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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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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 a static 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 was 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.

1. Introduction

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

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

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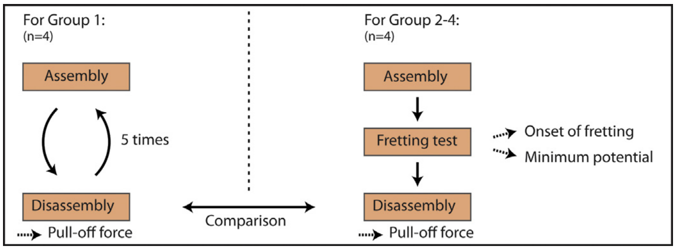

Fig. 1. Detailed overview of the methodology used in this study. The performed steps and the obtained output variables are included.

bearing surfaces. With increasing head diameter the incidence of revision rises even more [27]; 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 lubrication [28]. 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 bearings [26]. 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 [29–31].

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, offset [34]), implantation (e.g. assembly force, presence of contaminants [32]) and patient specific parameters (e.g. loading [33]) 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

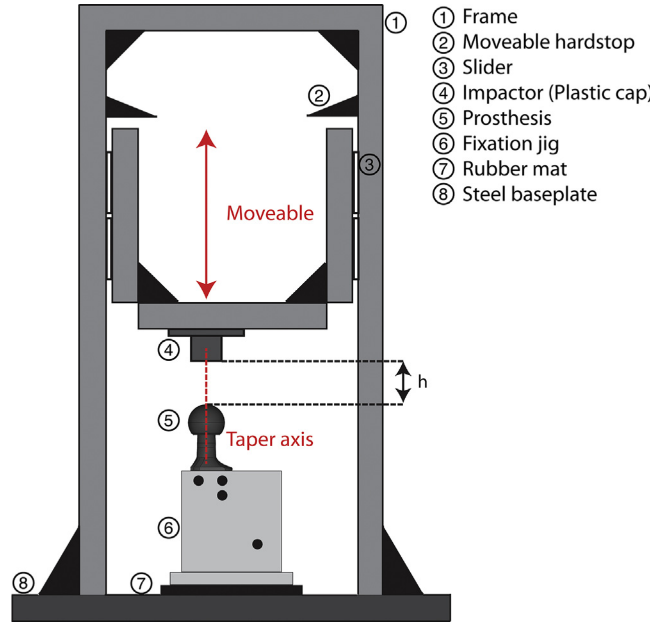

Fig. 2. Custom-made drop rig to impact the implant components. The stem/ball head assembly was rigidly fixed to a holder while applying an impaction. Sliders between the holder and the stabilisation frame ensured a limited friction loss.

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.

2. Materials and methods

Two sets of experimental investigations were performed. A detailed overview of the methodology is illustrated in the flowchart in Fig. 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.

2.1. 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 (Fig. 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.

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.

	Assembly force [kN]	Fretting test	Axial force [kN]	Pull-off force assessment
Group 1 (n = 4)	3/4.5/6 (consecutive)	No	–	Yes
Group 2 (n = 4)	4.5	Yes	1	No
Group 3 (n = 4)	6	Yes	1	Yes
Group 4 (n = 4)	6	Yes	3	Yes