INTRODUCTION: Vitamin E doping of highly cross-linked polyethylene is a method for ensuring 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 antioxidantative properties of vitamin E. In addition, an acetabular shell, Regenerex™, (Biomet Inc. Warsaw IN), was developed for clinical use. This acetabular shell has a porous titanium surface for bone ingrowth fixation.

It is essential to perform prospective clinical follow-up studies in order to establish that materials perform in vivo as expected and 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. 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). 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 material and evaluate if the reduced wear properties are maintained during in vivo use.

RSA can also be used to monitor implant stability over time. With markers in the surrounding bone, acetabular cup and the femoral stem migration can be monitored with respect to the pelvis and femur, respectively.

The purpose of this study was to conduct a prospective RSA clinical study of 51 total hip replacements in order to evaluate femoral head penetration into vitamin E stabilized polyethylene and implant stability of the acetabular cups and femoral stems.

METHODS: 47 patients (51 hips) were 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 pelvis 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 insert due to creep and wear of the material. The placement of the beads allows for measurement of femoral head displacement into the liner as well as acetabular and femoral component stability. Each patient received a Regenerex™ and a Biomet stem with a 32mm femoral head.

RESULTS: Currently, 43 hips have been followed for 6 months, 38 at 1 year, 22 at 2 years, and 7 at 3 years. The median superior femoral head penetration was 0.03±0.01mm at 6 months, 0.03±0.02mm at 1 year, 0.03±0.01mm at 2 years, and 0.07±0.02mm at 3 years; none of which were significantly different (Figure 1). The acetabular components were stable with the median acetabular cup migration in the proximal direction being 0.12±0.03mm at 6 months, 0.09±0.03mm at 1 year, 0.11±0.04mm at 2 years, and 0.00±0.08mm at 3 years, and again, none were significantly different from one time point to the next (Figure 2). The median femoral stem distal migration was 0.11±0.02mm at 6 months, 0.16±0.27mm at 1 year, 0.08±0.14mm at 2 years, and 0.01±0.15mm at 3 years. While most stems were stable throughout the current time course and the median subsidence at each time point was not significantly different, three stems that had substantial subsidence by 6 months. All of these stems stabilized by 2 years. The greatest subsidence of 9.4mm in one of these stems 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.

DISCUSSION: The low early femoral head penetration with the vitamin-E stabilized polyethylene liner is excellent. The small amount of penetration which does not significantly increase over time, suggests that it is likely due to creep of the polyethylene. This amount of creep is low relative to that reported for non vitamin-E stabilized highly cross-linked polyethylene measured by similar techniques. At 3 years, all acetabular components were stable with respect to both migration and rotation. While most stems were stable throughout, the high standard error at 3 years results from one stem that migrated substantially by 6 months (9.4mm), which remained stable at 1 and at 3 years. This is the longest term documentation of in vivo wear performance of vitamin E stabilized highly cross-linked polyethylene. The early stability of the Regenerex™ shell and femoral components is promising. Continued long term follow-up is important to document successful device performance.

SIGNIFICANCE: This study represents the longest term in vivo follow-up of vitamin-E stabilized polyethylene and acetabular and femoral component stability at 3 years using the RSA measurements in THA patients.

REFERENCES: