

# Cementless Total Hip Replacement with a “Lateral Flare Stem” : An Average of 15 Years Follow-up of Previously Reported Cases

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## Abstract

**Introduction:** To demonstrate the physiological mechanical forces on the medial and lateral femoral cortices in Total Hip Replacement (THR), the cementless “lateral flare” femoral stem has been developed, established, and clinically validated at our institution. The mid-term outcomes had been reported, and therefore, the long-term outcomes of this femoral stem were evaluated in this study.

**Patients and methods:** A total of 62 hips in 58 consecutive patients, which had been previously reported, were investigated by physical examinations, radiographic evaluations and telephone interviews.

**Results:** There were 49 hips in 45 patients (79.0%) available for long-term follow-up. of the 49 hips; the mean duration of follow-up period was  $15.8 \pm 1.5$  years (10.1-17.9 years). There were no cases of critical stress shielding which required revision surgery of any femoral components. Consequently, no femoral components have been revised at the time of this report.

**Discussion:** Besides the lateral expansion, this femoral stem has a trapezoidal shape of the cross section in the proximal one-third, and a flat posterior surface with a fixed anteversion in the neck. Because of these features, this stem could demonstrate the physiological forces on femur and the stabilization against rotation forces encountered inside the femoral canal.

**Conclusion:** The lateral flare stem is a promising prosthesis with a carefully considered design, which provides not only initial stability but long-term stability and bone preservation throughout a long follow-up period.

**Keywords:** Total Hip Replacement (THR); Long-term follow-up; Lateral flare; Cementless femoral stem; Rest fit fixation

## Introduction

Due to the clinical success of the Total Hip Replacement (THR) for patients with Osteoarthritis (OA), the indication for THR has been increasing. It is estimated that approximately 378,000 cases of primary THR were performed in the United States in 2015, and THR cases are predicted to increase in future [1,2].

The first modern THR was developed in England in 1938 [3]. Since then, there have been several improvements made to the initial design as well as the materials employed. Initially, the secured fixation of the prosthesis to the host bone was recognized as a critical task to be accomplished. First, with John Charnley's introduction of acrylic cement [4], later with the cementless osseous integration of the implanted introduced in 19795, and then this problem seemed to have been completely vanquished. Over time, cemented arthroplasty has declined in favor of cementless techniques for several reasons including debris production, “cement disease”, adverse cardiopulmonary vascular events on pressurization, fatigue of the bone-cement interface over time, and surgeon-dependent techniques.

Recent reports have estimated that more than 88% of all femoral stems employed cementless technology in the United States [5-7]. However, it soon became apparent with the long-term studies in a younger, higher demand patients that neither cemented nor cementless implants could ensure long-term survivability [6-9]. This is because neither appeared to restore the physiological loading of the femur as evidenced by aseptic loosening, subsidence, stress shielding, diaphyseal hypertrophy, and thigh pain. These clinical challenges questioned the wisdom of implanting devices, whether cemented or cementless, in patients with expected longevity and higher demands. In the case of cementless implants, there is also a widely held belief that “poor bone quality” and certain femoral geometries (i.e. osteoporosis and the Dorr classification type C stove-pipe appearance) are contraindications for the use of cementless technique [8].

From the previous clinical experience with THR, it is evident that most arthroplasty devices do not restore the normal physiological loading of the femur [10]. This is most likely because most devices are predicated using the static biomechanical model defined by John Koch in 1917 [11]. In his article, it was hypothesized that the medial femur experienced compression and that the lateral femur was always subjected to tension. This belief has led to some designers to

incorporate a medial collar on the femoral implant to ensure medial loading of the femur and to prevent subsidence [12,13].

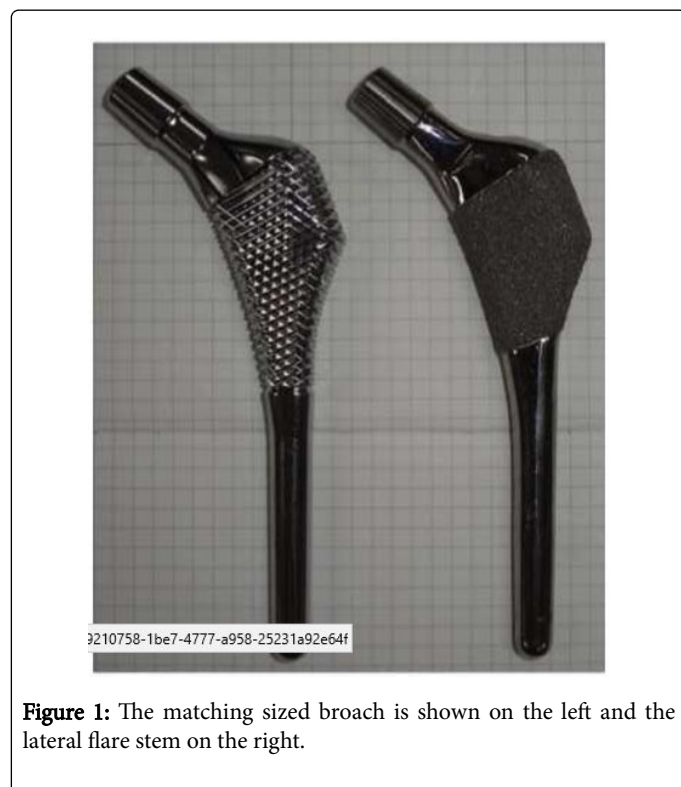
Moreover, to achieve an initial rigid stability of the cementless stem necessary for subsequent osseous integration to occur, cementless implants employ a “press fit” technique. The press fit of a femoral component into the medullary canal is analogous to the manner in which a nail becomes fixed into a piece of wood by using a combination of frictional and circumferential hoop stresses. However, this technique is highly dependent upon the presence of adequate femoral bone quality and geometry.

The press fit technique has also been associated with an increased risk of intraoperative peri-prosthetic fracture of the femur [14]. The risk of fracture has been reported to be increased by as much as three to four fold with the introduction of short stems due to the fixation forces being concentrated over a smaller surface area of contact within the proximal medullary canal.

In contrast to the press fit means of achieving the initial fixation of the stem, an alternative method, a “rest fit” fixation with a “lateral flare” stem, was introduced [11]. The promising midterm clinical outcomes had been demonstrated, and therefore, the long-term follow-up on the previously reported population of patients was evaluated in this study.

## Patients and Methods

A total of 62 hips in 58 consecutive patients underwent THR with a cementless lateral flare stem at our institution from January 1998 to December 2000. These were enrolled in a previous study [10] (Figure 1).



**Figure 1:** The matching sized broach is shown on the left and the lateral flare stem on the right.

All surgeries were performed by a single surgeon using a standard posterior approach. Both acetabular and femoral components (FMP

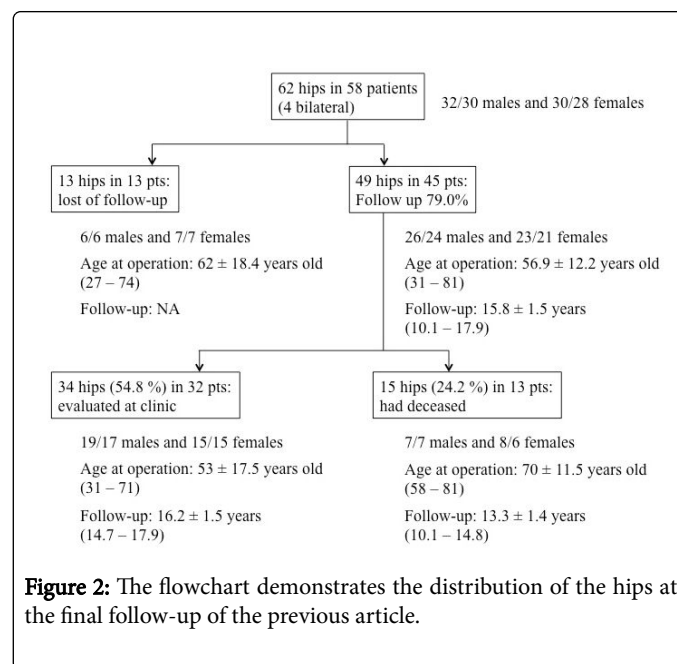
Acetabular System and Revelation Hip Stem, DJO Global, and/or StelKast Acetabular System, StelKast McMurray, PA, USA) were implanted without bone cement. Full weightbearing ambulation with a walker was initiated on either the operative day or first postoperative day, depending upon the time of day that the surgery was performed.

In the present study, we had endeavored to contact all 58 patients between December 2014 and December 2017. Once contacted, the patients were evaluated in person in our clinic or by telephone interview. In addition to assessment of patient’s history, documentation of any additional revision surgery was made. A radiographic evaluation was obtained with antero-posterior and lateral films of the involved hips as well as antero-posterior view of the pelvis. Subsequently, the presence of pelvic or femoral osteolysis, pedestal formation, progressive radiolucent lines, stress shielding, cancellous or cortical thickening and visible peri-prosthetic bone density changes were reported.

