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Anatomic Total Shoulder Arthroplasty: Component Size Prediction with 3-Dimensional Pre-Operative Digital Planning

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Abstract

Background: The rate, complexity, and cost of total shoulder arthroplasty (TSA) continues to grow. Technology has advanced pre-operative templating. Reducing cost of TSA has positive impact for the patient, manufacturer, and hospital. The aim of this study was to evaluate the accuracy of implant size selection based on 3-D templating. Our hypothesis was that pre-operative templating would enable accurate implant prediction within one size.

Methods: Multicenter retrospective study of anatomic TSAs templated utilizing 3-D virtual planning technology. This program uses computed tomography (CT) scans allowing the surgeon to predict component sizes of the glenoid and humeral head and stem. Pre-operative templated implant size were compared to actual implant size at the time of surgery. Primary data analysis utilized unweighted Cohen's Kappa test.

Results: 111 TSAs were analyzed from five surgeons. Pre-operative templated glenoid sizes were within one size of actual implant in 99% and exactly matched in 89%. For patients requiring a posterior glenoid augment (n = 14), 100% of implants were within one size of the template and 93% matched exactly. For stemless humeral components (n = 87) implanted, 98% matched the pre-operative template within one size with 79% exactly matched. For stemmed components (n = 24), 88% of cases were within one size of the preoperative plan and exactly matching in 83%. Humeral head diameter matched within one size of the pre-operative template in 84% of cases and exactly matched in 72%.

Conclusion: Pre-operative 3-D templating for TSAs can accurately predict glenoid and humeral component size. This study sets the groundwork for utilization of pre-operative 3-D templating as a potential method to reduce overall TSA costs by managing cost of implants, reducing inventory needs, and improving surgical efficiency.

Keywords

Arthroplasty, prosthesis, replacement, shoulder

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Introduction

The annual growth rate for shoulder arthroplasty in the USA is 13%.[1,2] This is three times the growth rate of total hip arthroplasty and two times that of total knee arthroplasty, both of which are plateauing in growth.[3] In 2011, 53 000 shoulder arthroplasties were performed in the USA alone. This figure was projected to rise above 160 000 in 2020 (before factoring in COVID-19).[4] In anatomic total shoulder arthroplasty (TSA), appropriate component positioning is crucial for optimum long term outcomes. Failure or loosening of glenoid or humeral implants account for over 50%

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of all complications in anatomic TSA often resulting in the need for revision surgery.[5] Revision TSA has been reported to lead to poorer outcomes than primary TSA, illustrating the importance of correct size and placement of implants at the time of the index procedure.[5,6]

More recent technology has permitted significant advances in technical accuracy compared to the historical approach of templating 2-dimensional radiographs using stencils and laminated component overlay for sizing of components.[7] 3-D templating software developed for shoulder arthroplasty allows virtual surgery with determination of component size prior to the actual surgery. Software programs based on pre-operative computed tomography (CT) scan DICOM images enable the surgeon to perform cuts, modify versions, visualize and select implant sizes, assess virtual range of motion, and determine positioning that may minimize component wear and impingement. This technology could potentially reduce factors that lead to failure of TSA such as glenoid loosening caused by both humeral and glenoid component malpositioning, which could lead to incorrect sizing.[8–10] These benefits and the improved implant selection and placement through pre-operative planning have driven interest in these methods.[11–17]

Though pre-operative planning software and patient-specific technology has been shown to be beneficial in TSA,[18–20] most of these studies have been aimed at demonstrating the accuracy of positioning of implants in anatomical studies. The literature is relatively limited on use of such planning tools for prediction of implant sizes needed for a given case.[15,18,21–24,25] Lee, et al utilized a 2-D templating too, however, they had overall low level of agreement with pre-operative templated sizes and actual surgical implant sizes.[25] The aim of this study was to evaluate the accuracy of component size selection for both the humerus and glenoid based on digital templating using one such program (BLUEPRINT™, Wright Medical, Memphis, TN). Our hypothesis was that pre-operative templating enables accurate predictions within one size for each of the implant components that were ultimately used during surgery.

Methods

IRB was obtained from all institutions participating in the study.

