasis on leveraging statistical techniques for optimal design. The logistic model methodology was applied to analyze a survey of hip surgery specialists, revealing that the physician's age does not influence the decision to use a customized implant. Furthermore, the review highlighted a knowledge gap at the intersection of statistics and design discipline concerning implant customization.

Significance: Despite the recognized importance of customization in implant design, there remains a dearth of contributions from the design discipline perspective in the existing literature, indicating substantial room for improvement and the need for interdisciplinary integration.

Conclusion: The integration of statistical methods in implant design is crucial, emphasizing the need for multidisciplinary approaches and customization to enhance patient satisfaction. This study provides a foundation for future research that could transform the field of hip arthroplasty through more personalized and effective solutions.

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1. Introduction

Hip arthroplasty, a vital surgical procedure in orthopedics, aims to restore the functionality of the hip joint affected by various pathologies and structural damages. Hip arthroplasty, or hip replacement, refers to the surgical procedure where the hip joint is replaced by a prosthetic implant. Revision arthroplasty involves a second surgery to replace or repair the prosthetic implant if it fails or wears out over time. These conditions can severely restrict joint movement and cause pain, impacting both the patient's well-being and their family. The decision for joint replacement with implants is made when less invasive treatments fail to improve the patient's quality of life [1,2].

A primary indicator of the increasing demand for arthroplasty devices is the projected rise in the number of surgeries. According to Schwartz et al. [3], who analyzed data and employed statiscal models to project trends of incidences of hip revision arthroplasty (rTHA) from the National Inpatient Sample (NIS) of the Healthcare Cost and Utilization Project (HCUP) and project a continuous increase in the incidence of primary total arthroplasty in the United States, affecting revision arthroplasty rates. This study's findings indicate that by 2030, an increase in the incidence of hip revision arthroplasty (rTHA) between 43 % and 70 % is expected compared to 2014.

This increase is observed not only in individuals over 60 years old but also in younger populations aged 55–74. years, which have shown an uptick in the incidence of revisions over the study period. This trend can be attributed to several factors, including higher rates of sports-related injuries and early-onset arthritis among younger individuals. Additionally, advancements in surgical techniques and implant materials have made hip arthroplasty a more viable and attractive option for younger patients, promising quicker recovery times and longer-lasting results. These findings align with those of Oh et al. [4], who performed a detailed examination of data from the California Healthcare Cost and Utilization Project spanning 2007 to 2010. Oh et al. utilized statistical analyses, including chi-square tests and multivariate logistic regression, to assess trends in patient demographics and comorbidities associated with primary hip arthroplasty, and found that patients undergoing primary hip arthroplasty tend to be younger and exhibit a higher prevalence of depression, drug or alcohol abuse, along with the presence of medical comorbidities. Consequently, the need for customized and statistically optimized implant designs has become more pressing to accommodate the diverse requirements of a broader age range.

Given the increasing prevalence of disorders necessitating hip arthroplasty and the substantial costs associated with revision surgeries, it is imperative that implant designs demonstrate both effectiveness and efficiency [5–7]. These challenges are further compounded by the exorbitant expenses incurred during revision procedures. Consequently, the design of orthopedic implants for hip arthroplasty emerges as a pivotal research area, wherein customization and adaptation to individual patient needs are paramount.

This research endeavors to tackle these challenges by integrating statistical models and methods into orthopedic implant design. Such integration holds the promise of not only enhancing the design of customized implants but also incorporating factors pertinent to user satisfaction. Through a systematic review of scientific literature, this study seeks to elucidate the relevance, applicability, and prevailing trends of statistical models in hip arthroplasty implant design. The adopted methodology, encompassing data analysis and co-occurrence mapping techniques, facilitates a comprehensive exploration of the existing literature, thereby unveiling key trends and identifying areas ripe for improvement. Furthermore, an integral aspect of this study involves applying logistic models to a survey of orthopedic specialists, wherein variables such as age and the decision to employ a customized implant are considered.

Statistical models, in this context, stand out for their ability to allow for a more accurate assessment of key variables such as durability, patient-specific aspects like the perception of success, lifestyles, the surgeon, the type of implant, among others [8]. Their relevance is particularly prominent in the context of customized implant design, where a more precise adaptation to each patient's anatomical and biomechanical characteristics is required, allowing for an improvement in user satisfaction [9–11].

Specifically, in the context of hip arthroplasty, statistical models such as cohort analysis and survival analysis play a crucial role [12–15]. These models enable longitudinal studies of patient groups, offering valuable data on the durability and effectiveness of implants over time. Other methods, such as correlation analysis and multivariate analysis, are used to understand the relationships between multiple variables and their impact on implant outcomes [16–20]. While these statistical approaches provide a comprehensive and detailed perspective, which is crucial for the continuous evaluation and improvement of implant designs.

Additionally, techniques such as the interpretation of statistical data and regression analysis have been identified as important methods in this field [21–23]. These approaches are essential for making informed decisions aimed at improving the patient experience and outcomes. For example, both linear and logistic regression analysis has been key in identifying factors contributing to the success of arthroplasty, allowing for the estimation of the strength and direction of the association between variables, as well as adjusting for potential confounders [24–27]. These statistical methods provide an objective and accurate interpretation of clinical data, which is indispensable in the quantitative assessment of postoperative satisfaction and the perceived success of these interventions.

Having precise and detailed information is crucial for adequately preparing health systems and production processes [28–32]. This information is critical for prioritizing research directions in the development of medical devices, such as implants for hip arthroplasty. Furthermore, understanding the conditions affecting patients undergoing hip arthroplasty will enable the development of design methodologies that address not only the creation of high-quality implants but also the overall environment surrounding them [33–36]. This encompassess pre- and postoperative care, implant adaptability to the patient's lifestyle, and other factors contributing to overall user satisfaction [37–44].

The article encompasses various sections, including the methodology, results, discussion, and conclusions. The methodology section delineates the systematic literature review conducted to explore the utilization of statistical models in customizing orthopedic implant design and identifying satisfaction predictors in hip arthroplasty. In the results section, findings from the systematic literature review are presented, supplemented with data analysis and co-occurrence mapping techniques, to investigate the statistical models used in predicting satisfaction in hip arthroplasty and designing orthopedic implants. This section also demonstrates the application of the logistic model to the results of the interviews conducted with specialists, probing the applicability of customized implants.

