# EARLY ASEPTIC LOOSENING OF UNCEMENTED FEMORAL COMPONENTS IN PRIMARY TOTAL HIP REPLACEMENT

## A REVIEW BASED ON THE NORWEGIAN ARTHROPLASTY REGISTER

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**The Norwegian Arthroplasty Register recorded 24 408 primary total hip replacements from 1987 to 1993; 2907 of them (13%) were performed with uncemented femoral components. We have compared the results of eight different designs, each used in more than 100 patients.**

**Survivorship of the components was estimated by the Kaplan-Meier method using revision for aseptic loosening of the femoral component as the end-point.**

**At 4.5 years, the estimated probability of revision for aseptic loosening for all implants was 4.5%, for the Bio-Fit stem 18.6% (n = 210) and for the Femora stem 13.6% (n = 173). The PM-Prosthesis and the Harris/Galante stem prostheses needed revision in 5.6% and 3.6%, respectively. The clockwise threaded stem of the Femora implant needed revision in 20% of right hips, but in only 4% of left hips.**

**The short-term results of the four best uncemented femoral components (Corail, LMT, Profile and Zweimüller) were similar to those for cemented stems, with revision for loosening in less than 1% at 4.5 years. The importance of the control of innovative designs and the registration of early results is discussed.**

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The Norwegian Arthroplasty Register has recorded 24 408 primary total hip replacements (THR) and 3824 revision operations from September 1987 to January 1993. An earlier report showed relatively poor results from uncemented THR in Norway from 1987 to 1992 (Havelin et al 1994), especially for femoral components. Many types of uncemented femoral component had been used, with major differences in design.

We now report the short-term results, at 0 to 5.4 years, for eight different types of uncemented femoral component used in Norway.

## PATIENTS AND METHODS

Norway has 4.2 million inhabitants, and all THR operations are reported to the Norwegian Arthroplasty Register (Havelin et al 1993). From September 1987 to January 1993, 3141 uncemented femoral prostheses had been implanted in primary operations (13%). A total of 17 different types of femoral component had been used, but only eight designs had been implanted in more than 100 hips. The results for these eight types, in 2907 hips, have been studied and compared. The prostheses were the Bio-Fit (Richards, Memphis, Tennessee), the Corail (Landos, Chaumont, France), the Femora (Chas F Thackray, Leeds, UK), the Harris/Galante (Zimmer, Warsaw, Indiana), the LMT (Biomet, Warsaw, Indiana), the PM-Prosthesis (Aesculap, Tuttlingen, Germany), the Profile (DePuy, Warsaw, Indiana), and the Zweimüller (Allo Pro, Baar, Switzerland) (Table I). There was a total of 2421 patients, 486 of whom had bilateral operations. The distribution of age, gender and diagnosis in each group is shown in Table II.

All revision operations were reported to the Registry and linked to the primary operation by the patients' national social security number. The follow-up period was 0 to 5.4 years. Information on the revisions included details of components that had been changed or removed and the reasons for revision. In our survival analysis, only revision or removal of the femoral component for aseptic loosening of the stem was used as an end-point. Other reasons for revision, such as dislocation, infection and socket loosening, were excluded from this analysis.

Survival curves were constructed by the Kaplan-Meier method (Kaplan and Meier 1958), defining survival time as the time from the primary THR to revision due to aseptic

