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A 28-year clinical and radiological follow-up of alumina ceramic-on-cross-linked polyethylene total hip arthroplasty

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Abstract

Aims

Our aim in this study was to describe a continuing review of 11 total hip arthroplasties using 22.225 mm Alumina ceramic femoral heads on a Charnley flanged femoral component, articulating against a silane cross-linked polyethylene.

Patients and Methods

Nine patients (11 THAs) were reviewed at a mean of 27.5 years (26 to 28) post-operatively. Outcome was assessed using the d'Aubigne and Postel, and Charnley scores and penetration was recorded on radiographs. In addition, the oxidation of a 29-year-old shelf aged acetabular component was analysed.

Results

The mean clinical outcome scores remained excellent at final follow-up. The mean total penetration remained 0.41 mm (0.40 to 0.41). There was no radiographic evidence of acetabular or femoral loosening or osteolysis. There was negligible oxidation in the shelf aged sample despite gamma irradiation and storage in air.

Conclusion

These results highlight the long-term stability and durability of this type of cross-linked, antioxidant containing polyethylene when used in combination with a small diameter alumina ceramic femoral head.

Take home message:

- We report the results of our continued review of 11 total hip arthroplasties using 22.225 mm Alumina ceramic heads on a Charnley flanged stem, articulating against a silane cross-linked polyethylene. In addition, oxidation analysis was carried out on a 29-year-old shelf aged acetabular component.
- The mean total penetration remains 0.41mm at a mean follow up of 27.5 years (range 26-28 years). Latest radiographs show no acetabular or femoral loosening or osteolysis. Negligible oxidation was detected in the shelf aged sample despite gamma irradiation and storage in air. The results highlight the long-term stability and durability of this type of cross-linked, antioxidant containing, polyethylene when used in combination with a small diameter alumina ceramic head.

Introduction

Cross-linked polyethylene (XLPE) is commonly used in total hip arthroplasty (THA). Long-term results however, are still awaited and there remain potential concerns about its use. These include impaired mechanical properties, the biological activity of the wear debris, increased sensitivity to roughened countersurfaces and its long-term oxidative stability in vivo.[[1,2]]

We therefore present a follow-up report of a previously published prospective study of an alumina ceramic on XLPE Charnley low friction arthroplasty (LFA).[[3]] Retrieved Charnley prostheses have shown damage to the surface finish of the femoral head and this has been linked to increasing wear.[[4,5]] An alumina femoral head was introduced to enhance scratch resistance. The initial rationale behind the use of XLPE was to allow the inclusion of an injection moulding manufacturing process to minimise material waste. Chemical cross-linking with silane was a required step in this process. Secondary machining was still however needed to achieve the required tolerances.

This was the first clinical application of a ceramic on XPLE bearing in THA. The mean follow-up of 27.5 years (26 to 28) is significantly longer than other published studies involving XLPE.[[6-8]]

Patients and Methods

This prospective study was initiated in 1986. The femoral components were all Charnley flanged design, manufactured from high-nitrogen-content, cold-formed stainless steel with a parallel neck rather than a tapered design (Depuy, Leeds, United Kingdom). A 0.2 mm Ultra High Molecular Weight Polyethylene (UHMWPE) sleeve was applied to the neck to act as a cushion between the metal neck and alumina ceramic head. This was assembled at the time of manufacture.

Acetabular components were all of standard, long-posterior-wall, flanged, Charnley design, manufactured with XLPE using an injection moulding process with secondary machining. The XPLE was manufactured from 100 000 molecular weight polyethylene which was chemically cross-linked using a silane grafting and thermal cross-linking process. As part of the manufacturing process, Irganox 1076 (Ciba Specialty Chemicals, Basel, Switzerland), a hindered phenol antioxidant similar to vitamin E, was added prior to injection moulding. The components were terminally sterilised using gamma irradiation in air using a 25 kilogray dose.

The study included 19 hips in 17 patients (13 men and four women). Two patients had a bilateral procedure. All operations were carried out in a Charnley clean air enclosure in combination with full body exhaust suits, through a trans-trochanteric approach, using Palacos cement (Heraeus, Wehrheim, Germany) and femoral canal occlusion with an autologous bone plug.[[9]] Seven patients have died. One single stage revision was undertaken for deep infection following bladder surgery 17 years after the initial operation. There have been no other revisions.

Nine patients (11 THAs), remain and continue to be reviewed regularly. The outcome was assessed using the modified d'Aubigne and Postel, and Charnley scores. Wear was measured at each follow-up by a single observer (PDS), using a manual uniradiographic method with standardised radiographs, corrected for magnification.[[10,11]]

An analysis of oxidation was carried out on an unimplanted acetabular component with a shelf-age of 29 years. This was packaged in an air permeable packet inside an opaque box, stored at room temperature. Cross sections (200 microns thick) were prepared using a microtome and a standard test method (ASTM F2102-13) was followed allowing measurement of the oxidation in the section.[[12]] Surface oxidation was taken as a mean of three traces of 20 points to a depth of 3 mm. The bulk oxidation index was taken as a mean of three traces of five points centred on the bulk of the sample.

RESULTS

The mean age of the nine remaining patients at the time of the initial surgery was 46.6 years (26.4 to 58.4). The mean follow-up is now 27.5 years (26 to 28). The mean d'Aubigne and Postel, and Charnley scores remain excellent with a mean score of 5.9 (5-6) for pain, 5.6 (3-6) for function and 5.6 (4-6) for movement.

