Proximal cement fixation in total hip arthroplasty—first results with a new stem design

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Abstract Stem loosening and stress-shielding are problems encountered in cemented hip arthroplasty. Could proximal stem fixation by partial cementing solve the problem? More physiological transmission of forces with only proximal cement fixation seems to be possible with this recent development (Z-stem, Option 3000, Mathys Orthopaedics, Bettlach, Switzerland). In a prospective clinical trial, this new implant was used for total hip arthroplasty in human patients. One hundred and thirty-three (133) total hip replacements in 123 patients were performed between April 1996 and January 2003. All of them were followed up regularly; 53 were analysed with the EBRA-FCA method (Einzel Bild Röntgen Analyse—femoral component analysis), whereas the rest were analysed using conventional follow-up X-rays. Eighty-six (86) patients with 95 hips could be examined in August 2004 to obtain mid-term results. At this stage, the mean follow-up time was 61 months (5.08 years), with a maximum of 100 months (8.33 years). Up to October 2004, nine cases needed a revision. The clinical data collected reported an average Harris Hip Score of 89.3 (good). The EBRA-FCA analysis reported a mean subsidence of less than 1.5 mm after the first two years, under the EBRA threshold of predicted loosening. At the latest follow-up (at an average of 61 months), there was an average stable subsidence of 2.4 mm in general. Eight (8) patients presented with

subsidence of more than 5 mm. The results of the new implant seem to be encouraging. Finally, comparing our results to other fixation concepts will require longer follow-up periods.

Résumé Le descellement fémoral et le « stress-shielding » sont des problèmes fréquemment rencontrés dans les prothèses totales de hanche cimentées. Est-ce qu'une cimentation partielle proximale de la tige peut résoudre ce problème ? Une transmission plus physiologique des contraintes exercées simplement sur la fixation proximale cimentée est possible avec le développement récent de la prothèse Z-stem Option 3000, de chez Mathys Orthopaedics. Lors d'une étude prospective, ce nouvel implant a été utilisé chez l'homme. 133 prothèses totales de hanche sur 123 patients ont été réalisées entre Avril 1993 et Janvier 2003. Tous ces patients ont été suivis régulièrement. 53 ont bénéficié d'une étude avec la méthode EBRA - FCA, le reste des patients a été analysé selon des méthodes conventionnelles, avec suivi radiologique. 86 patients sur 95 hanches ont été examinés en Août 2004 pour une évaluation à moyen terme. Le suivi moyen de cette étude a été de 61 mois (5,08 ans) avec un maximum de 100 mois (8,33 ans). Depuis Octobre 2004 9 cas ont nécessité une révision. Les données cliniques nous indiquent un score moyen de Harris de 89,3 (bon). L'étude par la méthode EBRA indique qu'il existe un petit enfoncement de la pièce fémorale inférieure de 1,5 mm après deux ans d'implantation. Un plus long suivi (61 mois) montre qu'il existe un enfoncement moyen de 2,4 mm et 8 patients ont présenté un enfoncement de plus de 5 mm. Les résultats de ce nouvel implant sont encourageants. Il nous semble nécessaire de comparer ce nouvel implant avec d'autres fixations et avec un plus long suivi.

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Introduction

In hip arthroplasty, the transmission of forces acting on the femoral head to the shaft take place through the trabecular system of the proximal femur [4, 9, 11]. After stem implantation, there is a redistribution of forces, with relief of the bone in the region of the stem. This relief leads to bone remodelling or bone loss [9, 15, 16, 17, 21]. Atrophy, which often takes place in the proximal part of the femur when prosthetic stems are anchored distally, is an expression of this unphysiological transmission of forces and bone adaptation. This could result in stress-shielding and, ultimately, loosening. In uncemented hip arthroplasty, this atrophy, along with distal stem buttressing, leads to swinging of the stem proximally and, thus, to subsequent loosening that is often described clinically [23]. Proximal transmission of force thus seems more physiological and is achieved with a few cementless stems by an appropriate design [13, 25]. With cemented stems, the load is transmitted over the entire length of the stem. With a new developed partially cemented prosthetic stem (Option 3000, Mathys Orthopaedics, Bettlach, Switzerland), it has been possible, for the first time, to combine the proximal transmission of force with cement fixation [9]. The stem, which can be anchored in the proximal femur using the press-fit technique, is partially cemented in this region only after the definitive implantation of the stem, and the uncemented polished distal end of the stem is very slender. This part of the stem takes over the function of alignment, and tight fixation in the diaphyseal section of the femur is not necessary. Compared to a conventionally cemented stem, biomechanical testing showed that the parameters of primary stability with regards to interface movement were similar or even better [4, 7, 9].

