*Research Article*

# Outcomes of femoral component revision using uncemented modular titanium stems and the effect of the distal design.

**Ibrahim El-hawary, Hesham Ali, Mohamed Ali, Mohamed El-Shafie and Karam R. Abdelsamie.**
Department of Orthopedic, El-Minia Faculty of Medicine

## Abstract
**Aim of the work:** Femoral revision component subsidence has been identified as predicting early failure in revision hip surgery. This comparative cohort study assessed the potential risk factors of subsidence in two commonly used femoral implant designs. **Patients and Method:** A comparative cohort study was undertaken, analyzing a consecutive series of patients following revision total hip arthroplasties using either a tapered-modular (TM) fluted titanium or a porous-coated cylindrical modular (PCM) titanium femoral component, between April 2006 and May 2018. Clinical and radiological assessment was compared for both treatment cohorts. Risk factors for subsidence were assessed and compared. **Results:** In total, 65 TM and 35 PCM cases were included. At mean follow-up of seven years (one to 13), subsidence was noted in both cohorts during the initial three months postoperatively ($p < 0.001$) then implants stabilized. Subsidence noted in 58.7% (38/65cases) of the TM cohort (mean 2.3 mm) compared to 48.8% (17/35) of PCM cohort (mean 1.9 mm; $p = 0.344$). Subsidence of PCM cohort were significantly associated with extended trochanteric osteotomy (ETO) ($p < 0.041$). Although the ETO was used less frequently in PCM stem cohort (7/35), subsidence was noted in 85% (6/7) of them. Significant improvement of the final mean Oxford Hip Score (OHS) was reported in both treatment groups ($p < 0.001$). **Conclusion:** Both modular TM and PCM revision femoral components subsided within the femur. TM implants subsided more frequently than PCM components if the femur was intact but with no difference in clinical outcomes. However, if an ETO is performed then a PCM component will subside significantly more and suggests the use of a TM implant may be advisable.
**Keywords:** Femoral, arthroplasties, femoral implant designs

## Introduction
The number of total hip arthroplasties (THAs) and revision arthroplasties (revision THAs) continues to increase year on year in developed countries.[1] A total of 27,605 first time revisions of a hip prosthesis have been linked within the National Joint Registry of England and Wales (NJR) to primary hip arthroplasty surgery records for the period between 2003 and 2017.[2]

Revision hip arthroplasty is undertaken for several indications, including aseptic loosening, pain, lysis, adverse soft tissue reaction to particulate debris, infection, and periprosthetic fracture. Revision surgery often presents a spectrum of complex surgical challenges and is considerably more costly to the healthcare system than primary surgery. [3]

The risk of further rerevision is higher than risk of first-time revision following primary hip arthroplasty. One of the most common causes of femoral re-revision surgery is component subsidence. [4-6]

The primary goal of successful revision hip surgery is to achieve immediate implant stability[7] and to achieve early rehabilitation and functional recovery and good long-term outcomes.

Currently, a number of different methods are available for femoral component revision of which uncemented modular femoral components have become increasingly popular[8] Modularity of the femoral component allows for optimal and independent “fit and fill” of the proximal and distal femoral segments with restoration of leg length and offset.[5,9,10]

Tapered femoral components which effectively wedge into the femoral diaphysis with axial loading, achieving fixation over a relatively shorter femoral diaphyseal segment[11-13] The porous coated cylindrical implants relies on scratch implant bone contact over a longer diaphyseal segment to achieve primary stability[14]
Good clinical and radiological outcomes are reported, with excellent mid- to long-term survival for modular implants. [13,15,16-20] However, femoral component subsidence is still a concern with these types of implant.[6,21]

We conducted a comparative cohort study in patients who underwent revision surgery with uncemented modular tapered components (TM) compared to porous-coated cylindrical femoral components (PCM) and evaluated component subsidence in both type of the implants and analyzed the potential risk factors.

