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Orthopaedic Surgeons Appropriate Use Criteria for Humeral Component Design During Primary Anatomic Total Shoulder Arthroplasty

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Abstract

Background: Total Shoulder Arthroplasty (TSA) is known to be one of the popular surgeries that are performed for managing severe diseases of the shoulder joint. The characteristic of the humeral component implemented in TSA greatly affects the postoperative results, however, development and choice of the design remain issues among the orthopaedic surgeons.

Aim: The purpose of this paper is to set up the criteria to use the appropriate humeral component design in primary anatomic TSA for the betterment of patients' outcomes and the greater uniformity in the surgical procedure.

Method: This study employed the Delphi method, parallel focuses consensus panel discussion, and a review of past literature. Specialists in the field of orthopaedic surgery must have had years of TSA surgery involved in the study and patients' records. On data gathering, questionnaires, interviews, and imaging were used. This is due to the consensus of experts' knowledge, and statistical confirmation of the formulated criteria. The ethical clearance was sought, and approval was obtained, consent was also obtained from the participants, and it was made very clear that their information would remain confidential and would be protected.

Results: The patients total was 500, and their age range spanned from 45 to 85 years with equal distribution of males and females. The humeral components utilized were monoblock in 35% of the patients, modular in 45% of the patients, and stemless in 20% of the patients. Survey revealed that component selection was carried out based on the following patient factors in which the surgeons had an almost perfect consensus of 85-90%. The statistical analysis supported the criteria that vital requirements for a successful strategy were met; more profound results were proven as related to the proper utilization of

components. The AUC concurred with the existing guidelines but gave more specifics, which showed where the need for enhancement was.

Conclusion: The derived AUC for choosing the humeral component in TSA offer practical recommendations for orthopaedic surgeons, improving the accuracy of the operation and its impact on the patient's well-being. Therefore, the study is a useful contribution towards orthopaedic surgery with a passionate call for more research and practice of standard principles.

Introduction

Total Shoulder Arthroplasty (TSA) is the surgical intervention to relieve pain and improve function in patients with end-stage shoulder joint diseases including osteoarthritis, rheumatoid arthritis or post-traumatic arthritis among others. This process entails the act of resurfacing the bones in the shoulder with two artificial parts known as the humeral component that mimics the head of the humerus and the glenoid component that imitates the socket part of the shoulder bone. TSA has also undergone certain changes since its emergence in the early 1970s; surgical procedures and implantable devices produced have also seen some enhancements thus enhancing patients' welfare [1].

One of the features of TSA that has emerged as very crucial in the recent past is the type of the humeral component. Understanding of the features of the shoulder's humeral component is crucial in the evaluation of an overall result of the surgery and such factors as stability, range of motion, and implant's service life. Several designs are available for selection: monoblack, modular, stemless, and many of them have their pros and cons [2]. Monoblock designs are less complicated and are generally employed in less complicated situations such as cavity

Such approach helps to make sure that established criteria are adequate and feasible and can be used for various clinical cases. Thus, it seems reasonable to expect that by offering well-

preparations that do not require significant adjustments intraoperatively, whereas modular designs give more flexibility because adjustments to the restoring interarch dimensions can be made during surgery according to the measured patient's tissues. Stemless designs do not involve the use of the humeral stem that is required to be fixed into a medullary canal; they are increasingly used being less invasive to bone tissue and easy to revise in the future, if necessary [3].

Thus, numerous advances in the design of the humeral component have been made, and still, several questions remain before the orthopaedic surgeons' choice. The first reason is due to a common variation in the patients' skeleton, quality of bone, as well as the pathology of the particular disease. Also, new practices do not have strict protocols other than common experiences and thus, varying approaches are used depending on the surgeon's chances. Such an attitude can lead to different results, with some of the patients having non-ideal implants due to the inappropriateness of the choice [4].

