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Clinical and radiological results with a 36-mm cobalt-chrome prosthetic head, cross-linked Durasul liners associated with Allofit cups: a more than 10-year follow-up period

Pierre Georis, Thierry Thirion and Philippe Gillet

Abstract

Background: Highly cross-linked polyethylene is currently a common articulation surface used for total hip arthroplasty (THA).

Aim: The aim of the present study is *in vivo* assessment of highly cross-linked Durasul polyethylene linear and volumetric wear when associated with a 36-mm prosthetic femoral head.

Methods: We retrospectively reviewed clinical and radiographic data of 78 patients (81 hips) having primary THAs using Durasul liner combined with a 36-mm CoCr prosthetic head. All of them were followed for more than 10 years. Patient outcome was assessed with the Harris Hip Score (HHS) preoperatively and at last follow-up. 2-D prosthetic head penetration into polyethylene, 3D wear rates and cup migration were evaluated.

Results: The preoperative and last follow-up HHS were 50.43 +/– 10.42 and 97.44 +/– 5.51 respectively. The annual penetration of the prosthetic head into Durasul® liner was 0.029 +/– 0.003 mm. The annual linear penetration and volumetric wear extrapolation rates using Charnley and Ilchmann formulas were 37.84% and 57.76% respectively of that seen with conventional polyethylene liner. At last follow-up, the total loss of material in Durasul represents only 0.15% of the initial polyethylene mass. We did not observe any significant cup migration in the study group.

Conclusions: Results are promising, and we believe that these data authorise the continued use of highly cross-linked polyethylene liner associated with a 36-mm prosthetic head for total hip arthroplasties in older patients. More long-term follow-up studies are mandatory before we feel comfortable with the project of using cross-linked polyethylene in young and active patients instead of ceramic-on-ceramic bearings.

Keywords

Hip replacement, PE wear rate, volumetric wear

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Introduction

For decades total hip arthroplasty (THA) has been 1 of the most successful surgical interventions in medicine. However the optimal bearing surface remains controversial. In 1995, Harris demonstrated that production of wear particulate debris is the main factor leading to periprosthetic osteolysis, aseptic loosening and long-term failure of an implant.[1] The longevity of a THA with a metal-on-polyethylene bearing may be limited by wear of the polyethylene.[2–4] To reduce the volume of wear debris generated at the bearing surface and thereby improve the longevity of the prosthesis, several changes in the manufacturing process of conventional polyethylene have been made over the last 2 decades. Highly cross-linked polyethylene is currently a common articulation surface used for THA.

Orthopaedic Department, University Hospital Sart-Tilman, Liège, Belgium

Corresponding author:
Pierre Georis, CHU de Liège - Hôpital du Sart Tilman, University Hospital Orthopaedic Department, Avenue de l'Hòpital, 13, Liège 4000, Belgium.
Email: pierre.georis@chu.ulg.ac.be

Durasul was developed in conjunction with W. Harris and the Massachusetts Institute of Technology. It has demonstrated improved wear performance over conventional polyethylene in laboratory testing.[5] The unique wear-resistance of Durasul is achieved through an electron-beam radiation process (95 KGy at ~120°C). Irradiation creates cross-links in the material's structure. The polyethylene is then subjected to a thermal treatment to remove free radicals (melting at 150°C for 2 hours). Sterilisation is obtained under ethylene oxide (EtO).[6–8]

On the other side dislocation represents, after aseptic loosening, the second most frequent complication in THA with occurrence of 2–3% following a primary THA and 10% in revision arthroplasties.[9,10] Factors contributing to impingement and dislocation include soft tissue, bone components, orientation of the prosthesis and design of the implants.[11] The range of motion (ROM) of the articulation is function of the effective position of the implants but also of the technical ROM influenced by the manufacturer's implant design. In order to obtain a sufficient postoperative hip mobility and stability; THA should provide a head-neck ratio of at least 2:1.[12] The use of a large prosthetic head size could increase hip stability and greatly prevent the possible risk of dislocation.[13,14]

Highly cross-linked polyethylene theoretically allows the use of thinner inserts than with conventional polyethylene. Thinner inserts allow for larger diameter heads. This provides greater freedom of movement to patients and participates in reducing the risk of dislocation.

