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Original Article

Incidence of Modern Alumina Ceramic and Alumina Matrix Composite Femoral Head Failures in Nearly 6 Million Hip Implants

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ABSTRACT

Background: Because of improvements in ceramic materials and manufacturing, the incidence of ceramic failures has decreased over time. Recent concerns with corrosion have contributed to an increase in ceramic ball head utilization. The purpose of this study is to report the incidence of modern alumina bearing failures from a single major ceramic manufacturer in nearly 6 million hip implants and to identify trends in the modes of failure of these implants.

Methods: Beginning in the year 2000, CeramTec AG (Plochingen, Germany) began a comprehensive program for reporting and gathering failure data on its products. From January 1, 2000, to December 31, 2013, over 3.2 million pure alumina (PA) and 2.78 million alumina matrix composite (AMC) ceramic ball heads were implanted worldwide. During this period, there were 672 PA and 28 AMC femoral head fractures. The fractures were analyzed with respect to time to failure, head size, and implant factors.

Results: The incidence of clinical fractures of modern PA femoral heads and AMC femoral heads was 1 in 5000 (0.0201%) and 1 in 100,000 (0.0010%), respectively ($P < .0001$). The majority of implant failures (80%) occurred within 48 months following surgery ($P < .01$). Fractures were usually associated with specific events such as trauma, mismatched components, and dislocations. Large-diameter PA heads were associated with a lower rate of fracture compared to smaller-diameter femoral heads (0.0316% for 28-mm heads vs 0.0080% for heads 32 mm or greater [$P < .01$]). Similar trends were observed with AMC heads. The neck lengths of the femoral ball heads were also a factor: a short-taper 28-mm ball head was more likely to fracture compared to other neck lengths ($P < .01$).

Conclusion: Modern PA ceramic heads are reliable with extremely low risk of fracture. The reliability is even better with AMC heads.

Total hip arthroplasty (THA) is effective at relieving pain and improving function in patients with end-stage arthritis of the hip joint [1]. Improvements in materials, increased head and neck length options, and concerns with trunnionosis have led to an increasing utilization of ceramic ball heads. Lehil and Bozic reported on the trends in THA implant utilization in the United States from 174 hospitals participating in the Orthopaedic Research Network hospital consortium. The authors reported that ceramic on highly crosslinked polyethylene utilization increased from 6% in 2001 to 38% in 2012 [2]. In 2014, 49% of implanted femoral heads registered with the American Joint Replacement Registry were ceramic ball heads [3]. Advantages of ceramic ball on highly crosslinked polyethylene articulation include potentially improved wear rates and reduced risk of corrosion and fretting between the femoral stem and head interface [4,5].

Concerns of ceramic fracture and increased implant cost remain the principal barriers to wide adoption of ceramics. The risk of fracture has remained relatively low over the past 3 decades. Fritsch and Gleitz [6] performed a failure analysis on 4341 first-generation alumina ceramic ball heads and reported a 0.06% clinical fracture rate with a spherical alumina (Biolox) ball head. Subsequent improvements in manufacturing and material properties have further increased the reliability of subsequent generations of ceramic components [7]. However, the literature on fracture risk is

