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Can we predict the humerus stem component size required to achieve rotational stability in metaphyseal stability concept?

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Background: Implant manufacturers typically offer several sizes of a humeral stem for shoulder arthroplasty so that time zero fixation can be achieved with the optimal size. Stem size can be templated preoperatively but is definitively determined intraoperatively. The purpose of this study was to determine if preoperatively acquired parameters, including patient demographics and imaging, could be used to reliably predict intraoperative humeral stem size.
Methods: A cohort of 290 patients that underwent shoulder arthroplasty (116 anatomic and 174 reverse) was analyzed to create a regression formula to predict intraoperative stem size. The initial cohort was separated into train and test groups (randomly selected 80% and 20%, respectively). Patient demographics, anatomical measurements, and statistical shape model parameters determined from a preoperative shoulder arthroplasty planning software program were used for multilinear regression. The implant used for all cases was a short-stemmed metaphyseal-fit prosthesis.
Results: Metaphyseal bone density, humeral statistical shape model parameters, and humeral intramedullary canal diameter were identified as highly predictive of intraoperative final humeral prosthesis size. On the train group, a coefficient of determination R^2 of 0.63 was obtained for the multilinear regression equation combining these parameters. When analyzing the cohort for the prediction of stem size in the test group, 95% were within plus or minus one size of that used during surgery.
Conclusion: Preoperative criteria such as humeral geometry and proximal humeral bone density can be combined in a single multilinear equation to predict intraoperative humeral stem size within one size variation. Embedding the surgeon's decision-making process into an automated algorithm potentially allows this process to be applied across the surgical community. Predicting intraoperative decisions such as humeral stem size also has potential implications for the management of implant stocks for both manufacturers and health-care facilities.

The primary stability of uncemented humeral stems relies on either diaphyseal press-fit fixation or on metaphyseal stability through cancellous bone. There has been a trend in modern designs of cementless humeral components toward a metaphyseal fit rather than a diaphyseal fit.[6] The first metaphyseal fixation humeral stem was introduced over 2 decades ago by Matsen et al. The design concept of metaphyseal fixation is to achieve primary implant stability as a result of a tapered design impacted into the cancellous metaphyseal cone to avoid subsidence, rotation, or tilt. Secondary stability is achieved due to bony ingrowth into the roughened or porous coating on the stem.

Multiple humeral stem sizes are available due to the variability of patient anatomy. During surgery, the choice of stem size required to achieve metaphyseal stability is based on subjective criteria such as bone hardness, rotational stability, or pull-out strength. Several complications have been observed in relation to the humeral stem, including loosening, intraoperative and postoperative humeral fractures, stress shielding, bone resorption, bone remodeling, and malalignment.[1,3,4,6,8-11,13] While an oversized stem has been reported as a risk factor for stress shielding,[13,16] an undersized stem

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has been reported as a risk factor for malalignment[1] and subsidence.[15] To avoid oversized stem, the filling ratio has been reported to be crucial.[16] To avoid under sizing, the intraoperative rotational stability has been reported as a key factor. Although some studies elucidated the best filling ratio to avoid stress shielding (<70%) and to help the surgeon to avoid the too big stem, we miss information regarding how the rotational stability can help to avoid the undersized stems and subsidence. As such, humeral stem size choice to achieve rotational stability needs to be investigated to reduce complications associated with poor size selection.

Few studies have looked at the accuracy of preoperative templating for humeral component selection in total shoulder arthroplasty. Buzzell et al reported on analog templating of preoperative radiographs in 31 total shoulder arthroplasties with a long stem. They found that preoperative templating accurately predicted stem size in 38.5% of attempts and was within one size of the actual implant 94% of the time.[4] Interobserver reliability was moderate (kappa. 0.53). Lee et al used digital templating on 25 patients undergoing total shoulder arthroplasty with the Tornier Aequalis system.[9] They accurately predicted stem size 36% of the time and were within one size in only 77% of the cases. They found interobserver reliability was only fair to moderate (kappa, 0.39-0.72). Both of the above studies used diaphyseal-fit stems and do not address the metaphyseal stability itself.