The discussion emphasizes the multifactorial complexity of hip implant design and highlights the significant contributions of studies in arthroplasty. However, a significant gap in the literature regarding customized implant design and its impact on patient satisfaction is identified. The conclusion underscores the importance of integrating statistical methods in implant design and emphasizes the need for multidisciplinary approaches and customization to enhance patient satisfaction.

2. Methodology

This study aims to conduct a comprehensive literature review on the use of statistical models in predicting satisfaction in hip arthroplasty and designing orthopedic implants. To accomplish this aim, we employed a systematic literature review methodology, supplemented with data analysis using co-occurrence mapping techniques on the identified studies.

We conducted a systematic search in the Scopus database using key terms such as 'hip arthroplasty', 'satisfaction predictors', 'medical device design', 'implants' and 'industrial engineering'. This search included all relevant studies published up to December 16, 2023, to ensure a comprehensive dataset for analysis. The search process was iterative, refining the relationships between terms to yield results that were relevant and aligned with the research objective.

The methodology encompassed an initial selection of pertinent articles by reviewing the titles and abstracts of the articles retrieved through the systematic search in the Scopus database. This review focused on evaluating each article to the central objective of the study: examining statistical models applied in predicting satisfaction in hip arthroplasty and designing orthopedic implants. Articles not aligned with this objective were excluded at this stage and the inclusion criteria for the systematic literature review were studies published in peer-reviewed journals, studies focused on hip arthroplasty, studies utilizing statistical models, and studies published in English. The exclusion criteria were studies not related to hip arthroplasty, studies without statistical analysis, and studies published in languages other than English. To complement the thematic analysis, Vosviewer software was employed for co-occurrence analysis. Additionally, logistic model methodology was applied to interview results from experienced orthopedic surgeons in hip surgery,

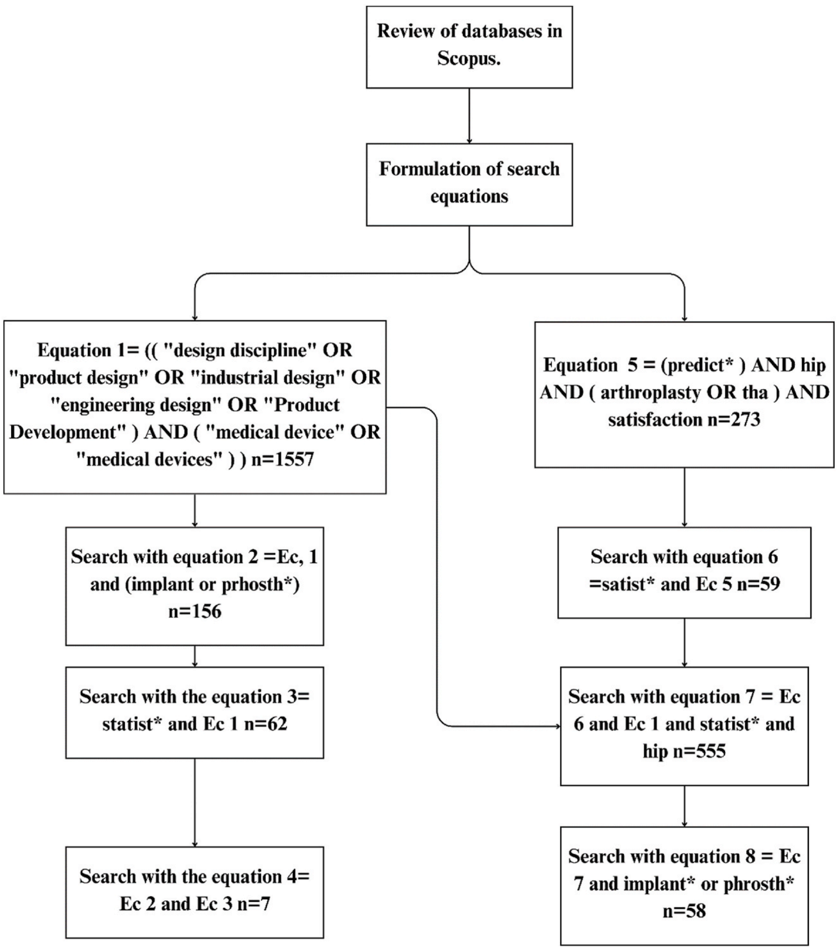

Fig. 1. Scheme for the formulation of search queries in scopus for study area analysis.

considering variable such as the surgeon's age and the decision to utilize custom-designed implants. Data analysis was conducted using the R statistical software [45].

3. Results

This section presents findings from a thorough review of literature on orthopedic implant design and evaluation for hip arthroplasty, focusing on the use of statistical methods. Within orthopedics, there is a burgeoning interest in customizing implants to enhance surgical outcomes and patient satisfaction. Statistical analysis plays a pivotal role in this domain by facilitating the assessment of efficacy, safety, and design optimization.

The review scrutinizes prior studies that have been seminal in this research field, analyzing how researchers have applied a variety of statistical techniques to comprehend and enhance hip implant design. Methodologies such as regression analysis, factorial analysis, and analysis of variance are explored, shedding light on their significance and applicability in specific investigations. This not only aims to elucidate the advantages and limitations inherent in each approach but also how underscores such studies have directly influenced improvements in implant design, steering both clinical and technical decisions towards optimal patient outcomes.

After establishing the context and emphasizing the importance of statistical analysis in hip implant design, we present the findings from a systematic literature review conducted through searches in the Scopus database. Specific search queries were employed to capture relevant studies in the field, including key terms related to implant design and various statistical techniques. The logical sequence for constructing the search equations is illustrated in Fig. 1.

For the relevant research on the study topic, the queries are shown in Table 1. Query 1, which establishes a general relationship between the design discipline and medical devices, outlines a diverse and expansive research field. Introducing the term "implants" or "prostheses" in query 2 refines the search, yielding more specific outcomes that demonstrate the relatively narrower focus of research related to these types of medical

Devices. When the term statistics is introduced in queries 1 and 2, there is a considerable reduction in results, indicating that the application of statistical methods in implant design is a little-explored area. In queries 4 and 6, it can be observed that the obtained results show signs of a knowledge gap in the interdisciplinary intersection of implant design, arthroplasty, and satisfaction predictors.

Refining the search with the introduction of terms like "implants" or "prostheses" in query 2 yields the results more specific. This reduction in the number of articles indicates that, while design in the context of medical devices constitutes a broad field, research specifically focused on implants and prostheses is more limited.

