High rates of implant fracture of a generic polished tapered femoral stem

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Abstract

Objectives: Cemented polished tapered stems have demonstrated excellent long-term outcomes. Based on this concept, many generic tapered stems have been released into the market. The aim of this study was to evaluate implant-related complications of 1 specific stem design.

Methods: Between 2010 and 2017, 315 total hip replacements were performed using a Fortress stem (Biotechni, La Ciotat, France). Patient records and radiology were retrospectively reviewed for implant-related complications. A failure analysis was performed on the failed Fortress stems in order to determine the cause of premature failure.

Results: 7 (2.2%) patients sustained a fracture of the neck of the implant after a mean of 5 years (range 50–81 months). All fractures were atraumatic, originating at the introducer inlet of the stem. All fractured occurred in obese patients (BMI >33 kg/m²) with a small sized prosthesis. Of these, there were 5 135° and 2 125° stems. Fracture risk was 23% (7/30) for patients with a small sized stem and a BMI >30 kg/m². All cases were revised using a cement-in-cement technique or a cementless modular revision stem. Failure analysis on the retrieved stems revealed a stress riser at the bottom of the introducer inlet.

Conclusions: An alarmingly high rate of early implant fractures was seen using this specific type of cemented stem, particularly when using smaller implant sizes in obese patients. Although based on a proven design, a specific modification led to a stress riser in the neck area, which resulted in a high incidence of implant failure. This series underlines the importance of a stepwise introduction into the market of new orthopaedic devices even when based on established concepts. Generic stems may not behave as the original stem upon which it was designed.

Keywords

Cemented stem, generic, hip arthroplasty, implant fracture, revision, stem design

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Introduction

Femoral stem fracture is a well-known but uncommon complication of total hip arthroplasty. The first generation of Charnley-type, stainless steel femoral stems fractured in approximately 4.1% of patients.¹ Failure was mainly caused by the material's low fatigue strength, metallurgical defects, insufficient stem cross-sectional area and poor cement support.^{1–7} Fatigue stress can be caused by unfavourable biomechanics such as varus position, loosening, implant design or surface damage. Further research also revealed causes such as corrosion at the head-neck interface, defects caused by laser etchings, implant malposition or patient morphology.^{8–11} Improvements in stem design

and metallurgy reduced the incidence of this serious complication and it is now a very rare event.^{12–14} Gilg et al.¹⁵ estimated the incidence of stem fractures to be 0.003%, based on annual reports of worldwide registers and clinical studies published in Medline-listed journals.

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Figure 1. Fortress stem, designed by Biotechni (La Ciotat, France).

The Exeter stem is a tapered, polished, cemented stainless steel stem that functions as a taper – slip. It has excellent long-term survival rates.^{13,14} Numerous companies used this concept to design a stem of their own. Biotechni (La Ciotat, France) also introduced their stem, called Fortress, which is discussed in this paper (Figure 1). This study was conducted because of an abnormal failure rate that could not be explained. The aim of this study was to report about this complication and evaluate possible causes.

Materials and methods

This retrospective cohort study reports about all Fortress stems that were implanted in our hospital, University

Table 1. Type of implants used considering neck-shaft angle, stem size and head diameter.

		Number of Patients
Neck-shaft angle (degrees)	135	78
	125	236
Stem size	8	37
	9	84
	10	113
	11	63
	12	9
	13	9
Head diameter (mm)	32	278
	28	33

Hospital Leuven. In total, 315 total hip arthroplasties (THA) were performed in 275 patients between November 2010 and March 2017. The senior author (SG) performed all surgeries using a posterior approach. Third generation cementing technique with optimal pressurisation was used for every stem using Simplex + Tobramycine bone cement (Stryker Orthopaedics, USA). All patient records and radiographs were retrospectively reviewed for any implant-related complications. The cement mantle was graded using the classification of Barrack.¹⁶ Also age, time of surgery, implant sizes and body mass index (BMI) were gathered. Basic statistics (mean values) were obtained through Excel (Microsoft Office).

