Implant Breakage Risk for Modular Fluted Tapered Stems in Revision Total Hip Arthroplasty at 5-Year Follow-Up

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Research article

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Abstract

Background: Modular stems in revision total hip arthroplasties allow diaphyseal fixation and optimal restoration of the architecture of the proximal femur. Several studies report metaphyseal implant breakage in the mid- to long-term and therefore a huge impact on survivorship. We aimed to evaluate a specific design of uncemented modular fluted tapered stems (MFT) to analyze survivorship and clinical and radiological outcomes.

Methods: In a retrospective study, we identified 99 patients who had surgery using the same design of MFT implant between 2012 and 2014. Patients were mainly male in 53% and mean age was 73 years. Indications were 33 aseptic loosening, 24 periprosthetic fractures, 23 periprosthetic joint infection, 1 instability and 18 were complex primary arthroplasties. Survivorship, complications and clinical outcomes, were assessed. Mean follow-up was 5 years.

Results: There was no implant breakage. At 5-year follow-up, the survivorship free of revision for aseptic loosening and free of revision for any reason of the femoral stem were 100% and 99%, respectively. At last follow-up, they were 94% and 81%, respectively. Six implants were revised. A mean stem subsidence of 6 mm was noted in 9 cases; 1 was revised for aseptic loosening. The Harris hip score was 89. The risk of revision was significantly higher for shorter diaphyseal implants ($p=0.026$).

Conclusion: At mid-term follow-up of 5 years, the MFT studied reported an excellent survivorship and clinical outcomes with no specific complications. Unlike literature reports, no specific complications occurred with this design. Satisfying clinical outcomes and limited subsidence are consistent with previous reports though.

Level of evidence: IV – Case series

Introduction

The popularity of modular fluted tapered femoral stems (MFT stems) is growing due to the adaptation of these implants and the increased incidence of revision total hip arthroplasty (THA) [1-3]. These uncemented prostheses provide effective and stable diaphyseal press-fit fixation on all planes, even for major metaphyseal substance losses [4–6]. TMFTs are mainly used for revision arthroplasty for septic [7] or aseptic [8] unsealing or following a periprosthetic fracture [9–11]. They are used to a lesser extent for damage control surgeries after failed osteosynthesis of fractures of the upper extremity of the femur [12], on a metastatic localization or primary tumor of the femur. The modularity of these stems is an asset for optimal restoration of the architecture of the proximal femur, the offset, anteversion, length and overall stability of the arthroplasty.

Several authors report implant fractures at the stem-metaphyseal seal junction that impact the survival of these prostheses and lead to avoidable complications for the patient. The incidence of implant fractures is variable, ranging from 1 implant out of more than 500 aseptic revisions [8] to 30% of implants in 15

years [13]. By biomechanical and chemical analysis of 3 ZMR (Zimmer, Warsaw, Indiana) implant fractures, Lakstein et al [14] underscore a mechanism of micro-friction between prosthetic parts that are not perfectly unified, leading to wear and then fracture of the Morse taper. These findings were supported by Van Houwelingen et al [6] who report 18.5% fractures in 10 years for the standard ZMR implant. Similarly, in a study on the PFMR stem (Protek, Sulzer Orthopedics, Switzerland), Dumoulin et al [13] focus on two types of implant fracture related to the conception and design of the implant: disassembly of the Morse taper from the diaphyseal part due to a mismatch in the dimensions of the two parts, and disassembly of the Morse taper from the metaphyseal part due to intraoperative assembly difficulties.

Our main hypothesis was that implant fracture and therefore survival of MFT revision stems depends on the type of implant. Our secondary hypothesis was that the modularity of MFT revision stems alone did not increase the risk of implant fracture.

The objective of this study was to analyze the survival, clinical and radiographic outcomes and medium-term complications of an uncemented modular fluted tapered revision stem.

Materials And Methods

By prospective collection of clinical data, we identified patients in our institutional registry who benefited from THA with a specific modular fluted tapered stem (Modular Revision Stem [MRS]®, Mathys). All patients who received this MFT implant between 2012 and 2014 were included in a monocentric study. Both prosthetic revisions and primary prostheses were included.

