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.

Retro- stereoradiographic 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 to monitor for any unforeseen complications which might arise. RSA tests were run between time points to determine if changes in penetration or migration were significant at p<0.05.

RESULTS: Currently, 32 patients have been followed for 6 months, 24 at 1 year, and 7 at 2 years. The median superior femoral head penetration at 6 months was 0.02±0.01mm, at 1 year it was 0.04±0.02mm and at 2 years it was 0.04±0.02mm none of which were significantly different from each other, 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 0.13±0.03mm at 6 months, 0.07±0.03mm at 1 year, and 0.13±0.03mm at 2 years, and again, none were significantly different from one time point to the next, Figure 2. The median femoral stem migration in the distal direction was 0.16±0.30mm at 6 months, 0.17±0.39mm at 1 year, and 0.06±0.32mm at 2 years. While most stems were stable throughout the current time course and the median subsidence at each time point was not significantly different, 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 with the greatest subsidence had little or no further migration at 1 year. The stem which subsided 1.8mm at 6 months has migrated an additional 0.3mm by the 2 year follow up. The third subsided an additional 0.8mm at 1 year. The 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 42 patients will be examined at 6 months, 33 at 1 year, and 18 at 2 years before January 2011, allowing for further statistical analysis.

DISCUSSION: The early femoral head penetration and component stability with the new bearing material are excellent. The small amount of penetration and the fact that it is not significantly increasing over time suggests that it is likely due to creep of the material. This amount of creep 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, two have 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