Global Multi-Center Study Monitors the Clinical Results of E1™ Antioxidant Infused Technology and Regenerex® Porous Titanium Construct

As part of our continuing commitment to responsibly monitor the long-term clinical success of our orthopedic implants, Biomet has initiated a 10-year global multi-center study of E1™ Antioxidant Infused Technology and Regenerex® Porous Titanium Construct. Two-year follow-up outcomes have been promising with study sites around the globe reporting excellent results with these new technologies.

Study Sponsors

Biomet, Inc. and Massachusetts General Hospital

Study Goals

Document the long-term (10-year) radiographic and clinical outcomes of E1™ Antioxidant Infused Technology and Regenerex® Porous Titanium Construct in a group of male or female, primary total hip arthroplasty patients aged 30 to 75.

Study Design

One-thousand (1000) patients in need of a primary total hip replacement will be recruited from approximately 20 centers. As of March 31, 2010, 468 patients had been enrolled in the study with 430 of those patients having surgery. All patients have or will have received a primary acetabular component, utilizing a 32 mm femoral head, as part of a total hip replacement using one of four combinations of acetabular implants:

1. Titanium plasma sprayed RingLoc® shell with E1™ Antioxidant Infused liner
2. Titanium plasma sprayed RingLoc® shell with ArComXL® polyethylene liner
3. Regenerex® RingLoc®+ shell with E1™ Antioxidant Infused liner
4. Regenerex® RingLoc®+ shell with ArComXL® polyethylene liner

The study will measure wear and component migration via radiosteriometric analysis (RSA), in which small metal beads are implanted in the patient as well as the orthopedic components in order to precisely measure any change in position. Short-term femoral head penetration and long-term steady state wear of the polyethylene will be assessed using the Martell analysis technique. Stability of the acetabular and femoral components will be assessed using radiographic grading for loosening and osteolysis. In addition, all patients will complete self-administered questionnaires to assess the preoperative and clinical outcome of the surgery and patient satisfaction.

We are encouraged by the early-term results. Thirty-six hips have postoperative follow-up thus far: 25 hips with six months follow-up, 20 hips with one year follow-up and two with two-year follow-up. “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 crosslinked polyethylene by similar techniques.”[1]

Biomet has consistently developed hip products and associated technologies that have demonstrated long-term clinical success, such as ArCom® polyethylene, the Taperloc® stem and PPS® Porous Plasma Spray.[2,3]

An enclosed abstract reviews early-term results.

References

1. Bragdon, C.R. *et al.* Poster # 2344 from the Transactions of the 56th Annual Meeting of the Orthopaedic Research Society, March 6-9, 2010, New Orleans, LA.

2. Head, W. Arcom Isostatic Molded Polyethylene. Presentation. Fifth Annual Hip and Knee Arthroplasty Course. June, 2005.

3. McLaughlin, J. *et al.* Total Hip Arthroplasty with an Uncemented Tapered Femoral Component. The Journal of Bone and Joint Surgery, 90: 1290-6, 2008.

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