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ORIGINAL STUDY

Evaluation of Hylamer-zirconia hip arthroplasty in patients less than 50 years of age

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The purpose of this prospective study was to determine the clinical outcomes of patients who had total hip arthroplasties with a zirconia (Zr) - Hylamer pairing. Fifty-eight consecutive cemented total hip arthroplasties with a Hylamer cup and 22.25 mm Zr head were examined for component wear and failure. The SF-36 and Mayo hip score were used to evaluate patient outcome. Regression and Kaplan Meier survival analyses were used to determine outcome. The mean Mayo postoperative score was 94 points. The median post-operative SF-36 score was 84 points. The mean rate of wear was 0.097 +/- 0.02 mm/year, with no evidence of loosening or significant osteolysis at a minimum follow-up of 5 years. Kaplan-Meier survival analysis was 98% at 3-year follow-up and 94% at 5-year follow-up. This study has confounded previous reports relating to Zirconia-Hylamer counter-surface components.

Keywords : total hip arthroplasty ; Hylamer ; zirconia ; head penetration rate.

INTRODUCTION

The longevity of total joint arthroplasty relies on articulating surfaces that are durable and produce little polyethylene debris, reducing osteolysis and loosening. Acetabular and femoral head components have been investigated as to which combination produces the least friction and wear. In an effort to improve wear characteristics of the acetabular liner, Hylamer was introduced as an alternative to ultra high molecular weight polyethylene (UHMWPE). (DePuy-DuPont Warsaw, IN, USA) *In vitro* studies demonstrated better wear properties with an increased modulus of elasticity and greater compressive yield strength of Hylamer as compared with conventional UHMWPE (*16,30,41*). Several studies examining the use of Hylamer with CoCr, stainless steel and alumina ceramic femoral heads have yielded results that did not reach the potential

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of the initial *in vitro* trials and have been concerning (*1,11,25,43*). Zirconia (Zr), a second generation ceramic was introduced as an ideal counterface for Hylamer in an effort to improve longevity of implants. The tribological characteristics of Zr make it an ideal articulating surface with low friction and wear characteristics in addition to improved strength and durability when compared with other ceramics (*6,9,24,51*). Concern over the failure of Hylamer as a counter-surface to these materials, however, resulted in it being withdrawn from the market, raising concern that all Hylamer implants should be withdrawn.

Many studies have demonstrated poor results or catastrophic failure with Zirconia femoral heads (*1,29,34,59*). This material has been studied extensively in the literature (*6,7,13*). Clarke *et al* reviewed its use in orthopaedics and expressed some concern over the dearth of studies at that time, detailing its clinical history (*13*). Hammadouche *et al* noted in 2002 that they could only find two studies that demonstrated favourable clinical results with the use of zirconia balls (*29*). Allain *et al* abandoned the use of zirconia heads having reviewed their results over eight years in combination with a polyethylene cup and titanium stem (*1*). Stewart *et al* recommended that given the adverse results of their study, a zirconia femoral head should not be combined with an alumina acetabular insert in a clinical setting (*59*). However, the combination of zirconia and Hylamer has not shown evidence to date of failure that is significantly greater than other counter surfaces.

The current authors examine the clinical and radiographic outcomes when these components were used in combination in a select cohort of patients under 50 years. In addition, the influences of component sterilization, component shelf life, patient age, gender, laterality and diagnosis on rates of wear in this cohort are examined. The authors also examine critically the mounting evidence against Hylamer components, and attempts to determine, in light of data presented, whether patients in whom Hylamer and zirconia have been implanted should have follow-up at more frequent intervals than those patients in whom non-Hylamer components have been implanted.

MATERIALS AND METHODS

A prospective study was conducted. The cohort being studied were those patients who from 1996 to 1997 had a total hip arthroplasty using a Hylamer cup with a Zr femoral head. There were 51 consecutive patients in total. Forty-seven patients with 58 arthroplasties were included in this prospective study of which there were 33 right hips and 25 left hips open. Of those patients who were not available for follow-up, one patient died 2 years following surgery from an unrelated cause, one patient was unable to attend radiographic evaluation, and two patients moved location and could not be contacted. The remaining patients were followed up for the full five year period. Patients ranged in age from 20 to 50 years (mean, 42.1, Standard deviation = 7.9). There were 26 women and 21 men. Eleven patients had bilateral arthroplasties, all of whom had the second procedure at least 2 months from the index procedure. The main diagnosis was osteoarthritis in 37 patients (44 hips) and eight patients (12 hips) had a diagnosis of rheumatoid disease. The remaining two patients had surgery for end stage osteonecrosis. Any patient who had a previous femoral or acetabular osteotomy was excluded from the study. Minimum time to clinical and radiographic follow-up was forty-nine months (range, 49-134 months, mean, 90 months).

The Elite total joint arthroplasty (Depuy Orthopaedics, Warsaw. IN, USA) was used in all patients. The Elite femoral component is a cold worked, austenitic stainless steel construct with an undercut Charnley femoral flange. Modularity of the femoral component allows the use of head sizes ranging from 22.25 mm to 32 mm diameter femoral heads. The 22.25 mm Zr head was used exclusively in this study. Yittria stabilized Zr has twice the fracture toughness of alumina (aluminium oxide) and as such can be created in a 22.25 head size that will not be at risk of fracture.

The Hylamer cup used was a solid polyethylene block with a minimum thickness of 6 mm. The cup size ranged from 40 mm to 53 mm. All components had a high posterior wall and a flange allowing high-pressure cement fixation. The longest shelf life for any liner in the current series was 4 months and none of the liners were irradiated in air. The acetabular and femoral components were cemented using Palacos polymethylmethacrylate (Howmedica, Limerick, Ireland) using third generation cementing techniques.

