HACTIV FEMORAL STEM COMPONENT REGISTERED IN THE NORWEGIAN ARTHROPLASTY REGISTER (NAR) FROM 2001-2011

Survivorship analysis of the HACTIV femoral stems implanted in Norwegian hospitals between 2001 and 2011: a review of 1274 prosthesis.

Abstract:

Between 2001 and 2011, 1274 HACTIV THA femoral stem prostheses (Evolutis, Briennon, France) were implanted in Norway. The epidemiological data and the complications are available in the Norwegian Arthroplasty Register which was set up in 1987. Data collection concerning all implanted components is compulsory. As a result extracted data allows for a global vision of the clinical performance independent from usual possible bias such as surgeon experience, or the geographical or social selection of the patients. This study compares the results of the Hactiv stem when combined with the 3 most frequently associated acetabular components. These are a cemented all PE cup, a cementless press-fit cup and a screw-in cementless cup. The results of each group do not allow a clear differentiation between the stem and the cup. The groups concerned are homogeneous on the distribution of the gender and on the operated side, but not on the criterion of the age.

The frequency of revisions is quite variable for each group. The revisions are mainly for reasons not directly connected to the femoral implant, but the frequency of femoral complications is higher when the Hactiv stem is combined with the cup which presents most complications. The reason may be due to the fact that this group is the youngest, therefore with an higher expectation level for clinical performance.

The results of the Hactiv stem alone are excellent with potential femur related revision frequency varying from 0,26 % at 3,47 years when associated with the Bicon-Plus cup and 0,78 % at 7.38 years when associated with the Reflection all-poly cup.

Résumé :

Entre 2001 et 2011, 1274 prothèses fémorales HACTIV (Evolutis, Briennon, France) ont été implantées en Norvège. Les données épidémiologiques et les complications sont disponibles à partir du Norwegian Arthroplasty Register mis en place depuis 1987. La collecte des données inhérentes à chaque implant posé est obligatoire de sorte que les données extraites permettent une vision globale des performances cliniques indépendantes des biais habituels possibles comme l'expérience du chirurgien ou la sélection géographique ou sociale des patients. L'étude porte sur la comparaison des résultats de la tige fémoral Hactiv combinée aux 3 composants acétabulaires associés le plus fréquemment dans le registre. Il s'agit d'un implant cimenté, un implant sans ciment press-fit et un implant sans ciment vissé. Les résultats de chaque groupe ne permettent pas une différentiation claire entre la tige et la cupule. D'autre part, les groupes concernés sont homogènes sur la répartition du genre et du côté opéré, mais ne le sont pas sur le critère de l'âge.

La fréquence des révisions apparaît très variable pour chaque groupe. Les révisions sont principalement motivées par des raisons qui ne sont pas directement liées à l'implant fémoral, mais la fréquence des complications fémorales est plus importante quand la tige Hactiv est combinée avec la cupule qui présente le plus de complications. La raison est certainement due au fait que ce groupe est le plus jeune des 3, donc demandeur de plus de résultat.

Les résultats de la tige Hactiv seule apparaissent excellents avec des taux de révision potentiellement imputables à l'implant variant de 0,26% à 3,47 ans quand associée avec la cupule Bicon-Plus et 0,78% à 7,38 ans quand associée avec la cupule Reflection all-poly.

Introduction:

1274 Hactiv cementless femoral components for total hip arthroplasties were implanted in different hospitals in Norway between 2001 and 2011, by multiple operators.

The Hactiv femoral components registered in the NAR for total hip arthroplasty were associated with different types and brands of cemented or cementless acetabular components. The three most common acetabular combinations including Hactiv femoral stems were the cementless Trilogy cup (Zimmer, Kalamazoo, USA) (34.0%), the Bicon-Plus Screw-in cementless cup (Smith&Nephew, Andover, USA) (30.3%), and the Reflection All-poly cemented cup (Smith&Nephew, Andover, USA) (29.9%). The remaining combinations with other type of cups (5.8%) having limited frequency for statistical significance, were excluded from the analysis.

The remaining 1200 THA have been reviewed and survivorship analysis and the three combinations have been compared for statistical difference due to cup choice.

The NAR offers exhaustive data on implants registered, complications at any stage (early, intermediate or late) and survivorship statistics, but does not offer detailed analysis of complications or failures.

It is therefore not possible in this review to provide detailed explanations of the difference in the results for each combination, nor to provide qualitative analysis with respect to hospitals, surgeons, or patients' variances.

