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# Stability of Endler Cementless Polyethylene Acetabular Cup: Long-term Follow-up

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**Aim** To investigate the possible influence of demographic and biomechanical factors on stability of the Endler cementless polyethylene acetabular cup.

**Methods.** This was a retrospective cohort study. Seventy-two patients (25 men, 47 women) bearing 82 Endler prostheses, all of which were implanted by the same surgeon in the period between 1985 and 1991, were invited for a control visit (final visit) in July 2003. During time between the surgery and the final visit, the patients were followed-up regularly and assessed for clinical and radiological signs of the Endler cup instability based on Krugluger and Eyb's criteria. The Kaplan-Meier product limit method and the Cox proportional hazard regression analysis were used to investigate the survival of the cup (time since implantation till the diagnosis of instability) and possible influence of the following factors: age and body mass index at the time of surgery, gender, achieved acetabular cup inclination angle, and acetabuloplasty and/or trochanter osteotomy performed during surgery.

**Results** The median follow-up period was 15 years (range 5-18). Cumulative survival rates at 5, 10, 15, and 18 years were 97.6% (95% CI = 94.2-100), 74.4% (95% CI = 64.9-83.8), 53.7% (95% CI = 42.9-64.5), and 44.5% (95% CI = 29.5-59.6), respectively. The median survival time was 18 years (13-18). Unsatisfactory acetabular cup inclination angle (<41 or >49 degrees) was a negative predictor of the cup survival ($P = 0.026$), whereas the interaction between the inclination angle and an unsatisfactory body mass index (>upper normal limit) was of borderline significance ($P = 0.056$). The analyzed demographic and biomechanical factors apparently explained only a minor part of the survival variability ($R^2 = 0.173$).

**Conclusion** This study further documents the impact of the acetabular cup inclination angle achieved at surgery on the Endler cup survival. However, it also suggests that the prosthesis survival might be influenced by other, non-biomechanical factors.

Aseptic instability is one of the late complications of the hip joint endoprosthesis surgery. Numerous factors are involved in the onset of this complication, one of them being the materials used in the manufacture of the endoprosthesis components. The bone reaction is induced by wear debris with consequent osteolysis (1). The so-called particle disease develops within 5 to 15 years resulting in aseptic loosening of the joint endoprosthesis (2). It has long been questioned whether this host reaction to various foreign particles around the prosthesis should be attributed to any particular material component (metal, bone cement, high molecular polyethylene), or whether all the components cumulatively contributed to the onset of the complications (3-6). Additional factors besides the prosthesis features, like surgeon's skill, patients' attitude, time, and biomechanical conditions, have been shown to influence the prosthesis survival (7-11). Of the biomechanical factors, high body weight (12) and an unsatisfactory acetabular cup inclination angle achieved at surgery (ie, <41 or >49 degrees) (13) have been shown to contribute to the prosthesis instability onset.

The cementless conical polyethylene acetabular Endler cup is a hip joint endoprosthesis with a good construction and fixation in bone, properties that would be expected to contribute to long-term stability. Its polyethylene structure, on the other hand, is thought to represent an important disadvantage. Polyethylene is a material, which wears out due to friction after a while in the area between the acetabulum and the head, and between the acetabulum and the bone stock. As a result, small particles appear and, if accumulated in great quantity, cause inflammation, ie, particle (polyethylene) disease (14,15).

Several follow-up studies have so far investigated the survival of Endler cup (12,14-18), evaluating between 96 (18) and 334 (17) prostheses for a median follow-up period of 5 (18) to 10 years (14). The present study refers to a cohort with a minimum theoretical follow-up period for a surviving prosthesis of 12 years (maximum 18), with the primary objective of evaluating the impact of biomechanical and demographic factors on the prosthesis survival.

## Patients and Methods

### *Design*

This was a retrospective cohort study undertaken in July 2003. Based on a medical history data search at the Department of Orthopedic Surgery, Zagreb University School of Medicine, a cohort of 100 patients were identified who met the following predefined criteria: a) had received the cementless conical polyethylene acetabular Endler cup (unilaterally or bilaterally); b) had been operated on by the same surgeon (to eliminate the "surgeon's skill" factor); c) at least 12 years had elapsed between the time of surgery and July 2003; d) radiographs of the operated hip taken immediately after surgery were available for analysis; e) data on age and body mass index (BMI) (or weight and height allowing BMI to be calculated) at the time of surgery were available; f) a description of the surgical procedure was available.

