Increased Press-fit Fixation Strength without Bone Damage due to Implantation

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Disclosures:
N.B. Damm: None. N.E. Bishop: 3B; DePuy Orthopaedics. M.M. Morlock: 3B; DePuy Orthopaedics.

Introduction: Joint registers show globally increasing numbers of uncemented joint implantations, with similarly increasing numbers of revision procedures [1]. Complications include loosening [1], periprosthetic fracture [2] and mal-positioning [3]: Loosening can arise due to insufficient primary stability achieved by the intra-operative press-fit [4], fracture due to excessive press-fit radial forces [2], and mal-positioning due to excessive implantation forces [5]. Increasingly rough surfaces are being introduced to improve fixation. In a previous study it was shown that rough surfaces increase bone damage during implantation due to shear stresses [6]. Although abrasive damage is always caused by axial shear press-fit implantation, it was demonstrated that press-fit pull-out force is dependent on the implantation force and is rather independent of surface roughness and of the extent of bone damage during implantation. The hypothesis of this study was that pull-out strength is increased if bone damage during implantation is eliminated by radial rather than axial shear press-fitting. This was investigated by repeating the previous experiment without abrasive bone damage.

Methods: An experimental implant-bone interface model was developed to apply a controlled press-fit by either AXIAL shear implantation (standard, wedge insertion) or RADIAL expansion implantation (Figure 1). The press-fit was generated under displacement control to achieve a nominal interference between a titanium plate representing the implant surface and a 10 mm embedded trabecular bone cube tilted at 3.5°. Push-in and pull-out forces (Figure 1) were recorded in the shear (axial) and normal (radial) directions. Three clinically used implant surfaces were tested (Polished, Beaded and Flaked) with nominal interferences 0.3 mm and 0.9 mm (n=3 for each combination), representing clinically low and high interferences, respectively. The high interference was shown previously to generate plastic compressive deformation of the bone, while the low interference generated no plastic damage [6]. Bone specimens were prepared from femoral heads, in defined orientations, and µCT scanned to determine the average bone volume fraction BV/TV (Scanco μCT 35, voxel size 15 μm). The press-fit efficiency ('Fixation Efficiency') ratio between maximum pull-out force and maximum radial force, indicates the fixation achievable within a safe radial force (to prevent bone fracture) and was used as the output variable for analysis (ANOVA, α=0.05).

Results: BV/TV was 0.26 ± 0.06, which is within reported values [6-8]. For the polished surface, no differences in the Fixation Efficiency ratios were observed between implantation modes or interference magnitudes (p=0.912 and p=0.882, respectively; Figure 2). The rougher surfaces (Beaded and Flaked) exhibited higher Fixation Efficiency ratios than the polished surface (p<0.001). The highest Fixation Efficiency ratios were found for RADIAL implantation for the rough surfaces at low (0.3 mm) interference and were 32-61% higher than for AXIAL implantation at low interference (p=0.001). The opposite was observed at high interference, where the mean Fixation Efficiency ratio was 11-32% higher for AXIAL implantation than for RADIAL (p=0.006). For RADIAL implantation the mean Fixation efficiency ratio was 10-22% greater for the flaked surface than beaded surface (p=0.042), but for AXIAL implantation 13-26% lower for the flaked surface than beaded surface (p=0.367).

Discussion: The hypothesis that radial implantation leads to higher pull-out strengths by the elimination of abrasive shear bone damage during implantation was supported for the lower interference of 0.3 mm: For RADIAL implantation at low interference, shear damage (as well as plastic damage) was eliminated and Fixation Efficiency ratios were the highest measured. For AXIAL implantation, damage is abrasive for any interference and for RADIAL implantation at high interference damage is plastic [6]. Thus, both plastic and abrasive damage modes during implantation decrease the press-fit efficiency. Low interference RADIAL implantation without any bone damage generates the best press-fit efficiency, indicating that the highest pull-out force can be achieved within a particular safe radial force limit. At high interference AXIAL implantation generates higher efficiency than RADIAL. However, RADIAL implantation has the potential clinical advantage of eliminating AXIAL implantation forces, which can cause component mal-positioning during normal AXIAL implantation [5]. If this radial implantation approach is used then a rougher, flaked surface is somewhat more efficient than beaded.

Significance: Bone damage occurs for both AXIAL and RADIAL implantation for clinically realistic press-fit interferences, and their respective plastic and abrasive damage modes reduce their press-fit capacity. Radial implantation at interferences below the plastic limit of the bone could be used clinically to maximise the press-fit efficiency, with the additional advantage of eliminating potentially dangerous implantation impact forces.

Acknowledgments: Financially supported by DePuy Orthopaedics.

Figure 1: Apparatus simulating press-fit implantation and schematic showing different implantation procedures.

Figure 2: Fixation Efficiency Ratio (mean ± standard deviation) per nominal interference compared for AXTAL and RADIAL implantation mode with SEM pictures of the clinically employed surface finishes (Polished, Beaded, Flaked).