As a consequence and because these results do not belong to one selected experienced surgeon, to a specific physiotherapy protocol, to a unique implant combination, or to a specific indication/gender/age of patient, the results can be considered as fully reliable and reproducible.

Materials:

1274 THA using an HACTIV femoral component were included in the Norwegian Arthroplasty Register (NAR) between 2001, year of the first implantation of the Hactiv stem in Norway, and 2011, year of latest available data from the register. In 2009, the HACTIV stem was the 9th most used femoral implant in Norway.

The frequency of use per year is described in table 1.

	Frequency	Percent	Valid Percent	Cumulative Percent
2001	10	0,78%	0,78%	0,78%
2002	98	7,69%	7,69%	8,48%
2003	105	8,24%	8,24%	16,72%
2004	117	9,18%	9,18%	25,90%
2005	264	20,72%	20,72%	46,62%
2006	120	9,42%	9,42%	56,04%
2007	149	11,70%	11,70%	67,74%
2008	149	11,70%	11,70%	79,43%
2009	126	9,89%	9,89%	89,32%
2010	78	6,12%	6,12%	95,45%
2011	58	4,55%	4,55%	100,00%
Total	**1274**	**100,00%**	**100,00%**	

Table 1: Primary Operation Year – HACTIV femoral stem

The three most common prostheses combinations (total of 1200 THA representing 94.2%) including Hactiv femoral stem are:

- Trilogy cementless cup (n=434)
- Bicon-Plus screw-in cup (n=387)
- Reflection All-poly (n=381)

The maximum length of follow-up for the HACTIV femoral component is 10.13 years with the Bicon-Plus cup, 7.89 years with the Trilogy cup, and 7.55 years with the Reflection All-poly cup.

The means and medians follow-up for the three combinations (calculated using the reversed Kaplan-Meier method) are summarized in table 2.

	Mean				Median			
	Estimate	Sd	95%CI		Estimate	Sd	95%CI	
			Lower	Upper			Lower	Upper
Reflection all-poly	3.47	0.099	3.28	3.67	3.34	0.127	3.09	3.59
Trilogy	4.46	0.094	4.28	4.65	4.64	0.159	4.28	4.95
Bicon-Plus	7.38	0.105	7.18	7.59	7.59	0.100	7.56	7.95

Table 2: Means and Medians for Survival Time

In the Norwegian Arthroplasty Register, the mean age for primary THA is 69.1 years. The female gender is more often concerned by THA surgeries than male gender (68.7% vs 31.3%), and the operated side is more often the right side than the left side (55.2% vs 44.8%).

The HACTIV femoral implants were used in statistically younger patients then average when combined with the Trilogy cementless cup (very significant)(mean 52.2 years [13.3, 89.8]) or the Reflection all-poly cemented cup (mean 61.1 [18.9, 91.2]). There was no difference in terms of age of patient for the Bicon-plus cohort, and there was no difference in gender or laterality for any of the three combinations compared to the average.

The data are summarized in table 3.

	Age			Gender	Laterality
	Mean	Min	Max	(% female)	(% right side)
Reflection all-poly	61.1	18.9	91.2	61.4	57.5
Trilogy	52.2	13.3	89.8	61.1	51.9
Bicon+	69.5	38	94.3	60.2	57.1

Table 3: Mean age, gender and laterality for the three combinations of cups used with Hactiv stems

Results:

The mean follow-up of the global 1200 Hactiv THA is 5.09 years. The Bicon-Plus combination has the longest follow-up (387 implants) with 10.13 years at maximum length and 7.38 years of mean FU (sd: 0.105, [CI 95%: 7.18, 7.59]). The Trilogy cup (432 implants) has a maximum length of FU at 7.89 years and 4.46 years of mean FU (sd: 0.094, [CI 95%: 4.28, 4.65]). The Reflection all-poly (381 implants) has a maximum length of FU at 7.55 years and 3.47 years of mean FU (sd: 0.099, [CI 95%: 3.28, 3.67]).

At the latest follow-up, 57 of the 1200 HACTIV THA had been revised, mainly for hip dislocation (15 cases, 1.25%), deep infection (13 cases, 1.08%), and acetabular loosening (12 cases, 1%).

There were 8 femoral loosenings (0.6%) mainly when associated with Trilogy cementless acetabular cups (5 cases, 1.15% of the Trilogy combination cases).

Revision rates are significantly dependent on the acetabular combination. When associated with the cemented Reflection cup, the revision frequency is 2.36% at the mean follow-up of 3.47 years, while when associated with the Trilogy cementless cup, the revision frequency is 6.25% at the mean FU of 4.46 years. In between, when associated with the Bicon-Plus screwed-in cup the revision frequency is 5.43% but at the mean follow-up of 7.38 years. See table 4.

