PAPER #25

A PROSPECTIVE, RANDOMIZED CLINICAL STUDY COMPARING MARATHON AND ENDURON POLYETHYLENE ACETABULAR LINERS: 3 YEAR RESULTS

Christi J. Sychterz, MS, C. Anderson Engh, Jr., MD, Charles A. Engh, Sr., MD

In 1999, the authors began a prospective, randomized study to compare the clinical performance of DePuy's highly crosslinked polyethylene acetabular liner (Marathon) to that of conventional Enduron polyethylene sterilized by gas plasma. Over the course of two years, 236 hips were enrolled in the IRB approved study. At the writing of this abstract, 126 patients had a minimum follow-up of 3 years. For these patients, we used a computer-assisted radiographic technique to measure polyethylene wear rates. At 3.2 years, the mean true wear rate for the Marathon liners was significantly less than that of the non-irradiated Enduron liners (0.12 vs. 0.22 mm/yr).Moreover, a significantly greater percentage of Marathon liners had true wear rates less than 0.1 mm/year than did Enduron liners (62% vs. 22%). These initial clinical data confirm laboratory tests demonstrating a reduction in wear with Marathon polyethylene as compared to non-irradiated Enduron polyethylene. The reduction in mean wear rate was coupled with a significantly greater proportion of low-wearing liners in the Marathon group. Of note, however, at this short follow-up both groups continue to have outliners with large head penetration rates, which tend to inflate the mean wear rate of each population.

PAPER #26

SHORT-TERM *IN VIVO* WEAR OF MARATHON™ CROSSLINKED POLYETHYLENE

Christian Heisel, Mauricio Silva, Mylene dela Rosa, Thomas P. Schmalzried, MD

Introduction: Crosslinked polyethylene (PE) was developed to reduce volumetric wear. Hip simulator studies have shown promising results. This study evaluated the short-term in-vivo wear of a moderately crosslinked PE.

Materials and Methods: In-vivo wear was measured in two different groups of patients after total hip replacement surgery. Twenty-four patients received a conventional non-crosslinked PE insert (Enduron™, DePuy) and 34 patients received a crosslinked PE liner (Marathon™, DePuy). Wear rates were measured on radiographs and correlated to patient and implant factors, including patient activity assessed by a computerized two-dimensional accelerometer (Stepwatch, Cyma, Seattle).

Results: Patients with conventional polyethylene showed a mean volumetric wear rate of 87.6 mm^3/year (range: 5-284 mm^3/year, SD=79 mm^3/year). The group with crosslinked polyethylene showed a mean volumetric wear rate of 17.0 mm^3/year (range: 0-70 mm^3/year, SD=19 mm^3/year).Wear in the group with crosslinked polyethylene was 81% lower than in the group with conventional polyethylene ($p<0.00001$). Accounting for differences in patient activity, the adjusted wear rates per million cycles for 70 kg patient weight were 53.3 mm^3 per million cycles (range: 2-191 mm^3 per million cycles, SD= 46 mm^3 per million cycles) for conventional polyethylene, and 15 mm^3 per million cycles (range: 0-52 mm^3 per million cycles, SD=16 mm^3 per million cycles) for crosslinked polyethylene, a 72% reduction ($p=0.0002$). No factors, other than the type of polyethylene, were identified that influenced the difference in wear rates between the two groups.

Discussion: Recognizing that the creep contribution to linear penetration is similar with both polymers during the first two years, the results of this study are promising. The in-vivo wear reduction with this crosslinked PE is consistent with the predictions of previous hip simulator studies.

PAPER #27

ASSESSING THE LONG-TERM PATTERN OF FEMORAL HEAD PENETRATION AFTER TOTAL HIP ARTHROPLASTY

Robert H. Hopper, Jr., PhD, Anthony M. Young, MS, C. Anderson Engh, Jr., MD, James P. McAuley, MD

Introduction: At long-term follow-up, femoral head roughening, or the accumulation of wear debris, may contribute to accelerated wear. Among gamma-irradiated liners, progressive oxidation may also increase wear rates. However, declining activity level associated with advancing age may lead to decreased wear rates. This study sought to characterize how radiographic wear progressed over time.

Methods: We identified 205 primary cementless total hip arthroplasties performed at a single institution that had a minimum 10-year follow-up and at least 6 follow-up x-rays. The first 6 x-rays were taken at an average of 1.4, 2.8, 4.3, 6.0, 7.8 and 10.0 years post-operatively. The study population included 127 cups sterilized with gamma-irradiation-in-air and 78 cups sterilized with ethylene-oxide. Using the pelvic anteroposterior x-rays from each hip, two-dimensional head penetration was measured and wear rates were calculated using several techniques.

Results: The mean population wear rate did not change significantly ($p=0.54$, repeated measures ANOVA) when 2, 3, 4, 5, and 6 follow-up x-rays were used to calculate the wear rate for individual hips. As an increasing number of follow-up x-rays were included in the wear rate calculation, the 95% confidence interval associated with the wear rate for an individual hip progressively decreased ($p<0.001$, repeated measures ANOVA).

Conclusions: For this population of hips, the wear rate tended to remain constant over time. Although we expected that the wear rates associated with the gamma-irradiated liners would significantly increase at some point during follow-up if oxidation degraded the polyethylene's wear properties, we found no evidence of clinically significant increases in late wear rates among these liners.

