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# Treatment of the Fixation Surface Improves Glenoid Prosthesis Longevity in-vitro

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**Abstract**

Many commercial cemented glenoid components claim superior fixation designs and increased survivability. However, both research and clinical studies have shown conflicting results and it is unclear whether these design variations do improve loosening rates. Part of the difficulty in investigating fixation failure is the inability to directly observe the fixation interface, a problem addressed in this study by using a novel experimental set-up.

Cyclic loading-displacement tests were carried out on 60 custom-made glenoid prostheses implanted into a bone substitute. Design parameters investigated included treatment of the fixation surface of the component resulting in different levels of back-surface roughness, flat-back versus curved-back, keel versus peg and more versus less conforming implants. Visually-observed failure and ASTM-recommended rim-displacements were recorded throughout testing to investigate fixation failure and if rim displacement is an appropriate measure of loosening.

Roughening the implant back ($R_a$ > 3 μm) improved resistance to failure ($P < 0.005$) by an order of magnitude with the rough and smooth groups failing at 8712 ± 5584 cycles (mean ± SD) and 1080 ± 1197 cycles, respectively. All other design parameters had no statistically significant effect on the number of cycles to failure. All implants failed inferiorly and 95 % (57/60) at the implant/cement interface. Rim-displacement correlated with visually observed failure.

The most important effect was that of roughening the implant, which strengthened the polyethylene-cement interface. Rim-displacement can be used as an indicator of fixation failure, but the sensitivity was insufficient to capture subtle effects.

Level of Evidence: Basic Science Study, Biomechanical Analysis.

## Introduction

The clinical incidence of glenoid component loosening in total shoulder replacement (TSR) remains high and increases dramatically at longer follow-up. Torchia et al. (1997) reported radiographic loosening rates of 44% at 9.7 years while more recent papers have reported 48.5% at 10 years and 66.4% at 15 years (Young et al., 2011). In an attempt to lower these loosening rates several types of glenoid components have been tried.

Current glenoid implant designs vary in several ways: the anchorage of the implant (keel or pegs), the level of conformity between the humeral and glenoid components, curve-back versus flat-back shape, and macrostructures for cement interlocking. The effect of all these parameters on loosening of cemented all-polyethylene glenoid components is still not well understood.

One design feature that has not received much attention is the roughness of the backside of the implant. Anglin et al. (2001) demonstrated a dramatic improvement to glenoid resistance to mechanical loosening in two specimens after sandblasting the backside of the polyethylene glenoid component. The importance of roughening the polyethylene-cement interface was also indicated by Nyffeler at al. (2003) who showed that the pull-out strengths of polyethylene pegs in cement was increased by an order of magnitude in pegs that had been roughened by sandblasting. The paper also reported clinical failure at the implant-cement interface from a retrieved implant (Figures 6 and 7 in Nyffeler at al. 2003).

The lack of clarity of the effects of design parameters relates to the fixation being embedded in the bone and impossible to observe directly. Instead, previous studies have measured implant ‘rim-displacement’ and relied on this as an indirect measure of loosening (Anglin et

al., 2001; Collins et al., 1992; Oosterom et al., 2004). This methodology is recommended by the American Society for Testing of Materials (ASTM F2028-14) and based on idealised cemented glenoids as a model. Due to the lack of clarity in experimental testing, studies investigating glenoid design features have largely utilised numerical methods to investigate stress patterns during various loading regimes. Lacroix and Prendergast 1997 predicted peg implants would perform better in normal bone, whereas keel would perform better in rheumatic bone, however Mansat et al. 2007 found no clear differences in stresses between peg and keel. In the case of flat-back verses curve-back, Iannotti et al. 2005 predicted higher rim displacements in flat-back designs if completely de-bonded and Swieszkowski et al. 2003 predicted high implant wear with glenoid to humeral head radial mismatch of 5 mm or more. Many finite element studies have been informative but cannot be predictive. Thus numerical methods can be a powerful supportive tool for the investigation of implant designs, however the variability in boundary conditions and interfacial conditions can result in varying conclusions and further highlight the need for a validated experimental approach that can be used in conjunction with numerical studies.

