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Westerman, AP, Moor, AR, Stone, MH et al. (1 more author) (2018) Hip stem fatigue: : The implications of increasing patient mass. Proceedings of the Institution of Mechanical Engineers, Part H: Journal of Engineering in Medicine, 232 (5). pp. 520-530. ISSN 0954-4119

https://doi.org/10.1177/0954411918767200

Hip Stem Fatigue : The implications of increasing patient mass.

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Keywords:

Hip Arthroplasty, Femoral Stem Fatigue, BMI, Failure

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Abstract

Background

General trends of increasing BMI have been observed in many western countries along with an increasing demand for joint replacement. Standards have been developed for testing the fatigue properties of femoral stems, however, the loads that these apply are based on a historic patient weight and may not be valid in the current patient population.

Methods

Several Fatigue tests were conducted using distally fixed titanium alloy stems positioned according to the ISO standard but with a cyclic load based on a current 75th percentile patient sample.

Results

Smaller sized stems (currently not weight restricted) fractured in ~30,000 cycles; whilst larger sized stems were found to have excellent durability under loads simulating walking and stumbling.

Conclusion

The results suggest that whilst the fatigue properties of medical grade titanium is very good the ISO pre-clinical durability testing standard does not represent the influence of femoral offset or stem size sufficiently to reflect safe design practice.

1. Introduction

According to the UK National Joint Registry, the average Body Mass Index (BMI) for Total Hip Arthroplasty (THA) patients has risen from 27.4 in 2004 to 28.7 in 2015, both of which fall within the 'overweight' category [BMI = 25-29] defined by the World Health Organisation. [1] This raises the question whether our devices are keeping up to date? This has been highlighted by authors such as Wroblewski et al who raised the issue of patients generally gaining weight after hip replacement and the subsequent potential for implant fatigue failure. [2]

The long term durability of most products is limited by fatigue brought about by the formation and growth of cracks within the structure. In the design of engineering components for fatigue, a factor of safety is utilised whereby the worst case expected load is multiplied by a constant so that during testing a greater load is applied than expected to provide a level of protection to the user. These factors of safety may be reduced as more stringent care is taken in the development of the device in terms of quality control. In aircraft design, for example, as weight is very critical the working load is very close to the fatigue load and thus safety is introduced to components by introducing a limited lifespan. In other areas, however, a factor of safety is common to allow for unexpected loads and provide confidence to the designer that the component will not fail. [3-5] Hence, stress (function of load) Vs. life (cycles to failure) curves are produced through rigorous testing, generally utilising laboratory controlled conditions that follow accredited testing standards.

Manufacturers are required to complete pre-clinical testing of stems for regulatory approval. This testing follows the international standard ISO 7206-4, with manufacturers conducting sinusoidal compressive loading for 5 million cycles, equivalent to up to 5 years of use. [6, 7] The load applied, however, is representative of 3 times body weight for a 75kg patient. This raises some immediate questions, firstly the force applied during walking has been reported as 3 times body weight, hence there is no scope in the standard to apply a safety factor; a load of 6 times body weight for example, or

10 times body weight as expected for a stumble.[8] Secondly patient mass is increasing and 75kg does not represent worst-case loading. Finally activity levels vary considerably in patients and the standard only represents a low activity patient; 2 million cycles per year has been reported to be common following hip arthroplasty.[9] Fatigue studies generally follow the ISO standard and represent a distally supported stem in a neutral position with fatigue fracture occurring near the fixation level. There have been several studies that have combined finite element analysis with experimental fatigue in order to predict stem failure. These studies have found that the maximum stress and crack initiation has been reported to be located in the anterior lateral aspect of the stem just beneath the fixation level where the bending moment is the greatest.[9-13] However, studies like this are very implant specific as the individual material and geometry of the stem dictates the specific location and magnitude of the maximum tensile stress/strain where cracks initiate. Ploeg et al compared the accuracy of different empirical models for predicting fatigue in titanium stems and concluded that the classic S-N curve proposed by Basquin was accurate at low stress levels. [5, 14] They additionally stated that differences in alloys and heat treatments used by manufacturers can vary the crystalline structure and thus alter the specific fatigue results for a given stem.

Concerns regarding dislocation, leg length and soft tissue tension have meant that an individual company's stem design now has various options for increasing femoral offset through changes made to both the neck of the stem and the taper in the head. [15] The greater femoral offset creates a greater torque applied to the stem and to its fixation and thus there are increasing clinical concerns of the potential for fracture in high offset stems particularly if they are implanted in a varus position and show signs of radioluscency. [16] The authors postulate that the current ISO standard may not represent worst case loading observed clinically. The aim of this study was to assess current trends in patient weight and to apply these in a fatigue test to a popular titanium hip stem as a means to assess the validity of the ISO standard and its sensitivity/consideration to femoral offset. A subsequent fatigue vs cycles to failure curve was additionally produced to facilitate design and a very aggressive stumbling study was completed to investigate the behaviour of the stem under adverse conditions.

2. Materials and Methods

2.1 Trends in patient weight.

A total of 48 patients' height, weight and BMI details were taken from a random sample of Total Hip Replacement (THR) cases (NIHR Leeds Biomedical Research Centre, Leeds Teaching Hospitals Trust, Leeds, UK) and statistically analysed in R (Vienna, Austria). As per National Health Service (NHS) Health Research Authority requirements the patient data utilized was previously collected and was not identifiable to the research team carrying out the research. A Shapiro-Wilks test was used to evaluate whether the data was normally distributed. [17]

2.2 Fatigue Testing of Femoral Stems

Two fatigue studies were undertaken. The first fatigue study involved the application of a peak sinusoidal load of 3.2 x Body Weight (BW) to the stems to simulate normal walking.[8] As body weight varied between individual patients a typical patient 75th percentile mass was applied. Only size 8 and size 10 stems (Table 1) were used as the smaller size 6 stem is weight limited to 60kg and thus the size 8 and 10 stems represented the smallest stems that were most likely to be affected by trends in patient mass. Components that survived 10 million cycles of fatigue were subjected to a further 50 stumbling cycles using a peak cyclic load of 9500N, representing 10 x BW as a worst case scenario to assess the ultimate durability of the stem.