The inclusion of the term "statistics" in queries 1 and 2 leads to a significant decrease in outcomes, as evident in queries 3 and 4. This decline in the number of articles suggests that the application of statistical methods in implant design remains relatively unexplored. This finding underscores an opportunity for future research to address this knowledge gap [46].

Finally, Queries 4 and 6 in Table 1 shed light on results indicating the presence of a knowledge gap in the interdisciplinary intersection of implant design, hip arthroplasty, and satisfaction predictors. These findings underscore the necessity for more integrated research that addresses these topics collectively, particularly given the rising demand for hip arthroplasties and the critical role of patient satisfaction in clinical outcomes.

3.1. Co-ocurrence map

In this study, a co-occurrence map was generated for searches derived from query 8, employing a thesaurus file to streamline the

Table 1
Scopus search queries related to design, custom implants, and statistical models in scientific research.

ID	Equation	Title, abstract and key words	Without filter
1	(("design discipline" OR "product design" OR "industrial design" OR "engineering design" OR "Product Development") AND ("medical device" OR "medical devices"))	1557	9097
2	("design discipline" OR "product design" OR "industrial design" OR "engineering design" OR "Product Development") AND ("medical device" OR "medical devices") AND (implant* OR prhosth*)	156	2094
3	(statist* AND ("design discipline" OR "product design" OR "industrial design" OR "engineering design" OR "Product Development") AND ("medical device" OR "medical devices"))	62	2029
4	statist* AND ("design discipline" OR "product design" OR "industrial design" OR "engineering design" OR "Product Development") AND ("medical device" OR "medical devices") AND (implant* OR prhosth*)	7	480
5	(predict*) AND hip AND (arthroplasty OR tha) AND satisfaction	273	9011
6	statist* and (predict*) AND hip AND (arthroplasty OR tha) AND satisfaction	59	3510
7	(ALL ((predict*) AND hip AND (arthroplasty OR tha) AND satisfaction) OR ALL ((("design discipline" OR "product design" OR "industrial design" OR "engineering design" OR "Product Development") AND ("medical device" OR "medical devices"))) AND TITLE-ABS-KEY (arthroplasty) AND TITLE-ABS-KEY (statist*) AND TITLE-ABS-KEY (hip))	NA	555
8	(ALL ((predict*) AND hip AND (arthroplasty OR tha) AND satisfaction) OR ALL ((("design discipline" OR "product design" OR "industrial design" OR "engineering design" OR "Product Development") AND ("medical device" OR "medical devices"))) AND TITLE-ABS-KEY (arthroplasty) AND TITLE-ABS-KEY (statist*) AND TITLE-ABS-KEY (hip) AND TITLE-ABS-KEY (implant* OR phrosth*))	NA	58

Note: Results for the search queries performed with outcomes depending on whether the filter was used or not.

presentation of common terms. Fig. 2 presents the co-occurrence map for query 8. Three primary clusters of interconnected terms are discerned: the first cluster, depicted in yellow, centers on medical aspects, encompassing terms such as “prosthetic design” and “patient satisfaction,” highlighting the critical importance of addressing patient experiences and needs in implant development. This approach suggests that integrating statistical methods can significantly enhance the customization of implant design and, consequently, improve patient satisfaction. This aligns with the study’s objective to explore the relevance and applicability of statistical models in optimizing implant designs.

The second cluster, depicted in blue, is associated with implant complications and patient-reported outcomes, emphasizing the importance of collecting and analyzing postoperative data. The inclusion of terms related to complications and patient feedback indicates an opportunity to apply statistical analysis in the long-term assessment of implant safety and effectiveness. Lastly, the green cluster focuses on tools utilized in medical research, such as the “Oxford Hip Score” and various questionnaires. While this cluster does not specify particular methods or statistical analyses, it underscores the importance of incorporating advanced statistical techniques to gain a comprehensive understanding of factors influencing arthroplasty outcomes and patient satisfaction. This directly supports the study’s aim to utilize statistical methods for improving the evaluation and optimization of implant designs. Techniques such as regression analysis and predictive modeling could prove instrumental in identifying key factors impacting patient satisfaction scores and clinical outcomes.

This co-occurrence analysis illuminates current areas of interest in hip arthroplasty research and underscores the need for deeper integration of statistical methods in implant research and design, potentially resulting in significant enhancements in treatment