In this clinical prospective study, 123 patients were treated with 133 of these new stems. As we were, well aware of the problems with fully cemented stems in hip arthroplasty, the study was designed to detect whether this new implant can reduce both loosening and subsidence and ameliorate clinical outcome.

Materials and methods

Implant design

The development concept of the new partially cemented stem (Z-shaft, Option 3000, Mathys Orthopaedics, Bettlach, Switzerland) is oriented to the physiological distribution of forces.

The aim was to obtain a durable result of total hip replacement, possibly free from thigh pain, and with a good primary and secondary stability. It was attempted to reduce the stiffening of the proximal femur, maintaining sufficient

resistance and stability, in order to minimise the effect of stress-shielding of the bone.

According to several authors [22], who claim that the part of the cancellous anchorage has to assure a good durable secondary stability, the operation technique is conceived to reduce bone damage.

The shaft is made of austenite steel highly alloyed with nitrogen (FeCrNiMnMoNbN; ISO 5832-9) and is shown in Fig. 1. The stem is modular (stem with inserted head), with a standard diameter of the limb joint of 28 mm. Thus, the stem can be combined with other products.

The stem exists in three sizes:

- Size 1: 160.5 mm length/57.3 mm diameter
- Size 3: 170.1 mm length/59.7 mm diameter
- Size 5: 179.1 mm length/62.1 mm diameter

In the case of cemented total hip replacement, stress is transmitted on the total length of the shaft. The advantage of a cementless total hip can be seen by the stress being transmitted mainly at the proximal part of the femur, as in a physiological system. Biomechanical tests prove that there

Fig. 1 Z-shaft stem

is an equal primary stability compared with totally cemented as well as uncemented stems [4, 9, 12, 14].

The prosthesis is partially cemented, so it can be used in those patients whose bone quality is not sufficient to obtain a sure primary stability through press-fit. Functionally, the stem can be divided in two sections along its axle: a proximal part for the load transmission and a distal part for stabilisation.

This proximal part, where the forces are transmitted, consists of a cranial press-fit region and, below this, of a cemented region. The cemented region is recognisable on the implant because of its deepening form. This circular deepening is filled with the cement through a long, straight, introductory stream, which exists on the ventral and dorsal side. With the help of openings (like blowholes) the flow of the cement forms a homogeneous mantel (Fig. 2), closed on the entire circumference and penetrating through the cancellous bone. The transmission of forces was studied [9] to act through the cemented fixing and the medial support (at the Shenton's arch). When the medial support is missing, the cement has to carry all of the load. Additionally, there can be advantages resulting from the limitation of the cement to the proximal zone:

- Absence of cement in the region with critical tensions, at the terminal part of the distal stem. Normally in this region, shearing forces on the stem–cement interface with loosening takes place.
- Reduction of the thickness of the proximal cemented mantel to 2–5 mm. Through the design of the volume

Fig. 2 Stem implantation and principle of proximal cementation

on the proximal femur, it is possible to achieve a thin mantel.

- Transmission of load to the bone in a proper zone better suited to receive stress as in the proximal femur region.
- Protection of distal bone in the case of a revision. A limitation of the cement at the proximal region of the implant is that it does not load the distal bone, but it facilitates the explantation and simplifies femur preparation for revision.
- Minimisation of intramedullary pressure during stem implantation could be proved when compared to other stems, reducing the risk of intraoperative fat cell pulmonary embolism [4].

The stabilising distal part has a long and thin form. It has to give stability to the implant during the twisting moment. According to the flexion of the femur, the region of stress has a different extension. Through the cortical medial adaptation, a lever with two supported points is generated. The reduced stiffness of the implant in the distal zone prevents or minimises the movements between the implant and the bone. Reduced stiffness permits a degree of elasticity in the distal femoral marrow.

The following indications were used for implantation of the stem (study protocol): coxarthrosis, hip dysplasia, rheumatoid arthritis, femoral head necrosis, femoral neck and head fracture.

Contraindications for this prosthesis were: unfavourable femoral morphologies; significant osteoporosis; revision with vast, metaphyseal bone defect (insufficient stabilisation of the proximal rotation of the implant); extreme proximal marrow enlargement, when the “marrow space” is formed in such a way that the prosthesis contacts the Shenton's arch proximally medially not more than 1/3rd of the length of the prosthesis distally. In these cases, there would be danger of locally excessive stress.

Implantation technique

In this study, the joint was exposed through Bauer's lateral transgluteal approach [2, 3]. The stem size, like the resection level in the femoral neck, was determined preoperatively using templates. After resection of the femoral neck, preserving the greater and lesser trochanters, the medullary cavity is reamed by hand using a two-stage cutting reamer along the axis of opening (longitudinal axis of the femur). The opening is then advanced with a conical reamer to beyond the tip of the greater trochanter and, with a box chisel, space is created for the shoulder of the stem in the greater trochanter. Then, shaping rasps are used in increasing size to widen the proximal femur up to the selected implant size. When the selected implant size is

reached, the handle on the shaping rasp is removed and a head of medium length is attached to the shaping rasp, initially according to the intraoperative tension and depth of insertion, and trial reduction is performed. If the test reduction result is satisfactory after image intensifier control, the shaping rasp is replaced by the final stem and optimal press-fit is achieved. This is followed by partial cementing, which is done in all cases with conventional bone cement using a special cartridge (Palacos, Merck, Darmstadt, Germany).

Clinical and radiological data

In a prospective clinical study under the rules of the ethics committee, 133 Z-shafts were implanted in 123 patients between April 1996 and January 2003. As there are many clinical trials with the results of fully cemented and non-cemented femoral stems for general discussion, a control group was not included in this study phase. The combination of components (Z-shaft size, cup and head material and size) were matched to the individual needs of every patient and indication, within the guideline combinations allowed by the study protocol. Indications and contraindications for total hip arthroplasty using Z-shaft stems also followed the defined rules of the study protocol.

For postoperative follow-up, all patients were examined at hospital discharge, six months after surgery and then once a year. For study assessment, the patients were

examined at a specific time (August 2004) clinically and radiologically, in order to obtain long-term results.

The following clinical criteria were evaluated:

- Harris Hip Score [11]
- Concomitant diseases influencing the Harris Hip Score
- General condition
- Physical activity
- Working activity
- Ability of walking
- Ability of standing
- IADL (instrumental activities of daily living, according to Lawson and Brody)
- Perioperative complications
- Time of implant

All patients examined for long-term follow-up assessment obtained a deep pelvic a.p. view and a Lauenstein view of the affected side. For Einzel Bild Röntgen Analyse (EBRA) examinations, the existing images of the regular postoperative examinations (discharge, six months and one year after surgery) were also used.

The following criteria were analysed:

- Position of the stem
- Position of the cup
- Cup pathology
- Shaft lysis
- Resorption and cortex hypertrophy

Fig. 3 Screenshot of the Einzel Bild Röntgen Analyse (EBRA) examination program

- Bridging
- Heterotopic ossification (according to Brooker's classification [5, 6])

The EBRA-FCA (Einzel Bild Röntgen Analyse—femoral component analysis) is a method that measures migration and subsidence of the shaft in total hip replacement using special software on a normal PC [5, 19, 25]. The method uses a series of radiographs for every patient, which are analysed in accordance with the comparability parameters given earlier. The radiographs that are not comparable are rejected from the measurement. With definitive mark points and lines, the migration is determined (Fig. 3). The most dependable parameter is the distance between the greater trochanter and the shoulder of the prosthesis. Then, a graphics program elaborates the data and presents them. The precision of the procedure is ± 1 mm. The EBRA measurement consists of four steps:

1. Digitisation of the radiographs
2. Marking of the radiographs with anatomical lines and reference points
3. Calculation and graphic results of the raw migration data
4. Analysis and elaboration of the data

The method is convenient to use and it needs about 20 min to give the results of stem migration.

Results

Starting from 2nd April 1996 and ending 31st January 2003, 133 Z-shafts (Option 3000) were implanted in 123 patients: 71 women and 52 men. The prostheses were inserted 71 times on the right side and 62 times on the left side: 10 patients, 6 women and 4 men, received the stem on both sides.

The average age of the patients at the time of operation was 72.2 years for the women, ranging from 43 to 87 years, and 69.2 for the men, ranging from 57 to 82 years.

The indications for Z-shaft arthroplasty ($n=133$) included:

- Arthrosis ($n=120$; 92.4%)
- Peritrochanteric femur fracture ($n=1$; 1.2%)
- Acetabulum fracture ($n=1$; 1.2%)
- Femoral neck fracture ($n=3$; 4%)
- Hip joint displacement ($n=1$; 1.2%)

For study assessment, patients were examined at a specific time (August 2004). We could examine 86 of 123 patients (69.9%) and 95 of 133 hips (71.4%) at that moment. Thirty-seven (37) patients (30%) were not followed up.

The reasons for non-follow-up were:

- Patients moved away/unable to communicate with: $n=24$
- Patients died (for other reasons than surgery): $n=6$
- Patients refused follow-up: $n=7$

Nine patients (7%) had a revision. One prosthesis was exchanged three months postoperatively due to infection. The other two occurred, respectively, after two years and three and a half years because of constant pain, in both cases, accompanied by radiologically confirmed loosening, while the reason for the revision of six prostheses remain unknown. One prosthesis was removed after three years for constant pain without clinical and radiological findings of loosening, while the reason for the revision of one prosthesis remains unknown.

It was not intended to use the same acetabulum component in every patient. Different kinds of cups were chosen according to the individual case and the anatomical situation, and they were allowed to be combined in the study protocol. The RM cup (Mathys Orthopaedics, Bettlach, Switzerland) was the most popular combination as a corresponding joint partner with the Z-shaft.

Clinical and radiological results

The Harris Hip Score [21] was calculated from the 86 patients/95 hips examined for long-term follow-up; the average value was 85.5 (on the classification zone: good). However, it has to be considered that a number of the hips ($n=49$; 51%) presented with concomitant diseases that affect the musculoskeletal system (such as occlusive arterial disease, gonarthrosis etc.). These diseases can exert a negative influence on the Harris Hip Score. The average value of “corrected Harris Hip Score” (without considering concomitant diseases) increases 2 points to 89.3, namely, at the border of the classification zone: very good.

Seventy-five percent (75%) of patients had no hip pain at all, only 3% reported a constant pain, 3% sometimes at rest and 19% sometimes but only during activity. Seventy percent (70%) of patients could rise from a chair without upper-extremities support and the remaining 30% needed support from their arms.

The average general state of the patients was “good” (range bad–fair–good–very good). The psyche and occupational activity was, on average, “good” (range bad–fair–good–very good) and their working ability was 75% on average (range 0%–100%). Twenty-four percent (24%) of the patients could walk for less than half an hour, 22% for a half to 1 hour, 19% for 1 to 2 hours and 35% could walk for more than 2 hours. Thirty-seven percent (37%) of patients were able to stand for less than half an hour, 20% for half to

1 hour, 21% for 1 to 2 hours and 22% could stand for more than 2 hours.

The IADL score (instrumental activities of daily living according to Lawson and Brody) is a score assessing the self-management of daily living in geriatric patients. We used this score to describe the daily-living feasibility of the Z-shaft patients. The score ranges from 0 points (“helpless”) to 8 points (“fit”). The majority of the 86 patients presented the best value of 8. No patient was recorded to be under a score of 2.

Perioperative complications (“adverse events”) were reported according to the regular data of primary surgery (123 patients/133 hips).

There was no intraoperative cement-related or other major cardiopulmonary complication. The adverse events recorded were a fissure of the femur stem, a trochanter fracture and a longitudinal fissure of the calcar. Postoperative intensive therapy was necessary for 1 to 2 days in four patients with pre-existing cardiopulmonary disease. Operative soft-tissue revision was necessary in two patients because of postoperative seroma formation. A difference in leg length greater than 2 cm was not found postoperatively. Neurological complications, such as injuries of the femoral or sciatic nerve, did not occur. The nine patients that had to be revised and the implant removed were described above.

Regarding all patients, the median time of implantation was 61 months (5.08 years), range 19–100 months.

The radiological results described as follows refer to all 123 patients/133 hips, as the regular postoperative and follow-up X-rays, and not only those of long-term follow-up, could be used.

An example of a correct position of the Z-shaft without pathological alterations is presented in Fig. 4. The radiography was performed on the occasion of the long-term follow-up in August 2004; time of implant was seven years (84 months).

With regard to the position of the stems, it could be observed that 33 shafts (24%) were found in a slight valgus position and 35 (27%) in a slight varus position. The rest ($n=65$; 49%) were found in a neutral position.

The cups presented a mean inclination angle of 40° . Twenty-six (26; 20% of the cases) had a flat inclination (under 35°) and two cases (1.7%) had an extremely steep inclination (over 50°). However, in our clinic, a flat inclination is voluntarily chosen in elder patients to prevent luxation.

Only four cases (3%) were reported with a cup lysis of more than 2 mm. Forty cases required screws to fix the cup (for example, RM cups, Mathys Orthopaedics, Bettlach, Switzerland): radiolucency was not observed in any of them and three of them (7.5%) had broken screws. Only in two cases was the cup ring dislocated.

Fig. 4 Z-shaft in the correct position

There were a number of cases with lysis of the shaft. The zone most affected was the region of the greater trochanter, with an average lysis of 1.32 mm.

Cortex hypertrophy concerns only the zone at the end of the prosthesis. This was reported in four cases and in three of them, a neutral position of the stem was found; only one of them had a varus position. In 27% of the cases ($n=36$) a medial calcar resorption was reported.

The term “bridging” is used to define the changing of the thickness between the end of the shaft and the border of the cortex. Twenty-seven (27%) of the shafts ($n=36$) showed bridging. However, there was no clinical relevance.