All surgery was performed by the senior surgeon, using a standard operating procedure. Each patient was placed in the supine position and an anterolateral approach was used with an osteotomy of the greater

trochanter. The trochanter was reattached using two 2.5 mm Charnley wires.

Patients were evaluated clinically and radiographically 3 months and 6 months after surgery and thereafter at yearly intervals. The Short Form 36 questionnaire (*45*) and Mayo hip score (*37*) were used to evaluate patient outcome subjectively and objectively. The short form 36 questionnaire is a generic health assessment instrument that evaluates scores for physical functioning, social functioning, and role limitation caused by physical problems and emotional problems, bodily pain, mental health, energy, and general perceptions of overall health. This score has been validated previously as a reliable summary outcome module (*17,18*). The raw Short Form 36 score was converted to a percentage score to allow for ease of nominal comparison. The Mayo hip score is a combined clinical and radiographic scoring system with a maximum score of 100 points. The clinical evaluation accounts for 80 points and the remaining 20 points are divided between the radiographic scores of the acetabular and femoral components. This scoring system is useful in that it provides for radiographic evidence of loosening, which may not be reflected in a strict clinical evaluation of outcome (*8,37*). Patients also were asked whether they were satisfied with the procedure and whether they would have the procedure again.

The extent of acetabular wear was assessed using the system of Livermore *et al* (*42*). Digital calipers were used to measure vertical and horizontal wear to within three decimal places (Absolute Digimatic, Bury St Edmond's, Suffolk, UK). A digital device was used in an effort to reduce error that has been reported using Livermore's method. Allowance was made for magnification on the radiographs by dividing the known diameter of the femoral head, 22.25 mm, by the measured diameter of the femoral head on radiograph. Plain radiographs were compared from the initial post-operative film to the most recent radiograph. Wear was expressed as mean rate of wear per year to facilitate accuracy using the Livermore technique. In addition, any creep observed within the first two years could be detected and not confused with overall wear (*61*).

Acetabular orientation was measured using the system of Engh *et al* (*22*). Osteolysis was evaluated on a standard anteroposterior radiograph of the acetabular component using Zones I to III according to DeLee and Charnley (*19*). Femoral osteolysis was described in relation to the Zones of Gruen *et al* (*27*). Osteolysis was defined as a progressive endosteal radiolucent lesion, not present on the initial post-operative radiograph, of greater than 5 mm in any direction (*43*).

Multiple linear regression analysis was used to determine the effects of age, gender, diagnosis, and weight on polyethylene wear. Logistic regression was used to evaluate whether age, gender, diagnosis or weight were predictors of failure (*33*). The end point was defined as radiographic failure with greater than 0.15 mm linear wear, migration of the socket greater than 3 mm or the presence of a progressive global radiolucency greater than 5 mm in any direction (*43*). The amount of linear wear was compared between gender, side, and diagnosis subgroups by the two-sample Student t-test. Mayo and SF-36 scores were tested for normality and found to have significant skewness according to the Kolmogorov-Smirnov test (*2*). Therefore, scores are presented as medians and ranges with the difference between preoperative and postoperative Mayo scores determined by the nonparametric Wilcoxon signed-ranks test. The Pearson correlation coefficient (r) was used to evaluate the association between continuous variables including age and linear wear as well as postoperative Mayo and Short Form 36 scores. Two-tailed values of $p < 0.05$ were considered statistically significant. Analysis of the data was done using the SPSS software package (version 11.0, SPSS Inc, Chicago, IL, USA).

All patients signed informed written consent to be included in the study in accordance with the Hospital clinical review and research board.

RESULTS

All patients had a significant improvement in Mayo score with a median improvement of 57 points (range, 21-67 points, $p < 0.0001$, Wilcoxon signed-ranks test) The mean postoperative Mayo score was 94 points (range 65-100 points ; standard error of the mean, 0.88). Mean postoperative Short Form 36 score was 84 points (range, 54-94 points). There was a positive correlation between the postoperative Mayo and Short Form 36 scores (Pearson $r = 0.68$, $p < 0.001$).

The mean rate of wear was 0.097 ± 0.020 mm per year (range, 0.026-0.152 mm/year). No patient had subsidence or migration of either component. No patients had osteolysis. Four patients had radiolucent lines of 2 mm about the acetabular component ; two patients had radiolucent lines in Zone I, one patient had radiolucent lines in Zone III, and one patient had radiolucent lines in Zones I and III. Radiolucent lines about the femoral compo-

nent were observed in two patients. One patient demonstrated a radiolucency of 4 mm in Gruen zone 7 and one patient had a radiolucent line of 4mm in Gruen zones 1 and 6.

Age, weight, gender, side, and diagnosis all were tested separately using multiple linear regression analysis. The two-sample Student *t*-test was used for gender, side, and diagnosis and the Pearson correlation coefficient (r) was used for age and weight. Males had more linear wear than females (0.11 ± 0.02 versus 0.09 ± 0.02, $p < 0.05$) and the right side was associated with greater wear than the left side (0.11 ± 0.02 versus 0.09 ± 0.02, $p < 0.05$). No significant differences were detected between osteoarthritis and rheumatoid arthritis and wear. In addition, no correlation was found between age and linear wear ($r = 0.08$, $p = 0.05$) or between weight and linear wear ($r = 0.09$, $p = 0.51$). To control for possible confounding among the variables, a multiple linear regression model was used to identify independent predictors of vertical wear. Results of the stepwise regression analysis indicated that male gender and right side were significant multivariate predictors of linear wear ($p < 0.05$ for each), whereas age, weight, and diagnosis had no significant prognostic impact (all $p > 0.05$).

