ilmedia

TECHNISCHE UNIVERSITÄT ILMENAU

Wuttke, Viola; Witte, Hartmut; Kempf, Katrin; Oberbach, Thomas; Delfosse, Daniel:

Influence of various types of damage on the fracture strength of ceramic femoral heads

Zuerst erschienen in:	Biomedizinische Technik = Biomedical Engineering. - Berlin [u.a.] : de Gruyter. - 56 (2011), 6, p. 333-339.
Erstveröffentlichung:	2011-12-01
ISSN (online):	1862-278X
ISSN (print):	0013-5585
DOI:	10.1515/BMT.2011.026
[Zuletzt gesehen:	43692]

Biomed Tech 2011; 56:333–339 © 2011 by Walter de Gruyter • Berlin • Boston. DOI 10.1515/BMT.2011.026

Influence of various types of damage on the fracture strength of ceramic femoral heads

Viola Wuttke[1,*], Hartmut Witte[2], Katrin Kempf[1], Thomas Oberbach[1] and Daniel Delfosse[3]

[1] Centre of Excellence Ceramics, Mathys Orthopaedie GmbH, 07646 Moersdorf/Thuer, Germany
[2] Fachgebiet Biomechatronik, Fakultät für Maschinenbau, Technische Universität Ilmenau, 98684 Ilmenau, Germany
[3] Mathys Ltd. Bettlach, 2544 Bettlach, Switzerland

Abstract

Ceramic-on-ceramic articulations are a frequently used bearing for total hip replacements. This success mainly is due to their excellent tribological properties. Ceramics can withstand high pressure loads due to its brittleness but only low bending stresses. A ceramic ball head fracture is the result of subcritical crack growth. This kind of fracture *in vivo* can abet by damage or contamination of the stem cone. The main goal of this work is to provide a risk assessment of different possible damage mechanisms and contaminations that may result in lower fracture strength of a ceramic ball head. To simulate potential causes, different types and dimensions of metal wire, foils, hair, and lubricants were inserted between the ceramic ball head and the metal cone of the stem. The test results clearly show that fracture strength is negatively influenced by most of the inhomogeneities between the cone and the head because they increase the peak stresses acting on a part of the ceramic ball head. The results of this article clearly confirm the demand for an undamaged taper fit "free of contamination" between the ceramic head and the metal cone during implantation.

Keywords: ceramic hip head; conical clamping connection; contamination; fracture strength; surgical handling-related risks; total hip replacement.

Introduction

Ceramic hip heads have become established for total hip replacement due to their excellent properties. The widely used alumina ceramic shows a high corrosion resistance and is biocompatible and bio-inert. Due to their high strength and hardness, ceramic implants are scratch-resistant and possess good wear properties. Despite continuous improvement of the ceramic material and implant design, the risk of a component fracture cannot be excluded [7]. Cases of material failure in the form of chipping or breakage are very rare. The failure rates of ceramic ball heads in ceramic self-pairing designs are reported between 0.004% and 0.06% [8, 9, 13, 24, 27]. Internal statistics of the Mathys Orthopaedie GmbH (Moersdorf/Thuer., Germany) signify failure rates of ceramic ball heads of 0.03% for head diameter of 28 mm and 0.008% for head diameter of 32 mm. The number of unreported cases is estimated to be thrice that in literature [27]. Some reasons for fracture are indicated after fall of the patients, other fractures occur while walking without trauma [8–10, 12, 15, 17–19, 20]. It is assumed that many of these failures without trauma could have been prevented with careful intraoperative handling [7, 13, 26]. Some case reports with ceramic head fracture postulate damaged cones or contaminations within the connection area as reason for breakage [14, 18, 19].

Therefore, the extent of handling-related risks was investigated in this study. As a result, various forms of damage to the metallic cone taper and contamination between the metal cone and ball head were examined to assess their effect on fracture strength and thereby the safety against ceramic breakage.