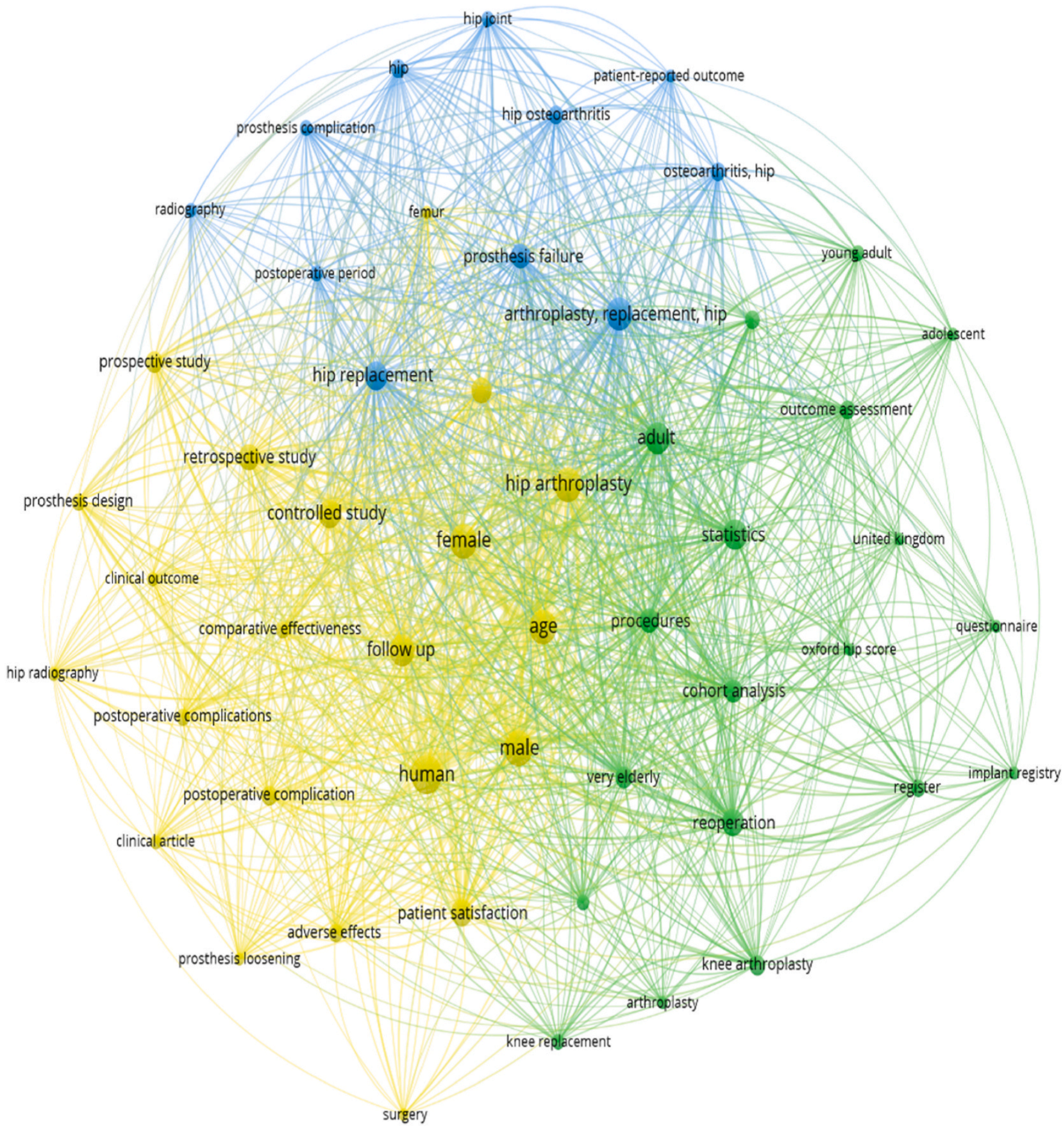

Fig. 2. Co-occurrence map for equation 7.

customization and patient quality of life. Fig. 3 depicts a direct linkage between prosthetic implant design and patient satisfaction, reinforced by elements such as questionnaires and patient-reported outcomes, indispensable tools for capturing invaluable patient experience information. These meticulously designed questionnaires not only capture qualitative data but also provide a foundation for quantifying and statistically analyzing patient satisfaction levels, thereby supporting the study's objective to enhance implant design through patient-centered data analysis.

This integrated approach, which merges implant design with patient satisfaction evaluation through statistical tools, underscores the significance of adopting a patient-centered methodology in hip arthroplasty. Analyzing this data yields a profound understanding of implant design efficacy and facilitates informed decisions aimed at enhancing patient experience and outcomes.

3.2. Statistical methods related to hip arthroplasty

The statistical methods utilized in implant design for hip arthroplasty and patient satisfaction are outlined in Table 2, encapsulating the statistical-related terms identified in the co-occurrence map derived from the result of search query 8.

"Cohort analysis" emerges with the highest frequency, indicating its paramount importance in longitudinal studies that track patient groups over time. "Survival analysis" signifies its role in assessing the long-term durability and effectiveness of implants. "Correlation analysis" and "multivariate analysis" are significant, indicating the application of these methods in comprehending the relationships between multiple variables and their impact on outcomes with hip arthroplasty implants.

"Data interpretation" and "regression analysis" are also recognized as significant methods, with their occurrences and linkages underscoring their relevance in statistical analysis within this field. Furthermore, terms such as "cost-effectiveness analysis," "intention to treat analysis," and "cost-benefit analysis," highlight the consideration of economic and methodological factors in evaluating implants for hip arthroplasty.

Collectively, the terms in Table 2 underscore the diversity and complexity of statistical methods employed in hip implant design and evaluation, emphasizing the importance of a comprehensive approach that integrating both clinical and economic aspects in decision-making related to orthopedic implants.

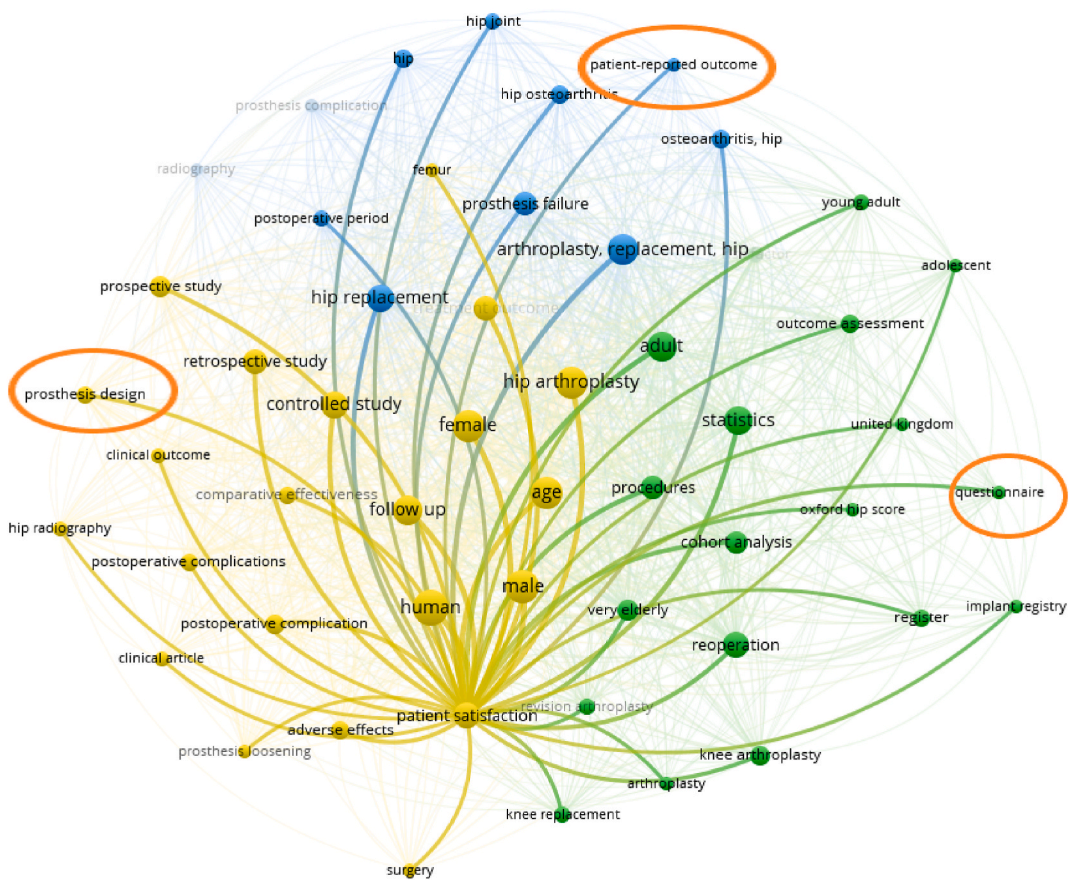

Fig. 3. Co-occurrence relationship for the results of query 7 with the terms implant design, patient satisfaction, and measurement instruments.

