J Orthopaed Traumatol (2007) 8:117–122
DOI 10.1007/s10195-007-0164-y

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Duofit total hip arthroplasty: a medium- to long-term clinical and radiographic evaluation

Received: 27 July 2006
Accepted: 1 February 2007
Published online: 11 May 2007

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Abstract We report the retrospective analysis of 716 cases of Duofit total hip arthroplasty performed from 1994 to 2005. Since 2004, both standard and lateralized stems were used, while previously only the standard type was available. The results show a low occurrence of complications and a good medium- to long-term survival. The good functional outcome, measured with the Harris hip score, confirms the validity of the prosthetic design and materials.

Key words Hip • Arthroplasty • Offset • Lever arm • Duofit

Introduction

Total hip arthroplasty (THA) is an established procedure for the treatment of coxarthrosis and many other pathologies. Factors important for the functional success and duration of the implant are:
- Stem stability (particularly regarding rotation)
- Cup stability
- Wear of materials
- Reconstruction of the rotational center.

To focus on one of the critical issues is an excellent strategy to isolate the variables and have precise scientific information. However, in order to maximize the general clinical performance, all the critical issues should be addressed.

The stability of both the cup and the stem, where most of the possible problems converge as primary failure mode, is the result of many synergic factors. As far as the primary mechanical stability of a non-cemented system is concerned, geometry and press-fit are the key parameters, while porosity, material and surface treatment affect the osteointegration and, therefore, the medium- to long-term stability. The wear of material is an even more complex problem. It not only can affect the long-term stability of the implant, but also may cause postoperative complications (e.g. metallosis, periprosthetic inflammation).

In recent times, the interest in femoral offset has increased [1–6, 19, 21–23], due to the many positive implications that a careful evaluation of this parameter may have on important issues such as wear of materials [7, 8, 16, 17], dislocation rate [9], range of motion (ROM) [10, 18], especially in abduction, and length restoration [4, 14].

The choice of the total hip replacement (THR) system should take into consideration the previously mentioned factors.

The Duofit (SAMO, Bologna, Italy) THR system used in this study is a press-fit titanium alloy (Ti6Al4V) straight stem with a proximal vacuum plasma-sprayed layer of pure titanium (RTT300), coupled with a press-fit titanium alloy cup, coated with a similar porous layer of pure titanium. In this study, we retrospectively reviewed the clinical and radiological results obtained with this system over 11 years of use (1994–2005).

Materials and methods

Between 1994 and 2005, we performed 716 THAs in 648 patients with the Duofit non-cemented prosthesis. Patients were clinically and radiologically controlled, with a mean 5-year follow-up (range, 1–12 years). Until 2004, all the 512 stems were

Table 1 Clinical characteristics of 648 patients who underwent unilateral (*n*=580) or bilateral (*n*=68) total hip arthroplasty between 1994 and 2005 with the Duofit prosthesis

Age, years[a]	67 (36–93)
Men, *n* (%)	246 (37.96)
Anatomic CCD angle[b]	128° (10º)
Anatomic offset, mm[b]	42 (7)
Concurrent pathologies, no. of hips	
Hypertension	50
Diabetes	115
Cardiac disease	29
Cerebral vascular disease	4
Respiratory disease	86
Main diagnosis, no. of hips	
Primary coxarthrosis	430
Perthes outcome	7
Post-traumatic necrosis	64
LCA outcome	50
Femoral neck fracture	165
Peroperative complications, *n*	
Calcar fracture	4
Femoral diaphysis	0
Local post-operative complications, *n*	
Early infection	10
Hematoma	11
SPE paralysis	1
Thrombophlebitis	25
Dislocations within 3 months	22
Dislocations after 3 months	3
General post-operative complications, *n*	
Pulmonary embolism	2
Severe anemia	14
Myocardial infarction	4
Autologous transfusions, units[b]	1 (?)

[a] Values are mean (range); [b] Values are mean (SD)
LCA, Lussazione Congenita dell'Anca (HIP Congenital Dislocation); *SPE*, Sciatico Popliteo Esterno (External Popliteal Sciatic)

standard; since 2004, after introduction of the lateralized design, 108 stems were standard and 96 were lateralized. The characteristics of the sample are shown in Table 1.

