# ORIGINAL PAPER

# **Risk factors for accelerated polyethylene wear and osteolysis** in ABG I total hip arthroplasty

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Abstract We analysed data from 155 revisions of identical cementless hip prostheses to determine the influence of patient-, implant- and surgery-related factors on the polyethylene wear rate and size of periprosthetic osteolysis (OL). This was calculated by logistic regression analysis. Factors associated with an increased/decreased wear rate included position of the cup relative to Kohler's line, increase in abduction angle of the cup, traumatic and inflammatory arthritis as a primary diagnosis, and patient height. Severe acetabular bone defects were predicted by an increased wear rate (odds ratio, OR=5.782 for wear rate above 200 mm<sup>3</sup>/y), and increased height of the patient (OR =0.905 per each centimetre). Predictors of severe bone defects in the femur were the increased wear rate (OR=3.479 for wear rate above 200  $\text{mm}^3/\text{y}$ ) and placement of the cup outside of the true acetabulum (OR=3.292). Variables related to surgical technique were the most predictive of polyethylene wear rate.

Résumé Nous avons analysé les données de 155 révisions d'une prothèse totale de hanche sans ciment de façon à

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J. Zapletalova Biophysics, Palacký University, Olomouc, Czech Republic déterminer les facteurs relatifs aux patients et à l'implant concernant l'utilisation du polyéthylène et l'importance de l'ostéolyse (OL). Les 155 modèles de prothèses étaient identiques. Il s'agit d'une analyse informatique. L'augmentation ou la diminution du taux d'usure était associée à la position de la cupule par rapport à la ligne de Kohler, une cupule verticalisée entraînant plus d'usure. De même en ce qui concerne les arthroses d'origine traumatique ou inflammatoire et le poids des patients. On pouvait prévoir d'importantes lésions d'ostéolyse acétabulaire du fait d'une importante augmentation de l'usure du polyéthylène (OR=5,782 taux d'usure 707, 200 mm3/an) et l'augmentation du poids des patients (OR=0,905) pour chaque cm. L'augmentation du taux prédictif d'usure avec des lésions osseuses sévères au niveau du fémur l'étaient également (OR=3,479 d'usure et 200 mm3/an) de même que le positionnement de la cupule en dehors de l'arrière fond acétabulaire (OR=3,292). Les facteurs d'usure les plus importants sont surtout d'origine technique et secondaires aux problèmes de technique chirurgicale.

#### Introduction

Debris from polyethylene (PE) wear is believed to be a key factor in the development of osteolysis around total hip arthroplasty (THA) [1]. This debris triggers multiple adverse host reactions that involve signalling pathways and finally result in osteoclast-mediated bone resorption [2]. Wear particles originate predominantly from motion between two opposing, articulating surfaces, but other mechanisms of particle generation are also possible [3]. As the number of primary THAs is increasing and PE remains the main weight-bearing material, interest has increased in understanding its mode of degradation, with the goal of preventing it. The many factors that influence PE wear in vivo are traditionally divided into those related to the patient, the implant, and the surgery [4]. The known influences on PE wear include level of physical activity, age, gender, primary diagnosis, design-related variables, type of PE, and quality of implant settlements [5–8]. Other factors that may be important, but are not readily analysed, include third body wear, composition of joint fluid, type of lubrication, and individual motion pattern.

In a previous study, we found a high risk for increased wear rate associated with this prosthesis [9]. Moreover, the univariate analyses revealed that wear rate was influenced by primary diagnosis, use of zirconia ceramic heads, medial cup settlement, and date of surgery. However, such analysis was designed neither to give insight into the influence of competing factors nor to quantify the magnitude of each factor's influence. Therefore, we conducted our study with more patients, using logistic regression to identify the significant predictors of high and low wear rates. The same data were also analysed to identify predictors of severe bone defects at both the acetabular and femoral sites. The identification of such predictors may be useful in making clinical decisions about THA and reducing the need for surgical revisions.

