Clinical Biomechanics 29 (2014) 861–868

Contents lists available at ScienceDirect

Clinical Biomechanics

journal homepage: www.elsevier.com/locate/clinbiomech

Preclinical trial of a novel surface architecture for improved primary fixation of cementless orthopaedic implants

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ARTICLE INFO

Article history:
Received 2 May 2014
Accepted 30 July 2014

Keywords:
Bone in-growth
Histology
Porous
Titanium
Stem
DMLS

ABSTRACT

Background: A new surface architecture for cementless orthopaedic implants (OsteoAnchor), which incorporates a multitude of tiny anchor features for enhancing primary fixation, was tested in an ovine hemi-arthroplasty pilot study.
Methods: Test animals were implanted with a hip stem component incorporating the OsteoAnchor surface architecture produced using additive layer manufacturing and control animals were implanted with stems containing a standard plasma sprayed titanium coating.
Findings: Intra-operative surgeon feedback indicated that superior primary fixation was achieved for the OsteoAnchor stems and rapid return to normal gait and load bearing was observed post-operation. Following a 16-week recovery time, histological evaluation of the excised femurs revealed in-growth of healthy bone into the porous structure of the OsteoAnchor stems. Bone in-growth was not achieved for the plasma sprayed stems.
Interpretation: These results indicate the potential for the OsteoAnchor surface architecture to enhance both the initial stability and long term lifetime of cementless orthopaedic implants.

1. Introduction

Total hip and knee replacement operations are routinely performed with generally successful outcomes. However, achieving good primary fixation, i.e. stability of the implant in the time period immediately after surgery, remains problematic for patients with poor bone stock. This is particularly the case in revision operations (Chung et al., 2012; Murphy and Rodriguez, 2004) where the patient's bone may already be osteoporotic and further bone damage can occur in removing the old implant. Although outcomes for implants with current surface coatings are generally very good, failure due to implant loosening does occur and a significant proportion of these are early failures after the initial operation (Melvin et al., 2014). Lack of good primary fixation can be a contributory factor in causing subsequent loosening and it has been shown that early migration of the stem after implantation is a predictor of subsequent implant loosening (Karrholm et al., 1994). It has also been reported that the effectiveness of the surface coating in providing early fixation influences the long term stabilisation of the stem (Callary et al., 2012). A new surface architecture for orthopaedic implants, OsteoAnchor (Harrison et al., 2013), has been developed at the authors' laboratory to improve primary fixation.

Long term stability of cementless orthopaedic implants requires effective primary fixation and secondary fixation to occur. Secondary fixation refers to the long term fixation of the implant, which is often achieved through bone in-growth into a porous coating on the implant (Valle et al., 2004). Effective primary fixation is required for successful secondary fixation to occur (Chang et al., 2011; Chanlalit et al., 2011; Gebert et al., 2009; Gotze et al., 2002; Sakai et al., 2006). If primary fixation is not achieved, excessive micromotions of the implant can result in the growth of fibrous tissue into the surface coating instead of hard bone (Cook et al., 1991; Soballe et al., 1992; Viceconti et al., 2001). This can lead to inadequate long term fixation of the implant. Loosening of the stem can subsequently occur and this may ultimately require revision surgery to be carried out. This problem is particularly relevant for patients with poor bone quality (Dayton and Incavo, 2005; Krischak et al., 2003).

Currently available surface coatings for cementless orthopaedic implants rely on press-fit and friction between the coating and the patient's bone to achieve primary fixation (Issa et al., 2014; Schiffern et al., 2005). It is therefore desirable that the surface coating exhibits a high coefficient of friction to enhance primary fixation and high porosity to facilitate substantial bone in-growth to provide long-term stable fixation of the implant. Sintered bead, plasma sprayed titanium, hydroxyapatite and wire mesh coatings have achieved very good clinical outcomes, but they possess relatively low porosity in the range of 30–50% and a low coefficient of friction (Levine and Fabi, 2010). More

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http://dx.doi.org/10.1016/j.clinbiomech.2014.07.007
0268-0033/

recently, highly porous metal coatings have been developed (Benazzo et al., 2010; Bertollo et al., 2011; Bobyn et al., 1999; Frenkel et al., 2004; Meneghini et al., 2010) with higher porosity and coefficient of friction (Bourne et al., 2008; Gilmour et al., 2009; Levine and Fabi, 2010; Shirazi-Adl et al., 1993; Zhang et al., 1999). The OsteoAnchor surface architecture has been developed to further improve on the frictional properties of the currently available coatings, whilst maintaining a high porosity in the region of 64%. The surface architecture incorporates a multitude of tiny anchor features which are built onto a porous substructure in a one-step additive manufacturing process (Fig. 1). These anchor features are designed to reduce micromotions of the stem after implantation by embedding into the patient's bone and providing immediate mechanical fixation of the implant.

The objective of the current study was to test the primary fixation and bone in-growth performance of this new surface architecture in a load-bearing preclinical model. The hypothesis of the study was that the anchor features of the OsteoAnchor surface architecture would provide superior primary fixation compared to the plasma-sprayed control surface coating, and combined with the higher porosity substructure this would subsequently leadto more extensive secondary bone in-growth and implant stability.

