

## 9 Years Follow up of a Fully Covered Hydroxyapatite Femoral Stem

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### Abstract

**Background:** Total Hip Arthroplasty (THA) using uncemented stems is a popular practice in the last decades, with constant improvement in the area of stem designs and surface finish. The implant survivorship is critical and a less than 10% revision at 10 years is been proposed for many Registers and Guidelines for commercialization and use. The Element Novation Stem (Exactech, Gainesville, Florida, USA) is an uncemented dual wedge stem fully covered with Hydroxyapatite (HA).

**Objective:** The study purpose is to report the minimum 9 years follow up results with the use of the Element Stem in primary THA in patients ranged 21 to 75 years.

**Methods:** Prospective study, patients aged 21 to 75 years, implanted with an uncemented dual wedge stem fully covered with HA and uncemented cup with Crosslink poly and 32 mm metal head, posterior approach with capsular reattachment and piriformis retention. One hundred and four consecutive patients (104 hips) were evaluated for a minimum 9 years after implantation. The mean follow-up period was 9.5 years. Harris Hip Score (HHS) and Merle d'Aubigné Postel score preop and at final evaluation was recorded, patient satisfaction was evaluated, and all complications during follow up period were analyzed. The radiographic evaluation on sequenced control was recorded according to Engh's criteria. And in case of radiolucent lines were detected, they were noted by Gruen zones on the femoral side. Dorr femoral shape was informing. Subsidence and stress shielding was also evaluated.

**Results:** One hundred and four THA in 104 patients were included in the initial serie, 54 females and 50 males (52%/48%). Follow-up of 9.5 years (range 9 to 10.2 years). Average age 56.8 years (range 42-75 years) at time of surgery. Clinical evaluation the Merle d'Aubigné Postel score improved 6.8 points and from the initial HHS 47.3 to 93.1 points at last follow up. Radiographic evaluation in 6 cases (5.3% at 3 months' subsidence was detected, average 1.4 mm (range 0-2.6 mm) with no clinical manifestation, 3 cases of subsidence were associated to intraoperative fractures (1 greater trochanter and 2 in the calcar area, all resolved with wire cerclaje). At final evaluation 3 patients died with the THA in situ, 7 cases were revised, total survivorship was 93.3% considering all revision. Radiographic evaluation detected patients with radiolucent lines under close follow up, with no clinical relevance at final follow up. Stress shielding of more than grade 2 was observed in only three hips, which was non-progressive at one year after surgery.

**Subjective Evaluation:** 86 cases (82.6%) excellent, 9 patients (8.6%) good, 6 cases (5.9%), satisfactory and 3 cases (2.9%) poor. All poor results linked to the intraoperative complications.

**Conclusions:** The radiological results confirm the benefits of this type of stem with good osteointegration. The clinical and subjective results at medium term follow up are promising. With good surgical technical and without complications the risk of aseptic loosening should be absent or minimal.

## Introduction

THA since the introduction by Sir John Charnley in 1965 has been considered the procedure of the century, yearly more than a million procedures are done in the USA [1,2]. Since then the designs and materials have improved. The uncemented concept (Morscher)3 was supported by the idea bone implant union (biologic fixation) achieving long lasting stability, and avoiding the so called cement disease [3]. The wedge shape facilitate fixation and uniform load transfer to the metaphisal zone. The HA cover has osteoinductive properties, allowing new trabecular bone formation, full filling the femoral canal and with a stable fixation even with initial micro movements in the initial stages [4-7]. The implant survivorship is critical, the NICE guide recommend an inferior 10% revision rate for acceptance and commercialization, similar is in different national registers (IE. Australian, Scandinavian) [7]. Yearly 5 new designs are presented to the market, so surgeons have to deal with the decision about with is better for our patients, dealing with insufficient data about clinical performance and follow up to support our practice [2,7,8].

## Methods

Clinical evaluation using HHS and Merle d'Aubigne Postel scores preop and postop during follow up [9,10]. A subjective evaluation for the procedure and patients expectatives were done with a scale 1 to 10 were 1-3 was poor, 4-5 fair, 6-8 good, 9-10 excellent.

### Radiographic Evaluation

Pre and postop digital standarized digital xrays, with a 1.2 magnification, centered on pubis. Acetabular side: declination angle, progressive radiolucent lines in the De Lee Charnley zones, migration (change in more than 5 degrees in position), screw breakage [11,12].

