

Preliminary results of a Cementless HA Coated Femoral Stem

**Comparison of functional outcomes for standard and
elderly patients: a multicenter review of 77 patients at 2
years minimum of follow-up**

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Abstract:

Cementless full HA coated femoral stems for THA procedures have been successfully validated for use in patients under the age of 65. Consequently, some orthopaedic surgeons have progressively extended their indications to patients that would have normally been selected for a cemented procedure. The analysis of a cohort of 77 patients with a mean age of 73.7, 49.3% of who were over 75 years old, provided comparative clinical results for 2 groups of patients according to age at surgery (less than 65 and over 75) at 2 years and 8 months of mean follow-up. The analysis of initial and latest follow-up PMA (Postel-Merle d'Aubigné) scores shows that even within a population with an initial low PMA score of 9.85 ([5-14] sd: 2.01, compared to the PMA scores of comparative studies ranging from 10.7 to 12.49 (1)(2)(3)), the final outcome is comparable to evaluations of younger patient groups (comparative studies ranging from 59.2 to 67.8 mean age at intervention (4)(5)(6)(7)). In addition, the final outcome is excellent and statistically not different whatever the age group. In conclusion the routine use of a cementless full HA coated stem for the elderly population is safe and reproducible.

Hypothesis for the study:

Cementless femoral implants must have immediately vertical and rotational intramedullary stability in order to avoid short term complications and loosening. Assuming that the immediate stability is correlated to the quality of the receiving host bone, the surgeon may hesitate when considering the use of cementless femoral stems for populations of patients characterized by a weak bone quality or density. The hypothesis is that cementless quadrangular implants coated with a calcium hydroxyapatite layer will provide similar clinical and functional outcomes in the elderly compared to a younger population.

Purpose of the study:

Cementless femoral implants for THA procedures have grown very much in use in recent years with the objective being to avoid granuloma osteolysis mid-term failures often associated with cemented implants. Long term outcomes of cementless implants are now available and are at least equivalent to the best "gold standard" cemented implants: "cementless tapered femoral stems yield long lasting fixation equaling or surpassing the best cemented stem results"⁽⁹⁾ and "uncemented stems performed better than cemented stems"⁽¹⁰⁾.

Nevertheless up until now many surgeons remain reluctant to use cementless stems for patients with fragile and low density bones (8), which include demineralized females and elderly patients. Despite this, some surgeons have chosen in their everyday practice to use cementless fully HA coated femoral stems for these categories of patients. It is important to know if there is any difference in functional outcomes and morbidity depending on the age groups, to confirm the continued use of cementless stems for most primary and simple revision indications.

The purpose of this study was to evaluate the performance and security of a cementless quadrangular femoral implant used for all orthopaedic patients requiring a total hip arthroplasty procedure for arthritis, CDH, necrosis or fracture pathologies.

The analysis focuses on the complications and the functional performance evaluated through the PMA score (Postel-Merle d'Aubigné).

Material and Method:

This data included the descriptive review with no comparison group of cementless full HA coated Hactiv® hip stems (Evolutis, Briennon, France), implanted from February 2005 to June 2009, with clinical and radiological data files available, updated and stored on a digital remote database (Orthowave, Houdain, France) and with a minimal follow-up of 2 years.

The global digital data base from which the data was extracted includes to-date 714 reported Hactiv files concerning 672 patients. The data base is exhaustive and prospectively informed.

The sorting and validation process lead to the elimination of:

- The files below the inclusion limit (less than 2 years of follow-up)
- The files lost to FU (missing review at follow-up period)
- The files including inconsistent data

The result is a consistent cohort of 77 files available for analysis and discussion. The 77 patient files were sorted and compared to evaluate intra-operative, early or late complications. Finally a subjective questionnaire was submitted to the patients to rate their level of satisfaction.

The patients were admitted for surgery in 4 different hospitals; surgery and evaluations were undertaken by 4 different orthopaedic surgeons. Multi operator studies validate the reproducibility of results.

77 patient files were validated for analysis. 51.4% females vs 48.6% males with a mean age of 73.1 ([38-89] sd: 8.49).

The mean age of the cohort was higher than comparative clinical reviews dealing with primary THA cohorts (1 to 7) ranging from a mean age of 56.7 years [36-79] for C.Perrier (1) to 67.8 years for T.Siguiet (5), so the analysis includes statistical correlation of age and functional performance.

Etiology was 89% osteoarthritis, 5% osteonecrosis, 4.5% fractures, and 1 case was a total hip revision re-implanted with a primary implant.

The surgical procedures were mainly postero-lateral (96%: Moore & adaptations) surgical approaches. In some cases (3) a lateral approach was preferred, and an antero-lateral was used in 1 case. In 3 cases surgical approach was not mentioned.

The implants used were exclusively HACTIV® cementless stems for the femoral side (79,7% standard offset neck & collarless, 11,2% standard neck and collared, 9% lateralized and collarless), associated with 28mm ball heads (54.83%) or 32mm ball heads (45.19%). The 28mm ball heads were generally associated with double mobility cups (82.21%), while most of the 32mm ball heads (65.21%) were associated with ceramic liners.