The aim of this study was to investigate the effect of the key design variables; keel versus peg, flat-back versus curve-back, conforming versus non-conforming and rough-backed versus smooth-backed on the life to failure of glenoid components subjected to cyclic loading. The second aim was to determine whether the ASTM recommended rim-displacement measure would correlate with direct visual observations of failure, thus providing confidence in its use as a measure of likelihood of loosening.

**Materials and Methods**

In this study, the inability to directly observe the fixation interface was solved using custom-made implants (Fig. 1). These samples are clearly different from commercial glenoid prostheses but allowed direct visual inspection of the fixation for failure (Fig. 2). The samples did not vary in the third dimension and will be described as 2D models/samples. Two-dimensional models are reasonable in this testing configuration because the contact in metal-on-polyethylene implants is point contact where the movement is predominantly superoinferior, with relatively small anteroposterior movement (Anglin et al. 2000). This 2D methodology has also been used in a previous paper (Junaid et al., 2010).

Sixty 2D samples, including 8 different designs were manufactured based on the design of commercial implants (see Table I). No macrostructures on the keel and peg designs were included. The commercially available designs were simplified to isolate the effects of design variations without confounding the comparison by also having different macrostructures. This was carried out due to the difficulty in standardising the macrostructures, since these vary from one implant brand to another. The 60 samples were further divided into 2 groups: 24 were smooth, as machined (roughness 0-2 μm), while 36 samples were roughened to 3-5 μm. Roughness measures of a typical smooth-back glenoid implant in clinical use were measured in the laboratory and found to be 1.58±0.59 μm (peg) and 1.29±0.24 μm (keel). A commercially available rough-backed implant was measured to have a roughness of 4.43±1.39 μm (peg), thus both smooth and rough samples were within the range required. The back of the implants were sandblasted to roughen the surface including the peg and keel features and a Talysurf surface profiler (Taylor-Hobson, AMETEK Inc., Pennsylvania, USA) was used to measure the surface roughness. $R_a$ is most commonly used as a measure of surface roughness and is defined as the arithmetic mean of the absolute values of the roughness profile from the mean line.

The glenoid components were implanted into a polyurethane bone substitute using PMMA bone cement (Simplex$^{TM}$ P, Stryker, New Jersey, USA) (Table II) by an orthopaedic shoulder surgeon (SS). The bone substitute blocks were prepared using a CNC machine to accurately cut out the glenoid back and accommodate a 2 mm cement mantle. The cement was hand-mixed at room temperature for approximately 90 seconds then poured into the bone substitute cavity. The volume of cement mixed was measured and consistent for each sample however, the volume used per sample was not controlled as this varied from one design to another. The implant was pressed into the cement using hand pressure and a conforming weight of approximately 0.5 kg was placed onto the glenoid surface to maintain the 2 mm mantle between the implant and bone and maintain a constant isotropic pressure during cement polymerisation. The mantle thickness was manually checked at the time of cementing to ensure it did not exceed 3 mm and was no less than 2 mm.

The cylindrical humeral head (radius 24 mm) was compressed into the glenoid using a horizontal load of 1800 N applied by a pneumatic cylinder (Junaid et al., 2010). All samples were cyclically tested with a frequency of 0.5 Hz under displacement-control and were tested in a water bath at 37±2 $^{o}$C as described in the testing standard ASTM F2028-14 using a servohydraulic machine (Instron 8874, Illinois, USA). The tests were halted and the water bath removed every 2000 cycles for the samples to be inspected visually for failure and failure progression. Subsequent to the visual inspection, a custom-made clamp fixed directly to the bone substitute block was used to clamp two linear variable displacement transducers (LVDTs) (Solatron Metrology, Bognor Regis, UK), which were aligned to measure the superior and inferior rim via reference pins inserted at the implant rim edge as specified by the ASTM standard (Fig. 1). The clamp was attached to the bone substitute block throughout

testing with only the LVDT removed intermittently during testing to ensure LVDT alignment and point of reference on the glenoid rim was consistent.

Emulating the ASTM standard, prior to cyclic testing, two additional samples of each design were quasi-statically loaded in a non-destructive test to determine the load and displacement to subluxation. The subluxation curves of the more- and less-conforming groups of components (Fig. 3) were averaged and 90% of the corresponding load was defined as the nominal vertical testing load during cyclic testing. The cyclic test set-up was displacement controlled to avoid sudden extensive failure progressions between inspections, and the actual testing load decreased slightly as failure progressed. To ensure the 90% subluxation load was maintained, the imposed displacement was readjusted every 4000 cycles. Cyclic loading was carried out from the centre of the glenoid to the superior rim, as described in a previous paper (Junaid et al., 2010). This imposed compressive loads on the superior rim and tensile loads on the inferior rim. This loading regime is supported by clinical findings of shoulder biomechanics showing predominantly superior loading and humeral head migration *in vivo* (Bergmann et al. 2007; Trial and Nuttall 2002). Initial failure was defined as when the failure crack was first visible, mid failure as when the crack reached the keel or first peg and failure was defined as when the failure crack reached the midline of the implant (Fig. 2).

The Anderson-Darling test was used to test for normality of the data and a non-orthogonal ANOVA test was carried out to test for statistical significance between the designs.

**Results**

All 60 samples irrespective of design failed from the inferior edge. Fifty seven failed at the implant-cement interface, two in the bone substitute and one at the cement-bone interface.

Significant differences were not found between any design pairs; only roughness had a clear effect ($P < 0.005$) (Fig. 4). The average number of cycles (±SD) to failure for the rough group was approximately eight times greater at 8712±5584 compared to the smooth group at 1080±1197 cycles.

When using the rim displacement measure it was also not possible to identify any statistically significant differences between any of the roughened design pairs (Fig 4). Rim measurements were not originally part of the study and were not carried out on the smooth samples. An important observation was that increasing inferior rim displacement was associated with progressive visual failure in all implant designs (Fig. 5 & 6). Rim displacement greater than 0.61 mm indicated with 95% confidence if a sample was no longer intact and had experienced either mid-failure or failure.

**Discussion**

The most important finding of this study was that a rougher surface of the back of the glenoid component increased the number of cycles to failure by an order of magnitude. In contrast, the study did not identify any significant effects of implant design. Improving the interface strength through roughness has been shown by Anglin et al. (2001), however, this is the first time a study has investigated design features and roughness together.

The most important methodological contribution was the creation of a method to observe crack formation around an implant during cyclic loading. Previously, it has never been shown that rim displacement does in fact correlate with initial or progressive loosening. The visual observation of failure progression – crack growth at the implant-cement interface - was correlated to the change of inferior rim displacement. The failure mode always initiated at the

inferior edge of the prosthesis, along the implant-bone interface as also found in a previous study (Raiss et al., 2011).

The common perception that the failure is in the cement-bone interface is mostly based on clinical studies that rely on radiographs. However, radiographic failure (radiolucent lines) between the implant and cement interface are not visible due to polyethylene being transparent itself making it impossible to differentiate any radiolucent lines from the polyethylene. It is also important to note that radiographic loosening detects gross loosening, however this study is aimed at investigating the early signs of failure where the resolution and accuracy needed are beyond the capabilities of current radiographic images.

Therefore these clinical papers can only conclude that there are radiolucent lines in the bone-cement interface but cannot conclude that there are no radiolucent lines in the implant-cement interface. Nyffeler et al. (2003) reported clinical failure at the implant-cement interface of a retrieved implant. Although this failure mode appears to be rare at the stages of failure where the implant is grossly loose, the authors suspect that this is an early failure mode and not as rare as is commonly thought due to the inability of radiographs to show failure in this interface. Gregory et al. (2009) also found early implant-cement failure testing in cadaveric bone in a similar cyclic glenoid loosening study using CT imaging, further strengthening the possibility of early implant-cement failure occurring that is not identifiable clinically. Further on-going work by the authors using cadaveric tissue has shown similar findings to Gregory et al. 2009 with early implant-cement interface failure evident in most samples and some cement-bone failure.

The experimental loading regime for this study was used specifically to analyse the type of failure mode observed and to investigate the hypothesis of whether implant-cement de-bonding due to tensile or compressive loading is the main contributor to failure. Furthermore limiting the test to superior cyclic loading is not an unreasonable testing regime as there is clinical and *in vivo* evidence to show predominately superior loading and humeral head migration in the glenohumeral joint (Bergmann et al. 2007; Trial and Nuttall 2002).