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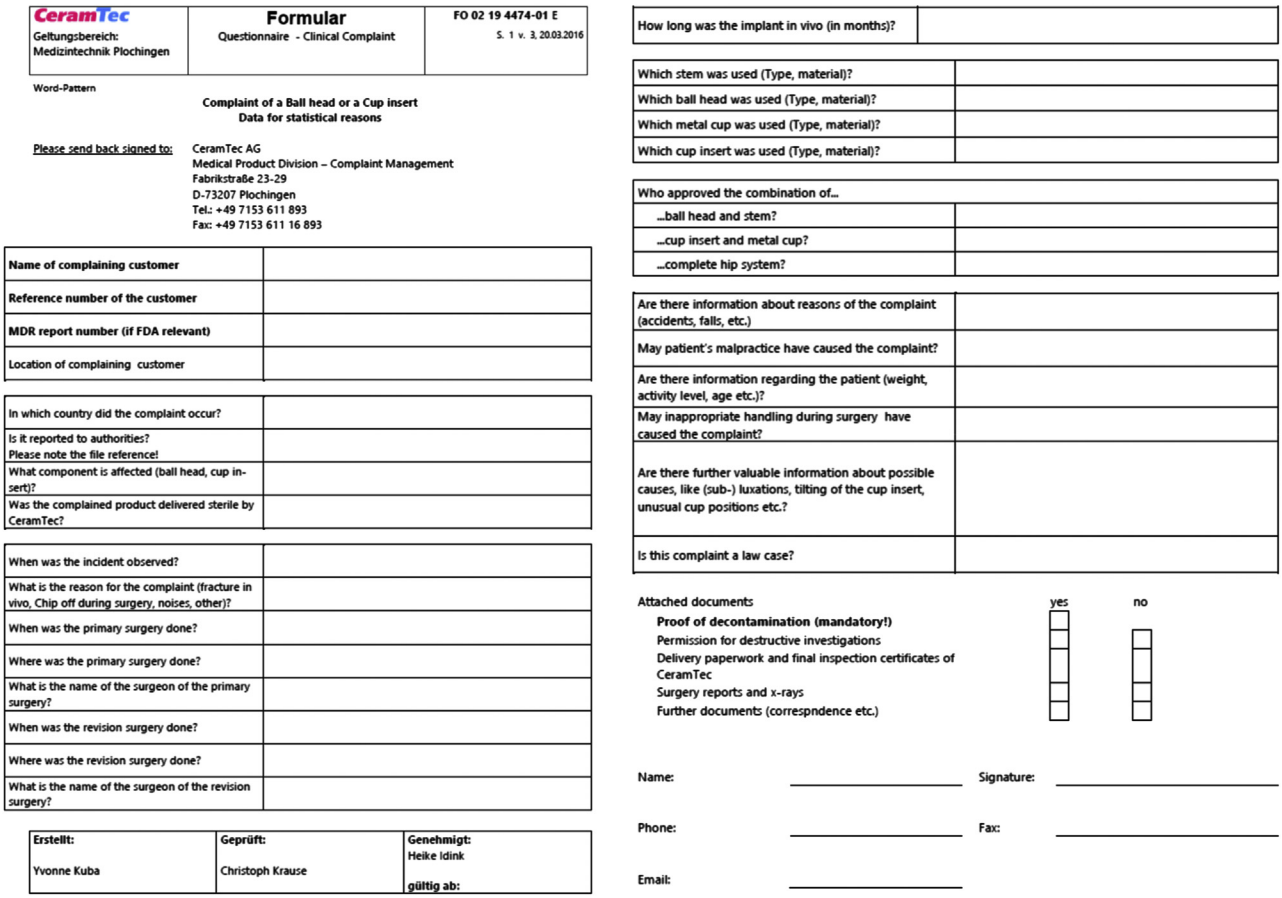
0883-5403/



CeramTec
Geltungsbereich: Medizintechnik Plochingen

Formular
Questionnaire - Clinical Complaint

FO 02 19 4474-01 E
S. 1 v. 3, 20.03.2016

Word-Pattern

Complaint of a Ball head or a Cup insert
Data for statistical reasons

Please send back signed to: CeramTec AG
Medical Product Division – Complaint Management
Fabrikstraße 23-29
D-73207 Plochingen
Tel.: +49 7153 611 893
Fax: +49 7153 611 16 893

Name of complaining customer	
Reference number of the customer	
MDR report number (if FDA relevant)	
Location of complaining customer	

In which country did the complaint occur?	
Is it reported to authorities? Please note the file reference!	
What component is affected (ball head, cup insert)?	
Was the complained product delivered sterile by CeramTec?	

When was the incident observed?	
What is the reason for the complaint (fracture in vivo, Chip off during surgery, noises, other)?	
When was the primary surgery done?	
Where was the primary surgery done?	
What is the name of the surgeon of the primary surgery?	
When was the revision surgery done?	
Where was the revision surgery done?	
What is the name of the surgeon of the revision surgery?	