Ninety-nine patients met the inclusion criteria. The procedure was hip replacement for 81 patients (82%). The indication for surgery was periprosthetic joint infection (PJI) in 23 cases (23%), aseptic loosening in 33 cases (34%), periprosthetic fracture in 24 cases (24%) and 1 case of instability (1%). The procedure was primary arthroplasty for 18 patients (18%). The indication for surgery was osteosynthesis revision following a fracture of the upper extremity of the femur in 8 cases (8%), fracture of the upper extremity of the femur without osteosynthesis in 4 cases (4%), tumor in 4 cases (4%), 1 case of osteonecrosis (1%) and 1 case of dysplasia with a history of childhood cervical osteotomy (1%) (Table 1).

Table 1
Indications for surgery

Hip replacement (no. [%])	81 (81,8%)
Periprosthetic joint infection	23 (23,2%)
Aseptic loosening	33 (33,4%)
Periprosthetic fracture	24 (24,2%)
Instability	1 (1%)
Primary arthroplasty (no. [%])	18 (18,2%)
Fracture of the upper extremity of the femur without osteosynthesis	4 (4,05%)
Osteosynthesis revision	8 (8,1%)
Tumor	4 (4,05%)
Osteonecrosis	1 (1%)
Dysplasia with osteotomy	1 (1%)
Total (no. [%])	99 (100%)

The interventions were performed by high-volume surgeons. The minimum follow-up was 2 years.

Of the 99 patients, 3 died during early postoperative hospitalization and were excluded from the analysis of clinical scores. Deaths were due to a complicated occlusive inhalation syndrome, acute pulmonary edema and respiratory distress with cardiac arrest on extubation. At the last follow-up, 2 patients had dropped out and were excluded from the analysis. During the follow-up, 28 patients died (including 3 postoperative deaths).

The mean age at the time of surgery was 73 years (range: 34 - 99 years), 53.5% of the patients were female. The average body mass index was 26 kg/m² (range: 14 - 38 kg/m²) (Table 2). Mean follow-up was 5 years (range: 2 - 7 years).

Table 2
Demographic and operative factors

Hips (no.)	99
Age at surgery (yr)	
Mean	73
Range	34 - 99
Sex (no. [%])	
Femme	53 (53,5%)
Homme	46 (46,5%)
BMI (kg/m2)	
Mean	26
Range	14 - 38
Stem diameter (mm. [%])	
14	15 (15.2%)
16	38 (38.4%)
18	29 (29.3%)
20	13 (13.1%)
22	3 (3.0%)
24	1 (1.0%)
Stem length (mm. [%])	
140	55 (55,6%)
200	44 (44,4%)
Standard metaphyseal base (no. [%])	72 (72,7%)
50	14 (14,1%)
60	25 (25,3%)
70	8 (8,1%)
80	12 (12,1%)
90	7 (7,1%)
100	3 (3%)
110	3 (3%)

Lateralized metaphyseal base (no. [%])	27 (27,3%)
50	6 (6,1%)
60	7 (7,1%)
70	3 (3%)
80	7 (7,1%)
90	2 (2%)
100	1 (1%)
110	1 (1%)

All procedures were performed with posterolateral approach. Femoral bone grafting was required in 7 cases (7%), autograft in 3 cases (3%), allograft in 2 cases (2%) and synthetic bone graft in 2 cases (2%). The diaphyseal implant measured 140 mm in 55 cases (56%) and 200 mm in 44 cases (44%). In the revisions, femoral stem change was associated with a change in the acetabular implant in 49 cases (60%) and the femoral head implant in 78 cases (96%). The implant used allows diaphyseal press-fitting. The metaphyseal base was variable in length with 2 offsets (standard 135° CCD and lateralized 131°) chosen by the surgeon according to preoperative planning. The metaphyseal base was locked to the femoral stem by a locking screw inserted through the metaphysis. The size of the base allowed restoration of the joint space and the center of rotation (Table 2). The Harris Hip Score [15] was used for the clinical assessment. A radiological study was carried out for all patients in a minimum follow-up period of 2 years. Preoperative bone loss was classified according to the Paprosky method [16]. These were Type I in 10%, Type II in 42%, Type IIIa in 32%, Type IIIB in 13% and Type IV in 3%. Clear lines at the prosthesis-bone interface, as well as the bone resorption according to the 7 Gruen zones were examined on the frontal radiography [17,18]. Subsidence was measured by the difference in distance between a fixed point on the femoral implant and a fixed point on the femur. It was considered significant if a difference greater than or equal to 3mm was found between the postoperative radiography and the follow-up radiographies. Subsidence was considered to be early if it occurred within one year after surgery, and late if it occurred after that time. The reference points on the prosthesis were the shoulder and the metaphyseal-stem junction and the reference points on the femur were cerclage or the middle of the lesser trochanter [19].