Beside the Endler cup, all patients received Zweymueller femoral stem as well. They were invited for a control visit in July 2003 (final visit), when a detailed medical history and a clinical exam were taken. For those who had not been diagnosed with prosthesis instability before the final visit, the visit included also clinical and radiological evaluation of the prosthesis. Patients (prostheses) were to be included in the analysis set provided the following criteria were met: a) the patient attended the final visit; b) the medical history data documented regular follow-up during the time since surgery till the prosthesis instability diagnosis or the final visit, ie, clinical and radiological evaluation of the prosthesis in time intervals of around 12 months (if not referring spontaneously due to subjective difficulties); and c) no local bone infection possibly interfering with the prosthesis stability had been recorded. Of the 100 patients, 24 did not attend the final visit and the prosthesis outcome could not be reliably determined (8 had died and 16 were lost to follow-up), and 4 were excluded due to the bone infection occurrence. This left 72 patients with 82 implanted Endler acetabular cups for the final analysis.

### *Radiological Evaluation Methods*

The first post-operative X-ray was usually taken on the second post-operative day. The anteroposterior view was used to determine the acetabulum inclination angle using Delphi Visual Pascal software (19). The angles were classified as "satisfactory" if in the range of 41 to 49 degrees and as "unsatisfactory" otherwise (13). At the later visits, anteroposterior and lateral views were used for the following assessment: a) evaluation of the bone reaction around the cup using DeLee and Charnley's method which divides the contact surface of the cup into 3 zones in each projection, allowing for a separate assessment of bone reactions in each zone (20); b) recording of diffuse or thin sclerotic lines around the cup threads, radio-

**Table 1.** Criteria for radiological classification of endoprosthesis stability according to Krugluger and Eyb (14)

| Endoprosthesis | Criteria |
|---|---|
| 1. Stable | sclerotization yes/no |
| | visible threads or radiolucent line of 1 mm in width in a single area |
| 2. Early instability* | visible threads or radiolucent line of 1-2 mm in two areas |
| 3. Probable instability* | visible threads or radiolucent line of 1-2 mm in width in two or more areas |
| | osteolytic defect of >2 mm |
| 4. Definite instability* | visible threads or radiolucent line of 1-2 mm in width in several areas |
| | osteolytic defect >2 mm |
| | endoprosthesis migration which may be cranial or medial |

*Considered as an unstable endoprosthesis.

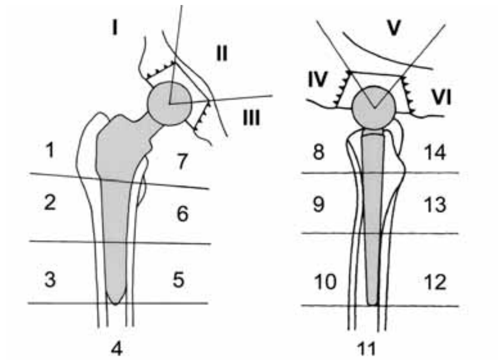


**Figure 1.** Radiological zones around the hip prosthesis components used to assess the bone reaction according to DeLee and Charnley (20).

lucent lines, osteolytic defects distal to the cup, changes in the position of the cup and proximal shaft reactions. Based on these parameters, the endoprosthesis stability was assessed and classified according to Krugluger and Eyb's criteria (14) (Table 1). Figure 1 illustrates radiological zones around the prosthesis components, Figure 2 shows a typical X-ray finding of an unstable prosthesis, Figure 3 shows a typical X-ray finding of a stable prosthesis, and Figure 4 shows a typical microscopic appearance of severe polyethylene debris in the tissue around the implant.

### *Statistical Analysis*

The primary outcome was the prosthesis survival. For this purpose each implanted prosthesis was considered as an independent case (21, 22). The follow-up period was defined as the time elapsed from the prosthesis implantation until the final visit (July 2003) or until the diagnosis of instability (whichever happened first), and was determined per prosthesis. Summary statistics is reported for the cohort's characteristics.

To describe time-to-event data, where "event" is the occurrence of the prosthesis "failure", ie, instability, Kaplan-Meier product-limit estimator was used (Greenwood method for confidence intervals). Time to "failure" was calculated in years, as time elapsed since the surgery until the actual moment of the instability diagnosis. Since the patients were followed-up regularly, the time of diagnosis was treated as the "failure" time although these observations were actually interval censored. All hips for which good stability was confirmed at the final visit were considered as censored observations.