Duofit prosthesis

The Duofit stem is a straight, non-cemented stem of titanium alloy (Ti6Al4V). The proximal part has a vacuum plasma spray coating of pure titanium (RTT300). The 300-µm coating presents an average porosity of 30% with an average pore dimension of 60 µm. The stem has an ovoid proximal section that becomes elliptical in the distal part (Fig. 1). The CCD angle is 135° in the standard version and 125° in the offset version. The stem is available in 8 sizes, ranging from 115 to 165 mm length. Offset and vertical drops of stem vary according to the combination of stem size and CCD angle.

The cups present the same coating as the stems, with or without lateral stabilizing wings. The axial section is elliptic, in order to obtain the best press fit. All the models are provided with two or three blunt-edged holes for the screws, with diameters ranging from 44 to 70 mm.

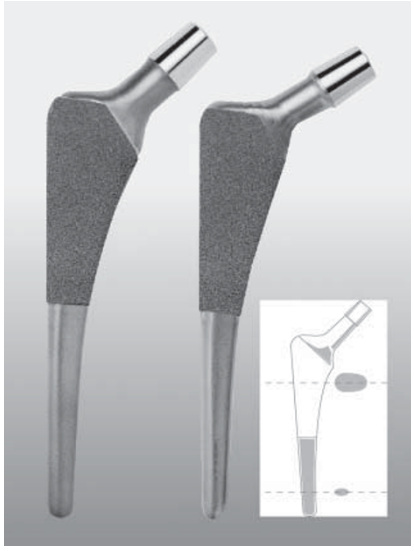

Fig. 1 Standard and offset Duofit models. *Insert*, proximal and distal sections

The articular heads we used are made of Co-Cr-Mo alloy, high nitrogen degree, stainless steel, or ceramic (Table 2). The metallic heads have 5 different lengths of the Morse cone housing, allowing a fine regulation of the position of the centre of rotation within a range of 14.5 mm, and a diameter of 28 mm. The ceramic heads are available in 3 sizes with a diameter of 28 mm and in 3 sizes with a diameter of 32 mm, all of them with 3 different neck lengths.

Surgical procedure and follow-up

The surgical approach was straight lateral according to Hardinge [11]. Anti-thromboembolic prophylaxis started the evening before surgery with low molecular weight heparin (LMWH) and was continued for 30–40 days. The post-surgical course foresaw some active movements of the lower limbs starting the first day, the use of a spanner pillow and immediate load. Patients were clinically and radiologically investigated before surgery, after surgery and for up to 11 years using the Harris hip score and evaluating the stem position and the presence of spot welds, heterotopic ossification, and radiolucent lines.

Table 2 Material couplings for Duofit inserts and heads

Material	Hips, *n* (%)
Ceramic/Ceramic	372 (52)
Ceramic/UHMWPE	215 (30)
Metal/UHMWPE	129 (18)

UHMPE, ultra-high molecular weight polyethylene

Table 3 Data comparison between Standard and Lateralised models

	Standard stem	Lateralized stem
Patients, *n*	557	91
Leg-lenght discrepancy, mean (SD)	8 (0.5)	4 (0.3)
ROM, mean (SD)		
Abduction	40° (3°)	43° (4°)
Adduction	26° (2°)	28° (3°)
Ability to walk 2 km (within 3 months), *n* (%)	43 (7.7)	10 (11)
Step-after-step stair climbing without tutor (within 3 months), *n* (%)	29 (5.2)	8 (8.8)
Early dislocations, %	25	0

Results

No cases of thigh pain were recorded. Rehabilitation was easy and successful in most cases. Passive motion, one month after surgery, was good and painless. The average Harris hip score increased from 28.8 to 94.6 six months after surgery. A poor result (<70 points) was obtained in 15 hips (2.1%) while good (70–89 points) and very good (≥90 points) results were achieved in 701 cases (97.9%). Two cases of aseptic mobilization were recorded, both associated with nickel allergy. There were 10 cases of infection (1.5%) of which 3 were deep and 7 were superficial. There were 22 cases of early dislocation (within 3 months) and 3 cases of late dislocation. Radiographic controls, performed 6, 12, and 24 months after surgery and up to 11 years of follow-up, showed 8 cases of radiolucency around the stem and none around the cup.

