Clinical Wear Studies of the Use of a New Highly Cross-linked Polyethylene Liner in Total Hip Replacement

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INTRODUCTION

Periprosthetic osteolysis resulting from the tissue response to billions of micron and submicron polyethylene wear particles released from articulation is the number one long-term problem in total hip replacements with conventional polyethylene. Wear increased with conventional polyethylene when large diameter femoral heads were used, and were subsequently abandoned. Highly cross-linked polyethylene was developed at Massachusetts General Hospital to reduce the amount of adhesive and abrasive wear. With the development of this low-wear material, the advantages of increased range of motion and stability due to the use of larger femoral heads became possible. Extensive wear and mechanical studies were performed on this material prior to clinical use; including testing on the Boston hip simulator up to 27 million cycles, which resulted in favorable gravimetric analysis and a reduction in secondary oxidation as compared to conventional polyethylene.[10] Highly cross-linked polyethylene has now been used as the bearing surface of total hip replacement at Mass General since December 1998.

Our lab at MGH utilizes two main methods of measuring the bedding-in and wear of the polyethylene liners *in vivo* from clinical radiographs. Radiostereometric analysis (RSA) is a method for accurately measuring three-dimensional relative displacements. It requires the use of a calibration cage with fixed tantalum markers and two x-ray generators (Figure 1). Tantalum beads are also placed in the polyethylene liner at surgery (Figure 2). This specialized setup allows simultaneous stereo-radiographs of the patient either standing in front of or laying on top of the cage to be taken. A pair of films creates three-dimensional geometry for wear and stability measurements.[1, 2, 5] One of the most commonly used non-RSA

Figure 1: Specialized standing RSA setup with calibration cage behind the patient and two x-ray generators (A) in front. The hip is positioned at the intersection of the two x-ray beams. The x-ray sources are fired simultaneously to produce stereo-radiographs. This photograph was taken in the new RSA dedicated radiology room at Massachusetts General Hospital on Yawkey 3.

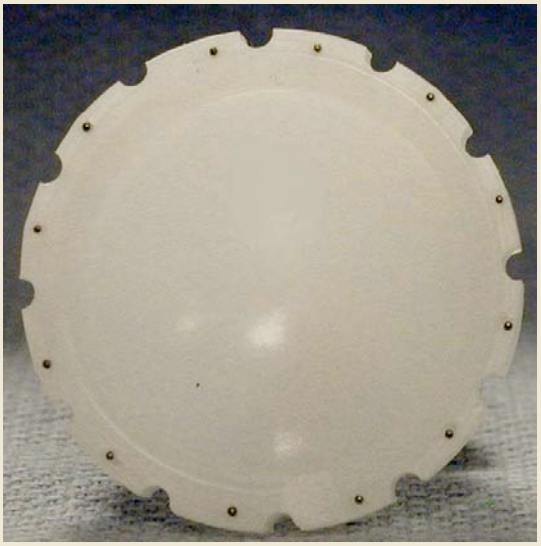

Figure 2: Highly cross-linked polyethylene hip implant liner with 1.0mm tantalum beads inserted for use in RSA wear studies.

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Figure 3: The Martell program utilizing edge detection algorithms, bases the measurement of the displacement of the femoral head between different time periods on specific user clicks on the radiograph. This image displays the visual output given to the user indicating the direction and magnitude of the femoral head movement into the polyethylene liner with a vector.