Since humeral component design has been increasingly recognized as a critical factor in TSA, and due to current status of TSA as one of the major concerns of orthopaedic surgeon, the present effort is directed to identify Appropriate Use Criteria for the inclusion of primary anatomic TSA. The reference objectives include: The main aim is to establish a format for optimizing the selection of the appropriate humeral component by surgeons for specific patient characteristics and context situations. Thus, the study aims to improve patients' quality, decrease the variation in surgical activities, and encourage the use of research data by orthopaedic surgeons [5].

The formation of AUC calls for a stepwise approach of postulating, assembling, and polls of specialists, as well as clinical data and consensus. defined recommendations with regard to the typology of humeral components and specific surgical contexts that would require the use of this or that kind of part, the AUC can contribute to the formulation of most reasonable strategies for practice based on the evidence currently available [6].

The ramifications of the study are immense for the surgical practices as well as patients' management. First of all, adopting AUC as the criterion to measure the performance of methods used to predict MACE after TSA can result in higher levels of reliability and reliability when it comes to patients' outcomes. Standardized who guidelines help surgeons to decide and choose the best design of the humeral component compatible with each individual patient's anatomy with the consumption of the best surgical outcomes. This is especially in challenging situations whereby the type of implant to be used strongly determines the outcomes of the intervention [7].

Secondly, the conclusions which are derived from the present research can be useful to extend the current knowledge and practice in the sphere of orthopaedic surgery basing on the exploitation of the identified gaps in the existing literature. Even though many studies have been published regarding TSA and implant design, there is a scarcity of guidelines to report on suitable usage of humeral components with detailed research. Thus, this study can be useful for orthopaedic surgeons, educators, and policymakers as a source of a structured approach towards implant selection.

Thus, there is a good potential for the AUC to improve the education and training of orthopaedic surgeons. When integrated into training and education programs, the criteria will enable the surgeons learn more current evidence and discovery to practice better. This knowledge can enhance the techniques used in surgeries, the decisions made and consequently the quality of the patient care offered to them [8].

The conclusion of this research study is not only on the final destiny of a patient who has been admitted in the hospital or a practice that is acted out on the operation theatre floor. Thus, promoting the guidelines based on evidence can help the AUC increase the general efficiency within healthcare. It is possible, however, to decrease the rate of complications, revisions, and reoperations through adherence to standardized measures, resulting in saving for both, patients and the health care entities. In addition, the criteria can enhance the interaction among stakeholders concerning the treatment of patients who are slated for TSA.

Therefore, the creation of Appropriate Use Criteria for the humeral component design during primary anatomic TSA is a significant advance toward enhancing patient outcomes and refining the standards of osseous reconstruction carried out by orthopaedic surgeons. The study solves an existing problem in the current literature and offers an effective model for the protection of evidence-based decision making. The AUC can offer beneficial assistance in relation to the choice of the proper humeral component for the specific patient and, in this way, improve the overall efficacy of TSA surgeries and the uniformity of the surgeons' practices, as well as contribute to the progress of orthopaedic surgery as a discipline. Such effects impose the necessity and significance of the current work on patient-oriented outcomes, evidence-based clinical practices, and health care delivery systems [9].

Methodology

This work will make use of mixed research and applied methodologies to set the AUC for the choice of humeral component at the time of primary anatomic TSA. With regard to the choice of the method, the study is conducted using Delphi method with additional consensus panel and retrospective analysis of clinical data. The Delphi method is used to carry out a survey of opinions from a group of distinguished orthopaedic surgeons comprehensively. It is a process that entails several cycles of surveys in which specialists give feedback, and the consensus is constructed structurally. The consensus panel discussions support the Delphi method by offering an opportunity for intensive discussions concerning the essential issues, and thus, the panel comes to an agreement with the AUC [10].

Targeted population in this study consists of orthopaedic surgeons who have operation experience of more than 20 cases of TSA. The criteria for inclusion of surgeons include minimum of 10 years practice and must have done a minimum of 100 purely anatomic TSA ops. The authors cover the geographical area and practice of the surgeons to get a wide view. Patients with previous failed TSA, those with postoperative follow up of less than 12 months or those patients seen by surgeons who performed <30 TSA's per year or predominantly had non-shoulder orthopaedic practice where the index procedure is the NSA. Moreover, the retrospective analysis component entails collecting the medical records of patients who have received primary anatomic TSA in the last five years. The study included patients who have severe shoulder joint disorders that required TSA and for whom patient data was complete preoperatively and postoperatively. Outliers such as patients who had operations that were not the first time they visited the theatre are not included to keep it confined to index operations only [11].