Complications included one case of heterotopic ossification. This was Grade II (*5*) identified on radiographs taken at follow-up and was not clinically significant. In addition, there were four patients identified with trochanteric wire breakage. This was identified radiographically but did not manifest with any clinical symptoms.

All but one patient were satisfied with the procedure and would have the procedure again. There were no component failures and no patient required revision in this cohort. Similarly there was no radiographic evidence of components at risk of failure. In light of this, the authors used 0.15 mm wear/year as an indicator of a hip at risk of failure. This is an order of magnitude lower than used in similar studies (1.5 mm total linear wear) and reflects the excellent outcome observed with the zirconia - Hylamer pairing at medium term follow-up (*43,67*).

Kaplan-Meier estimated survivorship is 98% at 3 years follow-up (confidence interval = 96-100%) and 94% at 5 years (confidence interval = 88-100%) (fig 1).

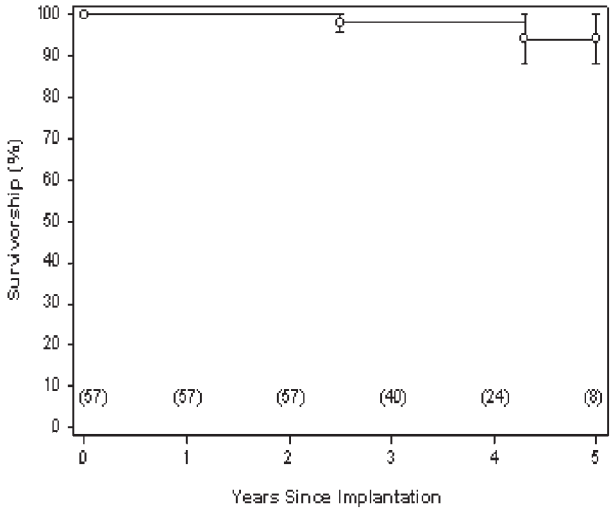

Fig. 1. — Survivorship Analysis

DISCUSSION

Aseptic loosening from particulate debris in total hip has prompted the orthopaedic industry to explore bearing surfaces that are durable and demonstrate little friction or wear. In an effort to improve the durability and surface characteristics of conventional UHMWPE, DePuy produced a polyethylene that had increased crystallinity, thereby increasing the modulus, yield strength, tensile strength, creep resistance, fatigue resistance and density with no loss of molecular weight. Of note, these properties were shown to be improved in an *in vitro* study prior to use in patients. This product was marketed as Hylamer and because of its improved wear characteristics was used widely, particularly in younger patients with higher physical demands (*16,41*). The Hylamer acetabular liner was marketed as an ideal complementary component to Zr ceramic heads and the combination of both was expected to give optimal wear characteristics (*16,24*). It was in light of these data that the current authors anticipated improved long-term outcomes with a combination of Hylamer acetabular cups and Zr counterfaces in the younger population with high physical demands.

Several reports on Hylamer have, however, been universally condemning with higher than anticipated wear rates and early osteolysis. Chmell *et al* (*11*) showed a 4.2% failure rate of 143 hips with a minimum time to follow-up of two years. Livingston *et al* (*43*) also have shown mean wear rates of 0.27 mm per year and a clear correlation between early wear and osteolysis using a Hylamer liner. Graeter and Nevins (*25*) report nine of 78 patients (11.5%) with osteolysis of greater than 1 cm^2 at a mean follow-up of 3.8 years. In addition, Vaughn *et al* (*64*) reported on a single case of failure of an alumina ceramic head with a Hylamer liner. Wroblewski *et al* showed a mean rate of penetration of the cup of 0.22 mm/year in 71 patients but discontinued their use of Hylamer despite excellent results and no revisions (*67*). These results have prompted the withdrawal of Hylamer from the market and have given concern that patients with existing implants should be recalled.

The results that the current study presents differ markedly from previous reports on Hylamer acetabular components. The authors believe that the reasons may be multifactorial. Femoral head size, metal backing, component fixation, patient age, manufacturer mismatch (*49*) and oxidation from sterilisation are all factors that can be implicated in poorer results seen in previous studies.

The femoral head used in the current study, 22.25 mm, is smaller than previous reports on Hylamer acetabular components. The standard Charnley head has been shown previously to have a decrease in volumetric wear when compared with larger sized femoral heads. Several studies have shown that larger head size is associated with greater volumetric wear (*12,14,20,42,46*). In those studies reporting adverse outcomes using Hylamer liners, Chmell *et al* (*10*) report using 28 mm and 32 mm femoral heads. Livingstone *et al* (*43*) used 28 mm femoral heads in 196 of 233 arthroplasties. The head sizes of those that were not 28 mm in diameter were not detailed in the report. In the single case of failure reported by Vaughan *et al* (*64*), a 28 mm femoral head was used in combination with an uncemented 8 mm thick Hylamer cup. Larger head sizes could also be implicated in increased linear and volumetric wear using ceramic countersurfaces (*3*). In the report by Allain *et al* (*1*), documenting poor outcomes using a Zr component, a 28 mm femoral head was used throughout the study, as compared with the smaller 22.25 mm femoral head used in the current series. The difference between these reports and that which the current study presents could be explained on the basis of femoral head size alone however it is likely that a combination of factors produced the optimal results obtained.

