

Cementless cpTI EcoFit® Hip stem system – a minimum 2 years Follow Up

Introduction

Using the cementless hip prosthesis has become a gold standard in most Orthopedic Centers. The variety of stems available is the response of the market to different variables such as the needs of a surgeon, experience of the operating team, degree of pathology, quality of bone tissue and age of a patient. Despite this vast variety of stems only a few are believed to be universal in terms of different pathologies. EcoFit® is one of them since it may be used for total as well as for hemi-hip arthroplasty. It is indicated for a broad array of deformations and cases such as:

- Arthrosis
- Femoral neck fractures
- Dysplastic hip deformity
- Avascular necrosis
- Post operative deformation
- Deformation in rheumatoid arthritis
- Severe joint destruction (cyst, some tumors, joint fractures)

Intervention in severe hip arthritis aims at pain elimination as a priority but the axis of a successful operation remains a well-fitted restoration of joint natural biomechanics that depends on application of the right stem along

with aligning the length of lower limbs and correct neck offset adjustment. Optimal embedding of the stem promotes accelerated function recovery due to good osteointegration of the implant with the bone.

In years 2004-2013 we have performed 593 operations with a Titanium stem EcoFit® (Implantcast GmbH, Buxtehude, Germany). The minimal follow-up period was 2 years. This retrospective study (2 to 4 years follow-up, mean 2 year 4 month) examines the results of the titanium coated EcoFit® Stem implantation.

The Stem's characteristics

The EcoFit® hip stem is of a collarless, straight, monoblock, flat tapered wedge design. The stem has a rectangular cross sectional geometry to provide rotational stability and tapers from proximal to distal (7° in frontal plane and 3.5° in sagittal plane) with a stem – neck angle (CCD angle) of 138°. The stem is designed in both a standard offset and a lateralized offset version to allow lateralization of the patient's femur without increasing leg length.

The neck has a Morse type 12/14 taper to mate with a modular femoral head. The taper has an angle of 5.7°, a length of 13.5 mm and roundness of 0.008 µm. The taper has a machine-turned surface finish producing circular grooves to provide enough roughness. A threaded hole for the insertion instrument attachment is provided on the superior lateral surface of the

proximal stem body. The implant is manufactured from Titanium 6 Alumina 4 Vanadium (TiAl6V4) alloy acc. To ISO 5832-3.

The stem is coated with plasma sprayed cpTi (commercially pure titanium), meeting the specification of ISO 5832-2.

The EcoFit® titanium coated stem is available in 10 sizes from 132.5mm – 160 mm in length in both standard and lateralized offset version (Tab.1).

SIZE (MM)	6,25	7,5	8,75	10	11,3	13	13,8	15	18	20
LENGTH	133	135	138	140	143	145	148	150	155	160
OFFSET* (MM) - STANDARD	34,5	35	35,8	37	37,1	38	38,3	39	40	42
OFFSET* (MM) - LATERALISED	42,3	43	43,6	44	44,9	46	46,1	47	48	49

Tab.1 Overview EcoFit Hip System

Materials and Method

In years 2004-2013 we treated 546 patients with application of cementless EcoFit® stem – 350 women and 196 men. 47 patients had bilateral THR so there were 593 operations in total. The mean age of the patients is 64.3 years old with the range of 32 to 93 years old.

The most common articulation we used was TiN head on polyethylene (PE). In most cases we used Eco Fit acetabular cups (556) or Cephtar cups (24). However, in extraordinary cases we used other cups with the ceramic-on-ceramic articulation (13). In some cases we used other heads than TiN. [Tab3].

The majority of the patients presented with hip pain and ROM limitation. The diagnosis of the patients includes 495 osteoarthritis, 31 rheumatoid arthritis, 12 osteonecrosis of the head and 8 neck fractures.

The procedures were performed in the same hospital by same 3 surgeons using the same surgical technique. A modified Harding's approach was used to the majority of our patients. In 8 cases we used the Direct Anterior Approach (DAA). Patients underwent the same standardized post-operative treatment with the exception of those with atypical intraoperative events - peri-femoral fracture (2 cases), full acetabular reconstruction (3 cases) - and one case of post-op hip dislocation.