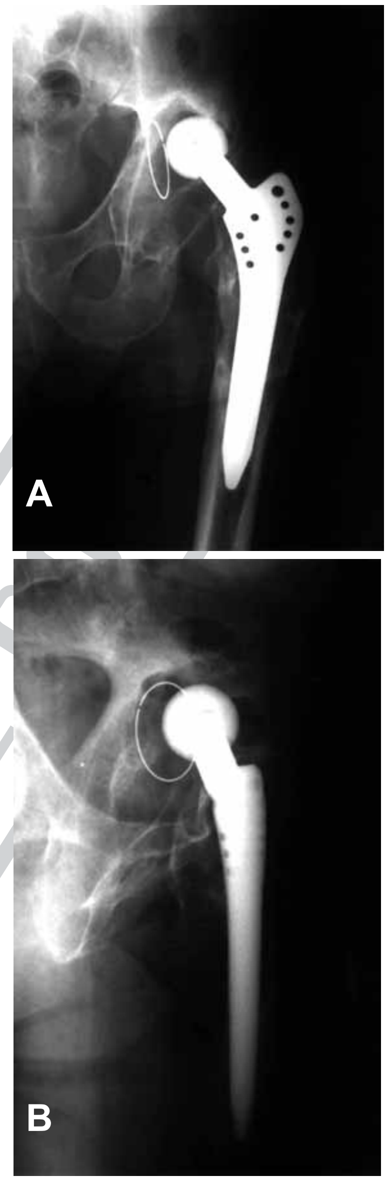


**Figure 2.** Radiographs of an unstable total hip endoprosthesis 15 years after surgery. The anteroposterior (**A**) and lateral (**B**) view show extensive osteolytic destruction at the caudal part, with migration of acetabulum cup and subluxation of the head.

To analyze the impact of demographic and biomechanical factors on the prosthesis survival, Cox proportional hazard regression analysis was used (maximum likelihood estimation solved by the Newton-Raphson method; ties method: Efron's approximation to log likelihood). The following independent factors were considered in the analysis: age at the time of surgery, gender, in-

