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Abstract

The effect of cyclic loading on the torsional stiffness of a polished double tapered femoral stem was investigated *in vitro*. Initial torsional stability was compared to torsional stability following cyclic loading. Stems were removed from the cement mantle and reinserted without the use of additional cement. Torsional stability was measured following reinsertion and following further cyclic loading.

Subsidence of the stem was observed. No difference in torsional stiffness was observed during loading. No difference between the stiffness prior to extraction and following reinsertion was observed.

Torsional stiffness of an Exeter stem does not decrease following axial subsidence under cyclic loading. Stability is retained following reinsertion into the original cement mantle. Debonding of the Exeter stem is not associated with rotational instability of the implant.

Key words: torsional stiffness, polished double taper, debonding

Introduction

A total hip replacement (THR) stem is exposed to a combination of torsional and axial loading forces *in vivo* (1, 2). This occurs particularly during activities of daily living that require standing on the flexed hip, such as rising from a chair and stair climbing. Under those circumstances, a posteriorly directed force is applied on the prosthetic head, generating an internal rotation moment about the long axis of the stem. In a telemetrised in vivo experiment it has been shown that peak torque during stair climbing reached 20Nm in the early postoperative period (1). It was further speculated that torsional forces might well become higher at a later date, when the patient has fully rehabilitated from the operation. Immediate torsional stability of a THR stem has been found to be due to several factors, including use of cement (3). Prosthesis geometry is also relevant, with flatter and curved shapes being more stable than cylindrical and straight ones (4-7).

To the best of the authors' knowledge, the torsional stability of a polished double tapered cemented stem has not been investigated. This type of stem is known to subside by a few millimetres within the cement mantle in vivo, due to creep of the acrylic cement within the first 1-2 years of use (8-11). This subsidence would be expected to improve the torsional stability of the system by engaging the tapered stem into a tighter interlock within the cement mantle. Hence it was hypothesised that, given the amount of subsidence expected, no measurable variation in torsional stability or stiffness will be observed.

During the conduct of revision THA, access to the acetabular component may be facilitated by removal of the femoral component with retention of the well fixed femoral cement mantle. The second hypothesis is that following the extraction and reinsertion of the implant the stem will return to the initial torsional stability following adequate setting of the implant into the cement mantle.

This study was designed to investigate the torsional stiffness of the Exeter stem following periods of loading, generating subsidence of the stem, and to assess the torsional stability of the stem following removal and reinsertion of the stem in the existing cement mantle.

Materials and Methods

An experimental model was developed using *Sawbones* medium left femora (model 3303, Pacific Research Laboratories, Inc., Vashon, WA). The study examined the torsional stability and migration of the Exeter stem following periods of cyclic loading and relaxation prior to and following extraction and reinsertion of the stem. Focus was then given to the extraction and reinsertion process to examine the torsional stability of the Exeter implant immediately following reinsertion.

All implantations were performed by the same orthopaedic surgeon with the use of custom made implantation guides to provide reproducible positioning in three planes. The cement used in all cases was Surgical Simplex P (Stryker Corporation, Rutherford, NJ, USA) hand mixed at approximately one cycle per second for 60 seconds at atmospheric pressure and at 22±1°C and poured into the femur without pressurisation. Cement restrictors and centralisers were used for all cases.

The position of the stem relative to the femur was verified for the initial specimens by standard anterior-posterior and lateral radiographs. This was done to ensure that the alignment of the stem was neutral with respect to the axis of the femur. Alignment was assessed using PACS CD-viewer software (Agfa-Gevaert). Stem alignment was measured three times for each specimen by two independent observers and averaged.

The LVDTs were calibrated using an LVDT calibration device (Sylvac D 50 P). Given the sensitivity and the energising voltage of the LVDT in combination with the data acquisition equipment used the minimum measurable displacement was calculated to be 0.2μm.

Anatomical cyclic loading consisted of a single force of 650N applied at 1Hz to the head of the implant using a custom built pneumatic load rig. The long axis of the femur was positioned at an angle of 10° in the frontal plane and 11° in the sagittal plane using a purpose designed femoral constraint. This setup provided similar loading to peak hip reaction force during normal walking (2) and included both a longitudinal and torsional component.

Torsional stiffness was assessed using a Hounsfield Materials Testing Machine (Hounsfield Test Equipment Ltd., Salford, England) and a purpose designed torsional testing rig (Figure 1). This rig was designed to generate pure torsion about the long axis of the implant, such that the distal tip experienced only rotation and no translation. The specimens were cycled from 0 to 6Nm using a cross head speed of 10mm/min for 10 cycles. Applied torque was plotted against rotation, the gradient of which provided the torsional stiffness of the specimen in Nm/degree.

In addition measurements were made of the movement of the stem relative to the femur during the six day loading protocol to relate the torsional stiffness (Nm/degree) to any rotation of the implant within the cement mantle. Relative displacement of the implant with respect to the femur was measured using two Solartron DC spring return linear variable differential transformers (LVDTs) with a calibrated range of ±5mm. The LVDTs were mounted on the surface of the femur and pins were fixed to the implant through oversized holes drilled through the femur and cement. The first pin was positioned 60mm from the proximal shoulder of the implant and the second

100mm from the first. The displacement of the implant was determined by scaling the displacement measured by the LVDTs relative to the length of the pin.

Reinsertion within the experimental model was carried out by removing the stem from the cement mantle and cleaning the stem with acetone followed by water to remove any residue and then dried. The stem was then replaced into the original mantle.

Exeter +37.5mm No.1 stems (37.5-1 Exeter) were used for the study. The extraction and reinsertion process was further investigated using the more common Exeter +44 No.1 stem (44-1 Exeter).

Two femora were used to initially investigate the torsional characteristics of the stem using a six day protocol. Within this protocol the stem was loaded for four days before the extraction and reinsertion process was carried out. Prior to extraction the stems were loaded for six hours a day followed by 18 hours of relaxation. The torsional stability of the stem was measured at the end of every six hour loading period and prior to extraction. For the two days following the extraction and reinsertion process the specimens were loaded in two hour blocks for six hours a day in order to determine if there were any rapid changes in torsional stiffness following reinsertion.

Four femora implanted with 37.5-1 Exeter stems were then used to investigate the extraction and reinsertion process. The torsional stiffness of the system was measured immediately prior to extraction, immediately post-reinsertion and post-reinsertion following 'setting' of the implant. During reinsertion the implant was inserted to the same marker on the stem as for the initial insertion. However, the implant was not forced into the mantle during the reinsertion. This was done in order to emphasise any variations in torsional stiffness that may exist as a result of the implant not setting correctly into the mantle. The setting process is similar to the setting of machine tapers, used in order to keep a taper shank tool in place.

Setting of the implant was carried out using either 10 loading cycles within the cyclic loading device or a hammer. Setting of the stem using 10 loading cycles was achieved using a cyclic load of 0-1800N with a frequency of 1 Hz for 10 cycles. This loading was intended to simulate 10 steps the patient takes onto the revised hip following surgery. Setting of the implant using a hammer was carried out by applying no more than three light taps to the proximal shoulder of the implant such that the force was inline with the long axis of the stem.

The same specimens were used for both setting procedures. The implants were extracted, reimplanted and set using 10 anatomical loading cycles. The implants were then extracted a second time, reimplanted and set using a hammer. Torsional measurements were taken following initial implantation, following each reinsertion and following subsequent setting of the implant. No loading of the specimen took place prior to the first torsional stiffness measurement.

The investigation of the extraction and relocation process was then extended to include the 44-1 Exeter stem. Four femora were used for the 44-1 Exeter study. Setting of the 44-1 Exeter stems was carried out with 10 anatomical loading cycles only.

All processes including initial implantation, loading, reinsertion and torsional measurements were undertaken at 37±1°C.

Results

The position of the implanted stems relative to the *Sawbones* femur was measured to have a mean(±SD) of 0.3°(±0.1°) showing that the stems were implanted in a neutral and repeatable position.

The distal migration of the head of the implant in the direction of the applied load is shown in Figure 2. Subsidence measurements between 0.15 and 0.5mm were observed over the 86,400 loading cycles.

The gradient of the force-displacement diagram was similar for the anterior and posterior loads, indicating that the stem possesses equivalent torsional stiffness in both directions. The torsional stiffness for the posterior load is clinically significant for stair climbing, which produces torque values 83 per cent larger than for walking (2), and is therefore used as the torsional stiffness value.

Levene's test showed no statistically significant difference between the torsional stiffness during the first four days of testing ($P<0.01$). The torsional stiffness values for the two specimens are presented in Figure 3.

Following the extraction and reinsertion process the torsional stiffness was immediately reduced. The torsional stiffness returned to the original value following two hours of cyclic anatomical loading (Figure 3). No quantifiable rotation of the implant relative to the bone was observed during torsional tests carried out over the first 86400 loading cycles. The reduced torsional stiffness of the reinserted stems was accompanied by observable relative rotation at both LVDT positions of approximately ±0.15 degrees. Relative rotation returned to zero with the increased torsional stiffness observed following two hours of loading. A Mann-Whitney U test found no statistically significant difference between the values of the torsional stiffness measured before and after the reinsertion process once the specimen had been loaded.

The results from the study of torsional stability focusing on the extraction and reinsertion process are presented in Figure 4. The results for the Exeter 37.5-1 stem show a similar response to reinsertion as seen in the long term study. A Mann-Whitney U test found significantly reduced stiffness at the reinsertion state ($P=0.33$) for the Exeter 37.5-1 stem.

Figure 4 shows the results for the same study for the Exeter 44-1 stem. A Mann-Whitney U test found no statistical significant difference between the three trials for this implant. The immediate reinsertion stability of the Exeter 44-1 stem was improved as a result of the proximal geometry of the stem and the tendency of the stem to positively relocate, in effect setting itself without the need to use either anatomical loading or a hammer.

The positive relocation of the stem removed the need to carry out the hammer tap study with this stem. Setting of the stem using 10 anatomical loading cycles was carried out for completeness.

Discussion

An experimental protocol has successfully been developed that enables axial subsidence and torsional stiffness of the femoral components of THA to be studied.

This study showed that with the tapered design of the Exeter stem distal migration did not result in a reduction in torsional stability of the prosthesis. Clinical follow up of 17 years indicated that the Exeter stem moves distally within the cement mantle, without disruption of the cement-bone interface (9, 12). Micromotion at the cement-stem interface has important implications for the generation of wear particles and the long-term life of the implant (4, 13). Cement surface wear is more pronounced on the lateral part of the anterior surface and the medial part of the posterior surface of the stems; this pattern of polishing is consistent with repeated torsional micro-movement generated via internal rotation (13-15). A stem with a polished surface finish greatly reduces wear particle generation and appears to retain the debris on the surface of the stem without significant damage to the cement mantle (13).

The number of steps taken by a total hip patient has been estimated at approximately 1.1 million per year (16). The majority of the implant subsidence occurs within the first two years of implantation and for an Exeter stem is about 1.2mm with a tendency for the head to migrate posteriorly at approximately 0.3mm per year in the first year (11, 12, 17).

If the source of the posterior migration is attributed to cement creep then, in conjunction with the stabilising mechanism of subsidence (11), it will have little or no effect on the rotational stability of the stem. The number of loading cycles used for this study correlates to 1 month of equivalent loading for an active patient. This study produced 0.15mm to 0.5mm of subsidence which more closely represents 1.8 to 6 months activity. Hence, some care should be taken in interpreting the direct *in vivo* relationship of these data.

A comparison of Figure 3 and stem angular rotation for reimplanted and fixed stems shows that as the torsional stiffness of the system approaches the original torsional stiffness, the rotation of the implant with respect to the femur returns to zero. A relative displacement of zero indicates that the taper of the implant has engaged the femur-cement system and that effective fixation, under torsional loading, between the implant and cement is maintained. This is in keeping with the hypothesis that an Exeter stem implanted with a suboptimal cement mantle will resist rotational torque following compression at the interfaces (12).

The torsional stiffness of the stem has been shown to be related to the setting of the implant. This is not directly proportional to the force of reinsertion as the geometry of the implant and the retained cement mantle will affect the force required to obtain a true setting (where true setting is defined as being the setting required to achieve the original torsional stiffness). In the case of the 44-1 Exeter stem the setting force was negligible as a result of the retained proximal-lateral cement mantle. The 37.5-1 Exeter on the other hand required some force either in the form of three hammer taps or 10 cycles of anatomical walking loads to obtain a true setting of the implant. 10 cycles of anatomical loading was chosen as a small and repeatable number of cycles, true setting of the implant could be observed by the sound of the implant popping back into place and while less than 10 cycles were not tested it was observed that no more than 3-4 cycles were required to obtain true setting.