The primary endpoint was implant survival free of revision for any reason (including isolated metaphyseal implant change) as well free of revision for aseptic loosening.

The secondary endpoints were clinical outcome as illustrated by the HHS score, complications and radiographic analysis.

Statistical analysis

A Survival Analysis (by means of Kaplan Meier product limit estimation) was carried out based on the follow-up time and the revision. Confidence intervals were calculated using the log-log transformation. Descriptive statistics included mean, median, standard deviation 25% & 75% percentiles and ranges. Between-group differences were compared using non-parametric tests: Wilcoxon 2- Sample Test and in case of more than two groups, the Kruskal Wallis Test.

All statistical analyses were performed with SAS version 9.4 (SAS Institute Inc., Cary, NC, USA).

Results

There were no implant fractures over an average follow-up period of 5 years.

At the last follow-up there were 6 femoral stem revisions (6%) due to: 2 cases of aseptic loosening, 2 PJIs (including 1 recurrence which benefited from a 2-step revision), 1 case of instability and 1 case due to other reasons. There were 2 cases of early revision (< 3 months), 1 case of instability (revised with a dual-mobility cup and change of the metaphyseal part for a longer metaphysis without loosening of the diaphyseal implant) and 1 PJI. There were 4 cases of late revision (> 1 year), 2 cases of aseptic loosening of the femoral implant, 1 PJI and 1 aseptic loosening of the acetabular implant (with correction of the metaphysis without loosening of the diaphyseal implant).

At the 5-year follow-up, the survivorship free of revision for aseptic loosening of the femoral stem was 100% (Fig. 1a) and the survivorship free of revision for any reason was 99% [95% Confidence Interval (CI) = 91.5 to 99.8%] (Fig. 1b).

At the last follow-up, survivorship free of revision for aseptic loosening was 94% [95% (CI) = 78% to 98.5%] (Fig. 1a) and the survivorship free of revision for any reason was 81% [95% CI = 58 to 92%] (Fig. 1b).

At the 5-year follow-up, solely for the population that had a prosthetic revision, the survivorship free of revision for aseptic loosening and for any reason was 100% and 98.5% [95% CI = 90 to 99.8%], respectively (Fig. 2).

At the last follow-up, solely for the population that had a prosthetic revision, the survivorship free of revision for aseptic loosening and for any reason was 96% [95% (CI) = 75% to 99.5%] (Fig. 2a) and 80.5% [95% CI = 54 to 92.5%], respectively (Fig. 2b).

All revised diaphyseal implants were 140 mm long. As such, the risk of revision was significantly higher for stems 140 mm long compared to stems 200 mm long ($p=0.026$). The risk of revision was not significantly influenced by age, gender, BMI, or stem diameter.

At the last follow-up, the average Harris Hip Score was 89 (range, 56 - 100). Regarding pain, 50 patients (70%) were asymptomatic at that time.

We identified 10 (10%) intraoperative complications including 8 femoral fractures (2 Vancouver type AG, 1 Vancouver type AL, 3 Vancouver type B, 4 Vancouver type C). Intraoperative fractures did not affect implant survival. Ten (11%) postoperative complications were identified, including 5 dislocations, 2 periprosthetic fractures, 1 PJI, 1 aseptic loosening and 1 disabling thigh pain in relation to a distal femoral plate osteosynthesis. We identified a total of 6 dislocations (6%) and the rate of dislocation in the revision surgery group was 8% (no dislocations for primary prostheses).

For the radiographic analysis, we identified 9 cases of subsidence of an average of 6 mm [3 - 15]. There were 8 cases of early postoperative subsidence. (Fig. 3) It was late and more than 10 mm in 1 case, progressively increased and was associated with other signs of loosening; aseptic loosening was diagnosed, and the stem was revised (Fig. 4).

The risk of subsidence was not significantly influenced by age, gender, BMI, stem length, or stem diameter.

