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ORIGINAL PAPER

Metal release and corrosion effects of modular neck total hip arthroplasty

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Abstract Modular neck implants are an attractive treatment tool in total hip replacement. Concerns remain about the mechanical stability and metal ion release caused by the modular connection. Five different implant designs were investigated in an experimental set-up. In vivo conditions were simulated and the long-term titanium release was measured. Finally, the modular connections were inspected for corrosion processes and signs of fretting. No mechanical failure or excessive corrosion could be identified for the implants tested. The titanium releases measured were extremely low compared to in vivo and in vitro studies and were not in a critical range.

Résumé Dans les prothèses totales de hanche l'utilisation d'implants avec col modulaire est d'une utilisation fréquente et pratique. Néanmoins, cette utilisation laisse persister des doutes sur la stabilité mécanique et sur le relargage des ions métalliques. 5 différents implants ont été étudiés en reproduisant les conditions in vivo, en mesurant le relargage de titane et en évaluant la corrosion et les lésions du col. Ce travail n'a pas permis de mettre en évidence d'échec secondaire à une corrosion excessive, et les taux de titane sont restés extrêmement bas dans les limites de l'acceptable.

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Introduction

In current total hip arthroplasty, modularity between the head-neck connection of the femoral stem is well established [1]. More recently, implants with an additional modular connection between the neck and stem have become more popular. The ability to adjust the head centre relative to the stem axis intraoperatively, by connecting the neck in different positions, guarantees high versatility during surgery.

The mechanical loading conditions of the neck-stem connection fundamentally differ from the well-established head-neck connection. The forces at the established head-neck connection are transmitted centrally through the head resulting in low stresses. In contrast, the eccentric load on the modular neck-stem connection leads to higher stresses at the connection.

Fretting caused by micro-motion between the modular components may lead to particle and ion release to the surrounding tissue [4, 12, 21]. Titanium-containing particles may cause the release of cytokines that are associated with periprosthetic bone loss [25]. Such particles may get trapped between the articulating surfaces of the artificial joint resulting in third-body wear [21]. Furthermore, mechanically assisted crevice corrosion (as a combination of fretting and crevice corrosion) may attack the alloy and lead to implant failure [7]. Modularity is often associated with corrosion effects and is seen as a weak link with a possible source of complications [24]. A multicentre retrieval analysis of 231 modular hip implants revealed corrosion processes at the modular head-neck connection in more than 28% of the cases [8].

The aim of this study was to analyse and compare the corrosion effects and to evaluate the particle and ion release of the modular neck hip implants currently used. The following questions were addressed: (1) Are there differences in the total titanium release between different implant designs? (2) How does the geometry of the taper influence the titanium release? (3) Are there differences in the titanium release over time?

Material and methods

Three implants were analysed (Fig. 1): Eco-Modular® (Endoplant, Marl, Germany), Varicon® (Falcon Medical, Mödling, Austria), Metha® (Aesculap, Tuttlingen, Germany) and SPS-Modular® (Symbios, Yverdon, Switzerland). All implants were made of Ti-6Al-4V alloy. Additionally, a universal modular neck adapter (Bio-Ball®, Merete, Berlin, Germany) which is connectable to standard hip stems (12/14 taper) was included. This adapter was combined with a CF30®-stem (Zimmer, Warsaw, IN, USA). The Metha® and SPS-Modular® taper shapes were oval, designed with a female stem connection. All other taper geometries were round and had a male stem connection (Fig. 1).

The stem and neck sizes were chosen on the basis of the femoral size of an average patient. Comparable biomechanical loading conditions were achieved by selecting similar femoral anteversion and head neck diaphyseal (CCD) angles and lateral offsets for all implants (anteversion: 6.8°; CCD: 133.1°; lateral offset: 46.5 mm).

The taper angles were determined using a coordinate measuring machine (CMM) (MarVision MS 222, Mahr, Göttingen, Germany; accuracy: ±2.3 µm) and the surface roughness was analysed using a roughness measurement instrument (Perthometer M2, Mahr, Göttingen, Germany; accuracy: 12 nm). The stems and modular necks of each design were randomly paired. The resulting taper angle differences (cone angle differences) were calculated and the total surface roughness of each couple was determined quadratically. All geometrical measurements were repeated five times.

The assembly load and environment play a major role in the initial stability of modular connections [16]. To simulate surgical conditions the modular connections were connected wet by a hammer stroke. The stems were orientated in 10° adduction and in 9° flexion resulting in bending and torsional loading of the stem and stem-modular neck connection according to ISO 7206 (Fig. 2). A sinusoidal load of between 0.3 kN (min.) and 2.3 kN (max.) was applied for 10×10^6 cycles. The frequency was repeatedly altered between 3 Hz (100,000 cycles) followed by 15 Hz (900,000 cycles).