Preoperative Templating

All anatomic TSAs from five surgeons from various institutions were retrospectively reviewed when digital planning of cases had been performed during the period from July 14, 2015 through April 30, 2019. We excluded reverse TSAs, revision TSAs, hemiarthroplasties, and fracture cases. Pre-operative planning was performed using a commercially available 3-D planning tool, (BLUEPRINT™, Wright Medical, Memphis, TN). This planning tool is based off of CT scans which provides reproducible, algorithm-based assessments of osseous geometry of the glenoid and proximal humerus.[26,27] This software program facilitates determination of component sizes for the glenoid and humeral head and stem, by permitting the surgeon to configure placement with feedback as to version, inclination, and fit.

Surgical Implants

As the BLUEPRINT program is proprietary for one company's implants, we used only these implants for our study (Wright Medical, Memphis, TN). Surgeons had selected their preferred glenoid and humeral component size in each case. (Figure 1A). Glenoid components consisted of standard and posterior augmented designs. Two different humeral stems were used, the short nucleus stem for a stemless system (Figure 1B) and standard stemmed implant option (Figure 1C). The humeral head has options for both soft-tissue balancing (STB) and non-STB implants which includes additional options for both offset and height.

Data Analysis

The pre-operative templating plan for all cases from all surgeons was sent to one institution for collation of the data. The implant records for the respective cases were sent independently for review and analysis. Patient information was deidentified. The pertinent information collected on actual surgical implants used during surgery included the sizes for glenoid component, humeral head diameter, and humeral stem. Sub-stratification of humeral head diameter data was also performed for STB and non-STB implants, as well as, glenoid components with augmentation. The actual implant sizes were then retrospectively compared to the pre-operatively templated data. Primary data analysis consisted of an unweighted Cohen's Kappa to test absolute agreement. Statistical analysis was conducted using SPSS v. 25.0 (IBM Corp., Armonk, NY).

Results

Population

Data from 111 TSAs were collected from the five participating surgeons for all cases templated within the study dates. All cases were templated pre-operatively for glenoid size, humeral stem size, and humeral head diameter. Fourteen (13%) of the included cases utilized a posterior glenoid augment. On the humeral side, 87 (78%) were templated for stemless implants, and 24 (22%) for a standard stem design. Of the 87 stemless implants, 10 (9%) utilized STB humeral heads versus 77 (91%) which used anatomical (non-STB) humeral heads.

Implant Size Matching

Table 1 illustrates the rates of matching accuracy of the pre-operatively templated implant size to the actual surgical

Figure 1. (A) Axillary radiograph demonstrating a glenoid component with a 15° posterior augment. (courtesy Michael T. Freehill). (B) Grashey radiograph demonstrating a stemless design humeral component with a nucleus stem and a non-soft tissue balancing humeral head component. (courtesy Michael T. Freehill). (C) Grashey radiograph demonstrating stemmed and high-offset humeral head components. (courtesy Michael T. Freehill).

components implanted. Pre-operative templated glenoid sizes were within one size of the actual glenoid component implanted 99% of the time and exactly matched 89% of the time (kappa 0.878, 95% CI 0.809-0.947). When a posterior glenoid augment (n = 14) was utilized, 100% of implants were within one size of the template with 93% matching the pre-operative prediction exactly (kappa 0.875, 95% CI 0.630-1.112).

Humeral implant selection demonstrated similar results. Of the stemless humeral components (n = 87) implanted, 98% matched the pre-operative template within one size with 79% exactly matching the template (kappa 0.619, 95% CI 0.482-0.755). For the stemmed components (n = 24), in 88% of cases the stem selected was within one stem size of the pre-operative plan and exactly matched in 83% of cases (kappa 0.509, 95% CI 0.249-0.769).

Table 1. Implant Size Matching.

