INTRODUCTION:
Total elbow arthroplasty (TEA) is commonly employed for disorders of the elbow. Loosening and wear of TEA have been attributed, in part, to a poor re-creation of the elbow’s flexion-extension (FE) axis, defined by the centers of the capitellum and trochlea. Current surgical techniques are based on a visual estimation of the FE axis. A study investigating the effect of surgeon accuracy in defining this axis found errors upwards of 10° in each of the coronal and transverse planes. A surgical technique that can improve the accuracy and reproducibility of intra-operative alignment may well reduce complications arising from abnormal articular tracking and loading.

This study evaluated the accuracy of navigated humeral component alignment in total elbow arthroplasty under varying conditions of simulated bone loss. We hypothesized that an image-based navigation system would improve humeral component positioning, with navigational errors less than or approaching 2.0 mm and 2.0°.

METHODS:
Eleven paired cadaveric distal humeri were imaged using a 64-slice CT scanner (GE – Light Speed Ultra, USA), and a 3D surface model was reconstructed. The implant and distal humerus were each secured to a receiver from a magnetic tracking system (Flock of Birds, Ascension Tech, USA). Each implant was modified, reducing the stem length by 75%, in order to evaluate the navigation system independent of implant design constraints.

Implant alignment was performed with and without navigation, and under 2 scenarios – (1) intact humeral bone stock (Stage I); and (2) loss of the distal aspect of the humerus (Stage II). Implant alignment was performed on the left side of each pair while the landmarks of the right side were referenced during Stage II navigated alignment.

Humeral component implantation was performed using the standard instrumentation of the Latitude® total elbow arthroplasty (Tornier, USA). For non-navigated alignment, the location of the FE axis was estimated on the distal humerus using visual cues. Using the supplied commercial instrumentation, humeral preparation was performed using standard surgical techniques by a fellowship trained upper extremity surgeon (GJWK). The implant was positioned within the humeral canal and aligned with the surgical cuts; its position was then recorded (Non-Nav-I). For the Stage II non-navigated alignment (Non-Nav-II), the distal aspect of the humerus was removed at the level of the proximal aspect of the olecranon fossa and the alignment process was repeated.

For navigated alignment, the implant was aligned with the FE axis of the CT surface model, which was registered to the landmarks of the physical humerus using the iterative closest point (ICP) algorithm. For Stage I navigated alignment (Nav-I), registration landmarks encompassed the distal humerus. For Stage II alignment (Nav-II), registration landmarks only encompassed the non-articular region of the distal humerus. Stage II alignment involved a registration to the contralateral (right) surface model. Navigated implant positioning was based on aligning a 3D computer model calibrated to the implanted with a 3D model registered to the distal humerus.

RESULTS:
Implant alignment error was significantly lower for navigated implant alignment (P < 0.001) (Figure 1 & 2). For Stage I bone loss, navigated alignment error was 1.3 ± 0.3° in rotation and 1.2 ± 0.3 mm in translation while non-navigated error was 5.9 ± 3.8° and 3.1 ± 1.3 mm. For Stage II bone loss, navigated alignment error was 2.0 ± 1.3° and 1.1 ± 0.5 mm while non-navigated error was 12.2 ± 3.3° and 3.0 ± 1.6 mm. Implant alignment error was greater for the non-navigated Stage I alignment scenario, compared with the Stage I non-navigated alignment (P < 0.001).

For Stage I non-navigated alignment, 72% of the specimens had an implant alignment error greater than 2° while 45% were greater than 5°. For the Stage II non-navigated alignment, the lowest alignment error was 7°, with 82% of the specimens having an alignment error greater than 10°. For navigated alignment, only 3 specimens had an alignment error greater than 2° - all for the Stage II alignment.

DISCUSSION & CONCLUSIONS:
As hypothesized, image-based navigation improved the accuracy of humeral component placement to less than 2.0 mm and 2.0°. Further, somewhat alarming outliers in implant position (i.e. maximum errors in Figures 1 & 2) were measured for the non-navigated group, particularly in the presence of Stage II bone loss. Significant implant malalignment may well increase the likelihood of early implant wear and post-operative complications. The improved accuracy and consistency of implant placement is in agreement with studies at the knee and hip.

The denuded distal humeri employed in this study represented a best case scenario. Visualization of anatomic landmarks will likely be worse clinically due to the presence of the radius and ulna as well as the limited surgical approaches typically employed. For the non-navigated positioning only a single experienced surgeon was evaluated, it is likely that the mean non-navigated alignment errors and the resulting number of outliers would increase significantly for a less experienced surgeon. This is the first reported study to compare an image-based navigated alignment technique with a conventional non-navigated approach using a commercial total elbow arthroplasty. It is likely that improved implant positioning will lead to reduced implant loading and wear, resulting in fewer implant-related complications and revision surgeries. Clinical studies are needed to confirm the superiority of navigated TEA.

REFERENCES: