DEVELOPMENT OF FATIGUE STRENGTH VERIFICATION METHODS FOR A NOVEL HIP REPLACEMENT DESIGN

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Abstract

Orthopaedic implants such as joint replacements can experience impact and cyclic loads several times the weight of the body. There is an incentive to preserve bone by minimising the wall thickness of prostheses. This is enabled by novel biomaterials with improved strength, including transformation toughened ceramic composites. In pre-clinical testing there is a particular focus on tribology and wear performance, but the structural integrity of thin walled prostheses must also be verified before clinical use. The large safety factors of thicker, over-engineered devices can no longer be relied upon, so thorough fatigue-life analysis and testing must be conducted. Standard test methods exist for traditional implant designs, but a challenge to the bioengineer is the development of clinically representative *in-vitro* tests and computational analysis methods for novel designs. This report presents the development of pre-clinical analyses and tests for a case study design: a large bore modular acetabular cup, comprising a transformation toughened ceramic bearing insert and a titanium alloy outer shell.

Two approaches were used in the pre-clinical verification: computational analysis and physical testing. Initially, the *in-vivo* stress distribution in both designs was predicted with Finite Element (FE) analysis, using supporting bone models derived from clinical CT scans. Clinical variability was incorporated by modelling a range of loads and implant positions. There is abundant mechanical test data for the Ti-6Al-4V medical titanium alloy material, so it was possible to analyse the shell's fatigue failure risk using the FE stress predictions. For the ceramic bearing component, published fatigue strength data for the material was sparse. Therefore, *in-vitro* tests were conducted, reproducing predicted *in-vivo* stress patterns, under extreme magnitude fatigue and static loading and worst-case surgical positioning.

According to the FE predictions, the thin wall section of this design led to a high steady-state stress in the titanium alloy shell, with a smaller magnitude dynamic stress. Therefore, to assess the predicted performance of the ductile titanium shell under the combined loading, resulting stresses were analysed using the conservative Soderberg method. Taking lower bound literature data for the yield strength and endurance limit of plasma sprayed Ti-6Al-4V material, a reserve factor of 2.40 was predicted in comparison to the Soderberg method's constant life limit. In the event of a surface scratch in the shell creating additional stress concentration, a minimum reserve factor of 2.04 was predicted. For the ceramic bearing insert, a peak tensile stress of 166 MPa under 5 kN loading was predicted. Compared to a reported typical material strength value, this was predicted to give a safety factor of approximately 6.9. In physical testing, no insert or shell failures occurred after 10 million cycles. Following fatigue testing, no cups failed under 100 kN static loading, representing over 100xbody weight.

This study employed a combination of computational modelling and physical testing to verify the structural integrity of a case study joint prosthesis concept under worst case static and fatigue loading conditions. Similar methods could be applied to a wide range of novel prosthesis designs, and are particularly relevant as implant designs aim to conserve bone at the expense of reduced safety factors compared to over-engineered traditional designs.

1 INTRODUCTION

Orthopaedic implants such as joint replacements can experience impact and cyclic loads several times the weight of the body as a result of normal activities [1] and occasional traumatic events, such as stumbles and falls [2]. Developments in the strength of implant biomaterials have increased safety factors of traditional designs. Particular effort has been focussed on ceramic biomaterials, where the state of the art is the transformation toughened ceramic composite [3]. With the application of these materials, traditional, small bearing diameter, thick walled implant designs may have become considerably over-engineered.

There is an incentive to minimise the wall thickness of implants, because this enables the diameter of the bearing to be maximised without the cost of additional bone removal during surgery. This benefits the younger patient: bone stock preservation is beneficial upon revision of the implant, and a larger bearing diameter reduces the risk of dislocation, which permits patients to return to more vigorous activity. There is likely to be a trade-off between increased material strength and reduced implant wall thickness, so the structural pre-clinical verification of new implant designs is essential. The majority of the loads experienced by orthopaedic implants are cyclic, so fatigue analysis and testing must be conducted. Standard test methods exist for traditional implant designs, but a challenge to the bioengineer is the development of clinically representative *in-vitro* tests and computational analysis methods for novel designs.

Hip replacements are one of the most commonly used orthopaedic implants. Modular acetabular cups- the socket part of a hip replacement bearing couple- comprise a bearing insert for low wear articulation, and a metallic outer shell featuring a surface treatment permitting fixation to the bone through osseointegration. A sketch of an implant representative of a typical modular acetabular cup design in clinical use is shown in Figure 1a. The present example considered a transformation toughened ceramic composite bearing cup featuring a Ti-6Al-4V shell with a rough vacuum plasma sprayed Titanium and Hydroxyapatite (HA) coating. The insert and shell are assembled using a tapered interference fit, permitting a range of implant size options. In this example, the interference fitted outer cup has an additional intended role: to generate a protective compressive residual stress field in the thin bearing shell rim.

With this bone-conserving acetabular cup concept, featuring a brittle ceramic material, low wall thickness and assembly pre-stresses, detailed analysis of the fatigue stress scenario is of particular importance. This study reports a proposed pre-clinical analysis programme, for application to novel ceramic orthopaedic implants, using the thin walled acetabular cup concept as a case study.

2 METHODOLOGY

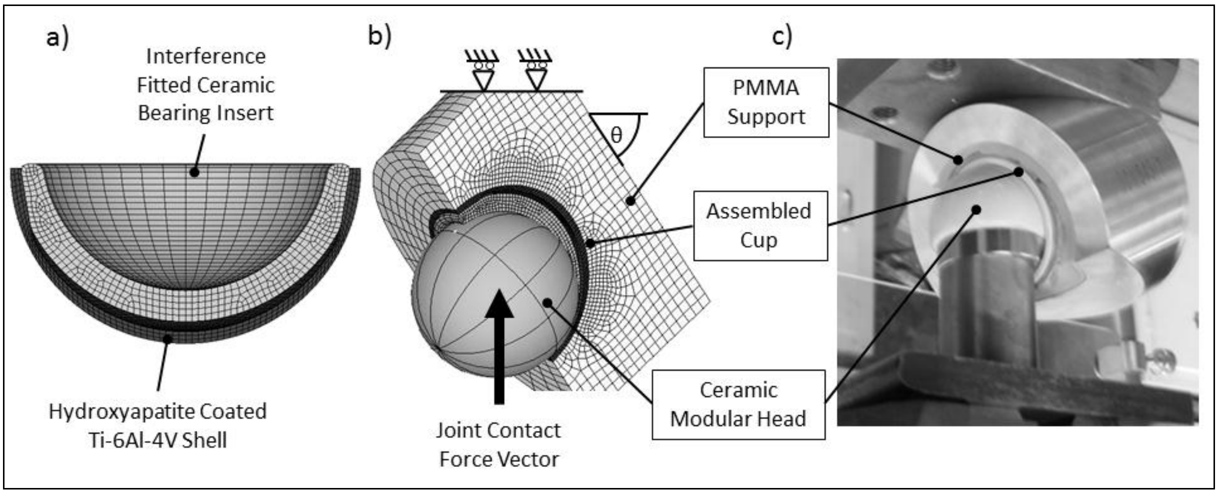

Figure 1: Acetabular Cup Geometry with FE Mesh (a), Inclined Loading Boundary Conditions (b), and Photograph of Physical Test (c)

Two approaches were used in the pre-clinical verification: computational analysis and physical testing. Initially, a structural FE analysis was used to predict the stress distributions arising from interference fitted assembly and superimposed *in-vivo* loading. Implant geometry was generated using SolidWorks CAD software (SolidWorks Corp., Concord, MA, USA). This was imported into ANSYS 12 FE analysis software (ANSYS Inc., Canonsburg, PA, USA). The implant was assigned material properties as listed in Table I.

Table I. Assigned Material Properties

Model Region	Material	Young's Modulus (GPa)	Poisson's Ratio
Bearing Insert	BIOLOX Delta (CeramTec AG, Plochingen, Germany)	350	0.22
Shell	Ti-6Al-4V ELI Alloy ASTM F136-08	110	0.34
Support Material	PMMA	2.8	0.3

The model was meshed with twenty-node hexahedral elements at a density which was verified with a convergence analysis. Coulomb friction was defined at the taper interface between the insert and shell with a coefficient of friction (COF) of 0.3. A single, rigid, spherical target element representing a modular ball head was used to load the bearing, with frictionless contact. The base of the support material was constrained against motion in all directions, and a 5kN joint contact force representative of jogging was used to load the head. To simulate a range of surgical positioning and loading scenarios, the angle between the force vector and the cup axis was varied between 30° and 75° in 15° increments. The FE model with its loading and boundary conditions is shown in Figure 1b.

The assembly loading was predicted to generate a residual tensile stress in the titanium shell, over which the *in-vivo* joint contact force was predicted to create additional cyclic tension. The predictions of the FE model were therefore analysed using the conservative Soderberg method for plastic materials [4, 5]. The reserve factor under these conditions was analysed using Equation 1:

$$K_f \, \sigma_{amp} / S_e + \sigma_{mean}/S_{yt} = 1/N_f \qquad (1)$$

where:
K_f = the fatigue stress concentration factor,
σ_{amp} = the amplitude of the cyclic stress,
σ_{mean} = the mean stress level,
S_e = the endurance limit of the material, 387MPa for grit blasted and HA coated Ti-6Al-4V [6],
S_{yt} = the yield strength of the material, min. 760MPa [7] and
N_f = the resulting predicted reserve factor.

K_f was calculated by Equation 2:

$$K_f = 1 + q(Kt-1) \qquad (2)$$

where q is the notch sensitivity factor and Kt is the stress concentration factor. A worst-case assumed notch sensitivity factor of q = 1 was used for this analysis. Two approximated K_t values were applied to represent surface finish factors (K_s), representing a machined surface finish (K_t = 1) and a forged or scratched surface finish (K_t = 3) [8].

Considering the bearing component, published fatigue strength data for the BIOLOX Delta ceramic material was sparse. One study in the literature set out to assess its fatigue life under cyclic flexural stresses of peak 300 MPa, double the maximum *in-vivo* stress for modular heads, with autoclaving to represent accelerated aging. However, they observed no fatigue failures and measured no reduction in static strength after 20 million cycles, representing approximately 20 years of service [9]. Therefore, initial analysis took into account the static strength of the ceramic component under peak loads, by comparing the peak tensile stress to a conservative estimate of the tensile strength, 600 MPa, based on a reported flexural strength of 1384 MPa [3]. For more rigorous verification, *in-vitro* tests were developed, to reproduce the predicted *in-vivo* stress patterns, under extreme magnitude fatigue and static loading and worst-case surgical positioning.

Ten cups were fatigue tested using an Instron 8878 servo-hydraulic axial test machine (Instron Corp., Norwood, MA, USA. Capacity 25 kN). Five cups were potted in aluminium cylinders with PMMA (Technovit 3040, Heraeus Kulzer GmbH, Hanau, Germany) at 45º and sinusoidally loaded between -0.758 kN and 7.58 kN (approximately 7.5 x bodyweight, R = 0.1) at a frequency of 30 Hz for 10 million cycles. Five more cups were potted at 60º and loaded between -0.580 kN and 5.80 kN (approximately 5 x bodyweight, R = 0.1) at 30Hz for 10 million cycles. The 60º test setup is shown in Figure 1c. Following fatigue testing, the cups were disassembled and the ceramic components were inspected using dye penetrant to identify any surface damage. Finally, static burst tests were carried out on six additional cups, 3 inclined at 30º and 3 at 60º, using an Instron 1196 electromechanical test machine at a 0.5 kN/s ramped loading rate, until failure or a load of 100 kN.

3 RESULTS

3.1 FE Analysis

Figure 2 shows the 1st Principal (tensile) stress in the ceramic bearing insert, under assembly conditions and the range of *in-vivo* loading. Assembly was predicted to generate an axisymmetric residual tension field with a peak of 31.0MPa on the external surface of the insert, over which the service loading superimposed a local patch of biaxial tension. This generated a peak tensile stress of 164 - 166MPa around 30° to 45° inclination. The interference fit generated approximately 112MPa of compression in the shell rim, which protected this thinner section of the shell against excessive tension at steeper inclinations. Therefore the worst case was predicted at 30° inclination, where the stresses can be approximated to a cycle of mean stress σ_m = 98.5MPa and stress amplitude σ_a = 67.5MPa (or stress ratio R = 0.19).

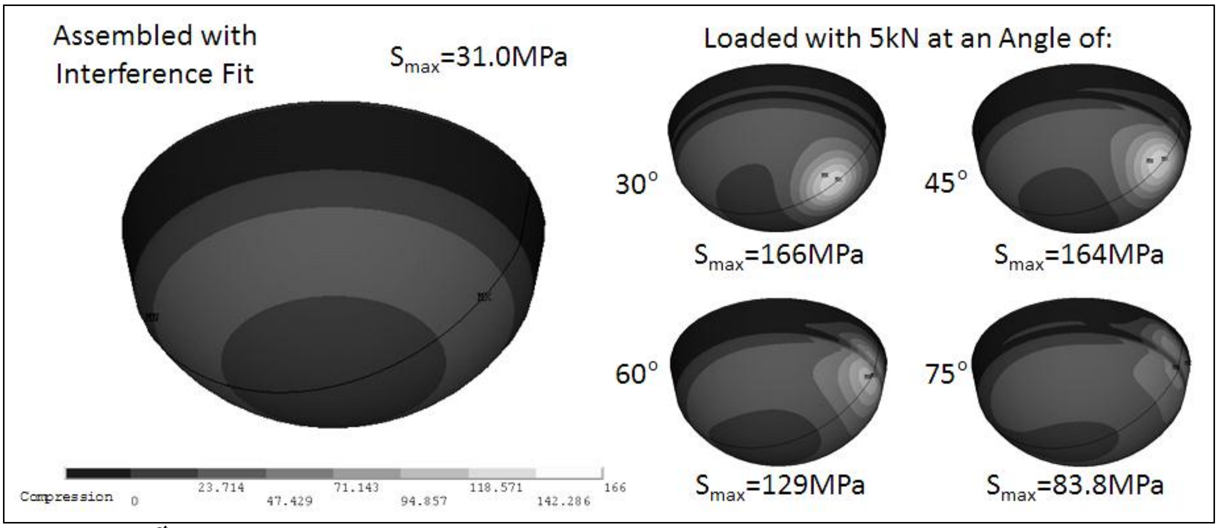

Figure 2: 1st Principal Stress in the Ceramic Bearing Insert. Residual Assembly Stress (left) alone and with Superimposed Joint Contact Force Loading at a Range of Inclination Angles (right).

Figure 3 shows the von Mises equivalent stress in the titanium alloy shell, under the assembly and loading conditions. Assembly generated axisymmetric residual hoop tension with a peak of 274MPa at the shell rim. This was increased to a maximum of 303MPa at 75° inclination. This is can be approximated to a worst-case cycle of mean stress σ_m = 288.5MPa and stress amplitude σ_a = 14.5MPa (or stress ratio R = 0.90).

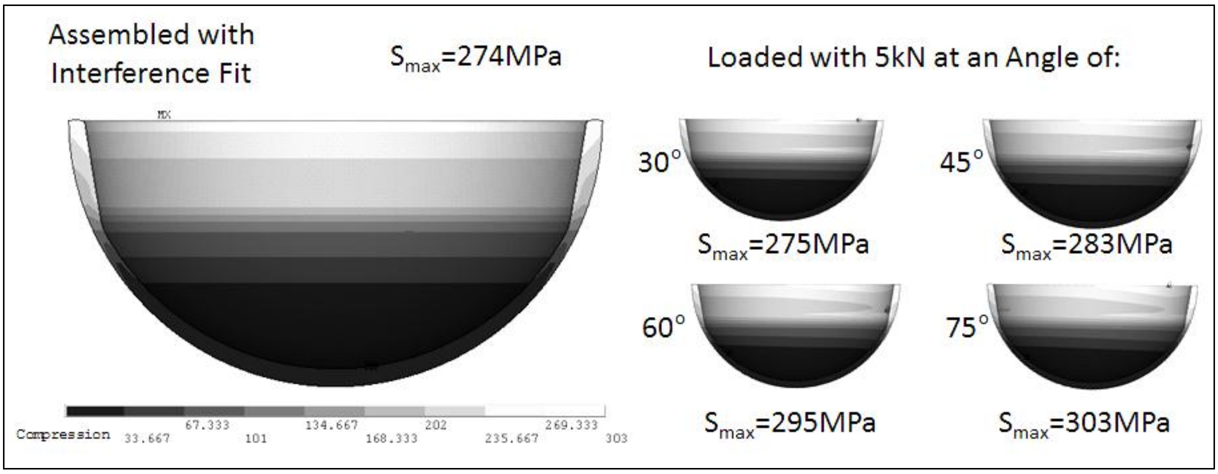

Figure 3: von Mises Equivalent Stress in the Titanium Alloy Shell. Residual Assembly Stress (left) alone and with Superimposed Joint Contact Force Loading at a Range of Inclination Angles (right).