The main limitation of the study was that each design group consisted of 3 or 6 samples. The reason for this discrepancy in numbers is due to the initial aim of producing 3 distinct roughness groups with 3 repeats. However, the roughing techniques using sandblasting alone was insufficient to achieve a higher roughness group, thus the roughness groups were pooled and compared to the smooth group. The relatively small group numbers may have prevented identifying statistical significance of design effects even when such effects may exist. However, a post-hoc power analysis of the 16 groups (8 design groups in both the rough and smooth groups) shows the study to have more than 80% power ($\alpha$=0.05). Despite this, a post-hoc analysis of the rough and smooth groups separately to identify the power of the design features within the group found the power to be considerably less than 80%. This may indicate that the sample number per group was insufficient for analysing the design effects in detail. Despite this, the results show a general trend that effects were not detectable within the boundaries of a standardised test and therefore indicates other factors may be more influential to the fixation strength such as roughness, bone quality, cement penetration, component positioning and surgical technique. The number of cycles to failure in the smooth (n=23) and rough (n=36) groups demonstrated a clear dependence on roughness above all other design parameters.

The other limitation (and strength) is the use of the 2D sample configuration, which clearly differs from the geometry of commercial glenoid components. It is difficult to evaluate the effect of this simplification, but the justification is it allowed interfacial failure to be observed directly and it can provide both verification and greater insight for studies using more realistic models where the failure would not be visible. The loading scenario reflected a higher loading regime to what is typically expected in a glenoid implant for the reason that a 2D experimental set up was used. *In vivo* work by Bergmann et al. 2011 showed peak loads at 200% body weight, approximately translating to 1400 N. Although, the compressive load used at 1800 N was higher than the ASTM standard, it was not physiologically unreasonable due to the 2D setup of the experiment. Such a set up will require a contact pressure that is reflective of the physiological contact pressures (3D setup) rather than using the same loads in absolute terms. Therefore to ensure comparable testing conditions, the contact pressures in the 2D setup was compared to a 3D setup using Hertzian contact mechanics, showing contact pressures to be comparable with 4.1 and 5.9 MPa in the 2D and 3D scenario respectively. Therefore, while the 2D loads were higher than the clinical 3D loads, the resulting interface stresses were comparable to those of the clinical setting. In addition to making allowance for similar contact pressures, published *in vivo* data (Bergmann et al. 2011) and simulation data (Anglin et al. 2000) suggests these test parameters are proximate to peak loads experienced physiologically.

It was speculated that the omission of macrostructures may have had an effect on the results; this was carried out due to the difficulty in standardising the macrostructures for investigation. Since these vary from one implant brand to another, the study focussed on the key design features that glenoid implants have in common. To include various macrostructures could have diluted the comparison on cause of failure or resistance to failure.

This study was carried out for two purposes: to investigate key design features and to validate a quantitative method of measuring failure progression. The authors plan to test this measurement method on 3D commercial implants for further validation testing. Further study on the nuances in macrostructures and their effects on fixation in keel and peg designs is needed and may be more suited to a 3D setup.

Large standard deviations were observed in all designs, particularly for the roughened samples, despite the controlled nature of the experiment. This may be as a result of variations in the level of cement interlocking in the implant surface and bone substitute. Indeed further study of the surface topography and surface patterns of the implant back may be interesting to investigate further but was beyond the scope of this study. In regards to the consistency of cement penetration/interdigitation, although this was not measured to ensure consistency for every implant, the cementing technique reflected clinical practice and was carried out by a clinical colleague. This is believed to more accurately reflect clinical conditions as opposed to ensuring equal cement penetration throughout the cement mantel.

There is a question of whether using bone substitute is relevant. The choice in using bone substitute that is validated to the density range and compressive properties of human bone is believed to be valid in this case and in alignment with the ASTM standard (F2028-14). By removing an element of large variation in the study this allows for more conclusive tests to be carried out on other contributing factors to fixation failure. As mentioned, the results in this study also concurs with a cadaveric study using CT imaging showing early interfacial failure at the implant-cement interface (Gregory et al. 2009) and further on-going work by the authors using cadaveric tissue also supports this finding. It may be that due to the cementing conditions, cement adheres better to dry bone substitute than real bone, however both the

cement-bone and implant-cement interfaces experience the same load transmissions, therefore it could be argued that the failure ranking would remain the same despite possible variations in interfacial strengths. However, investigating the efficacy of different designs in light of varying bone conditions and cement penetration is still a necessary part of investigating glenoid fixation failure which is beyond the scope of this study.