Overall, metaphyseal fit stems make predictive preoperative templating more difficult because stem size is affected by proximal humeral bone density. Accurate templating will therefore require an assessment of local bone density. Investigating local bone density measurement in the proximal humerus, Blakeney et al demonstrated that known 2-dimensional radiographic and novel 3-dimensional (3D) measurements of bone density can reproducibly be measured from computed tomography (CT) scans.[2]

The purpose of this study was to evaluate the relationship between the stem size required to achieve metaphyseal stability and preoperative criteria including patient age, sex, etiology, humeral geometry, and proximal humerus bone density.

Our hypothesis was that there exists a linear relationship between these preoperative variables that when determined will allow the intraoperative prediction of humeral stem size.

Materials and methods

Inclusion criteria and demographics

The study received institutional review board approval and all patients provided informed consent to participate. A retrospective analysis of prospectively collected data was performed including all the patients that underwent primary shoulder arthroplasties performed by a single surgeon (GW) between 2014 and 2019. There were 181 female patients (62%) and 109 male patients (38%) with a mean age of 72 years (range, 34-99 years) at the time of the arthroplasty. For inclusion in this study, patients required a diagnosis of primary glenohumeral osteoarthritis (66%, N = 192), massive rotator cuff tear (17%, N = 48), or cuff tear arthropathy (17%, N = 50). All other diagnoses were excluded. Preoperative CT scans of the shoulders were performed prior to each arthroplasty and demographic data were collected.

Surgical technique and implants

All patients were treated with Aequalis Ascend Flex (Tornier, Montbonnot-Saint-Martin, France) anatomic (40%, N = 116) or reverse (60%, N = 174). The same short stem metaphyseal fixation implant was used for both anatomic and reverse TSA and the size used during the surgery was collected for each patient.

The short stem used in this study is available in 8 different sizes ranging in length from 66 to 94 mm based on size (Fig. 1). The stem is made of titanium and has a proximal porous coating (plasma spray) on the metaphyseal section for bone ongrowth.

A deltopectoral approach was used in all patients. The subscapularis was incised and released, and a tendon-to-bone and tendon-to-tendon repair was done afterward with 5-6 nonabsorbable sutures. The humeral head was resected with a free hand technique after removal of osteophytes and identification of the anatomic neck. After placing the glenoid component, the humeral canal was entered and sized with sounders to know the maximum size which can be used to avoid a filling ratio >70% (usually the stem size must be at least 2 sizes inferior to the maximum sounder used). Then, the humeral canal was progressively broached with a polished broach in order to compact the cancellous bone for the final implant. These compactors have the same shape as the humeral implant and were used to test rotational stability after full seating. The smallest implant with rotational stability was chosen. The definitive implant with a 1 mm press-fit was then impacted into place. If rotational stability was not achieved with a broach 2 sizes smaller than the sounder (filling ratio >70%), then the surgeon decided to cement the stem to avoid a filling ratio >70% and a risk of stress shielding.[16] During the study period, 23 patients required cement fixation due to insufficient rotational stability. Impaction bone grafting was never used during the surgery.

CT scans 3D reconstruction

Full 3D reconstruction of each shoulder joint was performed by automated software analysis (Glenosys v10.5.3; IMASCAP, Plouzané, France), which included bone segmentation, landmark detection, and anatomical measures computation.

