Early RSA Evaluation of Wear of Vitamin E Stabilized Highly Cross-linked Polyethylene and Stability of a New Acetabular Component

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INTRODUCTION

Vitamin E doping of highly cross-linked polyethylene is a new method for insuring long-term oxidative stability of highly cross-linked ultra-high molecular weight polyethylene for use in total joint arthroplasty. *In vitro* research and development studies have shown that this material has improved wear performance, retention of mechanical properties, and a high resistance to oxidation due to the anti-oxidative properties of vitamin E.[1]

In addition, a new acetabular shell system, Regenerex™, (Biomet Inc. Warsaw IN), has been developed and introduced for clinical use. This new acetabular shell has a porous titanium surface with reported improvements for bone ingrowth fixation.

With the introduction of these new materials for clinical use in total hip arthroplasty, it is essential to perform prospective clinical follow-up studies in order to establish that the beneficial properties of these materials can be demonstrated *in vivo* as well as to monitor for any unforeseen complications which might arise.

Radiostereometric analysis (RSA) is an accurate method of measuring relative motion over time from a series of specialized RSA radiographs. With this technique, penetration of the femoral head into the polyethylene insert due to creep and wear of the material can be measured in the early post-operative period, (6 months – 3 years). Thereafter, subsequent penetration of the femoral head will be due primarily if not exclusively to polyethylene wear. Long-term RSA follow-up can establish the true, steady state wear rate of this new material and establish that the reduced wear properties are maintained during *in vivo* use.

In addition, RSA can be used to monitor implant stability over time. This new polyethylene insert will be used with the new Regenerex acetabular components and it will be possible to study the long-term stability of this new component in the same group of total hip replacement (THR) patients.

Therefore, the purpose of this study is to conduct a prospective RSA clinical study on 50 patients receiving total hip replacements in order to evaluate implant stability, short-term femoral head penetration, and long-term steady state polyethylene wear.

METHODS

Fifty patients are being recruited into a 5 year, IRB approved, RSA and clinical outcome study. Informed consent was obtained from all patients. At surgery, up to nine 0.8mm diameter tantalum beads were placed into the pelvic bone and femur using a specialized gun inserter. Using a customized jig, tantalum beads were pressed into pre-drilled holes of each anti-rotational tab of the vitamin E doped polyethylene liner at surgery. The placement of the beads allow for measurement of femoral head displacement into the liner as well as acetabular and femoral component stability. Bi-planer RSA radiographs are scheduled immediately postoperatively, at 6 months, 1, 2, 3, and 5 years post-operatively. Clinical assessment is made at each time period using a variety of patient questionnaires including the EQ5D, Harris Hip Score, and the UCLA activity score. Clinical evaluations of the radiographic finding are also performed.

RESULTS

Currently, 19 patients have been followed for 6 months and 9 at 1 year. The median superior femoral head penetration at 6 months was 0.01±0.01mm and at 1 year it was 0.03±0.03mm, Figure 1. This early penetration, which has been shown to be primarily due to plastic deformation, is lower than the reported creep of other highly cross-linked polyethylene liners of 0.1mm. The acetabular components were all stable with the median acetabular cup migration in the proximal direction being 0.15±0.03mm at 6 months and 0.09±0.05mm at 1 year, Figure 2. The median femoral stem migration in the distal direction was 0.17±0.49mm at 6 months and at 1 year it was 0.13±1.02mm. While most stems were stable throughout the current time course, the high standard errors result from three stems that had substantial migration at 6 months of 1.3mm, 1.8mm, and 9.4mm. Currently, the stem that migrated 9.4mm had no further migration at 1 year. The other two are pending 1 year follow-up. This 9.4mm change was visible in plain radiographs but the subsidence of the stems in the other two patients (1.3 and 1.8mm) was not. The three patients are doing clinically well with no symptoms. It is expected that 27 patients will be examined at 6 months and 20 at 1 year by February, allowing for better statistical analysis.

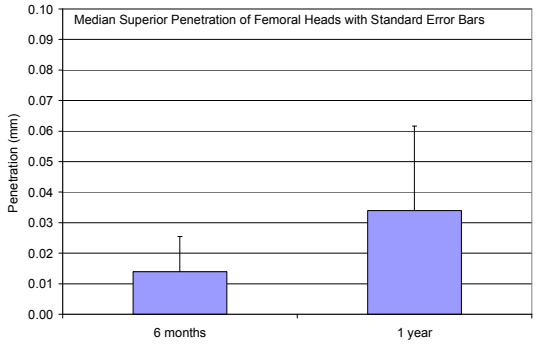

Figure 1. The median femoral head penetration into the Vitamin E doped polyethylene liners at 6 months and 1 year. This penetration, due primarily to creep, is lower than that reported with other forms of highly cross-linked polyethylene.

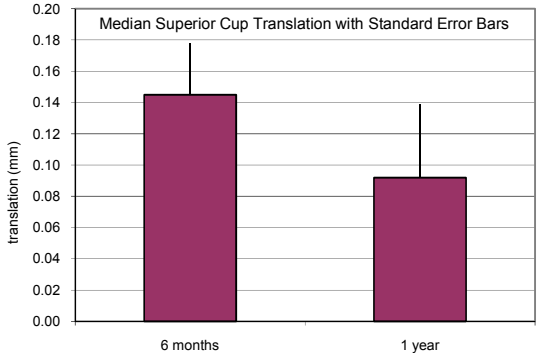

Figure 2. The median superior migration of the Regenerex shell at 6 months and 1 year indicate excellent initial stability of the new component.

DISCUSSION

The early femoral head penetration and component stability with the new bearing material are excellent. The small amount of penetration is likely due to creep of the material which is surprisingly low relative to that reported for other forms of highly cross-linked polyethylene by similar techniques. The three stems which had substantial subsidence were viewed radiographically to be undersized and may represent a learning curve in the use of this femoral stem system. So far, one has stabilized at 1 year. Previous RSA studies have shown that continued early subsidence is a predictor of late failure and these cases require close monitoring. While the early clinical data on the Regenerex shell with vitamin E doped highly cross-linked polyethylene is encouraging, continued longer term follow-up is required.

REFERENCES

[1] Oral et al., Biomaterials, 2004, 25:5515-5522.

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