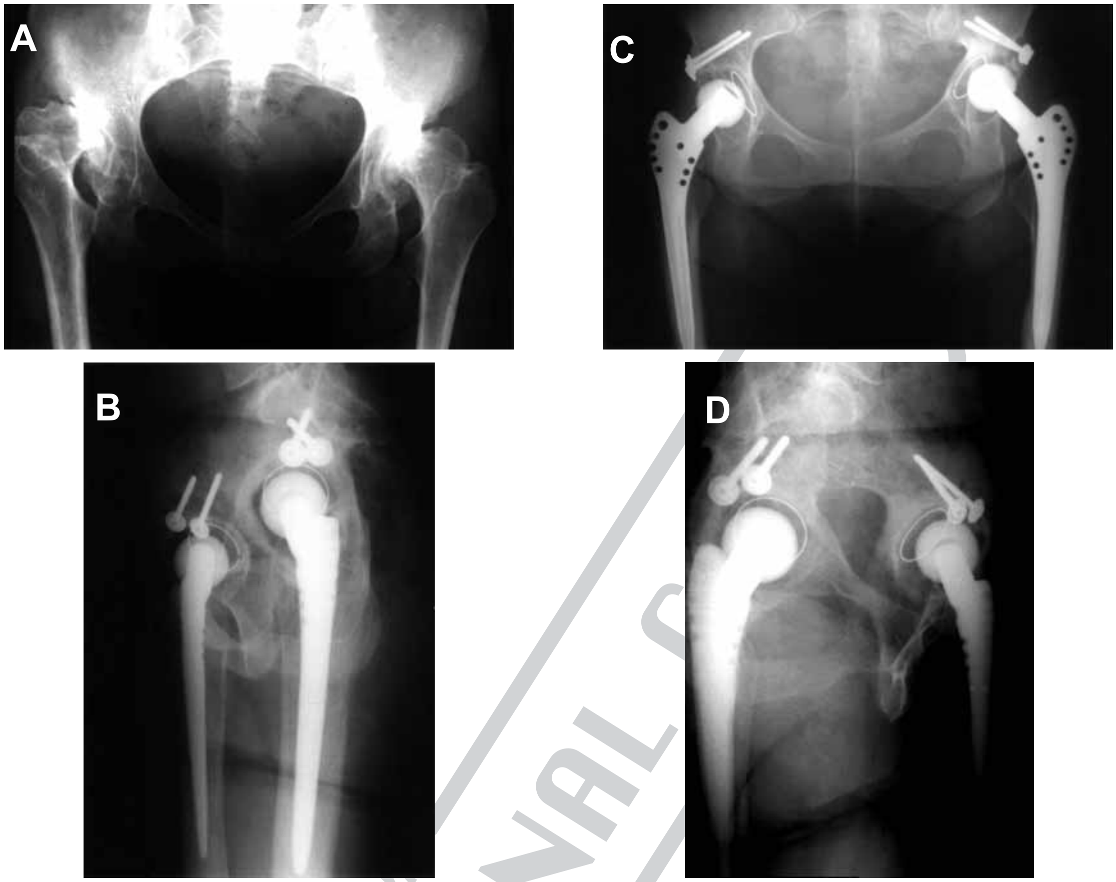


**Figure 3.** Radiographs of a stable total hip endoprosthesis 16 years after surgery. Solid bone at the bone implant site with no signs of implant migration interface is shown. **A.** Anteroposterior view of the both hip dysplasia before operation; **B.** Lateral view of the right total hip endoprosthesis; **C.** Anteroposterior view of bilateral total hip endoprosthesis 16 years after surgery; **D.** Lateral view of the left total hip endoprosthesis.

clination angle of the implanted acetabular cup (dichotomized as “satisfactory” if within the range of 41 to 49 degrees, “unsatisfactory” otherwise), acetabuloplasty performed (yes/no), trochanter osteotomy performed (yes/no), and body mass index (BMI) (dichotomized as “satisfactory” if below upper limit of normal, “unsatisfactory” otherwise). Since BMI was not recorded during the follow-up and the last visit BMI values were in general agreement with BMI at the time of surgery, BMI at the time of surgery was considered in the analysis, and the constant hazard ratio assumption was considered met. Several regression models were generated: the main effects model, and then models including interaction terms (2-way, 3-way, 4-way, and all possible interactions). For the models including interaction terms, hierarchical forward selection with switching method for subset selection was applied (with a maximum number of terms in a subset limited to 8 due to the limited sample size). In this stepwise algorithm, the model building starts with no terms in the model. Then, a term

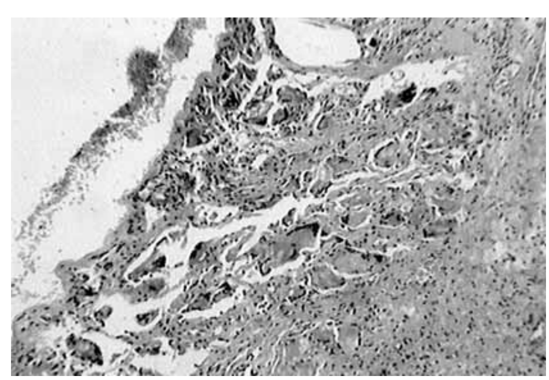

**Figure 4.** Microscopic appearance of severe polyethylene debris in the tissue around the implant. The biopsy was taken at re-operation of an unstable prosthesis.

**Table 2.** Characteristics of the analyzed cohort of patients with implanted Endler acetabular cups

| Patients/prostheses | No. (%) |
|---|---|
| Patients: | |
| toal | 72 |
| men | 25 (34.7) |
| age at the time of surgery (years) (mean±SD, range) | 44.6±7.2 (26-59) |
| patients with normal BMI* at the time of surgery | 38 (52.8) |
| Prostheses: | |
| total | 82 |
| post-operative inclination angle (degrees) (median, range) | 45 (20-60) |
| prostheses with a "satisfactory" inclination angle† | 41 (50) |
| prostheses with performed acetabuloplasty | 15 (18.3) |
| prostheses with performed trochanter osteotomy | 13 (15.9) |
| duration of the follow-up (years) (median, range) | 15 (5-18) |

*Body mass index. BMI beyond the normal range indicating overweight or obesity is an unfavorable prognostic factor for prosthesis survival.
†Post-operative acetabular cup inclination angles falling below 41 degrees or beyond 49 degrees are considered "unsatisfactory", ie negative prognostic factor for the prosthesis survival (13).