## Methods

A retrospective analysis of prospectively collected radiological and clinical data, was undertaken. In total, 130 patients who had undergone a revision THA with a TM fluted titanium component (Reclaim; Depuy Synthes, Warsaw, Indiana, USA, or Restoration; Stryker, Mahwah, New Jersey, USA, or ZMR; Zimmer, Warsaw, Indiana, USA) or PCM titanium component (ZMR; Zimmer, Warsaw, Indiana, USA) were included from April 2006. Surgeon preference and different time periods were the rationale for different component usage. A total of 30 cases were excluded from the study as there was less than one-year radiological follow-up. Patients who were unable to attend the clinic for the final follow-up were mailed a questionnaire and their final available radiological data were evaluated. The mean follow-up period was seven years (one to 13 years).

A total of 100 femoral revisions were assessed: 65 performed with a TM component (22 Reclaim, 14 Restoration, and 29 ZMR) and 35 undertaken with a PCM component (Zimmer ZMR). Patient demographic data were collected and compared **(Table I)**. The preoperative pattern of bone loss was classified according to the method of Della Valle and Paprosky[22] and the preoperative Cortical Index (CI)[23] was measured and compared. Evaluation of the osteoporosis was assessed with the CI using diameter of the femoral diaphysis (x) and the internal diameter of medullary canal (y). CI is obtained by the ratio between thickness of cortical bone (x–y) and diameter of femoral shaft (x)[[23]] at the isthmic region. Four sub-groups were determined; Group. 1 Excellent: CI: =/> 0.55; **Group. 2** Good: CI: 0.45 to 0.54; Group. 3 Average: CI: 0.35 to 0.44. Group. 4 Poor: CI: =/< 0.3424.

**Table (I):** Patient demographic data.

| Characteristic | Taper modular | Porous cylindrical modular | p-value |
|---|---|---|---|
| **Patients, n** | 65 | 35 | N/A |
| **Mean age (range)** | 69.7 (30 to 85) | 68.1 (28 to 88) | 0.651 |
| **Male gender, %** | 52 | 48 | N/A |
| **BMI* (range)** | 29.5 (22 to 47) | 27.8 (19 to 40) | 0.633 |
| **Paporosky classification, n (%)** | | | 0.244 |
| **1** | 6 (9.3) | 1 (2.9) | |
| **2** | 20 (30.8) | 12 (34.3) | |
| **3a** | 38 (58.5) | 22 (62.9) | |
| **3b** | 1 (1.5) | 0 (0) | |
| **Mean cortical index (range)** | 0.5 (0.3 to 0.7) | 0.5 (0.3 to 0.6) | 0.239 |
| **Poor, n (%)** | 3 (4.6) | 2 (5.7) | |
| **Average, n (%)** | 8 (12.3) | 5 (14.3) | |
| **Good, n (%)** | 40 (61.5) | 18 (51.4) | |
| **Excellent, n (%)** | 14 (21.5) | 10 (28.6) | |
| **Reasons for revision, n (%)** | | | 0.254 |
| **Aseptic loosening** | 42 (64.6) | 26 (74.3) | |
| **Second stage periprosthetic infection** | 8 (12.3) | 6 (17.4) | |
| **Adverse tissue reaction** | 3 (4.6) | 1 (2.3) | |
| **Periprosthetic fracture** | 12 (18.5) | 2 (11.4) | |
| **ETO, n (%)** | 36 (55.4) | 7 (20) | < 0.001 |

BMI, body mass index; ETO, extended trochanteric osteotomy; N/A, not applicable.

Operating technique

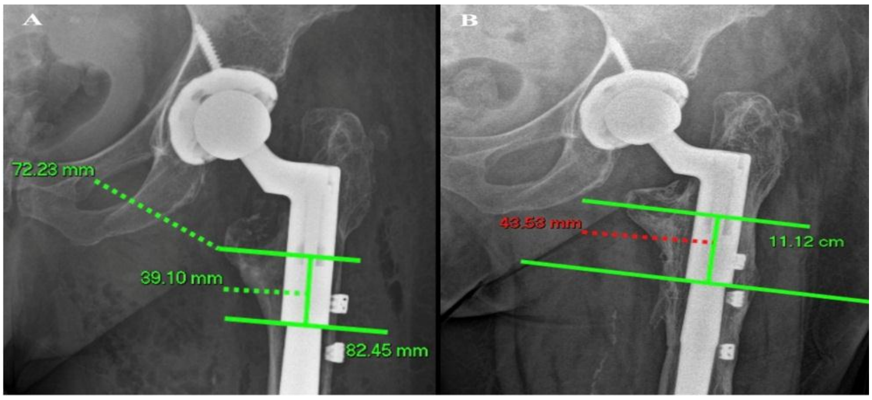
All procedures were performed through a posterior approach. An extended trochanteric osteotomy (ETO) was utilized when required to facilitate implant removal and permit optimal implantation eg: varus femoral diaphyseal remodelling or to facilitate cement removal.

