

DEVELOPMENT AND VALIDATION OF A NOVEL PATIENT SPECIFIC GUIDE SYSTEM FOR MINIMALLY INVASIVE TOTAL SHOULDER ARTHROPLASTY

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INTRODUCTION

Patient Specific Instruments (PSIs) are increasingly being used to improve the accuracy of surgical procedures, especially arthroplasty, where precise bone preparation and implant placement are critical in the procedure's success (Farron et al., 2006; Favre et al., 2008). To the authors' knowledge, arthroplasty PSIs have only been applied to traditional, highly-invasive surgical approaches, such as those described by Hendel et al. (2012). However, PSIs can enable the development of minimally invasive surgical techniques by reducing the surgeon's need to clearly visualise anatomical landmarks. Therefore, the purpose of this work was to design and evaluate a novel PSI for shoulder arthroplasty which would allow the entire procedure to be accomplished through a minimally invasive approach.

MATERIALS AND METHODS

The PSI was developed in conjunction with a new minimally invasive approach for shoulder replacement that reduces incision size – an incision just large enough to pass a stemless humeral component – and eliminates the traditional transection of the subscapularis, which is used to access the joint. This involves cutting between and retracting the infraspinatus and teres minor muscle bellies. This approach reduces recovery time and enhances the likelihood a patient will recover full joint function. However, it prevents en face access to the articular surfaces, which are traditionally required for placing guide wires, reaming, and drilling.

To accommodate this approach, we developed a PSI that would enable a trans-humeral bone tunnel to be accurately drilled starting from the lateral humerus, which could then be used to guide further humeral bone preparation and insert a glenoid guide pin. To use the humeral bone tunnel to place the glenoid guide pin, it was necessary to design a PSI that could align the humeral tunnel axis with the desired guide pin axis. Therefore, the PSI was designed as a two sided guide that incorporated unique anatomical features from both the humerus and scapula (Figure 1). By combining the features of both bones into one PSI, the guide effectively locks the two bones together in a predefined pose.

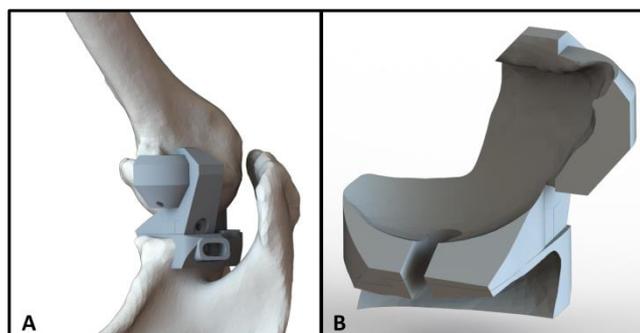


Figure 1: Two-sided intra-articular PSI. (A) CAD rendering of PSI registered to the humerus and scapula such that they are placed in the correct position and orientation. (B) This render illustrates the contoured surfaces of the guide which correspond to anatomic features on each bone. As well, note the thin black lines that denote the parting lines of the modular subcomponents.

This design is achieved using a combination of pre-operative imaging and planning, and computer aided design (CAD) software. First, 3D reconstructed models of the humerus and scapula were created from CT and imported into a CAD package (SolidWorks, Dassault Systèmes, Paris, France). The desired guide axis orientation and insertion point were identified for each bone. The bone models were moved such that the axes were collinear thus allowing a guide pin to be placed and bone tunnel to be created concurrently. In this way, the pose of the two bones is fully defined except for the medial-lateral humeral translation and flexion-extension rotation that can be adjust to optimize surgical factors such as joint laxity. The PSI is then constructed using the articular surfaces to provide complete physical registration with the bones. Modularity was designed into the guide to enable it to be assembled intra-articularly, further reducing invasiveness, and allowing the thickness of the guide to be adjusted – depending on joint laxity – to optimise passive compression within the joint which aids in guide registration.

The PSI was trialled in one cadaveric specimen with standard osteoarthritic changes. The guide was fabricated using a 3D printer (Form1+, FormLabs, Somerville, MA, USA). The accuracy in orienting the bones was assessed by recording the relative pose of the humerus and scapula using a Polaris tracking camera (NDI, Waterloo, ON, CA) with the guide in place. This pose was compared to the preoperative plan by performing an Iterative Closest Point (ICP) (Besl and McKay, 1992) registration between the bone models and bone surface digitizations. This registration process resulted in 6 DOF transformation data between the achieved and preoperatively planned humeral pose.

RESULTS

Comparison of the preoperative plan and achieved humeral pose demonstrated that the PSI could accurately position the joint to within 1.7mm (Figure 2). The humeral orientation was also accurately controlled with differences of 1.5° flexion-extension, 2.2° abduction, and 2° internal-external rotation.