In 2001, Muratoglu et al.[7] showed that cross-linked polyethylene volumetric wear is independent of the head diameter between 22 and 46 mm. The insert must have a minimum 3-mm thickness. A minimum 5-mm thickness is suggested (7-mm for 22-mm head).[7] This allows the use of a 36-mm prosthetic head combined with a minimum 52-mm diameter cup.

A possible complication related to implant thinness is liner fracture. Because the hip kinematics includes a piston effect up to 10 mm, fracture toughness reduction of cross-linked polyethylene reaches more than 30%.[15] In 2004, Bradford et al.[16] demonstrated that there was consistent evidence of surface cracking, abrasion, pitting and scratching on polyethylene inner surface on liners removed from early failure of defective metal shells after 10 months (recalled patients). The phenomenon was not predicted by *in vitro* hip simulator studies. The discrepancy between *in vitro* and *in vivo* wear surfaces may be due to variability in terms of *in vivo* lubrication and cyclic loading or may represent early surface damage mechanisms that are not well demonstrated by long term simulator studies.

The aim of the present study is *in vivo* assessment of highly cross-linked Durasul polyethylene linear and volumetric wear when associated with a 36-mm prosthetic femoral head. We evaluated the behavior status of Durasul when it was combined with a 36-mm CoCr head or with a 28-mm CoCr prosthetic femoral head. We also hypothesise that Durasul combined with a 36-mm head could produce less wear than a conventional polyethylene liner in association with a 28-mm ceramic femoral head.

Material and methods

Between May 2003 and September 2005 91 prostheses were implanted in 88 patients. All THA were performed by the same surgeon in the same hospital. Sex ratio male/female was 30:58 with a mean age of 74.31 (range 62–89) years at the operation. To date, mean age of patients reaches 85.20 years. Among them 20 patients died for unrelated cause to hip surgery but 10 of them after more than 10 years follow-up. These 10 patients were included to the study. We retrospectively reviewed clinical and radiographic data of 78 patients (81 hips) having primary THAs using Durasul liner (Zimmer Inc, Warsaw, IN, USA) combined with a 36-mm CoCr prosthetic head (Protasul). All of them were followed for more than 10 years. All patients received an Allofit acetabular cup (Zimmer Inc, Warsaw, IN, USA) of 52 mm (n = 22), 54 mm (n = 18), 56 mm (n = 17), 58 mm (n = 16), 60 mm (n = 4), 62 mm (n = 3) and 64 mm (n = 1). When osseous bone stock was sufficient, patients received a cementless Spotorno (CLS) stem (n = 17); the large majority of patients received a MS-30 cemented stem (n = 64). These 81 THA constituted the study group.

The first control group (control A) was composed of 16 THA with a Durasul liner combined with a 28-mm Protasul prosthetic head. The second control group (control B) was composed of 40 THA with a conventional polyethylene (UHMWPE) Sulene liner combined with a 28-mm Biolox prosthetic head. All patients from control groups were followed for more than 10 years (control A: 11.2 years, control B: 11.5 years).

Patient outcome was assessed with the Harris Hip Score (HHS) preoperatively and at last follow-up. We also collected adverse events and complications.[17]

Digitised radiographs taken at 6 weeks, 6 months, 1 year, 2 years, 5 years and at last follow-up were used for radiographic analysis. All measurements were performed on pelvic standing radiographs. *In vivo* penetration of the prosthetic head into the polyethylene was determined as 2D linear femoral head penetration on anteroposterior pelvis radiographs. The first 6 months after implantation, we took into account bedding-in penetration (difference between 6-week and 6-month radiographs).[18] After this 6-month period, we interpreted measurement differences as true wear.