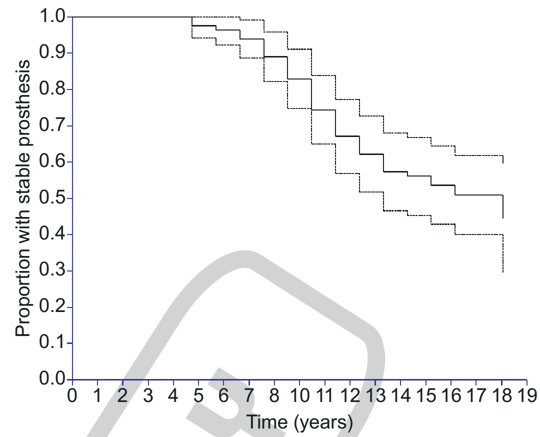


**Figure 5.** Kaplan-Meier survival curve for the 82 prostheses with the median follow-up period of 15 years. Dotted lines represent the 95% confidence intervals.

is found that, when added to the model, achieves the largest $R^2$ value. At each step when a term is added, all terms in the model are switched one at the time with all candidate terms not in the model to determine if they increase the value of $R^2$. If a switch can be found, it is made and the candidate terms are again searched to determine if another switch can be made. When the search for possible switches does not yield a candidate, the subset size is increased by one and a new search is begun. The algorithm is terminated when a target subset size is reached or all terms are included in the model. The selection of the best model for analysis of data was based on the achieved final log likelihood. The best model was found to be a 7-terms model (main factors or 2-way interaction terms). NCSS 2004 software (NCSS, Kaysville, UT, USA) was used.

## Results

The 82 followed-up prostheses were all implanted between 1985 and 1991, and the median duration of the follow-up was 15 years (range 5-18). The main characteristics of the analyzed cohort are summarized in Table 2. The most common indications for the endoprosthesis implantation were the consequences of various developmental anomalies (42.8%), followed by degenerative hip changes (19.1%), post-traumatic conditions (13.6%), idiopathic aseptic necrosis of the femoral head (18.2%), and systemic disease (6.5%). All recorded prosthesis failures were due to instability of the Endler cup, whereas Zweymueller femoral stems remained stable throughout the follow-up period for all hips.

Cumulative survival rates (product-limit analysis) for the 82 followed-up prostheses were 97.6% (95% CI = 94.2-100) at 5 years, 74.4% (95% CI = 64.9-83.8) at 10 years, 53.7% (95% CI = 42.9-64.5) at 15 years and 44.5% (95% CI = 29.5-59.6) at 18 years. Median survival time was 18 years (95% CI = 13-18) (Fig. 5).

The model for the Cox proportional hazard regression analysis, selected based on the achieved log likelihood, comprised 7 independent variables (4 main factors and 3 interaction terms)

**Table 3**. Summary of the Cox proportional hazard regression analysis of the prosthesis survival*

| Independent variable | Log Likelihood | $R^2$ value | $R^2$ change | Coefficient | *P* |
|---|---|---|---|---|---|
| Start | -166.5376 | 0.0000 | 0.0000 | | |
| Acetabuloplasty (yes) | -165.9590 | 0.0140 | 0.0140 | -24.7758 | 0.9998 |
| BMI (satisfactory) | -165.6721 | 0.0209 | 0.0069 | -0.4605 | 0.3256 |
| Inclination angle (satisfactory) | -164.1423 | 0.0567 | 0.0359 | -1.2832 | 0.0260 |
| Trochanter osteotomy (yes) | -163.6233 | 0.0686 | 0.0119 | -24.2045 | 0.9999 |
| Acetabuloplasty vs inclination angle | -163.1266 | 0.0798 | 0.0112 | 1.5094 | 0.0798 |
| Acetabuloplasty vs trochanter osteotomy | -162.3096 | 0.0980 | 0.0182 | 48.6649 | 0.9998 |
| BMI vs Inclination angle | -158.7346 | 0.1733 | 0.0753 | 1.3707 | 0.0556 |

*The fitted model was selected based on the achieved final log likelihood (see Patients and Methods for details). The selection of independent variables to enter the model was closed at 25 iterations. The last three independent variables are interaction terms (vs indicates interaction). Estimated model: Exp(-24.7758-0.4605×BMI)–1.2832×(inclination angle)–24.2045×(trochanter osteotomy)+1.5094×(acatbuloplasty)×(Inclination angle)+48.6649×(acatbuloplasty)×(trochanter osteotomy)+1.3707×(BMI)×(inclination angle).