The patients were treated on a supine-lateral position on a standard operation table. The spinal anaesthesia was used.

We used the long curette to probe the femoral canal before broaching. The first broaching of 6.25 was used in all patients. The repetitive broaching was then performed until the proper size was discovered. In some cases with anatomically wide peri-trochanteric area the bone grafting was used.

All patients with standardized post-op treatment had a full weight mobile bearing next day after the surgery. Individual physical therapy was utilised in the hospital for the gait training and recovery of ROM. However, for the first 3-4 days any active muscle training or extensive hip movement beyond minimal is avoided.

Lateral approach requires a small incision of the gluteus medius fascia on the greater trochanter and its later reinsertion. This situation requires that extensive or forceful movement be avoided for at least 7-10 days until scar tissue forms at greater trochanter insertion of fascia.

Each patient underwent a post-op clinical examination of lower limbs length, ROM and evaluation of X-ray – in each case two comparative X-rays were available - before and shortly after the operation. The X-rays are standard APs visualizing at least 1/3rd of proximal femur length. All but one patients came for post-op control examination within 18-20 months after the operation.

Different stem sizes were used. The most common stem size was 8.75 (210 hips), and the second was 7.5 (85 hips). Stem size distribution is summed-up in table 2.

stem sizes	number implanted
6,25	48
7,5	85
8,75	210
10	65
11,25	45
12,5	48
13,75	36
15	35
17,5	18
20	3
total	593

Tab.2 EcoFit sizes implanted

Clinical evaluation included hip dedicated scores: a 10 point visual analogue pain score and Harris hip score. Patients were asked to rate pain by intensity from 0 to 10. Pain rated above 3 was considered as significant.

Results

593 total hip replacements using the EcoFit® stem. 546 patients were followed for at least 2 year.

There were two cases of septic complications – both of them late. One patient developed a peri-implant abscess with pus leaking 8 months after surgery while the other had the complication 13 months after surgery and involved loosening of both the stem and acetabulum (Cephtar Implantcast GmbH). Both cases were treated with entire implant resection with no application of spacer. After 6 months we re-embedded the implant – this time of a different type to avoid substance allergy as potential cause of the complication.

Type/year	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	total
EcoFit Stem cementless (IC GmbH)	14	40	57	68	80	103	80	47	45	59	593
EcoFit Cup (IC GmbH)	10	39	54	65	80	87	80	47	44	50	556
Cephar cup (IC GmbH)	3	1	2	2		15			1		24
Other cups	1		1	1		1				9	13
TiN head (IC GmbH)	13	40	56	67	71	87	80	40	40	50	544
Other head	1		1	1	9	16		7	5	9	49
PE insert (IC GmbH)	13	40	56	67	80	102	80	47	45	50	580
Other insert (ceramic)	1		1	1		1				9	13

Tab.3. Types of implant and articulation in years

The 2 cases of intra-operative peri-femoral fractures (one due to thigh geometry after osteotomy, the other due to lesser trochanter fracture) had to be fixed with 1 loop of ORFIL cerclage wire. Both cases evaluated after 2 years had a great outcome.

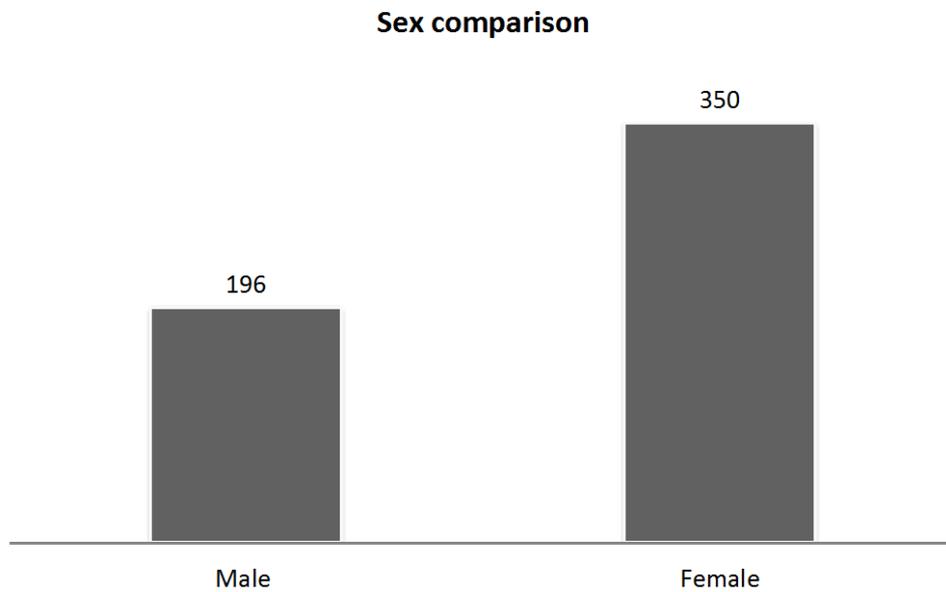
None of the stems loosened after 2 years follow up except the case of infection complication.

