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CORR Insights®: 3D-printed Handheld Models Do Not Improve Recognition of Specific Characteristics and Patterns of Three-part and Four-part Proximal Humerus Fractures

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Where Are We Now?

To justify widespread adoption of any classification scheme, a high degree of inter- and intra-observer reliability must be demonstrated. The reliability of assessing proximal humerus fracture patterns using widely-held classification systems such as that of Neer and Hertel based on plain radiographs has been fairly low, though the addition of advanced imaging such as two-dimensional (2-D) and three-dimensional (3-D) CT scans appears to improve both inter- and intra-observer reliability [4]. More recently, using 3D printed models alone in the surgical planning process has been found to improve interobserver reliability over plain radiographs and both 2D and 3D CT scans using the Neer system, though the observed agreement with the printed models was only moderate [2]. In these studies, where the kappa values using the guidelines of Landis and Koch were reported as "substantial" and "moderate," respectively, we must recognize that a high proportion of cases will still be misclassified. As a consequence, clinical outcomes research based on these classifications may result in misleading results.

A recent meta-analysis [7] based on randomized trials comparing fracture fixation of various anatomic sites both with and without the use of 3D-printed models determined that blood loss, surgical time, fluoroscopy use, clinical outcomes, and achievement of anatomic reduction all favored 3D modeling. A limitation of this study was the inclusion of multiple fracture types and the small number of patients in several included studies. Furthermore, the effect size for many of the surgical outcome measures could be quite small based on the reported 95% confidence intervals. The only included study involving complex three- and four-part proximal humerus fractures [8] found a reduction in operative time, blood loss, and fluoroscopy time, though the clinical outcomes at final follow-up were similar. It is not clear, however, whether the mean 15-minute decreased operative time and approximately 55 cc decreased blood loss with 3D models is clinically significant. A retrospective study [3] comparing conventional preoperative planning using plain radiographs and both 2D and 3D CT scans with both computer-assisted virtual planning and 3D-printed models found shorter operative time, less blood loss, and less fluoroscopy in the latter groups compared to the conventional group. Planning time was shorter in the computer-assisted planning group compared with the 3D model group. Once again, the reported differences in the surgical parameters were small. Whether these differences justify the direct and indirect costs of routine use of 3D models, including the creation (personnel, software, hardware), storage, and potential sterilization, remain unclear [5].

In their current study, Spek and colleagues [6] examined 20 adult

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patients with complex three- and four-part proximal humerus fractures that were deemed difficult to classify and determined that the addition of 3D-printed handheld models to a series of plain radiographs and both 2D and 3D CT scan images did not improve interobserver reliability for the majority of fracture characteristics being studied. Additionally, the handheld models did not improve fracture classification using either the Neer or Hertel system. There was also no difference in agreement between residents and attending orthopaedic surgeons as to whether the 3D models aided in fracture pattern classification.

These findings suggest that the routine use of 3D-printed models may not be beneficial for classifying proximal humeral fracture patterns beyond the information gained from currently available imaging modalities. Specifically, use of these models as the sole determinant for recommending surgical intervention based on fracture displacement should probably be avoided at this time based on the results of the current study.

What is particularly concerning about the findings of the current study is that the addition of the 3D-printed models did not improve the ability of attending surgeons to identify particular fracture characteristics and classify patterns above that of the surgeons in-training. This would seem to indicate that a level of subjectivity exists within the classification systems themselves. Based on the results of the study, we should invest fewer resources determining whether handheld models improve preoperative fracture classification. The answer, according to Spek et al. [6], is a resounding "no."

Where Do We Need To Go?

The current study raises some important questions that warrant further study, namely: (1) In what capacity does the use of the 3D-printed model provide benefit to care for patients with proximal humerus fractures who have already been indicated for surgery? (2) What is the potential role of preoperative computer-assisted virtual surgical planning for proximal humerus fractures both with and without 3D model printing?

In the only published randomized study that I am aware of assessing the surgical utility of 3D modeling for three- and four-part proximal humerus fractures [8], patients underwent preoperative planning using either two orthogonal radiographs and a thin-cut 2D CT scan versus plain radiographs, a 3D CT reconstruction with simulated fracture reduction using specialized software, and a handheld 3D-printed model. The use of 2D CT images in the control group represents a difference from the current paper, though a prior study [1] found that the use of 3D CT did not offer improvement in classification or treatment recommendations over 2D CT, except among junior residents. Regardless, to fully demonstrate the positive influence of the handheld models independently, researchers should ensure that both study groups are provided with all of the imaging modalities generally available today, including 3D CT images. Furthermore, future studies should determine whether these improvements can be replicated among surgeons of all levels of experience or if those with less experience would demonstrate greater benefit. Finally, we need a better understanding of the costs associated with the computer-assisted software and the model creation in light of the minimal—14-minute—surgical time difference reported.

Computer-assisted planning can involve virtual reduction of the fracture and selection/placement of implants even without the use of 3D handheld models. One study [3] reported improved operative parameters for the virtual planning and 3D model group compared to the conventional planning group, though it is not entirely clear whether the differences are clinically significant. From a cost perspective, more data are needed to determine whether the 30 minutes of virtual planning is cost-efficient with the 18 minutes of reduced operative time. Computer planning time may be even higher for surgeons performing a lower volume of proximal humerus fracture surgery.

How Do We Get There?

The primary potential advantage of 3D-printed models likely will be realized in more complex proximal humerus fracture patterns that have already been indicated for surgical intervention. Specifically, the 3D models can provide the surgeon with a tactile modality for planning fracture reductions and correct placement of hardware. Future studies for determining the utility of the 3D models in the clinical realm should be designed based on objective surgical parameters such as operative time, duration of fluoroscopy use, estimated blood loss, adequacy of fracture reduction, and perhaps most importantly, on patient outcomes. Given the dearth of available evidence, the utility of 3D models versus computer-assisted fracture planning alone needs to be validated. The reported differences in these parameters have been fairly small in the literature so far and, therefore, justification for utilizing either technology necessarily requires demonstrating larger, more clinically relevant differences. Furthermore, future studies must assess whether surgeons with extensive experience with proximal humerus fracture fixation will derive any meaningful benefit from these technologies.

A comparative study of this type needs to be performed in a high-volume Level 1 trauma center to achieve sufficient patient numbers. Only three-part and four-part fractures should be included and should be randomized either to planning through the use of standard imaging including 2D and 3D CT or to planning with additional use of the 3D-printed model versus computer-assisted planning. To determine which surgeons would most benefit from either the 3D model or computer-assisted planning, surgical data need to be stratified for surgeon volume and/or clinical experience. There will be a learning curve for use of the planning software, which should be taken into account regarding planning time. Innovation can often be costly, and cost benefits with both of these technologies must be demonstrated, either by calculating operating time savings compared with increased planning time and/or by reduced intraoperative implant wastage. As there are no currently defined minimal clinically important differences for surgical parameters such as intraoperative blood loss, surgical time, and use of fluoroscopy, any potential benefit must be considered in light of a rigorous cost-benefit analysis. Finally, any comparison of patient-reported functional outcomes should be viewed in light of minimal clinically important differences.

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