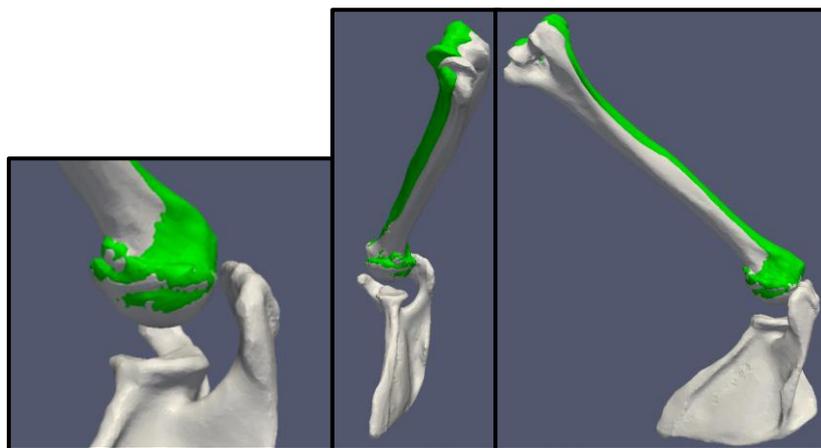


Figure 2: Computer renderings of the achieved humeral alignment relative to the pre-operatively planned humeral position and orientation. Note that the grey scapula humeral models represent the pre-operative plan, and the green humeral model is the achieved pose as determined from optical tracking data and the registration procedure.

Additionally, the cadaveric trial produced important qualitative findings. First, the PSI could be successfully inserted through a minimally invasive incision, and modular components were easily assembled intra-articularly. Second, once assembled, the PSI was readily registered to the scapula and through manipulation of the humerus it was possible to feel the articular surface ‘lock’ onto the guide. Third, once located, the humerus, PSI, and scapula

were appreciated to form one rigid construct. Finally, increasing PSI thickness increased passive joint compression and aided in guide registration.

DISCUSSION

To date, PSIs and CAOS in general have focused on improving surgical accuracy; however, despite achieving this goal, patient outcomes have often not improved in the mid- to long-term (Burnett and Barrack, 2013; Krych and Pagnano, 2009). With this in mind, we sought to develop a novel PSI that overcame the clinical shortcomings of previous systems by combining improved surgical accuracy with a reduction in operative invasiveness, thus improving post-operative recovery time and functional outcomes.

Evaluation of the developed PSI demonstrated that it could be effectively used through a minimally invasive muscle-splitting approach, which will allow surgeons to avoid the more traditional but highly invasive subscapularis release techniques which Lapner et al. (2015) identified as leading to poor functional outcomes. This evaluation also found that the PSI can orient the joint with a sufficient degree of accuracy to guide pin placement with much higher accuracy to that reported by Iannotti et al. (2012) for freehand insertion while also greatly reducing invasiveness.

We intend to continue optimizing the PSI design and conduct further investigations to confirm these findings across a range of shoulder anatomy and to determine the final implantation accuracy achievable using these guides. In conclusion, this novel PSI has been shown to be suitable for minimally invasive arthroplasty and may represent a new avenue in improving the clinical impact of CAOS systems. A patent application has been produced to protect this novel intellectual property.

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DISCLOSURES

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Patient Specific Instruments (PSIs) are becoming an increasingly common method to provide surgeons with assistance in accurately performing procedures; however, to our knowledge, these new instruments have only been applied to traditional, highly invasive surgical approaches. However, PSIs have the potential to decreased surgical invasiveness by reducing the surgeon's need to clearly visualise anatomical landmarks. Therefore, we designed and evaluated a novel PSI for minimally invasive shoulder arthroplasty.

The proposed minimally invasive approach prevents en face access to the articular surfaces and thus the PSI was designed to guide the accurate placement of a trans-humeral bone tunnel which would permit surgical steps to be conducted. To accurately create this tunnel and place a guide pin in the glenoid, the PSI was designed as a two sided guide that incorporates unique anatomical features from both bones, which would lock the two bones in a predefined pose relative to one another. Proper registration of the PSI is aided by the joint's passive compression force, which is not disrupted due to the soft tissue sparing approach. Once the bones are locked together, a guide pin could be passed through the humeral head – creating a bone tunnel to guide later humeral bone preparation – and into the glenoid to guide reaming and drilling. By designing the guide in this way, it is possible to avoid the need to perform surgical steps with a clear en face view.

The PSI was created by loading 3D reconstructed CT models of the humerus and scapula into a CAD package, aligning the desired humeral and scapular guide axes such that the bones' relative pose is fully defined, and finally constructing the guide itself between and around the articular surfaces, such that sufficient anatomical features are incorporated to provide complete physical registration with the bones. This PSI was subsequently customized, based on a cadaveric specimen and fabricated using a 3D printer. The PSI's usability and accuracy in achieving the pre-operative plan were then assessed using optical tracking and surface based registration procedure.

Results of the evaluation demonstrated that the designed PSI is capable of accurately registering the two bones to within 1.7mm and 2.2° of the intended pre-operative plan, while also effectively reducing the invasiveness of the surgical procedure. Therefore, this novel PSI may represent a new avenue to improve the clinical impact of CAOS systems, by achieving good surgical accuracy, but with a greatly reduced invasiveness.