Heterotopic calcifications were observed in 42% of the patients ($n=56$) and were described using Brooker’s classification [6, 8, 15]. They reported a discrete calcification without the need for revision (Brooker I or II). The rest of the patients presented no or very slight calcification (Brooker I or none).

The EBRA method as described earlier was developed first at the University of Innsbruck, Austria, in 1984 [5, 6]. It measures the subsidence and migration of stems with a high accuracy (92%). (Other methods, e.g. RSA (Röntgen

Table 1 Subsidence (axial shaft migration) (median)

Month class	No. of observations	Median	Pctl	25th pctl	75th min	Max
0	38	0.00	0.00	0.00	−0.18	1.18
1–3	22	−0.06	−0.43	0.00	−1.87	0.31
4–6	22	−0.37	−0.92	0.00	−2.93	1.47
7–12	32	−0.34	−1.33	0.00	−4.06	1.68
12–24	45	−0.96	−1.75	−0.40	−4.36	1.04
24–36	29	−1.43	−2.84	−0.65	−7.50	1.37
36–48	21	−2.68	−4.57	−0.65	−9.57	1.06
48–60	19	−1.61	−2.48	−0.74	−11.33	2.58
60–72	9	−3.04	−5.12	−2.54	−7.08	0.73
+72	10	−2.15	−2.95	−0.67	−8.41	−0.17

stereophotogrammetric analysis) show even higher levels of precision but are invasive. In RSA, the patients are prepared intraoperatively with some tantalum markers placed near to the prosthesis (e.g. at the greater and less trochanter) and with metal markers implanted in the bone) [19, 25].

EBRA needs a minimum of two plain deep pelvic, good quality, digitised, radiographs at different points of time. Pictures not suitable for the system (radiographs not true antero-posterior stem not fully visible etc.) are strictly and automatically rejected. So, finally, 53 of 133 Z-shaft total hip prostheses (39%) could be examined by EBRA.

As a minimum of two radiographs are essential, the mean number of radiographs available was five. Two patients presented a maximum of ten radiographs from different timepoints.

The mean follow-up from patients analysed by EBRA was 56 months.

Tables 1 and 2 show the course of the axial shaft migration (subsidence) during the follow-up months. For this purpose, the months are divided into classes. The median and mean are respectively considered. Figure 5 shows the development of subsidence graphically. In general, migration starts about six months after implantation and has its peak after 12 months.

The system detects subsidence amounts from 1 mm and more; >2 mm is considered relevant, >5 mm is regarded as predicting a bad clinical outcome [25]. Table 3 shows the clinical outcome of those patients with >5 mm subsidence detected by EBRA.

Tables 4 and 5 show the course of the variation of the angle between the bone and the stem axis during the follow-up months. For this purpose, the months are divided into classes. The median and mean are respectively considered.

EBRA measures the distance between four different “landmarks,” starting from the greater trochanter (defined as “medial one”) and the shaft at both sides (eight points in total, ending with “lateral 4”). Then, we looked for statistical correlations. The only relevant interaction found was between subsidence and both points at the very end of the stem (point 4). “Shift 4” is calculated as the half of the sum of the absolute middle for the medial distance at reference point 4 and the absolute middle for the lateral distance at reference point 4:

$$\frac{ABS(\text{medial}4) + ABS(\text{lateral}4)}{2} \quad (1)$$

In Spearman’s test ($p=0.0006$) and Pearson’s test ($p=0.0004$), the correlation is statistically significant. This means that, together with any vertical migration, a

Table 2 Subsidence (axial shaft migration) (mean)

Month class	No. of observations	Mean	Lower 95% CI for mean	Upper 95% CI for mean	Dev	Std min	Max
0	38	0.04	−0.03	0.11	0.22	−0.18	1.18
1–3	22	−0.32	−0.56	−0.08	0.55	−1.9	0.31
4–6	22	−0.54	−1.0	−0.07	1.04	−2.9	1.47
7–12	32	−0.61	−1.0	−0.20	1.16	−4.1	1.68
12–24	45	−1.1	−1.4	−0.77	1.08	−4.4	1.04
24–36	29	−1.8	−2.6	−1.1	1.89	−7.5	1.37
36–48	21	−2.7	−3.9	−1.5	2.65	−9.6	1.06
48–60	19	−2.4	−4.0	−0.75	3.35	−11	2.58
60–72	9	−3.2	−5.3	−1.2	2.67	−7.1	0.73
+72	10	−2.4	−4.2	−0.72	2.41	−8.4	−0.17

Fig. 5 Development of subsidence (53 shafts)

movement of the shaft in the lateral-medial direction occurs.

Discussion

Shaft loosening following stress-shielding in cemented hip arthroplasty remains a permanent problem. So could only partially cementing a shaft in the proximal part of the femur avoid these unwanted effects?