		Indicator for Revision		Total
		Primary	Revision	
Product in Acetabulum	Reflection all-poly	372	9	381
		97.6%	2.4%	100%
	Trilogy	405	27	432
		93.8%	6.2%	100%
	Bicon+	366	21	387
		94.6%	5.4%	100%
Total		**1143**	**57**	**1200**
		95.2%	**4.8%**	**100%**

Table 4: Percentages of revision for the three combinations of cups used with Hactiv stems

The detailed analysis of failures indicates that the revision risks reported concern either or both of the articular components: acetabular or femoral loosening, dislocation, femoral fracture, infection, pain…

The comparison of three acetabular combinations should therefore show differences when considering items directly related to the acetabular component such as acetabular loosening and dislocation.

But surprisingly, the results on the femoral side are substantially different depending on the acetabular combination: the femoral loosening frequency is 4 times greater when Hactiv stems are associated with Trilogy cups than when associated with the Reflection cup (1.16% vs 0.26%). Also, 2 femoral fractures (0.46%) and 2 cases of thigh pain (0.46%) were reported when associated with the Trilogy cup, while no case was reported for the two other combinations on the same two items.

Revision frequencies for deep infection are also substantially different depending on the combination as there is a 4 fold difference between the 2 cementless cups: 0.46% for the Trilogy cup versus 1.81% for the Bicon-Plus cup. The Reflection cemented cup is in between with a 1.05% revision frequency, which may suggest that the effect of antibiotic cement is limited with respect to infection prevention: Reflection cemented cups started being used in 2004. The use of plain cement (without antibiotics) was completely banned in Norway in 2003, and consequently the Reflection cups

associated with Hactiv stems were cemented only with antibiotics cements.

Dislocation is the main risk for revision among the 1200 THAs. It is the major risk for both the combinations with the Reflection and the Trilogy cups, but with a 4 fold frequency difference (0.52% vs 2.08%). Dislocation is not the major risk for the Bicon-Plus combination (1.03%). The major risks with the Bicon-Plus is cup loosening and deep infection (1.81% for each item).The frequency of revisions is detailed in table 5.

The number and frequency of prostheses that have not been revised differ for the three combinations. This slightly affects the width of the confidence intervals because of a higher uncertainty when the numbers are small.

	Reflection		Trilogy		Bicon-Plus		Total	
	Freq.	Percent	Freq.	Percent	Freq.	Percent	Freq.	Percent
Acetabular Loosening	2	0,52%	3	0,69%	7	1,81%	12	1,00%
Femoral Loosening	1	0,26%	5	1,16%	2	0,52%	8	0,67%
Loosening (both)			1	0,23%	1	0,26%	2	0,17%
Dislocation	2	0,52%	9	2,08%	4	1,03%	15	1,25%
Deep infection	4	1,05%	2	0,46%	7	1,81%	13	1,08%
Fracture of femur			2	0,46%			2	0,17%
Pain only			2	0,46%			2	0,17%
Other			3	0,69%			3	0,25%
Total	**9**	**2,36%**	**27**	**6,25%**	**21**	**5,43%**	**57**	**4,75%**

