Reliability and accuracy of digital templating for the humeral component of total shoulder arthroplasty

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Abstract

Background: This experimental study evaluated the interobserver reliability and accuracy of pre-operative digital templating for humeral head size, stem size and neck angle for total shoulder arthroplasty.

Methods: Twenty-five patients underwent a total shoulder arthroplasty with a single prosthesis. Four independent, blinded surgeons (two experienced shoulder surgeons and two PGY-6 fellows) used pre-operative radiographs and templating software to generate templates of the humeral head, stem and neck for each patient. Interobserver reliability was calculated using weighted kappa (κ) analysis. Accuracy was assessed by comparing templates to actual implant sizes.

Results: Interobserver reliability was fair to substantial ($\kappa = 0.26$ to 0.71) for head size, fair to substantial ($\kappa = 0.39$ to 0.72) for stem size and slight to fair ($\kappa = 0.16$ to 0.34) for neck angle. Templated head size, stem size and neck angle had accuracies of 53%, 77% and 68% within one size variation, respectively. Experience did not affect accuracy ($p = 0.11$ to 0.48).

Conclusions: Digital templating is not a useful guide for pre-operative surgical planning and should not be used to select a prosthesis.

Keywords

Accuracy, digital templates, digital templating, interobserver reliability, prosthesis, shoulder arthroplasty

Date received: 23rd February 2014; accepted: 18th August 2014

Introduction

Total shoulder arthroplasty (TSA) for glenohumeral joint degeneration is a very successful procedure with predictable pain relief and substantial improvements in motion and function.^{1–3} In 2009, approximately 33,000 patients underwent a total shoulder arthroplasty in the USA.⁴ It is not without complications, however.^{5–9} In a recent study by Chin et al., the overall complications rate following total shoulder arthroplasty was 12%, with rotator cuff tearing, glenohumeral instability and periprosthetic humeral fracture being the three most common.⁶ Interestingly, only one out of 431 TSAs evaluated had glenoid loosening requiring re-operation. With 75% of shoulder arthroplasties performed by surgeons who only carry out four per year, pre-operative templating can be a useful tool in avoiding adverse patient outcomes.²

Pre-operative templating for shoulder arthroplasty allows the surgeon to evaluate the height and diameter of the humeral head, the angle of the metaphyseal cut and the diameter and length of the humeral stem.¹⁰ It also ensures that the proper equipment and prosthetic sizes are available at the time of surgery and allows surgeons to anticipate possible surgical complications

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beforehand.^{11–13} Although it is considered that pre-operative templating can decrease surgical time and complication rates, only one study has evaluated the reliability and accuracy of pre-operative templating for total shoulder arthroplasty. Buzzell et al. found that, by using magnified templates provided from a manufacturer, there was substantial intra-observer reliability for head and stem size selection, whereas inter-observer reliability was substantial for head size and moderate for stem size. Additionally, they found that the accuracy of templating the head (44% to 66%) and stem (84% to 95%) within one size variation.¹¹ To our knowledge, no study has evaluated the effectiveness of pre-operative digital templating of proximal humeral components for shoulder arthroplasty.

Analogue, or manual, templating has been a useful tool in joint arthroplasties for many years; however, it has become less practical with the growth of digital imaging because magnification issues arise when combining digital images with analogue templates.^{14,15} Digital templating offers a way to avoid these errors with quicker, more cost-efficient templating that can be easily stored for future reference.¹⁶ It has also been shown that the accuracy of pre-operative digital templating in knee and hip arthroplasty meets or exceeds that of analogue templating, thus giving more support for the use of entirely digital techniques.^{12,17–22} The aim of the present study was to measure the interobserver reliability and accuracy of pre-operative digital templating in shoulder arthroplasty and to compare the findings with those previously reported using analogue techniques.

