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A biomechanical assessment of fixation methods for a coronoid prosthesis

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article info abstract

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Background: The coronoid process is an integral component for maintaining elbow joint stability. When fixation of a fracture is not possible, prosthetic replacement may be a feasible solution for restoring stability. The purpose of this in-vitro biomechanical study was to compare fixation methods for a coronoid implant. Methods: A coronoid prosthesis was subjected to distally-directed tip loading after implantation using four fixation methods: press-fit, anterior-to-posterior screws, posterior-to-anterior screws, and cement. Testing was performed on seven fresh-frozen ulnae in a repeated-measures model. Rounds of cyclic loading were applied at 1 Hz, for 100 cycles, increased in 50 N increments up to a maximum of 400 N. Micro-motion of the implant was quantified using an optical-tracking system. Outcome variables included total displacement, distal translation, gap-

ping, anterior translation and axial stem rotation. Findings: Cement fixation reduced implant micro-motion compared to screw fixation, while the greatest implant micro-motion was observed in press-fit fixation. Comparing screw-fixation techniques, posterior–anterior screws provided superior stability only in distal translation. The implant did not experience displacements exceeding 0.9 mm with screw or cement fixation.

Interpretation: Cement fixation provides the best initial fixation for a coronoid implant. However, the stability provided by both methods of screw fixation may be sufficient to allow osseous integration to be achieved for long-term fixation. Large displacements were observed using the press-fit fixation technique, suggesting that modifications would need to be developed and tested before this technique could be recommended for clinical application.

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1. Introduction

Traumatic elbow injuries can lead to significant elbow instability and disability. The coronoid process, which is a bony triangular eminence that projects from the anterior portion of the proximal ulna, is an integral component for maintaining elbow joint stability. This structure may be damaged in the setting of a traumatic injury, and given its importance for stability, Type II and larger coronoid fractures should be treated surgically with open reduction and internal fixation (ORIF) [\(Pollock et al., 2009a,b\)](#page--1-0). While relatively uncommon, larger comminuted fractures that cannot be managed by ORIF pose a challenge in restoring elbow stability and can result in significant patient disability. The results of coronoid reconstruction with allografts and autografts have

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been historically poor, emphasizing the need for a reliable prosthetic device to adequately manage coronoid deficiencies [\(Chung et al.,](#page--1-0) [2007; Van Riet et al., 2005](#page--1-0)). When ORIF is precluded due to comminution or osteopenia, a coronoid prosthesis may be a viable solution to restore elbow stability. Presently, there are no prosthetic devices of this nature available to address this clinical scenario. Biomechanical investigations have shown that initial stability of the implant is essential for proper fixation and osseous integration, which reduces the risk of component loosening and prolongs implant survival ([Pilliar et al., 1986;](#page--1-0) [Soballe et al., 1992\)](#page--1-0). Excessive implant micro-motion has been shown to promote the ingrowth of fibrous tissue, which compared to bone ingrowth is insufficient to ensure long-term stability [\(Collier et al., 1988;](#page--1-0) [Kienapfel et al., 1999; Pilliar et al., 1986; Soballe et al., 1992\)](#page--1-0). The resulting aseptic loosening is the most common reason for performing revision surgeries of elbow prostheses, with revisions being typically more technically challenging, time consuming, costly, and having a higher incidence of complications than the initial joint replacement [\(Barrack, 1995; Barrack et al., 1995; Jafari et al., 2010; Kamineni &](#page--1-0) [Morrey, 2004; Lavernia et al., 1995; Loebenberg et al., 2005; Ulrich](#page--1-0) [et al., 2008](#page--1-0)).

To our knowledge, no previous studies have examined the optimal fixation method for a prosthetic replacement for the coronoid process. Previous bio-mechanical investigations have shown that coronoid prostheses can restore stability to coronoid deficient cadaveric elbows. As such, examining potential fixation methods for implementation of such a device would be useful prior to clinical use. Press-fit cementless fixation, screw fixation, and cement fixation are all feasible options which should be investigated ([Alolabi et al., 2011; Gray et al., 2013](#page--1-0)). Therefore, the purpose of this study was to determine the optimal fixation method of securing a coronoid prosthesis in the proximal ulna. We hypothesized that cement fixation would minimize the micro-motion of a coronoid prosthesis, while the greatest displacement would occur with the press-fit method.

2. Methods

2.1. Prosthesis design

Morphological dimensions of the coronoid process from 18 cadaveric specimens (mean age 64.4 years [range 42 to 90 years], left arms: 11, right arms: 7, male arms: 11, female arms: 7) (Table 1) were measured from computed tomography scans (Mimics®: Materialise BV, Leuven, Belgium). A coronoid prosthesis was developed based on the following dimensions of the coronoid process: height, proximal-distal depth, medial-lateral width, and facet angles. Coronoid cartilage thickness was incorporated into the prosthesis design using the results from a parallel study conducted in our laboratory [\(Rafehi et al., 2011\)](#page--1-0). The implant was fabricated from stainless steel using CAD–CAM technologies. Two threaded holes in the distal surface of the implant ([Fig. 1](#page--1-0)) were used to attach and secure an optical tracking device, in order to monitor its motion relative to the ulna. Two through holes in the stem accommodate screws for antero-posterior (AP) and postero-anterior (PA) fixation methods.

2.2. Specimen preparation and mechanical test setup

The soft tissues were removed from seven fresh frozen ulnae (mean age 79 years [range 60 to 88 years], left arms: 5, right arms: 2, male arms: 6, female arms: 1) (Table 1) and the distal sections of the bones were potted in bone cement. Digital calipers were used to measure the height of each coronoid process, and an oscillating sagittal saw was used to simulate a 40% (Type II) transverse coronoid fracture that is commonly encountered clinically ([Doornberg et al., 2006; Regan &](#page--1-0) [Morrey, 1989](#page--1-0)).

The coronoid prosthesis was secured to the bone using the following four techniques in order: press-fit method, AP screws, PA screws, and cement. After the 40% coronoid osteotomy, a cavity slightly smaller than the implant stem was created in the cancellous bone located in the central region of the fractured surface. Press-fit fixation was accomplished by impacting the stem of the implant into the cavity.

Two 2.4 mm cortical screws (Synthes, Missisauga, ON, Canada) were used for AP fixation. A 1.8 mm drill bit was used to drill holes directed posteriorly through the fracture surface, exiting through the posterior surface of the proximal ulna. The screws were then passed through the implant and securely fixed into the cortical bone of the posterior

Table 1

Specimen data.

The number, age, sex, and relative number of right and left specimens used for both the morphological ($n = 18$) and biomechanical study ($n = 7$).

	Morphological study	Biomechanical study
Number of specimens (N)	18	
Left/right	11/7	5/2
Male/female	11/7	6/1
Mean age/range (years)	$64(42-90)$	79 (60-88)

ulna. The screw threads did not engage the prosthesis, thus achieving lag screw fixation.

The AP screw holes were widened to accommodate larger machine screws (UNF#5-40, $D = 3.18$ mm) for PA fixation. These were passed anteriorly through the posterior surface of the ulna, through the prosthesis, and then were secured on its anterior surface with two stainless steel nuts. The screw threads did not engage the bone or the prosthesis. AP and PA screw fixation schematics are shown in [Fig. 2](#page--1-0).

After the press fit and screw fixation techniques were tested, a rotary milling tool was used to widen the void in the metaphysis of the proximal ulna to create space for surgical cement (Simplex™ P bone cement, Stryker, Hamilton, ON, Canada). The opening in the fracture surface was then filled with cement, and the stem of the prosthesis was pressed into place and held stationary until the cement hardened.

2.3. Prosthesis tracking and loading protocol

Optical trackers (Optotrak Certus®, NDI, Waterloo, ON, Canada) were mounted on the shaft of the ulna and on the prosthetic device to quantify motion of the prosthesis with respect to the ulna [\(Fig. 3](#page--1-0)). A stylus attached to a third optical tracker was used to digitize three points on the base of the articular face of the prosthesis (medial, ridge, and lateral) to monitor the micro-motion of the prosthesis throughout the testing protocol. The greater sigmoid notch and two flat points on the posterior surface of the ulna were also digitized in order to generate an anatomical coordinate system (shown in [Fig. 4](#page--1-0) with the three types of motion described in this study) for each specimen using a method previously described ([McDonald et al., 2011; Sabo et al., 2011](#page--1-0)). Relative motions were determined with respect to the anatomical planes of the body.

The four fixation methods were subjected to mechanical testing via a materials testing machine (Instron 8501®, Instron, Canton, MA, USA). Load was applied to the coronoid prosthesis using a custom designed fixture, developed to fit congruently against the medial and lateral facets of the implant. The load applicator was used to simulate loading imparted by the distal humerus. Distal loading was applied to the ridge of the implant's articular surface, midway between the base and tip of the prosthesis.

Fixation methods were tested sequentially, first using the press-fit method, followed by AP, PA, and then cement fixation. Cyclic loading was applied to the prosthesis for eight cyclic loading regiments. Maximum cyclic loads ranged from 50 to 400 N in increments of 50 N, where each regiment lasted for 100 cycles at 1 Hz. Testing continued to the end of the loading protocol, or to the point of failure, which was defined as a displacement in any direction exceeding 2 mm at any one of the three digitized prosthesis points.

The loading protocol used in this biomechanical study was based on the typical loads experienced within the human elbow. The maximum elbow flexion strength has been shown to occur at 90°, where a force of approximately three times the weight of the body has been estimated to pass through the elbow with heavy lifting [\(Kai-Nan & Morrey, 2000](#page--1-0)). Given this information, a force of approximately 2000 N may in some highly aggressive scenarios, be experienced in the elbow joint. The ulnohumeral joint is expected to experience 800 N of this force, based on the work of Halls and Travill, who reported that an applied axial force is distributed across the joint with 40% crossing the ulnohumeral joint and 60% crossing the radiohumeral articulation [\(Halls & Travill,](#page--1-0) [1964\)](#page--1-0). This estimate of 800 N across the ulnohumeral joint is a maximum loading case; unlikely to be experienced by a patient postoperatively and would be distributed over the entire articular surface of the greater sigmoid notch. Applying a force of this magnitude to only the anterior 40% of the coronoid process would be well in excess of the regular physiological load experiences in this area, as such, the maximum load for this study was reduced to 400 N, approximately half of the maximum potential load, to more accurately represent potential loads experienced by patients in post-surgical rehabilitation,

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