The fit of modular hip prostheses is guaranteed by the conical clamping design between the stem and the ball head, thus achieving a long-term and self-locking connection [28]. Self-locking is based on the principle of the Morse taper of the cone [4–6] with a defined cone ratio of 1:10 [25], defining a cone angle of 5°43.5′.

Axial force is required to tighten or loosen the connection. The resulting stress distribution in the ceramic head depends on the contact area with the metal taper and the friction coefficient between the metal and the ceramic [2, 11]. Dürr [7] determined the stress distribution in a ceramic head by means of a finite element analysis and showed that the zones with the highest stress were found in the contact zone, close to the relief groove, in the area where ceramic head breakages typically occur *in vivo* [14]. This is why the examined disturbances were applied to this area.

With this study, we tested two hypotheses with regard of their negative influence on the fracture strength of a ceramic ball head:

- Any damage or inhomogeneity in the taper fit will cause peak stresses in the ceramic. Depending on the extent of their effect, they may prove fatal to the ceramic component.
- Any reduction of the friction coefficient between the metal cone and the ceramic head will lead to an increase in circumferential stress. Again, depending on the extent of the effect, it may prove fatal to the ceramic component.

*Corresponding author: Viola Wuttke, Centre of Excellence Ceramics, Mathys Orthopaedie GmbH, An den Trillers Bueschen 2, 07646 Moersdorf/Thuer, Germany
Phone: +49-36428-494620
Fax: +49-36428-494220
E-mail: viola.wuttke@mathysmedical.com

Materials and methods

Fracture strength was measured by the application of an axial force in accordance with ISO 7206-10 [16] (see Figure 1). Here, test pins that exactly met the characteristics of the stem cone (dimensions, 12/14 cone; material, Ti_6Al_4V; surface texture, circumferential grooves with Rz=6.3 µm) were used. All examined Al_2O_3 ceramic heads (Bionit, Mathys Orthopaedie GmbH) were size 28 l (external diameter, 28 mm; long neck length). This size was chosen because its fracture strength is lowest in comparison to the other types of ball heads with shorter necks or larger diameters. The load was applied at a constant rate of 0.04 mm/s until material failure occurred. The maximum load achieved is denoted as the fracture strength.

The requirements of the US Food and Drug Administration (FDA) served as guideline. Accordingly, the mean value of a measurement series has to be higher than 46 kN, and at the same time, there should be no single value lower than 20 kN [23]. On the basis of *in vivo* measurements on different hips by Bergmann et al. [3], another critical factor can be added. Loads of 10–12 kN can become critical for the patients.

Ceramics burst without warning (the so-called brittle fracture). Despite high-purity raw materials, intrinsic failures, for technological reasons, cannot be avoided and stand, e.g., for micropores, giant grains, inclusions. Furthermore, extrinsic failures which can result from hard machining cannot be precluded. On the basis of the statistical distribution of the intrinsic and extrinsic failures, a high standard deviation of the fracture strength is to estimate [21, 22, 28].

Based on these facts, reference tests were performed with n=10. In the burst tests with different simulations, the fracture strengths showed lower standard deviations. It was presumed that the influence of simulated damage on fracture strength was higher than the standard deviation. So each test with simulations was performed five times (n=5). The software VISUAL-XSEL version 10.068 (CRGRAPH, Munich, Germany) was used for statistic evaluation. The level of significance for the t- and U-tests was implemented with 5%.

The simulation of intraoperative worst-case handling conditions (see Figure 2) that may affect the conical clamping connection between the ceramic head and the cone of the stem

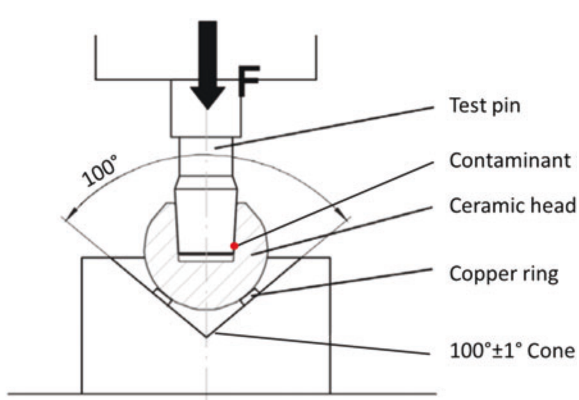

Figure 1 Test set-up following ISO 7206-10, according to Weisse et al. [24].

