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Proximal load transfer with a stemless uncemented femoral implant

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Abstract Bone stock preservation is crucial when performing total hip replacement in young patients. The aim is to save good bone stock for a possible revision procedure. Furthermore, there is an increasing demand from young and active patients to receive a new joint which allows a normal or nearly normal life style. With this in mind, we began, in 1993, to develop a new femoral implant. The purpose of this ultra-short stem was a physiologic strain distribution on the proximal femur with a proximal load transfer from the implant to the femoral bone. Main features were an almost complete absence of the diaphyseal portion of the stem, a well defined lateral flare with load transfer on the lateral column of the femur, and a very high femoral neck cut. These innovations resulted in a conservative implant on both the bone stock and the soft tissues. This implant, in the first years, was recommended only for young and active patients. Over the last thirteen years, this project has undergone several modifications but the basic principles of the implant have remained the same. In the present review, we present the rationale, the surgical technique and the clinical and experimental results so far obtained with this implant.

Key words Bone stock • Femoral neck • Lateral flare • Load transfer • Total hip replacement • Young

Introduction

For many years, hip implants have been designed following the pattern of load transmission on the proximal femur predicated by Koch of Johns Hopkins University, Baltimore. In 1917 [1], he published an extended study on the subject, presenting his mathematical analysis of the forces present in a cadaveric femur during the unilateral support phase of gait. His model contemplated the presence of compression forces on the medial column and tension loading on the lateral column of the proximal metaphyseal region of the femur (Fig. 1) It was a very basic and mechanical model which did not consider at all the effect of the muscular forces. The basis of his model was the simple observation that the body's centre of gravity is, during the unilateral stance phase of gait, medial to the loaded limb. For this reason he stated that the proximal femur had to endure a varus bending moment.

Koch's treatise was so strongly presented that it stood recognized as the perfect model of hip biomechanics for the next 70 years. It was the source for the design and testing of hip replacement prostheses. Most of the femoral implants currently available on the market have been designed according to his representation of load distribution on the proximal femur. Because of the Koch model, only the medial region of the proximal femur is employed for prosthetic support. The so-called lateral flare and the

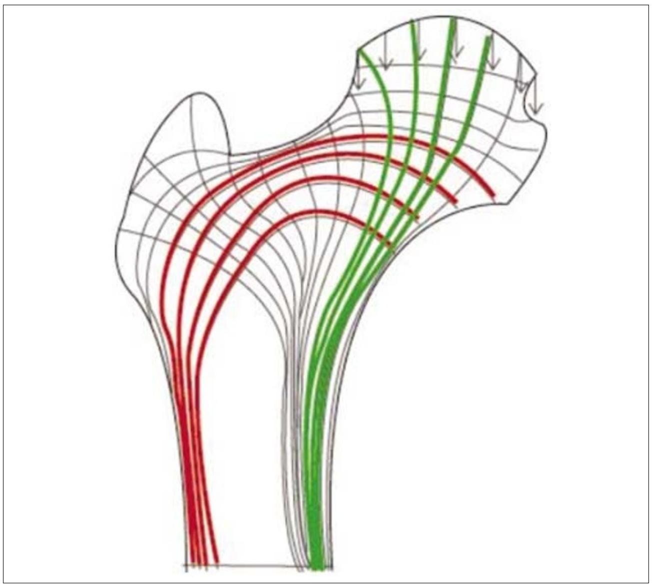

Fig. 1 The classic model of load transmission according to Koch. Compression forces are present on the medial column (*green*) and lateral tension is present on the lateral column (*red*)

region below the greater trochanter were considered of no use for load transfer and consequently ignored in most of the femoral designs.

The first factual reason to question Koch's theories is the histological study of the proximal femur. It is commonly accepted that compressive forces are associated with the formation of cortical bone, and that tension load is associated with areas of cancellous bone. This is commonly referred to as Wolff's law. However, both radiographic and histological analyses of the metaphyseal trabeculae of the medial and lateral regions of the proximal femur show that these two areas are indistinguishable in a normal femur. The bone appears to be disposed in a way which could be explained only accepting that similar, but not necessarily equal, forces act on both the medial and the lateral femur, and that these forces deliver compressive loads. Furthermore, it is evident that dense cortical bone is present along the entire lateral aspect of the femur, from the apophyseal line of the greater trochanter to the epiphyseal line proximal to the knee. The presence of dense cortical bone in the lateral aspect of the femur is by itself, according to Wolff's law, the proof that compressive forces act on the lateral column.