The particles and ions released from the stem-modular neck connection were measured using a fluid reservoir filled with 800 ml calf serum (diluted to a protein content of 30 g/l, at 37°C, pH: 7.4). Serum was chosen because proteins are reported to affect the corrosion resistance of titanium alloy [11, 14]. The serum was continuously circulated by a peristaltic pump from the reservoir to a small simulation chamber which surrounded the modular connection (Fig. 2).

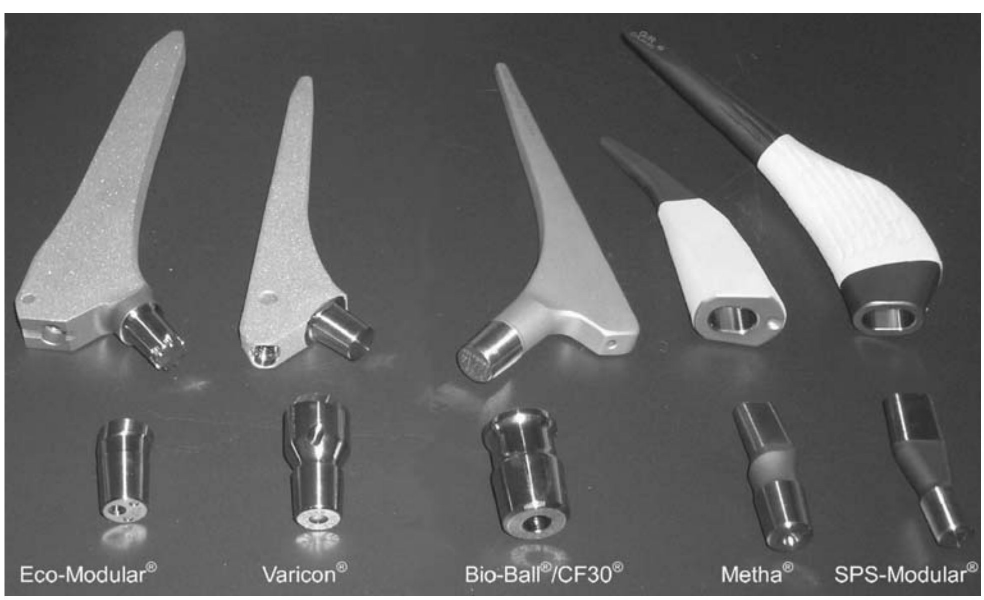

Fig. 1 Implant designs investigated. The oval modular taper of the two designs on the *right side* are female connections

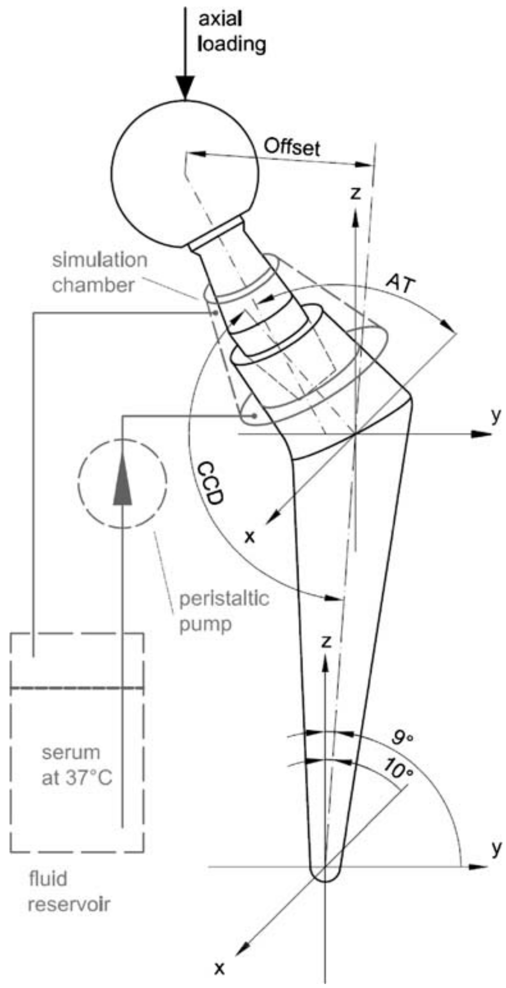

Fig. 2 Alignment of the stem and modular neck relative to spatial coordinates. The peristaltic pump continuously circulates serum between the fluid reservoir and simulation chamber

The titanium concentration of the serum was analysed using HR-ICP-MS (Element2, Thermo Fisher Scientific, Bremen, Germany) at intervals of 0, 1×10^6, 2×10^6, 4.5×10^6, 7×10^6 and 10×10^6 cycles. In order to detect not only ions but also particles in the serum, the samples were first digested with high purity nitric acid (HNO_3) and hydrogen peroxide (H_2O_2) following a standardised, well-established procedure [10]. The titanium mass was calculated based on the test medium's volume and the measured titanium concentration.