3 patients complained of persistent pain during weight bearing 3 and 6 months after operation. The pain had no relation with osteointegration and resolved after 12 months from operation in all 3 cases.

There was one case where patient suffered from a trauma 6 weeks after operation, which resulted in a mid-shaft femoral fracture below the distal end of the stem. During surgical intervention the stem was found to have integrated well with the bone in the canal and the fracture was fixed with trochanteric plate.

One patient developed deep vein thrombosis while he had a prior history of thrombosis. The symptoms faded after treatment with low molecular weight heparin.

One patient had the dislocation 3 weeks post op. The close reduction was done. There was no need for open surgery.



Tab.4 Sex comparison (n=546)

Patients reported pain using the analogue 10 point scale. Pain lessened for all patients after surgery as the pain mean preoperative score of 6.8 (range 2-10) dropped to mean follow-up score of 1.1 (range 0-2). One patient in the follow up examination was treated with the analgesic injection.

data	No
Hips	593
Patients	546
Male	196
Female	350
Mean age	64,3(32-93)
OA	495
RA	31
Necrosis	12
Neck fractures	8
Pain score	6,8(2-10)
Harris Hip Score	50,3(26-70)

Tab.5. Pre-operative assessment

The mean Harris Hip Score before implantation was 50.3 (range 26-70) and improved to a mean follow up score of 87.2 (range 50-98).

In one patient we observed a change of the implant position. The stem 3 weeks post operation seemed to sink deeper from the initial position. We did not decide to re-operate and the patient recovered soon.

data	No
Pain score	1,1(0-2)
Harris Hip Score	87,2(50-98)
Complications	9
Infection	2
Dislocation	1
Pain post op	3
Peri-femoral fractures	2
Deep vein thrombosis	1
Satisfied patients	98,3

Tab.6. Post- operative assessment

Discussion

All 546 patients (underwent the procedure of total hip replacement with the titanium EcoFit® femoral stem) reported pain relief and better function with a vast majority reporting the relief as significant (a drop in 10 point scale by more than 3 points). There was a significant improving of ROM. The Pain and Hip Score improved rapidly after the surgery.



Fig.1 EcoFit stem 6 month post op

In evaluation of titanium coating we were observing both: the primary fixation and possible allergic reaction. Only in one case we observed a change in stem position which we attribute to having implanted too small stem size with respect to canal's diameter based on X-ray and procedure history analysis.

EcoFit® stem could be applied in many patients with different pathologies. The number and variety of our group of patients supports the universality of the implant. In light of the vast array of technological solutions today we identify this multifaceted one with optimal coating structure that maximizes the primary fixation. It may be successfully used in vast majority of patients with hip arthritis.

Our observations confirm that EcoFit® Stem is easy to implant in both: the usual antero-lateral access as well as with DDA which requires good exposition of proximal femur and correct positioning of the lower limb. After limb positioning on the operating table we had no problem with subsequent implanting of EcoFit® stem with DDA.

The 2 years follow-up results point to a very good adaptation of the stem in the femoral canal with quick and strong osteointegration. EcoFit® allowed for full weight bearing directly after the operation. Many sizes to choose from and the offset possibilities make the custom choice of implant to individual patient easy and optimal. Based on these results, the titanium coated EcoFit® stem for the total hip replacement has proved to be a reliable, save and proper implant at the follow up period.

The results seem to be more promising and credible with a 5 years follow up planned.

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