When the lateralized stem was used, we observed an interesting improvement in some clinical findings (Table 3), such as smaller leg-lenght discrepancy, greater ROM, earlier functional recovery, and lower rate of early dislocation. However, the small size of the sample does not allow any statistical inference.

Discussion

As stated earlier, the relevant factors for the functional success and duration of an implant are stem stability, cup stability, the wear of materials and the reconstruction of the rotational center, with a high degree of correlation among these factors.

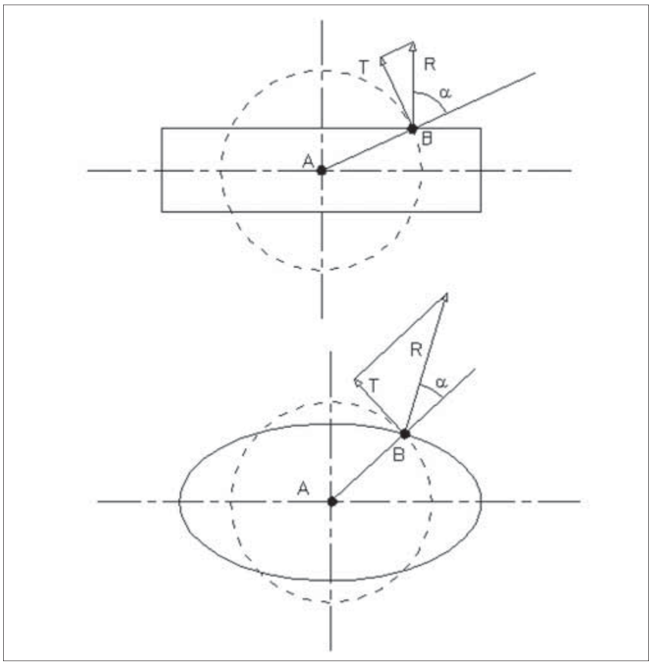

Fig. 2 Angle of opposition to rotation of the stem

The rotational stability of the implant is mainly determined by its geometry, and namely by the shape of the section orthogonal to the stem axis (Fig. 2). The angle of opposition to the rotation of the stem is the angle α between the vector of the reaction forces *R* in the point *B* of the section and the line from *B* to the centre of rotation *A*. Neglecting the friction forces, the reaction forces at the surface of the stem are perpendicular to the surface by definition. Thus, as α increases, *T* (the efficient component of *R*) increases accordingly. Considering only the kinds of shapes viable to our purposes, in presence of equal *T* components, the rectangular one gives the smallest *R*, thus allowing a minimum stress on the bone structure; however, it determines a concentration of stresses on the corner. On the other hand, a circular section opposes no resistance to the rotational motion, thus generating no concentration of stresses at the bone-implant interface.

A compromise is the ellipse shape (Fig. 2), which ensures a reliable resistance to the rotational motion and an optimal distribution of stresses at the bone-plant interface.

Matching the elliptical with the wedge shape, which increases the transversal stability, the ovoid shape is obtained (Fig. 3). As shown in Figure 1, the Duofit stem has an ovoidal shape in the cross section and a wedge shape in the axial section, which can maximize the stability in both directions. Also in the case of the cup, geometry is a critical factor to obtain a good press fit and a good primary stability. A hemispherical shape tends actually to interfere with the acetabular bone in the polar zone of the

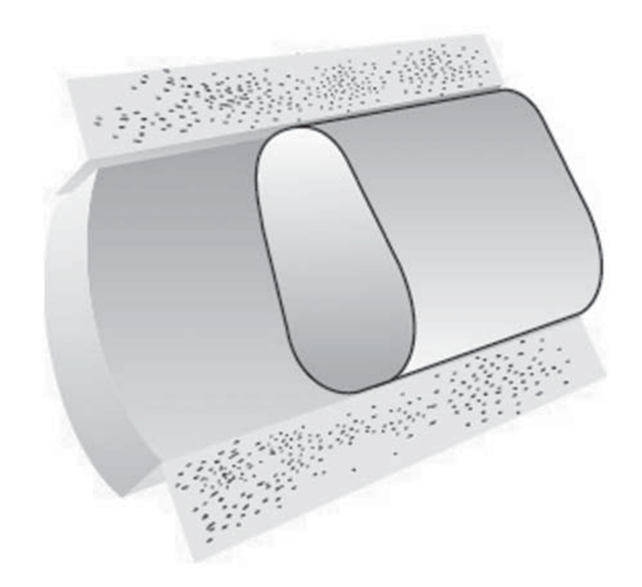

Fig. 3 Ovoid section of a stem

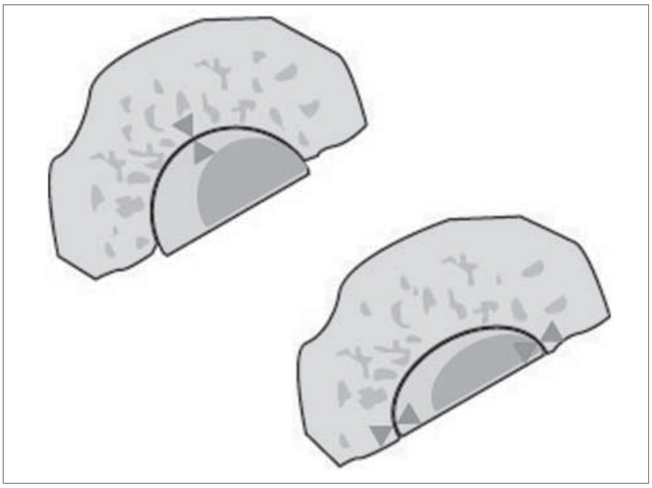

Fig. 4 Design of the prosthetic cup

cup itself. This may prevent the complete insertion of the cup in the acetabulum, resulting in a poor mechanical stability of the implant (Fig. 4). On the contrary, an elliptical shape of the axial section of the cup (as with the Duofit cups) ensures its full insertion in the acetabulum; the mechanic contact with the bone is equatorial (instead of polar), allowing a much stronger primary stability.

When it was not possible to obtain a sound press fit, due for instance to dysplasia or osteoporosis, the winged cup or the screw fixation of the standard cup turned out to be effective solutions.

The wear of materials is one of the main causes of failure in the hip arthroplasty implants. Wear effects occur primarily at the head/insert and cup/insert interfaces. Beside the nature of the materials employed, studies have shown that the most influencing factor in the wear mechanism is the femoral offset [7, 8, 12].

Let's consider the following three definitions (Fig. 5):

1. The *center column diaphysis* (CCD) angle is the angle between the diaphysial axis and the femoral neck axis;
2. The *femoral offset* is the distance between the femur diaphysal axis and the center of the joint.
3. The *lever arm* of the abductor muscles is the distance between the tangent to the greater trochanter and the center of the joint [13, 20].

The femoral offset directly affects the lever arm of the abductor muscles, and the wear rate consequently. In the monopodalic standing, in fact (Fig. 6), the center of gravity moves towards the hanging leg, and the momentum on the femoral head of the body weight force is balanced by the abductor muscles, which lever arm PF is much smaller than that of the body weight FR. Therefore, in order to