PAPER #28

CONSTRAINED ACETABULAR LINERS: MECHANISMS OF FAILURE

Andrew G. Yun, MD, Douglas Padgett, MD, Paul Pellicci, MD, Lawrence D. Dorr, MD

Although constrained acetabular liners have been successfully used for the treatment of recurrent hip instability, their usage has led to a growing number of associated complications. Twenty-seven patients with 29 hips who experienced failure of the constrained acetabular construct were retrospectively reviewed to define mechanisms of failure. Of these patients, 8 had a recurrent failure of another constrained liner. The four modes of failure were failure of fixation, liner dissociation, biomaterial failure, and femoral head dislocation. As constrained liners are highly subject to mechanical overload, the risk of failure can be minimized by reducing prosthetic impingement and avoiding technical errors.

PAPER #29

ASPIRIN PLUS VENAFLOW VS. LOVENOX PLUS VENAFLOW FOR DVT PROPHYLAXIS IN TKA PATIENTS

Geoffrey H. Westrich, MD, Thomas Sculco, MD, Richard Laskin, MD, Russell Windsor, MD, Steven Haas, MD

Introduction: The purpose of this study is to compare the combined efficacy of aspirin with pneumatic compression (PC) vs. low molecular weight heparin (LMWH) with PC for deep vein thrombosis (DVT) prophylaxis in unilateral total knee arthroplasty (TKA) patients.

Methods: Two hundred twenty-nine patients were prospectively randomized to receive aspirin plus PC (Group A) or LMWH plus PC (Group B).VenaFlow® calf pumps (PC) were applied bilaterally to both groups in the recovery room and remained on while the patient was non-ambulatory. Group A received aspirin (325 mg BID for 4 weeks postoperatively). Group B received Lovenox®, (a LMWH), initiated 2 hours after epidural catheter removal approximately 48 hours postoperatively, 30 mg BID until hospital discharge; upon discharge, 40 mg QD for three weeks. The incidence of DVT was monitored twice by Doppler Ultrasound; POD 3-5 and 4 weeks postoperatively. Any patient with a positive ultrasound on POD 3-5 was removed from the study and treatment protocol was initiated.

Results: POD 3-5, 219 patients underwent ultrasounds revealing a 16.9 percent (37/219) DVT incidence; Group A-17.9 percent (19/106) and Group B- 15.9 percent (18/113). Postoperative week 4, 150 patients underwent ultrasounds revealing a 3.3 percent (5/150) incidence of secondary DVT; Group A- 5.5 percent (4/72) and Group B- 1.3 percent (1/78). (No significant differences in DVT incidences.) No complications were reported due to the Aspirin, Lovenox® or PC device.

Discussion and Conclusion: This is the first study to demonstrate the efficacy of combining modalities for DVT prophylaxis. For instance, both groups demonstrated lower DVT rates relative to historical controls using LMWH (38 percent) or aspirin plus plantar PC (27 percent).

PAPER #30

XIMELAGATRAN FOR PREVENTION OF VENOUS THROMBOEMBOLISM IN KNEE REPLACEMENT

Charles W. Francis, MD, Scott D. Berkowitz, MD, Philip C. Comp, MD, PhD, Jay Lieberman, MD, Jeffrey S. Ginsberg, MD, Guy Paiement, MD, Gary R. Peters, MD, Anne W. Roth, MS, Jennifer McElhattan, MS, Clifford W. Colwell, Jr., MD

Background: In a prior study, ximelagatran, an oral direct thrombin inhibitor, dosed at 24 mg twice daily, showed similar efficacy to warfarin for prevention of venous thromboembolism following total knee replacement. The present study was conducted to determine if a higher dose of ximelagatran would be superior.

Methods: This randomized, double-blind trial compared 7 to 12 days of oral ximelagatran, 24 or 36 mg twice daily, starting the morning after surgery, with warfarin begun the evening of the day of surgery. The composite end point of the rate of total venous thromboembolism, as confirmed by bilateral venography, and/or all-cause mortality, and the incidence of bleeding were the main outcome measures.

Results: Of 2301 patients randomized, 2285 received at least 1 dose of study drug, and 1851 had adequate venography or symptomatic venous thromboembolism. The efficacy of oral ximelagatran 36 mg twice daily was superior to that of warfarin for the primary endpoint of venous thromboembolism and/or all-cause mortality (20.3 percent vs. 27.6 percent, $P = 0.003$). There were no significant differences between groups for major bleeding (0.8 percent vs. 0.7 percent), perioperative indicators of bleeding, or wound characteristics, nor for secondary endpoints of proximal deep vein thrombosis, pulmonary embolism, and/or death (2.7 percent vs. 4.1 percent, $P = 0.171$).

Conclusions: The efficacy of oral ximelagatran 36 mg twice daily started the day after total knee replacement was superior to that of warfarin for prophylaxis of venous thromboembolism, with similar bleeding and no requirement for coagulation monitoring or dose adjustment.

Key words: Deep vein thrombosis, pulmonary embolism, venous thromboembolism, oral direct thrombin inhibitor, ximelagatran, total knee replacement, prophylaxis. The FDA has not cleared the drug or device for the described purpose (AstraZenica-Ximelagatran).