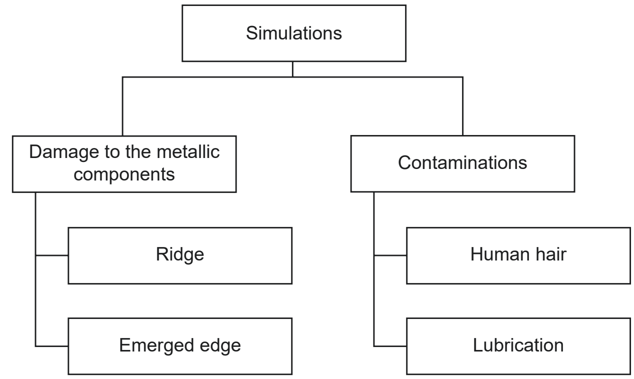

Figure 2 Overview of mechanisms tested.

was carried out with different extents of damage by varying the dimensions and amount of damage or contamination.

Different kinds of damage to the metallic components were simulated. This form of damage may, for example, be caused by a surgical instrument. On the one side, a ridge was simulated by inserting a titanium wire. A ridge can be formed by hitting a notch. On the other side, the so-called emerged edge was simulated by inserting a metal foil onto the cone. The emerged edge should imitate material deformation after a careless clash on the metal cone on the upper end.

The influence of the ridge dimension was examined by wires with different diameters. Wires made of pure titanium grades 2 (d=0.4 mm) and 4 (d=0.25 mm) were inserted along the taper of the test pin. The wires were applied along the whole length of the load-transferring area of the cone (see Figure 3A). This method complements a test series of Weisse et al. [24] with 5- and 10-mm-long scratches on the metallic tapers.

The emerged edge was simulated with the aid of metal foils (RECORD Metall-Folien GmbH, Muehlheim am Main, Germany) made of non-alloyed steel. The examined metal foils had a diameter of 4 mm and varying thicknesses (0.025, 0.05, 0.075, 0.1, 0.2, 0.3, and 0.4 mm). In the tests, the metal foils were bent over the upper edge of the test pin (see Figure 3B).

The simulations of different contaminations in the conical fit, as they may be caused intraoperatively by soft and fatty tissues getting between the cone and the head, were carried out with human and equine hair and lubricant.

Human hair has different diameters. To investigate this effect, a human scalp hair with a diameter of 75 µm and a horse hair with a diameter of 250 µm (see Figure 3C) were used. The hair was laid along the cone of the test pin, and the head was afterward placed on the cone.

For the simulation of fatty tissues, different quantities (5, 10, and 20 mg) of AutolTop 2000 machine lubricant (Autol Schmiertechnik GmbH, Wuerzburg, Germany) were used (see Figure 3D).

Results

To determine the influence of the different types of damage to the metal cone, the fracture strength of the ceramic head was

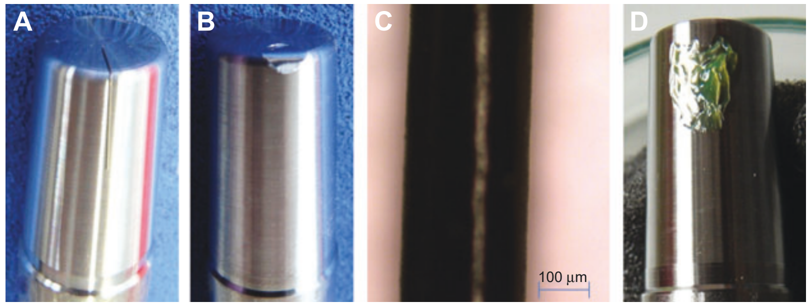

Figure 3 Damage simulations.
(A) Titanium-wire (d=0.25 mm), (B) metal foil (d=4 mm), (C) horse hair (d=250 µm), (D) lubricant (10 mg).

measured in accordance with ISO 7206-10. In the following diagrams, the fracture strength of the ceramic head put on a damaged cone, using the average from five separate tests, is compared with the reference test, i.e., a ceramic head put on a pristine cone without any damage or contamination.

