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CFP prosthetic stem in mini-invasive total hip arthroplasty

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Abstract Mini-invasive surgery preserves soft tissues and bone as much as possible, in order to minimize surgical trauma and blood loss, and hasten functional recovery. Hip replacement carried out with the CFP prosthetic stem (Waldemar Link, Hamburg, Germany) allows preservation of the femoral neck; furthermore, the implantation can be performed mini-invasively through a small incision. This paper reports the short- and mid-term results of 331 patients (353 implants) who received the cementless CFP stem over a 7-year period. Good or excellent clinical results were obtained in 96.6% of patients, as judged by the Harris hip score at last evaluation. Thigh pain was experienced in the first postoperative year in only 2% of cases. Many patients have taken up amateur sports. Complete integration of the prosthesis occurred in 99% of cases. Radiographic evaluation revealed that bone remodeling was good in 90% of cases; the stress distribution tended to be through the mid-lower third of the stem and toward the lateral cortical bone in the remaining 10%. Stress shielding was infrequent. The results confirm the good performance of the press-fit hemispherical cup and the validity of the biequatorial design.

Key words Arthroplasty · CFP · Hip · Mini-invasive surgery

Introduction

Mini-invasive surgery has played a decisive role in the recent development of cementless hip prostheses for use in conservative hip replacement operations. In the conservative surgical approach, the surgeon removes only those tissues affected by the pathology for which hip replacement is necessary: cartilage, osteophytes, the femoral head and sometimes the synovial membrane are removed, while all healthy tissues are preserved. The bony architecture is preserved as much as possible, especially the cancellous bone, the endosteal circulation, and the mechanical stress distribution systems (essential for subsequent bone remodeling). Thus, the prosthesis is does not replace the joint, but it is inserted into the normal bony architecture and becomes an integral part of it [1].

Following these principles, since 1983 my colleagues and I have opted to preserve the femoral neck during hip arthroplasty, and we have used the Biodynamic biequatorial prosthetic cup (Howmedica, Limerik, Ireland) in order to preserve the acetabular bone [2–7]. The advantages of this approach have been confirmed experimentally and demonstrated clinically: our experience comprises 498 implanted prostheses ([6, 8] and unpublished results), including a long-term follow-up [8].

This experience contributed to the development of the CFP stem and TOP acetabular cup (Waldemar Link, Hamburg, Germany), which were first tested clinically in 1997 (Orthopaedic Clinic, University of Genoa, Italy). Innova-

tions in the design of the stem include longitudinal crests, a mobile rim (neckpiece), and an antetorsion as well as anteversion inclination. The stem is composed of titanium, aluminum and hydroxyapatite, and is available in 20 variations: overall, the stem comes in two different versions that differ in the radius of the curvature, and for each hip 5 stem sizes are available.

The CFP stem derives its name from the fact that it is designed for use in a "collum femoris-preserving" technique, a mini-invasive surgery that preserves and respects as much as possible the joint structure (bone stock and soft tissues). Implantation of the CFP stem involves limited surgical trauma and blood loss, accelerates functional recovery, and offers excellent primary stability [4, 5]. Since the stem does not require cement fixation, it is more easily replaced than cemented prostheses at a future moment, should this be necessary, at least as long as the stem is small. Furthermore, the absence of cement implies that the host bone at the prosthesis-bone interface is in better condition. These considerations provide the rationale for using cementless prostheses in young and active patients who, because of their long life expectancy, are more likely to experience aseptic loosening. Implantation of the CFP stem is mini-invasive because the femoral neck can be exteriorized through a small incision, without exposing the greater trochanter. The TOP cup, named because its design has a "trabecular oriented pattern", is a biequatorial prosthesis that optimizes preservation of the acetabular bone stock, since it does not need deep excavation and has no protrusions; it is inserted in the same orientation as the acetabular bone.

In this paper, I summarize my clinical experience using the CFP stem in total hip arthroplasties performed over a 7-year period at orthopaedics clinics in Genoa and Monza, Italy.

Patients and methods

Between April 1997 and July 2004, a total of 368 patients (22 bilateral) underwent total hip arthroplasty with the CFP stem (collum femoris-preserving stem; Waldemar Link, Hamburg, Germany). The surgeries were performed at the Orthopaedics Clinic of the University of Genoa until 2002 (303 patients), and thereafter at the Policlinico di Monza, in Milan Province, Italy (65 patients). The immediate postoperative and mid-term outcomes of the operations were evaluated on the basis of the clinical records available in December 2002 for patients treated in Genoa and in July 2004 for patients treated in Monza.