Table 2
Terms related to statistics in the results of query 8.

Terms	Ocurrences	Link strenght
Cohort analysis	19	816
Survival analysis	4	188
Correlation analysis	3	128
Multivariate analysis	3	128
Data interpretation, statistical	3	120
Regression analysis	3	95
Cost effectiveness analysis	2	99
Intention to treat analysis	2	99
Cost benefit analysis	2	85
Cost-benefit analysis	2	85
Confidence interval	2	79
Predictive value	2	73

3.3. Authors related to design, satisfaction, statistical analysis, and arthroplasty

Regarding the most pertinent authors in the research topic of hip arthroplasty, satisfaction factors, and implant design, Table 3 presents the top 10 most cited authors. It is notable that each author has contributed to only one publication, and the authors with the highest number of citations are Bayliss et al. [47], garnering 446 citations for their research analyzing the survival of total hip and knee replacement implants in patients with advanced osteoarthritis. Their findings underscore an elevated revision risk in younger patients, challenging the trend of performing these surgeries in younger age groups.

Additionally, Espehaug et al. [32] concentrated on the completeness of the registry in the Norwegian National Arthroplasty Register (NAR), underscoring the significance of enhancing the registry's completeness in less common implants and in cases requiring revision.

Katz et al. [48] examined the correlation between the volume of surgeries performed by surgeons and its impact on patient-reported functionality and satisfaction levels. Parker et al. [49] conducted a comparative study between two types of implants in patients with hip fractures, contrasting the outcomes of using a cemented Thompson hemiarthroplasty versus an uncemented Austin-Moore prosthesis. Their findings revealed that patients receiving the cemented prosthesis experienced less pain and achieved better mobility recovery, with no significant differences observed in mortality or implant-related complications.

In a different context, Winther et al. [50] investigated the implementation of the "fast-track" approach in hip and knee arthroplasties at a Norwegian university hospital. The findings unveiled high patient satisfaction, reduced hospital stay lengths, and low revision rates, alongside enhancements in health-related quality of life and functionality. Glassou et al. [52] conducted a comparative analysis of the risks of readmission, repair, and mortality within 90 days post-surgery in orthopedic departments with "fast-track" programs in Denmark. Departments implementing "fast-track" observed shorter hospital stays without an increase in risks of readmission, re-operation, or mortality. In the realm of knee arthroplasty, Karachalios et al. [51] evaluated the long-term outcomes of total knee arthroplasty using the Advance Medial-Pivot method. Their study indicated a high success rate with significant improvements in patient function and quality of life, endorsing the effectiveness of this technique.

Piedade et al. [55] explored the effects of tibial tuberosity osteotomy in primary total knee arthroplasty (TKA). Analyzing 1474 TK A cases, including 126 with tibial tuberosity osteotomy and 1348 without it, they encountered intraoperative and postoperative complications related to the osteotomy, such as tibial fractures and skin necrosis. Although no significant differences in revisions were observed at two years, the conclusion was that osteotomy should only be performed when necessary and with adequate surgical expertise due to the associated risks.

Table 3
Showcases the most cited authors in the field of hip arthroplasty, patient satisfaction, and statistical methods.

Authors	Publications	Citations
Bayliss et al. [47]	1	446
Katz et al. [48]	1	178
Espehaug et al. [32]	1	153
Parker et al. [49]	1	123
Winther et al. [50]	1	87
Karachalios et al. [51]	1	66
Glassou et al. [52]	1	55
Schmidutz et al. [53]	1	55
Ferruzzi et al. [54]	1	52
Piedade et al. [55]	1	45

Note: This table displays the most cited authors within the domain of hip arthroplasty, patient satisfaction, and statistical methods, offering insights into influential works and contributions to the field.

Lastly, in the context of hip arthroplasty, Schmidutz et al. [53] evaluated stem design in patients engaged in sports activities. Following a comprehensive follow-up, their research highlighted the critical importance of adapting implant design to meet the specific needs and activities of patients, thereby enhancing the overall success and satisfaction with hip arthroplasty procedures.

3.4. Overview of study areas from search queries

Fig. 4 illustrates the distribution of document types by publication area, emphasizing a prevalence of health-related studies associated with the obtained results. This trend underscores a frequent and substantial collaboration between the fields of medicine and statistics, with a focus on aspects such as implant types and patient satisfaction. However, a lesser connection with the design discipline and its relation to implants is evident in the existing literature.

The scarcity of contributions from the design perspective highlights an opportunity for interdisciplinary integration. This absence of results underscores the need for more robust research examining how the design discipline can influence and be influenced by advanced statistical methods, particularly in the development of customized hip arthroplasty implants in the context of Industry 4.0 [56].

In relation to the results of search query 8 from Table 2 regarding statistical data analysis in implant design, there is a significant knowledge gap in research explicitly connecting statistics with design. While implant design involves a combination of creativity with technique, the integration of detailed statistical analysis is crucial for optimizing both functionality and user satisfaction. Future research should explore how statistical methodologies can be systematically integrated into the design process, especially to enhance user satisfaction with customized implants, leveraging technological advances in the manufacturing of implantable devices.

3.5. The role of statistical methods in hip arthroplasty

Hip arthroplasty stands as a transformative surgery designed to alleviate pain, improve mobility, and, consequently, enhance the quality of life for patients. Postoperative satisfaction and the perceived success of these interventions are of paramount interest, not only to patients and healthcare professionals but also to the design and improvement of prostheses and surgical techniques. Statistical methods are indispensable tools in the quantitative evaluation of these parameters, allowing for an objective and precise interpretation of clinical data. This paper elucidates the role that various statistical techniques play in the analysis of satisfaction and hip arthroplasty.