(Table 3). An unsatisfactory inclination angle of the acetabular cup achieved at surgery (<41 or >49 degrees) was identified as a negative predictor of the prosthesis survival (as indicated by the sign associated with the regression coefficient; $P=0.026$), whereas the interaction between the inclination angle and an unsatisfactory BMI (>upper normal limit) at the time of the surgery was of borderline significance ($P=0.056$) (Table 3). Reduction or expansion of the model, or substitution of any of the independent variables by factors "age" or "gender" or any other interaction term yielded poorer final log likelihood (and lower $R^2$). Although selected as the best one, the model apparently explained only a minor part of the survival variability ($R^2=0.173$) (Table 3).

## Discussion

The analyzed cohort was rather homogenous in that it comprised relatively younger adults (mean age at the time of surgery 44.6 years), apparently younger than in other studies evaluating survival of the Endler cup (12,14-18). As compared to these studies, the present study assessed a lower number of prostheses, ie, 82 vs 96 (18), 103 (14), 115 (16), 260 (12), or 334 (17), but the follow-up period was considerably longer: median 15 years vs 5 years (12,18), 5.4 years (17), 7 years (16), or 10 years (14). The prosthesis survival observed in the present study was in general agreement (comparable or slightly better) with that reported by others: at 5 years, 97.6% vs 94.8% (18) or 82.5% (12); at 10 years, 74.4% vs. 70.5% (14). As illustrated in Figure 4, where instability was diagnosed polyethylene wear particles could be demonstrated in the intercellular spaces, explaining the cup instability by the host's reaction resulting in osteolysis.

The main limitation of the analysis of potential biomechanical/demographic predictors of the prosthesis survival comes from the retrospective nature of data, which precluded consideration of other factors, such as BMI as potentially time-dependent covariate. Despite this drawback the present data support the importance of an adequate acetabular cup inclination angle for the prosthesis survival, a finding reported by others as well (13). The results further suggest that age (at least in the range of ages seen in the analyzed cohort), gender, and other considered factors had no significant impact on the primary outcome. The finding that BMI above the upper normal limit (found in 47% of the patients) was not a factor relevant for the prosthesis survival is likely due to the fact that the actual values were, most of the time, only slightly above the normal values. On the other hand, it appears that all of the considered factors explained only a minor portion of the survival variability. This suggests a role of other potentially relevant factors, likely non-biomechanical/non-demographic that remained unidentified in this study. The role of inflammation induced by polyethylene particles in the onset of aseptic prosthesis instability has been rather well documented (23,24). Degenerative changes of the hip joint are associated with a varying level of local inflammation even before the endoprosthesis implantation (25,26). It seems appealing to hypothesize that individual disposition to pro-inflammatory reaction may be a factor of interest in polyethylene cup survival.



### References


1 Wilert HG, Buchhorn GH, Semlitsch M. Particle disease due to wear of metal alloys. In: Morrey BF, editor. Biological, material and mechanical considerations of joint replacement. New York: Raven Press; 1993. p. 129-45.

2 Harris WH. Osteolysis and particle disease in hip replacement. A review. Acta Orthop Scand. 1994;65: 113-23.

3 Santavirta S, Nordstrom D, Metsarinne K, Konttinen YT. Biocompatibility of polyethylene and host response to loosening of cementless total hip replacement. Clin Orthop Relat Res. 1993;(297):100-10.

4 Santavirta S, Gristina A, Konttinen YT. Cemented versus cementless hip arthroplasty. A review of prosthetic biocompatibility. Acta Orthop Scand. 1992;63:225-32.

5 Kobayashi A, Freeman MA, Bonfield W, Kadoya Y, Yamac T, Al-Saffar N, et al. Number of polyethylene particles and osteolysis in total joint replacements. A quantitative study using a tissue-digestion method. J Bone Joint Surg Br. 1997;79:844-8.

6 Linter F, Huber M, Boehm J, Attems J, Lhotka C. The significance of the human body's response to particles released from prosthetic implants. In: Zweymüller K, editor. Twenty years of the rectangular straight stem, fourteen years of the conical cup. Where do we stand? Where do we go? Proceedings of the 4th Vienna Symposium. 2nd October 1999, Vienna, Austria. Bern: Verlag Hans Huber; 1999. p. 55-72.