Hylamer liners in uncemented metal backed cups were used in reports by Chmell, Livingston, Vaughn, Kim and Collie (*11,15,40,43,64*). Cemented all polyethylene Hylamer cups were used throughout the current study. Charnley's initial report on linear wear rates of 0.07 mm per year in cemented arthroplasty has been difficult to challenge and similar results using cement have been consistently reported (*10,26,44,53,55*). The expansile nature of the acetabular osteolysis observed in patients with uncemented cups is similar to that seen in those reports on adverse outcomes using Hylamer liners (*31,54*). Such catastrophic osteolysis was not observed in the current series of all polyethylene cemented acetabular cups. Whether the uncemented cup or whether the cup-liner interface micromotion is responsible for this expansile osteolysis or a combination of both will not be answered conclusively in the current study. It is clear, however, that cement fixation of non-metal-backed cups appears to have delayed if not obviated apparent acetabular osteolysis and loosening in this series.

Another possible confounding variable in evaluating wear in uncemented metal backed acetabular liners has been delineated by Sychterz *et al* (*62*). These authors showed a change in position of the polyethylene liner in relation to the metal cup can cause a change in the relative position of the femoral head, thereby altering the measurement of linear wear. This factor is not considered in previous reports where higher than expected wear rates using uncemented Hylamer liners were found (*11,15, 40,43,64*). It is possible therefore that positional change could have exaggerated wear rates inadvertently. This possible cause of apparent wear would, however, be expected to affect comparison radiographs using both conventional 415 GUR polyethylene and Hylamer. As such, in

those studies where comparison groups were used, positional changes in the liner cannot be implicated in poorer apparent outcomes using Hylamer. A more likely explanation for poorer outcomes is micromotion at the metal-polyethylene interface, which may cause backside wear and early osteolysis. In all 193 cases reported by Chmell et *al* (*11*), uncemented Ti shells with Hylamer inserts were used. Titanium alloys have previously been implicated in oxidative corrosive wear and third body generation by backside wear. Scott *et al* (*58*) also implicate backside wear in early failure, in a retrieval analysis of 12 Hylamer liners. All of the retrieved liners had deformation and burnishing consistent with micromotion between the liner and the shell. In addition, Scott *et al* (*58*) implicate micromotion in generating fluid pressure about the cup, which may contribute to retroacetabular osteolysis. A Hylamer monoblock cemented acetabular component was used by the current authors, thereby eliminating this mode of failure.

Considerable manufacturer variability between the acetabular cup and femoral head is evident in previous outcome studies on Hylamer. This has previously been shown to contribute to changes in head liner congruency and increased wear (*3,42,56*). In the study by Chmell *et al* (*11*), less than 15% of the reported cases had femoral and acetabular components produced by the same manufacturer. Similarly in the review by Livingston (*43*), De Puy Hylamer liners and femoral heads were compared with conventional polyethylene cups and Osteonic femoral heads. In that study, the rate of linear wear was similar, whereas those with components from different manufacturers recorded the greater rates of wear. Previous work by Wright *et al* (*65*) showed that stresses in standard polyethylene cup-counterface articulations were increased when non-conforming components were used. These stresses were increased with enhanced polyethylene liners, which are more sensitive to conformity. Hylamer has an increased modulus of elasticity when compared with conventional 415 GUR polyethylene, and therefore is more sensitive to finite component mismatch. Therefore the tribologic properties of Hylamer may have been undermined by poorly conforming counterfaces from different manufacturers.

The role of gamma irradiation in air and subsequent oxidative damage to polyethylene has implications in the adverse outcomes related to Hylamer. Several studies have shown that oxidation of acetabular liners impacts mechanical properties of the polyethylene, and can result in increased fatigue failure of these components (*23,60*). In an effort to address this, Hylamer was gamma irradiated in a nitrogen atmosphere followed by vacuum packing in 1993. From 1995 onward Hylamer has been sterilised with gas plasma without irradiation. Collier *et al* (*15*) have reported that the impact of oxidation may be greater in Hylamer than in conventional polyethylene. The hypothesis of Collier *et al* (*15*) was that the sparse amorphous zones of the material allowed for a localized concentration of oxidative destruction. Therefore the impact of oxidation may be more detrimental in Hylamer than in conventional polyethylene liners. This hypothesis has been confirmed by other studies on Hylamer liners (*64,68*). Mckellop *et al* (*47*) have shown that free radicals produced by oxidation may also potentiate the oxidative process implicating longer shelf life with poorer wear resistance (*35,63*). Kiely *et al* have also demonstrated that Hylamer implanted after a shelf life of greater than 10 months had a poorer outcome (*39*). In the current series, there were no polyethylene liners irradiated in air and the longest shelf life was 4 months.

The more favourable results obtained in the current study also may be attributable to the combination of a Hylamer cup used in conjunction with a Zr counterface. The tribological advantages of ceramic femoral heads in general and Zr in particular have been well reported (*4,6,9,24,46,51*). Despite a large volume of *in vitro* work to support the tribologic nature of Zr, the literature has few reports on Zr femoral heads *in vivo*. Minakawa *et al* (*48*) observed that of eight retrieved Zr heads all had significantly less surface damage than stainless steel, CoCr, and Ti counterfaces. Hummer *et al* (*34*) however report two cases of catastrophic fracture of Zr femoral heads in a series of 189 patients. In one patient, a fall contributed to the fracture whereas in the other patient a mismatch in the Morse taper was regarded as the cause of failure. Allain *et al* (*1*) reviewed 78 hips with a Zr femoral head, Ti_6Al_4V stem and

cemented polyethylene cup at a mean time to follow-up of 5.8 years. Survivorship analysis showed that only 63% were *in situ* at 8 years. The discrepancy between these two reports and the current authors' experience with Zr is multifactorial. Cuckler *et al* (*16*) have shown that angle mismatch in taper and bore surfaces can result in clinical fracture of ceramics. Therefore, they recommend that ceramic femoral heads from one manufacturer should not be used with stems from another manufacturer. This is particularly relevant when non-oxidized and re-oxidized sintered ceramic are used. In the current series, all components were from the same manufacturer therefore the potential for component mismatch was reduced. In addition, the current study reports on a single type of Zr, the sintered re-oxidized form. The re-oxidation of the surface molecules may confer an additional stability and prevent microscopic surface imperfections. This has not been proven to date and further *in vitro* testing is warranted to validate this hypothesis.

