Five year experience of Vitamin E Stabilized, Irradiated Ultrahigh Molecular Weight Polyethylene wear and stability of Regenerex™ Acetabular Shells and Femoral Components using Radiostereometric Analysis (RSA)


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Introduction: It is well documented that long-term performance of total hip arthroplasty is often compromised by implant loosening secondary to osteolysis caused by wear of the ultrahigh molecular weight polyethylene (UHMWPE) lining the acetabular shell. Cross-linking of UHMWPE through irradiation improves its wear characteristics compared to conventional non-irradiated polyethylene, but also produces residual free radicals that decrease the oxidative stability of the polyethylene. In vitro research and development studies have shown that the anti-oxidative properties of vitamin E improve UHMWPE performance by stabilizing free radicals while retaining the physical and chemical properties of UHMWPE.

The porous titanium surface of the Regenerex™ acetabular shell was developed for improved bone in-growth fixation. Uncemented acetabular components have shown improved long-term stability over cemented components and thus have contributed to longer-term implant success. Initial osseointegration of uncemented components is critical to the success of the implant, as it has proven to reduce the rate of future aseptic loosening. With increased bony in-growth, there is less micromotion at the bone-implant interface and therefore reduced risk of loosening. The increased porosity of the Regenerex™ shell promotes early bony in-growth with the goal of greater long-term stability. Studies show that a greater pore size improves the strength of the fixation with the bone, and the Regenerex™ shell employs this larger pore size. The pore size encourages the propensity for bony in-growth and ultimately improves stability and long-term implant performance.

The purpose of this prospective clinical study of 61 total hip arthroplasties (THA) was to evaluate femoral head penetration into vitamin E stabilized polyethylene (VEPE) and the implant stability of Regenerex™ acetabular shells and related femoral stems using RSA. Plain radiographs were also assessed for radiolucencies to determine if their presence corresponded to implant micromotion.

Methods: Fifty-seven patients (42 males and 15 females), all of whom suffered from osteoarthritis, gave informed consent to participate in a five year, prospective Institutional Review Board approved, RSA and clinical outcome study. Six patients were bilateral and had both hips enrolled in the study, for a total of 63 observed hips. Each patient received a VEPE liner, a Regenerex™ acetabular shell, and an uncemented stem with either a 32mm or 36 mm cobalt chrome femoral head. Forty-seven patients received 32mm femoral heads and 13 recently included patients received 36mm heads. Tantalum beads were inserted into the VEPE, the pelvic bone surrounding the periphery of the acetabular shell and the femoral bone surrounding the stem to measure femoral head penetration into the polyethylene, and acetabular shell and femoral stem stability over time, using RSA. RSA and plain radiographs were scheduled immediately postoperatively (up to 6 weeks) and 6 months, 1, 2, 3, and 5 years after surgery. Double examinations were performed at the 6 month and 2 year follow-up visits to establish the precision of the RSA measurements. The Wilcoxon signed-ranks nonparametric test was used to determine if changes in penetration or migration were significant over time and the Mann-Whitney nonparametric test assessed differences in penetration and migration between the two head size groups at p≤0.05.

Results: Currently, 55 hips have been followed for 6 months, 51 at 1 year, 46 at 2 years, 37 at 3 years and 8 at 5 years. The 36mm cohort data is not reported at this time because they do not have sufficient follow-up yet. The median± standard error (SE) superior head penetration into the polyethylene liner for the 32mm cohort was 0.05±0.01mm at 2 years, 0.06±0.01mm at 3 years, and 0.06±0.03 mm at 5 years (Figure 1). There was no significant increase in head penetration over time. The acetabular components were all stable with the median± SE acetabular cup translation in the proximal direction being 0.09±0.03mm at 2 years, 0.04±0.04mm at 3 years, and 0.15±0.11mm at 5 years. The median± SE acetabular cup rotation was -0.08±0.15 degrees at 2 years, -0.04±0.16 degrees at 3 years, and -0.52±0.28 degrees at 5 years. There was an early statistically significant difference in cup rotation between the 6 month and 1 year intervals (p=0.007), but no significant differences in cup translation among any of the time intervals. Radiolucent lines were present around 9 cups at the postoperative visit, 6 cups at 1 year, 7 cups at 2 years, and 4 cups at three years, and 2 cups at 5 years. The median± SE femoral stem distal migration was 0.10±0.17mm at 6 months, 0.10±0.19mm at 1 year, 0.06±0.07mm at 2 years, 0.04±0.27mm at 3 years, and 0.02±0.30mm at 5 years, with a significant difference in migration between the 6 month and 3 year intervals (p=0.029). While most stems were stable throughout the
current time course, three stems had substantial subsidence by 6 months. All of these stems stabilized by 2 years, with no further subsidence. One patient was revised before the 6 month follow-up due to sepsis.

Discussion: This study demonstrates low femoral head penetration with the VEPE liners with up to 5 years follow up. The early head penetration, probably due to creep, is substantially lower relative to that reported for non-vitamin E stabilized, irradiated UHMWPE measured by similar techniques. The small amount of penetration is less than what was seen in the first generation of highly cross-linked UHMWPE. At 5 years, all acetabular components were stable, however there was an early significant difference in rotation at 1 year, which is probably due to the early settling of the cup, since no further rotation was seen in any of the subsequent intervals. This observation of shell stability could be related to the increased porosity of the Regenerex™ shell, which may lead to improved long-term stability compared to other shells with a less porous surface. While most stems were stable to date, the high standard error and significant difference at three years results from one stem that migrated substantially by six months (9.4mm), which remained stable between one and three years, as well as two others that had a greater translation early on than the rest of the cohort. This study documents the longest-term evaluation of in vivo wear performance of vitamin E stabilized, irradiated UHMWPE. The early stability of the Regenerex™ shell and femoral components shows promise for long-term implant survivorship. Continued long-term follow-up is necessary to confirm successful device performance.

Significance: Radiostereometric Analysis shows encouraging early wear results of the Vitamin E doped highly cross-linked polyethylene at the 5 year follow-up as well as no significant migration of the cup or stem.

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References:

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