Erstellt:	Geprüft:	Genehmigt:
Yvonne Kuba	Christoph Krause	Heike Idink gültig ab:

How long was the implant in vivo (in months)?	

Which stem was used (Type, material)?	
Which ball head was used (Type, material)?	
Which metal cup was used (Type, material)?	
Which cup insert was used (Type, material)?	

Who approved the combination of...	
...ball head and stem?	
...cup insert and metal cup?	
...complete hip system?	

Are there information about reasons of the complaint (accidents, falls, etc.)	
May patient's malpractice have caused the complaint?	
Are there information regarding the patient (weight, activity level, age etc.)?	
May inappropriate handling during surgery have caused the complaint?	
Are there further valuable information about possible causes, like (sub-) luxations, tilting of the cup insert, unusual cup positions etc.?	
Is this complaint a law case?	

Attached documents	yes	no
Proof of decontamination (mandatory!)	☐	
Permission for destructive investigations	☐	☐
Delivery paperwork and final inspection certificates of CeramTec	☐	☐
Surgery reports and x-rays	☐	☐
Further documents (correspndence etc.)	☐	☐

Name: _____ Signature: _____

Phone: _____ Fax: _____

Email: _____

Fig. 1. CeramTec fracture reporting form.

often derived from a single institution's clinical series. Therefore, the purpose of this study is to evaluate the risk of ceramic ball head fracture through analysis of the quality control program of a major ceramic implant manufacturer. We looked to (1) determine the fracture rate of modern alumina and alumina matrix composite (AMC) ceramic ball heads and (2) determine the factors such as time, ball head size, and taper influence on ceramic ball head fractures.

Materials and Methods

CeramTec (Plochingen, Germany), a major supplier of ceramic components to major orthopedic manufacturers worldwide with over 90% market share, began a reporting and surveillance program to study the reliability of its ceramic components beginning January 1, 2000. This initiative was the result of the Medical Device Reporting regulation (21 CFR 803) which mandated device manufacturers, importers, and device user facilities report device-related adverse events and product problems to the Food and Drug Administration. As a result, CeramTec instituted a mandatory reporting of ceramic failures by major implant manufacturers through contracting. The process of reporting was standardized. First, the implant manufacturer was required to complete and submit all necessary information related to any ceramic failures (Fig. 1). Second, when possible, the retrieved, fractured ceramic components were subjected to detailed implant analysis including scanning electron microscopy to precisely determine the failure mechanism. Finally, based on the individual lot numbers from the failed ceramic component, the fracture was counted against the particular year when the implant was originally produced. For example, a fracture of a ceramic ball head produced in 2004 and occurring in 2010 was counted against the year of production.

Between January 1, 2000, and December 31, 2013, over 3.2 million pure alumina (PA) (Biolox forte) and 2.78 million AMC (Biolox delta) ball heads were sold and implanted. Providing manufacturing, design, testing, and proofing, CeramTec works with each implant manufacturer to provide specific ball heads for each femoral stem according to the manufacturer's design specifications. The company uses an “on-demand” manufacturing of ceramic components. Through estimates of utilization, an orthopedic implant manufacturer contracts for the production of ceramic components using quarterly targets. These numbers are adjusted on a rolling basis to ensure implant availability. Once the process achieves steady state, the production process functions as a replenishment program with no significant excess inventory leftover.

The incidence of ball head fracture for both PA and AMC was calculated and the trends of failures over time compared. Due to the small number of AMC head fractures over this period, only data pertaining to PA (Biolox forte) ball heads could be analyzed with respect to (1) time to failure; (2) ball head size; and (3) taper characteristics influence. Categorical variables were analyzed using the Fisher exact test, box plot, and chi-square analysis. Statistical analysis was performed using SPSS version 22.0 (IBM, Armonk, NY). Observed factors associated with AMC (Biolox delta) fractures were reported.