Humeral geometry related measurements

A first set of anatomical measures was focused on the geometric characteristics of the humerus. Several measurements characterizing the proximal diaphysis were made at two levels of the proximal diaphysis. Previously established by Tingart et al,[17] level 1 is defined at the most proximal point on the humerus where the outer and medial cortical borders become parallel and level 2 is defined 20 mm distal to level 1. According to Mather et al,[11] four distances were measured, $M1$ and $M3$ being the diameter of the outer cortex of the humerus at level 1 and level 2, respectively, $M2$ and $M4$ being the diameter of the internal cortex of the humerus at level 1 and level 2, respectively (Fig. 2). The same two levels were also used to measure the humerus proximal diaphysis cortical thickness described by Blakeney et al,[2] V_{bone} and $V_{cancellous}$ were defined as the humerus volume (in mm^3) between level 1 and level 2 where the corresponding Hounsfield units in the CT scan were higher than 220 and lesser than 220, respectively. Assuming a cylinder shape of the humeral outer and inner cortices between level 1 and level 2, with a fixed height $h = 20\ mm$, the corresponding cortical thickness was measured as[2]:

$$\text{Humerus Proximal Diaphysis Cortical Thickness} = \sqrt{\frac{V_{bone}}{\pi h}} - \sqrt{\frac{V_{cancellous}}{\pi h}}$$

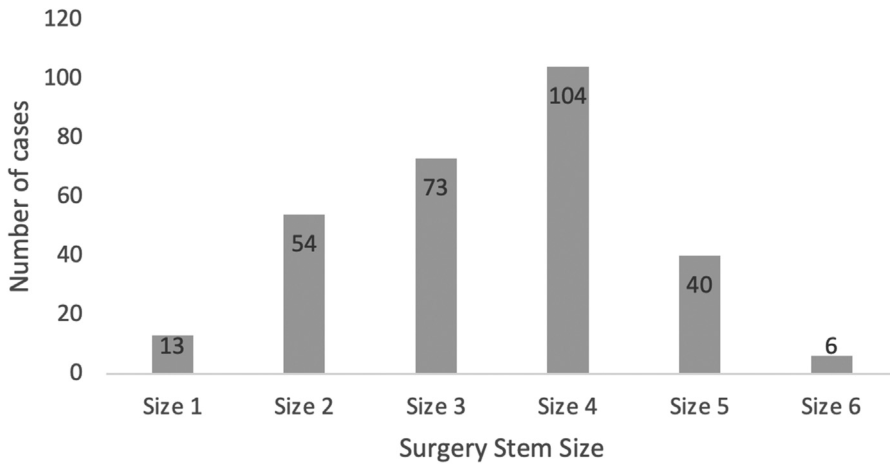

Figure 1 Stem sizes distribution.

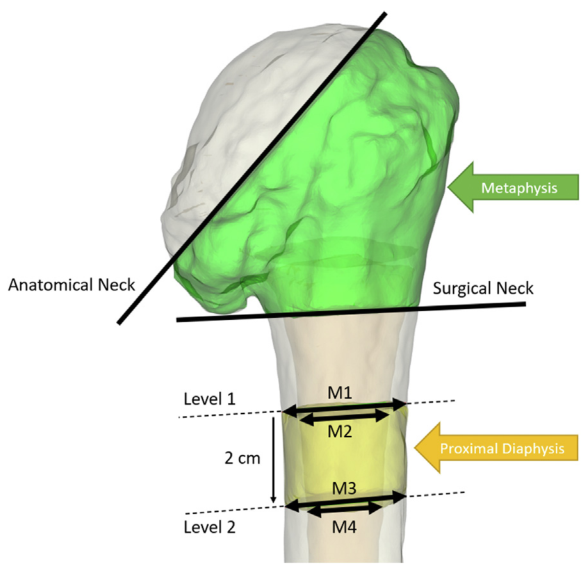

Figure 2 Humerus regions used for measuring geometry and bone density.

Humerus statistical shape model parameters

Statistical shape modeling is a well-established technique used in several fields of orthopedics like pathology prediction,[5] shape variation analysis,[7] or premorbid anatomy prediction.[12,14] Statistical shape models are built based on reference shapes that are used for matching correspondences and extract the so called "modes of variation," statistically describing the shape variation within the reference shapes.