After examination of the prosthesis-bone interface on the radiographies, 15 patients had clear lines, mainly Gruen's zones 1 (13 cases) and 7 (7 cases), and 14 patients had bone resorption. There was a line in at least 2 Gruen's zones for 9 patients, 1 of whom was re-examined for aseptic loosening. Bone resorption mainly concerned zones 1 (13 cases) and 7 (6 cases) without association with aseptic loosening.

Discussion

At the last follow-up, we identified no implant fractures. Therefore, the modularity of the revision stems is not synonymous with implant fracture. Several medium-term studies are already pointing to this conclusion [20,21]. The relative fragility of the metaphyseal-stem junction of revision implants has been well-examined and is due to several factors [22-24]. 1 / The design of the implant: the biomechanical study by Krull et al [25] highlights the importance of the balance between the diameter of the "male taper" and therefore the diameter of the stem and that of the female metaphyseal part. This stress distribution prevents overloading of the taper and therefore metal fatigue. 2 / The placement method and the choice of the implant size. After an analysis of 24 cases of implant fracture at this level, B. Fink [26] stressed the need to distalize the metaphyseal-stem junction in the femur (usually below the lesser trochanter). He recommends using shorter diaphyseal implants that follow the anatomical curvature of the femur to achieve a more distal press-fit, in combination with long metaphyses. Moreover, there should be close contact between the proximal metaphyseal implant and the medial femur (autograft, allograft, osteotomies). This was already addressed by Lakstein et al [14] who, after studying 6 ZMR implant fractures in a population of 165 patients, found a lack of bone support at the metaphyseal-stem junction in all cases of implant fracture. In all these cases, the stems were well sealed distally.

At the 5-year follow-up, the survival of the femoral stem without revision regardless of the cause was 99% [95% CI = 91.5 to 99.8%].

Few studies have analyzed a single type of implant in a heterogeneous patient and surgical population. The literature reports heterogeneous results with limited samples for MFT stems. Hashem et al [27] and Weiss et al [28] reported respective survival rates of 99% for 132 revisions in 4 years and 98% for 90 revisions in 5 years for the MP - Link prosthesis. For the same prosthesis, Rodriguez et al [29] and Amanatullah et al [4] respectively reported a survival rate of 95.6% for 71 revisions in 10 years and a survival rate of 97% for 92 revisions in 6 years. While, Ovesen et al [30] and Van Houwelingen et al [6] respectively reported a survival rate of 94% for 125 revisions in 4 years and 90% for 65 revisions in 7 years for the ZMR - Zimmer prosthesis. Finally, for the Revitan prosthesis, Zimmer Fink et al [31] reported a survival rate of 95.5% for 116 revisions in 7.5 years. The results of our series in terms of survival, regardless of the cause, were excellent and are consistent with other studies in both primary and revision surgery. Survival of different titanium MFTs varies minimally according to the type of implant used. On the other hand, while survival is often satisfactory, implant fractures may have negatively impacted the reputation of these modular implants. In the series that reported the lowest survival rate, Van Houwelingen et al [6] identified 5 implant fractures at the metaphyseal-stem junction.

In spite of satisfactory clinical results consistent with previous studies [7,28,32,33], we identified some complications. Instability was reported in 6% of the cases. The acetabular implants were single-mobility in 4 cases and dual-mobility in 2 cases. These early postoperative dislocations (< 3 months) did not require revision or repeat operations except in 1 case. In addition to the correct positioning of the cup, ensuring the right length of the metaphysis is a crucial element in the use of MFT stems. The patient who underwent revision was stabilized by the use of a longer metaphysis and a dual-mobility cup. It is important to endeavor to correct or maintain the levelness of the lower limbs. Systematic preoperative planning makes it possible to mark reference points, which are particularly useful in major bone lesions. However, we found that the incidence of instability is particularly low in the literature, including when the indications for revisions alone were isolated. In fact, Weiss et al [28] and Amanatullah et al [4], for example, found 19% instability. We believe this is due to the consistent use of dual-mobility acetabular cups in our department to mitigate the risk of dislocation when the tissue environment may be wanting [34,35]. In a review of the literature, Reina et al [34] reported an Odds Ratio of 3.59 for dislocations in revision total hip arthroplasty with a single-mobility acetabulum compared to those with a dual-mobility acetabulum.

