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**Low torque levels can initiate a removal of the passivation layer
and cause fretting in modular hip stems**

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Abstract

Taper connections of modular hip prostheses are at risk of fretting and corrosion, which can result in reduced implant survival. The purpose of this study was to identify the minimum torque required to initiate a removal of the passivation layer at the taper interface as a function of assembly force and axial load.

Titanium stems and cobalt-chromium heads were assembled with peak impaction forces of 4.5 kN or 6.0 kN and then mounted on a materials testing machine whilst immersed in Ringer's solution. The stems were subjected to an axial load (1 kN or 3 kN) along the taper axis. After a period of equilibration, a torque ramp from 0 to 15 Nm was manually applied and the galvanic potential continuously recorded.

Prostheses assembled with a force of 6 kN required a significantly higher torque to start a removal of the passivation layer compared to those assembled with 4.5 kN (7.23 ± 0.55 Nm vs. 3.92 ± 0.97 Nm, $p = 0.029$). No influence of the axial load on the fretting behaviour was found ($p = 0.486$).

The torque levels, which were demonstrated to initiate surface damage under either assembly force, can be readily reached during activities of daily living. The damage will be intensified in situations of large weight and high activity of the patient or malpositioning of the prosthesis.

204 words (maximum 200)

1 **Introduction**

2 Modular hip prostheses were introduced in the 1970s ¹ and have been routinely used in total
3 hip replacement operations ever since. These systems include a taper connection between
4 stem and ball head, giving surgeons the flexibility to adapt the geometry of the artificial joint
5 to the patient's anatomy intraoperatively. This can be realised by choosing suitable modular
6 head components allowing modifications of the head diameter and the offset of the prosthesis.
7 Modularity between the femoral stem and the ball head also enables the use of different
8 materials for the bearing components.

9 Despite a multitude of advantages, the stem/head taper connection of modular hip implants is
10 at risk of fretting, corrosion, and potential implant fracture ^{2, 3}. In recent years an increasing
11 number of postoperative complications have been observed for modular hip prostheses in
12 clinical applications ⁴⁻⁷. Macroscopic and microscopic inspection of retrievals have revealed
13 surface damage such as scratches, discoloration, fretting ^{8, 9}, wear and corrosion at the taper
14 interfaces ^{10, 11}. The root cause of the failure mechanism is complex, but likely has both a
15 mechanical and an electrochemical aspect. The reported surface damage appears to be a result
16 of oscillating, relative motions between the adjacent implant components, leading to a cycle
17 of removal of the passivation layer (fretting) and subsequent repassivation. In combination
18 with a fluid environment this may lead to corrosion ¹²⁻¹⁴. A small conical taper angle
19 mismatch between the adjacent components can result in the presence of crevices, which can
20 allow fluid ingress. These effects can potentially accelerate the overall corrosive damaging
21 process ¹⁵. As a further consequence of the interface motions, metal ions ^{16, 17} and wear debris
22 ¹⁸⁻²¹ are released, which remain in the periprosthetic tissue or migrate to other parts of the
23 body. Previous studies have indicated a link between wear debris and adverse tissue reactions,
24 such as, the generation of pseudotumours, allergic reactions and metallosis ²²⁻²⁴. Furthermore,
25 these particles might initiate osteolysis, leading to bone loss around the prosthesis and

ultimately the need to revise the implant. Aseptic loosening represents the most common cause of revision as reported in hip joint registries^{25, 26}.

Fretting induced postoperative complications appear to be more prevalent with large diameter metal-on-metal bearings (MoM). MoM bearings exhibit the highest revision risk of all frequently used bearing surfaces. With increasing head diameter the incidence of revision rises even more²⁷; this is speculated to be a consequence of higher frictional moments applied to the modular junction due to a larger head diameter especially in case of inadequate lubrication²⁸. High moments acting at modular junctions might accelerate fretting and corrosion, explaining why this issue is predominantly observed for these implants. However, MoM bearings with a head diameter of 32 mm or less are usually successful in the patient with revision rates comparable to other bearings²⁶. Many case reports regarding damage of large diameter MoM bearings are available in the literature. Some of these *in vivo* failures can be traced back to issues at the bearing interface between ball head and acetabular cup however, many clinically observed problems might be initiated by postoperative complications at the conical taper interface^{29, 30, 31}.