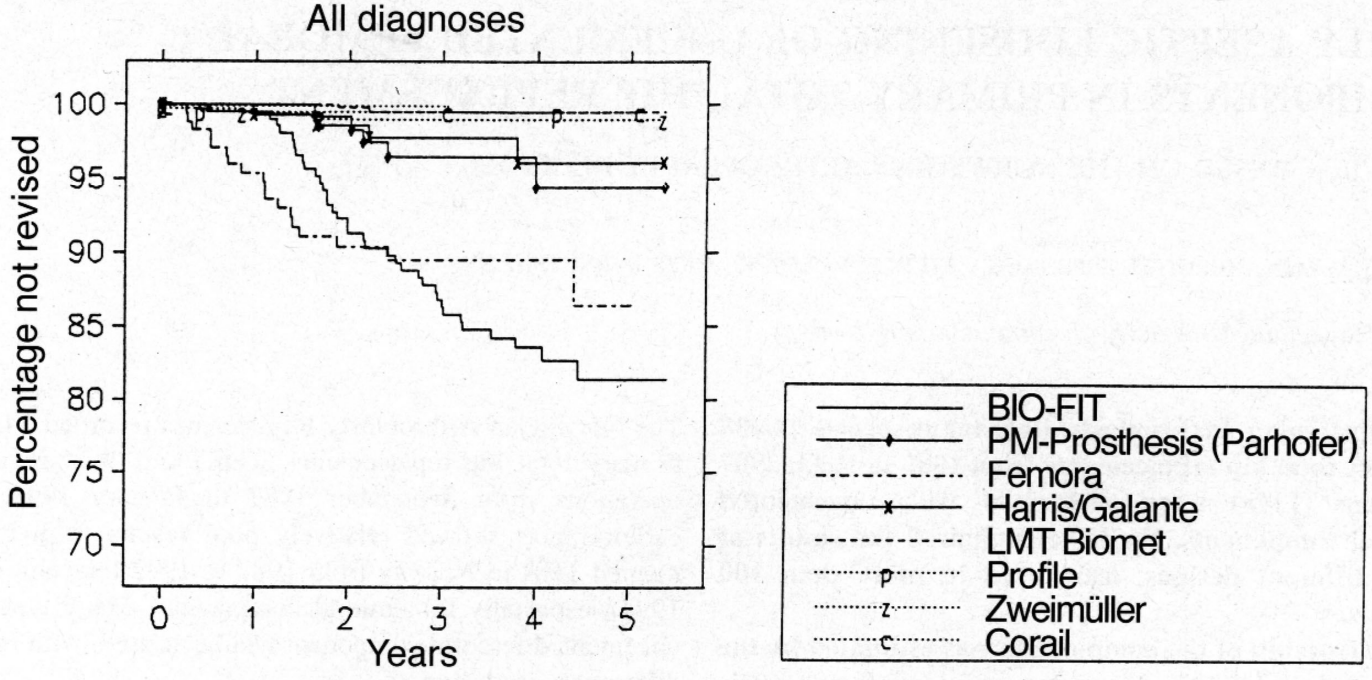


Fig. 1

Survival until revision (for aseptic loosening only) of eight designs of uncemented femoral component used in Norway from 1987 to 1993.

loosening of the stem. Survival times for patients who had died without revision were excluded. Patients who had emigrated (n = 36) were identified from the records of the Central Bureau of Statistics in Oslo and were also excluded. We used a two-sided log-rank test to determine the significance of differences in survival between the types of stem (Mantel 1966), and calculated confidence intervals by the Greenwood method.

We used the Cox proportional hazards model (Cox 1972) to compare the relative risk for revision, both with and without adjustment for gender, age group (< 40, 40 to 49, 50 to 59, 60 to 69, > 69 years) and diagnostic group. All analyses were performed using the BMDP statistical package (Dixon et al 1990).

## RESULTS

Table II gives the number of each type of primary femoral component, with data for age, gender and diagnosis. As expected there were differences between the patients having different types of prosthesis: LMT patients were older and had a lower ratio of men, the Harris/Galante patients were the youngest, with a lower ratio of primary osteoarthritis. Table III shows the number of each type of component remaining at risk at 3 and 4.5 years, with the cumulative survival at 4.5 years. The total revision rate for aseptic loosening of femoral components after 4.5 years was 4.5%. Kaplan-Meier analysis showed some significant differences, with revision of 18.6% of the Bio-Fit prosthesis, 13.6% of the Femora, 3.6% of the Harris/Galante and 5.6% of the PM-Prosthesis. The other uncemented femoral components (Corail, LMT, Profile and Zweimüller) all had failure rates of less than 1% after 4.5 years (Fig. 1).

The differences between the Bio-Fit and the Femora, and the Harris/Galante and the PM-Prosthesis were not statistically significant, but the differences between each of these four prostheses and the group with low failure rates (Corail, LMT, Profile and Zweimüller) were statistically very significant ($p < 0.0001$). There were no statistically significant differences between the Corail, LMT, Profile and Zweimüller components.

We compared the two groups of components. Those with proximal circumferential porous coating, hydroxyapatite coating, or rough sandblasted surfaces (Corail, LMT, Profile and Zweimüller) had a cumulative survival of 99.5% at 4.5 years. The others (Bio-Fit, Femora, Harris/Galante and PM-Prosthesis) had a cumulative survival of 87.9% at 4.5 years ($p < 0.0001$).

Survival analyses for smaller groups, subdivided by primary osteoarthritis or other diagnoses, gender and age below or above 50 years, gave similar survival curves (Fig. 2).

All the analyses were carried out with an individual hip as the unit. This may be suspect, since failure of one hip in the 486 patients with bilateral THR may influence the outcome in the other hip. We therefore analysed the results for the first hip only in patients with bilateral THR: our results were virtually unchanged.

For each type of component we found no significant difference between results for the first two years of use compared with those done later.

The Femora prosthesis showed significantly better results on the left side than the right ($p < 0.01$), with cumulative survival after 4.5 years of 95.8% and 80.8% respectively (Fig. 3). We found no difference between the right and the left hip for the other seven prostheses taken together.

The Cox model showed that patients having the Bio-Fit,

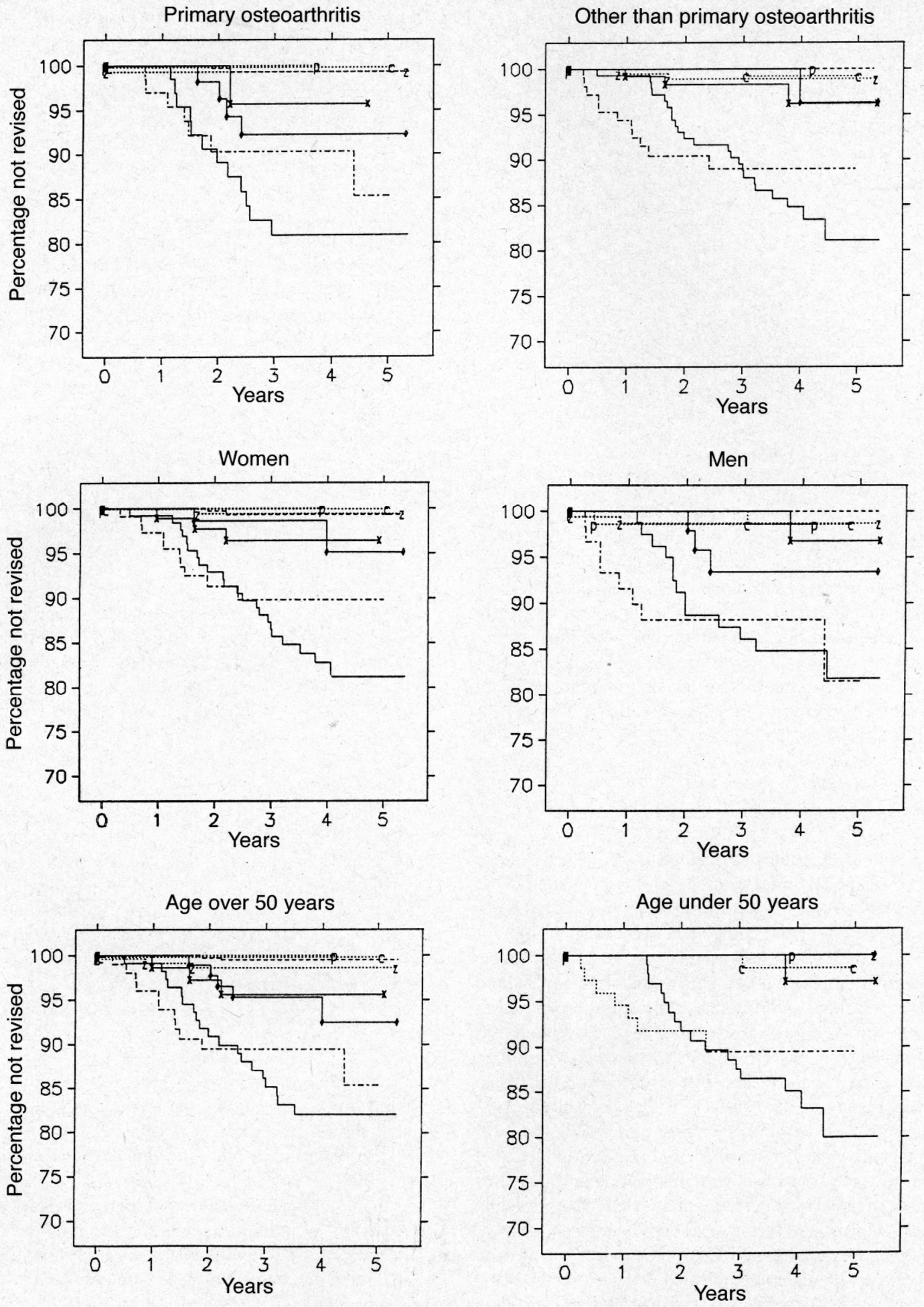


Fig. 2

Survival until revision (for aseptic loosening) of eight uncemented femoral components used in Norway from 1987 to 1993. Separate curves for primary osteoarthritis, other diagnoses, gender, and patients more than and less than 50 years old.

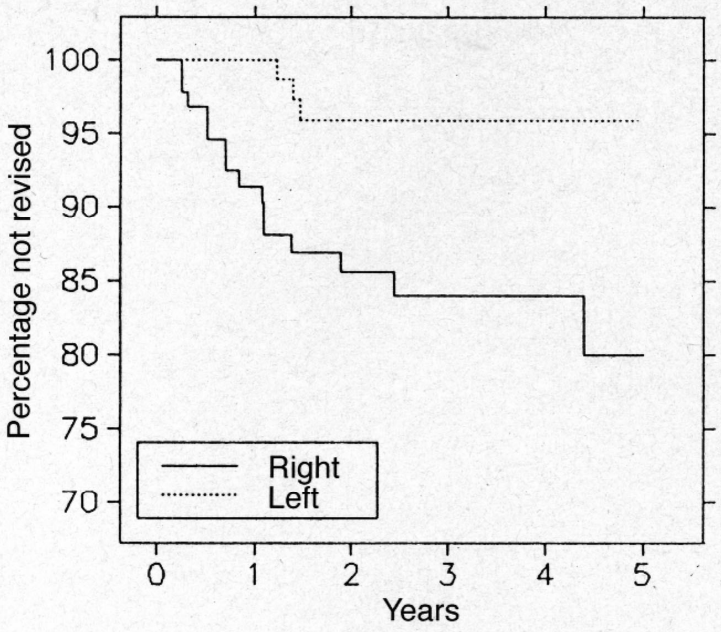


Fig. 3

Survival until revision (for aseptic loosening) of the femoral component of the Femora prosthesis in right hips (n = 93) and left hips (n = 80).