The patients were eligible for mini-invasive hip replacement because of the generally good quality of the remaining healthy femoral bone: in particular, they had a structurally intact femoral neck with near-normal inclination. The main issues of mini-invasive surgery are careful treatment of soft tissues, divarication of muscles that do not need to be sectioned, hemostasis to limit blood loss and correct drainage to avoid hematoma formation.

Surgical procedure

Two days before the procedure, patients in Genoa (but not Monza) deposited 1 unit blood. Just prior to the procedure, patients received routine prophylaxis with antibiotics and antithrombotics.

The CFP stem was combined with one of three different prosthetic acetabular cups, all which have biequatorial inserts. The surgical team used the Meròs cup (Gruppo Bioimpianti, Peschiera Borromeo (MI), Italy) in the first 50 operations (before 1998), the Plasmacup SC (Aesculap, Tuttlingen, Germany) in 33 cases, and the TOP hip acetabular cup (Waldemar, Link, Hamburg, Germany) in subsequent 338 operations. The cup was positioned by press-fitting, without screws, in all but two cases: in two patients, the acetabulum was fractured and the cup (one Meròs, one Plasmacup SC) required fixation with screws.

The operations were performed with a transgluteal direct lateral access: the incision was 12–15 cm for patients treated in Genoa, but only 8–10 cm for those treated at Monza. Osteotomy of the femoral neck (Fig. 1) was done at the isthmus (the narrowest straight part), perpendicular to the cervical axis. The distance between the osteotomy and the base of the greater trochanter was generally 1.5 cm (minimum, 1 cm), as this is the distance needed to preserve the femoral neck [9, 10]. The length of the lower limb after surgery was planned preoperatively and carefully checked during the operation, using the musculus gluteus minimus sectioned according to a personal technique (unpublished).

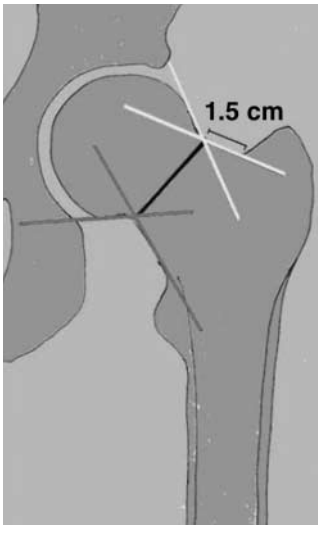

Fig. 1 Osteotomy of the neck of femur was performed at the isthmus, at approximately 1.5 cm from the base of the greater trochanter, perpendicular to the major cervical axis of the neck

Blood loss was limited, on average 150 ml blood intraoperatively and 450 ml postoperatively. Blood from the aspiration drain was reinfused in the first 6 postoperative hours. Transfusion of heterologous blood was necessary for 4% of patients in Genoa and 6% patients in Monza. The need for heterologous blood was not affected by the length of the surgical incision.

Rehabilitation began the day following the operation. Surgical drains were removed on day 2. Partial load bearing was permitted on day 3, and full load bearing was authorized 30 days after surgery.

Clinical and radiographic evaluations

Patients were evaluated in the immediate postoperative period, and then after two months and after 1 year. At each follow-up, patients were evaluated clinically and radiographically. Clinical outcome was evaluated according to the Harris hip scale, in which scores <70 indicate a poor outcome, scores 70–79 refer to a fair outcome, between 80 and 89 indicate a good outcome, and scores <90 refer to an excellent outcome.

Radiographic evaluation used standard anteroposterior and lateral projection radiographs. The immediate postoperative analysis assessed the position of the prosthetic cup as well as the alignment and fit of the stem. Since the prosthetic cups all had biequatorial inserts, the optimal slope at implantation, relative to the horizontal plane, is 55°±5° [2]. Follow-up evaluations assessed the biological response of the bone to the implant, and examined the implant for possible alterations. Heterotopic ossification was classified according to Brooker [11].

The position of the implanted cup, in particular the angle of inclination with respect to the horizontal and the depth of insertion into the acetabulum, was assessed radiographically in the DeLee and Charnley zones [12]. The response of the femoral bone to the implanted stem was evaluated using a modified version of Gruen's zones [13], adapted for the evaluation of the femoral neck after conservative arthroscopic procedures (T. Gruen, personal communication). Zones 1 and 7 were each divided into two parts, a and b: zones 1a and 7a specify the lateral and medial parts of the femoral neck, respectively, while zones 1b and 7b refer to the remaining areas of the original zones 1 and 7. For the purpose of this study, particular attention was given to the quality of bone in the lateral and medial parts of the femoral neck immediately below the rim of the prosthesis.