2D prosthetic head penetration into polyethylene (bedding-in and wear) assessment was performed using a specific analysis model created in the Imagika software (GreyStone, Paris, France). It uses an automatic edge detection to fit the contour of the prosthetic head and the cup.

The contour of the prosthetic head was determined by using 3 points. The known diameter of the head (36 mm or 28 mm) is used for calibration. The diameter of the cup was determined by using 5 points. The software determines both centers (head and cup) and measures the distance between them on all consecutive films. 3-dimensional wear rates were calculated according Charnley ($V = \pi r^2 w$) and Ilchmann($V = \frac{r^2 w}{2}(\pi + \pi \sin\beta + \frac{w}{r}\sin 2\beta) + 2rDw\cos\beta$) formulas.[19,20] The Ilchmann formula considers the directional vector of linear penetration of the prosthetic head into the polyethylene (Beta angle).[19]

Cup migration was evaluated using the EBRA-CUP software.[21]

All groups (study group, control A and control B) were compared with unpaired Student t-test with a level of significance set at 5%.

Results

In the study group, the preoperative and last follow-up HHS were 50.43 +/– 10.42 and 97.44 +/– 5.51 respectively. The same observation was made in both control groups. As in the large majority of hip procedures, patient's satisfaction is relatively high with a considerable improvement of life quality level. There was no significant difference (NSD) in HHS between all groups (Table 1).

Table 1. Preoperative and last follow-up Harris Hip Scores in study and different control groups.

	Preoperative HHS	Last follow-up HHS
Study group	50.43 +/– 10.42	97.44 +/– 5.51
Control A	51.27 +/– 12.34	97.23 +/– 4.94
Control B	50.35 +/– 14.21	96.47 +/– 6.34

HHS, Harris Hip Score.

Regarding bedding-in penetration of the prosthetic head into the polyethylene, we did not observe any significant difference between 3 groups (Table 2).

The annual penetration of the prosthetic head into Durasul liner was 0.029 +/– 0.003 mm and 0.032 +/– 0.014 mm for the study group and the control A respectively with a *p*-value of 0.087 (NSD). Contrariwise, the annual penetration of the head in control B reached 0.083 mm with a *p*-value of 0.00027 (SD).

Mean Beta angle calculated was 62.0° =/– 6.4° in study group, 64.0° +/– 7.2° and 63.5° +/– 9.8° in control A and control B respectively (NSD).

With the highly cross-linked Durasul polyethylene used in the study group, a 36-mm prosthetic head had unfavourable influence on the volumetric wear assessment compared with the use of a 28-mm prosthetic head (control A) but the wear volumes produced were relatively low (Table 3). The qualitative wear pattern of the highly cross-linked Durasul® polyethylene liner associated with a metallic (CoCr) 36-mm Protasul prosthetic head was the same as that of the conventional polyethylene liner associated with a 28-mm Biolox prosthetic head. The annual linear penetration and volumetric wear extrapolation rates using Charnley and Ilchmann formulas were 37.84% and 57.76% respectively of that seen with conventional polyethylene liner (Table 4). At last follow-up, the total loss of material in Durasul represents only 0.15% of the initial polyethylene mass.

We did not observe any significant cup migration in the study group as well as in control groups. The absence of cup migration at last follow-up may indicate very low polyethylene wear rates (Table 5).

At last follow-up, no complication was observed related to implant thinness in the study group.

Unfortunately, we observed 1 traumatic dislocation in 1 patient. It was a 62-year-old female who received a MS-30 cemented stem combined with a 36-mm prosthetic head associated with an Allofit 52-mm shell. This disoriented

Table 2. Bedding-in penetration of the prosthetic head into the polyethylene in all groups.

Study group	Control A	Control B
0.054 +/– 0.009 mm	0.056 +/– 0.008 mm	0.057 +/– 0.010 mm
Study group versus control A	*p* = 0.36	NSD
Study group versus control B	*p* = 0.42	NSD
Control A versus control B	*p* = 0.61	NSD

NSD, no significant difference.

