Original Article

Percutaneous upper extremity fracture fixation using a novel glass-based adhesive

Paul Zalzal^a, Oleg Safir^b, Adel Alhalawani^{c,d,*}, Marcello Papini^c, Mark Towler^{c,d}^a Oakville Trafalgar Memorial Hospital, Oakville, L6J 3L7, Ontario, Canada^b Mount Sinai Hospital, Toronto, M5G 1X5, Ontario, Canada^c Department of Mechanical and Industrial Engineering, Ryerson University, Toronto, M5B 2K3, Ontario, Canada^d Li Ka Shing Knowledge Institute, St. Michael's Hospital, Toronto, M5B 1W8, Ontario, Canada

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ABSTRACT

Objective: To develop a surgical technique for percutaneous upper extremity fracture fixation using a novel glass-based adhesive.

Methods: Three intact upper extremity cadaveric specimens with undisturbed soft tissues were obtained. Two were used to model a wrist fracture, and the third to model a proximal humerus fracture. Fractures were produced using a small osteotomy in a percutaneous fashion. Banna Bone Adhesive (BBA) was delivered to the fracture site percutaneously using a 16 gauge needle under bi-planar fluoroscopic guidance. After setting of the adhesive, the specimens were dissected to qualitatively assess BBA delivery and placement.

Results: The adhesive could readily be delivered through the 16 gauge needle with an appropriate amount of pressure applied to the syringe. Using the fluoroscope, the adhesive could be seen to flow into the fracture site with minimal extravagation into the surrounding soft tissues. Successful bonding of the fracture fragments was observed.

Conclusions: Percutaneous delivery of BBA into a fracture of the distal radius and proximal humerus may be a feasible fracture fixation technique. Biomechanical testing and animal model testing are required to further develop this procedure.

1. Introduction

Despite the widespread use of pharmacologic agents for treating osteoporosis, the number of fractures that occur in the elderly population continues to rise at a steady rate^{1,2}. In the United States, there are nearly 1.3 million fractures every year resulting in a healthcare burden of about \$10 billion per year^{3,4}. These fractures most commonly involve the upper extremities, usually at the distal radius, the proximal humerus or the spine^{3,5}. These injuries cause significant morbidity to the patient, stress for family caregivers, and financial burden to the health care system². Current fixation and stabilisation of these injuries is not optimised and has changed little over the years. Treatment of distal radius fracture, for example, usually consists of extended cast or sling immobilization, or surgical open reduction and internal fixation with pins, plates and screws followed by immobilization for 6 weeks^{5,6}. Cast or sling immobilization is disruptive to the patient's life and can threaten their independence⁷. Non-operative management of this type can be complicated by non-union, malunion, and stiffness⁵. Surgical intervention carries with it the usual operative risks which are

increased in the elderly population⁵. Development of new fracture treatment methods using modern adhesive technology is required.

The use of surgical cement to fill traumatic or surgically induced bone voids and gaps in the skeletal system is widespread, with three main material types dominating the literature on the subject: acrylics, composites and calcium phosphates. Acrylic bone cements are employed for hip, knee and spinal augmentation. However, concerns such as (but not limited to) impaired functioning of the immune system^{8,9}, thermal and chemical necrosis¹⁰ and lack of direct bone apposition around such implants¹¹ has encouraged other material developments. Cortoss (Stryker, USA), a Bisphenol-A-glycidyl dimethacrylate (BIS-GMA) resin enriched with ceramic particles, is an alternative to conventional acrylics^{12,13}. However, drawbacks are also associated with its use including; deletions in DNA sequences¹⁴ decreasing strength with respect to time¹⁵, impaired immune response¹⁴ and excessive elastic modulus¹⁵. Calcium phosphate cements (CPCs) have clinical interest due to their potential to be resorbed and replaced with new bone as part of the natural bone remodelling cycle without provoking an inflammatory response^{16–18}. Whilst some CPCs suffer from delayed

* Corresponding author at: Department of Mechanical & Industrial Engineering, Ryerson University, 350 Victoria Street, Toronto, ON, M5B 2K3, Canada.
E-mail address: adel.alhalawani@ryerson.ca (A. Alhalawani).

setting in the wet field environment, and viscosity contrary to injectable surgical procedures, their biocompatibility is not matched by acrylic or composite bone cements. The main deficiency associated with CPCs is their poor strength¹⁹. Glass polyalkenoate cements (GPCs) are a group of materials that have potential for skeletal cementation.

GPCs were initially developed in the early 1970's for use in restorative dentistry²⁰. They are formed by an acid-base reaction between a water-soluble poly(acrylic) acid (PAA) and an acid-degradable fluoro-alumino-silicate bioactive glass²¹. A polysalt matrix is formed in GPCs through the degradation of the glass, leading to the release of free cations which associate with the carboxylic anions from the PAA^{22,23}. The crosslinking mechanism is a continuous process during which acrylate networks are established, leading to the increase in strength over time²⁴. The cement used in this study has been reported in the literature with details around its chemical, physical, mechanical and biological properties^{25,26}. This cement is called Banna Bone Adhesive (BBA).

Various techniques such as dorsal and volar plating, fragment-specific plating, screw osteo-synthesis and external fixation, have been used for distal radius fracture fixation, however it still remains a challenge, especially for the elderly^{27–31}. Stabilizing distal radius fractures using CPCs has also been reported^{28,32}.

This study aims to provide proof-of-concept evidence that percutaneous fracture fixation can be achieved using BBA. We believe that this is the first work that shows how to optimize the upper extremity fracture fixation using injectable GPCs.

2. Methods

2.1. Glass synthesis

A single glass composition was formulated for this study (Table 1). The glass was prepared by weighing out appropriate amounts of the analytical grade reagents (Fisher Scientific, Ottawa and Sigma-Aldrich, Oakville, Canada) and mixing them in a container. Platinum (Pt.) crucibles and a Lindberg/Blue M model furnace (Lindberg/Blue M, Asheville, NC USA) with a UP-550 controller were used to melt the powders (1650 °C, 1.5 h). The melt was subsequently shock quenched in water to obtain frit which was then dried in an oven (100 °C, 1 h), and ground using a ball mill (400 rounds per minute, 15 min). The resulting powder was sieved to collect the < 45 µm particles which were utilised for subsequent cement preparation. A complete characterization of the glass can be found in²⁵.

2.2. Cement preparation

Cement samples were prepared by mixing the glass with poly(acrylic acid) (PAA, Mw = 50,000, Advanced Healthcare Ltd., Tonbridge, UK) and de-ionized (DI) water on a glass plate at a powder-liquid ratio (P:L) of 1:4, where 1 g of glass was mixed with 2 g PAA and 2 g DI water to create a paste. Complete mixing was achieved within 30 s at ambient room temperature (23 ± 1 °C). The cement was transferred, using a spatula, to a 10 ml syringe and then injected into the fracture site.

2.3. Wrist fixation

Two right-sided adult upper extremity cadaveric specimens were obtained from the Division of Anatomy, Department of Surgery, (University of Toronto, Canada). A percutaneous stab incision through the dorsum of the wrist was used to introduce a ¼ inch osteotome

Table 1

Composition of glass.

Oxide	SiO ₂	ZnO	CaO	SrO	P ₂ O ₅	Ta ₂ O ₅
Mole Fraction	0.48	0.355	0.06	0.08	0.02	0.005

(a)

(b)

Fig. 1. Distal radial fracture and fixation using BBA; (a) Lateral view of distal radius with osteotomy, (b) AP view of distal radius after adhesive applied percutaneously.

(Fig. 1a). A distal radius fracture was simulated and manual force was used to create complete displacement and dorsal angulation. The fracture was verified using biplanar fluoroscopy. Under fluoroscopic guidance, the fracture was reduced with in line longitudinal manual traction. Through the stab incision, 5cc of BBA was injected into the fracture site using a 16 gauge needle under fluoroscopic guidance. Traction was maintained for 5 min. The adhesive was allowed to set for 1 h. Fluoroscopy was used to verify fracture stability. Soft tissue dissection was then performed via dorsal and volar approaches to observe adhesive distribution.

2.4. Proximal humerus fixation

One right-sided adult upper extremity cadaveric specimen was used. A similar procedure as that described above was used to create a fracture through a stab incision on the lateral aspect of the shoulder. 10cc of BBA was injected into the fracture site (Fig. 2). Traction was maintained for 5 min then the adhesive was allowed to set for 1 h. Soft

Fig. 2. Injection of BBA into proximal humerus fracture.

tissue dissection through an anterior approach was performed to determine if there was any extravasation of the adhesive.

3. Results and discussion

Both the wrist and the proximal humerus fractures were easily accessible through the percutaneous stab incision. The BBA was readily injected through the 16 gauge needle and could be observed flowing into the fracture site using portable C-arm fluoroscopy. The wrist and shoulder were put through a range of motion and the fracture site appeared stable on fluoroscopy. Soft tissue dissection revealed that the BBA was largely contained in the fracture site with little extravasation into the soft tissues.

4. Conclusion

This technique for percutaneous upper extremity fracture fixation using BBA appears to be technically feasible in a cadaveric model. Biomechanical testing and animal models are currently underway to prepare for *in vivo* human pilot experiments. Biomechanical testing will aim to assess the strength and adhesion of BBA while ovine models are being employed to evaluate the safety of BBA in both non-critical and critical defects.

Conflict of interest

MT and AA are inventors of the Banna Bone Adhesive. The authors state no conflict of interest.

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