The age of the patients selected for Hylamer liner implants may also explain their apparent poorer outcomes in previous studies. The Hylamer-Ceramic combination counterface was originally marketed for use in the younger population because of the improved tribologic properties required in this population. Schmalzried *et al* (*57*) have previously alluded to patient age, when evaluating outcomes reported by Livingston *et al* (*43*), on Hylamer liners coupled with Al ceramic and metal femoral heads. Two factors were responsible for the apparent poorer outcomes reported in the Hylamer liner and Al femoral head group : The patients in whom Hylamer liner and ceramic femoral head combinations were implanted, were younger than the patients in the other groups studied, and secondly within this young population, surgeon bias would have selected those patients with higher physical activity demands. On this basis, comparison between two groups with different activity levels and physical demands is redundant. In the current study, the authors present a single group of patients younger than 50 years, again showing surgeon bias ; however, this does not confound observations but supports them because the outcomes of a similar cohort were evaluated.

Two recent studies have examined Hylamer liners and Zr femoral heads in outcome studies. Kim *et al* (*40*) compared CoCr with Zr femoral heads using a Hylamer liner in 70 patients. Although their results did not achieve statistical significance, there was a trend that mean rates of initial linear wear and volumetric wear were higher in those patients who had a Zr femoral head than in those patients who had a CoCr femoral head. This was apparent in the initial 3 years after implantation, however, at final follow-up there was less wear in those patients treated with a Zr femoral head. The rate of wear in those patients who received a Zr femoral head decreased to 0.08 and 0.02 mm at postoperative years 4 to 5 and at postoperative years 5 to 6, respectively. This report supports previous findings of Wrobleski *et al* (*66*) that the initial apparent wear in ceramic countersurfaces was caused by creep rather than wear. In the study by Kim *et al* (*40*) there was no evidence of acetabular or femoral loosening at 6 years after implantation. Patients with either acetabular or femoral osteolysis all were treated with a 28 mm femoral head. No patient with a 22.25 mm Zr femoral head and Hylamer liner was reported to have osteolysis. After this initial bedding in, wear rates in those patients who received Zr femoral heads and Hylamer liner were similar to those reported by the current authors. These findings confirm the current authors' observations.

In a recent review of a similar cohort of patients aged less than 50 years, using a Zr femoral head and a solid Hylamer acetabular cup, Norton *et al* demonstrated a failure rate of 67.6% at five years (*50*). The study is similar to the current authors' series in type of implant, method of implant fixation, operative approach and follow-up time. The difference in outcomes is striking. The only significant difference between the two studies is that the femoral head used by Norton *et al* was 28 mm as compared with a 22.25 mm femoral head used in the current series. Larger femoral head size may pose a greater disadvantage when the material used has a disproportionate increase in modulus, as compared to yield strength as in the case of Hylamer (*41*). It is difficult, however, to implicate a larger femoral head size as the single cause of poorer outcome when comparing the two series.

In a series reported by Wroblewski *et al* using Zr-Hylamer components with 22.225 mm Charnley Elite stems, the rate of wear was significantly greater than the current authors' series using similar components i.e. stems, cement and femoral head sizes (*67*). The overall clinical results of the Wroblewski series were excellent and similar to the current authors' data. The difference in wear however was a matter of concern. The current authors postulate that the difference in the shelf-life between the two series (less than four months in this study in contrast to less than one year in the Wroblewski study) may be responsible. There is evidence in the literature that suggests that Hylamer implanted after a shelf life of greater than 10 months has a significantly greater linear wear rate than in those implants with less than a 10 month shelf life (*39*).

Previous studies showing significant component failure as a result of polyethylene oxidation, component mismatch, and other variables prompted Hylamer to be withdrawn from the market. In the era of class action litigation against component manufacturers and health care providers, these reports were concerning and have prompted many physicians to recall patients with Hylamer components for physical and radiographic re-examination. Physician and patient concerns over adverse reports on Hylamer may, however be somewhat alleviated in light of the outcomes demonstrated in the current study. The combination of a cemented solid Hylamer cup and a second-generation ceramic smaller femoral head size may reduce or delay wear. Component manufacturer mismatch and oxidation of the highly crystalline polyethylene are two factors implicated in previous failure that were not relevant to the current study. In addition, this report shows that a Zr femoral head has demonstrated encouraging moderate term outcomes. These results can be compared to a similar group of patients reported by the senior author using stainless steel femoral component and a standard GUR polyethylene liner (*21*). Although direct comparison between the two studies is not possible, the two studies are comparable in that the patient's ages were similar, the surgical technique was similar, the femoral head sizes were similar and the method of estimating wear was similar. The overall probability of 20-year survival for a Charnley stainless steel femoral head and solid polyethylene cup was reported to be 75% and the 5 year survival of both components was 97%. As such, the current study compares favorably with Kaplan Meier survival of 94% at 5 years but one must bear in mind that this is specific to this study at a far earlier time point and must be viewed with consideration of other papers describing failures of this form of polyethylene.

The current study also confirms previous reports implicating male gender and increased linear wear (*36,38*). The influence of gender and wear may be due to greater physical demands in the male population. In addition lower wear rates in women may be due to a greater degree of disability in women and a poorer functional status prior to hip arthroplasty (*32*).

Younger age was not found to be a predictor of poorer outcome in the study. This does not confound previous observations on joint replacement where younger age is a predictor of increased wear because of the narrow range of the cohort studied (*28*). The median age of the cohort group was 42 years. A narrow range of ages within the cohort precludes meaningful comparison between younger and older ages. In addition, this cohort of patients younger than 50 years was selected for this combination of implants, because of the greatest risk of wear

Laterality as a predictor of wear has not been reported previously. Joshi *et al* (*36*) in a study of 51 patients with bilateral hip arthroplasty demonstrated that linear wear was related to gender and increased body weight, but was not side related. Although a power analysis was sufficient to eliminate type II error, the current authors are unable to establish a reasonable hypothesis for this finding.

The current study has shown that a cemented acetabular Hylamer cup has functioned well when used in combination with a 22.25 mm ceramic Zr head, in a high demand population of patients younger than 50 years, as observed at short term follow-up. In light of existing evidence demonstrating excessive wear with Hylamer cups, the authors do not recommend continued use of these implants. Nonetheless this study does demonstrate that not all

patients in whom Hylamer has been implanted should be concerned and that careful and routine follow-up may be all that is required in the medium term, post-implantation.

REFERENCES

1. **Allain J, Le Mouel S, Goutallier D, Voisin MC.** Poor eight-year survival of cemented zirconia-polyethylene total hip replacements. *J Bone Joint Surg* 1999 ; 81-B : 835-842.
2. **Armitage P, Berry G.** Statistical methods in medical research. Blackwell Science Ltd, Malden, MA, 1994, 3rd Edition, pp 397-400.
3. **Bartel DL, Burstein AH, Toda MD, Edwards DL.** The effect of conformity and plastic thickness on contact stresses in metal-backed plastic implants. *J Biomech Eng* 1985 ; 107 : 193-199.
4. **Boutin P.** [Alumina and its use in surgery of the hip. (Experimental study)] (in French). *Presse Med* 1971 ; 79 : 639-640.
5. **Brooker AF, Bowerman JW, Robinson RA, Riley RH Jr *et al*.** Ectopic ossification following total hip replacement. Incidence and a method of classification. *J Bone Joint Surg* 1973 ; 55-A : 1629-1632.
6. **Cales B**. Zirconia as a sliding material : histologic, laboratory, and clinical data. *Clin Orthop* 2000 ; 379 : 94-112.
7. **Cales B, Stefani Y, Lilley E.** Long-term in vivo and in vitro aging of a zirconia ceramic used in orthopaedy. *J Biomed Mater Res* 1994 ; 28 : 619-624.
8. **Callaghan JJ, Dysart SH, Savory CF, Hopkinson WJ.** Assessing the results of hip replacement. A comparison of five different rating systems. *J Bone Joint Surg* 1990 ; 72-B : 1008-1009.
9. **Charissoux JL, Najid, A, Moreau JC, Setton D, Rigaud M.** Development of in vitro biocompatibility assays for surgical material. *Clin Orthop* 1996 ; 326 : 259-269.
10. **Charnley J, Halley DK.** Rate of wear in total hip replacement. *Clin Orthop* 1975 ; 112 : 170-179.
11. **Chmell MJ, Poss R, Thomas WH, Sledge CB.** Early failure of Hylamer acetabular inserts due to eccentric wear. *J Arthroplasty* 1996 ; 11 : 351-353.
12. **Clarke IC, Fujisawa A, Jung H.** Influence of the ball diameter on polyethylene wear rates. *Trans Soc Biomater* 1993 ; 16 : 57-61.
13. **Clarke IC, Gustafson A, Jung H, Fujisawa A.** Hip-simulator ranking of polyethylene wear : comparisons between ceramic heads of different sizes. *Acta Orthop Scand* 1996 ; 67 : 128-132.
14. **Clare IC, Manaka M, Green DD et al.** Current status of zirconia used in total hip implants. *J Bone Joint Surg* 2003 ; 85-A. Suppl 4 : 73-84.
15. **Collier JP, Bargmann LS, Currier BH *et al*.** An analysis of hylamer and polyethylene bearings from retrieved acetabular components. *Orthopedics* 1998 ; 21 : 865-871.
16. **Cuckler JM, Bearcroft J, Asgian CM.** Femoral head technologies to reduce polyethylene wear in total hip arthroplasty. *Clin Orthop* 1995 ; 317 : 57-63.
17. **Dawson J, Fitzpatrick R, Carr A.** Questionnaire on the perceptions of patients about shoulder surgery. *J Bone Joint Surg* 1996 ; 78-B : 593-600.
18. **Dawson J, Fitzpatrick R, Murray D, Carr A.** Questionnaire on the perceptions of patients about total knee replacement. *J Bone Joint Surg* 1998 ; 80-B : 63-69.
19. **DeLee JG, Charnley J.** Radiological demarcation of cemented sockets in total hip replacement. *Clin Orthop* 1976 ; 121 : 20-32.
20. **Derbyshire B, Fisher J, Dowson D, Hardaker C, Brummitt K.** Comparative study of the wear of UHMW-PE with zirconia ceramic and stainless steel femoral heads in artificial hip joints. *Med Eng Phys* 1994 ; 16 : 229-236.
21. **Devitt A, O'Sullivan T, Quinlan W.** 16- to 25-year follow-up study of cemented arthroplasty of the hip in patients aged 50 years or younger. *J Arthroplasty* 1997 ; 12 : 479-489.
22. **Engh CA, Griffin WL, Marx CL.** Cementless acetabular components. *J Bone Joint Surg* 1990 ; 72-B : 53-59.
23. **Fisher J, Chan KL, Hailey JL, Shaw D, Stone M.** Preliminary study of the effect of aging following irradiation on the wear of ultrahigh-molecular-weight polyethylene. *J Arthroplasty* 1995 ; 10 : 689-692.
24. **Garvie RC**, **Urbani C, Kennedy DR, McNeuer JC.** Biocompatibility of magnesia-partially stabilized zirconia. *J Mater Sci* 1984 ; 19 : 3224-3228.
25. **Graeter JH, Nevins R.** Early osteolysis with Hylamer acetabular liners. *J Arthroplasty* 1998 ; 13 : 464-466.
26. **Griffith MJ, Seidenstein MK, Williams D, Charnley J.** Socket wear in Charnley low friction arthroplasty of the hip. *Clin Orthop* 1978 ; 137 : 37-47.
27. **Gruen TA, McNeice GM, Amstutz HC.** "Modes of failure" of cemented stem-type femoral components : a radiographic analysis of loosening. *Clin Orthop* 1979 ; 141 : 17-27.
28. **Hamada Y, Horiuchi T, Sano Y, Usui I.** The wear of a polyethylene socket articulating with a zirconia ceramic femoral head in canine total hip arthroplasty. *J Biomed Mater Re*. 1999 ; 48 : 301-308.
29. **Hamadouche M, Madi F, Kerboull L, Courpied JP, Kerboull M.** Charnley Kerboull total hip arthroplasty combining zirconia on polyethylene, a minimum 2 year follow-up prospective study. In : Gar**in**o J, Willmann G, editors. *Biocеramics in Joint Arthroplasty*. Thieme Publishing Group, New York, NY, 2002, pp 96-102.
30. **Harms J, Mausle E.** Tissue reaction to ceramic implant material. *J Biomed Mater Res* 1979 ; 13 : 67-87.
31. **Hernandez JR, Keating EM, Faris PM, Meding JB, Ritter MA.** Polyethylene wear in uncemented acetabular components. *J Bone Joint Surg* 1994 ; 76-B : 263-266.
32. **Holtzman J, Saleh K, Kane R.** Gender differences in functional status and pain in a Medicare population