There have been relatively few studies examining the mechanical aspects of taper junction failure, thus there is a paucity of knowledge regarding the interface micromotions at taper junctions. Experimental and numerical studies have reported micromotions at taper connections ranging from 3 to 41 μm at the stem/neck interface of bi-modular hip prostheses (modular neck stems)^{13, 32, 33} and from 8 to 25 μm between the stem and ball head of standard modular implants (fixed neck stems)³⁴. Correlations between interface micromotions and design (e.g. material coupling, offset³⁴), implantation (e.g. assembly force, presence of contaminants³²) and patient specific parameters (e.g. loading³³) have been reported in several experimental and numerical studies.

Hip joints allow the transfer of forces and moments from the upper to the lower body during activities of daily living leading to high bending loads at the hip joint. *In vivo* average peak loads range between 1.1 kN (knee bend) and 2.0 kN (going down stairs) for a body weight of 750 N depending on the performed activity ³⁵. For comparable patients, average torsional moments of up to 17.1 Nm during stair climbing with peak values of 70.5 Nm (stumbling) have been measured in the human hip joint ³⁵. Goldberg *et al.* ³⁶ and Mroczkowski *et al.* ³⁷ assessed the influence of the assembly load, the maximum axial load, the material coupling and the local assembly conditions on the fretting corrosion behaviour of modular taper junctions under cyclic loading using an electrochemical test method. However, loading of the hip joint during activities of daily living is a combination of axial forces and moments. Presently, the amount of torque required to initiate fretting is not yet known. Therefore, the purpose of this study was to identify the minimum amount of torque required to initiate a removal of the passivation layer within the taper interface as a function of assembly force and axial load. The effect of applied torque on the taper strength between the stem and ball head was also determined by using the pull-off force as an indicator for this parameter.

Materials and Methods

Two sets of experimental investigations were performed. A detailed overview of the methodology is illustrated in the flowchart in Figure 1 and Table 1 gives the breakdown of tests performed on each group of implants. The first part of the present study focused on mechanical aspects (taper strength) whereas the second part concentrated on electrochemical processes occurring at the taper interfaces of modular hip implants.

Pull-off force assessment

Four stems (Furlong H-AC, JRI, Sheffield, UK, Group 1, Table 1) with a caput-collum-diaphysis (CCD) angle of 140 °, and a 12/14 taper connection were used for this study. The femoral components were manufactured from a Ti6Al4V alloy (BS EN ISO 5832-3: 2012) and forged according to BS 7254-2: 1990. All of the stem tapers had a maximum roughness value (R_a) of less than 6.4 μm . Stems were assembled with 28 mm cobalt-chromium ball heads (size L, JRI, UK) by a single impaction using a custom made drop rig (Figure 2). The tapers were first cleaned with ethanol to remove any potential surface contamination and then assembled at ambient temperature with a drop rig. The drop rig was calibrated in order to establish the relationship between drop height and the peak assembly force. The rig was designed to minimise friction during assembly. The drop rig's impactor featured a plastic cap to reduce the impulse transmitted to the prosthesis compared to a direct metal-on-metal blow. A rubber mat was located between the jig and the base plate to act as a damper to reduce secondary vibrations. The impaction load vector was aligned with the taper axis.

The prostheses were then disassembled using a materials testing machine (Series 3300, Instron, Norwood, MA, USA) to determine the pull-off force as an indicator for the taper strength. The heads were removed from the stems by applying a tensile force at a stroke rate of 0.008 (± 0.0008) mm/s, maintaining the alignment tolerances specified in the standard ISO 7206-10: 2003. A custom-designed jig was constructed in order to perform the pull-off tests (Figure 3a). The assembly and disassembly process was then repeated 6 times for all four implants with assembly forces of 3 kN, 4.5 kN and 6 kN using the following sequences: $F_{ASS1} = 3 \text{ kN}$, $F_{ASS2} = 3 \text{ kN}$, $F_{ASS3} = 4.5 \text{ kN}$, $F_{ASS4} = 3 \text{ kN}$, $F_{ASS5} = 6 \text{ kN}$, $F_{ASS6} = 3 \text{ kN}$). These assembly load levels correspond to typical impaction forces applied by surgeons to assemble a hip stem with a head^{38, 39}. Due to a limited number of samples, the implant components were re-used and impacted with different load levels. In order to test the assumption that (a limited