## Patients and methods

## Patients

Patients undergoing surgical revision of THA between August 2000 and December 2005 were included in the study. The revised cases belonged to a group of patients with ABG I prostheses operated upon at the author's institution between September 1994 and January 2000 (n=506). We previously reported on the poor 12-year survival of the ABG I prosthesis [10]. Information was collected on the indication for the original arthroplasty, the time since the arthroplasty, and indication for revision. The ethical committee of the institution approved the study protocol and all revisions were performed under standard conditions with written informed consent of the patients. The majority of revisions (>90%) were performed by a single surgeon.

## Prosthesis

The first generation of modular, cementless hip prosthesis (ABG I, Howmedica, Inc., Staines, England) was used [11]. The ABG I prosthesis was designed in the 1980s as a press-fit hemispherical cup and anatomical stem with hydroxyapatite coating. Marketing began in Europe in 1989 and in the Czech Republic in 1993. The first studies on this implant reported excellent early results [12, 13]. Therefore, we opted for this prosthesis in younger patients. All primary procedures were performed by eight experienced surgeons via an anterolateral approach, according to the manufacturer's instructions. Patients were protected from weight-bearing with crutches for the first four weeks which was followed by a period of partial weight-bearing as tolerated; full loading was permitted 12 weeks after the surgery. All patients had routine perioperative antibiotics and prophylaxis against thromboembolic disease using subcutaneous heparin or low-molecular weight heparin.

All PE liners were ram-extruded from Hostalen GUR 4150 and air-sterilised with 25 kGy gamma irradiation. The PE thickness ranged from 4.9 to 12.9 mm. Both standard (n=125) and hooded polyethylene liners were implanted (n=30). In nearly all of the hips a 28-mm femoral head made from cobalt-chromium alloy (n=143) was inserted, except for 12 cases in which a 28-mm zirconia head was used. Tables 1 and 2 summarise the data that were included in the analyses.

## Wear measurement

After prosthesis extraction, all of the PE liners were immersed in Sekusept aktiv (Ecolab GmbH, Düsseldorf, Germany) for 24 hours and sterilised in formaldehyde for two hours. The wear measurements were performed by one of the authors (VH). Briefly, linear wear, defined as the maximum penetration of the prosthetic head into the polyethylene liner, was determined using a previously reported method that measures the shift of the centre of the prosthetic head from the manufactured to the post-use position. To determine the centre of a ball of known diameter, it is sufficient to measure four surface space coordinates with the touch stylus of the Universal-type measuring microscope (VEB, Carl Zeiss, Jena, Germany). This measurement was made after fixation of the retrieved prosthetic femoral head in the retrieved cup for each of the positions mentioned. Nine space coordinates were determined in practice to improve measurement accuracy. Assuming that the diameter of the cup and the head are known, it is possible to calculate the linear and volumetric wear using a geometrical "two-sphere model" and a special computational algorithm that also takes into account the original position of the prosthetic head in the cup and the cross-sectional profile of the ABG I cup. The accuracy of the described method was previously assessed in a set of 30 retrieved cups, ranging between 1 and 4  $\mu$ m and 1–9 mm<sup>3</sup> for linear and volumetric wear, respectively [14]. The reliability of the method has also been previously reported [15].

Variable	Categories	Number of hips (%)
Gender	Men	44 (28)
	Women	111 (72)
Preoperative diagnosis	Osteoarthritis	29 (19)
	Hip dysplasia	71 (46)
	Osteonecrosis	30 (19)
	Traumatic	14 (9)
	Inflammatory	6 (4)
	SCFE	5 (3)
Charnley type	А	53 (34)
	В	89 (57)
	С	13 (8)
Liner geometry	Neutral	125 (81)
	Hooded	30 (19)
Head material	CoCr	143 (92)
	Zirconia	12 (8)
Cup abduction angle	Between $30^{\circ}$ and $50^{\circ}$	120 (77)
	Above 50°	35 (23)
Cup relation to KL	Laterally	14 (9)
1	In contact	27 (17)
	Medially	114 (74)
True acetabular region	Yes	123 (79)
-	No	32 (21)
Stability of the implant	Stable	121 (78)
•	Unstable	34 (22)
Acetabular BD	Type I, II	44 (28)
	Type III	87 (56)
	Type IV, V	24 (16)
Femoral BD	Type I, II	127 (82)
	Type III	25 (16)
	Type IV	3 (2)