Postoperatively all patients were permitted to fully weight-bear, utilizing walking aids for the first six weeks but instructed to avoid active abduction for first six weeks where an ETO was used.

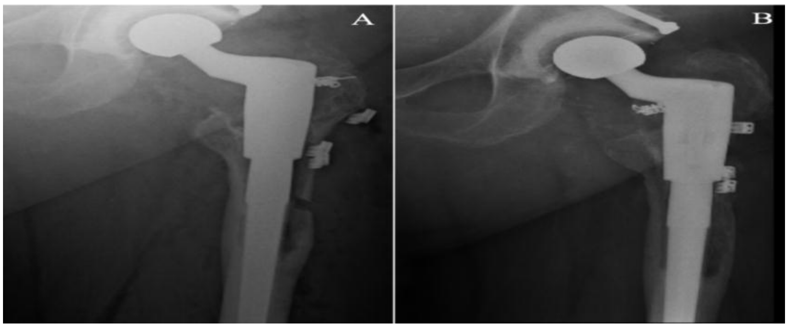
Functional outcomes were assessed using the Oxford Hip Score (OHS). Radiological assessment was by anteroposterior (AP) hip and lateral radiographs at day one compared with the subsequent radiographs at three months, six months, one year, and annually thereafter.

The amount of subsidence, implant stability, as well as evaluation of bone changes around the implants were assessed. All radiological measurements were performed using PACS (Picture Archiving and Communications System, Carestream; Eastman Kodak, Rochester, New York, USA). Subsidence was measured relative to a fixed landmark on the femur and the femoral component. The distance in millimetres between the most medial point of lesser trochanter and the junction of the proximal and distal segments of the femoral component were used (Fig. 1). The most medial point of the lesser trochanter has been shown the best bony landmark. [[25]]

All measurements were corrected for magnify-cation to determine the true subsidence. Measurements were calibrated for each radiograph using the known diameter of metaphyseal-diaphyseal construct of the femoral component and the known diameter of the modular femoral head and allow calculation of the magnification.[[26]] Two cross-reference points were also obtained to confirm the amount of subsidence; the distance from most distal cerclage wire or cable if used and the distance between the tip of the femoral component and the knee joint line. These were selected as reference points were always located in stable parts of femur. Other measurements such as the distance between upper cerclage wire or cable and tip of the grater trochanter could change in position with time and were thus unreliable **(Figure 2).**




**(Figure 1: A)** :Immediate anteroposterior (AP) radiograph and B) two years postoperative AP radiograph of a 75-year-old female, measuring of the subsidence of the tapered component. The distance in millimetres was compared in both radiographs.




**(Figure 2: A)** Immediate radiograph and B) one-year postoperative radiograph of a 62-year-old male showing the change in position of the cerclage cables.

Two sets of measurements were obtained by two independent observers. The interclass correlation coefficient (ICC) for measurements was obtained for both cohorts. Interobserver reliability between the two observers was 0.94 in the PCM cohort with (95% CI (Confidence Interval) 0.91 to 0.96) and in the TM cohort and was 0.91 with 95% CI 0.83 to 0.95).

Osseointegration of the implant was evaluated according to the presence or absence of radiolucent lines around the femoral component on the final follow-up radiographs. The femoral implant zone was divided into two equal parts: the proximal femur (corresponding to Grüen zones 2 and 6) and the diaphyseal femur (corresponding to Grüen zones 3 and 5).[[12]] The extent of the radiolucent line was evaluated in each of these two zones and any line located at the rim of the component (Grüen zone 1) was not taken into account[[12]] **(Table II)**.