number of) repeated impactions do not affect the taper strength, after each load step, the 3 kN assembly was repeated and the pull-off forces determined. A statistical test was performed to examine if the pull-off forces at 3 kN were independent of the time point when the tests were performed (at the beginning or at the end of the test series). The repetition of the 3 kN tests meant there was a larger available data set at this load level compared to the other load levels. For statistical reasons, only the first pull-off forces measured for an assembly force of 3 kN (F_{ASS1}) were used for subsequent analyses to maintain a constant sample size of $n = 4$ for each assembly load level. The recorded pull-off forces of F_{ASS1} (3 kN), F_{ASS3} (4.5 kN) and F_{ASS5} (6 kN) were used to determine the influence of the assembly force on the pull-off force. For statistical analyses non-parametric tests were preferred to parametric ones due to the limited sample size and an ambiguous data distribution. A linear regression was performed to determine a possible correlation between assembly and pull-off force. The significance level was set to $\alpha = 0.05$ for all of the performed tests (PASW Statistics 18, IBM Corporation, Armonk, NY, USA).

Fretting corrosion testing

For the second part of the study, similar implants with the same material specifications and surface characteristics were used as those for the pull-off tests. Flats were machined on the heads, removing 2 mm of material at each side to enable fixation in the torque rig. The prosthetic components were impacted along the taper axis using the same drop rig as detailed previously, with an assembly force of 4.5 kN (F_{ASS7} , $n = 4$, Group 2, Table 1) or 6.0 kN (F_{ASS8} , $n = 4$, Group 3 & 4, Table 1).

The assembled prostheses were inverted and then mounted with the head rigidly held in a non-conducting nylon base of the test rig whilst submerged in Ringer's solution (approximately 100 mm³) at an ambient temperature of approximately 22 °C (Figure 3b). The

1 flats of the ball heads were located in a rectangular hole in the base container. The base plate
2 of the test rig was rigidly fixed by bolts to a servohydraulic materials testing machine (Dartec
3 Series HC10, Dartec, UK). A static axial load ($F_{AX1} = 1 \text{ kN}$, Group 2 & 3 or $F_{AX2} = 3 \text{ kN}$,
4 Group 4, $n = 4$ each) was applied to the assembled prostheses along the taper axis using the
5 servohydraulic testing machine via a ball bearing and non-conducting nylon plates. The
6 implants were left *in situ* prior to starting each test until a constant galvanic potential had been
7 achieved for at least 30 min (incubation time ranged between 60 and 70 mins). An increasing
8 torque from 0 Nm up to approximately 15 Nm was then manually applied using an
9 instrumented bar attached to the fixation plates. The bar was instrumented with a strain gauge,
10 which had been previously calibrated, allowing the measurement of the applied torque τ
11 (Figure 4).

12 A tapped hole at the distal end of the stems enabled the electrical connection to a
13 potentiometer circuit. The circuit was completed with an electrode made of titanium that was
14 inserted in the base pot of the rig. A non-conducting bracket held the electrode in place and
15 enabled electrical isolation from the materials testing machine. During the test, the axial load,
16 changes in the galvanic potential as an indicator for an oxide film damage and the applied
17 torque were continuously recorded (sampling frequency: 10 kHz, LabVIEW Version 11.0.1,
18 National Instruments, Austin, TX, USA).

19 The recorded data (galvanic potential and torque) was filtered using a Savitzky-Golay filter
20 (smooth filter, no phase lag, MATLAB R2011b, MathWorks, Natick, MA, USA). Analyses
21 were performed using the change in potential relative to the steady-state condition (delta
22 voltage, δV). Therefore, a shift in potential was performed, so that the average potential at the
23 equilibrium condition was set to zero, since the initial potential differed slightly between the
24 specimen tested. The torque required to cause a drop in the potential of 0.05 V was identified
25 (onset of fretting) as equivalent to double the maximum noise of the raw data signal. The

influence of the static axial force and the assembly force on the required torque to cause a 0.05 V drop in the galvanic potential was analysed (PASW Statistics, IBM Corporation, Armonk, NY, USA). Following the fretting tests, the heads impacted with 6 kN (Group 3 & 4) were disassembled using the materials testing machine and the previously described test set-up. The pull-off forces were then assessed and compared to the findings from tests performed on Group 1 implants. For all statistical tests, non-parametric approaches with the Type-I-error probability of $\alpha = 0.05$ were chosen.

