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Executive Summary

Publication	**Mechanical failure of 113 uncemented modular revision femoral components.** RISK FACTORS FOR FRACTURE AND FAILURE WITH CASE CONTROL COMPARISON ANALYSIS Krueger DR, Guenther K-P, Deml MC, Perka C. From Center for Musculoskeletal Surgery (CMSC), Charité – Universitätsmedizin Berlin, Germany https://pubmed.ncbi.nlm.nih.gov/32349597/ (Abstract)
Study	There are only case reports and small case series describing mechanical failure of the modular junction in revision stems, but data from large patient cohorts are missing. The aim of this study was to investigate a large database with mechanical failure of a cementless modular revision stem following hip revision as the end point and compare them to a control group treated with the same implant design. Level of Evidence III
Implant	Cementless modular revision stem MRP-TITAN (PETER BREHM GmbH)
Patients	Study group: 113 reported cases (hips) with failed revision stem Control group: n=159 (163 hips), treated in 4 centres specializing in revision hip arthroplasty.
Follow-up	Study group: 113 reported cases with failed revision stem in the period 2008 to 04/2017 Control group: Ø 10 years (range, 5-16)
Methods	The scientists used a large database (PETER BREHM GmbH) containing patient demographic data, time to failure and implant details for all reported cases with failed revision stems.The length, diameter and implant type (straight or curved) of the distal component were recorded. The diameter, size and material of the ball head (same or different manufacturer) and the proportion of off-label use were documented. The size (S, M, L) and type (standard or lateralized) of the neck segment and the use of an extension sleeve were analysed. Data on the presence of periprosthetic infection, femoral bone defects and the use of an extended femoral osteotomy during restoration were not available. The manufacturer´s failure analysis of the fractured implants in 76 cases was included in the study. In 37 cases, the implant was not available to the manufacturer for investigation.The implants were checked for signs of improper use during implantation. Together with the implant information and operating reports, improper use was defined as a) macroscopically visible contamination (blood, fluid, tissue) in the area of the modular taper junction, b) off-label use of an extra-long ball head (≥ XL) or a modular ball head from another manufacturer, and c) missing contact marks (TiN) in the area of the head support of the "M6 screw" locking screw (insufficient locking of the taper junction). 113 cases with fractured modular MRP-TITAN components were identified in the time period between 2008 and April 2017. The number of 37,600 MRP-TITAN revision stems sold during this time period was used to calculate the fracture rate. Surgical, patient and implant-related risk factors were evaluated using a regression analysis with multiple imputation procedure and compared to a control group, where no implant fractures had been observed.

	The results of retrieval analysis of the fractured implants, which had been performed by the manufacturer, were available for analysis. The patient-related data (age, sex, height, weight, BMI) were analysed for statistical significance between the two groups (*Mann-Whitney-U-Test*). Furthermore, the size and type of implants in the control group and study group were compared. The statistical analysis was performed using IBM SPSS statistical software (IBM Corp.). The implant-related data (type, size, diameter, offset) were analysed.
Results	Between 2008 and April 2017, 113 cases of fractured revision stems were reported. Defect reconstruction in complex hip revision cases often requires the use of modular stems under suboptimal conditions. The authors emphasize that **considering the complexity of hip revision cases, the determined fracture rate of 0.3% is very low**. **The fracture rate of the implant without the cases with signs of improper use during implantation is only 0.11%.** The results of the study show that implant failure due to a modular component fracture is influenced by **surgical, implant-related and patient-related risk factors**. Demographic variables showed significant differences in sex ($p < 0.001$), height, weight and BMI ($p < 0.001$) between the study group and control group. No statistically significant difference was found in the age of the patients ($p = 0.060$). There was no implant fracture in the control group. In the study goup the patients with an implant fracture were predominantly male (76%; $p < 0.001$) and had a significantly higher BMI compared to the control group. Data on activity levels were not available. Complete radiological documentation was not available, so no statements can be made about the bone quality in patients with a fractured revision stem. In the study group 38% (43/113) of the femoral components were curved, compared to the control group with 60% (98/163). Extension sleeves were used in 35% (40/113) of cases in the study group and in 17% (28/163) of cases in the control group. Lateralized neck segments were used in 66% (75/113) of the cases. Unfortunately, data on the use of lateralized neck segments were not available in the control group. More neck segments of size S (56%, [63/113]) were used in the study group than in the control group (44%, [72/163]). The use of the **curved stem design** ($p<0.001$), **neck segments of the size M** ($p=0.028$) **or the size L** ($p=0.018$) were **protective variables against component fracture.** In all cases, the component fracture was located at the modular taper junction or at the taper of the extension sleeve. Examination of the implants (76/113) for failure modes revealed signs of corrosion at the taper in 11 cases. Signs of **improper use of the implant** during implantation were found in 72 cases. In 6 cases taper contamination (blood, bone or tissue) was macroscopically visible. In 39 cases an extra-long head ≥XL or a ball head from another company ("off-label") was used. The authors point out that **about one third of the implant fractures were associated with errors in the surgical technique that could have been avoided.** In 42 cases, lack of titanium abrasion (TiN coating) on the safety screw "screw M6" indicate insufficient tightening of the screw M6 with the required torque during implantation (insufficient securing of the taper junction). The authors point out that a secure taper junction is achieved by using a specific instrument (TOV) as part of the surgical technique recommended by the manufacturer.

	In 89 cases (79%) with a fractured implant, either a lateralized neck segment, an extra- long head, or a combination of both was used. The authors found a lower percentage of curved components in patients with implant failure (38%, [43/113]). The surgical approach used possibly has an influence.
Key Points	Regarding the fracture rate of modular stems and monobloc stems in hip revision, only limited data (small case series, case reports) are available in the literature. **„Compared to these published fracture rates, the 0.3% fracture rate in this study is at the lower end of this range in this complex patient population.“ The fracture rate of the MRP-TITAN revision stem without the cases with signs of improper use during implantation is only 0.11%.** According to the authors, lateralized neck segments and extra-long heads should be used with caution, especially in overweight patients. Whenever possible, the use of short and lateralized prosthetic neck segments should be avoided when using the MRP-TITAN revision stem. The manufacturer's implantation instructions and contraindications for the implant use must be considered. **Patients should be advised** about patient- and implant-specific risk factors, especially patients with increased risk factors (f.e. obese patients). Some authors in the literature suggest the use of non-modular revision implants. In contrast, the authors of this study emphasize that the reconstruction of defects and adequate restoration of biomechanical parameters as well as intraoperative adaptation to the anatomical situation, especially for complex and challenging revisions under suboptimal conditions, make the use of modular revision systems indispensable.
Abbreviations	BMI - Body Mass Index, TiN – titanium nitride, TOV – Torsionfree Preloading Instrument