This involves the use of questionnaires, interviews, and review of patient's medical history. In the case of Delphi method, the questionnaires are structured in a manner that aims to capture qualitative data pertaining to specific aspects of humeral component design such as indications, contraindications, as well as the designers' preference of humeral components for certain clinical situations. These questionnaires are completed in a cyclic manner where every cycle involves feedback from the previous cycle till a consensus is reached.

Some of the useful techniques used to collect data includes Surveys involve filling of questionnaires, structured interviews involve follow up interviews from surveys and selected experts are interviewed to give detailed information and explanations of issues as well as clear up answers from the surveys. These interviews are a type of interview that does not have fixed questions, which let the specialists explain their opinions in detail.

The data is made up of a medical record review drawn mainly from patient attributes, clinical necessity, surgical approach, implant styles and postoperative functions. Data is gathered using various Data collection forms which are standardized hence reducing variability in data. Evaluation of the medialization, lateralization, and positioning and incorporation of the humeral components is based on the pre-operative visit and radiographic and CT studies carried out pre-operatively and post-operatively.

The strategy for development of the AUC is laid out in a sequential and cyclical manner. Firstly, the bibliographic review includes an analysis of the guidelines, applicable best practices, and the state of research on the design of the humeral component for TSA. It will form the basis for the initial set of criteria for the review presented in this study [12].

The first round of the Delphi survey is then presented to the expert panel to complete, and it comprises of a Likert scale to aiding the experts in rating the appropriateness of the various humeral component designs for various clinical uses. This is acting in an unorthodox way as the perception of this practice may be a shock to some especially in the aspect of the method used for responses whereby the latter is analysed using descriptive statistics in order to evaluate the areas of consensus and dissensus. Information is given back to the panel and other cycles of questionnaires are taken for further elaboration of criteria. This process is carried out in cycles until it reaches a pre-determined level of consensus, often represented by the percentage of experts' consensus.

There is a set – up of consensus panel at various phases of the Delphi process to sort out deep points of disagreement as well as to offer the experts an opportunity to renew discussions. These are conducted in groups and the discussion is led by a moderator and the entire discussion is video and audio taped for scripting and later transcription.

Thus, the survey data are analysed using statistical tools, such as measures of central tendency and dispersion as well as inter-observer reliability. The final criteria are then checked using the data collected from the retrospective analysis to affirm that these criteria provide work in real-life clinical procedures. Other statistical tests like chi-squared tests as well as logistic regression analysis are conducted to assess the correlation between various designs of humeral components and the post-operative results [13].
The data for the study is willingly provided by the participants thus no data monetary compensation is given to the participants. The study is conducted according to the principles of ethics respect for persons, the principle of beneficence, and the principle of justice. All surgeries included patients who agreed to participate and signed for it, and the medical records of all these patients are reviewed. The consent process involves the presentation of information concerning the study, its objectives, the measures that will be undertaken, the possible hazards related to the study/benefits that are likely to be accrued, and measures to ensure that participant's voluntary to participate in the study.
Privacy of the participants is highly maintained throughout the research and strict measures of confidentiality are upheld. Every piece of data that is gathered is kept anonymous; each subject receives a code number to exclude the identification of more information about the individual. This electronic data is kept in password protected servers or in password protected disks which can be accessed only by those personnel who are allowed to do so. Paper documentation is stored in locked file cabinets in the locked rooms of the offices.
In addition, following the privacy and data protection policies; the participant's data in this study is collected and analysed following GDPR in the EU and HIPAA in the USA. The audit and data check schedules are followed to maintain the ethical practices and data security measures.
Thus, the methodology of this study incorporates a multifaceted and sequential approach toward the establishment of AUC for humeral component design in primary anatomic TSA. It further supports the strength of the study's framework by employing the Delphi method combined with panel consensus and retrospective analysis to provide effective guidelines for orthopaedic surgeons. The ethical issue is observed with a lot of concern in order to safeguard the participant's rights and privacy, making the study more valid. The resulting AUC seeks to improve patient's status, promote uniformity in surgical procedures, and in general – the progress of orthopaedic surgery [14].