	Matching Within One Size	Exact Matching	Kappa (95% CI)
Glenoid Size (n=111)	99%	89%	0.878 (0.809-0.947)
Glenoid Augment (n=14)	100%	93%	0.875 (0.630-1.112)
Ascend Flex Standard Humeral Stems (n=24)	88%	83%	0.509 (0.249-0.769)
Simpliciti Nucleus Stems (n=87)	98%	79%	0.619 (0.482-0.755)
Humeral Head Diameter, All Cases (n=111)	84%	72%	0.804 (0.735-0.873)
Humeral Head Diamter, On Stem Only (n=24)	79%	71%	0.712 (0.519-0.904)
Humeral Head Diamter, Nucleus Simpliciti Stems (Non-STB + STB) (n=87)	97%	84%	0.814 (0.735-0.892)
Humeral Head Diameter, Nucleus Simpliciti Stems (Non-STB) (n=77)	99%	71%	0.813 (0.731-0.896)
Humeral Head Diameter, Nucleus Simpliciti Stems (STB) (n=10)	80%	80%	0.687 (0.417-0.958)
	>90% Matching		
	80-89% Matching		
	70-79% Matching		

Humeral head diameter for all cases was matching within one size of the pre-operative template in 84% of cases and exactly matching in 72% of cases (kappa 0.804, 95% CI 0.735-0.873). Further sub-stratification of the humeral head diameter data shows that in the case of stemless implantation of an anatomical head, the humeral head predicted by the software plan was within one size of the implant in 99% of cases and exactly matching in 71% when the surgeon selected the non-STB heads. Soft Tissue Balancing heads still were within 1 size and exactly matching 80% of the time. Figure 2 illustrates the accuracy of the templated sizes in graph form.

Discussion

This study validated our hypothesis that virtual pre-operative planning can reliably predict the component size utilized for anatomic total shoulder arthroplasty. Glenoid component size selection was more accurately predicted than humeral components. The components pre-operatively templated matched within one size of the actual implant in 99% of cases for the glenoid, 98% for the stemless humerus, 88% for the stemmed humerus, and 84% for humeral head diameter. Though previous studies have assessed the ability of 3-D templating software in positioning of components, little data exists regarding the ability of pre-operative templating to identify the component sizes needed for surgery with a high level of accuracy.[11,15,18,19]

Pre-operative planning software and patient-specific technology has previously been shown to be beneficial in TSA.[18–20] Recently, Raiss et al published on glenoid implant size accuracy from their pre-operative planning using the same BLUEPRINT system (Wright Medical, Memphis, TN). They reported complete concordance of 85% between the pre-operative plan and final implant size selection in the anatomic TSA's. A methodological difference of that study in comparison to this current study was pre-operative awareness of the study which could elicit bias. In our study, the surgeon authors were not aware this study would be done as it was conceived at a later date.[16] Otherwise, most of the current literature has been focused on improvement in the accuracy of implant placement. Lee et al used Advanced CasePlan™ templating (Stryker Imaging, Flower Mound, TX, USA) for predicting humeral components with a 2-D templating system for TSA. The authors reported templating sizes for head, stem size, and neck angle matched implants within one size only 53-77% of the time.[25] A fundamental difference between the Raiss et al and the Lee et al is that the former was not assessing accuracy of implant sizes, but just reporting concordance between the plan and implant. Iannotti et al showed 3-D pre-operative templating software significantly improved glenoid positioning as compared to 2-D imaging with accuracy within 5° of inclination and 10° of version.[28] The study, however, did not assess the ability of the templating software to accurately predict implant sizes. In a randomized control trial, Hendel et al showed that 3-D pre-operative planning resulted in significant reduction in malpositioned glenoid components using patient-specific instruments.[22] Again, this study contrasted by assessing the ability of the 3-D pre-operative planning to predict implant sizes. This technology has been utilized for humeral head size selection with success by Lima et al in measurements of both humeral head diameter and height.[19] Utilization of 3-D pre-operative planning enables the surgeon to visualize or simulate the surgery prior to the actual case. Ultimately, this could help reduce the need for trialing of several different implant sizes before final selection which in theory could help reduce operative time, increase overall efficiency, potentially reduce complications such as fracture,[20] and identify poor cuts if size discrepancy is present. Further studies are warranted to help determine if these benefits could be realized.