To obtain a more complete geometric characterization of the humerus, a humeral statistical shape model (*HSSM*) was also adjusted on each humerus. The *HSSM* adjustment approach was previously described[14,18] and requires two steps. The first step consists of building the *HSSM* from the shapes of several non-pathological humerii, resulting in an average humerus shape, as well as the variation in shape of all the humerii called the modes of variation. This first step is made prior to the study; its output being a single model that can be adjusted on several new humerii that were not included to build the model. As shown in Figure 3, each mode of variation $HSSM_{\lambda 1} \ldots HSSM_{\lambda 6}$ can be used to deform the average humerus shape according to the variations within the initial non-pathological humerii used to build the *HSSM*. In the second step, for each humerus included in this study, the best values for $HSSM_{\lambda 1} \ldots HSSM_{\lambda 6}$ that minimize the distance between the resulting deformed humerus and the study humerus were determined. *HSSM* requires at least 5 cm of the proximal diaphysis to properly fit on the 3D humerus reconstruction. This fitting process was successful in 228 out of 290 humerii (79%). Adjusted values of $HSSM_{\lambda 1} \ldots HSSM_{\lambda 6}$ were measured on those 228 humerii and considered as additional indicators of the humerus geometry.

Humeral bone density related measurements

A second set of measures described by Blakeney et al[2] was focused on bone density characteristics. Humerus metaphysis cancellous and cortical bone densities were measured in the metaphyseal region between the surgical neck and the anatomical neck (Fig. 2) as the averages of Hounsfield units in the CT scan lesser and higher than 220, respectively. Humerus proximal diaphysis cortical bone density was also measured between level 1 and level 2 as the average of Hounsfield units greater than 220 in the proximal diaphysis region (Fig. 2).

Statistics and stem size prediction

Statistical analysis was performed on MedCalc Statistical Software version 19.6.4 (MedCalc Software Ltd, Ostend, Belgium; https://www.medcalc.org; 2021). Descriptive statistics were performed on the above measures. A multilinear regression model was built to predict the stem size for each case.

The initial study group was divided into two subgroups: "train group" with 80% of the cases to build the predictive model and "test group" with 20% of the cases to evaluate the performance of the predictive model. Both groups were randomly selected. Patient age, geometric, and bone densities characteristics (Table I) were used as independent variables in a multilinear regression model where the stem size was the dependent variable. As etiology and sex are qualitative variables, they were not used in the model. An automated weighted regression procedure was used. A stepwise method was used to properly enter the independent variables into the model (enter if $P \leq .05$). A chi-square test was used to test the normal distribution of the residuals. Coefficient of determination R^2 was measured to evaluate the goodness of fit of the model on the train group—it is the proportion in the dependent variable (stem size) explained by the regression model, its range is between 0 and 1. A value < 0.4 was considered a weak correlation, 0.4-0.6 was

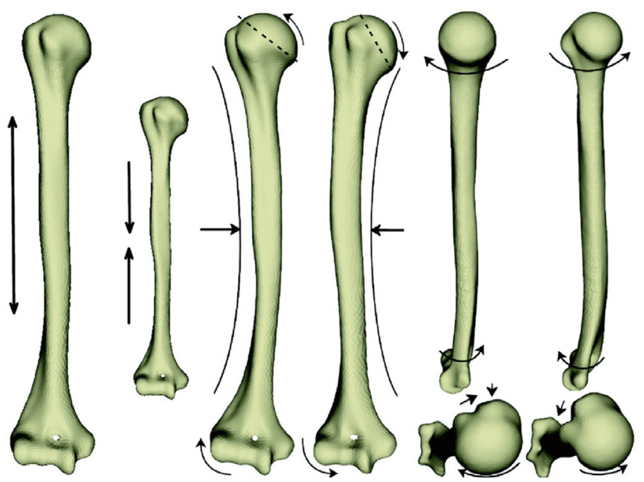

Figure 3 The anatomical limits of the humerus generated using the statistical shape model (reprinted with permission[14]).

moderate, 0.6-0.8 was strong, and >0.8 was very strong. In the test group, the percentage of correctly predicted stem sizes within one size variation was used as a clinically relevant performance indicator.