A new shaft component, with a metaphysial femur anchorage, was developed with the idea of exploiting the concept of proximal load transmission. The intention was to obtain a durable result, possibly free of pain in the thigh, with a good primary and secondary stability through reduced stiffening at the proximal femur, preserving a

sufficient resistance and reduced stress-shielding of the bone.

In this prospective study on the basis of 133 Z-shaft prostheses implanted, we reported on the medium- and long-term results with a maximum of eight years follow-up.

Today, a survival probability of ten years in 95% of the cases is possible for the shaft components of hip replacements [1, 14, 20]. This can be credited to the perfection of the implant's design and also to an improved cement technique (jet-washing, medullary-cavity stopper, vacuum-mixing technique, retrograde cement application). However, the current diaphysial anchored stems show atrophy of the bone tissue, especially in the proximal trochanter zone, with a consequent swinging and then loosening of the prosthesis, in the long term. Since the physiological transmission of forces takes place through the cancellous bone in the proximal femur, metaphysial anchorage seems to be reasonable. This is the new concept developed with the Option 3000 shaft. The special cement application after shaft setting (press-fit) leads to a homogeneous distribution around the neck of the prosthesis (see Figs. 2 and 4), as well as in the cancellous bed and minimises intraoperatively the risk of cardiopulmonary complications [4]. Moreover, biomechanical investigations have shown no difference, regarding the primary stability and the immediate loading capacity, between the partially cemented stems and the fully cemented stems currently available [4, 9].

In general, our study population obtained a good result with an average value of 89.3 for the Harris Hip Score, calculated without considering patients with concomitant diseases. The value lies in the zone classified as "good," but

Table 3 Clinical outcome of patients with >5 mm of EBRA subsidence ($n=8$)

Age	63	78	73	66	80	71	61
Time of follow-up (years):	7	6	6	8	6	8	4
Site of total hip replacement	R	R	L	R	L	L	L
Harris Hip Score:	58	99	100	88	49	69	58
Flexion:	90°	100°	100°	90°	90°	95°	90°
Extension:	5°	5°	10°	10°	5°	5°	5°
Abduction:	30°	30°	40°	40°	20°	25°	30°
Adduction:	40°	20°	30°	40°	10°	20°	10°
Int. rot.	0°	10°	40°	10°	10°	10°	10°
Ext. rot.	10°	20°	30°	10°	20°	10°	10°
Pain:	None	None	None	None	Constant	After activity	Constant
Rising from chair:	With upper-extremity support	Without upper-extremity support	Without upper-extremity support	With upper-extremity support	With upper-extremity support	With upper-extremity support	With upper-extremity support
Walking:	<1/2 hour	1–2 hours	1/2–1 hour	<1/2 hour	–	<1/2 hour	<1/2 hour
Standing:	<1/2 hour	1–2 hours	<1/2 hour	<1/2 hour	1/2–1 hour	<1/2 hour	1/2–1 hour
IADL:	6	8	8	8	8	6	8

Table 4 Variation/course of the angle between the bone and the stem (medians)

Month class	No. of observations	Median	Pctl	25th pctl	75th min	Max
0	38	0.00	0.00	0.00	−0.39	0.01
1–3	22	0.00	0.00	0.02	−0.95	0.73
4–6	22	−0.01	−0.17	0.24	−1.31	0.96
7–12	32	−0.00	−0.31	0.17	−1.59	1.23
12–24	45	−0.03	−0.36	0.19	−1.95	1.47
24–36	29	−0.09	−0.40	0.22	−1.89	1.46
36–48	21	0.17	−0.64	0.45	−3.09	1.63
48–60	19	0.18	−0.22	0.67	−1.74	1.07
60–72	9	0.09	−0.27	0.32	−2.57	1.60
+72	10	0.05	−0.70	0.70	−1.50	0.90

at the boundary of the “very good” zone. These results are equal to or better compared with fully and non-cemented stem systems used so far [18, 20]. Seventy-five percent (75%) of the patients were completely free of pain and when it did occur, this was mostly after a heavy load or strong activity. The general physical state of the patients was positive: the average was “good,” the psychological satisfaction with an average value of “middle” and the work ability was 75% on average, a good result if we consider the age of the patients—on average, 71 years of age.

Also, the IADL score showed a high percentage (79%) with the best score and most of the rest (11%) at the next score below. These results are comparable to fully and non-cemented stems with positive outcome [8, 11, 14].

Until the end of 2004, nine patients had a revision since 1996. The revisions were made because of constant troubles; in no cases did intraoperative or postoperative complications arise during the period after implantation of the prosthesis.