Femora, Harris/Galante or PM-Prosthesis had increased risks of failure (failure-rate ratios) by factors of 33, 26, 6 and 8 times respectively, compared with the other four prostheses. Adjustments for age and gender, and stratification for diagnoses, showed an even greater increase in failure-rate ratios for the worst group of four (Table IV). The effect of age on the risk for revision was inconclusive. Cox models restricted to the patients with primary osteoarthritis, or those with the other diagnoses, gave similar results to those for all hips.

## DISCUSSION

The overall results of the uncemented THR in Norway have been shown to be inferior to those for cemented THR (Havelin et al 1994). We have now shown that certain types of uncemented femoral component were responsible for most of the failures in the uncemented group. Despite the short period of observation, the results for Bio-Fit and Femora stems were significantly inferior to those for other uncemented femoral components. The early results for these two components are similar to or even worse than those reported for the Christiansen prosthesis, for which long-term results are known to be very poor with approximately 40% revised after ten years (Josefsson, Lindberg and Wiklander 1981; Sudmann et al 1983; Ahnfelt et al 1990; Ohlin 1990; Malchau, Herberts and Ahnfelt 1993).

Our analysis by hip and not by patient is a potential problem (Morris 1993), since strong interdependence of bilateral failures may compromise the analyses. However, our proportion of bilaterally operated patients (486 of 2421) was relatively low; less than 10% of the failures occurred in second hips and in no patient had both hips failed. We also found similar results in analyses with second hips excluded.

Our finding that results were similar early and late in the period under review, and the fact that all the implants were relatively new, indicates that learning curves cannot explain the inferior results.

The results in the better group (Corail, LMT, Profile and Zweimüller) with 99.5% survival after 4.5 years are similar to those reported for cemented femoral components (Havelin et al 1994). These are all of titanium with surfaces either rough sandblasted, porous-coated or hydroxyapatite-coated. The results for this group are promising although the mean follow-up for several of them was shorter than for others (Table III). The PM-Prosthesis ('Parhofer') was used in Norway without porous coating up to 1990, and the Harris/Galante, with only a small area of porous coating, had intermediate results as reported by others (Kim and Kim 1992), but they were still inferior to those of most cemented prostheses.

The relative failure of the Bio-Fit and Femora components may be due to their design. The Bio-Fit variant (Fig. 4) which was used is press-fit with a rather smooth surface

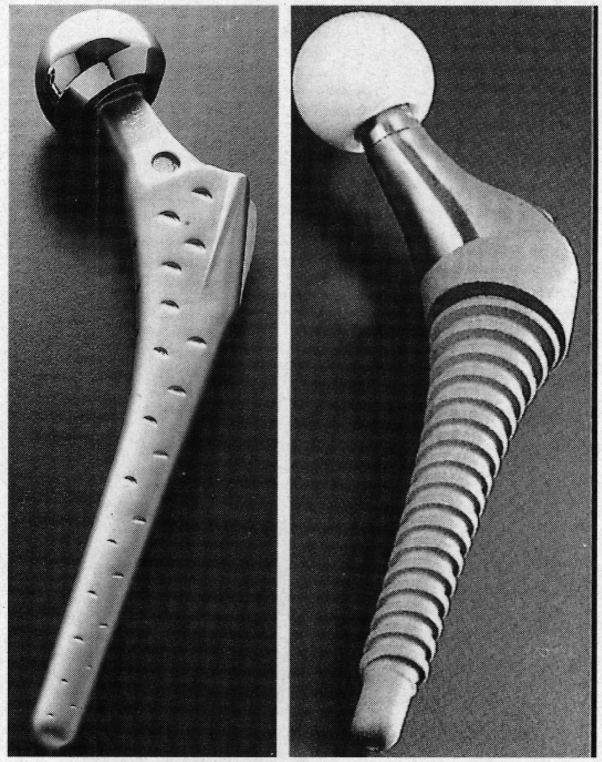

Fig. 4

The Bio-Fit component (left) and the Femora component (right).

of cobalt-chromium. Poor results have been found also for other smooth-surfaced press-fit prostheses (Duparc and Massin 1992).

