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ORIGINAL STUDY

Hylamer wear rates and shelf life : A clinical correlation

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We evaluated the performance of 84 Hylamer polyethylene components and zirconia modular femoral heads which were implanted in a single institution over a 5 year period. Patients were followed up for a mean of 6.2 years. The mean rate of penetration was 0.58 mm/year (0.05-1.0). Lot/batch numbers were available in the clinical case notes of 54 patients. Using the lot/ batch numbers, we were able to determine the Hylamer cups' shelf lifes. We found that liners with a shelf life greater than 10 months had a significantly greater linear wear (0.38 mm/year) than those implanted in less than 10 months (0.05 mm/year).

Key words : Hylamer ; wear ; shelf life.

INTRODUCTION

Wear of ultra-high molecular weight polyethylene (UHMWPE) acetabular liners is regarded as one of the most important factors limiting the life span of a total hip replacement (*30*). The longest surviving prostheses have low rates of penetration (*31*). Enhanced ultra-high molecular weight polyethylene (Hylamer) was introduced in 1991 in an attempt to improve the surface and wear characteristics of UHMWPE. Hylamer (Depuy Orthopaedics, Leeds, UK) is Hoechst-Celanese GUR 415 polyethylene treated by a proprietary process, involving high temperature and pressure, which changes the crystalline structure to an extended chain and was thought to cause enhanced physical properties including increased density, melting point, yield strength, tensile strength, modulus of elasticity, creep resistance and fatigue resistance (*3*).

At the time of its introduction, it was anticipated that Hylamer would therefore represent a significant advance in reducing polyethylene debris and osteolysis (*23*), and that the wear characteristics of a Hylamer acetabular surface in combination with a ceramic modular femoral head would improve in particular the long term performance of prostheses in young, active patients (*10, 14*). Results of *in vitro* testing of Hylamer indicated a 9% decrease in wear rate (*14*). These encouraging laboratory findings were supported by early clinical results which suggested that the rate of femoral head penetration into the Hylamer liners was lower than the rate of head penetration into conventional liners at 2 to 5 year follow-up (*27*).

However subsequent reports of high Hylamer wear rates in total hip replacement components have led to increased concern regarding these acetabular liners (*24, 28, 29*). Failure rates of between 4 and 67.6% at 5-6 year follow up have been reported (*1, 17*). While these materials are no longer available, subsequent industry curiosity over the

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success of Hylamer acetabular liners has led us to study our own cases.

The purpose of this retrospective study is to investigate the performance of Hylamer polyethylene components and zirconia modular femoral heads which were implanted in a single institution over a 5 year period.

MATERIALS AND METHODS

All the hip replacements in the present study were performed by five senior surgeons with use of a similar operative technique. An anterolateral approach was used and third-generation cementing techniques were employed. The Ogee flanged, angle bore designed Hylamer cups (Hylamer ; Depuy, Leeds, UK) pressurised the cement in the acetabulum as they were inserted. Cemented Charnley Elite Plus femoral stems were then introduced (*34*). A 22.225 mm zirconia ceramic femoral head was used.

The case notes and radiographs of all patients who had total hip replacements (THR) using the Hylamer/ Zirconia articulation combined with the Elite Plus stem were reviewed retrospectively. We specifically checked each patient's operation records to find out their acetabular cup's lot/ batch number. This information enabled us to determine the Hylamer cups' manufacturing date, and hence the shelf life. The shelf life was equal to the time interval in months between the manufacturing date and the implantation date. The evaluation consisted of clinical and radiological review, including the measurement of the Harris hip scores (*9, 16*). We obtained weight bearing anteroposterior (AP) radiographs of the pelvis centred over the symphysis pubis, and non weight bearing lateral views.

We measured wear of the Hylamer cup using the method described by Griffith *et al* (*7*) and popularised by Livermore, Ilstrup and Morrey (*11*). Osteolysis was evaluated on a standard antero-posterior radiograph in the acetabular component using the DeLee and Charnley zones I to III (*5*). Femoral osteolysis was described in relation to the Gruen zones (*8*). Osteolysis was defined as an expansile endosteal radiolucent lesion, not present on the initial post-operative radiograph, of greater than five millimeters in any direction.

RESULTS

Eighty four primary total hip arthroplasties in which a Hylamer acetabular liner was used as the bearing surface were performed at our institution between April 1994 and April 1999. Of the 84 patients, 79 (94%) were clinically and radiologically assessed. Four were lost to follow-up, and one patient refused to return to be reviewed. Five patients had bilateral Hylamer THRs. The Hylamer group consisted of 50 women and 34 men, with an average age of 43 years (range, 18-54), and an average weight of 74 kg ; these patients were followed up for a mean of 6 years (range, 4-8). Forty two (50%) patients had significant eccentric wear.