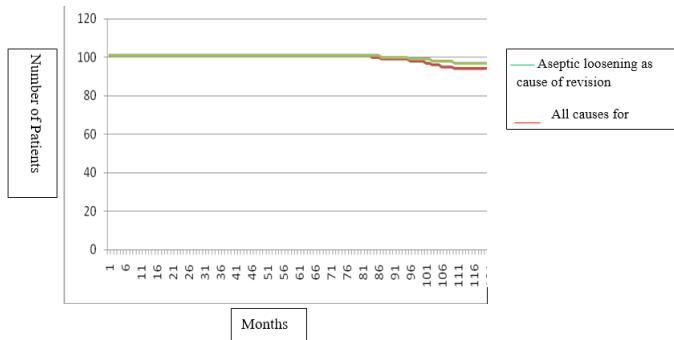
### Femoral Side

Osteolysis (progressive bone resorption, calcar erosion), radiolucent lines, cortical hypertrophy, subsidence (measured from the stem shoulder to the trochanter minor) [13-17].

## Results

One hundred and four THA in 104 patients were included, 54 females and 50 males (52%/48%). Follow-up of 9.5 years (range 9 to 10.2 years). Average age 56.8 years (range 42-75 years). Patients flow chart (Table 1). At final follow up 101 cases were evaluated, 3 patients died (with the prostheses in situ). 7 cases were revised (Table 2), resulting in 93% considering all revision causes, excluding infectious causes and non femoral causes the survivorship rate is 96%. Clinical evaluation the Merle d'Aubigné Postel score improved 6.8 points from preop to postop and from the initial HHS 47.3 to 93.1 points at last follow up

(Table 2). Radiographic evaluation in 6 cases (5.9 % at 3 months' subsidence was detected, average 1.4 mm (range 0-2.6 mm)) with no clinical manifestation, 3 cases of subsidence were associated to intraoperative fractures (1 greater trochanter and 2 in the calcar area, all resolved with wire cerclage). In the final xray evaluation detected 2 patients with radiolucent lines zone 1 and 7 Gruen classification, under close follow up, with no clinical relevance at final follow up (Figure 1).



**Figure 1:** Kaplan Meier.

	N	
Received patients	187	
Excluded	83	Older than 75 years 34 Fractures 29 Negative to participate 17 Pathologic fractures 3
Included in the study	104	
Evaluated at final follow up	101	(3 died).

**Table 1:** Patients flow chart.

Harris Hip Score
Preop score 45,7 average (range 28 to 65)
Final follow up score 90,1 average (range 61 to 96)
$p = 0,0002$
Merle d'Aubigné Postel Score
Preop, 10 points (range 4 to 12)
Final follow up 16 points (range 8 to 18)
$p = 0,030$

**Table 2:** Functional Results.

### Subjective Evaluation

86 cases (82.6%) excellent, 9 patients (8.6%) good, 6 cases (5.9%), satisfactory and 3 cases (2.9%) poor. All poor results linked

to the intraoperative complications. The fixation of 96 femoral stems (95.1%) was classified as bone ingrowth; the fixation of 5 femoral stems (4.9%) was classified as stable fibrous; no femoral component was considered to be unstable.

## Discussion

The uncemented stems won acceptance and increase the use during the last decades, but not all are similar in performance [1,7,8]. It is important to detect failure patterns, and have medium follow up to decide the better choice for the patients. In our series we use a dual wedge stem fully covered with HA, looking for self locking shape and metaphysis fixation, with this concept load transfer is converted from axial to radial compression, avoiding the stress shielding and anterior femoral pain [18,19]. Also the articular space is sealed and the particle migration limited and as result the proximal osteolysis is minimal or nonexistent. Similar wedge designs have reports with good clinical and functional results, even with a minimum subsidence [15,16,20-22]. The hydroxyapatite cover was proposed to induce the osteointegration in early staged, 3 months postop, doing the stem to be united to the bone without fibrous union, and consequently long lasting stability [22] (Figures 2, 3). This phenomenon is reported in several studies showed that the implant bone union is during the first 3 months, with inclusion of the HA in the new bone [22,23].