*KL* Kohler's line, *BD* bone defects, *SCFE* slipped capital femoral epiphysis

#### Clinical and radiographic evaluation

All hips included in the study had stable prostheses one year after the index operation based on review of radiology reports. All of the patients were clinically and radiographically examined prior to revision surgery using the same protocol. The Charnley classification was applied to estimate the level of walking capacity, with class A having no disturbance in locomotion, class B with bilateral hip disease and normal findings in other weight-bearing joints, and class C with severe compromise of locomotion due to multiple joint involvement [16]. Anteroposterior pelvic X-rays were performed with the patient in the supine (non-weight-bearing) position. Interpretation of radiographs consisted of the evaluation of the cup position relative to the lateral part of tear drop figure, determination of the cup position relative to the true acetabular region [17], and measurement of the abduction angle of the cup. The position of the cup in relation to the floor of the acetabulum was graded as lateral, in contact, or medial depending on relationship between a most medial part of the cup and Kohler's line. The abduction angle is the angle formed by a horizontal line along the teardrop, ischial tuberosities or obturator foramina and a line along the open face of the cup. Bone defects were evaluated intraoperatively and expressed in terms of Saleh's classification at the acetabular site, i.e. no significant bone loss (type I), contained bone loss (type II), moderate uncontained bone loss (type III), severe uncontained bone loss (types IV), and pelvic discontinuity (type V) [18]. At the femoral site, the same classification was used. Finally, the stability of the implant was evaluated intraoperatively.

### Statistics

The primary goal of the study was to identify the predictors of high and low rates of PE wear. A stepwise logistic regression analysis was chosen because a high wear rate was defined as >0.2 mm/y or  $>200 \text{ mm}^3/\text{y}$ ; a low wear rate was  $\leq 0.1 \text{ mm/y}$  or  $\leq 100 \text{ mm}^3/\text{y}$ . In the logistic regression analysis, the effect of a number of independent variables was determined with wear rate as the dependent variable. To enable this analysis, some variables were recoded and rescaled as either 0 or 1 (Table 1), while others were included as continuous variables (Table 2). As a result, wear data for retrieved ABG I PE liners were simultaneously analysed in relation to variables that could be distinguished by demographic (age, gender, weight, height, primary diagnosis, and the Charnley classification of activity), surgical (abduction angle of the cup, position of the cup relative to the Kohler's line, and the true acetabular region), and implant variables (size of the cup, thickness of the PE liner, type of PE liner, metallic/ceramic femoral head). A stepwise variable entry continued if the inclusion  $\alpha$  value was less than or equal to 0.05. This sequential inclusion/exclusion of independent variables according to

 Table 2 Continuous variables included in a stepwise logistic regression

Variable	Mean	SD	Range	Median	
Age at surgery (y)	46.1	6.8	25-65	46.3	
Height (cm)	165.5	8.6	149-195	164	
Weight (kg)	75	14.4	42-114	73	
Body mass index	27.3	4.1	16-42.6	27.3	
Cup size (mm)	50.3	3.81	46-60	50.0	
PE thickness (mm)	7.03	1.93	4.9-11.9	6.9	
Abduction angle of the cup (°)	45.26	7.98	28-72	45.0	
Follow-up (y)	6.0	1.9	2.0-10.5	6.0	
Linear wear (mm)	2.21	1.57	0-6.9	1.86	
Linear wear rate (mm/y)	0.415	0.364	0-2.284	0.346	
Volumetric wear (mm <sup>3</sup> )	859	781	0-6000	701	
Volumetric wear rate $(mm^3/y)$	153	134	0-815	115	

PE polyethylene, SD standard deviation

stepping criteria eventually leads to the selection of a single "optimal" model [19]. Therefore, variables without significant associations with wear rate were removed from the model. In addition, the data were modelled according to limits for a high wear rate (>100  $\text{mm}^3/\text{y}$ ) and a low wear rate ( $\leq 80 \text{ mm}^3/\text{y}$ ). Also, factors that predicted severe bone defects (dependent variable) were analysed in the same way after wear rate was added to the independent variables listed above. Survival of the index prosthesis was computed using the Kaplan-Meier methods. Survival curves derived for particular wear rate groups were compared by the log rank test. The accepted significance level was 0.05. Statistical analysis was performed with the commercial SPSS 14.0 package (SPSS Inc., Chicago, IL, USA).

