

# Poor survival of cementless Biomet<sup>®</sup> total hip

## A report on 1,047 hips from the Finnish Arthroplasty Register

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In Finland, almost 50% of all hip replacements done after 1989 have been inserted without cement. Biomet<sup>®</sup> components have been the most commonly used implants in cementless arthroplasties. Between 1985 and 1997, 4,300 prostheses were implanted because of primary osteoarthritis. 4 different acetabular component designs have been identified as Biomet implants (Mallory-Head, Romanus, T-TAP, Universal) and were used in 1,047 hips.

The 9-year survival of all arthroplasties using Biomet cups was only 65 (95% CI 61–69)%, while that of arthroplasties using T-TAP-cups was only 58 (52–65)%. In contrast, the 7.5-year survival of arthroplasties using Romanus cups was 85 (79–91)%.

The 98 (96–99)% 5-year survival of arthroplasties with Mallory-Head cups should be interpreted cautiously, since similar results of arthroplasties using the Universal cup with the same type of liner decline sharply to 93 (88–98)% only 1 year later.

The poor survival of Biomet cementless prostheses in our series seems to be related to the poor survival of the cup. This finding was common to all metal shell designs using Hexloc liners. We recommend that Biomet cups with Hexloc liners should not be used and patients who have had them inserted should undergo regular clinical and radiographic follow-ups.

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Submitted 99-01-14. Accepted 99-07-01

Norway, Sweden and Finland are among countries with comprehensive national arthroplasty registers. From the data collected by the Norwegian Arthroplasty Register and the Swedish Arthroplasty Register, it appears that in Norway and Sweden most hip prostheses are inserted with cement (Havelin et al. 1994, Malchau and Herberts 1996). In Finland, almost half of all hip replacements since 1989 have been inserted without cement. This is probably the highest fraction in the world (Nevalainen et al. 1997). Biomet components have been the most commonly used implants in cementless arthroplasties in Finland. We report a survivorship analysis of cementless Biomet total hip prostheses for osteoarthritis.

### Patients and methods

Data concerning 8,190 hip prostheses, implanted during 1985–1997, and recorded as Biomet pros-

theses were obtained from the Finnish Arthroplasty Register, which is part of the Finnish Implant Register, maintained by the National Agency for Medicines. The 4,300 prostheses inserted because of primary arthrosis were chosen for a more thorough analysis. The focus of the study was to determine the influence of the acetabular component on the survival of the arthroplasties.

4 different acetabular component designs have been identified as Biomet implants (Mallory-Head, Romanus, T-TAP and Universal). Information obtained from the supplier (Oy Kenn-Med Ab Biomet Helsinki, Finland) on the number of sold prostheses was used to determine the reliability of the Register data. From the supplier's data, we determined when and which design had been sold to each hospital. By comparing the exact number of implants sold in a month with the data of the Arthroplasty Register for the corresponding period, it was possible to extract a reliable series per hospital for each of the 4 cup designs. Consequently,

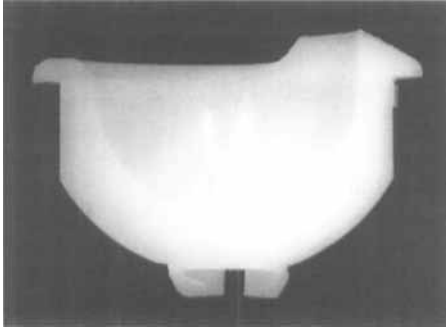


Figure 1. Cross-sectional photograph of the Hexloc liner. The polyethylene liner is several millimeters thinner at its rim than at its dome because of the hexagonal locking mechanism and the cylindrical design of the liner.

the specific data consisted of 302 T-TAP, 148 Romanus, 361 Mallory-Head and 236 Universal cups. The Kaplan-Meier survival curves for the 4 Biomet cup designs (n 1,047) were calculated from the data of the Finnish Arthroplasty Register.

The T-TAP is a threaded titanium cup, the Romanus is a plasma-sprayed partially threaded porous-coated titanium cup, which has also been used with hydroxyapatite coating. The Mallory-Head cup is a hemispherical porous-coated cup of titanium alloy, which has 4 peripheral fins. Titanium screws can be inserted through dome and rim holes. The Universal cup is a hemispherical porous-coated press-fit type cup of titanium alloy,

with a thickened peripheral flange. Titanium screws can be inserted through dome and rim holes. Until 1994, Hexloc type liners were used and then replaced by Ringloc type liners with a new design. The Hexloc liners were machined from extruded bar raw material and gamma sterilized in air. Rotation of the polyethylene liner in the metal shell was prevented by a hexagonal locking mechanism and the cylindrical design of the liner (Figure 1). According to the information obtained from the supplier (Oy Kenn-Med Ab Biomet, Helsinki, Finland), 6,924 Hexloc type liners were sold between 1986 and 1996.

Standard Kaplan-Meier estimates for survival were used. Figures in parentheses are 95% confidence intervals. Revision was used as the definition of failure. The patients were followed until the end of 1997 or until death.

## Results

The age distribution of cementless Biomet prostheses, compared with other cementless and cemented prostheses, is presented in Figure 2.

The number of prostheses implanted for primary arthrosis was 4,300. Of these, 2,045 (48%) were inserted in men and 2,253 (52%) in women. 3,261 (76%) were 65 years and younger and 1,039

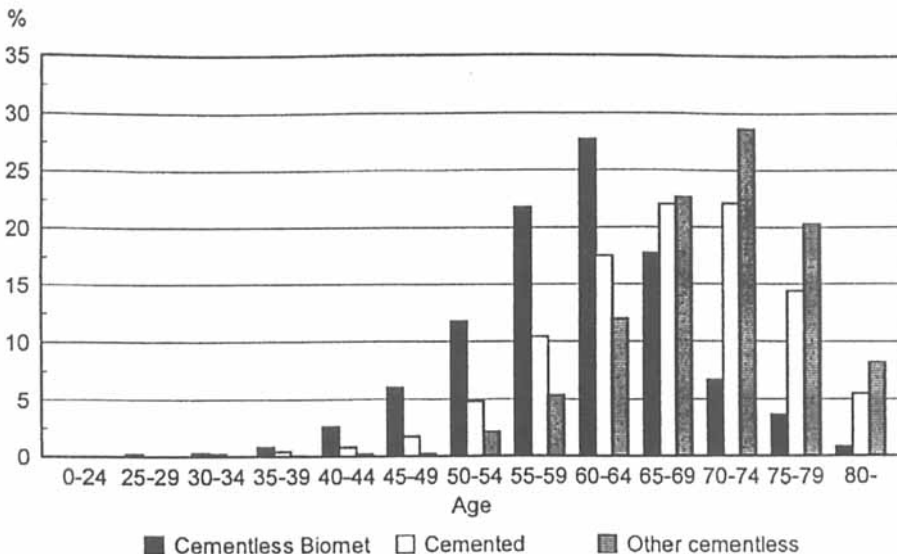


Figure 2. Age distribution of patients with cementless Biomet prosthesis compared to other cementless and cemented prostheses. The Finnish Arthroplasty Register 1980-1997.

**The reasons for revision in primary arthrosis of 4,300 implanted Biomet hip prostheses**

| Reason for revision          | Number | Percent |
|------------------------------|--------|---------|
| Loosening acetabular comp.   | 291    | 71      |
| Loosening both comp.         | 10     | 2.4     |
| Loosening femoral comp.      | 24     | 5.8     |
| Dislocation                  | 27     | 6.6     |
| Malpositioning of prosthesis | 18     | 4.4     |
| Fracture of bone             | 8      | 1.9     |
| Infection                    | 7      | 1.7     |
| Fracture of prosthesis       | 7      | 1.7     |
| Other reason                 | 20     | 4.9     |
| Total                        | 412    | 100     |

(24%) were over 65 years old. Of the men, 1,645 (80%) were 65 years or younger and 400 (20%) were over 65 years old. Of the women, 1,614 (72%) were 65 years or younger and 639 (28%) were over 65 years old.