Materials and methods

Twenty-five nonconsecutive patients who underwent total shoulder arthroplasty using a single commonly used press-fit prosthesis (Tornier Aequalis CoCr, Bloomington, IN, USA) were selected. A post-hoc power analysis was performed showing that 25 was an adequate number of patients. Selection criteria were patients indicated for primary shoulder arthroplasties that were templated using digital templating software. The digital templating software was only set-up for the Tornier Aequalis implant and only patients receiving that implant were included in the study. Patients undergoing revision arthroplasties, hemiarthroplasties and those procedures performed using either analogue or no templating were excluded. Post-traumatic, avascular necrosis and rotator cuff arthropathy surgery patients were excluded. Additionally, patients who had previous fractures or had outside imaging studies were excluded from the study. The primary diagnosis of the 25 patients was severe osteoarthritis. All surgeries took place between

1 January 2008 and 31 December 2010 and were performed by a single, experienced shoulder arthroplasty surgeon who performs greater than 100 primary total shoulder replacements per year.

The Tornier Aequalis implant is a press-fit shoulder prosthesis. Eleven head sizes (37 mm to 54 mm), seven stem sizes (6.5 mm to 15 mm) and four neck angles (125° to 140°) were available at the time of surgery (Table 1). All humeral implants were placed using the manufacturer's humeral reamers and intramedullary humeral head resection guides using a standard deltopectoral approach. The operating surgeon achieved an excellent press-fit for the humeral stem.

All 25 of the patients had pre-operative true AP, scapular Y and axillary lateral radiographs with a standardized 25-mm spherical magnification marker placed directly lateral to the humeral head, which was used to calibrate the templating software. The radiograph used for templating was an anteroposterior glenohumeral joint view. This radiograph was taken with the patient erect and turned 30° to 35° toward the side being X-rayed. The tube was positioned perpendicular to the plate. Digital templating of the pre-operative radiographs was performed using the Advanced CasePlan templating, version 1.6 (Stryker Imaging, Flower Mound, TX, USA). This software allows for magnification-calibrated radiographs without the use of traditional films and has shown good results with respect to templating for hip and knee arthroplasties.^{23,24}

Table 1. Tornier Aequalis prosthesis sizes available for surgeries.

Head size (mm)	Stem size (mm)	Neck angle (°)
37	6.5	125
39	7	130
41	9	135
42	11	140
43	12	
44	13	
46	15	
48		
50		
52		
54		

Digital templating of the humeral head size, stem size and neck angle was performed by four independent and blinded observers: two experienced orthopaedic surgeons (with 9 years and 44 years of experience) who perform over 100 shoulder arthroplasties annually and two PGY-6 fellows. Both attending surgeons had extensive experience in the use of pre-operative digital templating, whereas the fellows did not. The digital templates were compared with the actual implant size as dictated in the operative reports to assess their accuracy in predicting humeral head size, stem size and neck angle.

During stem preparation, the intramedullary canal was sequentially broached and reamed until proper sizing for a press-fit prosthesis was achieved. During trialing, the humeral component was rotated to ensure there was an adequate press-fit. In addition, once the trial stem was implanted, the proximal humerus was planned to match the exact neck angle of the stem. There were no incidences where the humeral stem were too small and there were no incidences of subsidence. All patients had postoperative radiographs showing implant hardware within acceptable limits.

Statistical analysis

Weighted (κ) analysis was used to calculate interobserver reliability for humeral head size, stem size and neck angle. Quadratic weighting was used to penalize greater distances further than the actual standard because that would have a more serious effect on clinical outcome. Interobserver comparisons included: attending to attending; fellow to fellow; and attendings to fellows. Four possible combinations existed for attending to fellow comparisons. Kappa values were interpreted according to guidelines set forth by Landis and Koch (Table 2).²⁵ The accuracy of digital templating compared with actual implant size was calculated as a percentage agreement and tested using a Wald chi-squared

analysis. The effect of experience on accuracy was tested using generalized estimating equations to account for the repeated measures within raters. Analyses were performed with SPSS, version 21 (IBM Corp., Armonk, NY, USA) ($\alpha=0.05$ for all analyses).

Results

Humeral head size

Pre-operative digital templating. Pre-operative interobserver reliability was substantial between attendings ($\kappa=0.71$), moderate to substantial between attendings and fellows ($\kappa=0.60$ to 0.70) and fair between fellows ($\kappa=0.26$) (Figure 1a).