At the beginning of the 1990s, Koch's theory began to be questioned. Fetto and Austin [2] observed that not only the histology of the proximal femur, but also other statements of Koch's theory presented several inconsistencies. The most evident was the estimate of the forces required to maintain the equilibrium of the pelvis during gait. Since he considered that the centre of gravity of the body was in the midline, he calculated that the abductor muscle had to generate twice the force of the body weight to prevent the body from falling toward the unsupported side. The amount of tension applied on the glutei insertion was, according to this model, obviously unreliable. Rybicki [3] measured that, with the Koch model, simple walking would subject the femur to a force equal to 70% of its fatigue strength. The risk of fracture of the greater trochanter would be too high and has no correspondence in clinical practice.

At the beginning of the 1990s, much attention was focused in the attempt to produce a more reliable representation of the stress transfer on the proximal femur during movements. The real innovation was the introduction of the muscular force and its action on the distribution of forces in the femur. Great help came from the use of computer technology [4, 5]. Modern software is able to analyse why a determined tool has to have specific characteristics and shape to withstand determined forces. Similarly, it is able to predict, given the material properties of cortical and cancellous bone and the forces acting upon the femur, the optimal form of the bone. When Fetto and Austin used the parameters of the Koch model, they found that the computer predicted an unnatural shape of the femur with an expanded diaphyseal diameter.

The introduction of the forces generated by the ileotibial band and the vastus lateralis-gluteus medius complex (Fig. 2) create a tension band effect lateral to the femur.

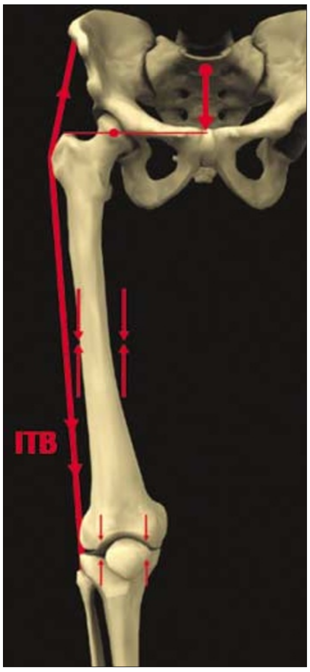

Fig. 2 The tension band effect produced by the ileotibial band (*ITB*) and the vastus lateralis-gluteus medius complex convert the tensile stresses on the lateral femoral column into compression load

This explains how the tensile stresses on the lateral femoral column are converted into compression load [4]. The new evidence of a compression force acting on the lateral femur is consistent with the anatomical evidence of the presence of cortical bone in the lateral column. When we move from theory to practice, this rethinking of the mode of load transfer on the entire proximal femur rather than only on the medial column revolutionizes completely the design requirements for an anatomic uncemented femoral implant.

Rationale for a stemless femoral implant

Once this modern view of load distribution on the proximal femur is accepted, it is clear that changes to implant designs are needed. To take advantage of load transfer function of the lateral proximal femur, an area named “lateral flare”, the shape of the lateral profile of the implants, must change. This region of the prosthesis, previously considered useless, has to deliver load on the lateral femur and so the straight shape in the lateral profile has to be abandoned, and replaced by a lateral protrusion designed to deliver stresses on the lateral flare. Unfortunately, the insertion of an implant with an effective lateral profile results in extensive bone removal from the greater trochanter region to maintain the axial alignment of the stem into the femoral canal (Fig. 3) [6]. The area of the greater trochanter is delicate and is a potential source of persistent pain when it is violated.

Fig. 3 Radiographic follow-up of a conventional lateral flare femoral implant. The insertion of such implants requires extensive removal of bone from the greater trochanter (*white arrow*) and, in spite of that, the lateral shape of the implant is still insufficient to deliver the load on the upper portion of the lateral flare (*grey arrow*)

In our research for a new implant that benefits from all the recent discoveries in hip biomechanics, we arrived to the conclusion that the only way to maintain the lateral flare and avoid greater trochanter damage was removal of the diaphyseal portion of the stem. Jasty et al. in 1993 [7], proved that the diaphyseal portion of the stem became useless once the implant became stable and bone ingrowth had occurred. In our initial idea, we felt that if this was true for a conventional stem, it had to be even more true for a stem which could rely on an extensive lateral flare for initial stability.

