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Novel adhesives for distal radius fixation: A biomechanical analysis

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ABSTRACT

Wrist fractures can be difficult to treat due to advanced age of the patient, medical co-morbidities, and comminution of the bone. This study examines the effectiveness of two injectable glass polyalkenoate cements (GPCs), derived from two different glasses (A and B), as minimally invasive treatments for distal radius fractures. Twenty-seven fresh cadaveric radial pairs were tested either in compressive fatigue or to quasi-static compressive failure. The radii tested to failure had one pair fixated with a GPC while the other was left intact. The radii tested under fatigue had one pair fixated with a GPC and the other with a volar locking plate. A wedge osteotomy was used to simulate a severely comminuted fracture. When loaded to failure, the radii fixated with a GPC made from glass A or B were found to be, respectively, at least 57% and 62% as strong as their intact biological pair (95% Confidence Interval, Lower). Using a paired *t*-test, the radii fixated with either adhesive were found to be significantly stiffer than their biological pairs fixated with a volar locking plate for all cycles of fatigue loading. The adhesives under investigation demonstrate promise as treatment for distal radius fractures. *In vivo* investigations are warranted to determine the effect that the adhesives have on the bone remodelling process.

1. Introduction

Each year there are over 640,000 cases of distal radius fracture (DRF) in the United States (US) alone, accounting for 18% of all fractures in adults and 25% in children (Nellans et al., 2012). Furthermore, the incidence of DRFs are on the rise as a result of osteoporosis becoming increasingly prevalent due to an aging population (Nellans et al., 2012). The most common treatment for DRFs has been to use a closed reduction method with plaster or fibreglass casting, accounting for 74% of all elderly patient treatments in the US (Chung et al., 2011). However, if bone quality is poor or the fracture is complex and unstable, as is often the case among the elderly, such treatment may not always be adequate. For example, Beumer and McQueen observed that 53/60 fractures treated non-operatively ultimately healed in a malunited position (Beumer and McQueen, 2003). As a result, there has been an increasing trend of surgeons using alternative treatment techniques such as external, percutaneous and internal fixation methods to treat DRFs (Chung et al., 2009).

The use of external fixation devices has been reported to improve the healing of severely comminuted fractures when compared to closed reduction techniques alone (Kapoor et al., 2000). The associated complication rate, however, is high, at 27%. Pin-tract infection was seen in 21% of these cases, screw loosening in 11%, and pin-site fracture in 4% (Ahlborg and Josefsoon, 1999). Furthermore, due to the necessity of prolonged hospitalization, external fixation is costly and patient mobility is severely limited. This has rendered external fixation devices an unpopular treatment option, accounting for only 1.3% of all cases (Chung et al., 2011).

Percutaneous fixation using K-wires is a minimally invasive alternative to closed reduction methods, accounting for 7.6% of all treatment cases (Chung et al., 2011). Willenegger and Guggenbuhl were the first to report the use of K-wires for radial fixation by inserting the wires at the styloid and anchoring them in the opposite cortex (Willenegger and Guggenbuhl, 1959). Kapandji improved on this method by inserting the wires from the dorsal aspect into the fracture gap, commonly referred to as the intrafocal method (Kapandji, 1976). While percutaneous pinning techniques offer advantages such as a short procedure time and the ability to withdraw the wires with relative ease, complication rates of 32% have been associated with the Kapandji method, and 40% with the Willenegger method (Strohm et al., 2004), including

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nerve irritation, swelling, pin-tract infection and wire migration (Strohm et al., 2004). The inability to sufficiently reduce the complication rate associated with these techniques has led some to question their suitability as a treatment option (Carrozzella and Stern, 1988).

Internal fixation methods offer suitable wrist function in the early post-operative period with minimal loss of reduction (Arora et al., 2011). The introduction of the volar locking plate (VLP) has led to nearly a six-fold increase in internal fixation treatments, from 3% of all treatments in 1996 to 17% in 2007, making it the most popular alternative DRF treatment option currently available (Chung et al., 2011, 2009). Despite the increased use of VLPs, a lack of any significant difference in pain or range of motion during the entire post-operative period has been observed when compared to non-operative treatments in the elderly (Arora et al., 2011). Furthermore, VLP is associated with a complication rate of 27% including carpal tunnel syndrome, complex pain, screw loosening and screw displacement (Arora et al., 2007).

A review by the International Society of Orthopaedic Surgery compared 48 randomised trials and found inconclusive evidence to support the decision to employ one DRF treatment over another (Handoll and Mdhok, 2003). The review also questioned whether surgical intervention of most fracture types produced consistently better long-term outcomes than traditional closed reduction techniques. As a result, there is demand for an objectively better DRF treatment option.

The use of Poly methyl methacrylate cement, commonly known as PMMA, for distal radial fixation was first reported in 1989 (Schmalholz, 1989), however it has not been embraced due to its lack of chemical adherence to bone (Kusleika and Stupp, 1983), unpredictability in dimensional changes during curing (Hagiwara et al., 2000), and an exothermic setting reaction that can lead to thermal necrosis (Mjöberg et al., 1984). Calcium phosphate bone cements such as the Norian Skeletal Repair System (SRS) (DePuy Synthes, MA, USA) are injectable and have been used clinically for radial fixation (Cassidy et al., 2003). Upon hardening in vivo, carbonated apatite is formed which has similar chemical and physical properties to bone (Constantz et al., 1995). An open reduction method with the use of K-wires is still required when using Norian SRS (Cassidy et al., 2003). While Norian SRS has been reported to accelerate healing over conventional fixation methods, a complication rate of 46% has been observed including problems around loss of reduction, carpal tunnel syndrome and infection related to the use of the K-wires (Cassidy et al., 2003).