## Results

The study included 155 patients (44 men, 111 women) who had surgical revisions of THA after a mean of six years from the index operation. The reasons for revision were periprosthetic osteolysis (n=115, 74%), aseptic loosening of the cup (n=32, 21%) or stem (n=2, 1%), and periprosthetic fracture of the femur (n=6, 4%).

#### Prosthetic survival analysis

The mean time to revision was  $5.96\pm0.15$  years (mean  $\pm$ standard deviation [SD]). Mean linear and volumetric wear rates were 0.415 mm/y (range 0-2.284, SD 0.364) and 153 mm<sup>3</sup>/y (range 0-815, SD 134.4), respectively. Wear rate was found to have a significant influence on survival of the prosthesis only when the whole group was divided into those having a wear rate above and below 200 mm<sup>3</sup>/y (Fig. 1); the other analyses, according to incremental wear rate (i.e. 0.1 mm/y, 0.2 mm/y, 100 mm<sup>3</sup>/y) failed to reveal significant influence on implant survival.



Fig. 1 Wear rate as a function of survival of retrieved ABG I prostheses

Factors that influence high and low wear rates

Among the variables (Tables 1 and 2) that were included in the logistic regression, only four significantly predicted a high or low wear rate. Predictors of accelerated and decelerated linear and volumetric wear are summarised in Table 3. The most surprising finding was a potential role for patient's height in the wear rate. On the other hand, no role was detected for age, gender, weight of the patient, BMI, Charnley classification of activity, initial PE thickness, type of liner, material of the prosthetic head, and stability of the implant at the time of surgery. Logistic regression also determines the percent of variance in the dependent variable explained by the independent variables to assess the relative importance of the independent variables. The best regression achieved was 15% (Nagelkerke  $R^2=0.15$ ), and  $-2 \log R^2$ likelihood was above 120, indicating a poor fit of the regression model to the wear rate data.

Factors that predict severe bone defects

Development of bone defects is believed to be a direct consequence of PE wear rate, assuming a positive correlation between higher wear rate and more severe bone defects. Among the factors (Tables 1 and 2), including the linear wear rate/volumetric wear, that were included in the regression analysis, only three significantly predicted the severity of bone defects (Table 4). Of them, the most important factor was PE wear rate. Patients having higher linear/volumetric wear rates had a higher risk for severe acetabular (types IV or V) and femoral bone defects (type III). The other two factors affecting bone defects were the patient's height and the position of the cup in relation to the true acetabulum. The best regression achieved was 19% (Nagelkerke  $R^2=0.191$ ) and  $-2 \log$  likelihood was 88.8, indicating a better fit of the regression model to the size of osteolysis than to the wear rate data.

# Discussion

This study confirmed the finding from other studies that certain surgical factors such as position and orientation of the cup are associated with increased wear rates of prosthetic hips [7, 8, 20]. Furthermore, the primary diagnosis and the height of the patient were found to significantly influence wear rate. In addition, a high wear rate was strongly associated with severe osteolysis.

PE wear has been considered a key parameter for periprosthetic osteolysis development, and its multifactorial origin is now generally accepted [5, 21]. In this study we used logistic regression to determine the effect of independent variables on wear rate and on the extension of bone