Results

The sample population covered both patients who underwent primary anatomic TSA and orthopaedic surgeons as the knowledge of the current practices and outcomes was derived from them. Study participants consisted of 500 patients who received primary anatomic TSA within the last five years. Patients' age varied from 45 to 85 years with the mean age of 64 years. Similarly, the gender split of the patient was almost equal both male and female patients Accounting to 52% and 48% respectively. The clinical circumstances that resulted in TSA were as follows: OA, 65%; RA, 20%; and PT Ajax, 15%. The attraction of a diverse clinical representation guaranteed the relevance of the findings in various patient circumstances.
Regarding the distribution of the humeral component designs employed in the study, Danks observed that it reflected the heterogeneity of surgical procedures. The type of prosthesis used in the 500 evaluations implemented monoblock designs in 35 percent of the cases, modular designs in 45 percent, and stemless designs in 20 percent. This distribution can be attributed to the current trends in usage and demands of the orthopaedic surgeons in the current society with the current designs leaning more towards the modular and stemless products. Although monoblack designs were commonly used, they were mainly selected for cases with less complicated anatomy.

The Delphi method and consensus panel discussions provided important criteria on the proper usage of humeral component designs in TSA. The criteria were divided into subgroups according to characteristics of the patient, his or her bone quality and anatomical conditions, the disease specifics. In case of good bone quality and normal anatomy of the patient, stemless designs were suggested because of the bone-conserving nature of the implant and ease of the revision surgery. According to the patients' particular anatomies or poor quality of bone, the modular designs were used to fit in during the operation. It was considered that monoblock designs were suitable for cases where there are not many anatomical issues [15].

The intra-class correlation of the study's results showed that orthopaedic surgeons were agreed on the developed criteria at a high level. Finally, in the Delphi survey's last round, 85% of the panellists endorsed stemless designs for patients with good quality bones, and 90% favoured the use of modular designs for challenging anatomy. Concerning the preferences for monoblock shapes, there was 75% of the observed agreement, indicating a certain level of opposition and complexity of the identified full-body cases. Such high levels of agreement speak to the strength of the criteria and to the possibility of this work promoting the systemisation of surgical procedures.

The quantitative analysis of the findings showed the importance of the criteria that have been identified. The results of chi-square tests used to analyse the relationships between the recommended humeral designs of the component and postoperative findings indicated that there was a statistically significant relationship. Positive outcomes included the following: patients with stemless designs had fewer post-operative complications than monoblock designs ($p < 0$. The same trends were found in anatomically complex cases regarding to the modular designs where range of motion and implant stability were classified higher with applied statistical differences of $< 0. 01$. Therefore, their assumption supports the suitability of the developed criteria and the possibility of enhancing patient outcomes.

The developed AUC were then compared to previously existing proxies or guidelines and best practices as observed in TSA to show areas of compliance or divergence. The general guidelines of TSA are available from well-stated organizations like the American Academy of Orthopaedic Surgeons (AAOS), however, no specific standards are mentioned regarding the design of humeral component. To the best knowledge of the current author, there have been no such practical, specific, and systematic clinical decision support AUC developed for use in any clinical application domains to address a range of clinical questions and particularly in this current study.

Among these there is a compliance with the existing guidelines in the consideration of patient-specific factors in implant choice. These guidelines also include the necessity of considering the quality of the bone, the variations in the anatomy, and the presence of pathological processes when selecting the appropriate humeral component as well as the AUC developed in the current literature. But the developed AUC offers a finer ground up on these factors and gives a clear cut proposal with regard to the abundant forms of designs that has become possible with newer technologies.

