■ HIP

Analysis of modular taper fractures of the revision hip stem Prevision and comparison of the original and current taper design

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Aims

The risk of mechanical failure of modular revision hip stems is frequently mentioned in the literature, but little is currently known about the actual clinical failure rates of this type of prosthesis. The current retrospective long-term analysis examines the distal and modular failure patterns of the Prevision hip stem from 18 years of clinical use. A design improvement of the modular taper was introduced in 2008, and the data could also be used to compare the original and the current design of the modular connection.

Methods

We performed an analysis of the Prevision modular hip stem using the manufacturer's vigilance database and investigated different mechanical failure patterns of the hip stem from January 2004 to December 2022.

Results

Two mechanical failure patterns were identified: fractures in the area of the distal fluted profile (distal stem fracture) and failure of the modular taper (modular fracture). A failure rate of 0.07% was observed for distal stem fracture, and modular fracture rates of 1.74% for the original and 0.013% for the current taper design.

Conclusion

A low risk of mechanical failure for both fracture types was observed compared to other known complications in revision hip arthroplasty. In addition, the data show that a design change did significantly reduce the risk of a modular fracture.

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Introduction

According to an analysis of revision total hip arthroplasty (THA) in the Australian Joint Replacement Registry, the most common reasons for re-revision are instability (33%), loosening (24%), infection (23%), and periprosthetic fracture (10%).[1] These are the challenges that need to be addressed in revision THA, and one of the tools to overcome them are tapered, fluted, modular cementless revision stems. Stem modularity with different proximal designs, and straight or curved distal components of varying length, allows adjustment for variation in bone defects and femoral anatomy. Both modular and non-modular tapered cementless revision stems generally show satisfactory results.[2-6] Currently, there is no evidence for the superiority of either design, and there are no scientifically based indications for choosing between modular and non-modular prostheses. In a systematic review comparing monobloc and modular revision hip stems, similar re-revision rates, dislocation rates, periprosthetic fracture rates, and infection rates were observed.[7] Significant differences were only detected in rates of subsidence and rates of intraoperative fracture. The authors, however, remarked that this may be influenced by selection bias, with more patients with a higher degree of bone loss potentially included in the studies on modular stems. The comparison of the outcome of different revision stem designs in the literature is also limited due to variations in implant designs, indications, and patient cohorts.[6]

An important aspect of modular hip stems is the biomechanical safety of the modular connection.[8,9] Particularly in the absence of proximal

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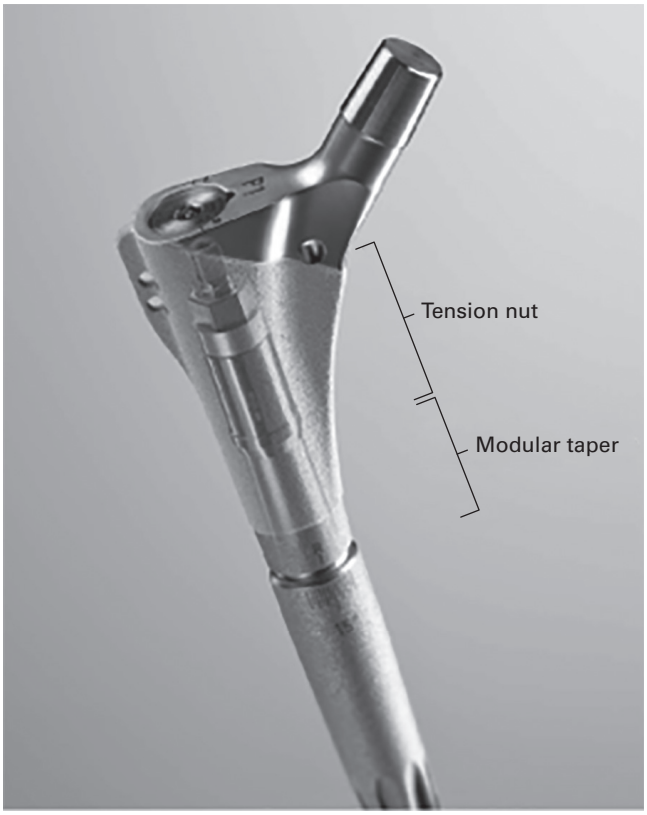

Fig. 1

Design of the modular connection, with two-piece tension nut and modular taper.