The act of complete debonding of the stem-cement interface by removing the implant and reinserting the implant did not negatively affect the torsional stability of the implanted stem. So long as the debonding is followed by a period of loading, such as walking to obtain a true setting of the implant, then there is no evidence to suggest that the implant will not function correctly in terms of torsional stability.

This protocol was developed for the measurement of both the distal migration of the stem and the torsional stiffness of the specimen. Loading of the implant (including measurement of the displacement) and torsional stability of the implant therefore needed to be carried out on two separate devices. There are two technical points of note arising as a result of the relocation of the specimen from one device to the other. The PMMA and bone analogue used within this analysis are viscoelastic and the distal migration measurements were intended to measure both the elastic and viscoelastic displacement of the system. The exponential nature of the viscoelastic response resulted in the largest recoverable displacements occurring immediately after the removal of the load. However, distal migration data could not be collected over the fifteen minutes during the time the torsional data was being collected.

The second point of note was that the removal of the specimen from the anatomical loading rig created a discontinuity in the measurement of displacement. Hence, Figure 2 should be interpreted only as demonstrating progressive stem subsidence with loading. Confidence in the absolute values of stem displacement is limited because they rely on measuring extremely small tolerances within a complex model.

These limitations do not detract from the interpretation of the results however, as after only limited loading post reinsertion subsidence with a definable end point will occur, which correlates with the simultaneous return of optimal torsional stability of the system. This indicates that the Exeter implant after reinsertion assumes the position of the original prosthesis after only minimal postoperative loading.

This investigation has shown that the torsional stiffness of the Exeter stem is maintained as the stem migrates distally within the cement-bone system. Furthermore, it has been shown that removal of the stem from the cement mantle, resulting in the complete debonding of the stem-cement interface, does not adversely affect the torsional stability so long as adequate setting of the implant takes place after reinsertion. Setting of the implant is easily and quickly obtained by using either 3 taps of a hammer of 10 anatomical loading cycles, resulting in torsional stability equivalent to primary implantation.

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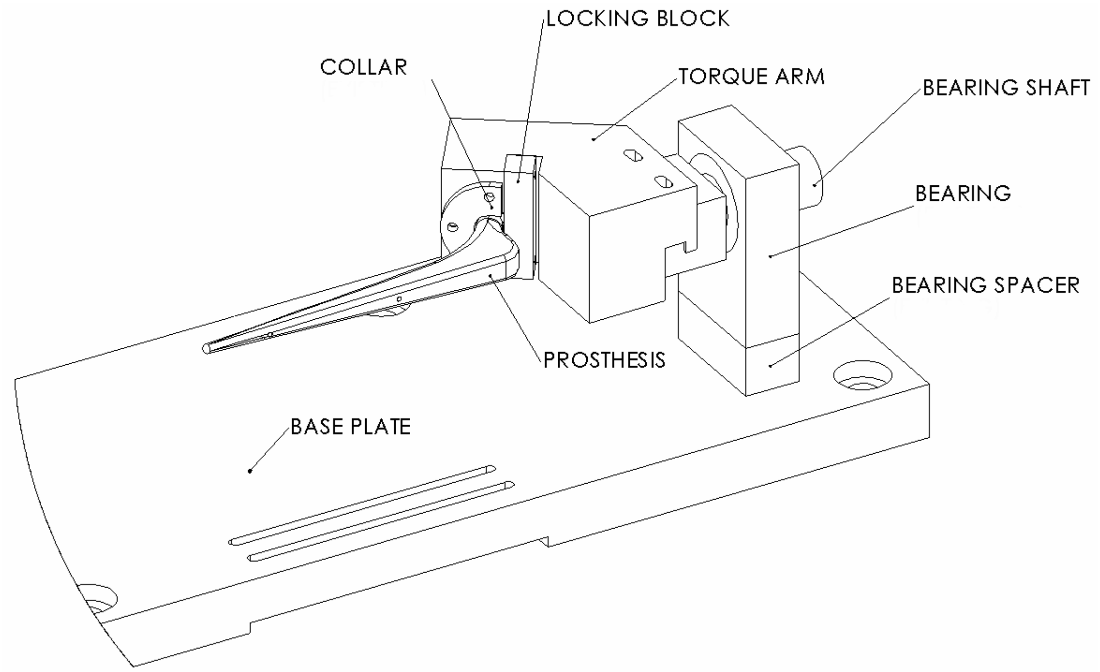

Figure 1. Torque rig with the femur removed to show the implant-torque arm coupling

This rig provided pure torsion about the long axis of the implant.