This comparison identifies some gaps and scopes for improvement in the existing guidelines. To the best of the author's knowledge, existing guidelines do cover the aforementioned need for customized implant choice to optimize the limb length discrepancy for each patient, but they do not specify the criteria defining the individual humeral component designs necessary to fulfill it. The developed AUC address this limitation by providing a built-up structure with instructions to aid surgeons to choose the most appropriate design based on actual findings and recommended standards. These specifics increase the practical value of the guidelines and contribute to better decision-making in the field of orthopaedics [16].

In addition, the developed AUC present the current progress in the designs of humeral components, including the stemless ones that are not seen in current guidelines prominently. Infusing considerations of stemless designs into the AUC also demonstrate the current trends and new developments in TSA, which allows the surgeons to make their decisions with the support of newest effective prognosis.

Therefore, the findings of the present investigation support the tuning and usefulness of the intended AUC for designing the humeral component in primary anatomic TSA. The demographic and clinical features of the patient samples offer an up-to-date description of the current practice and result situation, showed the flexibility of the humeral component type and its consequent influence on the results. The present findings strengthening the criteria through being consistent with the orthopaedic surgeons' opinion and statistically significantly related to the favourable postoperative outcomes. The comparison is made with other guidelines to emphasize on the effectiveness of using the developed AUC, which ensures that the existing gaps in the literature are well covered, and actual and comprehensive recommendations supported by the evidence base are provided depending on the particular clinical circumstances. Such observations reveal how the AUC can improve patients' treatment, make surgical procedures more uniform, and, overall, drive the development of orthopaedic surgery as a field [17].

Aspect	Key Findings	Recommendations
Patient Demographics	500 patients, mean age 64 years, 52% male, 48% female. Clinical conditions: OA (65%), RA (20%), PT Ajax (15%).	Ensure diverse clinical representation for relevant findings.
Humeral Component Designs	Monoblock (35%), modular (45%), stemless (20%). Trends towards modular and stemless designs.	Select modular for complex anatomy, stemless for good bone quality.
Outcomes and Preferences	Stemless designs: fewer complications ($p < 0.01$). Modular designs: better range of motion and implant stability ($p < 0.01$). High agreement among surgeons.	Use stemless for good bones, modular for challenging anatomy.

Discussion

The findings of this study offer valuable information on how the designs of the humeral component should be used when performing primary anatomic TSA. The surveyed data indicates a high degree of agreement among the respondents dealing with orthopaedics concerning the applicability of certain types of humeral components in particular situations. The high levels of agreement as well as statistically significant correlation between the recommended designs and the enhanced postoperative outcomes support the clinical relevance of the developed AUC.

These findings have one of the main clinical implications on improving the patient's outcomes as the option as result in developing the implant selection guidelines for surgeons. The criteria shed light on patient predictors such as the quality and density of the bone, anatomical zones, and pathology of the tissues, which are crucial in prognosis of the outcomes of surgery. Thus, the selection of the specific humeral component for the individual patient's characteristics can take specific account of prosthesis fit, stability and longevity that should in turn decrease the likelihood of complications and enhance functional results prosthetic.

From the study, several causes could be attributed to the variation in surgeon's preferences and practices as follows: first, there is a continuous change in implant designs thus complicating the issue by presenting new choices that are not necessarily accepted or comprehended by all. Surgeons admitted to using individual experience and the extent of their acquaintance with certain designs as possible rendering variations. Second, there have been not widely accepted and scientifically based criteria for the design of the humeral component which led to the use of the rules determined by an individual surgeon's discretion. To address these gaps, this study gives clear recommendations that operationalise GRC best practices, which can assist in decreasing variance for GRC practices.

It holds several strengths that make the study strong and that enhance the reliability of the conclusion that is arrived at. The Delphi method is supported by the consensus panel discussions and retrospective analysis, which means that the issue is viewed from many perspectives and methods. It also implies that since the panel of orthopaedic surgeons is diverse in membership, the practice locations, and the years of experience, the criteria can be considered generalizable. Furthermore, the features of this study include strict statistical examination of the findings that can be viewed as the confirmation of the mentioned opinions and suggestions with reference to their applicability in clinical practice [18].

Nonetheless, the present study has limitations which may reduce the conclusiveness of the findings. The sample size that has been used in this study is relatively large, but it may still be large enough to somewhat restrict the potential generality of the conclusions and recommendations given. A limitation of the patient cohort is that despite the heterogeneity in the set of patients, it may not include all possible clinical situations that may occur across extremely rare or complicated cases. There could be slight biases in evaluating the expert's opinions as well as giving a retrospective view of their entire patient's medical records due to the possible gaps and inconsistencies in the records. It was attempted to minimize these biases by having more structured data gathering and by performing multiple validation checks, however, are in inherent element.

The possibilities of using the developed AUC in clinical practice are rather promising and may help enhance the TSA procedure's objectivity and reliability. This way, the AUC can help convey certain and accurate recommendations regarding the utilization of the humeral component to the surgeons, and eventually, boost the effectiveness of the surgical procedures. This structured approach can be especially valuable in training and information new surgeons, so they adopted all present knowledge.

The role and expected impact on the outcomes of patients' health is quite significant. With predetermined norms for determining the implant lots, it is possible for the patients to get the most suitable humeral component for the certain clinical situation – here the fit of the implant will be better and more stable and there is less risk of such complications as their loosening or malalignment. Better outcomes of the operations lead to better satisfied patients, reduced rehabilitation time, and better functions in the future. Also, the implementation of AUC in surgical procedures can eliminate a lot of revisional surgeries hence decreasing the healthcare costs.

Thus, the present study offers an empirical foundation for the appropriate application of humeral component designs in TSA; however, the findings have to be advanced by future investigations to fill the remaining voids. Subsequent investigations may therefore concentrate on the large-scale multicenter trials in order to confirm the proposed guidelines in various practice environments. Moreover, it was stated that only a few long-term prospective studies, which would consequently observe patients over a long term, could give mileage and wear of varying designs of the humeral component.

Further, one could also consider the improvements in the design of the humeral component and technical possibilities of the TSA as further research topics. Advancements such as producing individual stem-specific humeral components with the help of a 3D-printing procedure adapted for the patient's individual characteristics might help enhance the fit and functionality of the implant. Further development of minimal invasive surgery and improved fixation technologies might have positive impact on patient's outcome and LOS. Furthermore, there is the ability to make TSA even more accurate with combination of computer-imaging techniques and computer-assisted surgery planning tools.

Therefore, in the discussion of this study's results, showing how the developed AUC influenced attitudes and clinical applications as well as outcomes in primary anatomic TSA, it is possible to conclude. Thus, the number and autonomy of criteria, the validity of evaluated objects, and high degree of specialists' consensus stress such criteria's objective nature and clinical applicability. At the same time, there are some shortcomings, however, the advantages of the study provide the basis for further standardization of the selection of humeral components and increasing the effectiveness of surgeries. This paper has established that the adoption of AUC can lead to improved consistency, decrease variability, and overall management of patients' care. It is expected that future work in TSA and the advancing technologies in the future can provide better improvements in the criteria and give better advancement in the TSA techniques and implant design that will be advantageous for the patients and furthermore enhancing the field of orthopaedic surgery.

Conclusion

The study was made successful in establishing the AUC in the design of humeral component in the primary anatomic TSA because of the highly acclaimed consensus among the orthopaedic surgeons in implant selection based on the patient's requirement for the postoperative improvement. These conclusions offer operational guidelines for surgeons with regards to bone density/quality, variation in human anatomy, and the aetiologic process that underpins the disorder, in an effort to improve the aim of treatments and patients' well-being. These AUC should be implemented in the clinical practice to serve the purpose of bringing consistency across similar practices, lessening of complications, and enhancing the patient's experience and quick recovery. Thus, this study greatly benefits the presence of orthopaedic surgery and provides the required guidelines within the existing best practices to continue the research on improving TSA techniques and its outcomes.

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