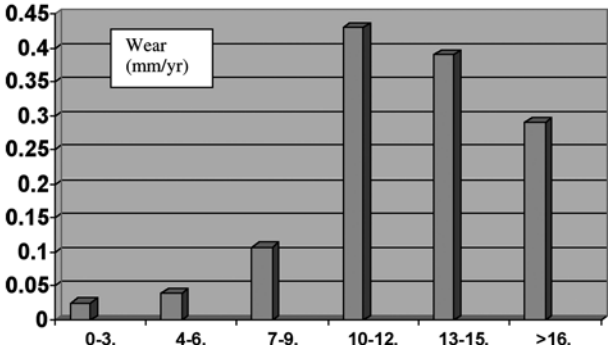

Fig. 1. — Relationship between total linear wear and time interval from production to operation (shelf life) in months.

The overall mean rate of penetration was 0.58 mm/year (range, 0.05-1.0/yr). Lot/ Batch numbers were available in the clinical case notes of 54 patients. We were unable to ascertain the lot/batch numbers in the remainig patients as their operative records were unavailable for review. Using the lot/ batch numbers, we were able to determine the Hylamer cups' shelf lifes. Of the cups for which we had lot numbers ,we found that liners with a shelf life greater than 10 months had a significantly greater linear wear (0.38 mm/year) than those implanted in less than 10 months (0.05 mm/year) (fig 1). All our acetabular components were implanted within the limits of the manufacturer's expiry date. There was a statistical difference between these two wear rates ($p < 0.01$) (Student's t-test). The group implanted at < 10 months shelf life actually had a longer mean implantation time (7.1 years) at review than the > 10 months group (4.8 years).

The Harris hips scores improved from a mean pre-op score of 46 (range, 32-54) to a mean post op

score of 94 (range, 82-98). At last follow-up the mean Harris hip scores were 88 (range, 76-96). There was no difference in the Harris hip scores between those hips which were implanted after 10 months and those which were implanted before 10 months.

Two patients required revision surgery, one for recurrent dislocation and one for early aseptic loosening. The patient with early aseptic loosening complained of persistent pain which resolved following revision of the acetabular component. The wear rate in this case was 0.11 mm/yr at revision (3 years post implantation). There was no evidence of significant acetabular osteolysis on plain films to account for the loosening. The component was revised to a conventional polyethylene liner.

DISCUSSION

More than 80,000 THRs using Hylamer acetabular components have been performed worldwide. There is now accumulating evidence that Hylamer has not lived up to its initial high expectations. The 0.58 mm/year average wear rate in this series is high and similar to wear rates of other hips with a Hylamer bearing that have been revised for high wear and osteolysis (*1, 6, 12*).

Hylamer was selected by us for use in this younger group of patients because of favorable preclinical and clinical results (*6, 21*). McKellop *et al* demonstrated that the wear resistance of Hylamer sterilised with gamma radiation in air was comparable with that of conventional polyethylene sterilised in the same manner (*15*). Early clinical results suggested that Hylamer liners had lower femoral head penetration rates than conventional UHMWPE liners (*23*). The average age of the patients in this study was 43 years. Pedometer studies have indicated that patients younger than 60 years of age with total hip replacements are 30% more active than those patients who are older than 60 (*20*). Schmalzried *et al* maintain that wear is a function of use, not time (*22*). Our results suggest that youth may be a contributory factor in the wear rates seen in this study as the mean age was 43 years at time of implantation.

Sterilisation and the role of gamma irradiation in air are believed to be key determinants in the accelerated wear rates of Hylamer acetabular liners. Sutula *et al* have demonstrated that gamma irradiation in air causes oxidative damage to polyethylene, and that this oxidation adversely affects Hylamer's mechanical properties (*26*). The resultant increased crystallinity is associated with a decrease in ultimate tensile strength, elongation to break and toughness. Hylamer is thought to be more susceptible to the effects of oxidation than conventional polyethylene because it contains sparse amorphous zones of material which allow for the accumulation of localised concentrations of oxidative destruction (*3*). Yamauchi *et al* confirmed this susceptibility to oxidative degradation by reporting head penetration rates of 0.21 mm and 0.37 mm per year for those liners sterilised with nitrogen and air respectively (*35*). Differences in sterilisation techniques may account for the discrepancies seen in the literature, and may explain the high penetration rates seen in our liners, all of which were irradiated in air.