Results

Correlation between assembly and pull-off force

The recorded pull-off forces were not influenced by the consecutive test protocol; no difference in the recorded pull-off forces for the repeated measurements at an assembly load level of 3 kN were found (Group 1, $1,223.3 \pm 190.5$ N, $p = 0.846$, Kruskal-Wallis-Test, Figure 5).

As peak assembly forces increased, the pull-off forces also increased significantly: $1,212.9 \pm 190.5$ N for 3 kN vs. $1,667.4 \pm 176.9$ N for 4.5 kN vs. $2,120.7 \pm 263.9$ N for 6 kN (Group 1, $p = 0.010$, Kruskal-Wallis-Test, Figure 6). A further analysis showed that the assembly force and the pull-off force were linearly correlated ($\text{adj. } R^2 = 0.793$, $p < 0.001$). The pull-off force was on average 37.6 ± 4.7 % of the assembly force. A significant difference in the pull-off forces between trunnions assembled with 3 kN and those impacted with 6 kN was found (Group 1, $p = 0.007$, pairwise comparison).

Fretting corrosion

In all of the performed fretting tests, four different segments of the electrical response could be clearly differentiated: First, an equilibrium of the galvanic potential at the commencement of the test; second, while applying the torque, a drop in the galvanic potential followed by, thirdly, an increase in galvanic potential and lastly, at the end of the test a second equilibrium segment, with a galvanic potential quite similar to the initial one, occurred (Figure 7).

The maximum drop in the galvanic potential during the second segment of the test was influenced by the assembly force: prostheses impacted with 4.5 kN showed a significantly higher maximum decrease in the galvanic potential compared to those with a 6 kN assembly force (-1.02 ± 0.43 V vs. -0.40 ± 0.08 V for F_{AX1} , Group 2 vs. 3, $p = 0.029$, Mann-Whitney-U-Test, Figure 8). In contrast, the applied axial force did not have an influence on the minimal potential achieved (-0.43 ± 0.19 V for F_{ASS8} , Group 3 vs. 4, $p = 0.343$, Mann-Whitney-U-Test, Figure 8).

The maximum torque applied during testing was similar for all performed tests with mean values of 14.43 ± 0.76 Nm ($p = 0.668$, Kruskal-Wallis-Test). The applied torque which corresponded to a 0.05 V drop in potential was significantly higher for prostheses assembled with 6.0 kN compared to those with 4.5 kN (7.23 ± 0.55 Nm vs. 3.92 ± 0.97 Nm for F_{AX1} , Group 2 vs. 3, $p = 0.029$, Mann-Whitney-U-Test, Figure 8). In contrast, no influence of the axial load on the torque at the onset of fretting was demonstrated (8.00 ± 1.62 Nm for F_{ASS8} , Group 3 vs. 4, $p = 0.486$, Mann-Whitney-U-Test, Figure 8).

Prostheses assembled with a force of 6 kN demonstrated the same pull-off force independent of whether a torque was applied or not ($2,279.3 \pm 364.5$ N, Group 1 vs. 3 & 4, $p = 0.686$, Mann-Whitney-U-test, Figure 6). However, prostheses assembled with a force of 6.0 kN and axially loaded with 1.0 kN showed a strong trend towards lower pull-off forces than those

loaded with 3.0 kN during the fretting test ($1,783.8 \pm 211.2$ N vs. $2,437.8 \pm 416.3$ N, Group 3 vs. 4, $p = 0.057$, Mann-Whitney-U-Test, Figure 6).

Discussion

In the last few years, fretting-induced postoperative complications of modular hip implants appear to be more and more prevalent following total hip replacement. In particular, fretting and corrosion at taper interfaces and adverse tissue reactions due to micromotions between the adjacent implant components are responsible for an increasing number of revisions. Therefore, this study set out to identify the minimum amount of torque required to initiate a removal of the passivation layer, which is considered as a possible starting point for early failure.