Demographics

There were 51 male and 224 female patients and the mean age at surgery was 63.5 years. The mean height was 162 cm, the mean weight was 71 kg and as such the mean calculated BMI was 26.8 kg/m². The diagnosis at the time of THA was osteoarthritis in 257 patients, dysplasia in 16, avascular necrosis in 14 and various reasons in 28 patients (stem revision, femoral neck fracture, rheumatoid arthritis, Legg-Calvé-Perthes, juvenile idiopathic arthritis). The left hip was replaced in 143 patients and the right in 172 patients.

Materials

2 different neck-shaft angles (125° and 135°), 6 different implant sizes (size 8–13) and 2 different head sizes (28 mm and 32 mm) were used (Table 1).

Analysis of the retrieved stems

In order to evaluate possible causes of implant fracture multiple tests were conducted by the Catholic University Leuven, Department of Materials Engineering, Belgium. Analysis of the retrieved stems was conducted on multiple levels. The chemical composition and microstructure of the alloy were evaluated by x-ray fluorescence and scanning electron

Figure 2. X-ray shows an AP-view of the pelvis with a stem fracture of the left hip prosthesis at the level of the base of the neck.

microscopy (SEM), respectively. SEM was also used to perform fractographic analysis of the fracture surfaces. The internal structure below the fracture surface was visualised using micrometre resolution computed tomography (μ CT). Finally, mechanical testing through a microindentation hardness measurement was performed. For further details on these measurements, please consult the appendix.

Results

7 patients (2.2%) showed a fracture of the implant at the level of the base of neck (Figure 2). Those fractures occurred on average 59.6 months postoperatively (range 50–81 months). Patients felt a sudden pain with no history of trauma.

Mean follow-up time for all patients was 68.7 months with a 97.8% survival rate of the femoral stem.

All fractures occurred in patients with a high BMI ($>33 \text{ kg/m}^2$ and a mean BMI of 34.6 kg/m^2). The smaller stem sizes (size 8 and 9) typically failed earlier than the bigger stem sizes (size 10). Fractures occurred in 5 stems with a 135° neck-shaft angle and in 2 stems with a 125° neck-shaft angle. A 32-mm head size was used in all 7 patients, 3 different lengths were used (Table 2). Cement grading (Barrack) of the femur showed grade A cement mantle in all stems. There were no signs of radiographic loosening or osteolysis.

Every fractured stem was revised. A cement-in-cement technique was used in 6 patients, performed by the senior author. 1 patient fractured her stem abroad (Los Angeles, USA) and was revised to a cementless, modular revision stem.

The retrieved stems were visually examined and showed a fracture through the base of the neck. All fracture planes propagated almost perpendicularly to the neck axis (Figure 3).

Chemical composition and microstructure of the alloy

The chemical composition of the surgical alloy used for the Fortress hip stems was determined by a WD-XRF measurement on the metallographic cross-sections. Impurities were well below 0.1 wt% each and 0.4 wt% in total for all samples. Overall, this corresponds to the nominal composition for wrought high-nitrogen austenitic stainless steel as specified by ISO 5832-9.¹⁷ Afterwards, the microstructure was imaged by optical microscopy and SEM. The microstructure appeared homogeneous throughout the entire cross-section. Overall, the average grain sizes appeared much smaller than the maximum allowed grain size of $89.8 \mu\text{m}$. No defects or delta ferrite could be observed. This indicates that the microstructure complies with the requirements of ISO 5832-9 for the microstructure of high-nitrogen austenitic stainless steels.¹⁷

Fractographic analysis of the fracture surfaces

Macroscopic examination. Distinct features of fatigue failure could be observed: an initiation zone, a propagation zone and a final rupture zone (Figure 4). The propagation zone, characterised by homogeneous beach marks, extends over the largest part of the fracture surface, whereas the final rupture zone is relatively small. This corresponds to a fatigue failure under low nominal stress in the absence of sudden overload or impactions. The orientation of the beach marks, which is indicative of the propagation of the crack, allowed to trace back the initiation point to the bottom of the introducer inlet (Figure 4).

