



## Poor mid-term results of total hip arthroplasty with use of a Hylamer liner

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**Clinical results after total hip arthroplasty with the use of a Hylamer liner have been described as being poor. In this study, polyethylene wear rates as well as clinical results were assessed after hip arthroplasty using a Hylamer liner.**

**Thirty patients were followed radiographically and clinically after total hip arthroplasty with a Hylamer liner. The mean follow-up was six years. Radiolucent lines and wear rates were evaluated in correlation to different parameters and clinical scores.**

**Radiolucent zones were found in 40% of the femoral and 27% of the acetabular components. Wear rates showed no correlation to the clinical scores, nor to other parameters. The SF-36 questionnaire showed inferior results compared to healthy controls.**

**These findings confirm the poor results described with Hylamer in current literature. A significant influence of the different patient or prosthesis specific parameters on the survival of the prosthesis could not be confirmed.**

**Keywords :** hip replacement ; polyethylene ; Hylamer ; wear debris.

### INTRODUCTION

Aseptic loosening is a major issue in prosthetic surgery. The most common cause of aseptic loosening of prostheses is tissue reaction to wear debris. Wear of polyethylene components in hip arthroplasty produces billions of wear particles annually, leading to a foreign body reaction and activation

of osteoclasts (1). Morawietz *et al* found a wear particle-induced membrane type in 54.3 % of periprosthetic membranes retrieved from 370 loosened hip prostheses (13).

To minimize wear, Hylamer, an ultra-high-molecular-weight polyethylene (UHMWPE) was introduced in 1991. This UHMWPE was hot isostatically pressed and showed an extended-chain crystalline morphology and thicker PE lamellae and higher crystallinity (2). This resulted in a higher elastic modulus, and increased compressive and tensile strength. Furthermore a greater resistance to crack propagation and creep deformation was reported (7,9). Hip simulator studies demonstrated

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that the wear resistance of Hylamer was at least equivalent to standard GUR 415 (12).

In recent years, early failures of Hylamer acetabular liners due to increased polyethylene wear have been reported (11,15-17,19,20). Different reasons were responsible for the increased wear rates. Various articulating materials, various head sizes, different manufacturers of the head and acetabular liner were discussed as possible factors (7,11,23). Furthermore high oxidation of the Hylamer acetabular liner caused by sterilization by gamma radiation in air was considered as one of the reasons for structure alterations leading to higher wear rates (21,23).

This study was performed to assess the wear rates and the radiological and clinical results of the Hylamer liner. Patient and prosthesis specific factors, clinical parameters and quality of life were correlated and analysed.

## MATERIAL AND METHODS

This study shows results achieved in 15 male and 15 female patients who received a Hylamer liner (Duraloc 1200, DePuy). The mean age at implantation was 59.2 years (SD = 10.3). The mean follow-up was 6 years (SD = 0.99). There were 11 right hips and 19 left hips; 7 hips had a 32mm and 23 a 28 mm head; 11 heads were ceramic and 19 metal; 7 stems were cemented and 23 cementless; one cup was sterilised by gas plasma, 9 by radiation in air and 20 by radiation in nitrogen.

The indication for THR was primary osteoarthritis (OA) of the hip in 14 cases (46.7%), aseptic loosening of a previously implanted acetabular component in 9 patients (30%), femoral head necrosis in 2 cases (6.7%) and postinfectious OA, pseudarthrosis and sequelae of Perthes disease in one each (3.3%). In 9 patients (30%) an autologous allograft was performed due to an acetabular defect. Relevant data was retrospectively searched in clinical records, surgery reports and radiographs taken at the last follow-up visit.

Radiological evaluation of femoral stem loosening was performed according to Gruen and of the cup according to DeLee (3,4). Wear was measured with the radiographic technique of Livermore *et al* (10). Calculation of linear wear per year was performed by measurement of the migration of the femoral head into the acetabular cup; initial postoperative anterior-posterior

radiographs of the pelvis were compared with the radiographs made at the last follow-up examination. The volumetric wear per year was calculated by the formula  $v = \pi r^2 w$  ( $v$  = volumetric wear,  $r$  = radius of the femoral head,  $w$  = measured linear migration of the femoral head through the polyethylene) (10). The Harris Hip Score was used for clinical evaluation (5). Quality of life was analyzed with the German version of the SF-36-health questionnaire (8).

Results were compared between various subsets of patients, based on sex, age, weight, primary or revision arthroplasty, ceramic or metal head, diameter of the head (28 vs. 32 mm), allograft, cemented or cementless fixation of the stem, polyethylene liner sterilization and time interval between manufacturing and implantation of the liner.

Statistical analysis was performed using the Statistical Package for Social Sciences for Windows, release 11.0 (SPSS GmbH, Munich, Germany). The t-test was used to compare the influence of different patient- and prosthesis-specific parameters on wear rates, and Spearman's test for correlation was applied. The level of significance was set at  $p < 0.05$ .

## RESULTS

At follow-up, no revision surgery has been necessary. Radiolucent lines (RLL) in the shaft area were found in 12 cases (40%). Two patients showed osteolysis in 1 Gruen zone, one in 2 zones, seven in three zones, one in 4 zones and one in 5 zones (fig 1).

Seven patients (26.7%) had radiolucent lines in the acetabular area, of which three each showed osteolysis in zone 1 and 3, and one patient had osteolysis in zone 1 and 2. In four cases this radiolucent line was less than 0.5 mm thick. All 3 patients with osteolysis in zone 3 had a RLL between 0.5 and 1 mm thickness (fig 1).

In all cases, wear of variable extent could be demonstrated. The mean linear rate of wear per year was 0.15 mm (min = 0.0046 mm, max = 0.4140 mm, SD = 0.09). The mean volumetric rate of wear per year was 95.87 mm<sup>3</sup> (min = 3.71 mm<sup>3</sup>, max = 255.45 mm<sup>3</sup>, SD = 64.69). The correlation of linear and volumetric wear rates with patient and prosthesis specific parameters showed no significant influence of either patient or prosthesis specific parameters (fig 2 & 3).

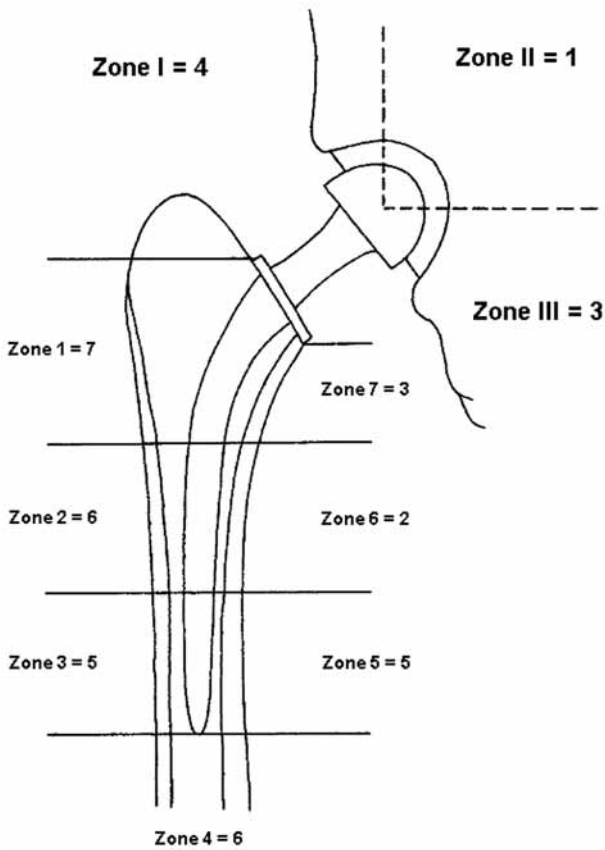


Fig. 1. — Localisation and number of osteolytic lesions according to Gruen and DeLee.

Clinical examination showed an average Harris Hip Score of 76.9 points (min = 23.5, max = 100, SD = 20.1). In the SF-36-health questionnaire relevant differences were found between the patients group and a healthy German reference group of similar age and the patients in the Swedish arthroplasty register, with respect to the parameters bodily pain, general health, vitality and social function. The results of the Hylamer group were inferior to the two control groups (fig 4).

Analysis of the correlation coefficients showed no correlation between the wear rates and the clinical scores.

### DISCUSSION

This study considers for the first time results of patients after total hip arthroplasty with the use of a

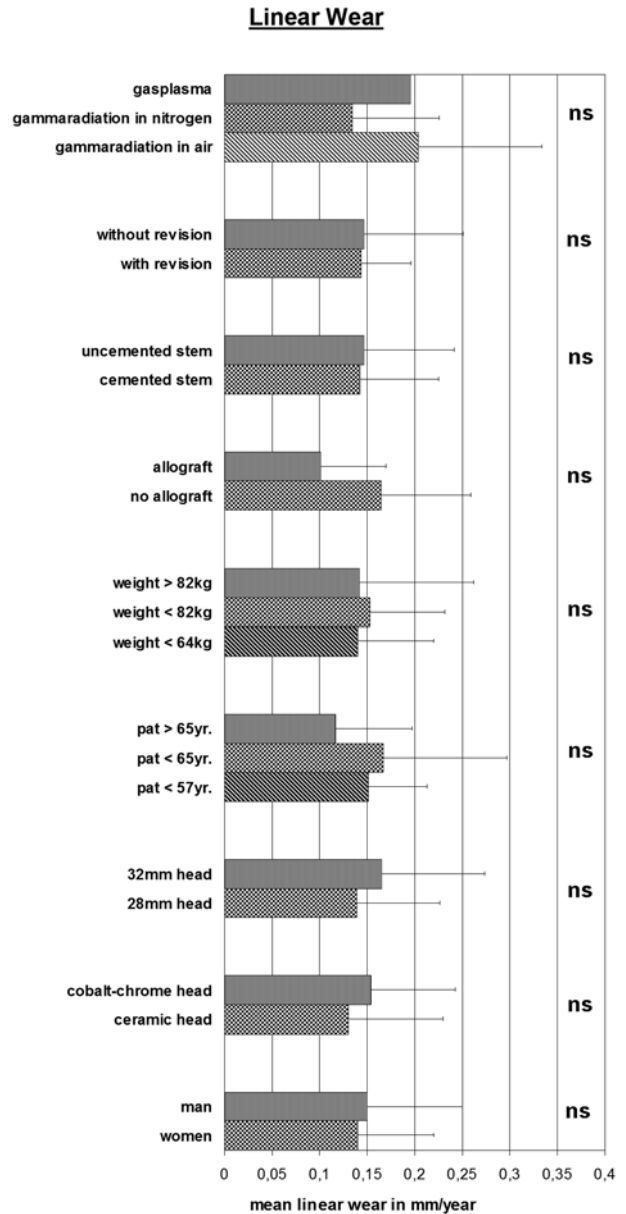


Fig. 2. — Linear wear corresponding to patients and prosthesis specific parameters.

Hylamer liner in correlation with radiological, clinical and prosthesis specific parameters and quality of life. The analysis of radiolucent lines showed a higher occurrence in our series than reported in literature (16). Furthermore the linear and volumetric wear per year were higher than the wear rates of conventional polyethylene and also

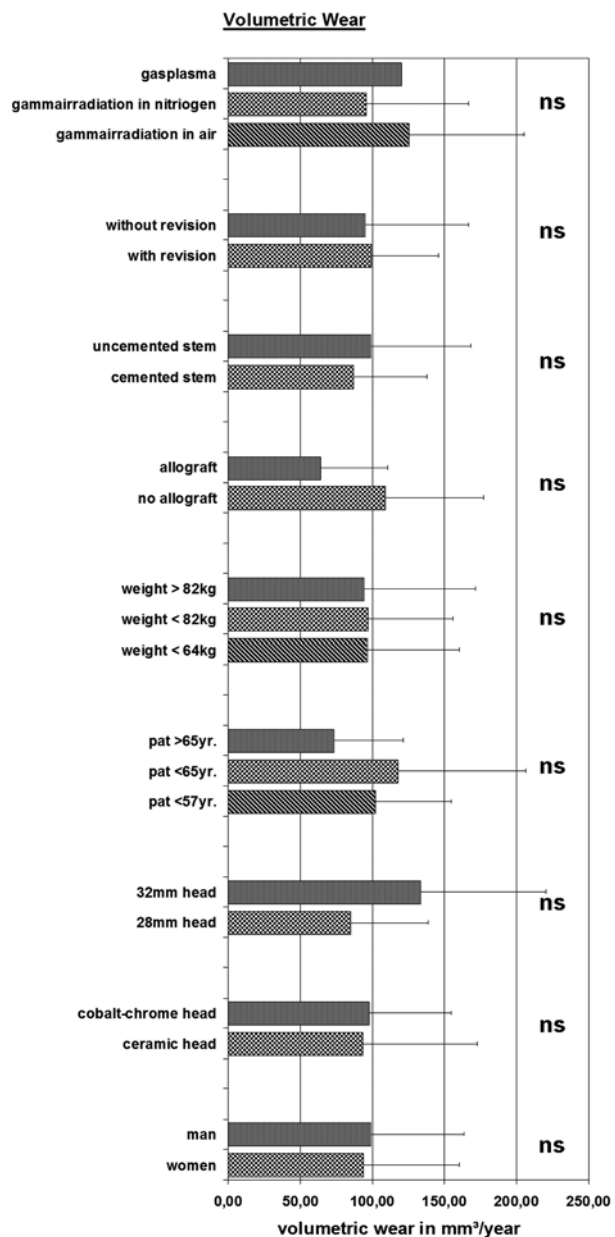


Fig. 3. — Volumetric wear corresponding to patients and prosthesis specific parameters.

than wear rates reported by other authors for Hylamer liners (16,17). Contrary to the literature no revision has been necessary until follow-up examination, because no patient had clinical symptoms of loosening. However, considering the radiological findings and the high wear rates, revisions are expected to be necessary on a longer term.