A closer look at the data shows that the stemmed humeral components had slightly worse predicted accuracy when

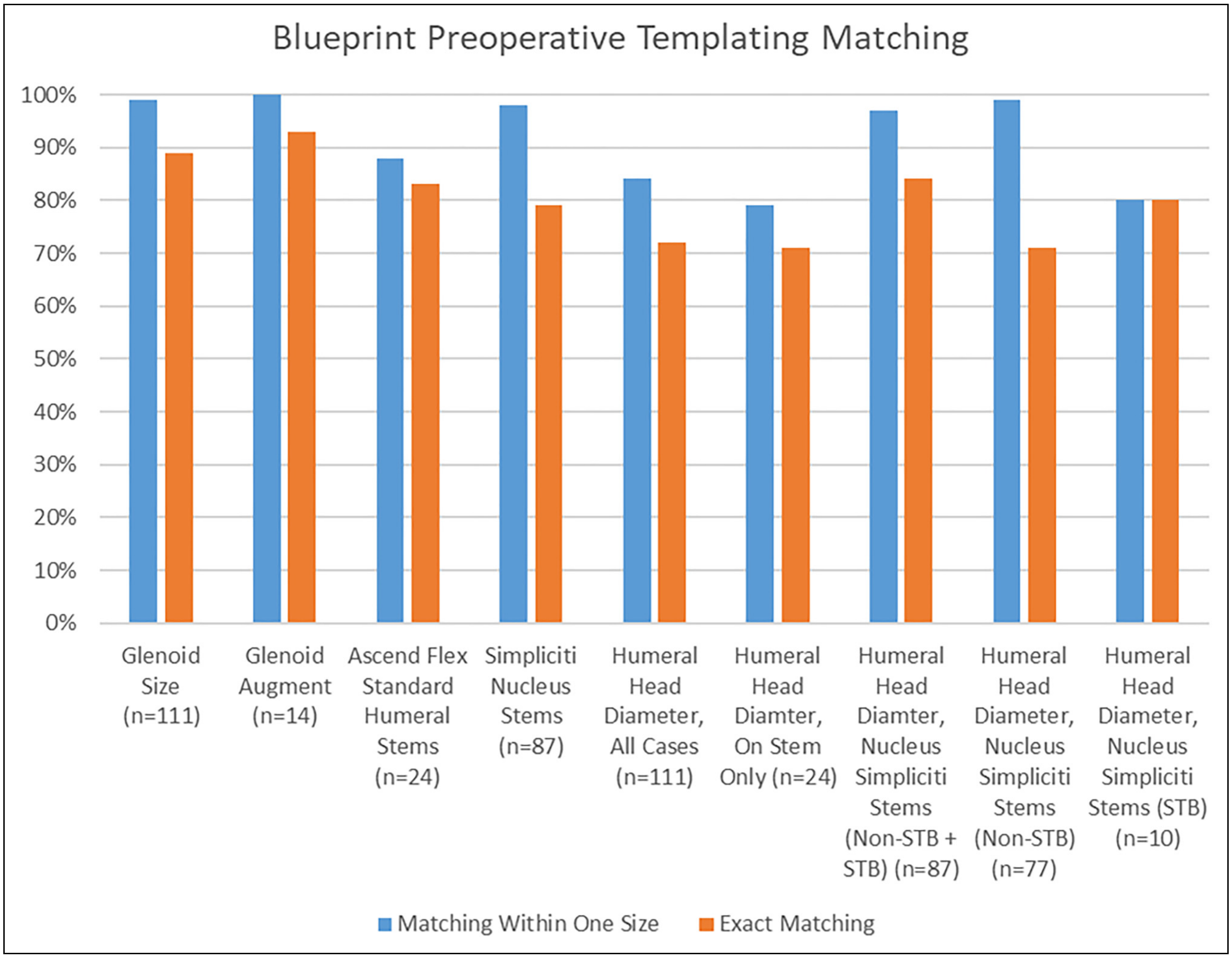

Figure 2. Illustration of accuracy of preoperative templating of implants.

compared to the nucleus stems from the stemless system. This is likely related to metaphyseal morphology differences of the proximal humerus resulting in less consistency when templating for a traditional stem. The accuracy with the humeral head sizes on the stemmed component was also overall lower at 79% matching within one size compared to 97% with a stemless humeral implant. This is likely secondary to the refinement of the offset and humeral version that can takes place after final stem selection and implantation determined at the time of surgery. Additionally, the inability to measure the retroversion of the humerus makes replicating the exact planned cut at the time of surgery more difficult. Future refinement in humeral sided templating technology and cut assistance could further improve the precision of stem pre-operative size predictability which would thus improve humeral head pre-operative predictability and definitive predictability at the time of surgery.