**(Table II):** Radiograph assessment of osseointegration.

| **Presence of radiolucent lines** | **Proximal femur, points** | **Distal femur, points** | **Quality of osseointegration** |
|---|---|---|---|
| Stage1: line absent | 10 | 10 | 20 points = very good |
| Stage 2: line < 50% | 7 | 7 | 17 points = good |
| Stage 3: line > 50% | 4 | 4 | 14 points = average |
| | | | < = 11 points = poor |

Initial (immediately postoperative) and secondary (final follow-up) bone stock were evaluated on the AP radiographs. All bone changes arising at points of contact with the implant were assessed, regarding generation, preservation, or even degradation, particularly evaluating cortical thickness, cortical bone density, and any cortical defects secondary to aseptic loosening processes. Grüen zones 1, 2, 3, 5, and 6 were successively and separately evaluated, knowing that zone 7, often absent in revision and is integrated to zone 6. This first evaluation on the immediate postoperative radiograph is used as a reference to estimate the changes in bone stock compared to the final follow up[[24]] and to study factors influencing the final result (secondary bone stock and secondary stability).[[24]]

A numerical score assessing bone stock, from +4 to −2 points, is given for every Grüen zone.[[24]] The final score is based on 20 points and the classification made in four categories: very good (20 to 18); good (16 to 14); average (12 to 10); poor (< 10) **(Table III).**

**(Table III)** :Evaluation of cortical lesions.

| **Numerical score** | **Cortical evaluation** |
|---|---|
| **+4** | No initial lesion nor further bone loss or complete cortical regeneration and/or filling of bone defects (density and thickness) |
| **+2** | Moderated decrease density or thickness or incomplete regeneration of initial defect or defect ≤ in 10 mm (secondary appearance) |
| **0** | Severe decrease density or thickness or no regeneration of initial defect or defect > 10 mm (secondary appearance) or pseudarthrosis of the greater trochanter. |
| **-2** | Major decrease density and thickness or cortical lysis (lysis of the greater trochanter or degradation of initial defect |

## Statistical analysis

Statistical analysis was performed using the statistical SPSS Version 23 software (IBM, Armonk, New York, USA). Fisher's exact test, chi-squared test, and Wilcoxon signed-rank test were used to compare categorical variables, while *t*-test were used to compare quantitative data. Any p--values < 0.05 were considered statistically significant. Logistic regression analysis was performed to evaluate the potential risk factors for the subsidence in both cohorts.

## Results

Mean age, Sex, BMI, indications for revision surgery, and preoperative bone quality were comparable between the two cohorts, however there was no direct matching between the cases (Table I).

Both cohorts reported significant improvements in their OHS ($p < 0.001$). In the TM cohort, the OHS improved from 19.51 (range 6 to 36) preoperatively to 32.07 (range 3 to 48) at last follow-up. In the PCM the OHS improved from 20.79 (range 6 to 44) preoperatively to 37.71 (range 9 to 48) at last follow-uphowever there was no difference between the two groups (p=0.122).

Subsidence of the femoral component was observed in both cohorts; 58.7% (38/65 cases) in the TM cohort compared to 48.8% (17/35 cases) in the PCM group (p = 0.344). No significant difference in the degree of subsidence was noted between either implant cohort (p = 0.472). The mean subsidence in the TM and PCM cohorts were 2.3 mm (0 to 19) and 1.9 mm (0 to 11) respectively. Femoral component migration was noticed in the first three months postoperatively (p < 0.001) with no further significant migration afterwards. **(Figure 3).**