The average fracture strength from the reference tests was 58.9±5.6 kN (average±standard deviation, n=10). With brittle materials, a high standard deviation is to be expected due to the statistical distribution of intrinsic and extrinsic inhomogeneities acting as potential crack initiation sites [21, 22, 28].

Influence of titanium wire

In the tests where the damage was represented by titanium wires, the wires had a strong-effect on the fracture strength. The result with the thinner titanium wire (d=0.25 mm) already failed to meet the FDA requirements. When the diameter of the titanium wire increased (d=0.4 mm), the fracture strength decreased further (see Figure 4). The results of the examined titanium wires differed significantly from the reference test (U- and t-tests; p<5%). In addition, the deformation of the wires after failure was determined. The wire with the smaller diameter (d=0.25 mm) was plastically deformed to a cross-section of 0.79×0.06 mm. The thicker wire (d=0.4 mm) was deformed to a cross-section of 1.24×0.1 mm.

Influence of metal foils

In the burst tests with metal foils, the influence on the fracture strength was again high. Even the thinnest metal foils (thickness=0.025 mm) led to a fracture strength below the required FDA average of 46 kN. The reliability of components when metal foils with a thickness of over 0.075 mm are used was so strongly affected that it would become a critical factor for patients. The fracture strengths are within the range of worst-case physiological loading, i.e., 10–12 kN for the metal foils from 0.1 to 0.4 mm (see Figure 5). There was a significant difference between all examined metal foils and the reference (U- and t-tests; p<5%).

Influence of hair

The results with human scalp hair (d=75 µm) showed no loss of fracture strength compared with the reference results (see Figure 6). The results with horse hair (d=250 µm), however, showed a significant deviation from the reference results (U- and t-tests; p<5%) and failed to meet the minimum requirements of the FDA. This means that with this type of contamination, there is a link between fracture strength and extent of contamination above a certain threshold value – albeit not as strong as with metal wires or foils.

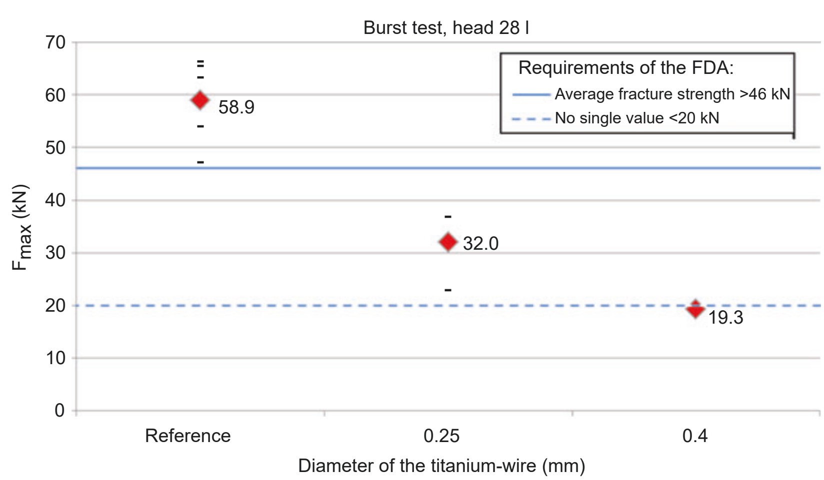

Figure 4 Series of measurement with titanium wire: fracture strength.