Figure 4 shows the contact pressure on the taper interface under assembly and loading conditions. At no point of loading did the predicted pressure drop below zero along a full section of the band, indicating that under non-impinging service loads, the interference fit would be sufficient to avoid disassembly of the cup-insert structure.

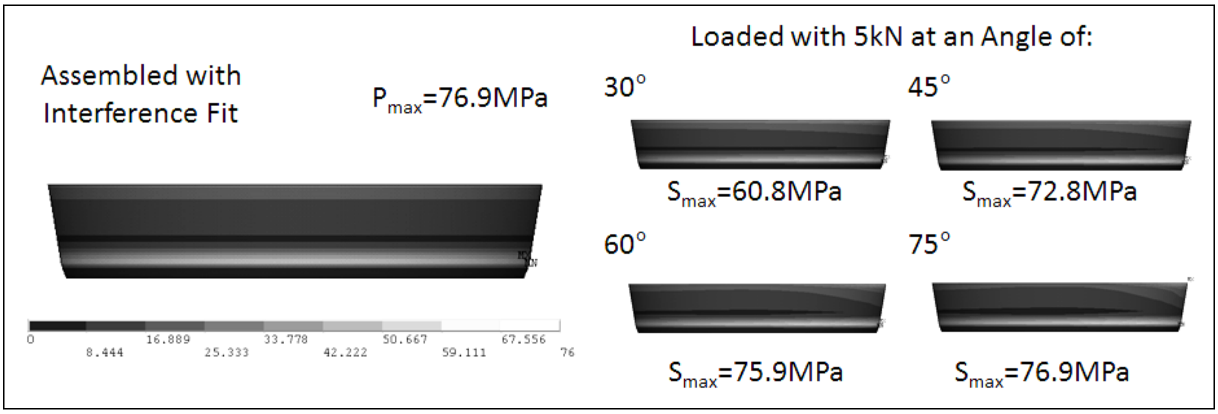

Figure 4: Contact Pressure on the Taper Interface. Residual Assembly Pressure (left) alone and with Superimposed Joint Contact Force Loading at a Range of Inclination Angles (right).

A Soderberg diagram was plotted using the worst case cyclic stress results from the FE analysis of the titanium shell, the 30° loading condition. A graph of the machined and forged/scratched surface conditions versus the Soderberg material endurance limit line is shown in Figure 5. The resulting reserve factors were calculated as 2.40 for a machined finish, and 2.02 for a forged or scratched surface finish.

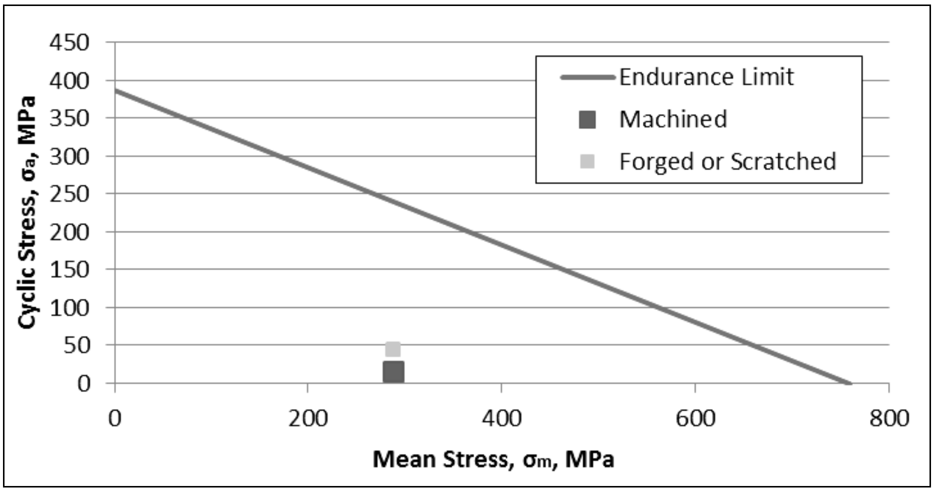

Figure 5: Soderberg Diagram indicating the Fatigue Reserve Factor for the Worst Case Titanium Alloy Shell Stress Conditions (75° Inclination) with a Machined and Forged or Scratched Surface Finish.