undergoing elective total hip arthroplasty. *Med Care* 2002 ; 40 : 461-470.

33. **Hosmer DW Jr, Lemeshow L.** *Applied Survival Analysis : Regression Modeling of Time to Event Data*. John Wiley & Son, Inc. New York, NY, 1999, pp 1-55.
34. **Hummer CD 3rd, Rothman RH, Hozack WJ.** Catastrophic failure of modular zirconia-ceramic femoral head components after total hip arthroplasty. *J Arthroplasty* 1995 ; 10 : 848-850.
35. **Iwase T, Warashina H, Yamauchi K, Sugiura S, Hasegawa Y.** Early head penetration into cemented Hylamer Ogee socket. *J Arthroplasty* 2003 ; 18 : 920-924.
36. **Joshi A, Ilchmann T, Markovic L.** Socket wear in bilateral simultaneous total hip arthroplasty. *J Arthroplasty* 2001 ; 16 : 117-120.
37. **Kavanagh BF, Fitzgerald RH Jr.** Clinical and roentgenographic assessment of total hip arthroplasty. A new hip score. *Clin Orthop* 1985 ; 193 : 133-140.
38. **Kennedy D, Stratford PW, Pagura SM, Walsh M, Woodhouse LJ.** Comparison of gender and group differences in self-report and physical performance measures in total hip and knee arthroplasty candidates. *J Arthroplasty* 2002 ; 17 : 70-77.
39. **Kiely PD, Harty JA, McElwain JP.** Hylamer wear rates and shelf life : a clinical correlation. *Acta Orthop Belg* 2005 ; 71 : 429-434.
40. **Kim YH, Kim JS, Cho SH.** A comparison of polyethylene wear in hips with cobalt-chrome or zirconia heads. A prospective, randomised study. *J Bone Joint Surg* 2001 ; 83-B : 742-750.
41. **Li S, Burstein AH.** Ultra-high molecular weight polyethylene. The material and its use in total joint implants. *J Bone Joint Surg* 1994 ; 76-A : 1080-1090.
42. **Livermore J, Ilstrup D, Morrey B.** Effect of femoral head size on wear of the polyethylene acetabular component. *J Bone Joint Surg* 1990 ; 72-A : 518-528.
43. **Livingston BJ, Chmell MJ, Spector M, Ross R.** Complications of total hip arthroplasty associated with the use of an acetabular component with a Hylamer liner. *J Bone Joint Surg* 1997 ; 79-A : 1529-1538.
44. **McCoy TH, Salvati EA, Ranawat CS, Wilson PD Jr.** A fifteen-year follow-up study of one hundred Charnley low-friction arthroplasties. *Orthop Clin North Am* 1988 ; 19 : 467-476.
45. **McHorney CA, Ware JE Jr, Lu JF, Sherbourne CD.** The MOS 36-item Short-Form Health Survey (SF-36) : III. Tests of data quality, scaling assumptions, and reliability across diverse patient groups. *Med Care* 1994 ; 32 : 40-66.
46. **McKellop H, Lu B, Benya P.** Friction, lubrication and wear of cobalt chrome, alumina and zirconia hip prostheses compared on a joint simulator. *Trans Orthop Res Soc* 1992 ; 17 : 402-404.
47. **McKellop H, Shen FW, Lu B, Campbell P, Salovey R.** Effect of sterilization method and other modifications on the wear resistance of acetabular cups made of ultra-high molecular weight polyethylene. A hip-simulator study. *J Bone Joint Surg* 2000 ; 82-A : 1708-1725.
48. **Minakawa H, Stone MH, Wroblewski BM *et al.*** Quantification of third-body damage and its effect on UHMWPE wear with different types of femoral head. *J Bone Joint Surg* 1998 ; 80-B : 894-899.
49. **Morlock M, Nassutt R, Janssen R, Willmann G, Honl M.** Mismatched wear couple zirconium oxide and aluminum oxide in total hip arthroplasty. *J Arthroplasty* 2001 ; 16 : 1071-1074.
50. **Norton MR, Yarlagadda R, Anderson GH.** Catastrophic failure of the Elite Plus total hip replacement, with a Hylamer acetabulum and Zirconia ceramic femoral head. *J Bone Joint Surg* 2002 ; 84-B : 631-635.