The stress shielding was examined with the Engh classification (1<sup>st</sup> degree: rounding off only of the proximal medial neck, 2<sup>nd</sup> degree: rounding off only of the proximal medial neck and anterior cortex at level 1 and the medial cortex at level 2, 3<sup>rd</sup> degree: extensive resorption of the medial and anterior cortex at level 1 and the medial cortex at level 2, 4<sup>th</sup> degree: cortical resorption below 1 and 2 into the diaphysis [15]). The study was approved by the institutional review board of our institution. The office had obtained the patients’ informed written consent for print and electronic publication of the study.

## Results

The values were expressed as mean  $\pm$  standard deviation. Of the 62 hips initially reported in 58 patients, the follow-up included 49 hips in 45 patients representing 79.0 % follow-up of the initially reported patient population (Figure 2). The pre-operative diagnoses of these patients undergoing THR were primary osteo-arthritis, secondary OA with avascular necrosis, fractured femoral neck with OA, and rheumatoid arthritis.



**Figure 2:** The flowchart demonstrates the distribution of the hips at the final follow-up of the previous article.

There were 13 hips in 13 patients who were lost to follow-up (21.0%). Of the 15 hips in 13 patients who had deceased, the follow-up period prior to death was  $13.3 \pm 1.4$  years (10.1-14.8 years). Prior to death, there were no complications reported by the patient's surviving relatives concerning the patient's hip surgery, no disability relative to the hips, and no indication for invasive surgery.

Of the 49 hips in 45 patients, the mean age at the time of operation was  $56.9 \pm 12.2$  years (31-81 years) and the mean duration of follow-up period was  $15.8 \pm 1.5$  years (10.1-17.9 years) (Figure 3).



**Figure 3:** The radiographic findings of the hip joint showed no critical stress shielding or any other reactions.

Two patients had received acetabular cup revisions 13 years after their index surgeries due to polyethylene failure of the acetabular component [16]. One patient, a 65-year-old female, displayed 2<sup>nd</sup> degree stress shielding of the proximal medial neck and anterior cortex 15 years after the initial total hip operation [17]. However, there were no cases of critical stress shielding which required revision surgery of any femoral components. Consequently, no femoral components have been revised at the time of this report.

## Discussion

Recently, there has been a trend to employ short, flat, and tapered wedge stems for reasons of “bone preservation”, in very minimally THR invasive surgery. However, the majority of these stems are derived from standard length designs with two-dimensional stability, which prioritized the loading on the medial and the metaphyseal and diaphyseal surfaces of the femur. Therefore, once the stems designed using these concepts are shortened, there is concern that they are less stable than their longer stemmed predicates, especially when implanted in the Dorr type C bones [10].

The original custom implants of this lateral flare design (Stanmore implants, Stanmore, UK) was first manufactured in 1989 to resist subsidence, preserve proximal bone mass, and provide excellent clinical outcomes in patients of all ages, bone quality, and geometry [17]. This design was either circumferentially grit blasted or coated with hydroxyapatite over one-third of the proximal end at the level of the lateral flare [18]. Following that, this design concept's performance demonstrated its ability to provide initial stability and bone preservation using an off-the-shelf in both the standard length in 1996 (Revelation Hip System, DJO Surgical, Austin, Texas, USA) and in a

short stem version in 2009 (MicroMax, DJO Surgical). The lateral flare stem is made out of a titanium alloy (Ti6AL4V) with a neck angle of 130°, a fixed anteversion of 12° for standard neck and a 6° anteversion with a reduced neck option available for unusual anatomies. The sizes of the femoral components vary from size 8 through 9, 10.5, 12, 13.5, 15, 16.5, and 18 mm distal diameters. The size number indicates the proximal diaphyseal diameter at the initiation of the 3° taper of the remaining stem. The length of the stem from the medial femoral condyle to the tip varies from 93 mm for size 8 to 124 mm for size 18. The surface finish of the proximal one-third of the stem consists of a circumferential porous coating of which the porous size is between 250 and 450 micrometers to achieve optimal bone ingrowth [18,19].

In contrast, the distal two-thirds of the stem below the Gruen classification zones 1 and 7 is tapered by 3°, highly polished, and intended to only ensure proper alignment in the femoral canal [20]. This tapered shape minimized the distal contact and load transfer to the cortex of the femur below the Gruen zones 1 and 7. The three-dimensional cross-section of the proximal third of the prosthesis increases proportionally with increase in size. Its posterior flat surface provides maximum contact for the transmission of loads to the femur during flexion activities, and its trapezoidal cross-section provides rotational support during activities such as stair climbing. Standard stems ranging from size 15 and larger in diameter have a clothespin slot at the distal end of the femoral stem to reduce stiffness of the femoral implant.