Accuracy of pre-operative digital templating. Among all observers, pre-operative digital templating accurately predicted head size 22% of the time and were within one size variation in 53% of the cases. Attendings and fellows had accuracies of 22% (62% within one size) and 22% (44% within one size), respectively (Figure 2a). Head size was templated too large (65%) more often than too small (13%) and there was no significant difference in accuracy between attendings and fellows (exact: $p=1.00$; within one size variation: $p=0.11$).

Humeral stem size

Pre-operative digital templating. Pre-operative interobserver reliability was moderate between attendings ($\kappa=0.51$), fair to substantial between attendings and fellows ($\kappa=0.39$ to 0.72) and moderate between fellows ($\kappa=0.60$) (Figure 1b).

Accuracy of pre-operative digital templating. Among all observers, pre-operative digital templating accurately predicted stem size 36% of the time and were within one size variation in 77% of the cases. Attendings and fellows had accuracies of 44% (80% within one size) and 28% (74% within one size), respectively (Figure 2b). Stem size was templated too large (40%) more often than too small (24%) and there was no significant difference in accuracy between attendings and fellows (exact: $p=0.10$; within one size variation: $p=0.48$).

Humeral neck angle

Pre-operative digital templating. Pre-operative interobserver reliability was slight between attendings ($\kappa=0.19$), slight to fair between attendings and fellows ($\kappa=0.17$ to 0.34) and slight between fellows ($\kappa=0.16$) (Figure 1c).

Table 2. Interpretation of kappa values.

Kappa	Strength of agreement
≤ 0	Less than chance agreement
0.0 to 0.20	Slight agreement
0.21 to 0.40	Fair agreement
0.41 to 0.60	Moderate agreement
0.61 to 0.80	Substantial agreement
0.81 to 0.99	Almost perfect agreement

Figure 1. (a) Digital templating interobserver reliability for humeral head size. (b) Digital templating interobserver reliability for humeral stem size. (c) Digital templating interobserver reliability for humeral neck angle.

Accuracy of pre-operative digital templating. Among all observers, pre-operative digital templating accurately predicted neck angle 27% of the time and were within one size variation (5°) in 68% of the cases. Attendings and fellows had accuracies of 30% (74% within 5°) and 24% (62% within 5°), respectively (Figure 2c). Neck angle was templated too large (53%) more often than too small (20%) and there was no significant difference in accuracy between attendings and fellows (exact: $p = 0.50$; within one size variation: $p = 0.20$).

Discussion

Pre-operative planning is an essential step in performing joint arthroplasties. Templating is a tool that allows surgeons to use pre-operative radiographs to predict prosthesis sizes and angles for use during the operation. Studies have shown mixed results for templating in knee and hip arthroplasty, although little information is known about its use for the shoulder.^{26–29} There has been one study regarding the reliability and accuracy of pre-operative analogue templates in shoulder arthroplasty; however, no studies have been published using digital templating or evaluating the use of templating for humeral neck angle.¹¹

The present study measured the reliability and accuracy of pre-operative digital templating for predicting

head size, stem size and neck angle in shoulder arthroplasty. With regard to accuracy, we were primarily concerned with whether the humeral components were predicted within one size variation. With newer implants, there tends to be 3-mm increments between head sizes, and so an accuracy within two or three head sizes would mean differences in head sizes up to 6 mm to 9 mm. Such a difference would be too large and has a high probability of resulting in an over-stuffed humeral head, which may fracture the humeral shaft. For these reasons, templating is considered to be useful if it is accurate to within one size. Pre-operative templates serve as guidelines for prosthesis size and proper fit must still be confirmed intra-operatively. There was fair to substantial agreement for digitally templating the humeral head component (Figure 1a). Templating the humeral stem was more variable; however, a fair to substantial agreement still existed among the surgeons (Figure 1b). Although there was greater agreement regarding the pre-operative digital templates of the humeral head, the templating stem size was much more accurate when compared to the actual implant inserted (Figure 2). This is not surprising because diameter was the only variable to consider for stem size, whereas the three largest head sizes also had two options for thickness. There were also eleven options for head size, compared to seven for stem size, which may