This study has shown a large beneficial effect from roughening the back side of the glenoid component. Although Anglin et al. (2001) first indicated the importance of roughening, based on the immediate failure of just two smooth implants, this study provides a more comprehensive analysis. In total hip and knee replacements, implant roughness have also featured in mechanical testing studies looking at the ultimate and fatigue strength of roughened metal acetabular cups and tibial trays respectively (Delaunay & Kapandji, 1997; Miyakawa et al., 2004; Pittman et al., 2006). While there has been no other studies on the effect of roughness on glenoid fixation, in a study of tibial tray fixation Pittman et al. (2006) found that roughness increased the interface strength. The acetabular cup is not thought to fail through an eccentric load mechanism such as those for the tibial tray and glenoid component (Rocking horse mechanism) however, Delauney and Kapandji (1997) did find better osseointegration of hydroxyapatite coatings on roughened cups compared to smooth. Likewise, Miyakawa et al. (2004) found osseointegration improved with roughened screws. Both studies on the acetabular cup investigate cementless fixations and therefore the findings from these studies cannot easily be related to the findings of this study. In the case of the femoral stem, detrimental effects of increased roughness on cemented stem loosening has been well documented (Howie et al., 1998) and are caused be very different fixation principles than those of the glenoid component and a comparison with these studies is not meaningful.

Significant effects were not found between 'keel' and 'peg' designs or between flat- and curve-back. However, implanting the prosthesis into bone substitute material does not take into account that flat-backed designs require more resection of the subchondral glenoid bone than curve-backed designs. Thus curve-backed designs may be more advantageous than indicated in this study. Previous work evaluating commercially available implants, have indicated that curve-backed and peg implants were superior to flat-backed and keel implants (Anglin et al., 2001). An FE study also predicted higher rim displacement in the flat-backed models and associated this with poorer fixation (Iannotti et al., 2005) while a clinical RSA study suggested that curve-backed peg components perform better (Nuttall et al., 2007). In contrast and consistent with the results of the present study, the clinical investigation by Szabo et al. (2005) did not find a significant difference in radiolucent lines between the curve- and flat-backed glenoid implants and another study showed that intermediate clinical and radiographic outcomes are comparable between peg and keel implants (Throckmorton et al., 2010). Nho et al. (2010) and Rahme et al. (2009) also reported comparable radiographic outcomes of keel and peg implants.

This study did not find a significant effect of prosthesis conformity. Although greater conformity led to larger forces being imposed as the subluxation limit was reached, this was counterbalanced by the 'humeral head' component moving further from the centre of the glenoids with less conformity, so both groups experienced loading which induced similar rocking motion. Although constrained designs have been superseded, the literature of more recent semi-constrained TSA designs is inconclusive. A recent retrieval study showed significantly longer survival of more conforming designs (5.6 years) compared to 3.1 years in the non-conforming designs (Nho et al., 2010). Also, Oosterom et al. (2004) and Lacroix and

Prendergast (1997) conclude that conforming designs are more durable. In contrast, Anglin et al. (2001) and Orr et al. (1988) suggest that the fixation of less conforming designs is stronger and Walch et al. (2002) showed a reduction of radiolucent lines associated with lower conformity designs.

In this, as in other studies, the subluxation force was resisted only by the geometry of the implant. In reality, the surrounding soft tissues, particularly in regard to less conforming designs, play a role in resisting subluxation. However, there is very little knowledge of the extent to which the soft tissues play a role and this greatly complicates the analysis of the effect of implant conformity. In this study, comparing the subluxation distances between more conforming and less conforming (3 to 4 mm respectively) shows a difference of 1 mm. In absolute terms the distance is not high enough to bring large soft tissue effects and in relative terms a 1 mm difference between conformities is small.

This study has established a direct link between increases in rim displacement and directly observed failure in all implant designs. Although previous studies have used rim displacement as an indirect measure of fixation failure (Anglin et al., 2001; Collins et al., 1992; Oosterom et al., 2004), there was no established link between rim displacement and loosening. This association provides confidence in the use of the ASTM recommended rim displacement as an indication of fixation performance.