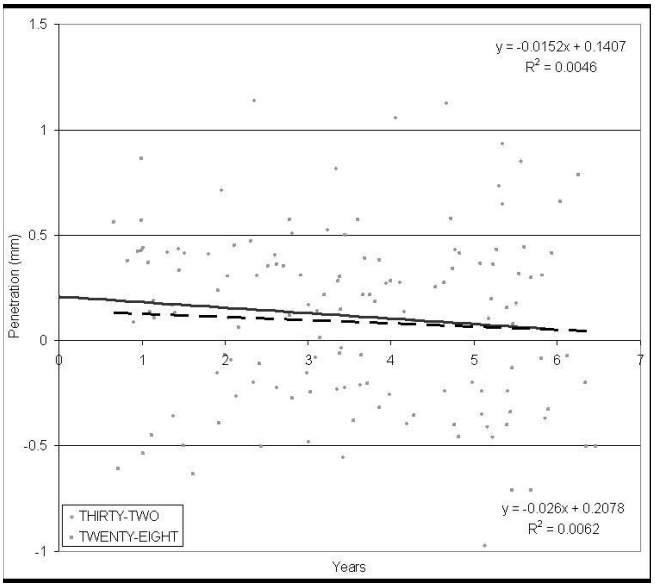

Figure 4: Total femoral head penetration measured with the Martell method for each follow-up radiograph as compared to the postoperative radiograph for a subset of 40 patients at a minimum 6 years follow-up. There is no significant difference in the slope of the linear regression lines (wear rates) from zero nor between the two head sizes.

methods for measuring femoral head penetration from clinical radiographs is the Hip Analysis Suite™ (University of Chicago, Chicago Il) software (Martell method) which is used to measure the two dimensional change in the position of the center of the femoral head relative to the center of the acetabular component which occurred between the post-operative A/P radiographs of the pelvis and each subsequent examination (Figure 3). The Martell method requires standard hip radiographs allowing for the analysis of larger patient populations.

The purpose of the three studies presented here is to continually evaluate clinical and radiographic outcomes at various time intervals with both the RSA and Martell methods using standard femoral head diameters (28 and 32mm) as well as larger head diameters (36 and 38mm).

METHODS

The HOBBL is postoperatively following three groups of clinical total hip replacement patients with highly cross-linked acetabular components. After institutional review board approval, all patient data are entered into the Harris Patient Registry which designed to collect demographic, clinical, radiographic and self-administered questionnaire data on all patients undergoing total hip replacement surgery at Massachusetts General Hospital. All patients' clinical outcomes are monitored radiographically and by self-administered questionnaires with Harris Hip, WOMAC, and UCLA tests. Additionally, the penetration of the femoral head into the polyethylene is being monitored by either RSA or the Martell method.

For this paper we selected a subset of 38 patient (40 hips of over 220 hips) receiving primary total hip replacement using highly cross-linked polyethylene coupled with 28 or 32 millimeter femoral heads with a minimum 6 years since operation. Radiographic monitoring and self-administered questionnaires were obtained for all patients at every follow-up.

The RSA group received highly cross-linked polyethylene liners with tantalum beads placed in the peripheral edge with equal numbers of patients receiving 28 and 36 millimeter femoral heads. Standard and specialty radiographs and questionnaires were obtained pre and post-operatively, as well as at 6 months, 1 year, 2 years, 3 years, 4 years and will be obtained at 5 years.

A group of patients with femoral heads over 32 millimeters in diameter coupled with highly cross-linked polyethylene implanted between were monitored. In addition to the standard clinical questionnaires and radiographic assessment, about thirty percent of the patients had suitable radiographs for wear measurement of the polyethylene with the Martell method.

Within each of the three study groups, statistical analysis including the Student's t-test, Mann-Whitney test, or ANOVA were performed. Statistical differences in femoral head penetration between head sizes and between total penetration and steady state wear rates were determined, as well as differences in self-administered questionnaire outcome parameters.