The mean follow-up of the cohort at latest FU was 2.7 years (2y & 255days, [2-4.33] sd: 0.58)].

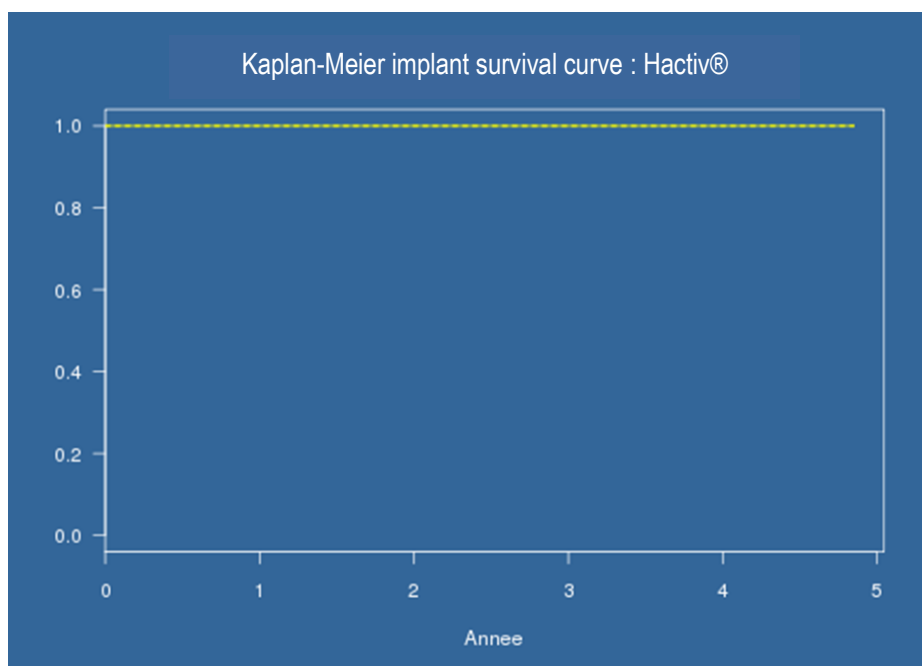
Results:

Within the 77 files reviewed, there were no intra-operative complications except for the THR (revision) case for which additional procedure time was needed to retrieve the failed implants and rebuild segmentary bony defects. The rehabilitation for this case was standard but the functional results remain in the lower limit of the cohort (14/18) due to an increased pain rating at 2 years evaluation: 4/6 on pain (it was 5/6 at 6 months FU).

There have been no early and no late complications reported.

There has been no revision within the 77 files.

The Kaplan-Meier survival curve for any reason for failure (removal of implant due to implant, isolated removal of femur or cup for any cause, clinical or radiological failure...) is 100% at 5 years, with a confidence interval (+/- 0.05%) at 1. (See chart 1). At this stage of the follow-up, this value is of course not significant and any adverse results would have been a cause for concern.



Graph 1: Hactiv® survival curve for any surgical, clinical or radiological failure.

At latest FU the functional outcomes improved significantly despite the fact that the initial PMA score was low at 9.85/18 (1, 2, 3, 11, 12), and that the mean age of the cohort was substantially higher than that of comparable studies available in the bibliography (1 to 7). J.Mayer had an initial PMA score of 12.4 in his study of 152 cementless femoral stems (12), C.Delaunay had a 11.2 pre-operative PMA for his review of 64 THA (11).

At initial evaluation, the full cohort scores were rated at a mean 2.01 on a scale of 6 ([0-5] sd: 1.12) for pain, at 4.16 ([2-6] sd: 0.92) for mobility, and at 3.65 ([1-5] sd:1.02) for walk (See table 1). But when analyzed according to age groups (2 groups: less than 65 y vs more than 75 y), discrepancies appear in the detailed scores: the >75 group demonstrates less pain than the <65 group (PMA pain: 1.97/6 vs 1.8/6), while the 2 other evaluation items have better scores for the <65 group (See table 2).

	Pain			Mobility			Walk			Total		
	score	interval	sd	score	interval	sd	score	interval	sd	score	interval	sd
Pre-Op	2.01	0;5	1.12	4.16	2;6	0.92	3.65	1;5	1.02	9.85	5;14	2.01
Latest FU	5.80	2;6	0.59	5.84	3;6	0.46	5.75	2;6	0.71	17.39	oct-18	1.35

Table 1: Detailed and total PMA score at 2 years of FU **full cohort**: Pre-op scores vs latest FU scores

		Pain			Mobility			Walk			Total		
		score	interval	sd	score	interval	sd	score	interval	sd	score	interval	sd
<65 group	Pre-Op	1.8	1;4	1.14	4.5	2;5	0.97	4.1	2;5	0.88	10.4	7;13	2.01
	Latest FU	5.9	5;6	0.32	5.9	5;6	0.32	6	6;6	0	17.8	16;18	0.63
>75 group	Pre-Op	1.97	0;5	1.07	4.19	3;6	0.82	3.5	1;5	1.08	9.72	5;12	1.89
	Latest FU	5.71	1;6	0.9	5.76	2;6	0.71	5.66	2;6	0.85	17.13	5;18	2.23

Table 2: Detailed and total PMA scores **according to age groups**: group<65 vs group>75

The final PMA evaluation at a mean FU period of 2.7 years is similar to published studies (1, 2, 3, 11): global cohort total PMA score at latest FU: 17.39 [10-18] sd 1.35.