This study focused on the assessment of one specific modular hip implant. Therefore, the results cannot be easily transferred to other designs and a general statement cannot be given without further investigation since the presented results are likely to have been influenced by the design parameters themselves. Discrepancies in the lever arm between the applied load vector and taper interface as well as subtle geometric differences (e.g. taper angle difference, taper length) are only a few of many criteria that can differ between modular implants available on the market. For the assembly process, a drop tower with an impactor with a plastic end cap was used. The plastic end cap acted as a damper and reduced the available energy of the accelerated mass of the drop rig. This study is furthermore limited by the direction of the applied axial load vector as it did not necessarily correspond to the *in vivo* load situation of the hip joint; in this study only one component of the hip contact force was considered³⁵. Furthermore, the torque was applied manually in this study, which possibly resulted in variations of the applied torque ramp during testing. However, due to the generally slow increase of the torque in this test set-up, this effect may be negligible. During daily

1 living activities the hip joint is subjected to a combination of axial load vectors and toggling
2 moments that may initiate continuous micromotions at the taper interface of modular
3 implants. The amount of these oscillating micromotions depends on patient- and implant-
4 specific parameters as well as on the activity levels. The presented test set-up is not able to
5 simulate this complex *in vivo* loading situation.

6 Within the framework of this study it was not possible to visualize small local surface damage
7 at the taper connection provoked by the assembly/ disassembly process or the fretting test. In
8 order to observe small local surface damage a high resolution method capable of scanning the
9 whole taper is needed since currently it is not absolutely clear which regions are affected by
10 these damages. The prostheses were submerged in Ringer's solution and not in synovial fluid
11 thus there were possible differences in the absolute values of the measured galvanic potential
12 during the fretting corrosion tests compared to an *in vivo* situation. Despite these limitations,
13 it is still possible to identify important factors influencing the fretting behaviour at taper
14 junctions.

15 Changes in the galvanic potential are an indicator of the electrochemical processes occurring
16 within the taper interfaces during *in vitro* fretting tests. The established test set-up was able to
17 differentiate the four different segments of the electrical response occurring during a fretting
18 test through assessment of the galvanic potential. At the beginning of the fretting test, a nearly
19 constant galvanic potential was observed, however, after applying an increasing torque, a
20 sharp decrease of the galvanic potential was recorded. This was most likely caused by a
21 removal of the passivation layer at the stem/head taper interface. While holding the applied
22 torque at a constant level, the re-passivation process began, giving rise to an increase in
23 galvanic potential. The potential at the end of the tests was similar to the initial potential
24 before applying a torsional moment.

Prostheses assembled with a lower impaction force (4.5 kN) exhibited a significantly greater decrease in the galvanic potential when a torque was applied compared to those assembled with a higher force (6kN). Additionally, with increasing assembly force the start of a removal of the passivation layer did not occur until higher levels of torque had been applied. Interestingly, the magnitude of the applied static axial force during the fretting test did not seem to have an influence on these two outcome parameters. This implies that the local contact situation (prevalent contact pressure and the location of the interlock) was mainly influenced by the assembly force; higher assembly forces likely cause a higher contact pressure at the interface. In case of a high contact pressure the electrolyte is presumably not able to access the whole taper connection. In contrast to a pure static axial force, the application of a torque appears to directly affect the interlock between stem taper and head. The application of a small torque can disrupt the interlock just slightly, whereas, higher torque levels can cause a complete twist-off of the head.

Previous studies have assessed a correlation between applied force and the onset of fretting, however, none have investigated the minimum torque levels required. The results of this study can be aligned with previously published *in vitro* fretting studies^{36, 37}: the force threshold to start the fretting processes at the taper interface is higher for implants assembled with a high impaction force (onset of fretting at ≈ 2.5 kN³⁷) compared to those pressed only by hand (onset of fretting less than 0.5 kN³⁷) or statically assembled with a load of 2.0 kN (onset of fretting less than 1.3 kN³⁶). For the sake of completeness, it should be highlighted, that in conjunction with the assembly load, the environment in which the implant components are assembled (wet or dry) also appears to play an important role, and can affect the initial stability of modular taper junctions³⁷.