The most notable feature of the lateral flare stem is the lateral flare expansion, which enables physiologic loading of the proximal medial and lateral femoral endosteal surfaces. This design concept is based on a dynamic model of hip biomechanics [11]. This model expands the Koch model to specifically include lateral soft tissues. It demonstrates how the lateral soft tissues of the hip and the thigh serve as tension bands during periods of unilateral support. These tension bands reduce the bending forces and can promote compression loading of the lateral aspect of the femur during unilateral stance phase of gait. This model supports the idea that the lateral femur may be employed as an additional base of implant support. To take advantage of this support base, the “lateral flare” of a specific geometry and dimension was incorporated into the design of the femoral component. This stem has both the virtue of its medial lateral geometry resting on the proximal metaphysis as well as a flat posterior surface with a fixed anteversion neck. This allows for maximum load transfer between the component and the posterior aspect of the femur along the calcar femorale during flexion activities. In addition, the stem has a trapezoidal shape in its proximal cross-section to stabilize the cementless implant against rotational forces encountered inside the femur canal during stair climbing.

The broach only technique for implantation of the femoral stem utilizes a broach device which has 1 mm recesses creating a circumferential cross-hatched surface. The external dimension of the broach matches the uncoated substrate dimension of the femoral component. Thus, cancellous bone is preserved within the canal. The stem is 0.5 mm wider than the matching size of the broach due to the proximal coating. Therefore, the stem can compact the remaining cancellous bone between the stem and the endosteal surface of the proximal femur.

Either the standard length or shortened version of the lateral flare stem achieves rigid fixation by “resting” on the compacted metaphyseal cancellous bone, which is achieved by tapping and not hammering the implant into its final position. This technique is termed a “rest fit” in

the femur [10]. Some other femoral stems have been reported to possess a lateral expansion [21]. However, these stems are missing other features found in the “lateral flare” design and thus are categorized as having only two-dimensional medial-lateral stability. The design of the femoral component employed in this study in providing the rest fit gives rigid initial fixation in the proximal metaphysis in all three dimensions. In this fashion, the light tapping insertion technique, the rest fit, avoids the hammering of a traditional cementless stem required to achieve initial fixation. Therefore, this design avoids the risk of intraoperative periprosthetic fracture. The secure, certain proximal metaphyseal fixation the lateral flare provides obviates the need for a traditional longer stemmed or cemented femoral component for osteopenic bone quality seen in renal dystrophy or elderly patients. It has also been shown to be suitable for the Dorr type C femora. Indeed, the distal portion of a standard length “lateral flare” femoral component functions only as an intra-medullary guide to achieving proper alignment in the femoral canal and not initial fixation. It can easily be supplanted by an extra-medullary alignment guide to assure proper alignment within the femoral canal when using a short stemmed component, without compromising the functionality of the implant in preserving physiologic femoral loading. Its purpose is to transfer load from the pelvis to the proximal femur in a truly physiologic fashion, although the successor model (Revelation microMAX System, DJO Surgical) has the same proximal shape with a shorter distal stem. The stability of the short stem will therefore not be compromised by shortening the length of the prosthesis. We have applied the short stem version for the majority of our primary OA THRs as well as for femoral neck fracture cases including all bone qualities, severe osteoporosis in renal osteodystrophy, the elderly, and in the Dorr type C geometries. The outcomes for femoral neck fractures are promising without aseptic loosening, critical subsidence, or any other stem complications seen with short-term follow-up [22]. This study does suffer from limitations of being a long-term follow-up in a population which includes elderly patients who have deceased; however, it should be noted that patients included in this study who have in fact deceased did not have evidence of stem failure or indication for prosthesis revision surgery at the time of their death. It is the intention of the authors to continue with follow-up of the patients on a biannual basis as long as they remain available for evaluation. Revisions of acetabular cups have been performed in two cases due to polyethylene wear [16]. However, even in these cases, the proximal lateral flare geometry of the implanted stems and the bone ingrowth appears to have prevented invasion of polyethylene debris into the proximal femur, limiting the affected joint space. This appears to explain the absence of femoral component loosening in the face of polyethylene failure of the acetabular component. In the cases reported, there was no critical stress shielding, no aseptic loosening of the femoral stem and no critical osteolysis of the proximal femur observed in the patients evaluated. Therefore, we believe the efficacy of the lateral flare stem design demonstrates physiologic loading of the proximal femur and provides a favorable long-term outcome for total hip replacement surgeries.

## Conclusion

THR with cementless “lateral flare” femoral stem with “rest fit” technique was followed-up and radiologic results assured secure, rigid, long-term survival of the implants. Therefore, it is our opinion that the unique proximal geometry of the “lateral flare” stem design based on a dynamic model of hip biomechanics provides significant initial

stability, preserves prosthetic fixation, and protects bone against loss over a long period of time.

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