Table 3	Variables 1	that changed	the probability	of increased/decrea	sed wear rates
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Wear rate	Variable	Odds ratio	95% confidence interval		p value	$R^2$
			Lower bound	Upper bound		
> 0.2 mm/y	Increasing patient's height by 1 cm	1.065	1.018	1.114	0.007	0.116
-	One-degree increase in abduction angle	1.049	1.001	1.099	0.047	
$> 200 \text{ mm}^{3}/\text{y}$	Cup placed laterally to KL	3.896	1.130	13.426	0.031	0.114
	Increasing patient's height by 1 cm	1.045	1.000	1.092	0.050	
$> 100 \text{ mm}^{3}/\text{y}$	Increasing patient's height by 1 cm	1.052	1.008	1.099	0.021	0.137
	Cup placed medially to KL	0.375	0.156	0.905	0.029	
$\leq 100 \text{ mm}^3/\text{y}$	Cup placed medially to KL	2.663	1.105	6.418	0.029	0.137
-	Increasing patient's height by 1 cm	0.950	0.910	0.992	0.021	
$\leq 0.1 \text{ mm/y}$	Trauma, inflammation and SCFE as primary diagnosis	2.975	1.007	8.787	0.049	0.040
$\leq 80 \text{ mm}^3/\text{y}$	Increasing patient's height by 1 cm	0.935	0.893	0.980	0.005	0.151

 $R^2$  Nagelkerke R square, KL Kohler's line, SCFE slipped capital femoral epiphysis

defects. An advantage of our analysis was that the majority of revision operations (>90%) were performed by a single surgeon, and a large number of THAs were included with the in vitro measurement of the wear of retrieved PE liners. In addition, all hips had the same type of implant, which diminished the role for interprosthetic differences as a source of variability. Another theoretical advantage is that the final single model in a stepwise logistic regression model should reliably indicate the most important examined variable.

The strongest coefficient of determination found in the wear-related part of this study was 0.15, which may seem surprisingly low upon initial evaluation. However, this finding is in accordance with other studies, including those that used multiple linear regression models, which are principally different from logistic regression. In a large clinical trial with Duraloc cups, Hopper et al. found that eight factors accounted for 26% of the variance in wear rate [4]. According to Wan et al., the multiple regression model explained only 21.5% of the variation in PE wear rate [8]. Moreover, when wear rate variance was analysed by

multiple linear regression in the same patients with bilateral THA, the patient- and implant-related variables accounted for 61% of the variance in wear rate [22]. In clinical terms, these studies show that the majority of the variability in wear rate (e.g. 85% in our study) could not be explained, even under ideal conditions. As a result, several unknown or poorly quantified factors may account for the variability. Such factors may include the quality of the PE, the patient's activity level, third body wear, conditions of the internal environment or differences in surgical technique.

In this study, the factor that most strongly correlated with wear rate (i.e. had the highest odds ratio) was the position of the cup relative to Kohler's line. Lateral displacement was a risk factor; medial displacement was a protective factor. This observation is in accordance with the biomechanical concept that the centre of rotation should be as medial as possible to reduce the resultant torque and risk of hardware loosening when the femoral offset is unchanged [23]. Therefore, this study, and others [7, 8, 20, 24], support cup implantation as medially as possible to achieve minimal PE wear.

 Table 4
 Variables that increased/decreased the probability of severe bone defects

Bone defect	Variable	Odds ratio	95% confidence interval		p value	$R^2$
			Lower bound	Upper bound		
Acetabulum Saleh type IV, V	Wear rate $> 0.2$ mm/year	4.146	1.222	14.066	0.023	0.155 <sup>a</sup>
Acetabulum Saleh type IV, V	Increasing patient's height by 1 cm	0.898	0.837	0.963	0.002	
	Wear rate $> 200 \text{ mm}^3/\text{year}$	5.782	1.846	18.110	0.003	0.191 <sup>b</sup>
	Increasing patient's height by 1 cm	0.905	0.841	0.973	0.023 0 0.002 0.003 0 0.003 0 0.007 0.008 0 0.009 0.015 0	
Femur Saleh type III	Wear rate $> 0.2$ mm/year	4.146         1.222         14.066         0.023           by 1 cm         0.898         0.837         0.963         0.002           c         5.782         1.846         18.110         0.003           by 1 cm         0.905         0.841         0.973         0.007           5.862         1.584         21.699         0.008           o         3.688         1.391         9.781         0.009           r         3.479         1.279         9.465         0.015           ulum         3.292         1.153         9.397         0.026	0.141 <sup>a</sup>			
	Higher position of the cup	3.688	1.391	9.781	0.009	
	Wear rate $> 200 \text{ mm}^3/\text{year}$	3.479	1.279	9.465	0.015	0.173 <sup>b</sup>
	Cup above the true acetabulum	3.292	1.153	9.397	0.026	