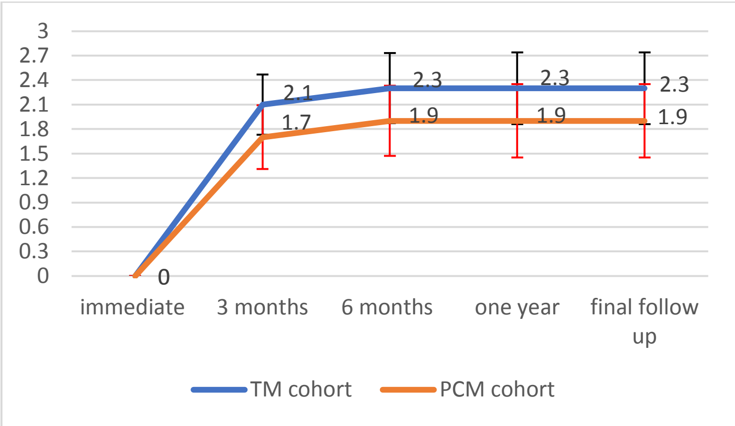



**Figure 3**

Graph showing the progress of the subsidence in both groups. The x-axis represents the time of follow-up and the y-axis represents the magnitude in millimetres.

Univariate statistical analysis showed ETO had a significant effect on the incidence of subsidence in the PCM cohort when compared to the TM cohort (p = 0.041/p = 0.629 respectively) (Tables IV and V). Other potential risk factors were not associated with a statistically significant effect on the subsidence in either groups (Tables VI and VII).

**(Table IV): Extended trochanteric osteotomy and primary stability in TM group.**

| **Tapered modular (TM) component** | **Subsidence** | | **p-value** |
|---|---|---|---|
| **ETO, n (%)** | **No (n = 27)** | **Yes (n = 38)** | 0.629 |
| **No** | 13 (48.1) | 16 (42.1) | |
| **Yes** | 14 (51.9) | 22 (57.9) | |

**ETO, extended trochanteric osteotomy.**

**(Table V):** Extended trochanteric osteotomy and primary stability in porous-coated cylindrical (PCM) group.

| **PCM component** | **Subsidence** | | **p-value** |
|---|---|---|---|
| **ETO, n (%)** | **No (n = 18)** | **Yes (n = 17)** | 0.041 |
| No | 17 (94.4) | 11 (64.7) | |
| Yes | 1 (5.6) | 6 (35.3) | |

**ETO, extended trochanteric osteotomy.**

**(Table VI):** Other potential risk factors of subsidence in the tapered modular (TM) group.

| Tapered component | Subsidence | | p-value |
|---|---|---|---|
| Cortical index, n (%) | No (n = 27) | Yes (n = 38) | 0.764 |
| Poor | 1 (3.7) | 2 (5.3) | |
| Average | 2 (7.4) | 6 (15.8) | |
| Good | 17 (63) | 23 (60.5) | |
| Excellent | 7 (25.9) | 7 (18.4) | |
| Mean Cortical Index (range; SD) | 0.51 (0.33 to 0.68; 0.08) | 0.48 (0.31 to 0.6; 0.07) | 0.249 |
| Paprosky classification (%) | | | 0.456 |
| 1 | 4 (14.8) | 2 (5.3) | |
| 2 | 9 (33.3) | 11 (28.9) | |
| 3a | 14 (51.9) | 24 (63.2) | |
| 3b | 0 (0) | 1 (2.6) | |
| Mean distal component length (range; SD) | 162.17 (140 to 235; 28.8) | 158.06 (140 to 235; 24.7) | 0.521 |
| Mean distal component diameter (range; SD) | 16.79 (14 to 22; 2.1) | 15.2 (14 to 22; 2.9) | 0.250 |

**(Table VII):** Other potential risk factors of subsidence in the porous-coated cylindrical (PCM) group.

| PCM component | Subsidence | | p-value |
|---|---|---|---|
| | No (n = 18) | Yes (n = 17) | |
| Cortical index, n (%) | | | 0.318 |
| Poor | 2 (11.1) | 0 (0) | |
| Average | 1 (5.6) | 4 (23.5) | |
| Good | 10 (55.6) | 8 (47.1) | |
| Excellent | 5 (27.8) | 5 (29.4) | |
| Mean cortical index (range; SD) | 0.5 (0.33 to 0.6; 0.08) | 0.5 (0.37 to 0.6; 0.07) | 0.964 |
| Paprosky classification, n (%) | | | 0.725 |
| 1 | 0 (0) | 1 (5.9) | |
| 2 | 7 (38.9) | 5 (29.4) | |
| 3a | 11 (61.1) | 11 (64.7) | |
| 3b | 0 (0) | 0 (0) | |
| Mean distal component length (range; SD) | 146.8 (115 to 220; 33.13) | 134.77 (115 to 220; 22.4) | 0.190 |
| Mean distal component diameter (range; SD) | 15.4 (12 to 19.5; 2.1) | 14.1 (12 to 19.5; 2.2) | 0.081 |