Descriptive statistics, though basic, are fundamental in providing an overview of the characteristics of the population studied [57]. In combination with inferential techniques, they allow for the contextualization of findings and facilitate the interpretation of more complex methods.

Additionally, meta-analyses and random and fixed effects models provide a quantitative synthesis of the literature, as demonstrated in the work of Romagnoli et al. [29], where dislocation rates among different implant designs were compared. These methods are especially valuable in integrating results from multiple studies, enhancing statistical power, and generalizing conclusions.

Chi-square tests and Mann-Whitney U tests, for example, have been extensively applied to assess the relationship between pain control perception and overall patient satisfaction [58]. These non-parametric methods are highly useful when dealing with categorical variables or when the data do not meet the assumptions of normality, which is common in perception and satisfaction measurements.

In their study, I. Shichman et al. [59] used a statistical methodology focused on non-parametric analyses. Continuous data were presented as means and standard deviations, and compared using the Mann–Whitney U test among the PA (posterior), DLA (direct lateral), and DAA (direct anterior) focus groups. Categorical variables were presented as absolute numbers and percentages and compared using Pearson's Chi-Square test and Fisher's exact test among the groups.

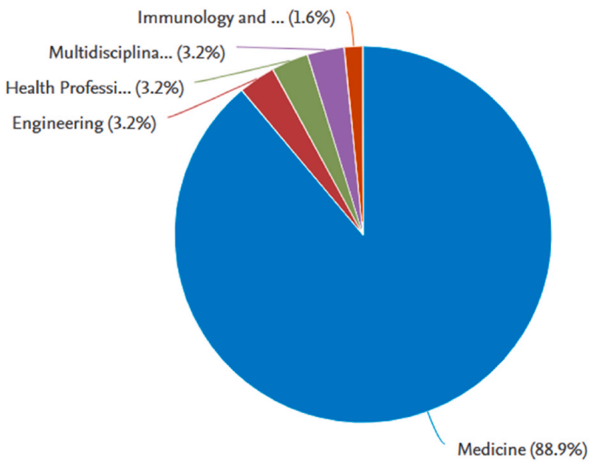

Fig. 4. Distribution of the results from query 8 according to the type of research area.

On the other hand, Welch's *t*-test and Student's t-test have been employed to compare means between groups, as demonstrated in the study by Samy et al. [60], where postoperative satisfaction between two total hip arthroplasty designs was compared. The use of these tests assumes a normal distribution of the variables of interest and homogeneous variances, conditions that must be verified before their application.

Analysis of variance (ANOVA) is another common method used in comparing multiple groups. J.B Hansen et al. [41] utilized it to contrast patient satisfaction and outcomes reported in different fast recovery pathways after arthroplasty. This technique is particularly useful when examining more than two groups or treatments and when controlling for the Type I error rate is desired.

The meticulous use of statistical methods in hip arthroplasty research aligns with scientific rigor and the commitment to the continuous improvement of clinical practice. These methods not only illuminate the efficacy and outcomes of current interventions but also guide the development of future surgical and prosthetic innovations, enabling a robust and systematic evaluation of satisfaction and postoperative outcomes.

The development of implantable devices from the perspective of design and customization through the application of advanced manufacturing techniques requires anticipating of factors affecting user satisfaction. The application of analytical tools and statistical methods to predict acceptance and success of these implants is crucial. In particular, logistic regression has proven to be a valuable statistical technique for identifying satisfaction predictors. Gerdhem et al. [21] highlight the use of logistic regression to determine predictive factors of satisfaction in arthroplasty patients, based on the EMS and EQ-5D instruments during a one-year follow-up period. This approach underscores the relevance of integrating predictive analysis into the design of implantable devices, steering towards solutions that significantly enhance the user experience.

Sinclair et al. [22] employed logistic and mixed-effects proportional regression models to assess the importance of surgeon-related variables in outcomes one year after hip arthroplasty, highlighting surgeon variability as a significant factor in postoperative outcomes, beyond patient characteristics such as age, gender, and comorbidities. This approach underscores the importance of predictive methodology in the design of customized implants, ensuring that user needs and expectations are meticulously considered.

3.6. Logistic regression models

Logistic regression models represent a fundamental statistical tool in data analysis in the field of medicine, especially in studies where the outcome is binary or categorical [61]. This type of model is particularly useful in cases where predicting the probability of an event's occurrence, such as patient satisfaction after hip arthroplasty, based on a series of predictors or independent variables [21,25,27,62,63]. Logistic regression is ideal for this purpose as it can handle both continuous and categorical predictor variables and is robust to situations where the relationships between variables are not linear.

Regression models, both linear and logistic, have been key in identifying factors contributing to the success of arthroplasty [22,64]. Regression allows not only for estimating the strength and direction of the association between variables but also for adjusting for potential confounders, offering a more accurate perspective of the relationship between independent and dependent variables.

Shichman et al. [59] conducted a binary logistic regression analysis to identify the variables linked with poor cement fill quality. The analysis drew on existing literature and adjusted the sample size to achieve 80 % power with an alpha level of 0.05. Projections showed unsatisfactory cementation rates of 7.0 % for posterior approaches and 15.0 % for anterior approaches. Furthermore, they evaluated inter-observer reliability using the intraclass correlation coefficient, considering values over 0.9 as good. All statistical analyses were carried out using SPSS statistical software (v.28) from IBM SPSS Statistics in the USA, where a p-value below 0.05 was deemed statistically significant.

On the other hand, Reito et al. [65] conducted a metaregression analysis to assess whether differences in the prevalence of confirmed ARMD revision at different detection levels remained after adjusting for publication year and follow-up time. In cases of high heterogeneity (p-value <0.1), a random effects model was used instead of a fixed effects model. This was determined using the I2 statistic, and if necessary, the DerSimonian-Laird estimator was used as a random effects model. Moreover, an Arcsine transformation was performed for the summarized measure, i.e., for the prevalence of confirmed ARMD revision. The Arcsine transformation was preferred over the logit transformation since zero prevalence was overrepresented in the study. All analyses were stratified by the implant concept (HR/LD THR/MD THR). Additionally, a "best case" sensitivity analysis was conducted using only femoral stems from studies with patients undergoing hip resurfacing.