Results

Stem size prediction

The resulting coefficient of determination R^2 on the train group was 0.63. Three measures from the humerus ($M4$, humerus metaphysis cortical and cancellous bone densities) and four measures from the humerus statistical shape model ($HSSM_{\lambda1}$, $HSSM_{\lambda3}$, $HSSM_{\lambda4}$, $HSSM_{\lambda5}$) were determined as significantly contributing to the stem size and thus included in the multilinear regression equation, their corresponding P values are reported in Table I. All other measures had a P value higher than 0.1 and were not included in the multilinear regression equation: patient age, $M1$, $M2$, $M3$, humerus proximal diaphysis bone density and cortical thickness, $HSSM_{\lambda2}$, $HSSM_{\lambda6}$. Additional chi-squared testing confirmed the residual's normal distribution ($P = .5154$) assumed by the multilinear regression analysis.

In the test group ($N = 42$), the stem sizes obtained by the multilinear regression equation were correct within one size variation for 40 cases (95%). Details of stem size prediction error are reported in Figure 4.

Discussion

This study demonstrates the existence of a multilinear relationship between the smallest stem size required to achieve rotational stability during the surgery and several preoperative criteria. Three preoperative criteria significantly contributing to the stem size prediction were measured on the patient's humerus ($M4$, humerus metaphysis cortical and cancellous bone densities) and four were measured on the humerus statistical shape model ($HSSM_{\lambda1}$, $HSSM_{\lambda3}$, $HSSM_{\lambda4}$, $HSSM_{\lambda5}$). To our knowledge, it is the first study to combine humeral geometry and bone density to predict the stem size selected during surgery. The clinical applicability of this prediction depends on the future addition of the model as a software feature.

In shoulder arthroplasty, diaphyseal-fit humeral component preoperative planning reliability was reported by Buzzell et al with an accuracy of 84% to 95% within one size variation,[4] and more recently by Lee et al with an accuracy of 77% within one size variation.[9] Both studies were based on preoperative templating using software or 2-dimensional radiographs by experienced and junior surgeons. The patient cohort was relatively small in both studies (31 and 15, respectively) and these studies used diaphyseal-fit stems which are designed to fill the canal and are templated without any regard to proximal bone density. In the same way, Schnetzke and Raiss did extensive research on metaphyseal press fit fixation. They never reported subsidence of the implant, neither loosening, the problems observed were malalignment and stress shielding: they reported the maximum size which should be used to avoid diaphyseal fit and stress shielding. Our study aimed to determine rather the smallest size to be used to achieve rotational stability. The stem used in the present study is designed to have a metaphyseal fit with the aim of a stress distribution at the proximal humerus, which more closely resembles normal anatomy. Sizing is therefore affected by the metaphyseal bone density.

This study is based on a single experienced surgeon (GW), humeral component size was evaluated intraoperatively based on the rotational stability of the compactor and without humeral stem preoperative templating. Retrospectively, the stem size was correctly predicted in 43% of the cases and with one size error in 52% of the cases. This means that 95% of the stem sizes were correctly predicted within one size variation. Compared to previous studies,[4,9] the result of the present study demonstrates that an automated 3D reconstruction and stem size prediction from a multilinear equation allows to determine within a one size variation the stem size to achieve rotational stability in the metaphyseal part determined intraoperatively by the surgeon.

Metaphyseal stability, assessed intraoperatively by testing the rotational stability, is the technique used by the senior surgeon and also is the technique recommended by the manufacturer. This

Table I
Anatomical measures distribution and contribution to stem size prediction.