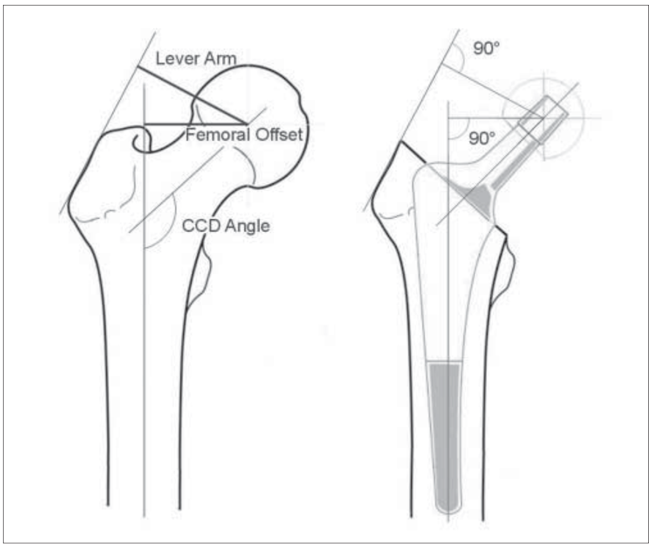

Fig. 5 Femoral offset and lever arm

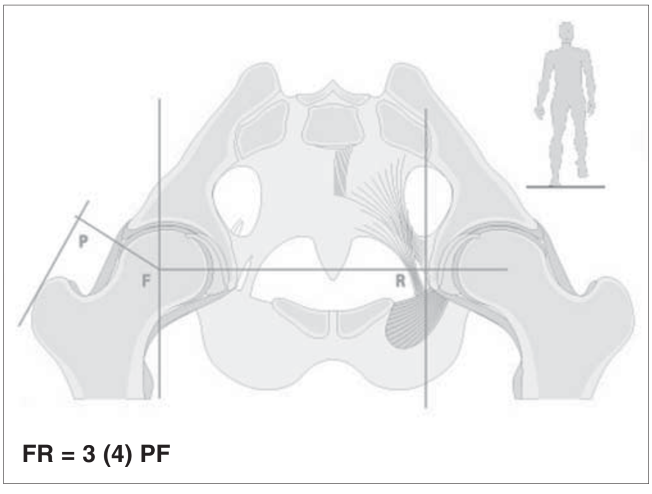

Fig. 6 Momentum of the abductor force and the body weight force

keep the balance, the muscular force must be a multiple of the body weight. Eventually, the combined effect of the muscles and the body weight results in a composite force, which is about four times the body weight. It is evident that, if the abductor lever arm FR increases, the force of the abductors, which is needed to balance, decreases accordingly, with positive effects against the wear of the materials at the joint [7, 24, 25].

Sakalkale et al. studied 17 patients with side-by-side prostheses [7] and 66 patients with single prostheses [8], using standard (135°) and lateralized (125°) stems; the average linear wear rate was 0.10 mm/year for lateralized stems (group I) and 0.21 mm/year for standard stems (group II) [7]; 0.10 mm/year for closely reconstructed offset (group I) and 0.26 mm/year for reduced offsets (group II) [8]. The Harris hip score improved from 33 to 87 for group I and from 34 to 88 for group II, while the failure rate, due to aseptic mobilization induced by polyethylene debris in all cases, was 2.5% in group I and 8.6% in group II [8].

At a fixed vertical drop, a poor reconstruction of the offset implies a laxity of the soft tissues that, along with a misplacement of the implant, the impingement of the osteophytes and the hyperactivity of the patient, is one of the possible causes of an early luxation. Many authors [1, 2] studied the value of the anatomic offset. Massin et al. [1] reported a mean offset of 41 mm (SD=6 mm) in 200 cases, while Noble et al. [2] observed a mean offset of 43 mm (SD=7 mm) in 100 cases. These considerations led to the development of lateralized stems with CCD angles of 125°, like the Duofit lateralized stem used in this study.

In the pathological hip, characterized by an alteration of the joint geometry, there is a natural proclivity to the medialization of the femur that the prosthetic implant must correct in order to enhance the tension and the efficiency of muscles.

This correction can be obtained by means of technical expedients or particular prosthetic stems that allow recovering the correct inclination and length of the natural healthy femur neck, the femoral offset and the muscles lever-arm.

The reported series seems to show that the Duofit THA is an effective and versatile prosthetic system, capable of good medium- to long-term survival and of fine restoration of the hip geometry thanks to the availability of both standard and extended offset stems. Even if the extended offset stem seems to be associated with faster functional recovery, further investigations are needed to completely assess the eventual advantages.

Disclosure of conflicts of interest No one of the authors has been funded or rewarded by SAMO for this study.

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