Together, these studies integrate advanced statistical analyses into the realm of hip arthroplasty. By addressing various aspects, ranging from patient comorbidities to surgical volumes, these statistical models facilitate a comprehensive evaluation of factors influencing patient satisfaction, cost management, and clinical success. This incorporation of sophisticated statistical methods highlights a continual dedication to enhancing the quality of patient care and operational efficiency within healthcare.

3.7. Application of the logistic model

Logistic regression serves as a standard method for modeling relationships between a binary outcome variable, which typically take values of 1 or 0. Such variables are prevalent in social, medical, natural sciences, where the response often indicates the presence or absence of a specific characteristic of interest [66]. These models are frequently employed in studies examining predictors of satisfaction in hip arthroplasty [21,22].

In this study, data were collected from a sample of 12 orthopedic specialists who have conducted hip arthroplasty surgeries in Colombia. Semi-structured interviews were used to gather the data. The logistic utilized in this study considers the specialists' opinions as response variables Y_i regarding the application of customized implants obtained through additive manufacturing in hip arthroplasty. This response variable takes the value 1 with probability p_i if the doctor chooses to apply the implant or 0 with probability $1 - p_i$, if the doctor does not. Age is considered as the independent variable, categorized into three levels (20–35, 36–50, >50). It is important to note that when including age as a factor, it must be incorporated into the model as a dummy variable [67]. Since there are 3 levels, only two variables (X_1, X_2). are considered in equation (1). The hypothesis of interest pertains to the influence of age on the doctor's decision, see equation (1).

$$\text{Logit}(\boldsymbol{p}_i) = \boldsymbol{\beta}_0 + \boldsymbol{X}_1\boldsymbol{\beta}_1 + \boldsymbol{X}_2\boldsymbol{\beta}_2 \quad (1)$$

The results are shown in Table 4.

It is observed in Table 4 that the p-values (0.355, 0.997) corresponding to the age ranges 36–50 and > 50, compared to the age range 20–35, do not exhibit a statistically significant difference, considering a significance level of 5 %. Based on these findings, it is concluded that factors other than the doctor's age predominate in the selection of customized implants.

In the context of logistic regression models, several goodness-of-fit tests and pseudo-R-squared statistics are used to assess the fit of the model to the data. Here, we interpret the following coefficients: Hosmer and Lemeshow test [61], McFadden's R-squared [68] and Nagelkerke's R-squared [69]. The adequacy of the logistic model, as confirmed by the Hosmer and Lemeshow goodness-of-fit tests (p-value = 0.9999) Hosmer y Lemeshow (p-value = 0.9999) [61], reinforces the validity of the results and their application in the study context.

While McFadden's R-squared value of 0.2055 confirms the above, because values for McFadden's R-squared between 0.2 and 0.4 are considered indicative of a good model fit in logistic regression [70]. Additionally, Nagelkerke's R-squared value of 0.3233 indicates that age explains approximately 32.33 % of the variance in the decision-making process of physicians regarding the application of customized implants obtained through additive manufacturing in hip arthroplasty. This value is relatively high for a logistic regression model, suggesting a reasonably good fit. These results reinforce the validity of the model and its applicability in the study context.

This highlights an important implication for the design of customized implants, emphasizing the necessity to focus on other factors potentially associated with the specific characteristics of the patient or to the technical expertise and experience of the doctor, beyond their age, to guide the customization of implants and achieve user satisfaction. It is important to note that when adding more factors to the logistic regression model, care must be taken to avoid overfitting, which occurs when there are more parameters to estimate than the sample size [71,72].

4. Discussion

The development of hip implants is a complex task that involves addressing a multifactorial challenges related to the degenerative joint pathologies. This complexity is evident in the imperative to minimize the risks of implant malfunction, considering that these devices are directly integrated into the human body, while ensuring patient satisfaction. The latter is crucial for enhancing patients' well-being and restoring their medical, functional, and psychological conditions. Studies by Khatib et al. [38] and Manero et al. [73] have underscored the importance of integrating biomechanical and psychosocial aspects into the design of implants for arthroplasty. However, to the best of the authors' knowledge, no studies have explored the link between the design of customized implants and satisfaction factors in hip arthroplasty.

In the Colombian context, Lopez-Rincon et al. [34] identified a higher rate of complications in hip arthroplasties, despite significantly lower costs compared to countries like the United States, Australia, France, and Canada. While this study sheds light on the economic perspectives of hip arthroplasty in Colombia, it does not specifically address aspects of implant design or its impact on quality of life, emphasizing the absence of detailed arthroplasty registries present in other countries. This gap underscores the necessity for a national joint replacement registry in Colombia, enabling the evaluation of modifiable variables to reduce early mortality, disability, and optimize functional outcomes.

In terms of medical device design for hip arthroplasty, innovation and customization of implants of implants emerge as critic aspects [74–76]. The statistical analyses in this study offer a comprehensive perspective, enabling implant designers and orthopedic surgeons to better understand how various variables can influence postoperative outcomes and patient satisfaction [12,77,78]. The application of models such as logistic regression analysis and other multivariate models reveals key patterns and relationships between patient characteristics and implant success.

In this discussion, the significance of statistical models in enhancing these aspects is underscored. Statistical analyses, such as those presented in this study, provide a comprehensive perspective, enabling implant designers and orthopedic surgeons to better grasp how various variables can influence postoperative outcomes and patient satisfaction.

Therefore, the design and development of hip implants entail not only engineering and medical considerations but also encompass ethical and social considerations, which are approached from a more human perspective by the design discipline [79,80]. The convergence of these disciplines underscores the necessity for a multidisciplinary approach to tackle the inherent challenges in

Table 4
Logistic model results.

	Estimate	Std. Error	Z_value	P_value
Intercept	−0.6931	1.2247	−0.566	0.571
Edad 36-50	1.3863	1.5	0.924	0.355
Edad >50	19.2592	4612.2021	0.004	0.997

creating implants that are not only functional and durable but also accessible and satisfactory for patients [81,82]. Such an approach ensures that the innovations in hip arthroplasty cater to the diverse spectrum of patient needs, blending technical excellence with ethical and social responsibility.

In this context, additive manufacturing emerges as a technology that, with the onset of industry 4.0, has facilitated the production of objects that would have been unattainable through other technologies. The design flexibility offered by additive manufacturing, particularly in arthroplasty, allows for the fabrication of implants that, in terms of anatomical fit, can conform to bone cavities with minimal disruption while simultaneously restoring the functional integrity of the human body [83]. However, the expenses associated with customized implants in hip arthroplasty, in comparison to standardized implants and associated medical procedures, signify that access to such medical devices is not yet universally attainable'.