A logistic regression analysis was performed using the significant risk factor of subsidence as previously determined by the univariate analysis. The risk effect of ETO on subsidence was assessed in both cohorts and the ETO was considered as high potential risk in the PCM cohort (odds ratio (OR) 9.273; p = 0.052) when compared to the TM cohort (OR 1.277; p = 0.629).

Implant integration in both groups showed satisfactory results and there was no statistical difference between the groups (p = 0.834). Osseointegration of the TM was evaluated as very good in 38 cases (58%), good in 19 cases (29%), and average in eight cases (12%). Osseointegration of the PCM was assessed as very good in 22 cases (62%), good in ten cases (28%), and average in three cases (3%).

Evaluation of bone stock on the immediate and final follow-up radiographs showed increased or improved bone stock in the TM and PCM cohorts. ($p = 0.001$, $p < 0.001$) Moreover, there was no statistically significant difference of the immediate and final postoperative bone stock in both cohorts (Table VIII).

**(Table VIII):** Changes of the bone stock in both cohorts.

| Bone stock | TM (n = 65) | PCM (n = 35) | p-value |
|---|---|---|---|
| **Immediate postoperative bone stock** | | | 0.774 |
| **Mean (range; SD)** | 13.8 (8 to 20; 3) | 13.9 (6 to 20; 3.4) | |
| **Standard error mean** | 0.37 | 0.58 | |
| **Final postoperative bone stock** | | | 0.197 |
| **Mean (range; SD)** | 15.2 (6 to 20; 3.2) | 16 (8 to 20; 2.8) | |
| **Standard error mean** | 0.39 | 0.47 | |
| **p-value** | 0.001 | < 0.001 | |

**PCM, porous-coated cylindrical cohort; TM, tapered modular cohort**.

## Discussion

Choice of the femoral component in revision THA is an important part of preoperative planning, to achieve the surgical objectives. Historically, PCM components were used for femoral revisions.[27] Subsequently TM components were introduced and have increasingly become the implant of choice for femoral revision surgery, especially in cases with extensive bone loss. The philosophy of implant choice is to obtain distal fixation in good quality bone distal beyond the tip of the previous component, where periprosthetic bone loss is present. The authors note that success has been reported using shorter components [[28]] but this was not employed in these cases.

The PCM and TM components are versatile revision hip prostheses that offer intraoperative versatility allowing adjustment of the version and lateral and/or vertical offset of the proximal segment which can improve hip stability and minimize leg-length discrepancy.[15,29-33]

Kirk et al., [[34]] reported that in comparison to a cylindrical design, a fluted tapered geometry demonstrated significantly less displacement when subjected to axial and torsional loading. Furthermore, in 2013, the Revision Femoral Arthroplasty Study Group (RFASG) reported that, despite their use in more complex cases, the tapered design had a reduced incidence of loosening, re-revision surgery, and femoral component-related failures compared to cylindrical designs.[[35]] They suggested that tapered designs need less femoral bone stock to achieve primary stability, however, they found a paradoxically higher incidence of subsidence. Cylindrical components, though less likely to subside, were found to be susceptible to ingrowth failure and loosening, particularly where a short isthmic segment (< 4 cm) or large canal diameter (> 18 mm) was present[35,36] The primary stability of the tapered implant is achieved by a bicortical bone implant surface and perfect implant wedging.[10,11,24] This stability prevents micromotion and may favour osseointegration in more compromised diaphyseal bone.[37] .