3.2 Physical Tests

No cups failed during 10 million fatigue cycles. No surface damage was observed on inspection using dye penetrant. No cups failed at 100 kN static loading. One cup was loaded to failure, which occurred at 187.5 kN.

4 DISCUSSION

This study set out to present a pre-clinical analysis method for novel orthopaedic implant designs under cyclic loading. A case study example modular acetabular cup was used, employing a transformation toughened ceramic bearing material and a titanium shell. Contemporary modular cups employ a titanium shell for fixation to the bone, but the present design featured a pre-stressed interference fitted assembly method, intended to impart protective compressive residual stress in the ceramic insert's rim. This is of importance in bone conserving implant designs, where wall thickness is lower than traditional, thicker walled, smaller bearing diameter cups, so higher stresses would be expected. The combined effect of these novel design features, a reduced safety factor compared to traditional designs and the use of the brittle ceramic material made pre-clinical strength verification of particular importance, to avoid *in-vivo* failures.

In this study, computational analysis was used to assess the residual and cyclic stresses generated in the two cup components under assembly and *in-vivo* loading. In both components, the peak stresses were predicted to be insufficient to cause static failure; the peak ceramic insert tensile stress was 166 MPa, 6.9 times below the 1384

MPa flexural strength, and the peak titanium alloy shell von Mises stress was 303 MPa, 2.5 times below the 760 MPa yield strength. However, owing to the cyclic loading above a high mean stress level in the titanium alloy shell, additional analysis was conducted to verify the fatigue strength of the assembled cup. A conservative analysis using the Soderberg method predicted reserve factors above 2 both in the ideal case, if the shell were machined, and in worse cases where cost could require shell manufacturing through forging, or if it were scratched during production. Both results indicate that the shell would not be stressed sufficiently to cause fatigue failure.

With insufficient material strength data available to perform a similar analysis on the ceramic shell, physical tests were conducted, and the assembled cups survived approximately 10 years' worth of high magnitude loading. The cups also demonstrated a very high static strength, in excess of 100 kN, equivalent to approximately 100 times bodyweight. It is likely that the bearing insert bottomed-out inside the titanium alloy shell, at which point its elastic support structure reduced the rate of increase in tensile stress, which may explain the high fracture load in the single cup which was loaded to failure.

The simulations and tests are subject to several limitations. Combining variability in loading, surgical positioning and the mechanical properties of the supporting bone and its interface with the implant, a highly non-deterministic situation exists. Confidence in the computational analysis could be increased with the consideration of these variables through probabilistic methods. However, there is no theoretical limit to the range and magnitude of traumatic loads which can be imposed upon orthopaedic implants, so worst-case test methods and conservative pass criteria must be defined. In this example, worst realistic case normal loading scenarios were simulated, and the results were analysed using conservative endurance limit, yield strength, stress concentration factor and notch sensitivity factor values. Even worse cases of surgical positioning could occur, but it must be assumed that these rare cases would be detected during clinical follow-up, and corrected. Further testing would consider the effects of traumatic loading with incomplete seating of the head in the cup, and dynamic bearing edge-loading.

5 CONCLUSIONS

This study employed a combination of computational modelling and physical testing to verify the strength of a nominal joint prosthesis concept under worst case static and fatigue loading conditions. Computational analyses based on conservative input data were corroborated by physical tests to indicate that the case study implant's structural integrity was sufficient to sustain extreme *in-vivo* loads, when correctly implanted and when malpositioned. Similar methods could be applied to a wide range of novel prosthesis designs, and are particularly relevant as implant designs aim to conserve bone at the expense of reduced safety factors compared to over-engineered traditional designs.

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