The second fatigue test aimed at generating a prediction of the number of cycles (steps) it may take for a given stem and patient BMI combination to fail. Traditionally in engineering this involves the generation of an S-N design curve where S is the applied stress amplitude and N the number of cycles to failure. As individual stem sizes have a different cross sectional area and offset the load has to be changed for each stem to consider a range of stress levels in the S-N curve. In practical terms in the study this involved analysing each stem size/offset in a finite element model to analyse the stress and then to subsequently apply a range of stress levels experimentally to different sizes of stems in order to reproduce a stress vs cycles to failure curve for the titanium stem design (Table 2). A modified version of Basquins' Law, Equation 1, was utilised to approximate the long term high cycle fatigue behaviour of the stem.[5, 14] In Equation 1, C and b are empirically determined constants, with b=1/8 considered a conservative value and b=0.03 proposed by Ploeg et al for titanium stems, σ_{amp} is equal to the stress amplitude, and N_f is the number of cycles to failure at the applied stress range. A finite element model (Section 2.2.2) was used to predict stress amplitude σ_{amp}, for the study. The loads / stress levels applied in this part of the study are not meant to represent the loads applied to the stem for a particular patient/ activity, but are intended to cause stem fracture at different cycles to failure, N_f values. Sets of σ_{amp} and N_f values were produced from each test and averaged to determine the fatigue strength coefficient "C" to complete the Basquin equation and allow a high cycle stress Vs. cycles to failure curve to be presented.

$$\sigma_{amp} = C\left[2N_f\right]^b \qquad \text{Equation 1.}$$

2.2.1 Components and component position.

Several sizes and neck offset varieties for a current un-cemented Titanium stem were taken from new old stock (Table 1 and 2) ; all products were in their original sterile packaging and had exceeded their hospital shelf life. As there is no evidence or scientific reason to suggest that the fatigue properties of a femoral stem may reduce with shelf age; this was considered appropriate. Matching 28mm diameter femoral heads were used with a +1.5 and a +8.5 head offset. Standard femoral neck offset and high offset femoral neck designs were selected. The head and neck offset combinations allowed for an additional evaluation of the effect of femoral offset within the ISO standard.

All specimens were fixed distally in polymethyl methacrylate (PMMA) bone cement (WHW Plastics, UK) within a stainless steel pot. Stems were positioned at 10° adduction and 9° flexion in a jig, as defined by the ISO standard (Figure 1) and load was applied relative to the vertical axes.[6] The distance from the centre of the femoral head to the embedding level was 80 mm; this was particularly important when the head/neck offset was altered.

For fatigue testing an Instron Electropulse e3000 (Instron, High Wycombe, UK) fatigue testing machine was used to apply an axial sinusoidal force to the femoral stems at a frequency of 7.5 Hz for a duration of 10 million cycles (Figure 2); this was greater than the recommended test duration from ISO. Wroblewski et al. reported that 10 million cycles was more realistic compared to the 5 million cycles the ISO standard requires. [2, 13] Note that the size 11 component required a much greater force to cause fracture and an Instron 5985 with a triangular load waveform was used for this stem to create fatigue failure. In all tests the load was applied as per the iso standard vertically downwards to the femoral head through a Delrin polymer block utilising a superiorly placed shear bearing, to allow lateral deformation of the stem and creating a reproducible test protocol.[18]

To simulate stumbling, a load 0.3-9.5 kN was applied in 0.1 seconds (10 Hz) ; this was repeated 50 times, or until the stem failed by fracture or by deformation. This corresponds to ~10 x Body Weight for a 97kg patient, significantly greater than that reported by Bergmann et al. who recorded 7 times body in-vivo in a patient whom had stumbled with an instrumented prostheses. [8] The aim of this very aggressive test was to investigate the toughness of the stem by determining whether the stem would fracture or whether it would be tough enough to simply deform.

2.2.2 Prediction of applied stress.

The femoral stem geometries for the components in Table 1, 2 were measured using a Nikon Shadowgraph and a Mittutoyo digital calliper (±0.05 mm) and subsequently modelled in Autocad three-dimensional computer-aided design software (Autodesk Inc., San Rafael, CA). The stem axis was defined as specified in ISO 7206-4. [6] The areas surrounded by the hydroxyapatite coating were measured and then subtracted by 0.155 mm (coating thickness) to obtain the dimensions of the Ti-6Al-

4V femoral stem. Additionally, key dimensions such as stem length, femoral offset, head offset, neck length and neck-shaft angle were checked against a published product catalogue. [19]

The finite element software ANSYS Workbench R 16 (ANSYS Inc., Canonsburg, PA) was used to investigate stress levels in the femoral stems at peak applied load. [20] To achieve this the model included all components in the loading system, from the Delrin block to the steel pot. All parts were assigned isotropic elasticity properties as defined in Table 3. [21] All contact regions were assumed to be fully bonded and a coefficient of friction of 1.0 was used. [12, 22-27]

Finite element models utilised SOLID187 higher order three-dimensional 10-noded tetrahedral elements and a mesh convergence test was completed to optimise computational time. For all of the components mesh convergence occurred when both the vertical deflection and maximum principal stress produced less than 1% variation compared with finer meshes. Maximum tensile stresses were subsequently compared for each stem/offset/head models. Finite element models were validated by comparing the predicted vertical deflection of the femoral head for each stem size under a range of loads against the experimental measurement, as shown in Figure 3 to ensure that results of the model were accurate.

2.3 Geometrical Considerations - Coverage

Stem coverage was defined as the percentage of the vertical aspect of stem length that was supported by cement when following the conditions specified by the ISO testing standard. Implant size/geometry were taken from the implant manufacturer's product catalogue and transposed into the vertical axes as defined by ISO; this was confirmed within the CAD model. [6, 19] Stem coverage was then calculated by subtracting the vertical component of neck length in the ISO axes (contributions of the stem plus the head) from the 80mm coverage distance (Figure 2) and then further subtracting this value from the manufacturers stem length. This enabled the percentage of coverage of the stem to be determined for each stem/head combination.

3. Results

3.1 Trends in patient weight

The mean height, weight and BMI of the 48 THR patients sampled was 163.8 cm $\pm$ 12.3 cm, 80 kg $\pm$ 16.5 kg and 29.3 $\pm$ 5.3 respectively (Average$\pm$ Standard Deviation). Subsequent statistical analysis suggest that the data was normally distributed at the 5% significance level. The frequency distribution of patient mass is shown in Figure 4. The 10th, 50th, 75th and 90th percentile of the patients' weights were 61.6 kg, 78.5kg, 89.5 kg and 103.2 kg respectively. The 75th percentile patient mass (89.5 kg) was thus adopted for the initial Fatigue testing of stems, instead of 75kg as defined in the ISO testing standard.