Table 5: Reasons and frequency for revisions

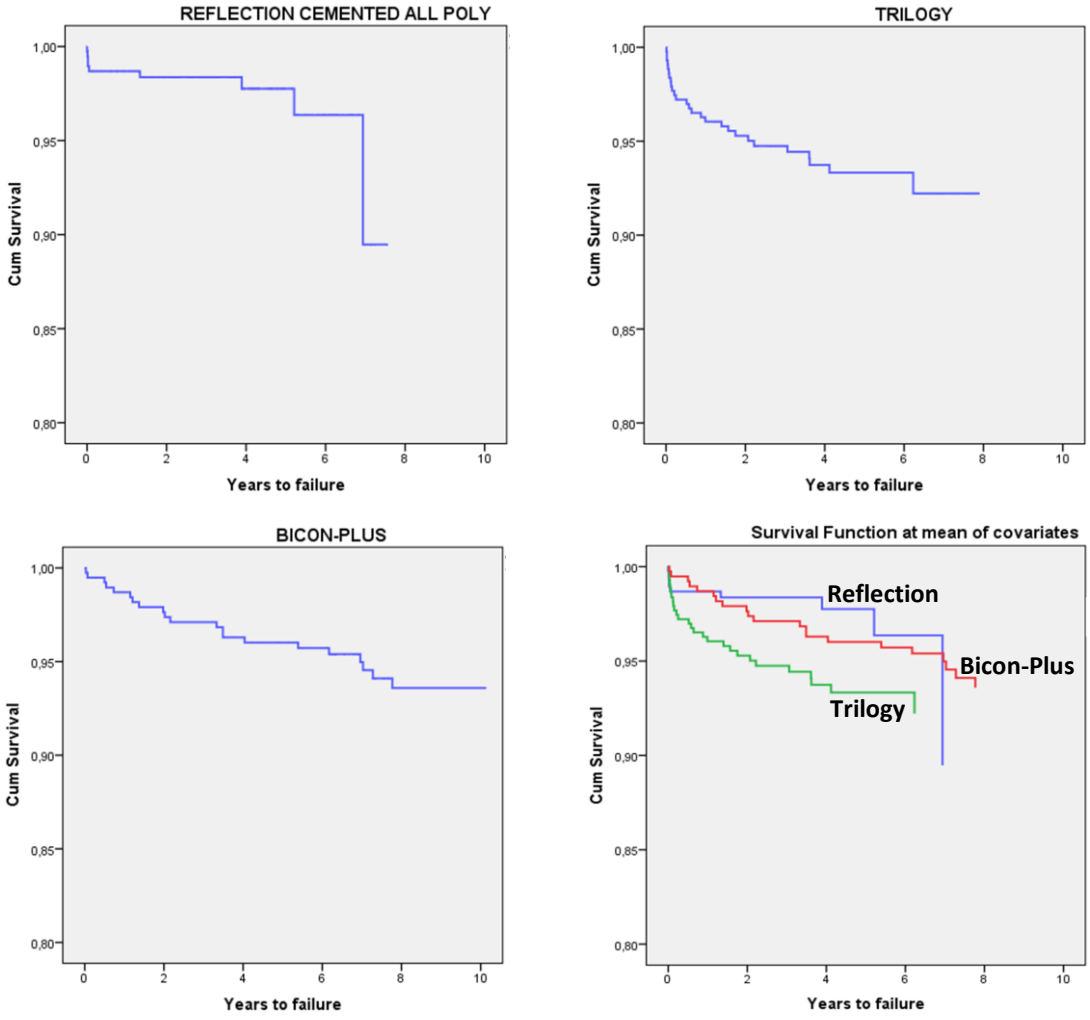

Table 6: Survival functions: Kaplan-Meier for each combination, Unadjusted Cox for the combined display

The probability of survival is consequently different for the three combinations:

- The probability of survival at 5 years for the THA associating the Hactiv femoral stem with the Reflection all-poly cup is 97.8% with a 95% confidence interval equal to [96, 99.6].
- The probability of survival at 5 years for the THA associating the Hactiv femoral stem with the Trilogy cementless cup is 93.3% with a 95% confidence interval equal to [90.7, 95.9].
- The probability of survival at 5 years for the THA associating the Hactiv femoral stem with the Bicon-Plus screw-in cup is 96% with a 95% confidence interval equal to [94, 98].

Due to the difference in revision frequency between the three combinations, the survival curves are displayed separately using the Kaplan-Meier method. Ultimately one figure using Unadjusted Cox survival method displays the three combinations in the same plot. The endpoint in all figures is any cause of revision. See table 6.

Discussion:

The results of the Hactiv stems registered in the Norwegian Arthroplasty register are highly interesting due to the comparison of three main and statistically significant combinations with different brands of acetabular cup. Most clinical studies provide a unique combination analysis and calculate different endpoint survival analysis: mainly survivorship rate for any cause of revision and survivorship rate for failure of the femoral side only.

Comparing three different combinations implanted in multiple Norwegian hospitals by surgeons of different experience, and for significantly different age of patients give a much larger prospect of the true clinical outcomes of an implant.

The three combinations vary not only in terms of type of acetabular cup, but also in terms of length of follow-up and in terms of mean age of the patients:

- Reflection all-poly is the second most used acetabular implant since the NAR was created. It is an all polyethylene cup designed to be cemented in the acetabulum. In addition Norwegian surgeons are highly experienced with third generation cementing techniques, and the use of antibiotics cement is systematic.
- Trilogy is the 8th most used acetabular implant in Norway. It is a titanium mesh coated metal back modular acetabular cup. Its mean of fixation in the acetabulum is a primary press-fit impaction and a secondary bony integration in the porous coating of the outer-shell.
- Bicon-Plus is a titanium metal back modular acetabular cup with no coating except for a grit blasted outer surface. It differs from the Trilogy with a screw-in the acetabulum fixation method.