Fig. 2

Comparison of the original (left) and current (right) design of the modular taper of the distal implant. After the shot-blasting process for surface hardening, the polished taper has a matte surface. Via the thread, the tension nut can apply tensional forces on the modular connection.

bone support, the connection between the proximal and distal components has to carry the entire load from the hip joint to the distal femur.[10] Unacceptably high fracture rates have been reported, especially with early generations of modular stems.[11] Biomechanical design improvements of current stems have included elements such as larger-diameter tapers and higher assembly forces.[9] However, authors who generally recommend the use of modular hip stems also continue to point out the potential risk of fretting, wear, corrosion, and ultimately fracture of the modular taper connection.[4,11-13]

To date, little is known about the mechanical failure rates of current modular revision hip stems. A recent review of the literature concluded that the majority of stem fractures following revision THA (54 of 77 published failure cases) were associated with modular revision hip stems.[14] In a review of 3,450 revision THA cases, only 0.5% were related to modular taper fracture.[15] A systematic meta-analysis which included 3,728 modular and 863 non-modular revision hip stem implantations observed six reported cases of hip stem fracture in the modular group, and none in the non-modular group, resulting in a fracture rate of 0.16%.[7] In a single-implant design series, a modular fracture rate of 0.33% in 37,600 implantations was reported,[16] and for another implant design, a 0.66% mechanical failure rate in 4,834 implantations was observed.[17] In the latter study, the implant failures were, according to the authors, "nearly always" modular fractures, but distal stem failures may also be included. Another analysis of 24 modular fractures of revision stems showed a typical failure pattern of an osseointegrated distal component in combination with a lack of medial bone support of the proximal component.[18] General risk factors for modular fracture include lack of proximal bone support, extra-long heads, high body weight, young and active patients, and lateralized or shorter neck segments.[10] Herold et al,[17] in their analysis of 32 clinical cases of modular revision stem failure, suggested that short proximal components should be avoided, with the component junction placed as distal as possible to minimize the risk of failure. This is also in agreement with findings from biomechanical analyses.[10]

Prevision (B. Braun Aesculap, Germany) is a cementless, modular hip stem with proximal and distal components made of titanium alloy. The distal fluted components are available in straight and curved versions in different stem diameters (12 mm to 24 mm) and lengths (200 mm to 400 mm). The proximal components offer three different heights (90 mm to 110 mm) and three different sizes (P1 to P3). The modular connection uses a taper fixation with free rotational positioning, and a two-piece tension nut to secure the taper fixation and decouple the clamping forces (Figure 1).

Table I. Patient and implant characteristics of 26 modular fracture cases in consecutive order. In case of unavailable information, the fields were left blank. Because straight stems were not marketed at time of the original taper design, all fractures with the original taper design involved curved distal components.

n	Sex	Weight, kg	BMI, kg/m²	Time to failure, mths	Proximal component size	Distal component size	Head size, mm	Head length
1	F	140	38.8	23.0	P1 + 0	12 × 280 curved	32	S
2	M	87	26.6	27.1	P3 + 20	18 × 400 curved	32	XXL
3	F	90	33.0	7.9	P2 + 0	12 × 280 curved	36	S
4	M	72	28.1	8.1	P1 + 0	14 × 280 curved	28	S
5	F	68	25.0	26.4	P1 + 0	14 × 360 curved	28	L
6	M	89	27.7	13.7	P1 + 20	18 × 320 curved	28	L
7	M	92	29.0	14.3	P1 + 20	16 × 360 curved	28	XL
8	M	85	26.8	34.5	P3 + 0	18 × 400 curved	28	M
9	M	104	34.4	15.6	P1 + 10	16 × 320 curved	28	S
10	M	96	26.0	13.6	P3 + 10	20 × 400 curved	32	L
11	M	88	28.4	10.3	P3 + 10	20 × 320 curved	28	M
12	F	92	31.8	13.1	P1 + 0	14 × 280 curved	32	L
13	M	91	30.8	15.9	P2 + 0	18 × 280 curved	28	M
14	M	95	29.3	22.2	P1 + 0	12 × 240 curved	32	L
15	M			60.7	P1 + 20	20 × 280 curved	32	L
16	M			24.5	P3 + 0	18 × 280 curved	28	L
17	F	62	24.2	44.1	P2 + 0	16 × 280 curved	32	S
18	M			78.0	P2 + 0	16 × 400 curved		
19	F	104	34.0	90.7	P1 + 0	18 × 280 curved	28	L
20	M	110	34.7	53.9	P3 + 0	14 × 280 curved	32	M
21	M	87	25.1	76.9	P1 + 0	14 × 280 curved	36	XL
22	F	130	43.9	78.5	P1 + 0	16 × 280 curved	28	M
23	M			84.7	P1 + 0	14 × 240 curved		
24*	M			47.3	P3 + 20	24 × 240 straight	36	XL
25	F	110	40.9	95.8	P1 + 0	16 × 320 curved	32	M
26*	M			73.9	P2 + 0	12 × 280 straight	32	M
Mean (SD)	30.8% F	95 (18.2)	30.9 (5.4)	40.6 (29.0)	P1: 53.8% P2: 19.2% P3: 26.9% + 0: 69.2% + 10: 11.5% + 20: 19.2%	N/A	28: 45.8% 32: 41.7% 36: 12.5%	S: 20.8% M: 29.2% L: 33.3% XL: 12.5% XXL: 4.2%