The stemless implant that we proposed has a very pronounced lateral flare and a very high femoral neck cut. This design produces a wedging effect between the proximal medial femur and lateral metaphysis, making distal migration of the implant virtually impossible.

Similar implants have already been used in the past. The mechanical advantages of such design have been proved both clinically and with mechanical testing [8, 9]. In 2001 Kim et al. [9] studied with strain-gauge rosettes the reaction of combined axial and torsional loads on human cadaver femora. They compared the results of a conventional reference stem with an experimental stem quite similar to the implant we used. The diameter was markedly reduced distally, the medial part of the proximal stem was more curved and the lateral part of the stem was designed to fit the lateral flare of the femur. They proved that the pattern and magnitude of the strains of the experimental stem were closer to those in the intact femur. Their conclusion was that a more anatomical proximal fit, without a distal stem contact, can provide immediate postoperative stability.

In the research for greatest initial implant stability, we decided to produce a design with a maximun anatomical fit in the proximal femur. Hence the lateral flare is more pronounced than in any other previously popularized implants and the femoral neck is fully preserved to maximize axial and torsional stability (Fig. 4). Whiteside et al. [10] quantified the amount of stability which could be gained preserving the femoral neck. They evaluated with an Instron stress-testing device 20 adult human cadaver femora to determine the effect of different neck-resection levels on torsional resistance of the femoral component. Their study proved that when all of the neck was preserved, torsional load to failure was significantly better than when the neck was damaged. They concluded that, without distal fixation, the femoral component is highly dependent on proximal geometry for resistance to torsional loading.

The new implant that we designed was first implanted in 1994 and was based on the assumption that enough sta-

Fig. 4 Radiograph of hip implant at the 4-year follow-up. The three typical features of the ultrashort implant are: (a) absence of the diaphyseal stem, (b) well defined lateral flare, and (c) total preservation of the femoral neck

bility was possible in the absence of the diaphyseal portion of the stem with a neck preserving technique and a lateral flare implant (Fig. 4). The advantage of the absence of the stem consisted in the possibility to introduce the implant with a curved movement below the greater trochanter that we named “round the corner”.

Clinical experience

An ultra-short custom-made implant with extensive proximal load transfer was implanted in 111 patients for a total of 131 primary total hip replacements from June 1995 to May 2004. Clinical and radiological results of this series have been recently published [11]. All implants were customised based on pre-operative data obtained from conventional radiology. Only in more recent years were some implants produced with CT data. At the time of the operation, the surgeon was given a single customised implant and a single corresponding broach.

Although the shape of the customized implants differed, the same design rationale and philosophy is recognizable. The implants were fully coated with a pronounced lateral flare and a very short diaphyseal stem. The main difference we recognized in reviewing our series was the length of the stem engaging the upper portion of the femoral diaphysis. The maximum extension of the stem below the lesser trochanter never exceeded 3 centimetres in this series. The specifically defined lateral flare was designed to engage the lateral femoral endosteal surface at or above the intersection of the mid-femoral neck axis and the lateral femoral cortex.

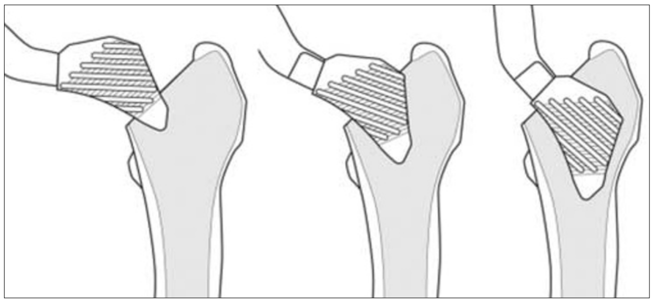

Fig. 5 “Round the corner” technique for femoral broaching and implant insertion

There are few but significant differences in the surgical technique of this implant. Because of the complete absence of the diaphyseal portion of the implant it is possible to achieve femoral broaching and stem insertion with complete respect for the greater trochanter and the glutei insertions. This technique requires that the broach is first inserted and hammered down in varus and then gradually tilted in to the correct alignment whilst progressing down the femoral metaphysis. This curved movement is feasible only with a very short device (Fig. 5).