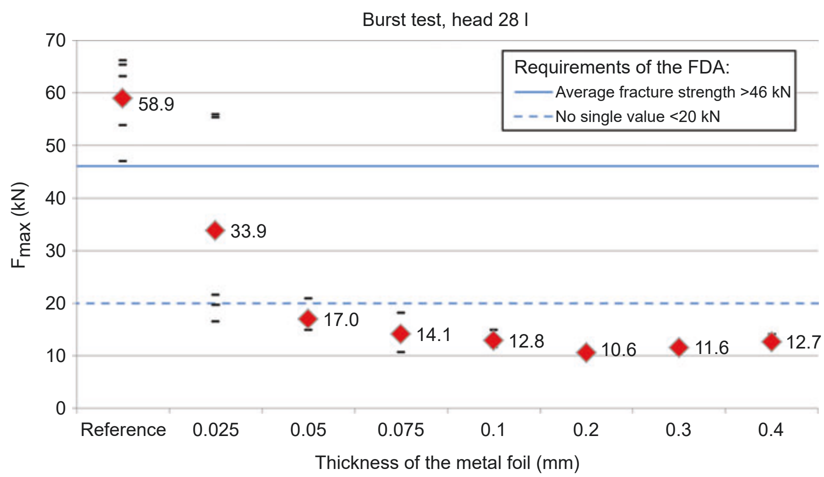

Figure 5 Series of measurement with metal foil: fracture strength.

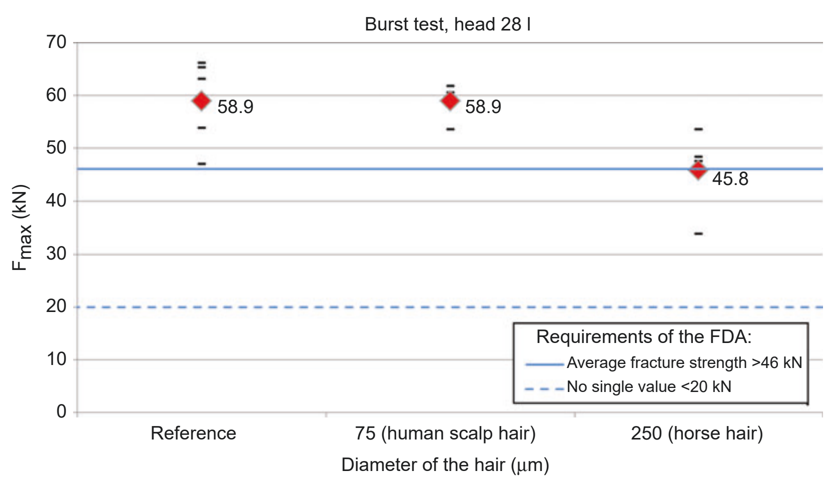

Figure 6 Series of measurement with hair: fracture strength.

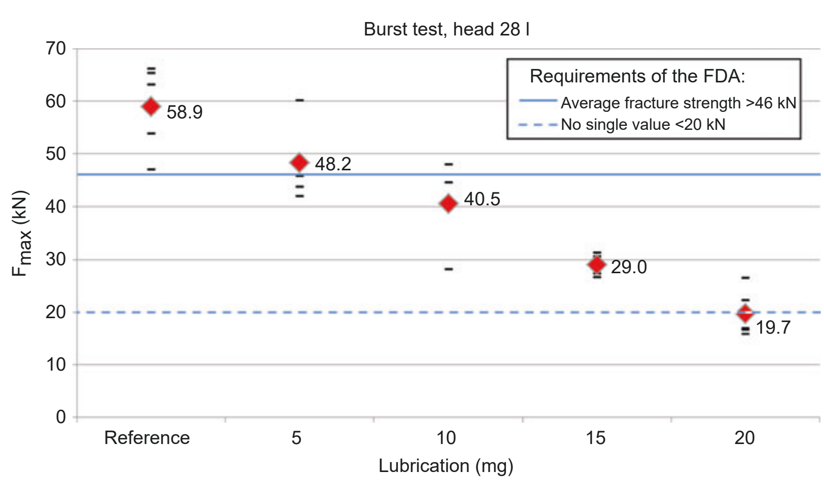

Figure 7 Series of measurement with lubrication: fracture strength.