Glass polyalkenoate cements (GPCs) have been commonly used in both restorative dentistry and orthodontics since their invention in the 1970s (Wilson and Kent, 1971). The ability of GPCs to bear load, to adhere to bone and to be biocompatible have driven the investigation of GPCs as an adhesive for orthopaedic applications (Alhalawani et al., 2016). GPCs can chemically adhere to bone and surgical metals (Akinmade and Nicholson, 1993), as well as release beneficial ions such as calcium (Ca) and zinc (Zn) without loss of strength (Boyd and Towler, 2005). An acid-base reaction between silicate based glass particles and poly(acrylic acid) (PAA), upon the presence of de-ionized water, initiates the setting reaction (Walls, 1986). Aluminium (Al) is included in the glass component of all commercially available GPCs (Towler et al., 2002). This has restricted their use for orthopaedic applications since Al ion release (Al^{3+}) has been associated with degenerative brain diseases and neurotoxic effects (Polizzi et al., 2002). The authors have previously reported on GPCs formulated with zinc (Zn) in place of Al, as Zn can also operate as a network modifier or intermediate (Boyd and Towler, 2005). The Zn ion (Zn^{2+}) has a positive effect on bone metabolism (Ma and Yamaguchi, 2001), is antibacterial and exhibits anti-inflammatory properties (Atmaca et al., 1998; Prasad, 2008).

Two GPCs will be considered in this paper, one derived from Glass A (mole fraction: SiO_2:0.48, ZnO:0.36, CaO:0.12, SrO:0.04), and the other from Glass B (mole fraction: SiO_2:0.48, ZnO:0.355, CaO:0.06, SrO:0.08, P_2O_5:0.02, Ta_2O_5:0.005). Glass A is a patented (US 7981,972), Al free ionomeric glass (Towler et al., 2008; Wren et al., 2008). Strontium (Sr) is incorporated in Glass A as Sr can replicate pre-osteoblastic cells and stimulate bone formation (Canalis et al., 1996). Glass B is a patent pending GPC formulation (PCT/CA2017/050854) incorporating Tantalum (Ta) at the expense of some Zn content. Ta is a glass former (Alhalawani and Towler, 2016) and has been used in orthopaedic applications in the past, including as a porous metal coating to improve implant fixation (Balla et al., 2010). GPCs formulated by mixing either of these glasses with polyacrylic acid (PAA) and deionized water have been shown to be injectable into a full upper extremity cadaver; the GPCs remained in the fracture site with minimal extravasation into the soft tissues (Zalzal et al., 2018).

The objective of this study was to investigate the biomechanical performance of GPCs derived from both Glass A and Glass B as minimally invasive treatment options for percutaneous DRF. A cadaveric model was used with tissue preparation and compressive loading methodologies similar to previously reported studies, where radii were tested under both compressive failure and fatigue (Synek et al., 2016; Blythe et al., 2006; Koh et al., 2006). We hypothesized that GPCs would generate more stable fixation than the VLP.

2. Materials & methods

2.1. Glass synthesis & cement formulations

The two glasses used for this study, A and B, were prepared by a glass manufacturer (Mo-Sci, Rolla, MO, USA) using specified mole fractions (Table 1) and particle sizes (Table 2). Glass A was annealed for 12 h at 640 °C to relieve internal stresses and increase working time. The annealing temperature was reached in three hours. Following annealing, the glass was then furnace cooled down to room temperature. Glass B remained un-annealed as the GPCs made from it have sufficient working time without annealing. GPC formulations (Table 2) were determined using trial-and-error in order to meet the requirement of ~6cc of material being fully injectable by hand through a 10–12 ml syringe fitted with a 14-gauge cannula. Mechanical properties of glass A and B (Table 2), including compressive and biaxial flexural strength, were investigated in previous studies.

2.2. Experimental design

Twenty-seven pairs of fresh radii from cadavers were obtained from two different sources (United Tissue Network, Phoenix, AZ and Mt. Sinai Hospital, Toronto, ON). Biological pairs (i.e., left and right) were arranged into groups of similar age and sex (Table 3). Radii tested quasi-statically until failure had one bone fixated with a GPC while the contralateral was left intact. Radii subjected to fatigue loading had one bone fixated with a GPC and the contralateral with a VLP.

2.3. Tissue preparation

Radii were held in frozen storage (-20 °C) until required for testing, when each radius was immersed in warm water until fully defrosted. All soft tissue was dissected, leaving the bone surface exposed (Fig. 1: a, b). A transverse osteotomy was performed 14 cm from the radial styloid, as in previously reported studies (Synek et al., 2016), using a reciprocating saw to ensure uniformity between specimens (Fig. 1: c). For those radii

Table 1
Compositions by mole fraction for Glass A and B.

	Composition (mole fraction)					
	SiO_2	ZnO	CaO	SrO	P_2O_5	Ta_2O_5
Glass A	0.48	0.36	0.12	0.04	–	–
Glass B	0.35	0.351	0.073	0.143	0.056	0.027

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