Descriptive results of 32 total hip procedures with dual mobility acetabular cup replacement with a minimum follow up of 3 years

Dr Bonnet, Polyclinique de Poitiers, Poitiers, France

This is part of an ongoing review of patients. At latest follow-up there were 74 patients. The patients have been reviewed and evaluated by the surgeon. The evaluator then reports patient data on a remote CRO database (Contract Research Organization: Orthowave 6) on a prospective registry basis.

The current review is based on the following data collection methodology:

- a file including patient data, aetiology, surgery report, complications, implant references and immediate post-op x-rays is created each time a patient is admitted for THA surgery
- patients are informed via a follow-up calendar included in the documents they receive when leaving hospital that they have to have their implant followed up by Dr Bonnet at 3 months, 1 year and every following year
- at each follow up period, the patient is evaluated for PMA (Postel – Merle d'Aubigné) score (*chart 1*), x-ray analysis, and complications. Data is recorded in real time on the CRO database
- study monitor (Evolutis) has the capacity anytime to control database and extract statistical information to comply with post-marketing CE requirements

At latest data extraction in January 2013, 32 total hip procedures had been reviewed with more than 3 years follow up independently from any patient selection. Apart from the initial follow up calendar, they are not re-summoned. Patients are reviewed as they come. Motivations for patients to come for the review appointments are of 2 types: either the patient strictly follows the review calendar received from day 1 after surgery, or the patient experiences problems or difficulties with their implant and visit the surgeon for a solution. The second motivation can have negative statistical effects on follow-up results.

3 years milestone has been selected, the cohort of 33 patients is sufficient to produce reliable results; earlier follow-up term has less scientific interest.

The devices with a minimum follow up of 3 years (average 3.4 years, min 3, max 4.7) were implanted in 2008 (20 cases, 60.6%) and 2009 (13 cases, 39.4%).

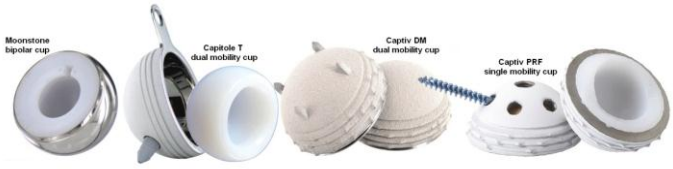
The patient gender includes a majority of female (21, 63.6%), mean age was 76 (min 68, max 89). The operated side was the right in 18 cases (54.5%) and the left in 15 cases (45.5%).

Postel-Merle d'Aubigné scoring chart

Score	Pain	Ability to walk	Mobility
6	No pain	Normal	Flexion of more than 90 degrees; abduction to 30 degrees
5	Mild and not constant : normal activity	Without cane but with slight limp	Flexion between 80 and 90 degrees; abduction of at least 15
4	Mild when walking : disappears with rest	A long time with a cane or a short time without cane and with limp	Flexion between 60 and 80 degrees; patient can reach his foot
3	Bearable with limited activity	With one cane, less than one hour or very difficult without a cane	Flexion between 40 and 60 degrees
2	Severe when walking; prevents from any activity	Only with canes	Flexion under 40 degrees
1	Severe even at night	Only with crutches	No movement : pain or slight deformity
0	Severe and permanent	Impossible	Ankylosis with bad position of the hip

Chart 1: PMA scoring chart for pain, ability to walk and articular mobility.

Most surgeries were primary procedures using standard primary implants (*HACTIV* femoral stems in 31 cases, *CAPTIV* Dual mobility cups in 28 cases, *CAPTIV PRF* fixed bearing cups in 2 cases, *MOONSTONE* Bipolar cup 1 case). 2 cases were partial revisions: 1 femoral component replacement with a *REACTIV* stem, 1 acetabular replacement with a *CAPITOLE T*.



Picture 1: type of acetabular component used in the study

Hactiv femoral stems are designed and manufactured by Evolutis (Briennon, France) on the model of quadrangular, double tapered, cementless implants used since 1984 in France and in the rest of the world with significant literature demonstrating the validity of the design and the effectiveness of the cementless fixation enhanced by a hydroxyapatite layer *(1)(2)(3)(4).* The *Hactiv* range includes standard and lateralized primary versions as well as revision versions. The standard primary version also has a collared option.

Picture 2: Hactiv (primary) and Reactiv (Revision) stems

Dependent on the extra-medullar morphology of the patients and according to the bone density, the surgeon can choose within these different options to ensure proper leg length and tensioning and to limit implant subsidence.

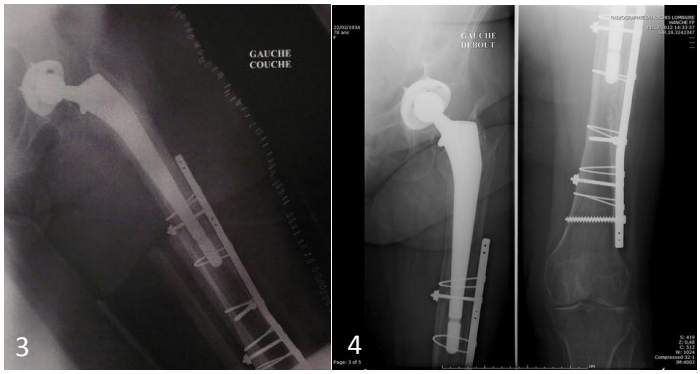
In the cohort, the surgeon mainly used standard and collarless stems (20 cases). 4 cases with standard neck-shaft angle were chosen in the collared version. 7 cases required a lateralized neck-shaft angle. The partial femoral revision case used a *Reactiv* Distal Locking stem, the partial acetabular revision used a tripod version of the dual mobility cup: the *Capitole T*.

The surgical approach used by the surgeon was the postero-lateral (Moore) approach for all cases including for the 2 partial revisions and the bipolar.

The bone quality was normal in 73.6% of the cases, dense in 5.2%, and porotic in 21%.

The clinical review and evaluation was undertaken by the operating surgeon. Each patient was evaluated a minimum of 4 times: pre-op, immediate post-op, 3 months and 3 years. 15 patients were reviewed at theses exact intervals. 13 were reviewed 5 times. 5 patients were reviewed more than 5 times mainly for second admittance for contra-lateral surgery of the hip (3 cases), one case for no specific reason at 1, 2 and 3 years but with a constant PMA score at 18 at each review, and the last case for the patient having had the femoral replacement with a *Reactiv* stem, and due to globally bad health.

There was one intra-operative complication and one immediate post-op complication. These concern the lady patient who was admitted for the femoral revision. During surgery, at removal time of the previous implant, the surgeon had to deal with a femoral fracture beneath the distal tip of the *Reactiv* stem. The fracture was reduced with a screwed plate and wires. At latest follow-up and despite re-intervention at 3 weeks post-op to treat a hematoma, the patient aged 78 has normal activity, low pain, and good mobility and is able to walk with the help of a stick. Her PMA score at 3 years is 13/18.



Picture 3 & 4: per-operative complication case of beneath the stem fracture treated with plate and wires. (3): immediate post-op, (4): 3 years post-op.

No other cases amongst the 32 patients had any pre, early or late complications. At this stage of the follow-up there were no minor or major revisions of any of the components. There were no implant failures either on radiological analysis and no aseptic loosening.

The mean age of the cohort at latest review was 79.4 years old (min 71, max 92), and 88% of the patients were between 73 and 84 years of age at time of the latest review.

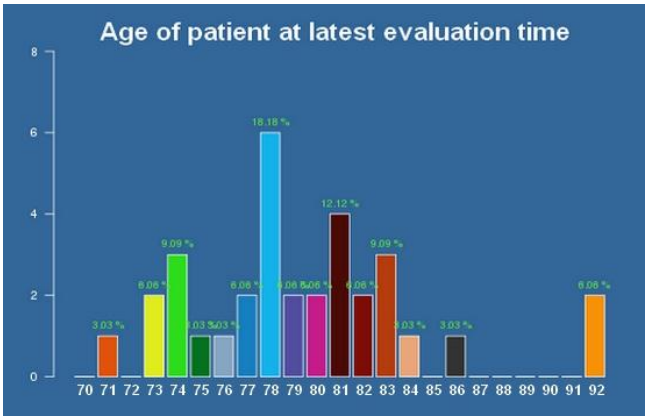
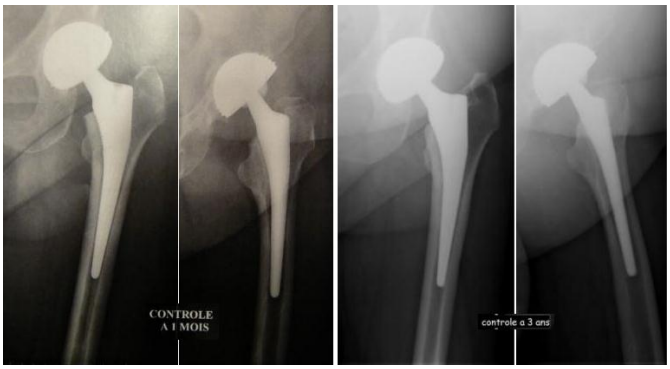