2. Methods

An ovine hemi-arthroplasty model was chosen for this preclinical study and the work was carried out using skeletally mature merino sheep (Surgical Research Australia, Adelaide, Australia). The study incorporated a post-operative recovery period of 16 weeks. Since this was a pilot study to test the efficacy of the new surface architecture, animal numbers were kept low: three OsteoAnchor sheep and two control sheep completed the 16-week trial period. The study was approved by the Flinders University Animal Ethics Committee. At the end of the trial period, the sheep were sacrificed and the femurs were excised. Cross-sectional slices of the femur and implant were extracted and were prepared for histological analysis to evaluate the bone in-growth into the porous architecture.

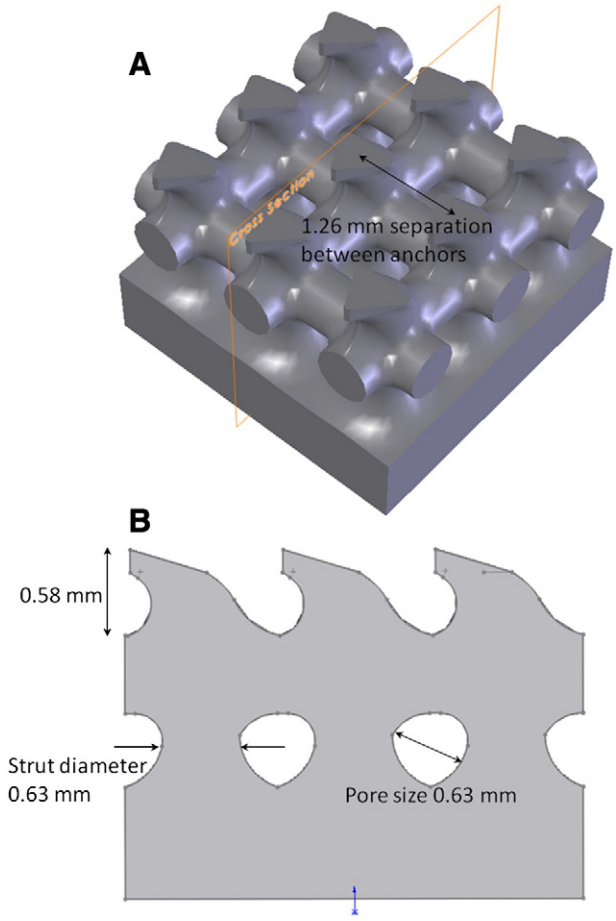

Fig. 1. OsteoAnchor surface architecture design.

2.1. Surface architecture and implant design

The detailed structure of the surface architecture for the OsteoAnchor stems was developed at the author's laboratory (National University of Ireland, Galway). The aim of this development process was to optimise the potential for primary fixation in the bone, ensuring sufficient strength to withstand in-vivo loading conditions and incorporating a highly porous lattice structure to enhance secondary bone in-growth. The final structure of the surface architecture that was developed incorporated a multitude of tiny anchor features on the bone-engaging side of the structure and an open-pore lattice beneath the anchor features to allow bone in-growth. The anchor features were specifically designed to embed into the bone during implantation, thus providing a secure fixation of the implant with the bone. A custom stem implant was developed which would incorporate the OsteoAnchor surface architecture and provide a press-fit in the trabecular bone of the metaphysis of the ovine femur. A number of design and prototyping iterations were required to optimise the stem geometry. Trial implantations were performed in excised ovine femurs to ensure that an adequate press-fit was achieved. The details of the final surface architecture and stem geometry design are given in the Results section.

2.2. Implant manufacture

The stems were manufactured using the direct metal laser sintering (DMLS) process (subcontracted to 3TRPD, Berkshire, UK using an EOS M270 DMLS system). The material used was Ti6Al4V. The OsteoAnchor surface architecture and the core geometry were built simultaneously to give a single, homogeneous part. Control implants were also manufactured with the same gross geometry as the OsteoAnchor stems, but with a separately applied plasma-sprayed porous coating of commercially pure (CP) titanium (Orchid Orthopaedic Solutions, Holt, MI, USA). The coating thickness for the control stems was 0.5 mm and had an average porosity of 30% or higher. This coating is representative of industry-standard plasma-sprayed cementless orthopaedic implants (Emerson et al., 2002; Mallory et al., 2001; Marshall et al., 2004).

Three different stem sizes were manufactured to allow the surgeon to intraoperatively select the stem which would give a good press-fit in individual animals. Standard 28 mm diameter, cobalt-chrome femoral head components were used (JRI Orthopaedics, Sheffield, UK), with a choice of three different neck length offsets. A custom surgical instrumentation set was designed and manufactured to facilitate broaching of the press-fit cavity in the metaphysis and consisted of a series of nine broaches of increasing size. The same instrumentation set was used during the operations for implanting the OsteoAnchor and control stems.

2.3. Surgery

Skeletally mature 3 to 4 year-old, castrated male Merino sheep (*Ovis aries*), bred for the purpose of research, were used in the study. Sheep were sourced from the Animal Facility, Flinders University, Melbourne, Australia. Sheep were a minimum of 50 kg in body weight with the mean and standard deviation of sheep weight between the OsteoAnchor and control groups closely matched (control group: 72.3 kg, standard deviation: 8.1 kg/OsteoAnchor group: 72.7 kg, standard deviation: 6.0 kg). A total of 8 sheep (hereafter referred to as NUIG 1–8) were used in the study. Due to the novelty of the press-fit implant design and associated instrumentation, optimisation of the