Influence of lubricant

In the simulations of fatty tissues or liquids, different quantities of lubricants were added to the conical taper. Again, the fracture strength distinctly decreased as the amount of lubrication was increased (see Figure 7). Above 10 mg of lubrication, the FDA requirements were no longer met. In comparison with the reference, there was a significant difference with all tested quantities (U- and t-tests; $p<5\%$).

Discussion

The tests that were carried out within the scope of this work showed an influence of various types of damage and contamination on the fracture strength of the ceramic ball head. Besides the limit values considering the FDA, another critical factor was commented on. This critical factor arose from measurements by Bergmann et al. [3]. *In vivo* loads are generally much lower than the FDA's required values. In a worst-case scenario where the patient trips without falling over, maximum forces of 870% body weight are generated [3]. This corresponds to 8.7 kN for a patient that weighs 1000 N (≈100 kg). Including a small safety factor, a limit of 10–12 kN is deemed to become critical for the patients.

Ceramic does not tolerate disturbance well. Especially, if one increases stress due to its brittleness, the ceramic cannot accommodate the damage through plastic deformation. The examined mechanisms simulated either the creation of high local tensile stresses in the ceramic or the reduction of friction in the conical clamping connection. The positive features of the connection, which are mainly defined by an equal force transmission, were strongly affected by damage and contamination. The applied tests according to ISO 7206-10 are for the determination of resistance to static load of modular femoral heads [16]. The static tests deliver no crack propagation. For examination of subcritical crack growth, dynamic compression tests should be further investigated.

The simulated damages on the metal components were investigated in case of intraoperative damage. Possible intraoperative partial damage on the metal cone can be caused by failure to follow instruction. In case a surgical instrument abuts on the open metal cone, a notch or deformation can form, depending on the shape of the instrument and the power of the clash. Two case reports described a cone that was worn by scraping [14, 19]; another case report related a fretting cone [18]. In general, a material deformation leads to a deviation from the original shape. With the creation of a notch, a ridge also appears. In a deformation caused by more power, the material will displace and emerge. To simulate these deformations at the metal cone, titanium wire for a ridge and metal foil for an emerged edge in different dimensions were used.

In all tests with metal wires and foils, the fracture strength decreased as the size of the metallic inclusion increased. For a given deformed thickness, the titanium wires lead to higher fracture strength than the steel foils. In other words, the influence of the steel foil was greater in comparison to the titanium wire. It would appear that the location of the disturbance and the width of the simulated damage also play a decisive role, not only its thickness. The influence of the location of disturbance will be examined in further theoretical and practical analysis. Damage to the cone in the area close to the upper edge is more detrimental than damage to the inferior part of the cone [7, 14]. This also makes sense when considering the difference in cone angle between the male metal cone (slightly smaller than 5°43.5′) and the female ceramic cone (slightly larger than 5°43.5′) because it is predominantly the upper part of the metal cone that comes into contact with the ceramic head.

In summary, the examined simulated damage on the cones strongly affected the fracture strength of the ceramic components. These findings do not correlate with the results of Weisse et al. [24] regarding scratches produced on the cones where the scratches did not significantly affect the fracture strength. Unfortunately, the exact dimensions of the scratches were not published. It seems logical that simple scratches and grooves would not affect the fracture strength much as long as the material is completely removed and does not rise above the original surface. However, scratches usually contain a middle groove as well as two raised ridges on each side of the scratch. The height of the ridge, which in the end determines the level of local stress increase, depends generally on the depth of the scratch. Other factors include the material itself, especially its elastic and plastic properties, and the roughness of the surface. A machined surface with fine grooves, as is standard for stem cones, may accommodate slight scratching without any detrimental effect on the fracture strength of a ceramic head because the ridges from a slight scratch may "disappear" between the larger original grooves of the cone.

The simulations with hair were done because, inside the operating room, although the surgeons are indeed dressed in sterile scrubs, nobody can guarantee that no loose hair from uncovered areas of the face will fall into the operating field. The examined hair only exerted a minor influence on the fracture strength due to its softness and good plastic deformability. The hair is plastically deformed and placed within the original machining grooves of the cone, thus not acting as stress raiser as long as it can be completely accommodated within the grooves. The examined horsehair, due to its larger diameter, showed a slight effect on the fracture strength as compared with human scalp hair. The thickness of a human hair is below the threshold where the fracture strength is affected. In this case, the main risk caused by a human hair that can transport germs would, therefore, be an increase in infection risk for the patients.