**Conclusion**

This study highlights the importance of implant surface roughness suggesting that roughening to Ra values greater than 3 µm will result in prostheses that are more likely to outlive the patient and avoid revision. However, further studies are needed to investigate if the results of

this in-vitro study will translate to improved performance in clinical practice. Significant differences were not found in relation to fixation design features of pegs versus keel, curve-versus flat-backed or conforming versus less conforming glenoid components and suggests that surgeons do not need to be overly concerned about which particular fixation design to be used.

The findings of the study support the use of rim displacement as a measure of fixation failure and that threshold values (in the present study 0.6 mm) that identifies fixation failure can be established.

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**Conflict of interest statement**

The authors have no conflicts of interest to declare.

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**Figure and Table legends**

Fig. 1: Samples cemented into bone substitute; flat-back peg (top-left) and curve-back keel (bottom-left). Two LVDTs were used to measure rim displacements at the superior and inferior parts of the component (right).

Fig. 2: Failure progression showing three modes of failure; no failure, mid-failure and failure.

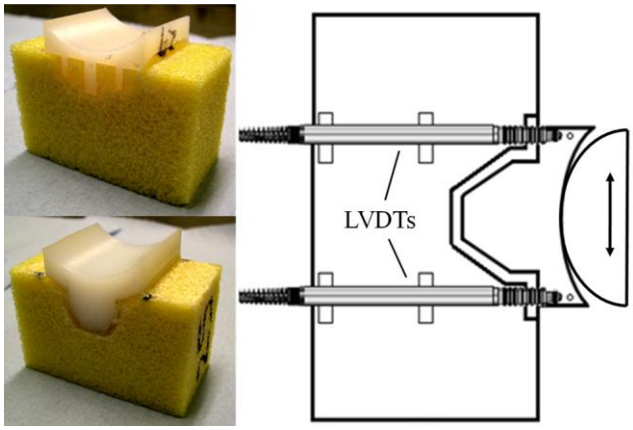
Fig. 3: Subluxation curve of 8 designs (n = 2 samples each). A significant difference in subluxation loads was found between the groups of implants with more or less conformity (*P* = 0.04).

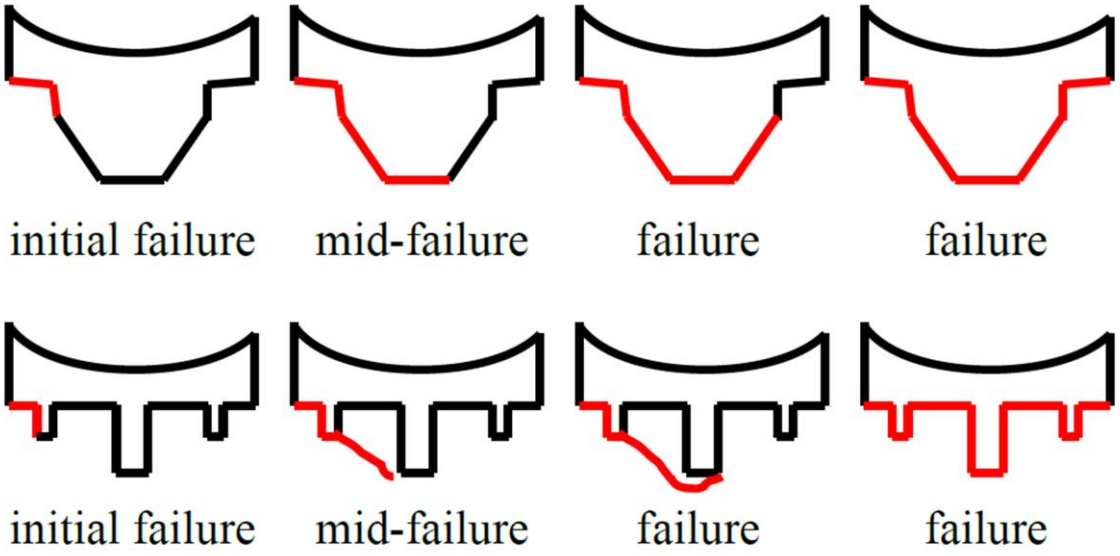
Fig. 4: Number of cycles to failure for samples of different designs and roughness (+/- SD).