Measure	Average	SD	Significant contribution to the stem size prediction	Corresponding *P* value
Patient age	72 yr	10 yr	No	>.1
$M1$	24.1 mm	3.1 mm	No	>.1
$M2$	18.0 mm	3.1 mm	No	>.1
$M3$	21.5 mm	2.8 mm	No	>.1
$M4$	15.0 mm	2.7 mm	Yes	<.0001
Humerus proximal diaphysis cortical thickness	3.2 mm	0.6 mm	No	>.1
$HSSM_{\lambda1}$	−0.552	0.8990	Yes	<.0001
$HSSM_{\lambda2}$	0.00710	0.8166	No	>.1
$HSSM_{\lambda3}$	−0.0940	0.6671	Yes	.0027
$HSSM_{\lambda4}$	0.370	0.8557	Yes	<.0001
$HSSM_{\lambda5}$	−0.200	0.7902	Yes	<.0001
$HSSM_{\lambda6}$	−1.017	1.0608	No	>.1
Humerus metaphysis cancellous bone density	22 HU	29 HU	Yes	<.0001
Humerus metaphysis cortical bone density	537 HU	93 HU	Yes	.0022
Humerus proximal diaphysis cortical bone density	1025 HU	134 HU	No	>.1

SD, standard deviation; *HSSM*, humeral statistical shape model; *HU*, Hounsfield units.

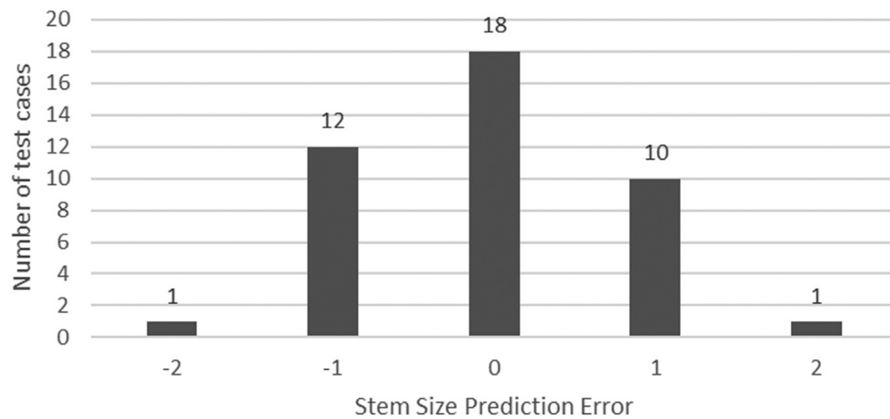

Figure 4 Stem size prediction error on test cases (20% cases not used to build the predictive model).

technique has demonstrated good results[10,19] and avoids stem oversizing and stress shielding, as well as subsidence.[13,16] This study is of interest as it distils an experienced surgeon's decision-making process into a single equation and makes it available for the broader surgeon community. These kinds of equations can also be adapted to other surgeons' experiences and needs to be tested more widely with other surgeons. Also, further studies are necessary to determine if the chosen stems provide enough stability to avoid subsidence in the mid- and long-term follow-up.

Other potential benefits of this study include considerations for implant stocks and logistics. With a reported stem prediction accuracy within one size variation of 95%, this potentially allows only three stem sizes in the operating room instead of the complete eight sizes. Furthermore, operating room staff preparedness intraoperatively with preassembly of reamers and broaches may optimize surgical time.

As in all medical fields, shoulder arthroplasty evolves over time depending on surgeons' practice and experience, published outcomes, and development of new implants. Metaphyseal stability concept has been proven to be promising with excellent clinical and radiological results reported in the literature.[6,10,15,19] Several studies were designed to determine the maximum stem size to be used to avoid stress shielding, whereas our study was designed to determine the minimum stem size to be used to achieve rotational stability of the metaphyseal part. This study is based on a single surgeon's activity in a fixed period (2014 to 2019), and thus reflects the decision process of a single surgeon over that time. This is one weakness of the study, and future research should include a larger group of experienced surgeons to compare their decisions on similar cases and study how their practice evolves over time.

Conclusion

Preoperative criteria such as humeral geometry and proximal humeral bone density can be combined in a single multilinear equation to predict intraoperative humeral stem size within one size variation. The ability to preoperatively select, with a high degree of certainty, the stem size that will be used intraoperatively has benefits with respect to implant stocks and surgical planning.

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