In the realm of operating room care and surgical planning, advancements in technologies facilitating the analysis of diagnostic images have been augmented through the integration of artificial intelligence [84,85], This, coupled with the expertise of the surgeon', aims to enhance treatment selection from a functional perspective. Conversely, robotic-assisted surgery aids in mitigating the risks associated with human errors during surgical procedures, thereby reducing the likelihood of implant failure and, consequently, enhancing the overall success of hip arthroplasty for patients.

Hence, several factors come into play when considering hip arthroplasty, encompassing aspects related to the patient and the implant [86]. Design as a discipline facilitating the creation of artifacts that establish a connection with the user from the outset, has had limited involvement in the development of such implants [74]. Furthermore, when referring to the patient within the context of arthroplasty, they are categorized as one of the users of the implant, with recognition of other stakeholders who also interact with the implant, including manufacturers, instrument technicians, and surgeons.

In the systematic literature review conducted, a significant gap was identified in studies addressing the design of customized implants and their impact on patient satisfaction. This gap appears to exist for several reasons. Firstly, the interdisciplinary nature required to combine knowledge from design, engineering, statistics, and medicine is complex and not always comprehensively addressed in current studies. Additionally, the technology necessary for implant customization, such as additive manufacturing, is still under development and has not been widely adopted in clinical practice [87–90].

Another factor is the lack of longitudinal and robust data that directly correlate the customized implant design with long-term patient satisfaction. The collection of such data requires significant resources and prolonged follow-up, which can be challenging for many research institutions [34].

To address this gap, it is essential to foster interdisciplinary research that integrates customized implant design with detailed evaluations of patient satisfaction. Future research should focus on developing and validating statistical models that can predict patient satisfaction based on specific implant design characteristics and preoperative and postoperative clinical data. Moreover, the creation of detailed and long-term arthroplasty registries could provide the necessary data to adequately assess the impact of customized implants on patient satisfaction [37,91,92].

These efforts align with the practical implications identified in this study. The findings of this study have important practical implications for clinical practice and future research. In the clinical field, the results suggest that integrating statistical methods into implant design can significantly enhance customization and, consequently, patient satisfaction [21,41,86]. This could lead to better postoperative outcomes, reducing the need for revisions and increasing patients' quality of life.

For healthcare professionals, these findings underscore the importance of considering individual patient factors when selecting or designing an implant. The use of predictive models and advanced analysis techniques can help identify which patients would benefit most from customized implants, thereby optimizing clinical outcomes and treatment efficiency [46].

From a research perspective, this study highlights the need for multidisciplinary approaches that combine design, engineering, statistics, and medicine to advance the field of arthroplasty [74]. The creation of research consortia bringing together experts from these diverse areas could facilitate the development of more advanced and personalized implantation technologies.

5. Conclusions

This study underscores the paramount importance of integrating statistical models and methods into the design of implants for hip arthroplasty, bridging the gap with the design discipline. Incorporating these models offers a unique opportunity to enhance implant customization, ultimately optimizing their effectiveness, safety, and longevity. Particularly, logistic regression and other multivariate models have emerged as invaluable tools for deciphering the intricate relationship between various patient variables and implant outcomes. These findings underscore the necessity for a multidisciplinary approach in implant design, wherein design, engineering, medicine, statistics, and patient psychology intersect to comprehensively tackle the challenges associated with hip arthroplasty.

Moreover, this study delineates and addresses the gap in scientific literature concerning the correlation between customized implant design and patient satisfaction in hip arthroplasty. It underscores the imperative for future research to delve deeper into this association, especially in regions like Colombia where studies are scant, and the absence of detailed registries hinders a comprehensive evaluation of implants. Ultimately, the conclusions draw from this research advocate for a deeper integration of advanced statistical methods and state-of-the-art technologies in implant design, always mindful of the ethical and social implications, to enhance the quality of life of hip arthroplasty patients.

The outcomes of the logistic model suggest that the age of the specialist doctor does not significantly influence the decision to opt for customized implants, opening new avenues for future research, particularly in employing logistic models to pinpoint satisfaction predictors in the design and application of orthopedic implants. These findings imply that factors beyond the professional's age may wield considerable influence in decision-making regarding implant customization, underscoring the necessity to delve deeper into the variables affecting patient satisfaction and clinical outcomes.

Subsequent studies should concentrate on exploring a broader spectrum of predictors, encompassing patient variables such as specific anatomy, pre-surgery physical activity, recovery expectations, and the doctor's experience with customization technologies. Leveraging advanced logistic models to analyze these variables will facilitate the development of a more sophisticated and personalized framework for implant design, thereby augmenting patient satisfaction and long-term outcomes. This approach will not only contribute to the refinement of orthopedic implants but also foster enhanced customization in treatment, ensuring that the individual needs and preferences of patient are considered in the implant design and selection process.

Integration of statistical methods in implant design is crucial, emphasizing the need for multidisciplinary approaches and customization to enhance patient satisfaction. Future research should focus on developing predictive models, exploring additive manufacturing technologies, creating long-term arthroplasty registries, fostering multidisciplinary collaborations, and evaluating the cost-effectiveness of customized implants. These directions will help bridge the identified gaps in the literature and contribute to the advancement of personalized implant design, ultimately improving patient outcomes and satisfaction.

Ethics approval and consent to participate

All procedures performed in studies involving human participants were conducted in accordance with the ethical standards of the author's institution and with international and national ethical guidelines and their amendments. The study was approved by the Research Directorate of the Instituto Tecnológico Metropolitano (ITM) of the author (Cooperation agreement No. 49 of March 1, 2021).

Consent for publication

No participants were contacted without their permission.

CRediT authorship contribution statement

Enrique Quiceno: Writing – review & editing, Writing – original draft, Visualization, Validation, Software, Methodology, Investigation, Formal analysis, Conceptualization. **Cristian David Correa:** Writing – original draft, Validation, Methodology, Conceptualization. **Jose A. Tamayo:** Writing – review & editing, Writing – original draft, Validation, Supervision, Methodology, Investigation, Data curation. **Alejandro A. Zuleta:** Writing – review & editing, Validation, Supervision, Resources, Methodology, Investigation, Conceptualization.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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