All data are presented as mean ± standard deviation (SD). An analysis of variance (ANOVA) was used to prove whether there were differences between the prostheses in total titanium release. Pearson's correlation test was performed to deal with geometrically related influences (total surface roughness, mean cone angle and delta cone angle) on total titanium release. Student's *t*-test was used to detect possible influences of the taper shape (round vs oval). Regression analysis was performed to demonstrate a progression in titanium release over time. All statistical analyses were performed using SPSS® software (SPSS® for Windows 16.0.1, SPSS Inc. Chicago, IL, USA). A p value < 0.05 was considered significant.

Finally, the tapers were carefully disconnected and inspected by scanning electron microscope (SEM) (Type 440, Carl Zeiss, Cambridge, UK) for corrosion effects.

Results

The total titanium release of all systems varied between 12 and 44 µg at the end of the test (Fig. 3). No significant differences in total titanium release were found between the tested implants ($p=0.66$). Table 1 summarises the results of the geometrical measurements. Neither the mean cone angle ($p=0.45$), the cone angle difference ($p=0.30$) nor the shape of the taper ($p=0.44$) had a significant influence on the total titanium release. Based on an almost significant ($p=0.06$) negative correlation coefficient of $r=-0.86$, the total surface roughness indeed seemed to have an effect. A significant linear progression in titanium release over time was found for the Eco-Modular® implant ($p<0.01$, $r=0.98$), the SPS-Modular® implant ($p<0.01$, $r=0.99$) and the Bio-Ball® implant ($p=0.04$, $r=0.90$). No linear correlation was found for the Varicon® implant ($p=0.30$, $r=0.59$) and the Metha® implant ($p=0.19$, $r=0.70$).

SEM revealed moderate signs of fretting in all tested connections. Figure 4 shows scars caused by micro-motion which perpendicularly obliterate machine lines. No severe corrosion effects were detected in any of the implants investigated.

Discussion

The literature unequivocally demonstrates that design- and material-related parameters influence micro-motion and

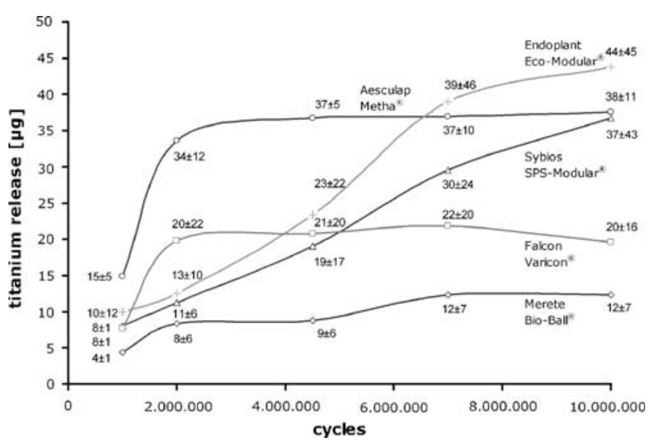

Fig. 3 Titanium release of the five implant designs during the course of simulation

Table 1 Results of the cone geometry measured

	Total surface roughness (µm)		Mean cone angle (°)		Cone angle difference (°)	
Endoplant Eco-Modular®	1.28	± 0.31	5.67	± 0.02	0.04	± 0.04
Falcon Varicon®	3.48	± 0.17	5.80	± 0.01	0.31	± 0.03
Aesculap Metha®	0.72	± 0.02	3.69	± 0.01	0.09	± 0.04
Symbios SPS®	0.34	± 0.01	5.01	± 0.01	0.10	± 0.02
Merete Bio-Ball®	12.15	± 0.39	5.68	± 0.00	0.11	± 0.03

fretting of implant connections [8, 9, 11, 13, 15]. However, no differences in total titanium release were found for the implant designs tested here. Compared to other studies the titanium release of all systems investigated in this study is low. A similar study on a modular neck hip implant design made of a titanium alloy revealed material loss of between 280 and 1,640 µg after 5.5×10^6 loading cycles [22]. Another study on a titanium plate-screw connection resulted in a titanium release of 849 µg after 1.2×10^6 loading cycles [13]. Lower concentrations ranging from 3 to 21 µg were also reported for plate-screw connections [11]. However, this study was only performed for 0.4×10^6 loading cycles.

