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Behavior of Hylamer polyethylene in hip arthroplasty: comparison of two gamma sterilization techniques

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Abstract Hylamer polyethylene was introduced in the 1990s as an alternative to conventional polyethylene. Its chemical and physical properties, and especially its high crystallinity, were claimed to improve resistance to wear. Initially Hylamer devices were sterilized by gamma radiation in air, then the technique was changed and gamma radiation was performed in the absence of oxygen. Clinical experience has shown the early loosening of some devices made from Hylamer. The aim of this study was to ascertain whether early wear and consequent osteolysis was linked to the sterilization method. We retrospectively compared 31 patients with hip prostheses with Hylamer liners sterilized by gamma radiation in air (group 1) with 30 patients with the same prosthesis, but sterilized in the absence of oxygen (group 2). The groups were similar for sex, age, disease, head diameter and material. Mean follow-up was 84 months and no clinical signs of failure were present. Radiographic measurement revealed that wear of group 1 was significantly greater than that of group 2 (0.23 mm/year vs 0.09 mm/year, $p=0.001$). Periacetabular and femoral osteolysis in group 1 was significantly greater than group 2. In conclusion, the method of sterilization might have influenced the outcome of Hylamer polyethylene liners.

Résumé Le polyéthylène Hylamer a été présenté dans les années 1990 comme une alternative au polyéthylène conventionnel. Ses caractéristiques chimiques et physiques, et

surtout sa haute cristallinité, devaient améliorer la résistance à l'usure. Tout d'abord l'Hylamer a été stérilisé par rayonnement gamma dans l'air, puis la technique a été changée et le rayonnement gamma a été exécuté en l'absence d'oxygène. L'expérience clinique a montré des descellements précoces de composants en Hylamer. Le but de cette étude était de découvrir si l'usure précoce et l'ostéolyse résultante étaient liées à la méthode de stérilisation. Nous avons comparé rétrospectivement 31 malades avec une prothèse de la hanche avec liner en Hylamer stérilisé par rayonnement gamma dans l'air (groupe 1) avec 30 malades avec la même prothèse, mais stérilisée en l'absence d'oxygène (groupe 2). Les groupes n'étaient pas différents pour le sexe, l'âge et la maladie, le diamètre de la tête et la matière. Le suivi moyen était de 84 mois et aucun signe clinique d'échec n'était présent. Les mesures radiographiques ont noté que l'usure du groupe 1 était notablement plus grande que celle du groupe 2 (0.23 mm/an contre 0.09 mm/an, $p=0.001$). L'ostéolyse périacétabulaire et fémorale dans le groupe 1 était nettement plus grande que dans le groupe 2. En conclusion, la méthode de stérilisation a pu influencer le devenir du liner en polyéthylène Hylamer.

Introduction

An ultra-high-molecular-weight polyethylene with increased crystallinity to improve wear resistance (Hylamer) was introduced in the early 1990s. Various methods of sterilization were used. Implants manufactured between 1992 and 1993 were sterilized by gamma irradiation in air. In 1993 gamma irradiation in an atmosphere of nitrogen was introduced, and since 1995 implants have been sterilized with gas plasma but without irradiation.

In in-vitro tests Hylamer was claimed to have better wear qualities than conventional ultra-high-molecular-weight polyethylene [9], although there was no universal agreement [13]. Other in-vitro studies showed that the wear resistance of Hylamer and conventional polyethylene sterilized by gamma irradiation in air was comparable [13].

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Early loosening of Hylamer liners was soon reported, one to three years after insertion. Potential damage to the implant material by high-energy radiation was also reported [14, 16]. Since 1996 the use of Hylamer liners has therefore largely been discontinued [2, 4, 11, 18]. King et al. [7] and later Kurtz [8] held the opinion that extended-chain morphology material (Hylamer) was more susceptible to oxidative degradation than was a conventional UHMWPE material of similar age.

The aim of this retrospective study was to compare two groups of patients, one in which Hylamer acetabular liners sterilized by gamma radiation in air had been inserted and the other in which Hylamer acetabular liners sterilized in a nitrogen atmosphere had been implanted.