The Femora prosthesis has a threaded screw stem (Fig. 4) of titanium. We could find no other report of the results for this component but good results have been reported for the SCL screw-in component with a screw which locks for rotation in the femur (Lang and Callea 1993). The inferior results of the Femora component in the right hip may be explained by the rotational forces produced by bodyweight. Both left and right prostheses have a right-handed

**Table I.** Characteristics of the eight most commonly used uncemented femoral components in Norway 1987 to 1993

| | Material | Design | Surface |
|---|---|---|---|
| Bio-Fit | Cobalt-chromium | Straight stem | Smooth with buttressed scallops |
| Corail | Titanium alloy | Straight stem | Fully hydroxyapatite (HA)-coated |
| Femora | Titanium alloy | Threaded stem | Blasted |
| Harris/Galante | Titanium alloy | Straight stem | Proximally porous-coated, not circumferentially |
| LMT | Titanium alloy | Straight stem | Proximally porous-coated |
| PM-Prosthesis | Titanium alloy | Curved stem | Smooth with inverse scallops, porous-coated late in the period |
| Profile | Titanium alloy | Anatomic stem | Proximally porous- or HA-coated |
| Zweimüller | Titanium alloy | Straight stem with rectangular cross-section | Blasted surface |

**Table II.** Age, gender and diagnosis of patients with eight different uncemented femoral components used in Norway 1987 to 1993

| | Bio-Fit (n = 210) | Corail (n = 1117) | Femora (n = 173) | Harris/ Galante (n = 157) | LMT (n = 500) | PM-Prosthesis (n = 151) | Profile (n = 266) | Zweimüller (n = 333) |
|---|---|---|---|---|---|---|---|---|
| Age (yr): | | | | | | | | |
| Min | 16 | 15 | 24 | 15 | 24 | 29 | 17 | 18 |
| Mean | 50 | 51 | 51 | 48 | 63 | 53 | 51 | 53 |
| Max | 82 | 84 | 75 | 83 | 87 | 78 | 75 | 71 |
| Sex: *percent* men | *38* | *37* | *34* | *41* | *30* | *43* | *38* | *47* |
| Diagnoses (%) | | | | | | | | |
| Primary osteoarthritis | *31* | *39* | *38* | *20* | *71* | *42* | *42* | *43* |
| Rheumatoid arthritis | *8* | *6* | *2* | *6* | *0* | *3* | *7* | *4* |
| Seq of fracture | *8* | *6* | *7* | *6* | *10* | *5* | *9* | *6* |
| CDH | *30* | *20* | *33* | *24* | *12* | *28* | *21* | *26* |
| CDH with dislocation | *7* | *10* | *5* | *26* | *2* | *10* | *1* | *4* |
| Other paediatric hip | *8* | *6* | *5* | *8* | *1* | *8* | *9* | *6* |
| Ankylosing spondylitis | *1* | *2* | *3* | *1* | *0* | *1* | *2* | *1* |
| Other diagnoses | *7* | *12* | *6* | *10* | *3* | *3* | *9* | *12* |

**Table III.** Number of hips at risk and Kaplan-Meier estimates of cumulative survival (until revision because of aseptic loosening) of the different uncemented femoral components used in Norway 1987 to 1993