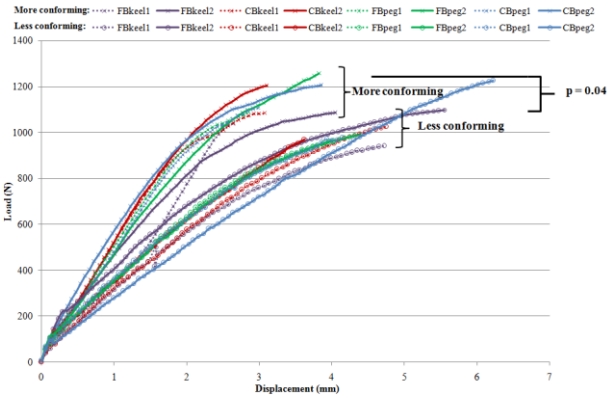
Fig. 5: Average inferior rim displacements with failure progression (before, at mid-failure and at failure respectively) for each of the eight roughened designs. Standard deviation is shown by error bars. Mid-failure: failure crack reached the keel or first peg; Failure: failure crack reached the implant mid-line.

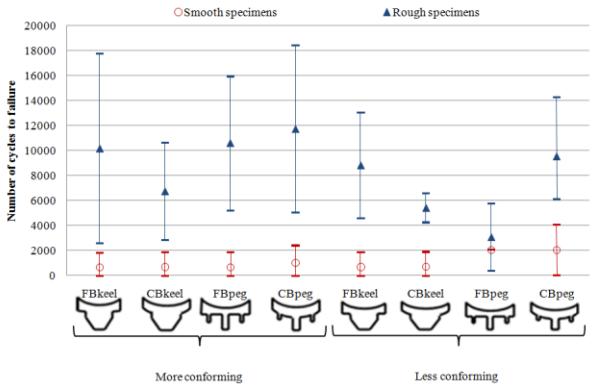
Fig. 6: Change in rim displacement with number of cycles in the non-failed, mid-failed and failed implant groups. Dashed lines are simple extensions to indicate the increase in rim-displacement from the average of the originally all non-failed samples to the rim-displacement when failure was first observed.

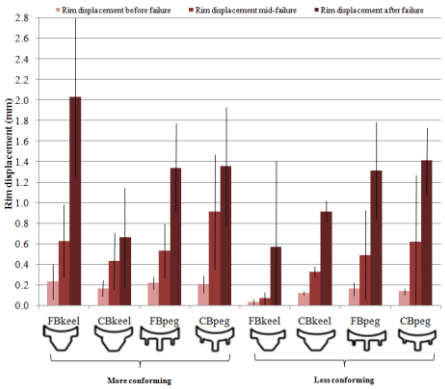
Table I: Overview of designs; two levels of backside roughness; two different fixations, peg and keel; two different backing shapes, flat-backed (FB) and curve-backed (CB); and two levels of conformity (larger radial mismatch indicates less conformity).

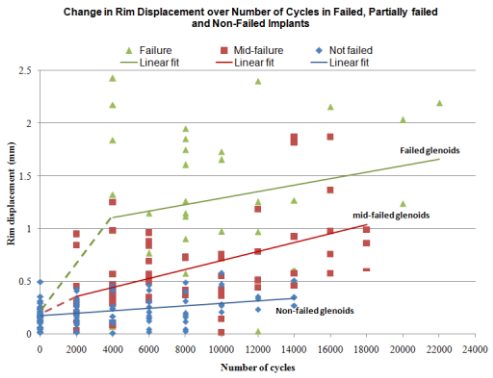












| | Smooth (Ra = 0-2 μm) | | | | Rough (Ra = 3-5 μm) | | | |
|---|---|---|---|---|---|---|---|---|
| Radial mismatch (glenoid radius) | Keel | | Peg | | Keel | | Peg | |
| | FB | CB | FB | CB | FB | CB | FB | CB |
| 5 mm* (29 mm) Less conforming |  n = 3 |  n = 3 |  n = 3 |  n = 3 |  n = 3 |  n = 3 |  n = 3 |  n = 3 |
| 1 mm* (25 mm) More conforming |  n = 3 |  n = 3 |  n = 3 |  n = 3 |  n = 6 |  n = 6 |  n = 6 |  n = 6 |

* Humeral head radius was 24 mm leading to mismatches of 5 mm and 1 mm when related to respective glenoid radii shown.