In the test with lubricant, it is evident that as the quantity is increased the fracture strength is reduced. A known relationship between the friction coefficient in the conical clamping connection and the fracture strength confirmed these results [24]. A lower friction coefficient permits the head to slide slightly deeper on the cone with the same applied load. This, in turn, leads to higher hoop stresses in the ceramic head and causes lower fracture strength. During a minimally invasive operation, it is difficult for the surgeon to hold the taper of the stem clean and dry. Case reports about ceramic head fractures *in vivo* showed residue, such as soft tissue inside the conical clamping connection and deformed and roughened metal cones [14, 18].

Depending on the amount of lubricant in the tests, a lubricating film is formed in the fit, which may reduce the total friction between the cone and the ceramic head by a critical amount. As a result, the normal wedge force created by the cone geometry increases until the circumferential stress becomes too high and the ceramic material fails. This is in accordance with the findings that as the roughness increases, hence the friction, the fracture strength of the ceramic component increases [25].

The weakness of this study lies on the fact that the simulated damages and contaminations cannot exactly reproduce *in vivo* situations. The strength of this study, however, is the large number of different mechanisms that were investigated *in vitro* using the same basic testing set-up. Most simulations were carried out because of case reports on *in vivo* ceramic head fracture [14, 18, 19], whereas other simulations were done because of various case reports without documented reasons for failure [8, 12, 15, 17, 18, 20].

The results clearly show that despite improvements in the materials, utmost care has to be taken intraoperatively to ensure that no damage or contamination is introduced, which might later lead to a catastrophic event.

Conclusions

Modular endoprosthesis with ceramic ball heads are used successfully as long-term replacements for hip joints. To support their use, the investigations of this study were carried out. The tests showed that most damages or contaminations of the stem cone disturbed the ideal contact between the metal and ceramic components. Depending on the extent of damage or contamination, past a certain threshold value, the ceramic ball head fails earlier in comparison to the undamaged reference situation. With the exception of the results with the human scalp hair, there must be an ideal contact given. Furthermore, contamination from materials, such as hair can transport germs and increase the risk of infection. Therefore, utmost care has to be taken intraoperatively to avoid such damage or contamination; otherwise, the revision risk for the patient would increase and likewise the costs for the health care system. Revisions or repeat revisions due to fracture of ceramic components might lead to a disastrous complication for the patient and the surgeon. Furthermore, the survival rate of the components after revision due to ceramic fracture is lower than standard revisions [1]. As a consequence, ceramic heads for primary surgery must never be placed on used, damaged, dirty, or even moist cone tapers.

References

[1] Allain J, Roudot-Thoraval F, Delecrin J, Anract P, Migaud H, Goutallier D. Revision total hip arthroplasty performed after fracture of a ceramic femoral head: a multicenter survivorship study. J Bone Joint Surg Am 2003; 85: 825–830.

[2] Bachnick M, Hasenpusch M, Richter H, Boenick U. Einfluss von Härte und Oberflächenqualität von Metallkonen auf die Bruchlast von keramischen Kugelköpfen bei Hüftendoprothesen. Biomed Tech 1994; 39: 302–306.

[3] Bergmann G, Graichen F, Rohlmann A, et al. Die Belastung orthopädischer Implantate. Messungen und praktische Anwendungen. Orthopädie 2007; 3: 195–204.

[4] DIN 228. Morsekegel und Metrische Kegel, 1987-05.

[5] DIN 254. Geometrische Produktspezifikation (GPS) – Reihen von Kegeln und Kegelwinkeln; Werte für Einstellwinkel und Einstellhöhen, 2003-04.