**Figure 2:** Preoperative AP xray, left hip with osteoarthritis.



**Figure 3:** Preoperative lateral view xray.

Survivorship of ha fully coated stems in the Register Norwegian in the period 1987 to 2004 was less than 1% at 4.5 years, 2.4% at 10 years and 4.9% at 15 years, including 5130 cases. These results are comparable with those obtained with Highly polished stems at similar follow up [20]. Pellegrini et al. [24] reported 2% of revisions at 6.5 years similar to Hozack et al. [25] achieved 100% of fixation, and 98% of cases free of pain; using uncemented proximal covered HA stems. With Bicontact® and modified Zweymuller® stems survivorship of 97,6% and 96% respectively at 10 years follow up [26,27] (Figures 4,5,6).



**Figure 4:** Inmediate postoperative anteroposterior xray.



**Figure 5:** 9 years follow up anteroposterior view xray showing excellent osteointegration.



**Figure 6:** 9 years follow up lateral view xray.

During the radiographic evaluation, with the use of uncemented stems signs of bone demodulation around can during sequential evaluations define a stable or instable stem, Engh [17] described these signs as mayor and minor. The absence of radiolucent lines, stress shielding in the trochanter minor and the formation of laminar bone around the stem allow us to assume a stable prosthesis. The Enghs criteria were described for cylindrical and fully titanium coated stems and applicable to all uncemented stems. In our serie we define the stem as loose when subsidence is progressive after 6 months and more than 5 mm, a radiolucent line progressive in consecutive evaluations, or resorption in the calcar zone. In the stem used in our serie there is a correlation from the xray evaluation and the findings during revision procedure. The signs described have a predictive value if they are present in early stages.

Khailly et al. [27] reported the presence of radiolucent lines around the stem have 100 sensibilities and 55% specificity predicting a future implant failure in the next 8 years. Systematic and schedule functional and xray evaluation are fundamental to acquire information on the stem performance, detect early failures and provide knowledge to the surgeon in order to use the better implant for the patient [27,28]. The design and fixation method determine the stability and consequently define the implant survivorship, actually there a huge number of implant presented in the market without clinical results [29]. In some cases, arises catastrophic results after initial promising stages like metal on metal prosthesis, Charnely Elite Plus, that were recalled, and remove from the market [30].

In order to avoid these situations national registers and international guides are developed to control implant behavior to protect the patients, and in some cases analyze the use of pharmaceutical industry on the with small control groups to detect early stages failure as was suggested by McCulloch et al. [31] and Schemitsch et al. [32]. It is proposed subsidence higher than 2 mm after the first 3 months postop is a sign for future early loosening [33,34], reported in studies with Roentgen Steriophotogrammetric Analysis (RSA) 1.2 mm and measured with EBRA or  $\leq 2$  mm with digital RXs, [34,35]. Our results showed 1.4 mm of subsidence during the first 3 months, non progressive, with no clinical relevance may attributed to the wedge shape of the stem and the osteoinductive properties of the HA cover, resulting in strong union bone implant.

Our results showing and average 1.4 mm subsidence is consistent with the reported and expected for this wedge design, and no progression detected after 3 months postop and present in 5.5% of our patients, suggest the stem get stability due to its shape and achieve strong bone union [34-36]. Similar subsidence pattern was informed by White et al., in a systematic review at 2 years follow up 0,29 to 4,5 mm  $\pm$  1,5 mm [37], and Campbell et al. [21]

with Corail Stem at 6 months' post implantation with average 0.58 mm. It is important to remark 3 on 6 cases were subsidence was detected have calcar fractures treated with wire cerclaje, they were limited in the weight bearing during 45 days and non of the were revised at final follow up, or have femoral pain or altered function [7, 21,31,32].

The survivorship results obtained in our series are consistent with the requirements of NICE guides and international registers at 10 years follow up, 93% including all causes for revision and for aseptic loosening as revision cause is 96%. Similar to successful stems like CLS Spotorno® [11,17,39,40] y Corail® [10,11,38,40], and even better than the 8% revision rate informed with LCU Link® [11,37,38,40]. The long term functional results are similar to those obtained with similar design Corail® o LCU Link® [38,40] and the improvements on HHS and Merle d Aubigne Postel score have statistically significance, and permanent on time.

## Limitations

The study is prospective, non comparative, with a medium term follow up. The advantages are all procedures were done by surgeons dedicated only to THA, and the use of uncemented stems as regular practice.

## Conclusions

The midterm clinico radiological results with the Element Novation stem are promising, with good osteointegration and a low aseptic revision rate.

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