**Survival and 95% confidence interval**

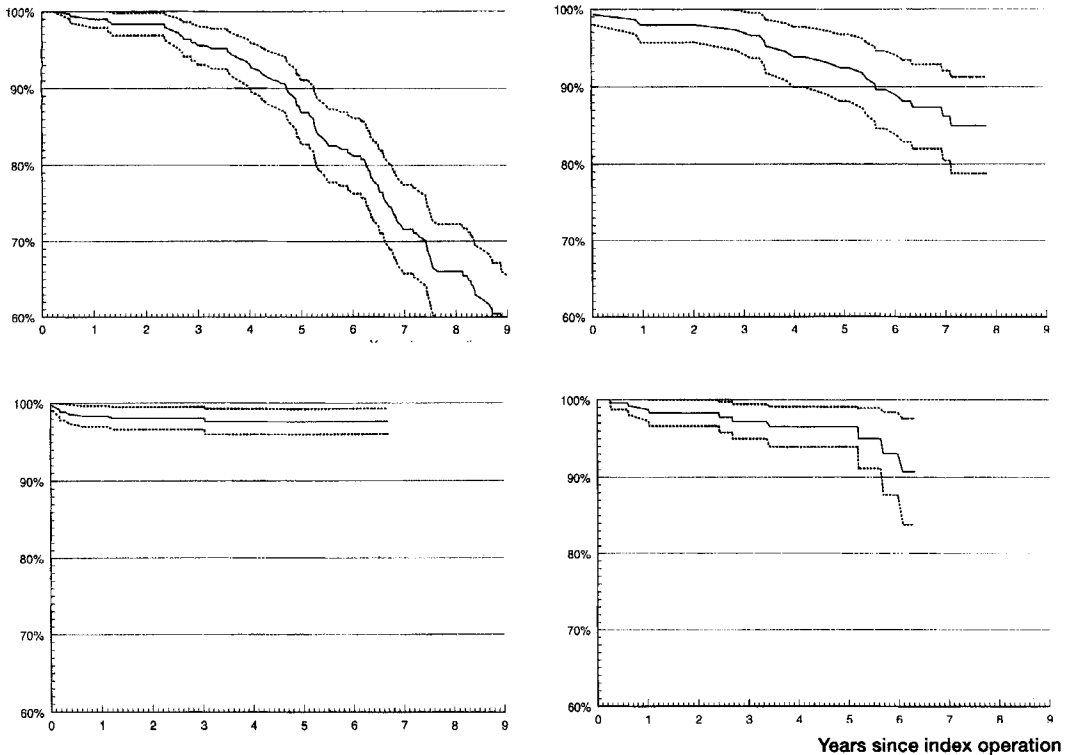


Figure 3. The Finnish Arthroplasty Register 1980-1997. Kaplan-Meier survival of prosthesis in primary arthrosis with 95% confidence interval. Upper left: Threaded cup (T-TAP; n 302), upper right: Romanus cup (n 148), lower left: Mallory-Head cup (n 361), and lower right: Universal cup (n 236).

The reasons for revision in primary arthrosis are presented in the Table.

Survival rates of total hip arthroplasties using different Biomet cups are presented in Figure 3.

**Discussion**

The survival rates for cementless hip prostheses vary (Manley et al. 1998) and none have exceeded those of cemented ones (Wroblewski and Siney 1992, Schulte et al. 1993). Nevertheless, the use of cementless components has steadily increased. In many studies (Bono et al. 1994, Owen et al. 1994, Hozack et al. 1996, Barrack et al. 1997), the poor performance of press-fit cups has been the success-limiting factor of the procedure. In several studies, the survival of the acetabular and femoral components are treated separately. However,

from the patient's point of view, this is irrelevant, since it is the survival and performance of the whole prosthesis that matters and the component with the poorest performance determines the outcome of the implant entity.