Table 3. Volumetric wear extrapolation rates using Charnley and Ilchmann formulas in all groups.

	Annual volumetric wear extrapolation (Charnley)	Annual volumetric wear extrapolation (Ilchmann)
Study group	29.52 +/–6.01 mm³	27.81 +/– 4.12 mm³
Control A	19.70 +/– 17.28 mm³	13.46 +/– 6.54 mm³
Control B	51.11 +/– 68.75 mm³	48.55 +/– 84.47 mm³

Table 4. Statistical analysis of volumetric wear rate differences between all groups.

	Charnley formula	Ilchmann formula
Study group versus control A	$p = 0.0046$ (SD)	$p = 0.0004$ (SD)
Study group versus control B	$p = 0.000042$ (SD)	$p = 0.00075$ (SD)
Control A versus control B	$p = 0.0000021$ (SD)	$p = 0.0000064$ (SD)

SD, significant difference.

Table 5. Medial and cranial cup migrations in all groups.

	Medial cup migration	Cranial cup migration
Study group	0.09 +/– 0.01 mm	0.13 +/– 0.02 mm
Control A	0.10 +/– 0.05 mm	0.12 +/– 0.02 mm
Control B	0.11 +/– 0.07 mm	0.14 +/– 0.03 mm

patient had fallen from a chair at 6 months after primary intervention. She was reduced under general anaesthesia in the emergency room and she is doing well since without any sign of polyethylene wear or cup migration.

Recently, we observed a stem subsidence with probable loosening in an 85-year-old female. She received 11.5 years before a MS-30 cemented stem with a 36-mm prosthetic head associated with a 54-mm Allofit cup. However, there is no sign of polyethylene wear or cup migration. Osseous scintigraphy confirms the loosening of the femoral implant. This patient is under further investigation for septic stem loosening due to probable infection.

Discussion

The main purpose of the present study was to assess and quantify wear rates of Durasul insert combined with a 36-mm Protasul prosthetic head. We also attempt to demonstrate that the use of larger prosthetic head did not influence the linear prosthetic head penetration into the highly cross-linked Durasul polyethylene compared with the use of smaller prosthetic head combined with conventional polyethylene. In parallel, we tried to verify if the use of larger than 28-mm prosthetic head had a favourable effect on dislocation rate.

Regarding bedding-in penetration of the prosthetic head into the polyethylene, we did not observe any difference whatever the prosthetic head diameter or the polyethylene type used. This is in opposition to the observations made by Olyslaegers et al.[22] for whom bedding-in penetration occurs in the first 2 years following implantation. They suggested that cross-linked polyethylene liners adapt more slowly to femoral head penetration. These observations seem to be confirmed by Digas et al.[23] and Manning et al.[24]

Some studies showed that cross-linked polyethylene inserts have a higher resistance to long-term wear than conventional polyethylene inserts.[25,26] This is corroborated by the results published of mid-term follow-up studies.[27–31] The present study confirms the wear rate reduction when using a cross-linked polyethylene insert compared with conventional polyethylene liner. We objectivised wear rates of 27.81 mm³ and 13.46 mm³ annually when using a Durasul liner combined with a 36-mm or a 28-mm Protasul prosthetic head instead of 48.55 mm³ annual wear rate when using conventional Sulene liner associated with a 28-mm Biolox prosthetic head. The use of Durasul liners lead to a drastic wear rate reduction of 37.84% and 57.76% respectively of that seen with the Sulene liner.

Other authors advocated that the use of a cross-linked polyethylene liner instead of a conventional type may reduce the wear rate up to 95% (range 70–95)[23,32–34] The results of our study are les optimist but we used a 36-mm prosthetic head while other authors reported observations based on the use of a 28-mm or a 32-mm prosthetic femoral head. It is clearly demonstrated that the larger prosthetic heads increases the friction surface in contact with the inner part of the polyethylene insert and at the same time produces more wear particles than smaller prosthetic heads.[35] Despite the use of a large ball, our study demonstrates less linear head penetration into the Durasul polyethylene insert than other authors using the same socket.[23,26,30] All these articles support the steady-state behavior of the Durasul liner and the hope of promising results in the future.

More recently, 2 meta-analyses clearly demonstrated that cross-linked polyethylene decreases the prosthetic head penetration rate in the liner and decreases the volumetric wear rate but surprisingly the hypothesis that cross-linked polyethylene has an advantage over conventional polyethylene in terms of reducing osteolysis or revision rate is contradicted.[36,37]

This is a retrospective study of more than 10 years follow-up, and unfortunately, we were not able to produce an equal amount of THA in the 3 groups. However, Sulene polyethylene liners constituting control B group have been used for a long time and its wear rate is well known. The control A group was composed of Durasul liners combined with a 28-mm prosthetic head. The small number of cases in this group is due to the preferential use of a larger prosthetic head in the large majority of the cases in prevision of limitation of the dislocation risk. A 28-mm prosthetic head was only used with cups less than 52-mm. The main purpose of this study was to measure wear in the Durasul acetabular liner and to determine if there was really a difference between cross-linked and conventional polyethylene whatever the prosthetic head diameter used. Our results demonstrate a drastic reduction in linear penetration of the prosthetic head (36 mm or 28 mm) into the highly cross-linked Durasul polyethylene compared with the conventional Sulene polyethylene combined with a 28-mm Biolox prosthetic head.

The most important factors influencing postoperative mobility and stability of the prosthetic hip are the head diameter and the neck geometry (head-neck ratio of 2:1).[12] Increasing the prosthetic head diameter enlarges the range of motion of the hip. In addition, stability is increased as a result of the larger prosthetic head being set deeper into the acetabular component compared to that of the smaller head size. As a result, the risk of impingement is lower and the risk of dislocation is reduced. Because of the relatively low wear rates objectivised in cross-linked polyethylene, the use of 36-mm prosthetic head becomes possible.[38] We are in agreement with the results published by Geller et al.[39] who demonstrated in 2006 that the use of large prosthetic heads (>32 mm) with a highly cross-linked polyethylene could be considered in patients with increased risk for dislocation. In their series of 45 hips, they mentioned 1 dislocation due to a grossly malpositioned acetabular component necessitating early revision.[39] In our study group, a disoriented patient had fallen from a chair at 6 months after primary intervention. The prosthetic hip was reduced under general anesthesia in the emergency room without implant revision because we did not objectivise any sign of polyethylene wear or cup and stem migration.

In the whole series, no cup migration was observed. No osteolytic area or radiolucent lines in the 3 cup's Gruen zones has been put in evidence.

Fortunately, we did not observe any complications related to implant thinness like liner fracture as predicted by Pruitt in 2005.[15] However, in our study group we must deplore a stem subsidence with probable septic loosening in 1 patient with no sign of polyethylene wear or cup migration.

Results are promising and we believe that these data authorise the continued use of highly cross-linked polyethylene liner associated with a 36-mm prosthetic head for total hip arthroplasties in older patients. To date, in our institution, the use of Durasul implants is a daily activity. Compared to this study group, we decided to change the use of a metallic prosthetic head (Protasul 36 mm) by a ceramic one (Biolox Delta 36 mm). Dahl et al.[40] clearly demonstrated that alumina heads performed better than cobalt-chrome heads after 10-year follow-up period. These findings support the use of alumina heads to reduce polyethylene wear in THA.

More long-term follow-up published studies are mandatory to check the validity of this hypothesis and before we feel comfortable with the project of using highly cross-linked polyethylene in young and active patients instead of ceramic-on-ceramic bearings. Considering that the type of implant used in our study group is mainly reserved for the elderly, obtaining long-term results with large cohort seems to be utopic.

Declaration of conflicting interests

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