This study focused on one 3-D templating system using only Wright™ medical primary anatomic TSA systems. There have been previous studies looking at accuracy of other 3-D templating systems, but few to our knowledge have looked at the potential of the templating software to accurately predict implant sizes. Iannotti et al utilized OrthoVis (Cleveland Clinic, Cleveland, Ohio) for planning of glenoid component orientation, however, they did not note significant difference in results compared to standard instrumentation.[18] Werner et al utilized Imascap™ (Brest, France) and illustrated improved accuracy of glenoid component version and accuracy compared to 2-D planning.[29]

In the current healthcare climate, it is important to stress initiatives to reduce implant costs and improving efficiency. Pre-operative templating with a 3-D planning tool is a potential cost-saving opportunity in shoulder arthroplasty. This could be realized via improved supply chain and inventory management, reduced central sterilization cost by streamlining tray size and dependence, and faster operative times. We believe that prediction of component needs for a given case, within one or two sizes, could lead to a substantial inventory reduction of what is brought to an individual case or in certain circumstances decreasing already limited hospital shelf space. Additionally, there could be cost savings for the manufacturer through reduced costs of goods (COGs). It has been reported that approximately 10% of implants are lost, damaged, or expire.[30] Ultimately, this could result in lower costs to the hospitals, and increased profit for the manufacturer.

A pre-operative estimation of implant size provides the surgeon with a foundation to work from and can help to serve as an additional check to an assessment of the anatomy intra-operatively. In response to an estimated 20% of dissatisfied patients' outcomes after total knee arthroplasty, the quest for more patient-specific implants was begun. This in theory would produce implants matched to an individual's *bony* geometry, potentially leading to a more durable outcome.[31] Patient-specific implants and instrumentation for making bone cuts utilizing preoperative CT scans has demonstrated precise accuracy and are comparable to computer-assisted surgery.[32] Customized implants for knee arthroplasty have been reported to provide both better rotational alignment and tibial fit without causing overhang of the tibial tray in comparison to three examined off-the-shelf implants.[33] Furthermore, patient-specific knee arthroplasty has demonstrated fewer outliers from neutral leg alignment when compared to conventional technique.[34]

The results of this study should be interpreted in light of a few limitations. Pre-operative templating was not compared between surgeons for assessment of inter- and intra-observer reliability of templating, nor was there a formal control group. The surgeons in this study routinely template their cases with this technology platform and although they did not know at the time of the surgery this study would be performed, it still may not be generalizable to all surgeons. Furthermore, although the data was over a four-year period, and all the pre-operatively templated cases by the respective surgeons were submitted, every arthroplasty over that time period was not templated by the surgeon. The study was also limited to primary, anatomic TSA. Therefore, the results of this study should not be generalized to other forms of shoulder arthroplasty at this point. While the ability to utilize and plan with this technology in other cases of shoulder arthroplasty is important and valuable, we felt it was first critical to demonstrate effectiveness in cases more straightforward. It is also important to note that the study demonstrates a high rate of agreement between pre-operative templating and the implant size utilized in surgery, but cannot conclude that this was the ideal implant size or the accuracy of its placement or position relative to the pre-operative plan. Additionally, the surgeons that ultimately placed the final implants for each case were the same surgeons that performed the preoperative templating. Because of this, it is possible the surgically implanted sizes were influenced by the preoperative templating sizes, thus confounding the data. However, as noted above, this study was conceived later, therefore the surgeons in our study were not motivated from a research standpoint to make the templated and implanted sizes similar. Finally, though the templating is a powerful tool, it does not integrate bone density/quality or soft-tissue factors which could impact final component selection.

Conclusion

This study demonstrates that pre-operative 3-D digital templating for anatomic TSAs can accurately predict the glenoid component size. The humeral component size prediction was very accurate with stemless implants, but less so with standard stemmed components. Pre-operative 3-D digital templating and computer simulation has the potential to reduce overall TSA costs by managing cost of implants and instrumentation, reducing inventory needs on an individual case basis, and helping to improve surgical efficiency.

Author Contributions

Declaration of Conflicting Interests

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Ethical Approval

Not applicable, because this article does not contain any studies with human or animal subjects.

Informed Consent

Not applicable, because this article does not contain any studies with human or animal subjects.

Trial Registration

Not applicable, because this article does not contain any clinical trials.

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