Chart 2: age of patients at latest evaluation

The PMA score of the cohort at latest follow-up is 17.4/18 (min 13, max18, sd: 0.97). Only one patient has a final PMA at 13. This patient has already been discussed earlier because of a bad overall health level and a difficult femoral revision surgery. One other patient has a final PMA at 16: this 78 years old patient has no pain and a very good range of mobility. There is no radiological sign of any kind with an identical x-ray image at the 1 year and the 3 years evaluation: no radiolucency, no migration and no loosening, and no bone remodeling at all. This patient has never achieved a better score since the beginning and the only difficulty concerns his walking ability which is almost unlimited (according to his own needs) but with some limping.

Picture 5: 78 years old patient at 3 years of FU with steady PMA at 16, limited only in walking ability.

All other patients have PMA scores between 17 and 18. Many scores of 17 (8/13) had previously reached the level of 18 at the 1 year evaluation and then declined. 4 of them already had a score of 17 at the one year evaluation, and only one case has kept improving their results from the one year landmark: this case had a 14/18 score at one year due to severe pain which progressively reduced to an actual slight and episodic pain possibly due to a lack of supéro-lateral bone coverage of the cup in this coxa-plana case. But at 3 years the radiologic analysis is very good with complete acetabular integration and no sign of radiolucencies.



Picture 6: 77 years old male patient at surgery with a low 14 PMA score at 1 year post-op, finally at 17 at 3 years of FU.

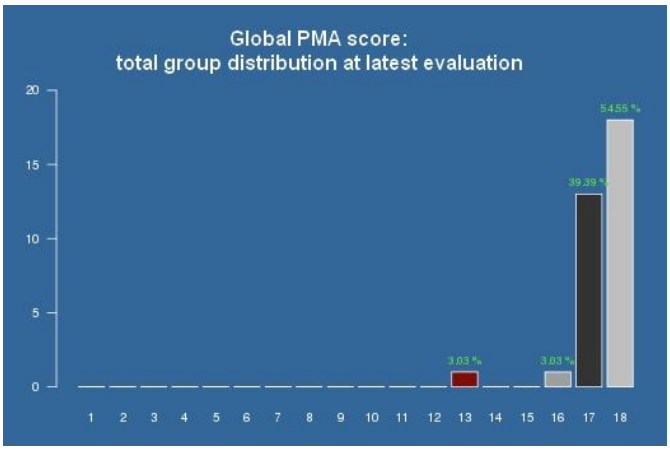


Chart 3: total group distribution of global PMA score at time of latest follow-up

The mean Global PMA gain is 7.9, (min 4, max 14, sd: 2.27). One patient had a score gain as high as 14 mainly due to the fact that the lady was admitted for femoral neck fracture. The pre-op evaluation was not possible and the surgeon had to quote the impossibility for the patient to walk by herself. This 73 years old female patient is classified PMA 17 at the 3 years review, her bipolar cup is very well tolerated with no limitation in mobility range and walking distance. A slight pain persists, as is classical with bipolar cups.