Microscopic examination. SEM micrographs of the fracture surfaces clearly showed beach marks and numerous parallel striations in the propagation zone, both are characteristic features of fatigue failure and indicate the direction of crack growth (Figure 5).

MicroCT analysis. The μ CT images confirmed the location of the fracture origin, as already observed with SEM, at the level of the inner surface of the introducer inlet, more specifically, the sharp transition between the vertical wall and the flat bottom (Figure 6).

Mechanical testing. The average microhardness was $290 \pm 15 \text{ HV}0.5$. The suffix 0.5 refers to the 0.5 kgf load that was applied for the test. According to ISO 5832-9, wrought high nitrogen stainless steels for surgical implants should have an ultimate tensile strength (UTS) of 740 MPa, which corresponds to a Vickers hardness of $\sim 230 \text{ HV}$. Overall, the material met this requirement.¹⁷

Discussion

Femoral stem fracture is a very rare complication of total hip arthroplasty. We reported on this cohort because of the

Table 2. BMI, time of fracture and type of implants used in 7 fractured stems.

	BMI (kg/m ²)	Time of fracture (months postoperatively)	Stem size	Neck-shaft angle (degrees)	Head diameter and length (mm)
Patient 1	35.0	50	9	135	32+0
Patient 2	35.0	52	8	135	32-4
Patient 3	34.7	52	9	135	32+0
Patient 4	33.5	59	9	125	32+0
Patient 5	34.6	61	9	125	32+4
Patient 6	34.7	81	10	135	32-4
Patient 7	35.0	62	9	135	32+0
Average	34.6	59.6			

BMI, body mass index.

Figure 3. Representative image of the fracture site in a retrieved stem. The arrow indicates the location of the fracture; dashed lines indicate the orientation of the fracture planes with respect to the neck axis.

alarmingly high rate of implant fractures. At an average of 5 years postoperatively, 2.2% of stems had broken at the base of the neck. At 5 years postoperatively, we calculated the fracture risk to be 23% in the group of patients with a BMI over 30 kg/m² and a small stem size (size 8–9). This shows that very small changes to a proven stem design can possibly lead to major consequences. The prevalence of stem fracture in the original Exeter stem is reported to be 0.2% at a minimum of 10 years follow-up.¹⁸

In line with the clinical data, which indicated high similarity in implant size (83% of stems were size 8–9), loading conditions (body weight ~100 kg) and time to failure, the implants show a strong resemblance in failure pattern. All fractures are located in the neck region and are due to fatigue failure. Furthermore, the onset of every fracture was at the level of the introducer inlet, which showed sharp transitions at the bottom of the screw hole or where the walls and the bottom of the oval driving slot come together (Figure 6). According to the laws of engineering, a sharp geometrical transition like this will act as a stress riser, which can initiate fatigue failure. Moreover, the inner surface of the introducer outlet was not polished to a

Figure 4. Pattern of fatigue failure showing the initiation zone (large arrow), the propagation zone (large dashed arrow) and a small final rupture zone (large double arrow). Small arrows showing the homogeneous beach marks in the propagation zone.

smooth surface finish, machining lines could be observed. A rough surface condition can also act as a stress riser initiating fatigue failure.

With respect to the analysis of the base material, the results confirm that the material complies with the requirements with respect to composition and microstructure and hardness of ISO 5832-9 for wrought high-nitrogen austenitic stainless steels,¹⁷ indicating that failure was most probably not due to material imperfections.

Other causes for failure as laser etching on the neck,³ poor cementing technique, implant neck corrosion,^{8,19} the use of elongated femoral heads,²⁰ excessive machining,¹¹ malposition of the implant or fixation problems were not present in this cohort.²¹

Although this implant is no longer available on the market, we believe this study to be clinically important as a significant number of patients with this stem in situ are still at risk for early failure. It is important to publish these poor results caused by faulty engineering in order to prevent similar problems in the future. We have demonstrated that small changes in design can lead to huge consequences. A lot of variations of the Exeter concept proved to be very successful while others failed.^{22,23} Unfortunately, other

Figure 5. Detailed SEM micrographs of the fracture surface representative for the propagation zone. Left image showing beach marks, right image showing striations, both features are indicative of fatigue failure.