Results

Mini-invasive total hip arthroplasty using the CFP prosthesis stem was performed over a 7-year period in 368 patients (Table 1). Since the patients were selected for the procedure on the basis of having generally good bone quality and a structurally intact femoral neck, there was an unusually low prevalence of dysplasia among the surgical indications, and the proportion of men was particularly high. The outcome of 331 patients (353 implants) was evaluated at a mean follow-up period from 1 to 7 years; follow-up information was not available for 37 patients.

Table 1 Characteristics of patients who underwent total hip arthroplasty with the CFP stem (Waldemar Link, Hamburg, Germany). A total of 37 patients were lost to follow-up

	Treatment group	Follow-up group
Patients, n	368	331
Implants, n[a]	390	353
Age, years[b]	60	60
Male, n (%)	220 (60)	199 (60)
Diagnosis, (of treated hips %)		
Coxarthrosis	82	80
Necrosis of femoral head	8	8
Coxarthrosis and dysplasia	6	8
Other	4	4
Prosthetic acetabular cup, n		
Meros	50	50
Plasmacup	2	2
TOP	338	301
Follow-up period, years	–	(1–7)

[a]Arthroplasty was performed bilaterally in 22 patients; [b]Values are mean

Clinical outcome

No general intra- or postoperative complications arose; in particular there were no vascular or neural complications, and luxation of the implant did not occur. Local complications included two spiral fractures of the femoral metaphysis and one fracture of the femoral diaphysis at the tip of the stem, two months after surgery. The two metaphysial fractures were treated by cerclage with a Dall-Miles cable or Dall-Miles plate (Styker Italia, Rome, Italy). The diaphysial fracture was due to a weakened external cortex, which resulted from boring the femoral canal (in fact, a contraindication to using the CFP stem). This patient was treated with osteosynthesis and then required reimplantation because of mobilization of the prosthetic stem. One patient developed a deep S. aureus infection responsive to oxacillin; two months after the first operation, the patient underwent one-stage surgery to remove the infected prosthesis and implant a new one.

In the first few postoperative months, 7 patients (2%) complained of thigh pain. This pain resolved within one year in 6 cases. A change in lower limb length less than 1 cm was recorded in 28 cases (8% of treated hips); no limb changed more than 1 cm.

The long-term clinical results, scored on the Harris hip scale, are reported in Table 2. Overall, excellent results were observed at the last clinical evaluation in more than 90% of treated hips, and only 4 poor results were recorded:

- The patient with S. aureus infection who required reimplantation
- The patient with diaphysis fracture at the tip of the stem, who also underwent reimplantation
- The patient who experienced persistent thigh pain, and
- One patient with progressive, massive detachment of the stem, several months after surgery. Two months after surgery, this patient was diagnosed with gastric carcinoma.

96% of the patients returned to a full normal lifestyle and were also able to take up sports (e.g. tennis, golf, cycling, walking) again at a good amateur level (12%).

Table 2 Clinical result at last follow-up, for 353 hip prostheses in 331 patients

Clinical result	Harris hip score	Implants, n (%)
Excellent	90–100	321 (90.9)
Good	80–89	20 (5.7)
Fair	70–79	8 (2.3)
Poor	<70	4 (1.1)

Immediate postoperative radiographic analysis

In the immediate postoperative period, the cup slope was <50° in 18 cases (5%), 50°–60° in 353 treated hips (92%) and >60° in 11 cases (3%). The cup sat correctly in the cotyloid cavity in 342 cases (97%), indicating preservation of the subchondral spongy lamina. The position of the cup in 4 cases (1%) was too deep, while in 7 (2%) it was too shallow and protruded over the edge of the acetabulum. A small gap beneath the prosthetic rim was seen in 2 cases (0.5%).

The stem was correctly aligned in 332 cases (94%), while it was aligned in varus or valgus in 18 cases (5%) and 3 cases (1%), respectively. The stem size was correct in 328 treated hips (93%); the stem was oversized in 14 cases (4%) and undersized in 11 (3%).

Radiographic outcome at mid-term

Over the follow-up period, the implanted cups did not detach, migrate or mobilize, and none presented osteolysis or radiolucent lines.