The mean total penetration was 0.41 mm (0.4 to 0.41), with a mean rate of penetration of 0.0147 mm/yr (0.014 to 0.016). The mean rate of penetration was 0.13 mm/year (0 to 0.32, one year post-operatively, 0.034 mm/year (0 to 0.098) between one and four years post-operatively and 0.007 mm/year (0 to 0.016) at the latest follow-up (Fig. 1). One patient had a contralateral Charnley metal on UHMWPE THA with a total penetration of 6.1 mm at 27 years, compared with 0.41 mm at 28 years in the XLPE and alumina ceramic combination (Fig. 2).

[[Fig 1]]

[[FigCap]]Maximum penetration 0.41mm (0.4 to 0.41). Mean rate of penetration 0.0147mm/year (95% confidence interval 0.0142 to 0.0152).

[[Fig 2]]

[[FigCap]]A pelvic radiograph of a patient with a conventional Charnley low friction arthroplasty, metal on non-crosslinked polyethylene bearing, and an alumina-on-cross-linked polyethylene bearing on the contralateral side. There was significantly greater wear in the conventional bearing.

The latest radiographs have shown no evidence of osteolysis or loosening. Early demarcation around the acetabular component one year post-operatively was noted in one patient but this has remained static and asymptomatic.[[13]] The mean surface oxidation index of the shelf aged XLPE component was 0.148 (0.131 to 0.190) and the mean bulk oxidation index was 0.132 (0.122 to 0.141).

DISCUSSION

The latest clinical and radiographic results of this prospective study remain excellent. Following the bedding in period, no further measurable wear has been noted. The mean rate of wear of 0.0147 mm/year represents a six-fold reduction compared with a conventional Charnley LFA using metal on non-crosslinked UHMWPE.[[14]] This bearing couple was not used after this study of 20 patients, as the bedding in period during the first year was thought to represent accelerated wear. It was later appreciated that most of the initial penetration was likely to be due to creep and the long-term results have been excellent. Manufacture of this injection moulded acetabular component was also a challenge. Injection moulding had been introduced to try and reduce material wastage and simplify manufacture. However, the components still required machining to achieve the desired tolerances. This paradoxically increased the complexity and cost of manufacture.

Contemporary XPLE has shown even greater reductions in rates of wear, albeit with larger diameter femoral heads. Mean rates of wear using radiostereometric analysis (RSA) ranging from 0.003 to 0.005 mm/year have been reported in randomised controlled trials, a ten-fold reduction compared with conventional UHMWPE.[[6,15]] Direct comparisons with this study are difficult due to the greater linear penetration of the small femoral heads which were used compared with the larger heads used in more recent reports [6, 15]. Studies of contemporary XPLE, however, only report mid-term outcomes[6, 15]; long-term results are awaited. Results to date are encouraging but there are concerns regarding impaired mechanical properties and increased sensitivity to adverse conditions such as roughened counterfaces.[[1]] These conditions become more prevalent with the passage of time and maintaining a smooth articulating surface is critical. Good initial surgical technique and the use of a ceramic head which provides a smoother, harder articulating surface with a better scratch profile can help maintain the performance of XLPE bearing surfaces.

The use of a small femoral head has also contributed to the longevity of this bearing couple by reducing volumetric wear.[[11]] Wear simulator data suggest that the volumetric wear of XPLE does not increase with increasing the size of the head.[[16]] This, however, is not borne out in vivo.[[7,17]] Using a small head reduces frictional torque which reduces the rate of acetabular loosening.[[18]] This is especially relevant to XLPE, which has a greater friction factor compared with conventional UHMWPE.[[19]]

Despite gamma irradiation in the air, 29-year-old shelf-aged samples have shown negligible oxidation and no deterioration in wear properties when tested in vitro at 15 years post shelving.[[20,21]] This is in contrast with non-antioxidant laden UHMWPE gamma irradiated in the air, which has shown oxidation indices above the critical level of one after only six years of shelf aging.[[22-24]]

Recent retrieval analysis of contemporary remelted XLPE has shown unexpected levels of oxidation despite there being no detectable free radicals at the time of implantation, at a mean of two years post-operatively.[[2]] The oxidised retrieved components also had no detectable free radical content, suggesting an alternative in vivo oxidative process.[[25]] These levels are currently below the critical thresholds needed to impair mechanical properties. In vivo oxidation, however, demonstrates an exponential pattern and therefore may reach critical levels in the second post-operative decade.[[23]] XPLE appears to have a greater susceptibility to oxidation compared with conventional UHMWPE due to the greater number of tertiary carbon atoms present within their structure. The carbon-carbon bonds of a tertiary carbon are more susceptible to oxidative scission compared with secondary carbon atoms in a non-cross-linked structure.[[26]] The anti-oxidant used in the manufacture of the XPLE used in this study may therefore have imparted a resistance to in vivo processes such as lipid mediated oxidation, also contributing to its overall longevity and the maintenance of wear properties.[[25]] Second generation vitamin E laden contemporary XLPE has shown resistance to oxidation in vivo compared with conventional XLPE and therefore may help to improve the long-term results of XLPE.

The limitations of this study include the uni-radiographic technique of wear measurement used. However, it has been validated by comparing radiographic measurements against direct measurements from retrieved implants, with a maximum intra-observer error of 0.1 mm.[[11,27]] It does, however, lack the accuracy and precision of modern techniques of measuring wear such as RSA, and is also only a two-dimensional method. This is, however, offset by the length of follow-up in this study. This series also lacks a comparative group and therefore other historical studies had to be used to make comparisons of the rate of wear.

In conclusion, the clinical and radiological results in these patients remain excellent. There remains no evidence of aseptic loosening. There was an initial bedding in period, after which there was an extremely low rate of wear. The results highlight the long-term stability and durability of this type of XLPE when used in combination with a small diameter alumina ceramic femoral head.

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