3.2 Fatigue testing at 75th percentile patient mass, followed by simulated stumbling.

The 75th percentile patient mass was converted to a fatigue testing load where the peak load was defined as 3.2 x BW in Newtons.[8] Consequently a peak cyclic load of 2800N was applied. Loading cycles to failure results are shown in Table 4. Size 8 standard offset stems with a +1.5 head offset fractured at an average of 121,734 $\pm$ 170683 cycles whereas the same stem with a + 8.5 head offset fractured at an average of 74376 $\pm$ 46395 cycles (Average$\pm$ Standard Deviation). A typical fractured stem is shown in Figure 5 where localised debonding of the hydroxyapatite (HA) coating was observed and fracture at the location of the stem support. All size 10 stems lasted the full 10 million cycles test duration without failure or noticeable debonding of the HA coating, hence larger stems were not tested.

The Size 10 stems were further subjected to 50 cyclic stumbling cycles (9.5 kN). None of the size 10 stems fractured under this extremely severe load; however, significant permanent vertical deformation >5mm relative to the potting axes was observed in all stems. Stems also demonstrated large areas (1-2cm^2) of HA debonding at the potting surface (Figure 5).

3.3 ISO Deformation/bending of stems

The vertical deformation of the stems as a function of load was predicted within the computational model following initial experimental validation for each stem size (Figure 3). Vertical deformation (Figure 6) provides a simple way to evaluate the stiffness of each stem configuration as loaded according to the ISO standard and provides a practical number surgeons can relate to. For a standard offset stem with a +8.5 head the vertical deformation under a load of 2800N increased from 0.84 mm for a Size 11 stem to 2.57 mm for a size 6 stem, a threefold increase, associated generally to the smaller cross sectional area/size of the stem that relates to a corresponding reduced moment of inertial of area (proportional to the radius to a power of 4). [28] The size 8 Standard stem (1.93 mm) deformed more than the same stem with a +8.5 head (1.53 mm) because the ISO standard uses a reference line from the head centre, thus the higher head offset requires the testing to be completed with a greater stem insertion into the cement mantle where the cross-sectional area and stem stiffness is larger resulting in reduced deformation.

3.4 Predicting the fatigue behaviour of titanium femoral stems.

In all FE models, the maximum principal stress in the stem was located on the anterior lateral aspect of the stem just above the cement mantle. Figure 7 illustrates a typical maximum stress contour for a size 8 femoral stem coupled with a 28 mm + 1.5 femoral head experiencing a load of 2800 N, highlighting the location of the maximum tensile stress on the lateral side at the furthest point away from the applied load. Considering the position of the stems as defined by ISO, the location of maximum tensile stress within the model corresponded to the location of the maximum applied bending moment (Figure 1,2). Experimentally, in all of the stems that failed, fracture initiated at this location and propagated across the stem; tensile stresses are associated with crack formation and growth and generally accelerate fatigue failure.

For each stem/head configuration in (Table 2) this provided one point on the S-N curve (Red dots in Figure 8). From each point a Basquin's constant "C was subsequently calculated and the average of these was used to plot the predicted fatigue performance of the stem for "b" equal to 0.125 and 0.03 (dashed lines Figure 8). The two upper most points on the graph represent size 11 stems that were loaded at an extremely high stress level. These stems failed in an average of 6075 $\pm$ 4767cycles representative of Low Cycle fatigue and were thus excluded from the calculation for "C" as Basquin's law is only appropriate for predicting high cycle fatigue failure. The remaining three stem sizes (n=3 each) were loaded to replicate continually reducing stresses failing with average durations of 74376 ± 46395, 121734 $\pm$ 170684, and 1220000$\pm$ 60827 cycles providing 9 points in total for the S-N curve. This allowed the constant of "b" and "C" to be predicted for the current stem to be equal to 0.071 and 824 MPa respectively.

4. Discussion

4.1 Trends in patient weight

The current study used a small population sample (N=48) for patient weight, however, the results were comparable to those published in the literature with a 75th percentile weight of ~90 kg, similar to that of Wroblewski et al.[8] The ISO standard suggests a load of 2300N is used for pre-clinical evaluation, equivalent to a patient weight of ~75kg. Additionally, the published ISO testing standard does not include a design safety factor that would be used in normal engineering design to provide an additional level of confidence. Hence, for an automotive component for instance a safety factor of 2 would mean that a weight of 150kg was used to test the device to be entirely confident that it would not fail for a 75kg patient. In orthopaedic implants it is often not possible to apply safety factors as designs are limited by human factors, such as the space available in the femoral canal, however, the authors feel that pre-clinical testing should reflect realistic worst-case loading conditions and that the loading, as defined by ISO should increase to 90kg, or the published weight limit.

The stiffness behaviour of the stem itself is related to the magnitude and the direction of the bending moment applied and the moment of inertia of area of the stem (geometry). The bending moment will increase linearly with both patient weight and total femoral offset.. The total offset is the combination of offset in the neck of the stem (standard and high offset options) and the head (+1.5 and +8.5). In the design selected, high offset necks were only available in size 10 and above, hence the size 8 stems were not tested in a high offset neck variant but with a high offset head only. Size 10 stems were tested in high offset head and neck options. The moment of inertia of area of the stem is a function of its cross section and how the material is distributed relative to the axes in which the load is applied. Hence, this is very subjective to the design, the size of the implant, and the coverage (how much is potted within the cement). The greater percentage of the stem length that is potted and the lower the combined offset will generate the stiffest stem (Table 5). Similarly the lighter the patient is and the larger the size of implant that they receive the least the stem will deform.

4.2 Fatigue testing at 75th percentile patient mass, followed by simulated stumbling.

Failure of the smaller size 8 stems was surprising as the stem did not have a published weight limit and all components failed after the equivalent of approximately 1 month clinical use. Size 8 stems with a +8.5 high offset head had a 12% (5mm) greater lateral femoral offset and a correspondingly higher bending moment than those with a +1.5 head, yet these withstood a greater number of cycles. The reason for this can be explained when considering the geometry along with the requirements for the ISO test. ISO specifies a coverage of 80mm from the centre of the femoral head to the surface of the cement support. This 80mm is made up of a vertical component from the femoral neck and a length component from the femoral stem. As the total implant neck length (femoral offset + head offset) gets larger, more and more of the 80mm coverage becomes taken up by the neck. This means that the percentage of coverage that comes from the length component of the stem reduces (Table 5). Hence according to ISO, when testing a Size 8 stem with a +1.5 head 51% of the stem length will be supported by cement. If the head offset increases to +8.5, 56% of the stem length will be supported by cement meaning that the stem is supported further in the cement where the cross section of the stem is much larger and as such the applied stress reduces. The ISO standard is thus very sensitive to the individual geometry of the stem, both in terms of the offset, and the change in the cross-sectional area of the stem with height as it is designed to fit the shape of the femoral canal.

The clinical danger of a higher femoral offset is the greater bending moment applied to the stem. However, in the authors opinion the ISO standards does not allow this to be investigated, as the conditions applied to the stem used in the present study became less severe for the higher offsets rather than more severe. It should be noted, however, that ISO testing of the stem occurs under only distal stem support and thus represents a very extreme testing regime; to the authors' knowledge no clinical fractures of these stems have been reported.[29] The fracture of smaller stems has some relevance perhaps to the increasing popularity of cement-in-cement revisions where smaller stems are inserted into a used cement mantle and highlights the importance of stem support in these cases. [30]

In contrast to the size 8 stems, the durability of the larger size 10 hip stems was quite remarkable in the testing results as despite the researchers best efforts to fracture these stems using an extremely aggressive stumbling cycle with a high offset stem and head combination no fractures occurred. The size 10 stems did bend during stumbling with permanent deformation, however, the absence of fracture provides a good degree of confidence as to the clinical durability of the design and the titanium materials utilised.

Clinically the stem is selected by the size of the femur so a more valid comparison for testing would be to develop a potting level that was independent to the neck length or offset. Thus the authors suggest that the potting level of the cement could be based on a distal measurement from the distal tip of the stem, or a proximal measurement from the collar as both of these would allow the changes in applied bending moment/stress produced by different stem designs to be investigated.

4.3 ISO Predicted deformation/bending of stems

For the 75th percentile patient mass, the size 6 stem with partial femoral support as defined by the ISO standard deformed ~2.5mm, whereas the size 8 and 10 stems deformed 1-1.5mm and size 11 stem ~0.9mm. This is important as the bending would transfer the resulting strain directly to the bone. The ISO standard becomes important in interpreting these results as the standard size 8 stem (+1.5 head) deformed more than the same stem with a high offset (+8.5) head (Figure 6) because the high offset stem was potted deeper within the cement and was thus stiffer (Table 5).

From a common sense point of view it would be expected that as the implant size increases the deformation would significantly reduce and as offset increases the deformation would increase. However, in the results the size 10 high offset stem/head deformed only slightly more than the size 10 standard implant. The 10 standard has 62% stem coverage (Table 5) and the size 10 high offset (head and stem) has 72% of the stem potted within the cement. Hence there is 10% more stem coverage with the high offset design making it potentially stiffer. However, the 10 standard has a total femoral offset of 37mm and the 10 high offset has a total femoral offset of 49mm. The 32% greater offset causes a proportional increases in the applied bending moment. Thus for the size 10 head/stem combination the deformation is more sensitive to femoral offset than to coverage / cross sectional area.

As the sizes of stems change the deformation may not necessarily follow any particular pattern as the flexibility of the stem could be more/less sensitive to either the change in offset or the change in cross-sectional area depending upon the stem design. The ISO standard simply adds more confusion as it fixes the coverage to 80mm which does not allow either the offset or the cross-sectional area of the stem to be considered independently. It is important to note here that with good proximal support the deformation of all stems would be negligible due to the reduced bending moment applied to the stem and the larger stem cross-sectional area superiorly. Conversely with less support and a more varus stem position the bending moment and resulting deformation would be greater.

In clinical practice there are fewer concerns regarding fracture or loosening for standard stems whilst high offset stems would be more likely to be a concern especially when implanted in a varus position where the bending moment is increased. There has been some anecdotal evidence clinically for high offset varus stems showing radioluscent lines. The results of the study suggest that, depending on the design, larger offset stems in combination with high BMI would produce greater deformation and thus greater strain to the bone.

4.4 Predicting the fatigue behaviour of titanium femoral stems.

The predicted fatigue curves represent two theoretical constants for the value of "b" from Basquins' Law. As the magnitude of "b" decreases the curve becomes flatter and favours a component less sensitive to stress. In Figure 8, the experimental data was curve fit resulting in a value of 0.071 for b and 824.5 MPa for "C", the later constant being similar to that proposed by Ploeg et al (893 Mpa). [14] The experimentally derived value of "b" was larger than that proposed by Ploeg (0.03) and perhaps more conservative. To refine the empirical formula more testing would be required, particularly at lower stress levels, however these require a considerable period of time to complete; current testing to 10 million cycles lasted approximately 3 weeks per stem, thus testing to 10^8 cycles would be impractical. Nevertheless the results of the study offer a refined equation of fatigue that is focussed on the specific stem investigated.

The change in stem cross-section and total femoral offset with design/size highlight the need to predict the applied stress levels in each stem design individually. In this study individual FE models were generated and were validated against experimental head deformation with good agreement. Under fatigue, cracks initiate at sources of stress concentrations and then propagate, hence the cyclic time for failure is the time for initiation and growth of the crack. An FE model is an approximation of the stem geometry, in this case reproduced from measurement as the specific CAD geometry was not available. Even with accurate CAD drawings the FE software approximates the shape by overlaying a mesh of elements onto the surface. Hence, specific microscopic details in shape and/or resulting from manufacture are not modelled and it is these details where cracks will initiate. Nevertheless, cracks are more likely to form at the point of maximum tensile stress as this type of stress pulls the material apart. In the literature models of femoral stems in the ISO position, or at heel-strike/mid-stance have reported the location of maximum tensile stress to be located at the anterior lateral edge of the stem. [12, 13] The FE results of this study confirmed what has been observed in the literature in terms of both magnitude and location of maximum tensile stress suggesting that the stress levels predicted in the study were relevant for the subsequent generation of an S-N curve. [22, 23]

The FE model represented materials as linear and elastic. In reality localised stresses will occur that exceed the elastic limit of the material and cause plastic deformation with stress relaxation. Hence the magnitude of stress predicted in an FE model is always an approximation. Additionally the number of cycles to failure is individual implant specific due to microscopic variations in manufacturing and materials. In this study (n=3) there was a large variation in cycles to failure >100%, at higher applied stress levels that reduced with lower stress levels to ~5%. Therefore, the prediction of the stress – cycles (S-N) curve in Figure 8 is an approximation. For design purposes the numbers of implants would be increased at each applied stress level to determine a greater statistical confidence.