Figures

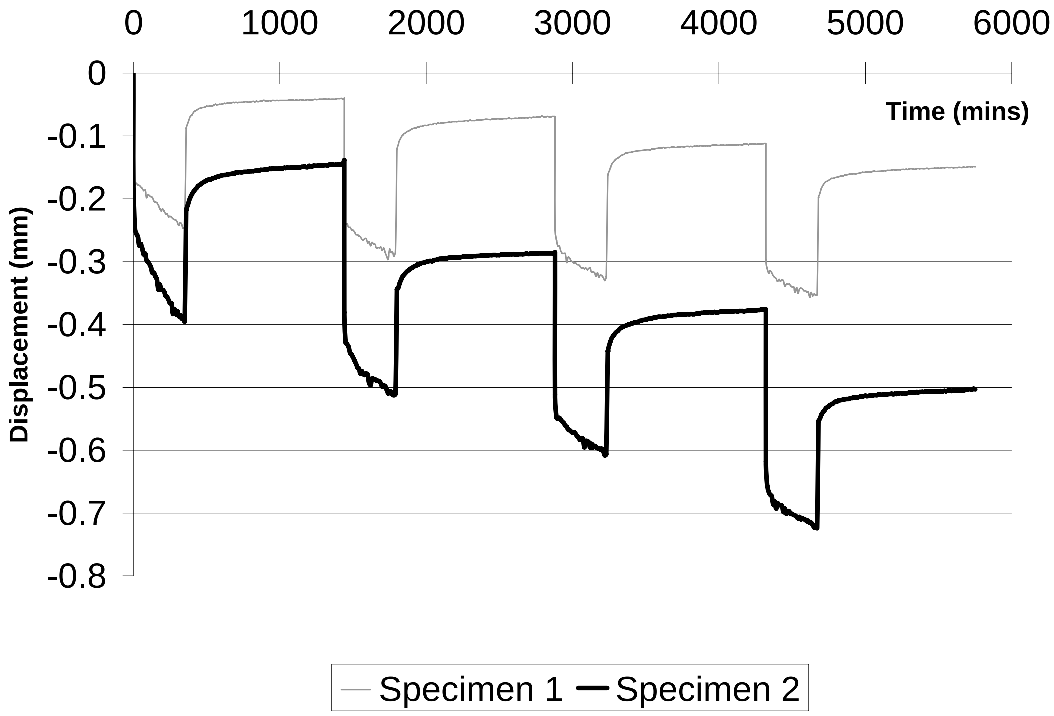

Figure 2. Distal migration of the stem over the 4 days of loading.

The displacements in the negative direction correlate to the loading period. Displacements occurring instantaneously correlate to elastic displacement of the system. Displacements occurring over time, the curved sections of the graph, correlate to the viscous and creep displacement of the system. Note that non-recoverable displacement occurs following each day of loading.