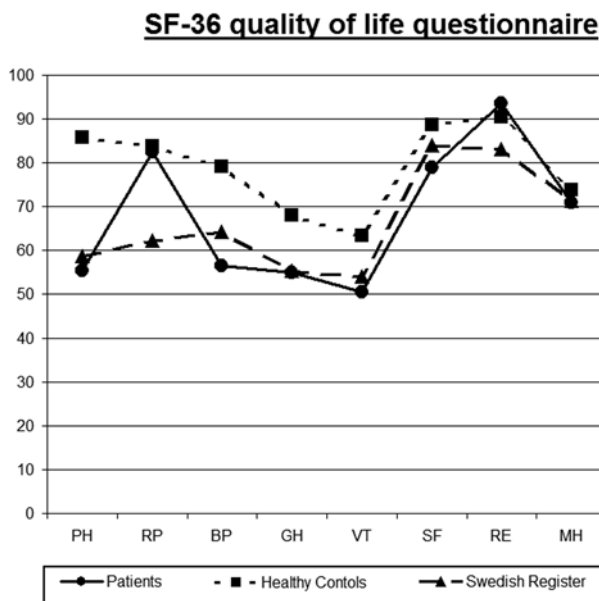


Fig. 4. — SF-36 quality of life questionnaire (PF-Physical Functioning, RP-Role Physical, BP-Bodily Pain, GH-General Health Perceptions, VT-Vitality, SF-Social Functioning, RE-Role Emotional, MH-Mental Health).

These four results already demonstrated in the literature suggest that Hylamer is the weak point (14, 16,17,19). The major problem seems to be oxidation of polyethylene, which affects its mechanical properties. Changes in crystallinity and a decreased resistance to mechanical stress are responsible for increased wear (21). Visentin *et al* could demonstrate higher crystallinity after sterilisation with gamma irradiation in air compared to liners irradiated in a nitrogen environment, and a different type of wear compared to traditional UHMWPE (21,22). This may be the reason why sterilization in gas plasma or gamma irradiation in air not only cause higher wear rates *in vivo* but also induce a more intensive biological response in the form of massive osteoclast activation and osteolysis (12,18,22). Our study confirms these findings. We found smaller wear rates for Hylamer liners radiated in nitrogen compared to liners sterilized by gamma irradiation in air, even though the difference did not reach significance. Furthermore, longer storage time of Hylamer liners after sterilization in air causes material alterations and increased wear (6). Scott *et al* and Yamauchi *et al* noted higher wear and loosening

ing rates with Hylamer liners with longer shelf life before implantation (16,23). Here also oxidation of polyethylene and changes in its properties appeared to cause early failure.

However, some authors discussed other factors which induce a higher wear rate of the Hylamer liner. The combination of a zirconia femoral head with the Hylamer liner showed higher wear rates and higher occurrence of osteolysis necessitating revision, compared to metal heads (7,14). The head diameter also showed differences in wear rates but without a significant clinical relevance (7). In our investigation we also noted higher wear rates for 32 mm cobalt chromium heads. However we found no significant differences between the wear rates caused by different head diameters nor caused by different material of the femoral head. Furthermore the amount of wear rates show no effect on the clinical results. A further possible reason for early failure of the Hylamer liner was the use of articulating components from different manufacturers (11,19).

Overall, high wear rates and early loosening of prostheses with Hylamer liners have been reported in the literature, even though the early results with a short follow-up reveal satisfying results (14,17,19, 20). Our study confirms these disappointing results. The high occurrence of radiolucent lines and the higher wear rates demonstrate a failure of this material even though no revision had been necessary at mid-term follow-up. Further parameters, like age, sex, body mass index and surgical technique, did not appear to have any clinical relevance in our investigation. Inferior results of the Harris Hip Score and the SF-36 life quality questionnaire compared to the literature may be caused on the one hand by patients with incipient loosening but no revision yet at the time of examination, on the other hand by a high proportion of patients in which a Hylamer liner was used for revision of a loose acetabular component. A weak point of our study and the reason for the lack of significance may be the small size and the heterogeneity of our study group. Furthermore the head penetration measured represented a combination of wear and creep, with the latter predominating during the first years, while the follow-up in this study was only six years.

In conclusion the main problem for early loosening of the Hylamer liner and high wear rates appears to be a change in the mechanical properties caused by a number of factors.

Further investigations of explanted Hylamer liners may explain the weak point of this initially promising material. For clinical practice regular radiological examinations are necessary to diagnose implant loosening early and to be able to perform revision surgery at an early stage.

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