5. Conclusion

Following a review of patient BMI, a 75th percentile patient mass was applied cyclically to a popular titanium femoral stem in an in-vitro fatigue test following the ISO standard. Deformation of stems was found to be very design specific, however, greater total femoral offset and smaller stem cross sectional area led to greater deformation. Fracture was observed in smaller stem sizes following a very short time period, suggesting that a weight limit should perhaps be applied to these stems. There have been no fractures reported clinically for these stems, and the test requirements are very aggressive, however, the results suggest that trends in patient mass should be adopted by current testing standards. Additionally, it was found that in the authors' opinion the testing standard did not represent the influence of femoral offset or stem cross-sectional area effectively and that the testing standard should thus be modified. Additionally, individual stem designs have specific features that may generate stress concentrations and if these features coincide with the ISO potting level where the applied stress is the greatest fatigue failure will occur more readily; thus the results of any fatigue study are very sensitive to the test procedure and the implant design.

Acknowledgement

This work was supported by the NIHR (National Institute for Health Research) through funding of the LBRC (Leeds Biomedical Research Centre).

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Table 1. Fatigue testing conditions and components for 75th percentile patient.

Stem Size	Head Size	Load Range Walking (kN)	Load Range Stumbling (kN)	Testing Machine W/S	Number of Specimens
8 Standard	28mm + 1.5	0.3-2.8	N/A	Instron e3000 Walking /e10000 Stumble	3
8 Standard	28mm + 8.5	0.3-2.8	N/A	Instron e3000 Walking /e10000 Stumble	3
10 Standard	28mm + 1.5	0.3-2.8	0.3-9.5	Instron e3000 Walking /e10000 Stumble	3
10 High Offset	28mm + 8.5	0.3-2.8	0.3-9.5	Instron e3000 Walking /e10000 Stumble	3

Table 2. Fatigue testing conditions and components for Stress vs Cycles to failure.

Stem Size	Head Size	Load Range (kN)	Testing Machine	Number of Specimens
6 Standard	28mm + 8.5	0.05 – 1.8	Instron e3000	3
8 Standard	28mm + 1.5	0.3 – 2.8	Instron e3000	3
8 Standard	28mm + 8.5	0.3 – 2.8	Instron e3000	3
11 Standard	28mm + 8.5	1.0 – 12.0	Instron e5985	2

Table 3. Material properties used within the finite element model and reference source.

Material	Young's Modulus (GPa)		Poisson's Ratio	
Ti-6AL-4V	105	Vidalain et al. (2011)	0.27	Vidalain et al. (2011)
PMMA Bone Cement	2.45	Wijayathunga et al. (2008)	0.3	Wijayathunga et al. (2008)
Co-Cr-Mo	220	Campioni et al. (2009), Pekedis & Yildiz (2011)	0.33	Campioni et al. (2009), Pekedis & Yildiz (2011)
Stainless Steel	200	Campioni et al. (2009), Pekedis & Yildiz (2011)	0.33	Campioni et al. (2009), Pekedis &Yildiz (2011)
Delrin®	3.1	Delrin (2010)	0.35	Delrin (2010)

Table 4. Fatigue results using 75th percentile patient mass. See Table 5 for stem geometry.

Stem Size	Head Size	Cycles
8 Standard	28 mm + 1.5	31,000
8 Standard	28 mm + 1.5	15,581
8 Standard	28 mm + 1.5	318,622
8 Standard	28 mm + 8.5	39,000
8 Standard	28 mm + 8.5	126,906
8 Standard	28 mm + 8.5	57,221
10 Standard	28 mm + 1.5	10,000,000
10 Standard	28 mm + 1.5	10,000,000
10 Standard	28 mm + 1.5	10,000,000
10 High Offset	28 mm + 8.5	10,000,000
10 High Offset	28 mm + 8.5	10,000,000
10 High Offset	28 mm + 8.5	10,000,000

Table 5. Comparisons of implant lateral femoral offset with ID of stem and head and the subsequent effect on ISO test configuration. [6, 19] As femoral offset increases a greater percentage of the stem length is located within the cement due to the 80mm potting level as defined by ISO. Notes: * measured from femoral axes for neck shaft angle of 135 degrees; ** assuming the femoral axes is at ISO angles.

Stem Dimensions			Head Dimensions			Final Dimensions			
Stem ID	Original Stem Neck Length (mm) *	Femoral Offset (mm)	Head ID	Head Axial Change (mm)	Head Offset Change (mm)	Total Neck Length (mm)	Total Femoral Offset (mm)	Neck input to ISO Test Height (mm) **	Stem coverage in ISO test (%) **
8 Standard	53.7	38	1.5	-3.5	-2.5	50.2	35.5	34.5	51
8 Standard	53.7	38	5	0	0	53.7	38	36.9	53
8 Standard	53.7	38	8.5	3.5	2.5	57.2	40.5	39.4	56
10 Standard	55.9	39.5	1.5	-3.5	-2.5	52.4	37	36.0	62
10 Standard	55.9	39.5	5	0	0	55.9	39.5	38.4	64
10 Standard	55.9	39.5	8.5	3.5	2.5	59.4	42	40.8	66
10 High Offset	65.8	46.5	1.5	-3.5	-2.5	62.3	44	42.8	68
10 High Offset	65.8	46.5	5	0	0	65.8	46.5	45.2	70
10 High Offset	65.8	46.5	8.5	3.5	2.5	69.3	49	47.6	72
11 Standard	56.6	40	1.5	-3.5	-2.5	53.1	37.5	36.5	64
11 Standard	56.6	40	5	0	0	56.6	40	38.9	66
11 Standard	56.6	40	8.5	3.5	2.5	60.1	42.5	41.3	68
11 High Offset	66.5	47	1.5	-3.5	-2.5	63.0	44.5	43.3	70
11 High Offset	66.5	47	5	0	0	66.5	47	45.7	72
11 High Offset	66.5	47	8.5	3.5	2.5	70.0	49.5	48.1	74

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Figure 1. Illustration of the fatigue testing configuration in line with the ISO 7206-4 standard. Note the location of the maximum bending moment (crosshairs).

Figure 2. Typical mounted specimen. Load was applied vertically downwards to the femoral head through a polymer block utilising a shear bearing, to allow lateral deformation of the stem. The stems were supported in PMMA cement and then further contained within a metal pot that was clamped rigidly to the base of the test machine. The maximum bending moment applied to the stem is located at the potting surface (crosshairs) where failure was expected. Percentage coverage is outlined.

Figure 3. Comparison of the load-deflection relationship of both the FE and experimental results of the Size 6 standard offset stem coupled with a 28 + 8.5 mm femoral head.