Analysis of the Biomet data from the Finnish Arthroplasty Register was complicated because the acetabular and femoral components as well as the material and the size of the femoral heads had not been recorded separately. However, with the sales records of the supplier linked to the data of the Arthroplasty Register, it was possible to extract a sufficiently comprehensive series of arthroplasties, using different types of Biomet cups from the Register. Since the beginning of 1996, femoral and acetabular components as well as the material and the size of the femoral heads have been listed separately.

When the performance of an individual prosthesis is considered, revisions due to aseptic loosening, fracture of the material and exceptional wear should be considered prosthesis-related. On the other hand, revision operations due to infection, malalignment and dislocations are related to the circumstances, the surgeon and the hospital. In this study, poor survival of the acetabular components in particular was observed.

From an earlier study, it is known that between 1989 and 1995, the most frequently revised cementless acetabular components were Biomet cups with a total of 473 revisions (Puolakka et al. 1997). This figure consists of 4 different designs: T-TAP, Romanus, Universal and Mallory-Head. The present study revealed that the reason for revision in primary arthrosis was aseptic loosening of the acetabular component in 71%, aseptic loosening of both components in 2% and aseptic loosening of the femoral component in 6% of the revisions.

The survival of arthroplasties using the T-TAP threaded cup was, as expected, the poorest. In the series of 302 arthroplasties recorded in the Finnish Arthroplasty Register, the Kaplan-Meier estimate of 5-year survival was 87 (83-91)% which fell to 58 (52-65)% at 9 years. Fox et al. (1994) have observed even poorer results with the T-TAP threaded cup, so that after a mean follow-up time of 62 months, 38% of the acetabular components were loose. On the contrary, Havelin et al. (1995) have

reported better results with the T-TAP threaded cup in the Norwegian Arthroplasty Register: the 5-year survival rate was 99 (97-100)%.

We have poor results, with a 5-year survival rate of 93 (88-97)% and a 7.5-year survival of 85 (79-91)% of 148 arthroplasties using Romanus cups. To our knowledge, survivorship analysis of the Romanus cup has not been published previously.

Short-term results with arthroplasties using the Mallory-Head cup were found to be good. At 5 years, the Kaplan-Meier survival rate for 361 arthroplasties was 98 (97-99)%. However, this result should be interpreted very cautiously, since it is only after 5 years that the survival of the Biomet Universal cup with the same type of liner drops steeply. This was shown in an earlier report with an intermediate 5-year survival of 98 (97-100)% of 223 arthroplasties using Universal cups (Puolakka et al. 1997), and where the 6-year survival fell to only 93 (88-98)%. Hozack et al. (1996) have previously reported an 11% revision rate of the Universal cup, with a mean follow-up time of 6 years (minimum 5 years). They also observed osteolytic lesions around the acetabular cup in 26% of the cases.

The poor survival of Biomet endoprostheses in our series seems to be related to the poor survival of the cup. This problem appears to be common to all metal shell designs using the contemporary Hexloc liner. Earlier findings in the literature (Hozack et al. 1996) and design alterations made on the liner support this conclusion. The other contributing factor to the alarming survival rate might be that Biomet cementless hip prostheses are more commonly inserted in younger patients than other cementless and cemented hip prostheses in Finland. Usually, prosthetic survival in younger age groups has been disappointing (Gross 1988, Dorey and Amstutz 1989, Malchau et al. 1993, Havelin et al. 1994, Devane et al. 1997).

We recommend that patients who have had Biomet cups with Hexloc liners inserted should have regular clinical and radiographic follow-ups.

The authors thank Anu Hirvonen, secretary of the Arthroplasty Register and Kenn-Med Ab Biomet, Finland, for their help in performing this study and also Jaakko Keränen, Tampere University of Technology, for the photograph.

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