Patients and methods

Between January 1991 and September 1998, 51 Duraloc sockets (Depuy) with Hylamer acetabular liners sterilized by gamma radiation in air were implanted at our institute. All patients were contacted, informed and invited to undergo a clinical and radiographic examination at the institute. Thirty-one patients accepted the invitation (group 1).

Among a cohort of 52 patients that had received Hylamer acetabular liners sterilized by gamma radiation in a nitrogen

Fig. 1 Outlines of head and socket circumferences based on the identification of five points on each contour. The shortest distances from the center of the head (O) to the outer surface of the socket (A), and to the intersection with the head circumference (A') are ascertained using the original Livermore method

Table 1 Characteristics of the two groups

Parameter	Group 1	Group 2
Method of sterilization	Gamma irradiation in air	Gamma irradiation in a nitrogen atmosphere
Number	31	30
Mean age at surgery (years)	53	57
Gender		
Female	18 (58%)	23 (76.7%)
Male	13 (42%)	7 (23.3%)
Pathology		
Sequelae of hip dysplasia	17 (54.8%)	16 (53.4%)
Coxarthrosis	8 (25.8%)	10 (33.4%)
Femoral neck fracture	3 (9.7%)	1 (3.3%)
Post-traumatic coxarthrosis	2 (6.5%)	1 (3.3%)
Femoral head necrosis	1 (3.2%)	1 (3.3%)
Sequelae of Perthes disease	—	1 (3.3%)
Articular coupling		
Met-pol	26 (83.9%)	26 (86.7%)
Cer-pol	5 (16.1%)	4 (13.3%)
Head diameter (mm)	28	28
Duration of follow-up (months)		
Mean	85	84
Range	44–105	64–112

atmosphere we selected 30 patients based on the availability of serial radiographic follow up. These patients constituted group 2. Characteristics of the two groups are shown in Table 1.

All patients were evaluated using the Harris hip-scoring system [6]. Radiographically we compared the immediate post-operative anteroposterior pelvic radiograph with the radiographs from the most recent follow-up [1]. The radiographic evaluation was based on the technique of Livermore (Fig. 1) [10]. X-ray films were digitized using a Vidar Diagnostic Pro digitizer (Vidar Systems, Herndon, VA, USA), with a spatial resolution of 300 dots per inch (dpi) and 12 bits/pixel. Linear and angular measurements on the digitized X-rays were taken as defined by Livermore et al. [10] using the tools available within the Image Pro Plus 4.5.1.22 software (Media Cybernetics, Silver Spring, MD, USA). An automatic outline of circumferences was added as an improvement to the original technique.

The measurement procedure exported the coordinates in pixel units in a standardised format. A Microsoft Excel macro was written to import the coordinates and to identify the line of minimal distance from the center of the head (point O) to the outer surface of the socket (point A), and the intersection with the head circumference (point A') (Fig. 1). That line defined the direction of maximum wear on the most recent radiograph. The difference in distance between A and A' between the two radiographs provided the amount of wear [10]. All measurements were converted from pixel units to millimeters based on the calibrated size of the prosthetic head.

Radiographic evaluation of wear was made by the same observer in both groups. The same X-rays were used to quantify periacetabular osteolysis in DeLee and Charnley's

Table 2 Clinical evaluation according to Harris hip score (HHS)

Class	Group 1 (n=31)	Group 2 (n=30)
Excellent (HHS 98–100)	0	0
Good (HHS 80–97)	21	15
Fair (HHS 60–79)	5	9
Poor (HHS <60)	5	6

zones 1, 2 and 3 [3] and Gruen's zones 1 and 7 [5]. Osteolysis was defined as a focal lesion in the periprosthetic bone not present on the initial radiograph [15]. The magnitude of osteolysis was measured as the greatest diameter of the lesion in horizontal as well as vertical axes.

A comparison was made of wear rate, normalised to the year, between Hylamer polyethylene liners sterilized by gamma radiation in air and sterilized without air.

Statistical analysis was performed by means of chi-square tests and Fisher's exact test for qualitative variables. The significance of differences between groups was assessed with the *t*-test.

Results

There were no significant differences in the Harris hip score between the two groups (Table 2).