*Patients implanted with the current design.
N/A, not applicable; SD, standard deviation.

The implant was launched in 2004. The first reports of fracture of the modular connection due to fatigue of the distal component taper were received in 2007. The design of the taper connection was subsequently improved and launched in the summer of 2008. This was achieved by an additional shot-blasting process of the distal component taper surface (Figure 2). This process causes a plastic deformation of the surface and generates large residual compressive stresses under the surface, resulting in an increase in fatigue strength.[19] At this stage of development, screening tests with increasing load levels until failure had shown that these design changes resulted in up to 25% higher fatigue strength of the modular connection compared to the previous implant design.

The current retrospective long-term analysis examines the distal and modular failure patterns of the Prevision hip stem from 18 years of clinical use and compares the mechanical safety of the original and current design of the modular connection.

Methods

In the European Union and most other countries, healthcare professionals are required to report any incident occurring with implants or other medical devices to the manufacturer. To analyze the occurrence of hip stem failures, all reports from the manufacturer's vigilance database in the period between 2004 and 2022 were analyzed and compared with the number of implantations in the same time frame. The current version of the modular taper was introduced in 2008. Straight conical distal components in addition to the curved components were launched in 2010 with the same modular taper design.

Intraoperatively occurring incidents (e.g. problems with assembly or disassembly of the implants) were excluded from the analysis. Modular connection failures were compared to other mechanical failure modes (i.e. distal stem fracture). The analysis was based on anonymized patient data from the manufacturer's vigilance database, and therefore ethical approval and patient consent were not necessary.

Statistical analysis. Descriptive statistics were used for patient and implant characteristics of mechanical failure cases (percentage, or mean with standard deviation (SD)). Median and range were used for time to failure. Failure rates were calculated based on the number of total implantations, or when