The applied maximum torque levels in this study were lower than the published values required to turn-off ball heads from the stems⁴⁰. Based on the results of Rehmer *et al.*, the

turn-off moments for a Ti-CoCr coupling are expected to be at around 22 Nm (4.5 kN assembly force) and 29 Nm (6 kN assembly force), respectively⁴⁰. This may explain why the ball heads in this study were still rigidly connected to the stems after performing the fretting test. The recorded pull-off forces for the implant design tested in this study are in the same range as those published by other authors even though different implants were used (0.8 kN to 2.7 kN)^{38, 40}. Small differences may be related to changes in the assembly forces, the taper geometry, such as, the taper angle mismatch and the roughness, or the design, which may affect the stiffness of the implant components themselves^{40, 41}. Multiple impactions as well as contamination of the interface prior to assembly may also have a great influence on the force needed to remove the head from the stem^{38, 40, 41}. However, the taper strength does appear to not be influenced by the fretting corrosion test. The pull-off forces of implants assembled with a 6 kN peak force and then subjected to 1 kN and 3 kN axial loads during the fretting test tended to be different. It could be speculated that in case of a small axial load the local stresses of the components (at the interface) are lower compared to those subjected to a higher axial force. Due to the application of a torque the ball head moved relative to the neck adapter. It could be that the maximum covered relative movement of the adjacent components was higher for those implants subjected to a smaller axial force; this could have provoked a slight loosening of the interlock. However, the mean pull-off force was not significantly different from the value of the reference group, which did not undergo the fretting tests (Group 1). The lack of a significant difference is most likely the result of the small sample size.

It is suggested that implantation and design parameters have a high impact on the seating behaviour during impaction, and on the location of the press-fit, the contact area, the contact pressure and ultimately the taper strength of the conical connection. Large diameter heads may offer a reduced seating distance compared to standard head diameters as a result of the

1 greater damping during the impaction. Larger heads offer a higher mass and friction force
2 (influenced by the taper geometry) within the taper connection leading to a higher damping
3 effect. Therefore, in case of a larger head size the transmitted impulse (energy) to assemble
4 the components may be lower compared to smaller heads. This could be investigated in
5 further studies.

6 A positive, linear correlation between assembly and disassembly force was found in this
7 study, similar to the results of other studies ^{40, 41}. It could be speculated that prostheses
8 impacted with a greater hammer blow are more resistant to frictional moments acting at the
9 joint; however, even under optimal conditions of alignment and orientation of the implant, a
10 removal of the passivation layer in taper interface cannot be avoided completely. The results
11 imply that the assembly force ranks among the most important factors influencing the risk of
12 undesirable electrochemical processes at the taper interface. Assembly forces, which might
13 generate a sufficiently high contact pressure at the interface resulting in very small
14 micromotions are not feasible during the operative procedure and may cause damage to the
15 host bone. Typical impaction forces measured experimentally are reported to be
16 approximately 3 to 5 kN on average ^{38, 39}. It could be speculated, that assembly forces
17 significantly higher than 6 kN are necessary to decrease the interface micromotions and to
18 reduce the damage of the passivation layer significantly. Especially in the case of multi-
19 modular hip implants with more than one taper connection the specification of an optimal
20 assembly procedure (direction of impaction and impact force) seems to be a major challenge.
21 These implants sometimes offer taper connections with non-similar taper axes (parallel or
22 different angle) so that general instruction guidelines cannot be easily developed.

23 The determined moments in the taper interface to start an abrasion of the passivation layer
24 were, in general (for all test groups), unexpectedly low and most likely in the same range of
25 frictional moments acting normally in the human body ³⁵. In situations of large weight and/ or

high activity levels of the patient, or malpositioning of the prosthesis, the frictional moments at the interface may be increased even further. Furthermore, in the case of a large lever arm between the interface and the load vector, such as the case of large diameter hip implants, the threshold to initiate fretting could be easily exceeded during activities of daily living. Therefore, large diameter hip prostheses may be more susceptible to the documented postoperative complications.

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Conflict of interest statement

All authors do not have any conflicts of interest, which are related to this study, to disclose.

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List of Figures and Tables

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process starts with an increased potential and ends when the potential comes up to the initial value.

Figure 8: Torque levels at the onset of fretting at different assembly forces and axial loads (a). Maximum drop in the galvanic potential while performing the fretting test for the two tested assembly forces and axial loads (b).

Table 1: Summary of the tested Groups and their applied assembly and axial forces. The table also includes information whether the implants were subjected to the fretting test or not and in which cases the pull-off forces were detected.

Figure 1

Figure 2

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