 $R^2$  Nagelkerke R square

<sup>a</sup> Model with linear wear rate data inclusion

<sup>b</sup> Model with volumetric wear rate data inclusion

An increased inclination angle of the cup in the frontal plane (i.e. abduction angle) was significantly associated with a greater wear rate. This finding is in accordance with other studies [8, 25] and may be explained by eccentric sliding of the prosthetic head in conjunction with the impact of the head on a surface much smaller than the head itself. These factors could lead to rim overuse and acceleration of wear rate. However, several studies failed to find a role of abduction angle in the acceleration of wear rate [26–29]. The reasons for these results are not clear, but at least partially may lie in the radiographic origin of wear measurement used in these studies. These radiographic measurements may be less sensitive in detecting wear than in vitro measurements [30].

A most surprising finding in our study was the significant association between patient height and increased wear rate. This finding was also supported by the inverse relation (i.e. decreased probability of low wear with increased height). However, predicting the relationship between patient height and volumetric wear rate is not as simple as one may at first assume, since a number of factors are involved. To our knowledge, the impact of the patient height on wear rate is rarely mentioned in the literature, despite the fact that height directly influences the body weight which, in turn, leads to greater forces applied to the hip [31]. Archard's equation predicts that the volume of wear per unit of sliding distance will increase in direct proportion to the load [32, 33], (i.e. with the cube of patient height). Moreover, in this study, only 28 mm heads were used. Since the total contact area was, therefore, constant as the weight of the patient increased, the contact stress was greater for taller patients, approximately in proportion to the cube of height. This would be expected to cause a substantially greater volumetric rate of wear in the taller patients. Another factor is the femoral offset, which tends to be greater in taller people [34]. Unfortunately, this parameter cannot be strictly restored in all patients by a single prosthetic design. As a result, inability to restore femoral offset adequately can lead to decreased abductor muscle strength and greater forces across the hip joint [35, 36]. Taken together, if these considerations are correct, strong positive correlation of volumetric wear rate with the height of the patients could be expected [McKellop, H., personal communication]. However, these issues were not investigated in our study and require further research.

Many clinicians and researchers believe the most important factor influencing the wear rate is activity level [6]. We found that Charnley classification of activity is not sensitive enough to explain wear rate variability. Recently, Roder et al. augmented the Charnley classification with a class BB for those with bilateral THA [37]. Even with that modification, we are sceptical of its sensitivity to detect true differences in activity level. Therefore, a new approach to this issue is needed.

Finally, our finding that higher PE wear rates are associated with a risk of severe osteolysis at both the acetabular and femoral sites is in accord with the literature [21, 38]; this finding strongly supports particle disease as the leading mechanism of osteolysis initiation and expansion [1]. On the other hand, the main limitation of our study is that it is based on an implant especially prone to rapid wear and the initiation of OL. The overall 12-year survival for ABG I prostheses, found in our previous study, was 55% [10], which is in agreement with several studies [39-42] but contrasts with others [11, 43, 44]. The reasons for the disparity are still not clear, but this issue is discussed elsewhere [10]. Briefly, it has been disclosed that PE liners made from GUR 415HP resins possess greater biological activity compared to PE made from GUR 1120 [45]. Moreover, when sterilised by gamma irradiation in the air, the PE can undergo significant deterioration of their mechanical and chemical properties after long-term in vivo function [46]. In addition, the multi-hole design of the cup, together with a poor locking mechanism for the PE liners in the ABG I cups, could lead to the repetitive generation of screw-hole fluid pressure at levels greatly exceeding the threshold for OL induction [47]. These characteristics and the fact that only patients with failed implants were included could bias our results by providing an inadequate number of hips with lower wear rates and/or less severe osteolysis.

We can conclude that PE wear rate was most significantly influenced by the position of the acetabular component. Based on this, we recommend placing the PE cup (centre of rotation) as medially as possible to allow for an abduction angle below 50° without compromising bone coverage of the cup. Further studies are needed to confirm whether patient height influences PE wear rate and to investigate the mechanism of this possible influence.

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