Figure 4. Frequency distribution of patient weight (N=48).

Figure 5. Typical fractured size 8 stem (@~33,000 cycles) and deformed size 10 stem after 10 million cycles of fatigue and 50 cycles of stumbling. Visible are sections where the hydroxyapatite coating (white) had broken away from the titanium stem under the excessive deformations applied. All size 8 stems fractured at the potting surface whereas the size 10 stems resisted fracture, even after severe stumbling cycles.

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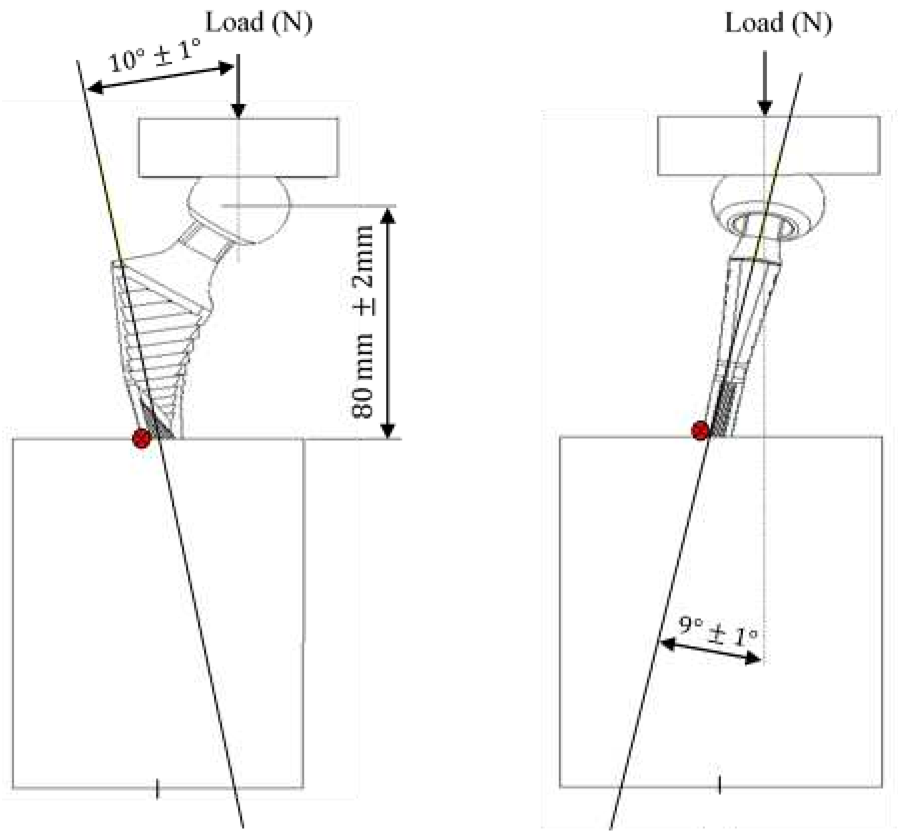
Figure 7. Maximum principal stress contour of a standard size 8 stem coupled with a 28 mm + 1.5 head experiencing a load of 2800N. Note the location of the peak tensile stress in red, at the junction of the stem and the potting surface, corresponding also to the location of maximum bending moment and where fractures occurred.

Figure 8. Predicted S-N curves for titanium stems (dashed lines) and experimental results (dots) for two theoretical constants, worst case (conservative black line, b=0.125) as used in the literature (grey line, b=0.03), and curve fit of experimental results (red line, b=0.071).



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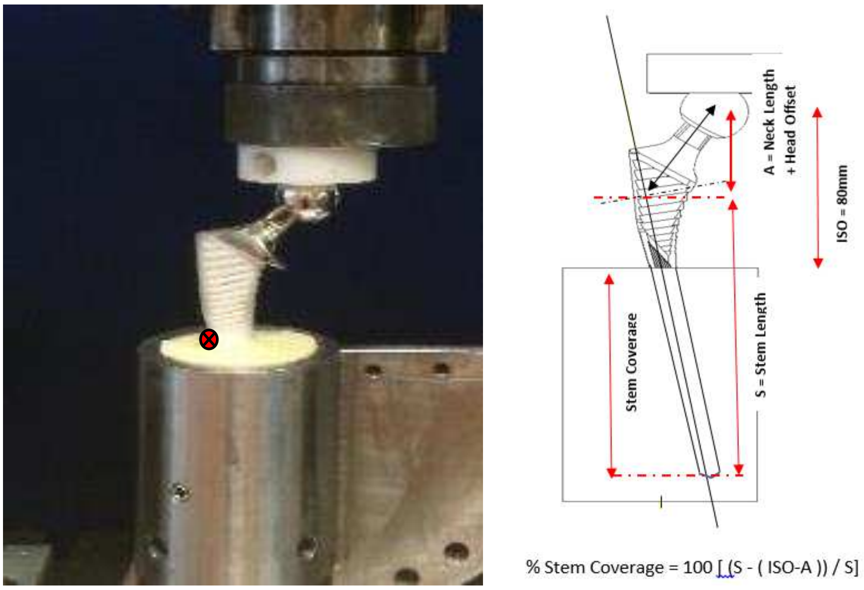

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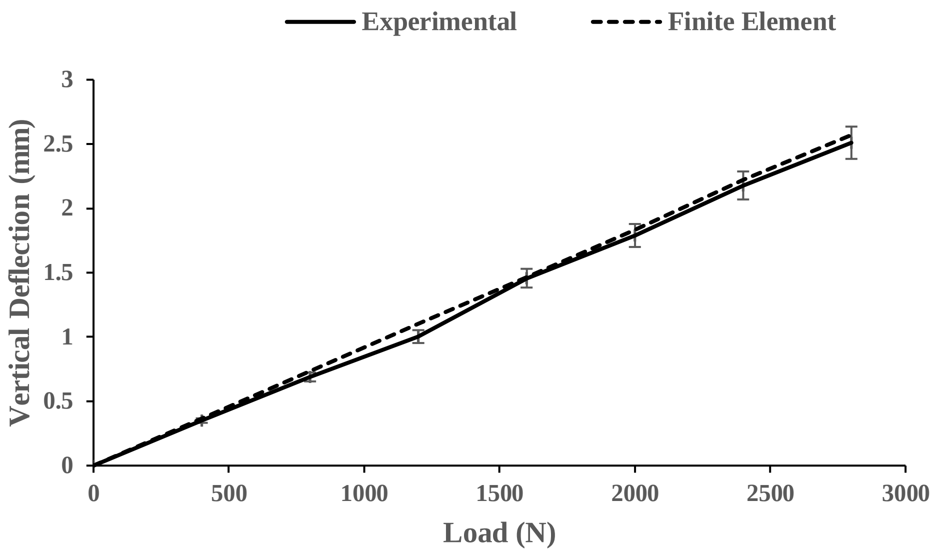