In the radiographic assessment of wear the repeatability coefficient was 0.501 mm for the same observer and 0.601 mm for different observers. In group 1 the mean rate of wear was 0.23 mm/year (SD±0.18 mm/year); and in group 2, 0.09 mm/year (SD±0.07 mm/year). The differences in wear rate was statistically significant ($p=0.001$). There was no correlation between acetabular cup diameter (and related thickness of polyethylene liner) and wear rate.

In group 1 there were seven cases without periacetabular osteolysis; 21 cases had osteolysis in one or two DeLee and Charnley zones, and three cases had osteolysis in all three zones.

In group 2 there were 23 cases without periacetabular osteolysis and seven cases had osteolysis in one or two zones. There were no cases with osteolysis in all three zones.

Osteolysis in the proximal femur was present in 25 cases in group 1 and in 16 cases in group 2 (Table 3). Eight patients

in group 1 and two in group 2 had undergone revision due to polyethylene wear.

Discussion

At the start of the 1990s Hylamer polyethylene was introduced by the manufacturer as being far superior to conventional polyethylene in terms of resistance to wear. For that reason it was recommended for use in young, more active patients with a long life expectancy (and therefore with a greater likelihood of having to undergo revision surgery). Unfortunately, after a few years the first failures of implants with Hylamer liners began to appear in the literature, paradoxically caused by accelerated and early wear. At our institute Hylamer was used widely in hip prosthesis liners in the 1990s. At that time the liners were sterilized by gamma radiation either in air or in a nitrogen atmosphere. Therefore, we were able to carry out a retrospective comparison of two groups of patients comparable for age at surgery, gender, and disease.

From a clinical point of view the outcome of surgery was, on the whole, good. The percentage of patients with a "fair" Harris hip score was similar in the two groups at 16–20% after seven years. However, despite the lack of clinical signs, the wear of the Hylamer sterilized in air was significantly greater than that of the same material sterilized without air.

The radiographic evaluation of wear was based on an improved version of the Livermore technique [10]. The repeatability of the original method, in the version based on digital radiographs [12] is 0.609 mm for the same observer and 0.680 mm for different observers. Therefore, the improvement of the technique yielded better repeatability.

The mean annual rate of wear of Hylamer liners sterilized in air (0.23 mm/year) was comparable to that described by Graeter and Nevis [4] and Livingstone et al. [11] on nearly 300 patients. Similar results were obtained by Sychterz et al., who observed a mean true wear rate, calculated with multivariate regression analysis, of 0.18 mm/year for Hylamer liners sterilized in air (62 patients) and 0.11 mm/year for Hylamer liners sterilized in absence of oxygen (46 patients) [17]. A study by Yamauchi et al. was very similar to our own, but yielded different results. The authors showed greater wear in the Hylamer sterilized in air, but the annual wear of the Hylamer sterilized without air was double that found by us. However, Yamauchi and colleagues stated that, besides the short follow-up, another limitation of their study was the difference in femoral head diameter, which was 26 mm in the "Enduron group", used as a control group, and 28 mm in the other two groups [19]. In our study the femoral head diameter was constant.

The biological response to wear particles generated by the polyethylene is manifested by osteolysis, which was evident in the proximal region of the stem and the periacetabular area. The rate of periacetabular and proximal femur osteolysis with the Hylamer sterilized in air was statistically significantly different from that with Hylamer sterilized in an atmosphere of nitrogen, and Hylamer

Table 3 Periprosthetic osteolysis

	Acetabulum			Proximal femur	
	No osteolysis	Osteolysis in one or two zones	Osteolysis in three zones	No osteolysis	Osteolysis in zone 1 and/or zone 7
Group 1 (n=31)	7	21	3	6	25
Group 2 (n=30)	23	7	0	14	16

Rate of osteolysis in the peri-acetabular zones (DeLee and Charnley zones 1,2,3), and in the proximal femur (Gruen's zones 1 and 7)

polyethylene liners sterilized in air showed, significantly greater wear than those sterilized without air after seven years. As a direct consequence of the increased wear, which was, however, clinically silent, we observed a high rate of periprosthetic osteolysis, which necessitated surgical revision.

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