Figures

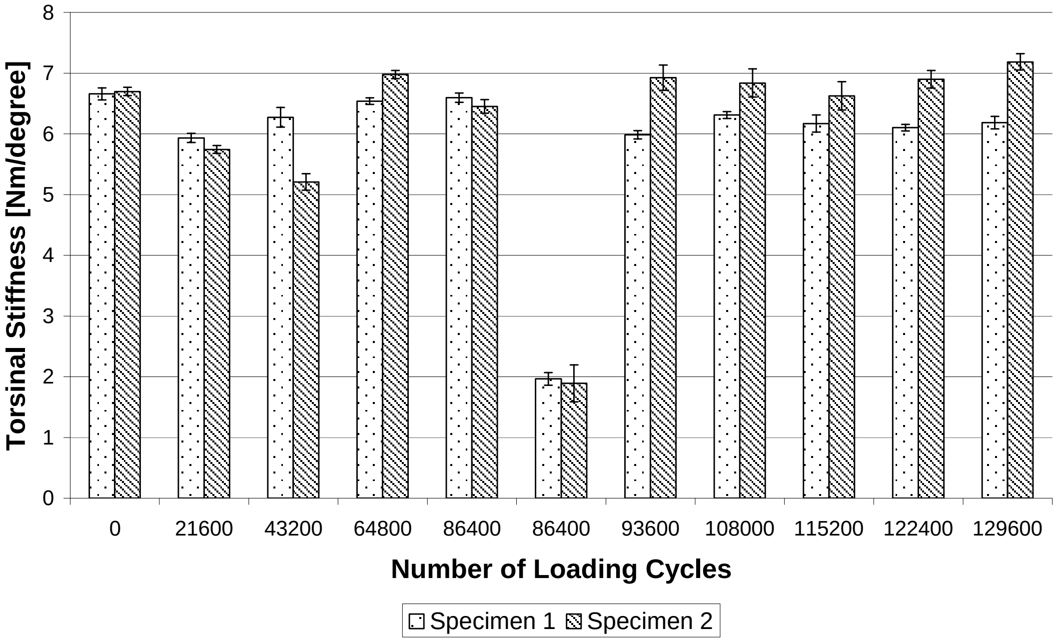

Figure 3. Torsional stiffness of the stems as a function of the number of applied loading cycles measured immediately after loading.

The second stiffness value reported for 86400 cycles is the stiffness measured following reinsertion. The error bars show standard deviation in the torsional stiffness values calculated for each of the 10 cycles.

Figures

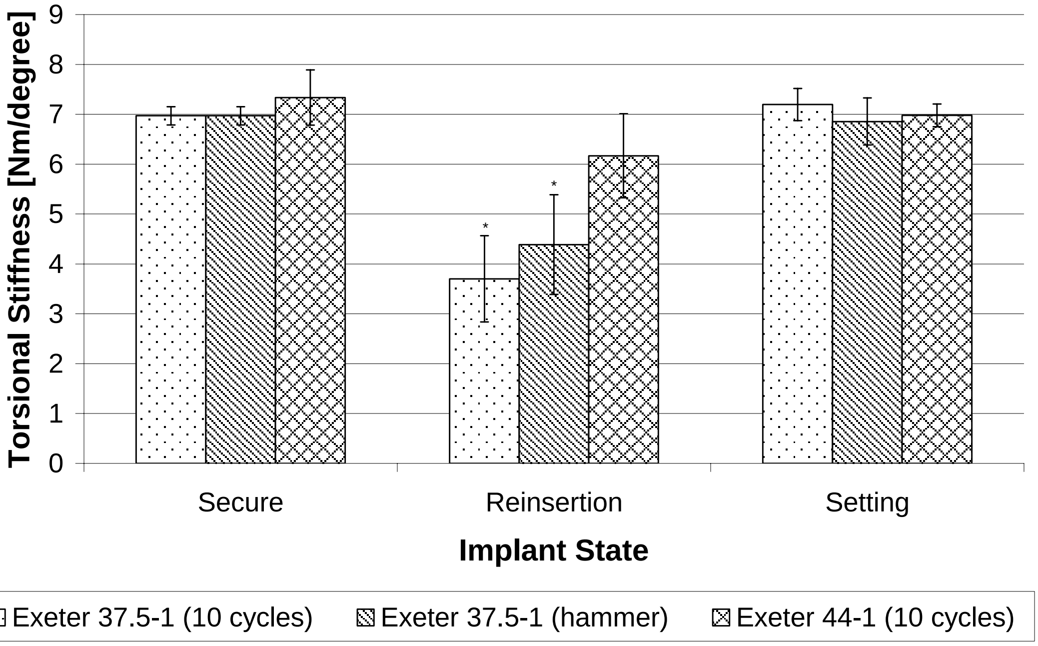

Figure 4. Torsional Stiffness for the three implant states where the third state is setting of the implant.

* indicates a statistically significant difference in stiffness from the secure stiffness value ($P<0.05$).

Two of the three bars show the torsional stiffness values of the Exeter 37.5-1 being set using either 10 anatomical loading cycles or 3 light taps of a hammer. The third bar shows the torsional stiffness of the Exeter 44-1 set with 10 anatomical loading cycles.