Regarding the prosthetic stem, we observed 2 cases of aseptic loosening in which the bone-prosthesis contacts degenerated and were replaced by fibrous tissue. Radiographically, this process was revealed by radiolucent lines, indicative of stress shielding. Integration of the implanted stem into the bone was generally good in the remaining 351 cases (99%).

Bone remodeling around the stem was good in 316 (90%) of these 351 cases, and there was no resorption at the femoral neck (Fig. 2). The intra-trochanteric metaphysial region had a uniform structure, and the cortical layers below the tip of the stem were of equal thickness, the same as in the contralateral femur. This radiographic pattern was observed even in the cases of undersized but properly aligned stems. However, in 63 of these 316 cases (20%), spot-welds were detected in the mid-lower third of the stem (zones 2, 3, 5 and 6), there was some evidence of stress shielding (radiolucent lines) and the external cortex in zone 3 appeared thickened (Fig. 3).

In the remaining 35 cases (10%), there was radiographic evidence of altered bone remodeling. Resorption at the prosthetic rim, resembling a rounded off-spur <3 mm (Fig. 4), was found in 21 cases: at the lateral part of the femoral neck below the rim in 10 cases, at the medial part in 5 cases, and in both zones in 6 cases. In 16 cases had evidence of a small gap beneath the prosthetic rim at the immediate postoperative radiograph. Radiographs of five treated hips had evidence of a line in Gruen's zones 1a and 1b; in one case in which the stem was undersized

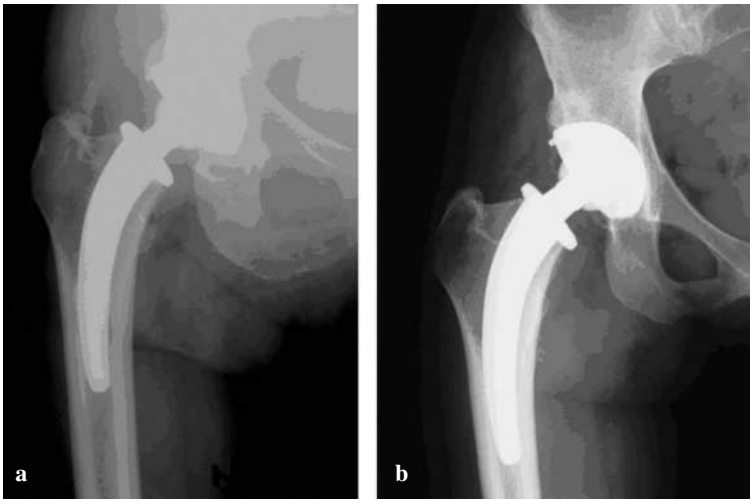

Fig. 2a-b *Good bone remodeling seen on anteroposterior radiographs of different patients who underwent total hip arthroplasty with the Link CFP stem.* **a** Follow-up at 4 years. **b** Follow-up at 5 years

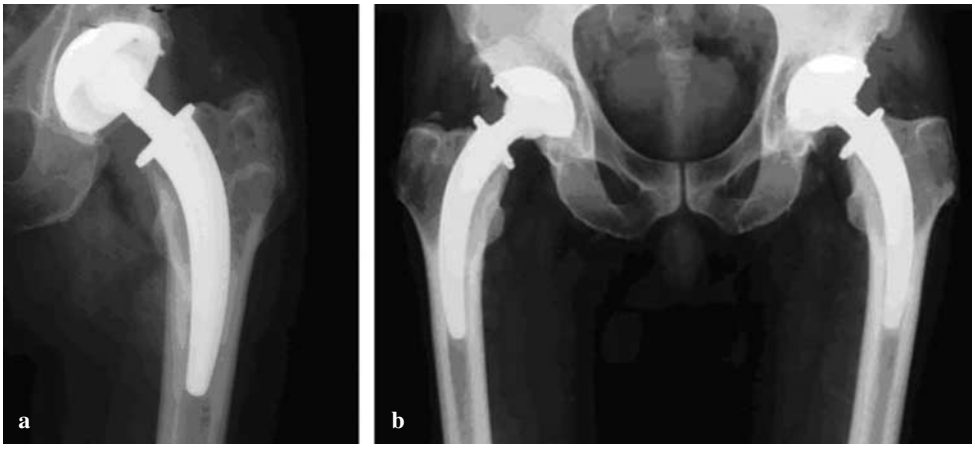

Fig. 3a, b *Bone remodeling characterized by spot-welds, mostly in the mid-lower third of the stem, and cortical thickening, especially in Gruen's zone 3.* **a** Follow-up of a patient at 1.5 years. **b** Radiograph of a patient who underwent arthroplasty bilaterally: 3 years after surgery of the right hip and 1 year after that of the left hip

Fig. 4 Bone resorption at the prosthetic rim in the lateral and medial parts of the femoral neck, resembling a rounded-off spur, seen at the 6-month follow-up. In this patient, the stem is slightly oversized. The fact that the rim was not resting properly was apparent even at the immediate postoperative radiograph

and in varus, this line extended into zone 2. One case had a radiographic "bridge" in zone 4. Stress shielding was associated with bone resorption in both lateral and medial parts of the femoral neck below the rim, and with demarcation lines; this was mostly seen in the 11 cases in which the stem was oversized.

