METHOD TO EVALUATE THE FIXATION OF IMPLANT COATINGS

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INTRODUCTION
Push-out testing is commonly used to assess the mechanical integrity of implant fixation ex-vivo. The accuracy of this type of test depends on precise alignment of the implant with the mechanical loading axis and stable support of the surrounding bone tissue [1]. A test method has been developed that meets these conditions.

The aim of this paper is to present this method as a means of evaluating initial implant fixation by reporting a time zero comparative study of a sintered asymmetric titanium (Ti) particle coating and a conventional sintered spherical Ti bead coating. Since the asymmetric particle coating has been shown to have a higher interfacial friction against bone [2], it is expected that the initial push-out strength for this coating will be significantly greater than the bead coating.

METHODS
Circular-segment-shaped implants (24.5 mm x 9.2 mm) of uniform thickness (5.7 mm – 5.8 mm) [3] were prepared with either a sintered asymmetric Ti particle coating (STIKITITE™, Smith & Nephew) or a sintered spherical Ti bead coating (ROUGHCOAT™, Smith & Nephew) applied to the top (proximal) and bottom (distal) surfaces.

A qualified veterinary surgeon inserted each implant into a circular-segment-shaped defect created in ovine cadaveric tibia using a Woodruff Key cutter (25 mm diameter). Defects were located 3 mm below and parallel to the medial tibial plateau with a height 0.2 mm less than the thickness of the implants to provide a slight press-fit [3]. After implantation, each tibia was machined into a smaller bone block and a Dremel tool was used to expose the centre of the inner face of the implant.

Push-out testing was performed using an Instron 5566 with 1 kN load cell. For each test, the bone block was secured in a custom support fixture connected to the test frame through a multi-axis vice such that the flat rectangular surface of the implant was perpendicular to the loading axis and a custom made plunger was inserted into a slot on the curved surface (Figure 1). Push-out occurred in the direction opposite to implantation at a rate of 1 mm/min. Peak push-out force was recorded for each implant.

RESULTS AND DISCUSSION
The custom support fixture provided uniform support for the bone tissue and allowed accurate alignment of the implant with the loading axis, thereby providing consistent results with narrow deviations in the data. Time zero push-out testing identified a considerable difference in initial fixation between the two coatings (Figure 2). This result is consistent with a previous report showing the asymmetric particle coating to have a higher coefficient of friction ($\mu$) against cancellous bone compared to the bead coating (mean $\mu$ = 1.40 vs. 1.18, respectively) [2]. Despite a lower coefficient of friction, the bead coating has shown stable fixation clinically [4], and thus, the asymmetric particle coating should be at least as successful in terms of implant stability, as indicated by early clinical results [5].

CONCLUSIONS
A push-out method was developed that provided the required support and sample alignment to accurately rank the initial fixation for sintered asymmetric Ti particle and sintered spherical Ti bead implant coatings. An in-vivo study of the two coatings is currently underway and will allow comparisons of long-term biologic fixation to the initial fixation data presented here.

ACKNOWLEDGEMENTS
Thanks are given to Stuart Ward for providing SEM images.

REFERENCES