Average clinical and radiographic follow-up was 5.3 years (range, 3–11 years). Two revision operations for polyethylene liner exchange were performed after 9 and 10 years. The femoral implant was stable and not revised in both cases. None of the other patients required stem or acetabular revision. When we reviewed the postoperative radiographs, we found the customized implant to be oversized compared to our wishes in 29 cases (22.1%).

In 7 cases (5.3%), a proximal femoral crack, never extending more than 2 cm, occurred intraoperatively. Such high rate of intraoperative fractures was caused by the lack of broaches of increasing sizes. These femurs received, nonetheless, the predetermined custom-made implant after metallic cerclage wiring (Fig. 6).

Average pain score using the Harris Hip Score system, at an average of 5 years after surgery, was 42 of 44 points, and 124 hips (95%) caused no or slight pain. The remaining 7 hips caused sporadic pain but these 7 patients stated that the pain did not limit activities of daily living. In 5 of these 7 patients, grades II-III Brooker heterotopic ossifications were present. None of the patients with intraoperative fracture and cerclage wiring had pain at follow-up. Thigh pain was never reported at any of the follow-up evaluations. The average leg length discrepancy was 0.9 cm preoperatively and 0.2 cm postoperatively.

Stem alignment was neutral in 116 femurs (89%), varus in 10 (7.5%), and valgus in 4 (3.3%). Calcar rounding was

Fig. 6 Radiograph of hip implant after 6.5 years. The implant is oversized. A proximal femoral crack occurred intraoperatively during stem insertion without impairing the long-term outcome

Fig. 7 Radiograph of hip implant at 3-year follow-up. Endosteal spot welds bridging the endosteum and the porous surface are visible in Gruen zones 2 and 6 (*white arrowheads*). This has been a common finding in this series

present in 78 femurs (60.1%) and was generally non-progressive 6 months after operation. Resorptive bone remodelling, in Gruen proximal zones [12], was seen in 5 cases of this series and was always associated with over-sizing of the distal stem. These cases with stress shielding were among the first treated in our series. Loss of cortical density, or cortical thinning, was never visible on conventional radiographs.

Endosteal spot welds on two sides of the implant were a common finding. Most commonly, bone bridging the endosteum and a porous surface were found in Gruen zones 2 and 6 (Fig. 7) or in Johnston zones 9 and 13 [13]. Forty-two percent of the implants had spot welds on both sides and another 20% only on the lateral side. This occurrence was more obvious in patients with good bone stock and radiographically undersized implants.

Moderate distal cortical hypertrophy was seen only in one case with an oversized implant. Any radiolucent line around the distal part of the stem was detected. A halo pedestal was present in 12 femurs (9.3%). A shelf pedestal was seen in 4 femurs (3.3%). All implants presenting a pedestal were oversized according to our criteria.

DEXA analysis

With conventional implants a regional redistribution of bone mass from the proximal to distal zones is commonly seen [14, 15]. The loss of proximal femoral bone mass has been traditionally termed “stress shielding” and has been linked to the transfer of loads to the diaphysis and the relative unloading of the proximal femur. It is currently clear that changes in bone mineral density (BMD) are not confined to the first 12 months after surgery [16].

Recently, we published our observations on the DEXA behaviour of 2 different ultra-short custom-made implants with proximal load transfer [17]. Two groups of ten patients were included in this retrospective study. The hypothesis of this study was that the two different designs and extension of coating would produce different courses of bone remodelling that could be detected with DEXA. In the first group (A), implants had a short stem extending 1–3 cm below the lesser trochanter and were fully coated. In the second group (B), implants were stemless, with a polished slender distal tip never extending below the lesser trochanter (Fig. 8).

A blinded and independent observer rated both radiographs and DEXA scans for each patient. The distinctive geometry of this implant and the almost complete absence of the stem, motivated us to modify the conventional subdivision in regions of interest (ROI). The common 7 ROIs reproducing the 7 zones of Gruen [12] have been, in this study, specifically reduced to 5 because of the absence of the stem. In particular, the conventional Gruen zones III and VI have been eliminated and Gruen zone IV became zone III according to our classification.