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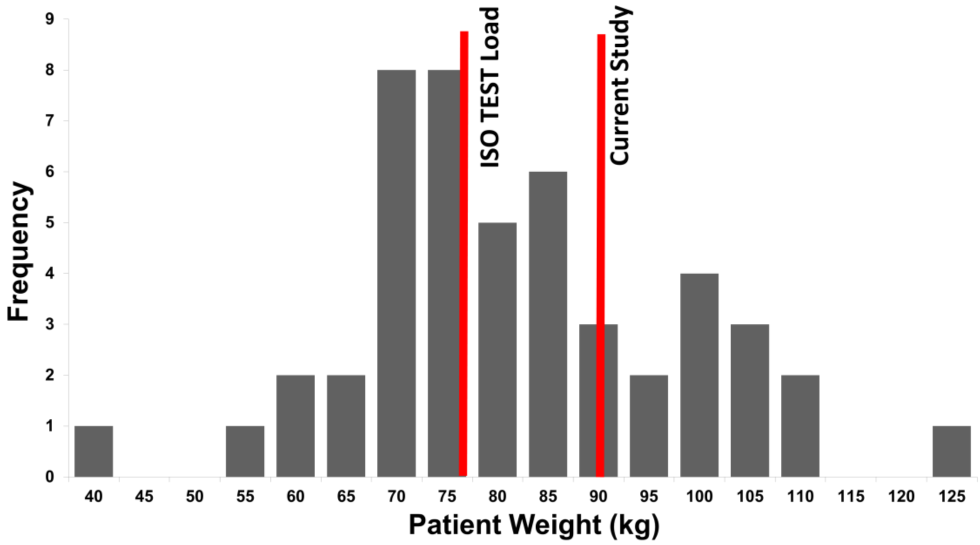

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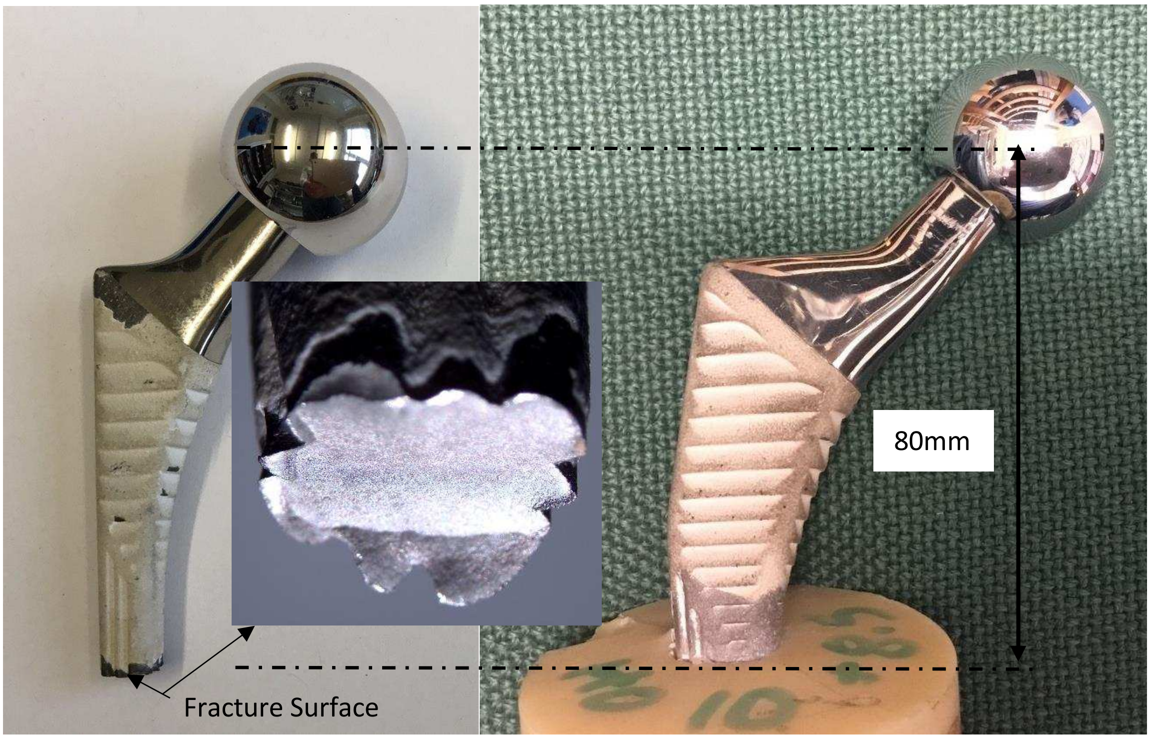