The Pain was rated 5.80 on a scale of 6 ([2-6] sd: 0.59), the Mobility at 5.84 ([3-6] sd: 0.46), and the Walk at 5.75 ([2-6] sd:0.71) (See table 1).

No patient felt permanent pain, even slight. 2 patients aged 71 and 83 felt pain when walking only. One patient, aged 77, had limited flexion. And one patient, aged 74, had severe pain when walking with crutches.

At final evaluation and according to the PMA score, 85.5% of the patients were classified "excellent" results (17<PMA<18), 9.2% had "Good" results (15<PMA<16), and 3.95% had "Fair" results (13<PMA<14).

One patient was classified "poor" (PMA<12) with a final score at 10/18 due to severe pain limiting his walking ability.

The subjective satisfaction questionnaire provided similar success measurement of the surgeries (answers rated from "poor" to "excellent"): to the question "are the results in accordance with your initial expectations?", globally the answers were excellent, so that, despite the fact that most of them are unable to practice strenuous or athletic activities, and that a small proportion (33%) are slightly limited in everyday activities, they massively answered "excellent" to the eventuality of having surgery on the opposite side. Pain subjective rating was also rated "excellent".

The radiographic files' analysis showed no sign of subsidence, nor of calcar resorption. Most cases show no sign of bone remodeling, except for one with a "surrounding" cortex thickening. On a radiological basis at latest FU there is no cause for concern for the stability and integration of the implants.

Discussion:

According to JP Vidalain (14) the PMA score should have been negatively affected by the mean age of the cohort: "the PMA score, and in particular the functional quotation for a population with mean age of 64.5 is inversely correlated to the age of the patients in the cohort".

The Hactiv cohort had a mean age of 73.01 for the global group, and a mean age of 79.7 for the >75 group at date of surgery. Despite this, the Hactiv stem results are **at least equivalent** to comparative implant evaluations ([Meije](#), Tornier for J.Mayer (3); [Corail](#), Depuy for G.Cohen and JP Vidalain (13)) available.

The latest FU PMA scores range between 17 and 17.65 : JP.Vidalain (13) explains his PMA score of 17.0 by the fact that older patients have poorer results in function ; J.Mayer (3) had a PMA score of 17.6 at 6.2 years of FU, but the mean age of his cohort at time of surgery was only 53 ; G.Cohen (12) also had an excellent PMA rating of 17.65 at 5 years of FU, but the initial mean PMA of his cohort was high at 12.5, meaning that the 152 patients included in the evaluation had higher pre-op activity levels. C.Delaunay (11) had a PMA score at latest follow-up of 17.4 improved from a pre-op PMA at 11.2 for a population aged only at a of mean 60 [36-73] and with 3.2 years of average FU and a minimum FU set at 2 years.

When we analyze the detailed score for each age group, the interesting point is that the >75 group recorded less pain than the <65 group, and at the same time lower mobility and walk scores. Although there was no statistical difference between the 2 groups for these detailed scoring results, it is interesting to note that the >75 group record the best gain from pre-operative to latest FU for both mobility and walk scores vs the <65 group: 1.57 vs 1.4 for mobility (+37.5% vs +31.1%) and 2.16 vs 1.9 for walk (+61.7% vs +46.3%) (see Table 3). When we consider that the walking ability criterion is usually the first one affecting aged cohorts, then it is of note that the functional performance of the Hactiv implants for elderly patients was highly satisfying.

	Pain		Mobility		Walk	
<65	4,1	227,8%	1,4	31,1%	1,9	46,3%
>75	3,74	189,8%	1,57	37,5%	2,16	61,7%

Table 3: Detailed PMA gain: group<65 vs group>75

Conclusion:

At this stage of the analysis the results provide reassuring information concerning the safety and the performance of the Hactiv implant in most THA indications, including the elderly (49.3% of the cohort was over 75 years old at time of surgery) with equally excellent results in pain and mobility for all age groups. The group>75 has a slightly lower result for walking ability probably more in relation with the mean age at latest FU (mean of 81.8 years). But this result also needs to be put in perspective bearing in mind the initial PMA evaluation which was comparatively the weak point for this group: indeed the >75 group demonstrated the best percentage gain on the walk criterion. This figure alone demonstrated that cementless quadrangular femoral stems enable elderly patients to recover good quality functional performance after THA.

These interesting results will of course need to be confirmed at longer follow-up.

Key Words:

Cementless Hip Prosthesis, PMA score, Aging population, Elderly.

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