The subsidence of the femoral component in this study was noted predominantly in the first three months postoperatively in both cohorts but stabilized over the next few months. While the range of the subsidence was comparatively more in the TM group than the PCM group, the difference was small and there was no significant correlation with the clinical outcome in either group and no corresponding increase in failure of ingrowth or loosening in either group. No femoral components in this comparative study were revised for subsidence or mechanical failure at a mean follow-up ten years in the PCM group and six years in the TM group.

The overall rate of the subsidence in this study was comparable to that reported by other multicentre studies in which the TM and PCM stems have been used in femoral revision. All these studies reported excellent short- and mid-term survivorship[15,18,19,38-43] The majority of the studies reported the reason for early subsidence is probably poor primary stability due to suboptimal press fit and insufficient to withstand the patient's loading of the limb during activities of daily living, resulting in a subsidence[18,42,44,45] Regarding the overall incidence of subsidence, our results are consistent with Sivananthan et al.,[42] who reported four femoral components (5.9%) in their series developed subsidence more than 5 mm from the initial postoperative radiograph, but established stable osseointegration thereafter[42] Kang et al.,[46] assessed the subsidence of fully porous coated ZMR stems in 37 hips. The mean subsidence was higher at 4.4 mm (0 to 35).

Five hips subsided by more than 5 mm (mean, 20.8 mm) (range 9-35). All five hips were deemed to be fibrous stable or osseointegrated; however, one femoral component was revised due to recurrent hip dislocation associated with early subsidence. The remaining 32 hips demonstrated a mean subsidence of 1.7 mm (range 0-5).

Component subsidence relative to canal fit of the distal part of the femoral component on the postoperative AP radiograph was assessed. In the five hips with more than 5 mm of subsidence, the mean component canal ratio was 0.78, whereas in the 32 hips with subsidence of less than 5 mm, the mean component-canal ratio was 0.93 ($p = 0.002$)[46] Lakstein et al.,[14] noticed that subsidence occurred in 11% of the patients (range 5 to 25 mm). The overall subsidence for this series was a mean 1.6 mm (SD 5.0). Two patients were symptomatic and had further revision surgery. The remaining patients with radiological evidence of subsidence showed stable osseointegration by 12 months postoperatively. To the contrary, Jibodh et al.,[18] did not report any femoral component migration in a series of 81 consecutive hips revised with a PCM femoral components. The authors attributed the lack of component migration to the implant characteristics as well as to the under-reaming by half millimetre, in order to obtain better primary fixation and stability[18]

We report a significant influence of an ETO on the initial subsidence in the PCM component and should be avoided, suggesting when using of an ETO it probably preferable to undertake reconstruction with a TM component. The other potential risk factors for subsidence in TM or PCM components, include the preoperative bone loss, femoral canal diameter, body mass index (BMI), and component length did not influence component subsidence, supporting previous results[12,38,39,42,47] Our study showed that component diameter did not correlate with the subsidence, provided a suitable femoral component diameter is selected, successful fixation was obtained.

It was noted in this study that the femoral components in both groups revealed good osseointegration at the final radiological evaluation. Furthermore, in both cohorts the proximal femoral bone evaluation revealed an overall increase of the bone stock ($p = 0.001$).

Our study has some limitations. It was a retrospective case comparison study, with variable time of follow-up and differing numbers in each group. There is a risk of selection bias as to which TM or PCM components were used. More types of TM components were used compared to PCM components. The choice of reference points effects accuracy of subsidence measurements. We chose reference points that were consistent and visible on all postoperative radiographs to mitigate this risk. Nevertheless, this study provides further information on the subsidence of commonly used modular revision femoral components with different design philosophies.

With respect to clinical outcomes, patients in this study reported a marked improvement in postoperative OHS compared to preoperative status irrespective of the time since revision surgery ($p < 0.001$). With correct implant selection, good surgical technique, and the appropriate use of ETO, excellent initial implant stability and longer-term implant survivorship with proximal bone preservation can be achieved.

In conclusion, both TM stems and PCM components subsided without significant difference in the reported clinical outcomes. TM stems subsided slightly more frequently than PCM components when the femur was intact, but this did not affect outcome. If an ETO is performed, then PCM component will subside more and a TM component should be considered.

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