The surface roughness showed a negative linear correlation to the total titanium release. With increasing surface roughness the titanium release decreased. Higher surface roughness may locally increase and evenly distribute the contact pressure [2] and thus decrease micro-motions between both components. The reported effect of increased micro-motion and fretting depending on the cone angle difference [20, 23] was not seen in this study. The implants showed different patterns with respect to progression in titanium release over time. For the Symbios SPS®, Endoplant Eco-Modular® and Merete Bio-Ball® implants the titanium release proceeds in a linear manner. However, the Aesculap Metha® and Falcon Varicon® systems showed a titanium release which increased during the first 2×10^6 cycles and subsequently remained stable (Fig. 3). Similar progressions are reported for wear studies on metal-on-metal joint bearings in total hip replacement [10]. During the initial run-in phase of those implants, the surface geometries of both counterparts adapt to each other. Such a mechanism may also occur at the modular connection leading to decreased micro-motion and resulting in a more stable connection. The explanation for the measured steady-state titanium concentrations over time in two of the five tested implant designs may be related to a limited fluid transfer between the crevice of the modular connection and the surrounding fluid. If the fluid transfer is restricted, metal ions caused by fretting may not enter into the surrounding fluid. In this case mechanically assisted crevice corrosion as reported by Gilbert et al. [7] may occur. Based on fretting and subsequent repassivation of the titanium, the local concentration of free oxygen will drop and this will result in an increased concentration of free metal ions in the crevice. The excess of metal ions then attracts chloride ions to form metal chlorides. These metal chlorides will react with water to form metal hydroxide and hydrochloride acid, lowering the pH and resulting in a hydrochloric acid solution with a very low pH in the crevice. The metal then loses its passive film and becomes thermodynamically unstable. Subsequent failure of the modular connection might occur. However, in this study neither mechanically assisted crevice corrosion nor other severe corrosion effects could be identified by final SEM analysis. No gross material failure occurred.

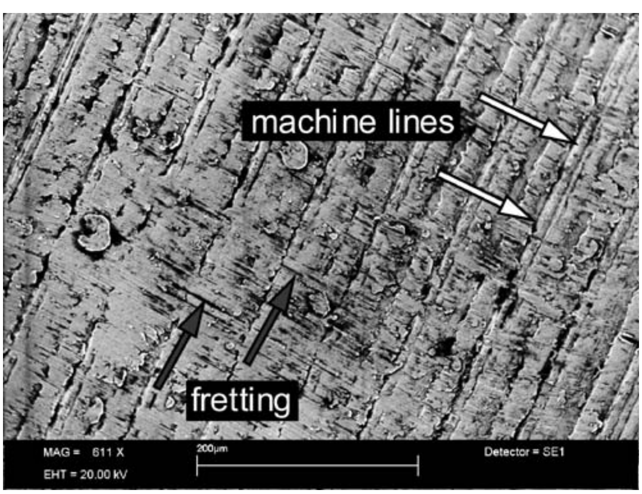

Fig. 4 Fretting scars run perpendicular to machine lines

Forces of normal gait were applied in this study [3]. For active or obese patients higher forces may occur in vivo, especially in combination with high offset necks.

Titanium is the commonly used implant material. In spite of its functional benefits and local biocompatibility, concerns exist about the long-term risks caused by the metal particles and ion release. Macrophage activation caused by titanium particles and increased cell mediator release has been observed in vitro and in vivo [18, 19]. In vitro chromosomal damage caused by high concentrations of titanium particles have also been reported [5, 6]. Nevertheless, such reactions depend strongly on the applied particle or ion concentration. Rogers et al. investigated the effect of different titanium particle concentrations on the cell mediator release and cytotoxicity [18]. They applied particle concentrations of between 14 and 58 μg/ml to human monocytes in vitro and reported an increase in cell mediator release depending on the particle concentration. However, a significant toxicity was not seen in their study. Assuming a patient activity of 2×10^6 cycles/year [10], the mean titanium release of all tested systems in our study would correspond to an annual total titanium release of about 6 μg to the whole organism. Compared to in vivo or other in vitro studies this concentration is extremely low. Clinically, reactions to titanium are rare and in vivo studies also confirmed no genotoxicity or cytotoxicity of titanium [17]. Consequently, the authors believe that the clinical use of these implants would appear to be appropriate.

The titanium concentrations exhibited quite a high variability. The measurement of small values near the threshold of a specific measuring method generates wide ranges. Thus, the variability measured for some values in this study may be related to the low values generally measured.

Conclusion

The results of this study are promising and can support limited clinical use of these implants. Very low concentrations of titanium release were found. No differences between the different designs in total titanium were seen. However, the surface roughness of the taper connection seems to affect the total titanium release of the implants tested. Different modes of titanium release over time were measured. No mechanical failure or excessive corrosion processes could be identified on the implants tested. Compared to in vivo and other in vitro studies extremely low concentrations of titanium release were seen. From the authors' point of view the measured titanium concentrations are within a clinically non-critical range. The safety of the modular neck-stem connection still needs to be proven in clinical studies.

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