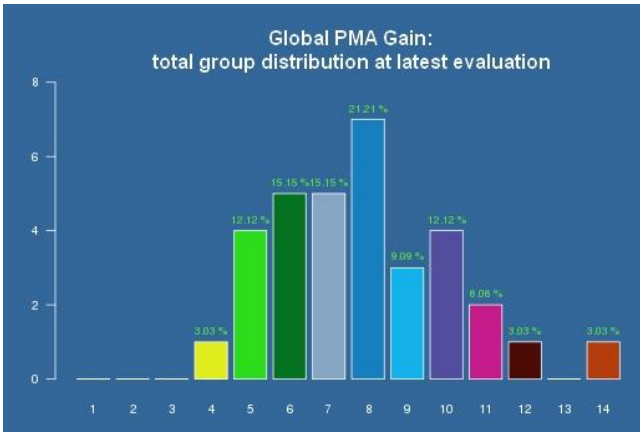


Chart 4: total group distribution of global PMA GAIN at time of latest follow-up

Most of the Global PMA gain is in the 5 to 10 interval. 2 patients have a Global gain of 11 points, and one of 12 points. The 2 patients aged 68 and 73 years old, with a global gain of 11 points share the same profile: an initial score at 7/18 due to severe pain, low flexion in the 40 to 60° range, and limited walking capacity. Surprisingly, both patients have reached the maximum PMA score within the 3 months post-op period and remain unchanged since then.

Picture 7: 68 years old patient with total PMA gain of 11.

The patient with a 12 points global gain also had a similar profile, with an initial score at 6/18. This patient had major difficulties to walk, even with the help of crutches. Now, at 82 years old, this patient has no pain, has excellent range of mobility, and walks freely any distance.

In detail, the maximum gain was achieved for pain evaluation: the average pain gain is as high as 3.76/6 (min 2, max 6, sd: 1). The final pain score is 5.6 on average (min 5, max 6, sd: 0.5) including 57.6% of patients feeling no pain at all and 42.4% of patients feeling slight and occasional pain not restricting their activities.

Picture 8: 79 years old patient with total PMA gain of 12.The cup is a single mobility Captiv PRF with PE liner.

The second maximum gain was achieved for walking ability 2.48/6 (min 1, max 6, sd: 1.06) despite the fact that 2 patients (6.06%) with scores of 3/6 and 4/6 could only walk with the help of sticks or crutches, and had limping or limited walking distance. The 31 remaining patients all reported a score of 6/6 translating to “normal” walking ability.

The mobility range of motion gain is always less impressive at 1.8/6 (min 1, max 4, sd: 0.92) as half of the patients (50%) have only improved their pre-op score by 1 point. Only one patient has an improvement of his mobility range of 4 points: this female patient claims full mobility range (flexion superior to 90° and 30° abduction) at 3 years post-op, but she was unable to flex more than 40° when she was admitted for surgery.

None of the patient files in the cohort has been closed for any reason related to the patient or to the implant.

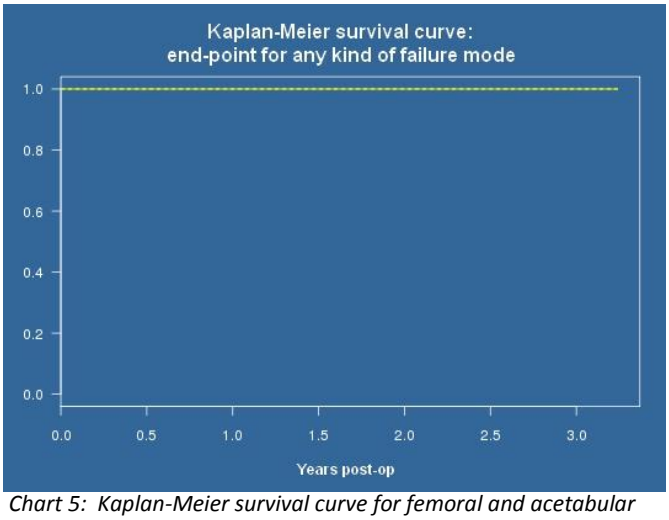


Chart 5: Kaplan-Meier survival curve for femoral and acetabular implant with end-point for any failure mode

At this evaluation milestone, 100% of the implants are still in place. The radiological analysis shows no sign of subsidence, loosening, or bone remodeling, including the 2 partial revision cases, or in the femoral neck fracture case, meaning that the long term stability of the cementless HACTIV femoral stems and CAPTIV acetabular cup components are reliable at 3.4 years FU analysis whatever the age, activity and health level of the patient.

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