In one of the three cases considered, the Z-shaft was changed after three months of implantation. The reason for this was a bacterial infection; thus, the revision cannot be ascribed to the type of prosthesis. In two cases, the revision took place after two years and after three and a half years, respectively. Both patients reported constant pain at the

thigh, together with radiological confirmation of loosening. We obtained no further information about the revision of the other six Z-shafts.

In cemented total hip prostheses, the loosening rates described in the literature differ from 0.9–8% [10]. Also, the loosening rates of non-cemented total hip prostheses are similar [7, 21, 22, 24]. However, the results of other studies differ; e.g. Krismer et al., in a study of 240 total hip replacements with a follow-up of nine years, reported a rate of 7% of aseptic loosening (in comparison to the two reported for the Z-shaft), and a rate of 5% for revisions due to other reasons [25].

For 33 of the radiologically observed patients that had a Z-shaft since 1996 until the end of 2004, a subsidence of >2 mm was reported. In these 33 cases, there were only three cases with a negative clinical result (with a Harris Hip Score classified as “bad”), one without pain in the thigh, the other two with constant pain. There were still three other patients with a Harris Hip Score classified as “moderate,” but all of them were free of thigh pain. The clinical results of the rest of the patients with subsidence were not different to the general average: the Harris Hip Score was good and they were, in general, free of thigh pain, some with pain but only during activity. Some authors suggest [12, 16] that it is possible that the stem itself subsides over time and finds a

Table 5 Variation/course of the angle between the bone and the stem (means)

Month class	No. of observations	Mean	Lower 95% CI for mean	Upper 95% CI for Mean	Std dev	Min	Max
0	38	−0.02	−0.05	0.01	0.09	−0.39	0.01
1–3	22	−0.03	−0.16	0.11	0.30	−0.95	0.73
4–6	22	−0.03	−0.24	0.17	0.47	−1.3	0.96
7–12	32	−0.15	−0.38	0.08	0.63	−1.6	1.23
12–24	45	−0.04	−0.23	0.15	0.63	−1.9	1.47
24–36	29	−0.17	−0.42	0.09	0.68	−1.9	1.46
36–48	21	−0.03	−0.49	0.43	1.01	−3.1	1.63
48–60	19	−0.03	−0.42	0.37	0.82	−1.7	1.07
60–72	9	−0.23	−1.3	0.87	1.43	−2.6	1.60
+72	10	0.02	−0.55	0.58	0.78	−1.5	0.90

new position where it can be anchored again solidly. In most studies, some cases of subsidence were present, but they did not automatically lead to unfavourable clinical results [22].

Osteolysis was observed in 78 cases, but 55% of them were located in the greater trochanter. With a very high probability, this has to be considered as artificial because of the implantation technique. The technique requires the employment of a box chisel, which is responsible of the surgical damage there. The average width of the damage was only 1.32 mm and if we discount the greater trochanter, only four cases had a lysis of more than 1 mm in size.

Possible causes for loosening or lysis have been discussed by several authors; they often reported the correlation between stem size and the occurrence of osteolysis [10, 15]. In our series, a prosthesis of too large dimensions appears radiologically only as incompletely sunk in the femur. Otherwise, there are no other reminders pointing to improper size.

Some authors [7, 23] discuss the polyethylene wearout of the cup as a possible cause for osteolysis. This was not observed in our population. The fact that the cup inclination in our study was, on average, 40° and those cases with an inclination under 35° (20%) are easily explained by the tendency to choose a flat cup position in elder patients to avoid luxation in muscular dysbalance.

Concerning the position of the shaft, new studies demonstrate that the stem angle has no medium-term influence on the clinical results. Within 33 Z-shaft prostheses with subsidence, 15 were implanted in a neutral position, nine in a valgus position and eight in a varus position.

At this point in time, concerning osteolysis and subsidence, it is not possible to affirm a longer interval of time, which can create significant problems. We have to wait for a study with a follow-up of at least ten years.

Of the 133 examined radiographs, 56 presented heterotopic calcification, although mostly Brooker I or II (smooth). Periarticular ossification of that grade should cause no problems; nevertheless, the calcification can sometimes influence the clinical results. Comparison studies show that periarticular ossification is more common in cemented prostheses than in uncemented ones [6].

The EBRA-FCA method is not as accurate as RSA, but its accuracy has been shown to increase up to 91% at five years follow-up [5, 25]. Besides, it is cheaper and less cumbersome than RSA. Since it does not require the intraoperative insertion of markers, the presence of foreign bodies in patients is not necessary. EBRA has an accuracy which is not comparable with the conventional methods of measurement [5, 25]. A further advantage of EBRA-FCA is that the variability of measured parameters is reduced by using only comparable radiographs. Fifty-three patients had

sufficient radiographs for EBRA, giving a total of 247, but 13% of the radiographs were rejected by the algorithm. This percentage of rejected radiographs is common; other authors using this method reported 15–20% of radiographs rejected by the algorithm. This means that, as in our study, the exclusion of radiographs can reduce the length of follow-up.