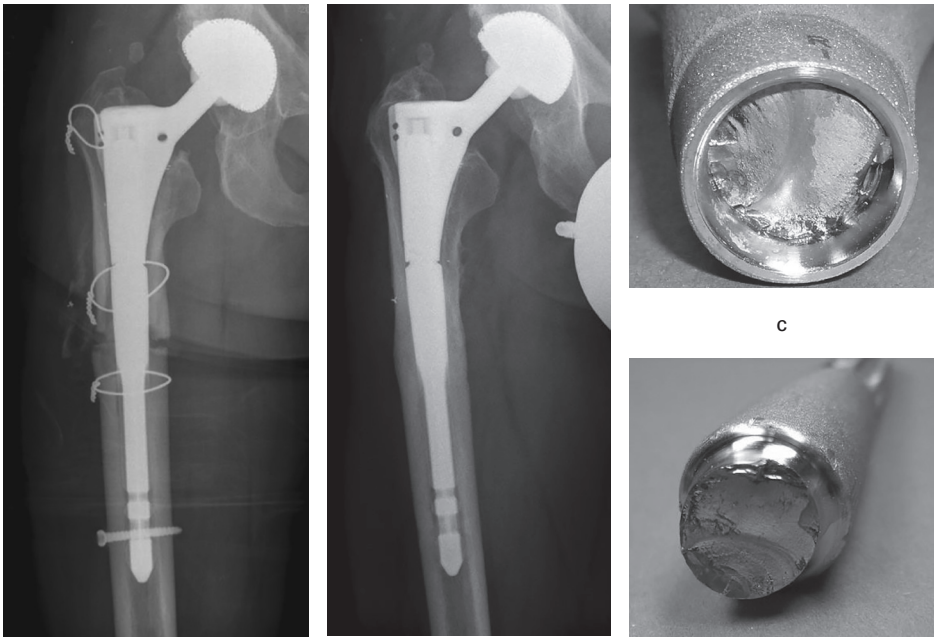

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Fig. 3

a) Anteroposterior radiograph of Patient #23 (male, aged 60 years) after implantation of a Prevision hip stem 240 mm curved (original taper design). b) Radiograph of the fractured hip stem after seven years. c) Proximal and d) distal fracture surfaces of the modular taper. Images of fracture surfaces reprinted with kind permission from Michael Morlock.

indicated, based on the number of implantations of specific implant sizes only.

Results

During the period analyzed, there were 1,378 implantations of the Prevision hip stem with the original taper design and 15,188 implantations with the current modular taper design. A total of 31 reports of postoperative mechanical failure were received. Of these, five were failures in the area of the distal fluted profile (distal stem fractures) and 26 were modular fractures, which included fractures of both the original and the new taper design of the distal component. No cases of mechanical fracture of the proximal component were reported to the manufacturer.

Distal stem fractures. In the five cases of distal stem failure, fractures occurred in stem lengths between 200 mm and 360 mm. Therefore, no relationship to the stem length was observed. The median time to failure was ten months (range, 3 months to 7.3 years). Fractures occurred in 12 mm and 14 mm hip stems only, and four of the five cases were observed with curved hip stems. No fracture was observed in stem diameters 16 mm to 24 mm. Based on the reported cases, and considering only the number of 12 mm and 14 mm curved stems implantations, the mechanical fracture rate for distal stem fractures of these biomechanically worst-case stems is calculated to be 0.07%.

Modular fractures. Of the total 26 cases of modular fracture, 24 were associated with the original taper design manufactured until 2008, and two with the current design. This results in a modular fracture rate of 1.74% for the original and 0.013% for the current taper design. Lot numbers of the fractured implant components were available in all cases except one, where the taper version was derived from the date of implantation. The analysis was based on retrieved implants, pre- and postoperative radiographs, and clinical background, depending on the available information in each case. A total of 19 implants were retrieved and could be analyzed by the manufacturer. Baseline data on patients and implant components are shown in Table I. A traumatic event was reported in only two cases, both of which were a fall on the stairs. Nonetheless, in both cases the analysis of the failure pattern showed clear evidence of a fatigue fracture. All other modular fractures provided no such information, but based on their clinical presentation and analysis of the failure pattern, they could also be classified as fatigue fractures.

A total of 30.8% of patients were female (n = 8), and patients' mean BMI was 30.9 kg/m^2 (SD 5.4). This differs markedly from the figures available for revision surgery from the German arthroplasty registry (EPRD), which show that, at least in Germany, Prevision patients have a mean BMI of 27.0 kg/m^2 (95% confidence interval (CI) 23.9 to 30.5) and 60.1% are female.[20]

The clinical presentation of the modular fracture cases showed that the distal components were typically very well osseointegrated, with little or no bone support for the proximal components. There was no concentration in individual hospitals and no relationship to individual component sizes or production batches. The assembly technique (extra- or intraosseous assembly of the modular components) was not systematically recorded at the time of the documentation and therefore could not be analyzed.

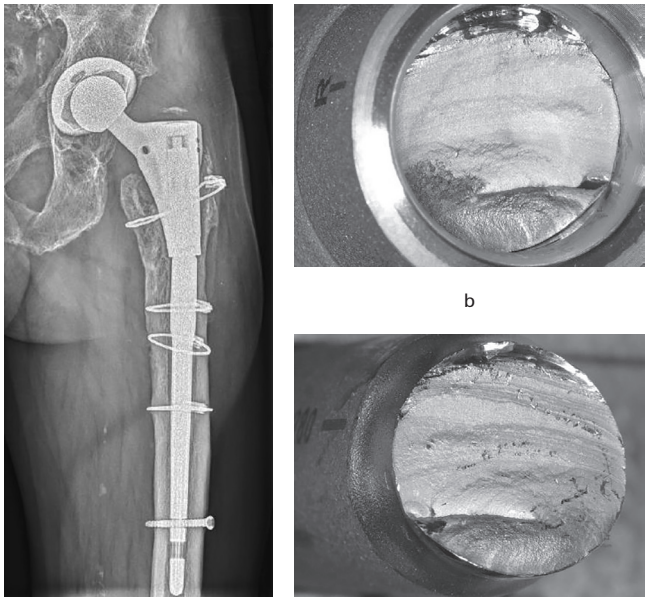

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Fig. 4

a) Anteroposterior radiograph of Patient #26 (male, aged 61 years at time of radiograph) after fracture of a Prevision hip stem straight 280 mm six years after implantation. b) Proximal and c) distal facture surfaces of the modular taper. Radiographs of the patient before failure were not available from the reporting clinic.

The median time to failure of all 26 reported cases of modular fracture was 26.7 months after implantation (mean 41 months (8 to 96)). The fractures occurred in all distal component diameters from 14 mm to 20 mm and therefore no correlation with stem diameter was observed (Table I). Straight stems were only launched in 2010, and both fractures of the current taper design were with straight stems. Modular fractures occurred in curved stems with a length between 280 mm and 400 mm, and based on implantation numbers, no correlation between stem length and risk of modular fracture was observed. However, the numbers are too small for statistical calculations.

Proximal components are available with height options of +0 mm, +10 mm, and +20 mm, which corresponds to a proximal component height of 90 to 110 mm (bottom to head centre). In addition, there are three sizes P1 to P3 with different diameters and offset. Most modular fractures (10 out of 26) were observed with proximal components of size P1 +0 mm (90 mm component height), which is also the most frequently used proximal component. The frequency of modular fracture cases for proximal components with a height of +0 mm of 69.2% (18 of 26 cases), and for size P1 proximal components of 53.8% (14 of 26 cases), roughly matches their overall frequency of use (70.8% and 76.4%, respectively) in all recorded revisions with the Prevision stem.

Two clinical cases of modular fracture of the original and current taper design are described below. Figure 3 shows a clinical case of a fractured Prevision hip stem with the original taper design. The hip stem was implanted through a transfemoral approach after periprosthetic fracture of a primary THA. Cerclage wires and distal locking screws were removed after successful osteotomy healing. After seven years, the hip stem fractured at the modular junction. Radiographs showed femoral hypertrophy at the sub-proximal hip stem and lack of proximal bone support with visible radiolucent lines. The fractured modular taper was consolidated with the proximal component and could not be non-destructively disassembled. The fracture pattern of the implant component showed typical signs of a fatigue fracture. The crack initiation starts on the lateral side, with the ongoing striation marks ending in a sudden fracture.

Figure 4 shows a clinical case of a fractured Prevision hip stem with the current taper design. After six years and two months, the hip stem fractured at the modular junction. The radiographs showed large trochanteric bone defects and lack of proximal bone support. Similar to the previous case, the fracture pattern of the implant component showed evidence of a fatigue fracture, with crack initiation on the lateral side of the implant.

Discussion

The modular connection of modular hip stems is subject to high stresses and has been frequently discussed in the literature as a potential source of mechanical failure.[4,9,11,13] However, recent analyses have shown satisfactory low failure rates of modular hip stems.[17,18] The aim of this analysis was to determine the clinical presentation and frequency of mechanical failure of the Prevision hip stem recorded in the manufacturer's vigilance database after more than 18 years of clinical experience, and in particular after a design change of the taper in 2008. Postoperative failures were divided into distal stem fractures, which could also occur in monobloc revision hip stems, and modular fractures.

Based on the data presented, curved, small-diameter distal components appear to be a risk factor for distal stem fracture of the Prevision hip stem, but still with a low fracture rate of 0.07% for 12 mm and 14 mm distal components. These findings are in agreement with biomechanical estimates that curved stems with a small cross-section and increased lever arm have the lowest fatigue strength. However, these conclusions are based on a small number of clinical failure cases and lack any statistical basis.