Heterotopic ossification was observed in 155 (44%) of 353 treated hips. According to Brooker's classification, ossification was grade I in 106 cases (30%), grade II in 28 cases (8%) and grade III in 21 cases (6%); no case of grade IV ossification was recorded. Ossification was observed on the greater trochanter close to the insertion of the musculi gluteus minimus and vastus lateralis, where the muscles converge with the periostium.

Discussion

Hip replacement with preservation of the femoral neck re-establishes the natural off-set, restores the hip to its natural equilibrium, and balances the tension of the medial and pelvitrochanteric muscles; it also minimizes transarticular stress [14]. The mini-invasive surgical approach to total hip arthroplasty – like that used for the patients described in this paper – makes an important contribution toward a good clinical outcome: at the long-term follow-up of 331 patients, functional recovery was good or excellent in 96.6% of the 353 treated hips. The mini-invasive surgical procedure was partly responsible for the absence of intraoperative complications (e.g. vascular and neural lesions) and for avoidance of luxation of the prosthesis in the immediate postoperative period.

The prosthetic hip showed good mobility. In no cases did the length of the treated limb change more than 1 cm, whereas this was a problem when the Biodynamic stem was used [4]. The prevalence of thigh pain was low (2%) in the first postoperative year, as expected for cementless prostheses; this finding indicates that the prosthesis was stable shortly after insertion, and that it permitted correct stress distribution during the bone remodeling process. The prosthetic cup was stable, even though it was implanted without screws (in most cases). Both clinical and radiographic findings confirmed that cementless, press-fit hemispherical cups are valid prostheses. Since the biequatorial cup requires little excavation of bone for implantation, it has a low risk of impingement and luxation. The ceramic materials of the prosthetic head minimized the formation of debris, which may explain the absence of osteolysis in this series.

One discouraging finding was the high percentage (44%) of treated hips exhibiting heterotopic ossification of grades I-III (but no grade IV ossification). To overcome this risk, we are now experimenting with a minimized version of the Watson-Jones method. Furthermore, we currently prescribe indomethacin to prevent heterotopic ossification (the patients reported in this paper did not receive any pharmacological or actinic prophylaxis against ossification).

An interesting observation from this large series is that a good long-term outcome is possible in cases in which the stem is undersized yet well aligned (provided that it is not too small). An oversized stem, however, may accentuate stress shielding.

Preserving the femoral neck during arthroplasty and maintaining a correct off-set reduce mechanical stress at the hip, and therefore lead to reduced prosthetic wear and debris formation. Use of the biequatorial acetabular insert, which provides contact area with the prosthetic head, is also advantageous in minimizing wear of the polyethylene liner, since it brings the edge closer to the horizontal (35°±5°). The CFP stem, when implanted in a mini-invasive technique, allows for good femoral bone remodeling, with restoration of the cancellous metaphyseal structure and the normal cortical thickness even below the stem tip, as demonstrated by radiographic evaluation. The observations of spot-welds in the mid-lower third of the stem, of bone resorption in the lateral part of the femoral neck below the prosthetic rim, and cortical thickening in Gruen's zone 3, observed in 10% of cases, indicate that there is a certain tendency for mechanical stress to distribute toward the external cortex at the mid-lower third, as predicted by our earlier analysis [15].

The clinical and radiographic outcomes of 353 total hip arthroplasties demonstrate that the CFP prosthetic stem is particularly indicated for use in mini-invasive surgeries with the scope of preserving the femoral neck. The stem is easy to implant within the context of a mini-invasive approach. The mid-term results with the CFP stem, like the long-term results with the Biodynamic stem [8], confirm the validity of the femoral neck-preserving approach.

Acknowledgments Development of the femoral neck-preserving approach was done in collaboration with P.M. Calderale, who also participated, with engineer A. Keller, in designing the CFP stem at Waldemar Link, Hamburg, Germany.

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