7 Kawamura H, Bourne RB, Dunbar MJ, Rorabeck CH. Polyethylene wear of the porous-coated anatomic total hip arthroplasty with an average 11-year follow-up. J Arthroplasty. 2001;16(8 Suppl 1):116-21.

8 Morscher EW, Dick W, Kernen V. Cementless fixation of polyethylene acetabular component in total hip arthroplasty. Arch Orthop Trauma Surg. 1982;99: 223-30.

9 Morscher E, Schmassmann A. Failures of total hip arthroplasty and probable incidence of revision surgery in the future. Calculations according to a mathematical model based on a ten years' experience in total hip arthroplasty. Arch Orthop Trauma Surg. 1983;101: 137-43.

10 Schmalzried TP, Guttmann D, Grecula M, Amstutz HC. The relationship between the design, position, and articular wear of acetabular components inserted without cement and the development of pelvic osteolysis. J Bone Joint Surg Am. 1994;76:677-88.

11 Teoh SH, Chan WH, Thampuran R. An elasto-plastic finite element model for polyethylene wear in total hip arthroplasty. J Biomech. 2002;35:323-30.

12 Seral F, Villar JM, Esteller A, Vivar FG, Abad I, Martinez Grande M, et al. Five-year follow-up evaluation of the noncemented press-fit titanium hip-joint endoprosthesis. Clin Orthop Relat Res. 1992;(283):49-56.

13 Kordelle J, Starker M. Migration analysis of cemented Muller polyethylene acetabular cups versus cement-free Zweymuller screw-attached acetabular cups [in German]. Z Orthop Ihre Grenzgeb. 2000;138:46-51.

14 Krugluger J, Eyb R. Bone reaction to uncemented threaded polyethylene acetabular components. Int Orthop. 1993;17:259-65.

15 Nizegorodcew T, Gasparini G, Maccauro G, Todesca A, De Santis E. Massive osteolysis induced by high molecular weight polyethylene wear debris. Int Orthop. 1997;21:14-8.

16 Hauser R, Jacob HA, Kern S, Schreiber A. The Balgrist hip cup – a 4-to-10-year survival analysis of cement-free hip cups [in German]. Z Orthop Ihre Grenzgeb. 1993;131:585-93.

17 Havelin LI, Vollset SE, Engesaeter LB. Revision for aseptic loosening of uncemented cups in 4,352 primary total hip prostheses. A report from the Norwegian Arthroplasty Register. Acta Orthop Scand. 1995;66:494-500.

18 Kutschera HP, Eyb R, Schartelmuller T, Toma C, Zweymuller K. Cement-free Zweymuller hip system. Results of a 5-year follow-up study [in German]. Z Orthop Ihre Grenzgeb. 1993;131:513-7.

19 Anticevic D. Biomechanical traits of the proximal femoral growth [in Croatian]. Dissertation. Zagreb: Zagreb University School of Medicine; 2000. p. 93.

20 DeLee JG, Charnley J. Radiological demarcation of cemented sockets in total hip replacement. Clin Orthop Relat Res. 1976;(121):20-32.

21 Schwarzer G, Schumacher M, Maurer TB, Ochsner PE. Statistical analysis of failure times in total joint replacement. J Clin Epidemiol. 2001;54:997-1003.

22 Ripatti S, Palmgren J. Estimation of multivariate frailty models using penalized partial likelihood. Biometrics. 2000;56:1016-22.

23 Granchi D, Verri E, Ciapetti G, Stea S, Savarino L, Sudanese A, et al. Bone-resorbing cytokines in serum of patients with aseptic loosening of hip prostheses. J Bone Joint Surg Br. 1998;80:912-7.

24 Hirashima Y, Ishiguro N, Kondo S, Iwata H. Osteoclast induction from bone marrow cells is due to pro-inflammatory mediators from macrophages exposed to polyethylene particles: a possible mechanism of osteolysis in failed THA. J Biomed Mater Res. 2001;56:177-83.

25 Jovanovic S, Dmitrovic B, Orlic D, Wertheimer B, Rubin O. Patohistologic changes of the femoral head and joint capsule in coxarthrosis. Med Biol Eng Comput. 1999;37 Supl 1:208-9.

26 Milavec-Puretic V, Orlic D, Marusic A. Sensitivity to metals in 40 patients with failed hip endoprosthesis. Arch Orthop Trauma Surg. 1998;117:383-6.


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