Figure 1: Reflection all-poly, Trilogy, Bicon-Plus

- Both the Reflection and the Trilogy began being recorded in the register in 2004 and are still being used at the latest follow-up. The Bicon-Plus was included in the register as early as 2001 and stopped being used in 2005, meaning that all the cases of Bicon-Plus have a minimum follow-up of 6 years.
- The mean age of patients for the Trilogy combination is significantly younger than both other combinations, meaning that the expectations and use of the implants are much higher in this young population, with possible consequences on complications and survival rates.

Over a 10 year period of use of the Hactiv stem in Norway, 57 revisions of patients have been reported for any cause of revision. The NAR does not provide details of which implant was revised during these revision surgeries, it is therefore not possible to calculate the probability of survival for the Hactiv stem alone and not dependent from an acetabular cup.

There have been 12 revisions for acetabular loosening, 13 revisions for deep infection and 15 for dislocation.

These 40 cases of revision have probably little to do with the femoral implant:

- acetabular loosening may be induced by technical errors such as cementing technique or size adaptation (especially true

for screwed-in cups), or in the longer term by PE wear osteolysis.

- deep infection is usually related to absence of prophylactic antibiotics, postoperative complications, weeping wounds, previous operations, and remote infections. Some authors includes also acetabular protrusion, alcoholism, elevated ESR rate, and the number of blood units transfused as deep infection predictors for THA procedures.
- dislocation may be caused by a wrong anteversion of the femoral stem or cup, or by a shortening of the limb because of an excessive femoral resection, dislocation risk can also be increased by the surgical approach, the tonicity of the patient and his behavioral compliance according to the surgeon's recommendations. Most of these cases are not related to the femoral implant itself.

Among the remaining 17 revision cases, all but four are associated with the Trilogy cup combination. These revision cases include 6 femoral loosening, 2 femur fractures and 2 revisions for persistent pain.

Again, as the NAR does not provide detailed data concerning the time of complication occurrence (early or late loosening, intra-surgery or trauma related fracture…) it is difficult to analyze and explain the revisions. The reliable information is that the Trilogy population is significantly younger than the rest of the cohort, meaning that on average the demand from this population in terms of expectation (mobility, pain, and tribologic performance of the artificial joint) is much higher than that of an older population. The level of use of the implants will also be more intensive, accelerating wear and failures despite a better original bone stock and muscular tonicity.

The Trilogy cup is one of the most widely used cup in Norway (9th cup in frequency used in 2009, 8th since the register was created in 1987) and in the world. Consequently the increased level of revision measured in the NAR for the Hactiv/Trilogy combination can reasonably be explained by the more demanding conditions of use as well as by the variations in training, experience and skills of the operating surgeons.

The frequency of potential femoral related revisions varies from 0.26% at 3.47 years of FU and mean age of 61.1 for the Reflection combination, to 3.00% at 4.46 years of FU and mean age of 52.2 for the Trilogy combination. The Bicon-Plus combination potential femoral related revision frequency reaches 0.78% at 7.38 years of FU and mean age of 69.5.

On average, the total cohort potential femoral related revision frequency reaches 1.43% at 5.09 years of FU and mean age of 60.6 years.

Conclusions:

National registers do not provide accurate and detailed clinical results. Their evidence level cannot be compared to a classical prospective randomized and comparative study in terms of scientific certainties, and registers do not allow fine analysis of post-operative complications or cross-data analysis on a selected number of procedures.

On the other hand, registers such as the NAR, and because of their comprehensiveness (compulsory inclusion of all patient undergoing a given arthroplasty, and compulsory updating of existing files) provide a wide vision of the real-life situation with no statistical bias such as surgeon's expertise or social level of group of patient.

The 1200 Hactiv stems followed in this study have been implanted on a 10 year period by a large number of differently skilled surgeons in different hospitals, for many different indications and on many different profiles of patients.

The conclusion is that the results published by the NAR are easily reproducible by most surgeons, resident or highly skilled.

Despite the fact that most of the revisions are not due to femoral related causes, the overall survival are very good: 97.8% at 5 years when combined with the Bicon-Plus cup.

When considering only potential femoral related revision causes, the revision frequency of the Hactiv stem is as low as 0.26% at 3.47 years with the Bicon-Plus and 0.78% at 7.38 years with the Reflection all-poly.

In conclusion, the Hactiv femoral component for THA appears to be a very secure and reproducible implant that can be indicated both for young patients and for the elderly. The reproducible surgical technique allows for confident usage and reassuring outcomes for both the patient and the surgeon.