| | | | Remain at risk | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | | 3 years | | 4.5 years | | | | |
| | Number | Mean follow-up (yr) | Number | % | Number | % | Revisions 0 to 5.4 years | Cumulative survival after 4.5 years (%) | 95% confidence intervals at 4.5 years |
| Bio-Fit | 210 | 4.0 | 173 | *82* | 32 | *15* | 35 | *81.4* | 74.1 to 87.4 |
| Corail | 1117 | 1.8 | 239 | *21* | 16 | *1* | 2 | *99.5* | 98.5 to 100 |
| Femora | 173 | 3.1 | 92 | *53* | 28 | *16* | 18 | *86.4* | 78.7 to 92.0 |
| Harris/Galante | 157 | 3.3 | 96 | *61* | 21 | *13* | 4 | *96.2* | 91.4 to 100 |
| LMT | 500 | 3.2 | 278 | *56* | 93 | *19* | 2 | *99.5* | 98.8 to 100 |
| PM-Prosthesis | 151 | 3.2 | 83 | *55* | 29 | *19* | 5 | *94.4* | 89.0 to 99.8 |
| Profile | 266 | 0.9 | 22 | *8* | 0 | *0* | 0 | — | |
| Zweimüller | 333 | 3.9 | 247 | *74* | 89 | *27* | 3 | *99.1* | 97.9 to 100 |

**Table IV.** Cox model. Effect of type of femoral component, gender and age on the relative risk for revision (failure-rate ratio) of uncemented femoral components due to aseptic loosening. Failure-rate ratio is given unadjusted and adjusted for the other factors and for diagnoses

| | | | Unadjusted | | Adjusted | |
|---|---|---|---|---|---|---|
| | Number | Revisions | Failure-rate ratio | p value | Failure-rate ratio | p value |
| Components | | | | | | |
| Bio-Fit | 210 | 35 | 32.8 | < 0.0001 | 36.4 | < 0.0001 |
| Femora | 173 | 18 | 26.3 | < 0.0001 | 30.5 | < 0.0001 |
| Harris/Galante | 157 | 4 | 5.8 | < 0.005 | 8.0 | < 0.001 |
| PM-Prosthesis | 151 | 5 | 8.0 | < 0.0005 | 8.8 | < 0.0005 |
| Others* | 2216 | 7 | 1 | | 1 | |
| Gender | | | | | | |
| Female | 1813 | 41 | 0.9 | 0.58 | 0.9 | 0.78 |
| Male | 1094 | 28 | 1 | | 1 | |
| Age (yr) | | | | | | |
| < 40 | 358 | 10 | 1 | | 1 | |
| 40 to 49 | 633 | 14 | 0.77 | 0.52 | 0.80 | 0.62 |
| 50 to 59 | 1068 | 27 | 0.77 | 0.50 | 0.95 | 0.90 |
| 60 to 69 | 695 | 16 | 0.68 | 0.33 | 1.52 | 0.41 |
| > 69 | 153 | 2 | 0.42 | 0.26 | 1.59 | 0.58 |
| Trend test for age | | | | 0.24 | | 0.26 |

* Corail, Profile, LMT, and Zweimüller

thread, so that the forces produced by standing up from a sitting position will tend to unscrew a prosthesis in the right hip, and tighten it in the left.

The Femora component was used only as part of a clinical trial in five Norwegian hospitals, in less than 200 patients. The Bio-Fit component was introduced before the Register was established, was freely available and has been used in approximately 1000 Norwegian patients. After a report from the Norwegian Arthroplasty Register (Havelin et al 1991), the manufacturer stopped the production of the Femora prosthesis, and the Bio-Fit prosthesis has since then only been used with cement in Norway. The Christiansen prosthesis was implanted in over 5000 Swedish patients (Ahnfelt et al 1990; Malchau et al 1993) and in over 6000 Norwegian patients before the findings from one hospital revealed the poor results (Sudmann et al 1983). The story of these three prostheses clearly shows the importance and success of nationwide or multicentre quality control of implants (Herberts et al 1989; Faro and Huiskes 1992).

The use of uncemented prostheses should still be considered to be experimental (Bauer 1992). New types of prosthesis should be introduced by controlled multicentre trials, designed to confirm good clinical results before they are freely available. We conclude that several types of uncemented femoral component give poor results. The comparison of the best of the uncemented femoral components with cemented stems will require larger numbers and longer observation periods, or well-designed prospective randomised trials.

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