The average subsidence increase after two years was smaller than 1 mm. Krismer et al. fixed a threshold value of subsidence to predict loosening at 1.5 mm after two years. The average value of our study collective was lower. After five years, the average subsidence was 2.4 mm, but after more than seven years, it decreased to 2.1 mm, so it seems that subsidence subsequently stabilised. Nevertheless, eight cases were detected by EBRA to have significant subsidence. All of them showed subsidence of more than 2 mm after two years, so their further subsidence could be predicted by EBRA. The average of the follow-up of these eight patients was 62 months. The subsidence was 11 mm in one case; three other patients had a subsidence of, respectively, 6, 7 and 8 mm; the remaining three patients presented a subsidence of 5 mm. It is also relevant to consider the course of migration: three patients reached a plateau after the onset of subsidence. This can be seen as a subsequent stabilisation at the value of 5–7 mm of subsidence. The patient with a subsidence of 11 mm presented discrete clinical findings: the Harris Hip Score was at the limit of the zone “moderate” and he did not report usual thigh pain, just occasionally and during activity. The other patient with 5 mm of subsidence presented a “bad” Harris Hip Score and he was also suffering from constant pain at the thigh. The Harris Hip Score of two other patients was “very good”; they are the same two patients as the three that subsequently stabilised. Although presenting subsidence of 5 and 7 mm respectively, they were completely free of thigh pain and were also in a very good general state. The patient that developed a migration of 11 mm, nevertheless, had a Harris Hip Score with a “good” value—he also complained of no pain in the thigh and his general state was good.

There were no large variations of the angle between the bone and the stem. The most negative average value is reported for the class of months 60–72 and it corresponds only to −0.23. If we look at the median value at the beginning of the follow-up, it is slightly negative and becomes positive in the course of the follow-up. Thus, we can affirm that the positions of the stems were slightly in varus or slightly in valgus, with the average value more strongly indicating a slight valgus position.

The medial and lateral distance of the stem are inter-related. In fact, if the prosthesis moves laterally, the medial distance will become bigger and the lateral distance will decrease. Looking at the average values, the prosthesis seems to move itself preferably to the lateral side. In fact, if

the values are negative for the lateral distance, the stem gets closer to the lateral border of the bone, and if the values are positive for the medial distance, the stem goes far away from the medial border of the bone.

Subsidence is connected with the variations of the medial and lateral distance at level 4 and the correlation between the subsidence and the factor “shift 4.” Thus, we can affirm that subsidence is accompanied by a movement of the stem in lateral-medial direction. This movement can also be caused by a rotation of the stem, which produces a variation of the stem–bone distance because of the different thicknesses antero-posterior and lateral-medial.

Conclusions

The Z-shaft Option 3000, Mathys Orthopaedics, Bettlach, Switzerland, aspires to physiological load transmission through its proximal metaphyseal anchorage and its distal stabilised part, trying as far as possible to preserve the condition of the bone around the prosthesis. The material (austenite steel highly alloyed with nitrogen) has an elasticity module that is very similar to that of bone. Furthermore, the prosthesis can be revised without injury of the femur in the case of loosening, due to its characteristic slender cemented anchorage.

Since 1996, 133 shafts have been implanted, nine of which have so far required a revision during the follow-up period. Subsidence affected 24% of the patients but its impact was quite small (2 mm) and the Harris Hip Score of the corresponding patients was mostly satisfactory. The majority of cases with osteolysis were related to the implantation technique. The position of the shaft did not seem to be a factor in subsidence. Heterotopic calcification did not appear to adversely affect the clinical results.

The Einzel Bild Röntgen Analyse (EBRA) analysis provides the answer to a difficult question: when did the migration start? The first six months seem to static; only after 1 year did EBRA report significant values. In the first two years, these values are below the threshold of predictive migration. The course of subsidence appears not to be progressive, but it seems to stabilise. The two extreme values suggest, nevertheless, a progressive course. The investigation concerning the correlation between the several parameters hints that subsidence is accompanied by a movement in the lateral-medial direction, and this is not due to rotation of the stem.

The clinical results are good. Most of the patients are free of pain (75%) and most of the remainder complained of pain only occasionally and during activity.

This concept of proximal hip stem fixation seems to be viable, so that the effect of stress-shielding mostly leading

to stem loosening can be avoided by using this new implant. But final results compared to other fixation concepts can only be determined from at least 10 years of follow-up.

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