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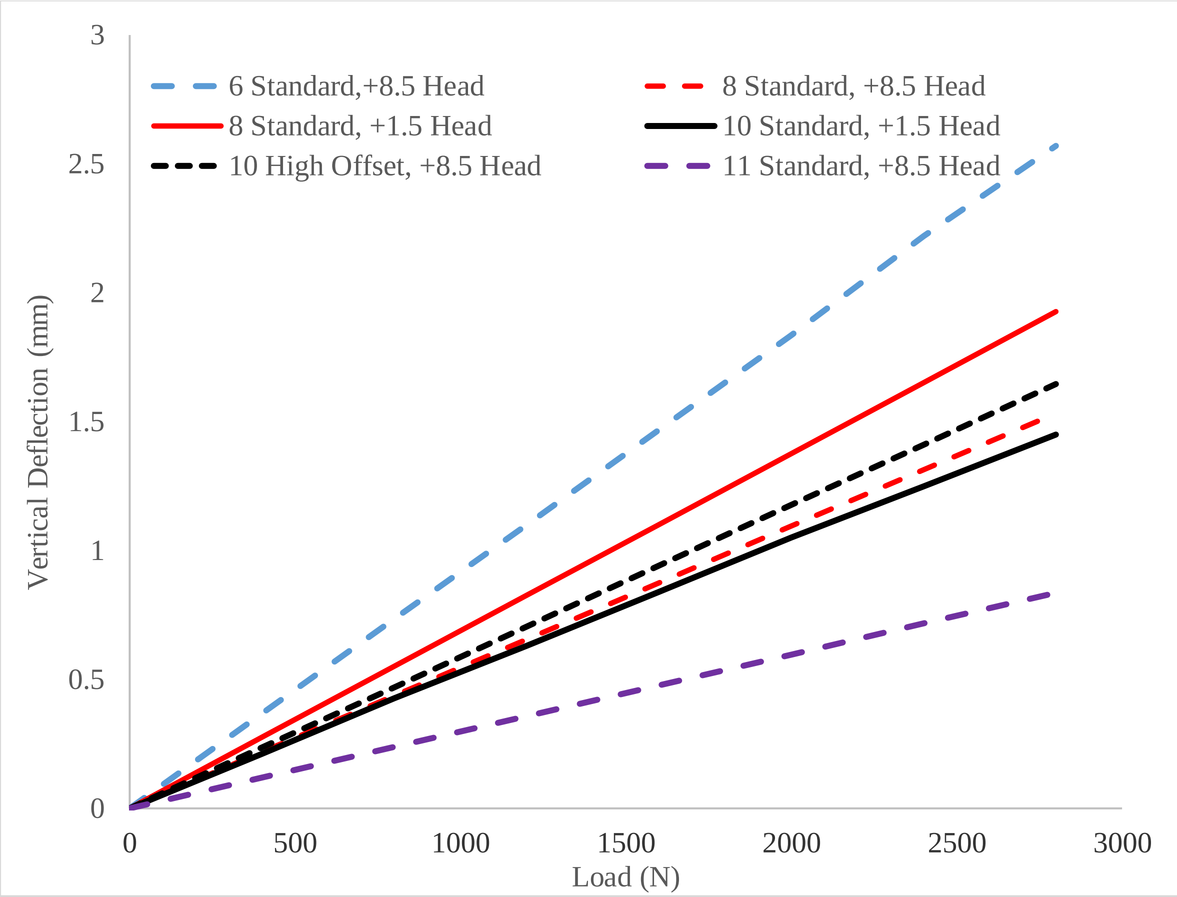

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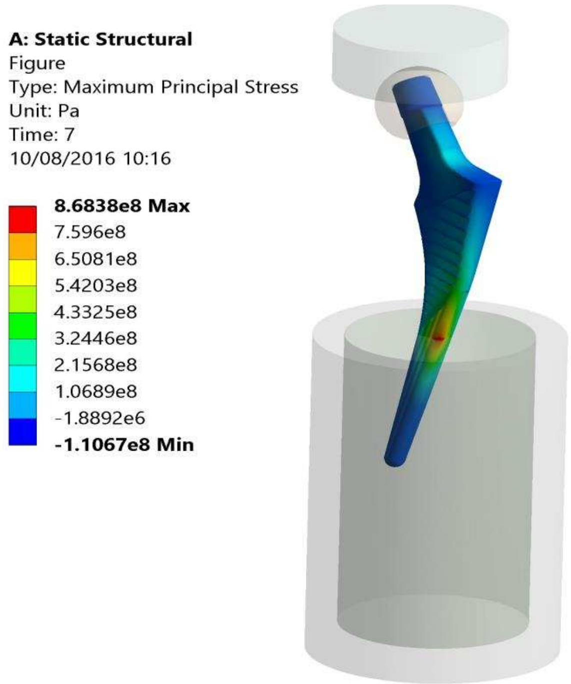

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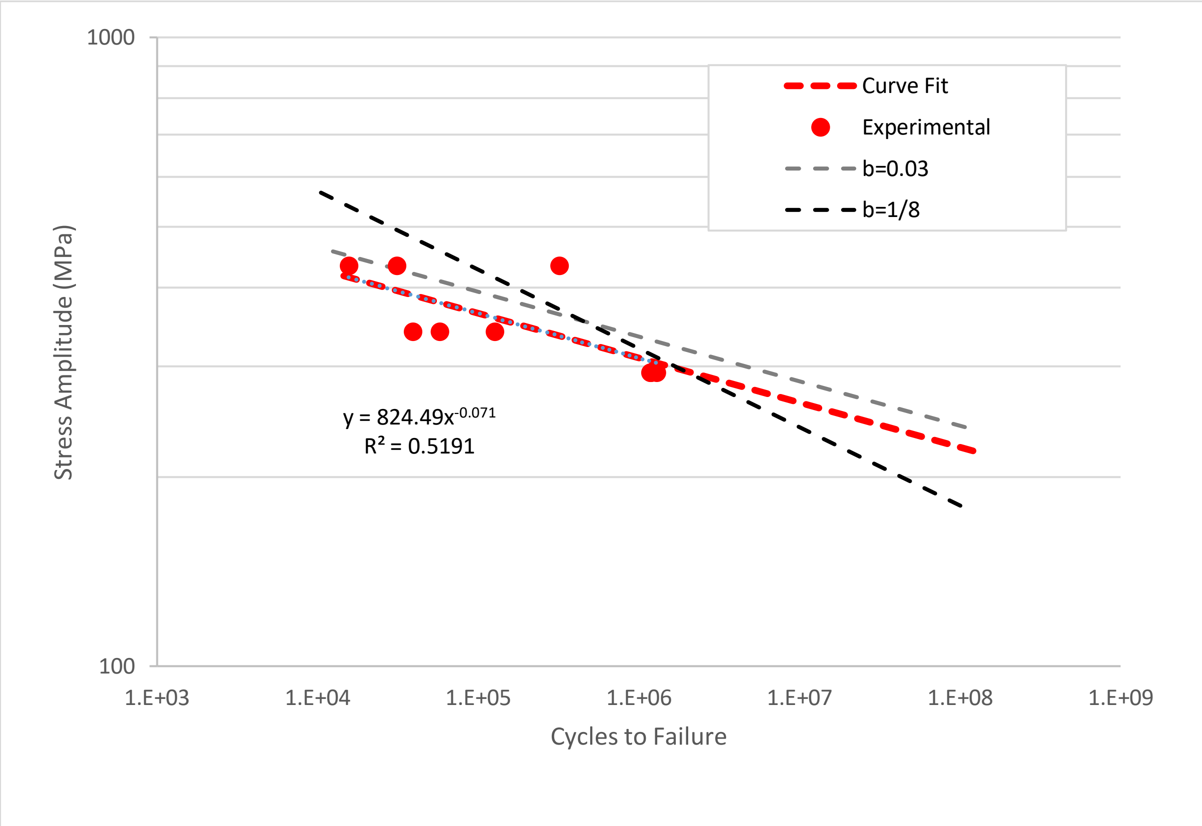

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