While such rates of mechanical fracture would be unacceptably high for primary hip stems, these numbers can be considered acceptable in the context of the bone defects that require treatment with this type of implant. For comparison, data from the German EPRD orthopaedic registry show an overall re-revision rate of 9.7% (95% CI 9.4 to 10.1%) for aseptic elective THA revision procedures within the first year.[20]

The present analysis shows that the risk of modular fracture with the current Prevision taper design is even lower, with an observed rate of 0.013%. There were only two cases of modular fracture in 14 years compared to 24 cases (1.74%) with the previous design, which clearly demonstrates that the modular taper improvements were effective in reducing this complication. This represents a reduction of two orders of magnitude in the risk of modular fracture. All fractures were due to fatigue of the distal component taper. There were no cases of failure of the modular taper by other patterns such as modular taper

loosening or taper corrosion.[21] In the analysis, no correlation was observed to distal stem length or diameter, or to proximal component size.

The mean time to failure of the described 26 modular fracture cases was 41 months after implantation (8 to 96), which is comparable to reports of 48 months (2 to 117) from 113 modular fractures of the MRP-TITAN hip stem (Peter Brehm, Germany),[16] or 5.5 years from 32 modular fractures of the Revitan stem (Zimmer Biomet, Switzerland).[17]

The conclusion that hardening the taper of a modular hip stem helps to reduce the risk of modular fracture is also consistent with results by Lombardi et al.[22] In 2007, the group reported that a similar change in the manufacturing process resulted in a 3.5-fold increase in taper strength. Later, a case series of 40 patients with the early design and 162 patients with the hardened taper design was published, showing a decrease in the rate of modular fracture from 15.8% to 4.5% at ten years,[23] although this may still be considered an unacceptably high failure rate for a modern hip stem.

Another factor that may also contribute to the biomechanical safety of the Prevision stem is the comparatively large proximal component, with a height of at least 90 mm. Based on analytical 3D modelling, Huber et al[10] stated that the optimal neck segment height should be between 70 mm and 90 mm to avoid high stress in the modular connection. The suggestion to avoid short proximal components is also consistent with the analysis of clinical stem failures by Herold et al,[17] who observed a significantly lower risk of implant fracture with longer proximal components (i.e. 75 mm to 105 mm), and with recommendations by Fink,[18] who suggested that a modular connection should be positioned as distally as possible.

In addition to implant design aspects, it should be considered that revision stems lacking medial proximal bone support generally are at higher risk for failure.[7,10,17,18] Modular failure due to contaminated taper surfaces has also been described,[24] as well as problems relating to non-adherence to the manufacturer's surgical technique for implantation and assembly.[16] Finally, patient-specific factors such as activity or body weight certainly play an important role.[10] The relevance of such factors is supported in the present analysis by the observation of a tendency to both slightly higher BMI values and a higher proportion of male patients in the cohort with implant fracture compared to the overall patient population.

The main limitation of this analysis is that additional implant failures may have occurred but were not reported to the manufacturer, despite the clinical users' legal obligation to do so. In addition, implant fractures may remain undetected due to the relatively asymptomatic clinical presentation, as has previously been reported in the context of modular fractures.[11] This is also consistent with some of the analyzed cases in this series where modular fractures of hip stems were only detected at routine follow-up.

An open discussion of risks, implant-related complications, and especially mechanical failure modes, is important so that surgeons can weigh the risks and benefits of different implant designs, especially in complex cases and in patients with poor bone stock. Attention has already been drawn to mechanical failures of modular revision hip stems in the literature,[16,17,25,26] and should continue to be the focus of further research to more clearly define optimal surgical decision-making, and most importantly to improve clinical outcomes for the patients.

Based on this knowledge, surgeons must decide on an individual patient basis whether an intraoperative selection of component sizes, an intraosseous assembly and stepwise achievement of the surgery goals, and a free adjustment of anteversion are required, and whether the clearly technically challenging use of a modular revision stem is indicated.

In conclusion, the modern design of the Prevision modular revision hip stem is associated with a significantly lower risk of mechanical failure compared to other complications generally associated with revision hip arthroplasty. Based on this analysis of distal and modular fractures, surgical decision-making for individual patients between modular and monobloc revision hip stems should not be primarily focused on aspects of mechanical implant stability.

Take home message

- An analysis of the manufacturer's vigilance database found a modular fracture rate of 0.013% for the Prevision hip stem with the current modular taper design.
- A modular taper design change in 2008 could reduce the risk of modular fracture by two orders of magnitude.
- Based on a small number of fractures, curved distal components of 12 mm and 14 mm diameter appear to be the biomechanical worst case for distal stem fracture with a fracture rate of 0.07%.

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M. Wagner: Writing – review & editing.

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