Figure 6. μ CT-based 3D visualisation of the lower (distal) fracture surface. The circle indicates the fracture origin.

orthopaedic implants also showed early failures caused by imperfect replicating. An interesting study examined another so called Exeter based stem (OptiStem) and found the design to be different in many aspects (weight, trunnion surface, trunnioncone angle and trunniontip radius) but none of them visible to the naked eye.²⁴ Small changes in design also led to poor results in the resurfacing hip arthroplasty. The Articular Surface Replacement (ASR) has a failure rate of 12.0% at 5 years, compared with 4.3% for the Birmingham Hip Resurfacing (BHR)²⁵ although these differed only very little in the design.

Conclusion

An alarmingly high rate of early implant fractures was reported with this cemented, tapered and polished stem. The main reason for failure is the sharp transitions at the level of the introducer outlet initiating fatigue failure. Furthermore, high body weight and small implant size will accelerate this process. Consequently, more fractures are to be expected in the future since fatigue stress caused by lesser loading (body weight) will only take more time. The use of this implant was stopped at our institution after the second fracture. Meanwhile, the Fortress stem is no longer available on the market. This study underlines the importance of a stepwise introduction into the market, as very small changes to a proven concept can be catastrophic.

Declaration of conflicting interests

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Appendix

Analysis of the chemical composition and microstructure of the alloy

Measurements were performed on metallographic cross-sections taken from the proximal zone of the hip stem below the lower (distal) fracture surface. Cross-sections were prepared as follows: samples were cut using a Secotom-10 sawing machine (Struers), embedded in phenolic resin (XPHB, NX Met) followed by grinding using 800, 1200 and 4000 grit SiC papers (Hermes) and polishing with a 3 µm and 1 µm diamond suspension (3-WM and 1-WM, Kemet) applying an automatic polishing machine (Pressair TF250, Jean Wirtz). Chemical analysis of the material was done by means of x-ray fluorescence (XRF, S8 TIGER 4kW, Bruker). In order to highlight the microstructural features, electrolytic etching was performed in 10% oxalic acid at 7V for 30 seconds. The microstructure was visualised by optical light microscopy (Leica DM ILM) as well as scanning electron microscopy (SEM, Nova NanoSEM 450, FEI).

Fractographic analysis of the fracture surfaces

Specimens including the upper (proximal) and lower (distal) fracture surfaces of the failed hip stems were sectioned by cutting using a Secotom-10 sawing machine (Struers) and were macroscopically examined in pairs. 1 fracture surface of each implant was selected for microscopic examination using SEM.

Visualisation of the internal structure below the fracture surface

1 fracture surface of each implant was selected for 3D visualisation of possible internal defects; image acquisition was performed using micrometre resolution computed tomography (microCT, Nanotom S, GE). The samples were carefully mounted on a holder, and centred and aligned with the rotation axis of the rotation stage. Tomographic projections were acquired for a 180° rotation angle, with a 0.2° rotation step.

X-ray source voltage and current were fixed at 150kV and 220 μ A for all scans. The installed target material consisted of tungsten on chemical vapour deposition (CVD) synthetic diamond. A 2-mm thick Cu filter was applied to filter out the soft part of the X-ray emission spectrum and reduce beam hardening artifacts. The voxel resolution in all scans was (8 μ m)³, which is the smallest possible resolution that can be obtained, while still keeping the entire sample within the field of view of the detector. Datos|x software was used to reconstruct the micro-CT scans and to export cross-sectional images. 3D renderings of the data were made in Avizo and Matlab.

Mechanical testing through a microindentation hardness measurement

Measurements were performed on metallographic cross-sections (prepared as explained above) using a micro-Vickers hardness tester (FV-700, Future Tech) applying a weight of 0.5 kgf. 5 indentations were made parallel to the medial-to-lateral axis of the stem, either in the centre of the cross-section or at the surface starting from the edge with a distance of 0.5 mm in-between, this on the medial as well as lateral side of the cross-section.