[6] DIN EN ISO 3040. Geometrische Produktspezifikation (GPS) – Maßeintragung und Toleranzfestlegung – Kegel (ISO 3040:2009); Deutsche Fassung FprEN ISO 3040: 2011, 2011–08.

[7] Dürr HR. Problemfall Keramikbruch. Was ist zu tun? Der Orthopäde 2009; 8: 698–703.

[8] Fritsch EW, Gleitz M. Ceramic femoral head fractures in total hip arthroplasty. Clin Orthop Relat Res 1996; 328: 129–136.

[9] Habermann B, Ewald W, Rauschmann M, Zichner L, Kurth AA. Fracture of ceramic heads in total hip replacement. Arch Orthop Trauma Surg 1996; 126: 464–470.

[10] Hannouche D, Nich C, Bizot P, Meunier A, Nizard R, Sedel L. Fractures of ceramic bearings. History and present status. Clin Orthop Relat Res 2003; 417: 19–26.

[11] Heimke G. The safety of ceramic balls on metal stems in hip arthroplasty. Adv Mater 1994; 6: 165–170.

[12] Heimke G, Griss P. Five years experience with ceramic-metal-composite hip endoprosthesis: mechanical evaluation and improvements. Arch Orthop Trauma Surg 1981; 98: 165.

[13] Heinz BC, Mallek D. Vorkommnisse bei Hüft- und Knieendoprothesen. Der Orthopäde 2005; 34: 47–54.

[14] Higuchi F, Shiba N, Inoue A. Fracture of an alumina ceramic head in total hip arthroplasty. J Arthroplasty 1995; 10: 851–854.

[15] Holmer P, Nielsen PT. Fracture of ceramic femoral heads in total hip arthroplasty. J Arthroplasty 1993; 8: 567–571.

[16] ISO 7206-10. Implants for surgery – partial and total hip-joint prostheses. Part 10: determination of resistance to static load of modular femoral heads. ISO 2003.

[17] Kern S, Schreiber A, Hilfiker B. Keramikkopfbruch – Eine seltene Komplikation in der Hüft-endoprothetik. Fallbericht und Literaturzusammenstellung. Z Orthop 1990; 128: 543–548.

[18] Krikler S, Schatzker J. Ceramic head failure. J Arthroplasty 1995; 10: 860–862.

[19] Panagopoulos A, Megas P, Tyllianakis M, Dimakopoulos P, Lambiris E. Ceramic femoral head fracture with massive metallosis and severe wear of the cone: a case report and review of the literature. Eur J Orthop Surg Traumatol 2006; 16: 55–59.

[20] Peiró A, Pardo J, Navarrete R, Rodriguez-Alonso L, Martos F. Fracture of the ceramic head in total hip arthroplasty: report of two cases. J Arthroplasty 1991; 6: 371–374.

[21] Richter HG. Fractography of bioceramics. Key Eng Mater 2002; 223: 157–180.

[22] Schmitt-Thomas KG. Integrierte Schadenanalyse. Technikgestaltung und das System des Versagens. 2nd ed. Berlin: Springer 2005.

[23] US Food and Drug Administration. Guidance document for the preparation of premarket notifications for ceramic ball hip systems. Rockville, MD: FDA 1995.

[24] Weisse B, Affolter Ch, Terrasi GP, Piskoty G, Köbel S. Failure analysis of in vivo fractured ceramic femoral heads. Eng Fail Anal 2009; 16: 1188–1194.
[25] Willmann G. Das Prinzip der Konus-Steckverbindung für keramische Kugelköpfe bei Hüftendoprothesen. Materialwissenschaft Werkstofftech 1993; 24: 315–319.
[26] Willmann G. Ceramics for total hip replacement – what a surgeon should know. Orthopedics 1998; 21: 173–177.
[27] Willmann G. Ceramic femoral head retrieval data. Clin Orthop Relat Res 2000; 379: 22–28.
[28] Willmann G. Bruchanalyse an keramischen Kugelköpfen für Hüftgelenkersatz. Materialwissenschaft Werkstofftech 2001; 32: 591–600.

Received September 27, 2011; accepted November 15, 2011