There were no cases of implant loosening and no thigh pain in both groups. Good contact between the prosthetic lateral flare and calcar and the metaphyseal bone was noted intraoperatively and on the postoperative radiographs in all cases.

Fig. 8 Bilateral total hip replacement. On the right, stem included in group A; on the left, stem included in group B

Table 1 Bone mineral density (BMD) in 5 zones of the hip, in two groups of 10 patients each who received different femoral implants

	R1	R2	R3	R4	R5
Group A	0.738	1.211	1.608	1.285	0.923
Group B	0.822	1.372	1.577	1.570	1.182

DEXA scans were obtained in all patients at the 2-year follow-up. Comparative results of BMD of the 5 ROIs in the two groups are reported in Table 1. A higher BMD was detected in ROIs 1, 2, 4, and 5 in Group B, confirming a preservation of the proximal bone mass and thus indirectly a more proximal load transfer. The single ROIs of the two groups were also compared with the corresponding ROIs of the contralateral femur. In Group B, BMD values in zones 1, 2, 4, and 5 were persistently more similar to the corresponding values of the contralateral healthy hip.

Discussion

In this paper, we presented the philosophy and the clinical experience we have had in the last 13 years with an innovative custom-made ultra-short femoral implant. This experience has lead to the production of a standard stem which is the result of the progressive and increasing confidence that we achieved with the dynamic model of force distribution on the proximal femur.

Computer technologies and a global rethinking of the role of muscular forces have made important contributions to our understanding of load distribution on the lateral femur. This area should no longer be ignored by hip implant designers because of its key role of support upon which a femoral component can rest. The addition of the lateral flare has proved to accomplish not only an increased stability [10] of the femoral implant but also an increased bone mass over time. Walker [6], with a lateral flare implant, demonstrated more than 95% bone preservation in the proximal femur 4 years after surgery.

Similarly, in our DEXA analysis, we found that, with good implant stability, no stem is better than a short stem. Implants included in Group B of our study [17] had an “extreme” design with the diaphyseal stem completely removed and this has shown even a better behaviour than Group A implants where only a very short portion of the stem was maintained. Comparison of BMD in the operated and non-operated sides in Group B was impressive. In all the 5 ROIs, the stemless implant, at the 2-year follow-up, had an almost identical BMD of the non-operated, contralateral side. This model, therefore, reduces the areas of stress concentration in diaphyseal bone and avoids stress shielding of the proximal femur. The effects of muscular forces change the processes of bone modeling and remodeling in the normal femur and an ideal hip substitution cannot ignore them. It is essential for implant design to acknowledge the right importance to the soft tissue factors acting on the hip.

The possibility to have these implants produced on a custom-made basis allowed us to evolve our criteria of implant profile. In the first years of our experience, we employed custom implants with a rather short but still present diaphyseal portion of the stem (Fig. 8). This choice was influenced by our little faith on a totally new

Fig. 9 Radiograph of hip implant after 4.5 years. Good clinical result in an overweight 51-year-old woman. The implant is undersized. Nevertheless, it is stable and endosteal spot welds are visible in Gruen zones 2 and 6

and revolutionary design. Once we realized the extent of the sound stability and good radiographic and DEXA behaviour of this design, we became more and more audacious and the implant became shorter and shorter. In the last years, we also realized that in young patients and in those with a good metaphyseal spongious bone, it is possible to rely on the trabecular bone of the femoral metaphysis for complete load transfer. Undersizing the implant, in presence of good bone quality, is, according to our results, something feasible and attractive (Fig. 9).

Since 2004, this implant is produced as a standard stem and it is currently available in 7 increasing sizes and with a dedicated set of instruments (DePuy, Leeds, UK). The standard implant is similar in shape to the last evolution of the custom-made ultra-short stem. The possibility of proceeding with progressive broaching has produced a dramatic change in the operative time, which is now comparable to that of a standard uncemented implant.

In summary, the geometry of this implant has proved to provide an effective initial stability, which seems to be preserved over time. This model duplicates physiologic loading patterns in the proximal femur, which account for the role of the various soft tissue forces. Adding the lateral flare allows removal of the diaphyseal portion of the implant.

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