The shelf life of the Hylamer acetabular liners has been reported to be an important determinant of the polyethylene's wear resistance. Wroblewski *et al* have shown that liners with a shorter shelf life showed a volumetric wear rate of 30% less than those with a longer shelf life (*32*). Gamma radiation causes chain scission by breaking chemical bonds, and creates reactive free radicals. Oxygen diffuses into the material and reacts with free radicals to cause oxidation, which leads to much shorter molecular chains (*18, 25*). McKellop *et al* have demonstrated that while gamma radiation may improve cross linking, the production of free radicals potentiates the oxidative process, and predisposes longer shelf lives to decreased wear resistance (*15*). Our data suggest that shelf life is a contributory factor in increasing wear (fig 1). We found that liners with a shelf life greater than 10 months had a significantly greater linear wear than those implanted in less than 10 months. All our acetabular components were implanted within the limits of the manufacturer's expiry date.

Implant conformity has been identified as being an important determinant of polyethylene wear. Manufacturers recommend using an acetabular

component and modular femoral head made by the same company. Manufacturer variability has been previously shown to contribute to changes in head liner congruency. Chmell *et al* have found a wear rate of 0.48 mm/year in a cohort of patients in which less than 15% of cases had femoral and acetabular components produced by the same company (*1*). Livingston *et al* found high rates of wear of Hylamer liners that had been used in combination with a variety of femoral heads, some of which had been produced by several manufacturers (*12*). Hylamer has an increased modulus of elasticity when compared to conventional polyethylene, and is therefore more sensitive to finite component mismatch. Component mismatch may be excluded as a possible explanation for the high rates of acetabular liner wear seen in this study because all the acetabular and modular femoral head components used were made by a single manufacturer.

The use of cemented and uncemented components is another potentially confounding variable as an explanation for the increased wear. Cemented all ultra high molecular weight polyethylene acetabular components were used in this study. Accelerated wear rates using this same combination have been previously described (*34*). Norton *et al* reported similar high rates of 0.62 mm/year (*17*). Cementless acetabular cups however have also been associated with increased acetabular wear. Using a cementless THR in combination with a Hylamer liner, Yamauchi *et al* reported a high rate of 0.37 mm/year (*35*). Livingston et al found similar high wear rates of 0.29 mm/year in 20 cases (*12*). These results suggest that the type of acetabular fixation is not primarily responsible for the reported increased wear rates of Hylamer.

The countersurface is a factor that, in previous studies, has been demonstrated to affect polyethylene wear (*33*). We used ceramic femoral heads in all our patients because of their excellent tribological and mechanical properties (*2, 4*). Zirconia, a second generation ceramic, was chosen as the modular femoral head because the rate of polyethylene wear has been reported to be lower than that measured for alumina ceramics, CoCr and SUS 316L alloy femoral heads (*10, 14*). Manawaka *et al* confirmed these findings from retrieval studies which demonstrated that ceramic produced less wear than metallic femoral heads (*13*). Our results, while acknowledging that the ceramic femoral head may contribute to the problem, suggest that the Hylamer polyethylene is the weak link of the zirconia/hylamer articulation, particularly when the other studies which have demonstrated increased Hylamer wear rates in association with different femoral head materials, are taken into consideration (*1, 12, 13, 17*).

In view of the high penetration rates, we reviewed all postoperative radiographs according to the criteria indicated by Ritter *et al* (*19*). We were unable to identify technical errors such as cement mantle deficiencies or implant malpositioning which would account for this increased wear. There was no significant acetabular or femoral osteolysis. Finally there is the question of surgical technique. We do not feel that this is a contributing factor. The surgical techniques employed were similar, regardless of the surgeon, and in particular, the high wear rates were not confined to any individual surgeon, but were expressed across the study group.

Despite the high wear rates which have been seen in our series, the Harris hip scores demonstrate the good short-term clinical results which have been achieved with this combination of bearing surfaces. Radiological interpretation thus does not always correlate with patient satisfaction. We have no patients who are currently under review for whom we are planning a revision procedure for increased acerabular wear rate.

In conclusion, our study demonstrates that the Hylamer polyethylene cups used in this cohort of patients are associated with increased acetabular wear. Those patients who have a Hylamer cup which has been implanted with a shelf life of less than 10 months appear to have a lower wear rate than those with a longer shelf life, and this may account for the discrepancies seen in the various reports in the literature.

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