RESULTS

Measurements of wear in highly cross-linked polyethylene using RSA and Martell method, have confirmed that no detectable wear occurred through clinical use with standard or large femoral heads. At a minimum 6 years, no patients had revision surgery or other complication such as loosening or periprosthetic osteolysis in the pelvis or femur after implantation of the total hip including a highly cross-linked polyethylene liner. The total femoral head penetration into the highly cross-linked polyethylene liner was very low for both head sizes (Figure 4). Patients with 28mm femoral heads had an average penetration rate which was not significantly different than that of the 32mm femoral head group ($p=0.91$). The expected amount of material creep was seen in the first year after surgery. Once steady state penetration took over, no significant difference in the wear rate was found between the head sizes nor was there a

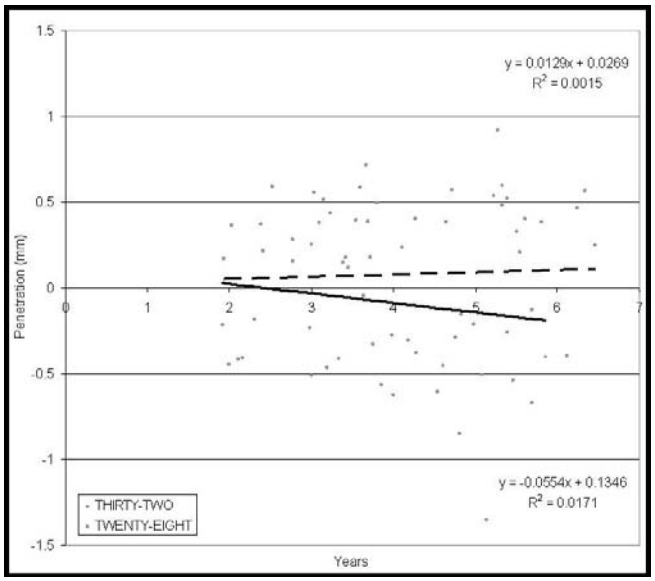

Figure 5: Steady state wear measured with the Martell method for each follow-up radiograph as compared to the one year radiograph for a subset of 40 patients at a minimum 6 years follow-up. There is no significant difference in the slope of the linear regression lines (wear rates) from zero nor between the two head sizes.

significant difference in the rate of wear from zero for either 28 or 32 millimeter femoral head sizes (Figure 5).

For the RSA group at four years follow-up, there were no reported complications or revisions for any of the patients. Because no significant femoral head penetration occurred after the first year of initial settling, the calculated rate of penetration decreased in the subsequent years. The median penetration rate of patients with 28 millimeter femoral heads was found by Mann-Whitney test to not be significantly different than those with 36 millimeter femoral heads.[3]

As in the other two groups, there was no sign of periprosthetic osteolysis nor any revisions performed on anyone in the large head group. At a minimum of 3 years follow-up, patients with large femoral heads also showed no detectable wear outside the error of the Martell software before or after the initial one year bedding-in period. No significant difference in the total penetration or steady state wear of the highly cross-linked polyethylene was found between patients with 36 and 38 millimeter femoral heads.[7]

Within all three groups, there was no periprosthetic osteolysis nor any revisions related to polyethylene wear performed over that period. Retrieval analysis has confirmed that little wear has occurred after *in vivo* use.

DISCUSSION

Highly cross-linked polyethylene showed favorable wear and oxidative properties in laboratory hip simulator studies.[8,9,10] The minimum 6 year follow-up study is one of the first published *in vivo* accounts of highly cross-linked polyethylene outcomes later than five years from surgery.[4] The HOBBL has shown after a minimum 3 and 6 years follow-up, no additional wear occurred after the initial settling of the polyethylene liner. This is a dramatic improvement from the wear results found when using conventional polyethylene liners.[6,11] In these clinical follow-up studies of total hip replacement patients with highly cross-linked polyethylene liners, the HOBBL has shown excellent clinical and radiographic results at both minimum 3 and 6 year follow-up with little to no detectable wear and no osteolysis. The total hip replacements performed with femoral heads larger than 32mm diameter showed both excellent wear characteristics and clinical results at a minimum three years. Hip reconstruction with large heads can now be considered in patients who may be at increased risk for dislocation. Mid-term clinical and radiographic results with this new material are excellent. Longer term follow-up is necessary to evaluate the implants' clinical and radiographic durability.

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