Figure 2. (a) Digital templating accuracy for humeral head size. (b) Digital templating accuracy for humeral stem size. (c) Digital templating accuracy for humeral neck angle.

account for some of the difference in accuracy. Although this helps to explain why digital templating for stem size was more accurate, it is unclear why its interobserver reliability was not as high. Pre-operative digital templating of the humeral neck angle was neither reliable nor accurate. There was slight to fair agreement for digitally templating the humeral neck component (Figure 1c) and the templates were only 68% accurate within one size variation (5°) compared to the actual implant inserted (Figure 2c). Considering that there were only four possible angles for the neck, these values are particularly low. Anatomic changes as a result of osteoarthritis such as an inferior humeral osteophyte may make it difficult to accurately assess articular morphology.

To our knowledge, this is the first study to evaluate the reliability and accuracy of pre-operative digital templating in the humeral component of shoulder arthroplasty, as well as the first to evaluate templating of any kind for humeral neck angle. The results have provided new insights into the effectiveness of digital templating in comparison to traditional analogue techniques and provide a launching pad for future research in templating for shoulder arthroplasty, including estimation of sample sizes for a fully powered study. Digital templating was found to have comparable reliability and

accuracy to analogue techniques in templating humeral head and stem sizes.¹¹ We are unaware of any published information available to compare analogue and digital templating for humeral neck angle. Similar to the study by Buzzell et al., our findings suggest that surgeon experience does not correlate with more reliable or accurate digital templating, except in the case of humeral head size reliability.¹¹ The attendings showed substantial agreement ($\kappa = 0.71$) in templating the humeral head, while the fellows had only fair agreement ($\kappa = 0.26$) (Figure 1a). Pre-operative templating is a useful tool for all surgeons and it is particularly important for those with less operative experience. Poor agreement illustrates the difficulty in templating shoulder arthroplasties. Because the humeral shaft is narrower in the sagittal rather than coronal plane, the templating, which is performed in the coronal plane, is likely less accurate and reliable. In future studies, two-dimensional (2D) templating for the shaft perhaps should be performed off of a lateral view of the humerus. For the head, utilizing computed tomography scanning may provide surgeons with a better representation of the actual implant needed.

Although we were able to determine the interobserver reliability of digitally templating the humeral

components, no intra-observer information was gathered. It has been shown that analog templating has substantial intraobserver reliability; however, it would be worth evaluating this in digital templating as well.¹¹ 2D radiographs are cost-effective and convenient to obtain, although they still present limitations when trying to template three-dimensional (3D) components of the humeral head. The use of 3D computed tomography (CT) scans for pre-operative templating yields higher levels of accuracy in hip arthroplasty, although, to our knowledge, no such study has tested 3D templating for the shoulder.^{21,30} The use of 3D CT scans may be the next big step in improving pre-operative templating; however, associated increases in time and cost may limit its acceptance as a practical replacement of 2D techniques.

Pre-operative digital templating is not a useful tool for total shoulder arthroplasty because it does not improve accuracy over analog templating to justify its higher cost and complexity. For surgeons, it is better to trest intra-operative trialing rather than digital templating. This becomes more difficult for inexperienced surgeons who are less familiar with identifying proper fit for humeral prostheses. It is especially important that they know the limitations of pre-operative templates because they perform the majority of total shoulder arthroplasties each year.² Templating may be a good option in post-traumatic or avascular necrosis cases where the anatomy is severely distorted, although it is otherwise an unnecessary step and could mislead surgeons when choosing implants.

The present study shows that pre-operative digital templating can predict humeral head and stem size with reasonable reliability and it is also fairly accurate for identifying humeral stem size within one size variation. However, at present, it is not an accurate tool for predicting humeral head size and is neither accurate, nor reliable for humeral neck angle. Additionally, experienced surgeons demonstrated greater interobserver agreement than inexperienced surgeons with regard to humeral head size. Experience did not otherwise affect the interobserver reliability or accuracy of digital templating. Digital templating is not a helpful guide for humeral stem component in total shoulder arthroplasty and its findings should not be considered in the final decision on which implant size to use.

Funding

This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors.

Previous presentation

This paper is not associated with a previous communication to a society or meeting.

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