51. **Panagiotopoulos EC, Kallivokas AG, Koulioumpas I, Mouzakis DE.** Early failure of a zirconia femoral head prosthesis : fracture or fatigue ? *Clin Biomech* (Bristol, Avon). 2007 ; 22 : 856-60.
52. **Patel AM, Spector M.** Tribological evaluation of oxidized zirconium using an articular cartilage counterface : a novel material for potential use in hemiarthroplasty. *Biomaterials* 1997 ; 18 : 441-447.
53. **Ranawat CS, Deshmukh RG, Peters LE, Umlas ME.** Prediction of the long-term durability of all-polyethylene cemented sockets. *Clin Orthop* 1995 ; 317 : 89-105.
54. **Ranawat CS, Dorr LD, Inglis AE.** Total hip arthroplasty in protrusio acetabuli of rheumatoid arthritis. *J Bone Joint Surg* 1980 ; 62-A : 1059-1065.
55. **Ranawat CS, Peters LE, Umlas ME.** Fixation of the acetabular component. The case for cement. *Clin Orthop* 1997 ; 344 : 207-215.
56. **Ritter MA, Meding JB, Faris PM, Keating EM.** Femoral head size : variation among manufacturers. *Orthopedics* 1996 ; 19 : 877-878.
57. **Schmalzried TP, Dorey FJ, McKellop H.** The multifactorial nature of polyethylene wear in vivo. *J Bone Joint Surg* 1998 ; 80-A : 1234-42 ; discussion 1242-3.
58. **Scott DL, Campbell PA, McClung CD, Schmalzried TP.** Factors contributing to rapid wear and osteolysis in hips with modular acetabular bearings made of hylamer. *J Arthroplasty* 2000 ; 15 : 35-46.
59. **Stewart TD, Tipper JL, Insley G, Streicher RM, Ingham E, Fisher J.** Severe wear and fracture of zirconia heads against alumina inserts in hip simulator studies with microseparation. *J Arthroplasty* 2003 ; 18 : 726-734.
60. **Sutula LC, Collier JP, Saum KA *et al.*** The Otto Aufranc Award. Impact of gamma sterilization on clinical performance of polyethylene in the hip. *Clin Orthop* 1995 ; 319 : 28-40.
61. **Sychterz CJ, Engh CA Jr, Shah N, Engh CA Sr.** Radiographic evaluation of penetration by the femoral head into the polyethylene liner over time. *J Bone Joint Surg* 1997 ; 79-A : 1040-1046.

62. Sychterz CJ, Engh CA Jr, Swope SW, McNulty DE, Engh CA. Analysis of prosthetic femoral heads retrieved at autopsy. *Clin Orthop* 1999 ; 358 : 223-234.

63. Sychterz CJ, Orishimo KF, Engh CA. Sterilization and polyethylene wear : clinical studies to support laboratory data. *J Bone Joint Surg* 2004 ; 86-A : 1017-1022.

64. Vaughn BK, Dameron TB Jr, Bauer TW *et al*. Early osteolysis following total hip arthroplasty with use of a Hylamer liner in combination with a modular ceramic femoral head. A case report. *J Bone Joint Surg* 1999 ; 81-A : 1446-1449.

65. Wright TM, Gunsallas L, Rimnac CM. Design considerations for an acetabular component made from an enhanced form of ultrahigh molecular weight polyethylene. *Trans Orthop Res So*c 1991 ; 22 : 248.

66. Wroblewski BM, Siney PD, Dowson D, Collins SN. Prospective clinical and joint simulator studies of a new total hip arthroplasty using alumina ceramic heads and cross-linked polyethylene cups. *J Bone Joint Surg* 1996 ; 78-B : 280-285.

67. Wroblewski BM, Siney PD, Fleming PA. Wear of enhanced ultra-high molecular-weight polyethylene (Hylamer) in combination with a 22.225 mm diameter zirconia femoral head. *J Bone Joint Surg* 2003 ; 85-B : 376-379.

68. Yamauchi K, Hasegawa Y, Iwasada S *et al*. Head penetration into Hylamer acetabular liner sterilized by gamma irradiation in air and in a nitrogen atmosphere. *J Arthroplasty* 2001 ; 16 : 463-470.