Our radiographic study showed a high rate of subsidence. However, the average distance was favorable compared to the results in the literature. Abdel et al [8] reported 2.4% subsidence of an average of 16 mm, Rodriguez et al [29] 2.8% and 8 mm, Van Houwelingen et al [6] 12.5% and 12 mm and Parry et al [9] 13% and 18 mm. In our series, 89% of the cases of subsidence were early and none of the stems were unsealed. This is specific to the press-fit technique and to implant wedging [36]. This should be taken into account in the preoperative planning and in the clinical (length of the lower limbs) and radiographic follow-up of the patient.

In addition, our radiographic study highlighted a proximal osseointegration defect. Although not associated with revision, we found a significant amount of clear lines and bone resorption mainly at the

metaphyseal level and in the body of the prosthesis. Similar findings were made by Rodriguez et al [29] and Amanatullah et al [4], with respectively 38% and 42% of lines at this level and 68% and 50% restoration of proximal bone stock. This is contradictory to the principle of bone remodeling and reconstitution of the proximal femur described above [37], particularly with the Wagner prosthesis [38,39]. Metaphyseal bone is often sclerotic during revisions and the operating procedure for MFT stems tends to bypass the stresses directly to the metaphysis. Therefore, it seems difficult to achieve better osseointegration at this level with the type of implant under study from a biomechanical point of view and also because of the bone lesions of the proximal femur. On the other hand, these radiographic signs are absent in the distal diaphyseal zone, which presents optimal osseointegration.

This study has certain limitations. The rationale for the study stemmed from the publication on implant fractures by several authors which justified an evaluation of our practice. Therefore, there is no control group. This evaluation of our practice of using an implant with a specific design made it difficult to conduct a comparative study in this heterogeneous population of patients, some of whom were operated on in an emergency. The objective was to study the survival of the implant and especially the risk of implant failure.

Another limitation of this work is the inclusion of indications for primary surgery. The rationale is related to the specific contexts in which these implants have been used. MFT stems had similar behaviors and homogeneous results in our entire sample population. These were primary but complex THAs and therefore comparable to revision surgery. Finally, our sample was an elderly population and mortality is high among these patients. Several patients died during follow-up, but none in the operating room. We found no indication that the implant was related to mortality which was primarily due to cardiac causes. The predisposition of these fragile patients makes them candidates for revision arthroplasty, and they require a reliable long-term implant and a reproducible technique.

Conclusion

Determining the most suitable revision implant is crucial when the bone stock of the proximal femur is uncertain. This series demonstrates an absence of specific complications or implant fractures. Metaphyseal modularity provides many advantages in difficult prosthetic surgeries. It should be combined with an informed choice of femoral implant and proficiency in the placement method to avoid any risk of implant fracture. Modular Fluted Tapered Stems provide excellent survival without implant revision for any etiology over the medium term.

List Of Abbreviations

MFT: Modular fluted tapered stems

THA: Total hip arthroplasty

PJI: Periprosthetic joint infection

CCD: Centrum collum diaphyseal angle

HHS: Harris Hip Score

BMI: Body mass index

CI: Confidence interval

Declarations

Ethics approval and consent to participate:

Ethical approval was obtained from the Ethics Committee of Pierre Paul Riquet Hospital of Toulouse, France. The requirement for patients' informed consent was waived due to the retrospective study design.

Consent for publication:

Not applicable.

Availability of data and material:

The datasets used and/or analyzed during the current study available from the corresponding author on reasonable request.

Competing interests:

Nicolas Reina is consultant for Mathys Ltd Bettlach, Switzerland. The other authors declare that they have no conflict of interest related to the publication.

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Authors' contributions:

TL participated in data collection, data analysis, interpretation of analysis, article development and revision. EC participated in the data analysis and interpretation of analysis. PC participated in the data analysis and interpretation of analysis. NR participated in the conception, study design, data analysis, interpretation of analysis, article development and revision. All authors read and approved the final manuscript.

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Figures

Figure 1

Kaplan Meier survival plot for revisions due to aseptic loosening (a) and for any revision (b)

Figure 2

Only revision stems: Kaplan Meier survival plot for revisions due to aseptic loosening (a) and for any revision (b)

Figure 3

Subsidence stable with follow-up. Pre-operative radiography (a), immediate post-operative radiography (b), 3 mm early subsidence at 2 months (c), stable at 1 year (d) then 5 years (e) of follow-up

Figure 4

Stem subsidence. Pre-operative radiography (a), immediate post-operative radiography (b), > 10 mm subsidence at 3 years postoperatively (c). The patient was revised for aseptic loosening