

## Dorr Award

# A Randomized Prospective Evaluation of Outcomes After Total Hip Arthroplasty Using Cross-linked Marathon and Non-cross-linked Enduron Polyethylene Liners

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**Abstract:** Cross-linked liners were introduced with the promise that they would substantially reduce polyethylene wear. In 1999, our institution initiated a prospective study to compare the outcome of total hip arthroplasty patients who were randomized to non-cross-linked Enduron liners with that of total hip arthroplasty patients who were randomized to Marathon polyethylene liners that had been cross-linked with 5 Mrad (50 kGy) of gamma-irradiation and heat-treated to eliminate free radicals. At a mean follow-up of 5.7 years, the clinical outcomes among the Marathon and Enduron liners were similar. However, the mean wear rate was  $0.01 \pm 0.07$  mm/y for the Marathon group, which represents a 95% reduction compared with the mean wear rate of  $0.19 \pm 0.12$  mm/y for the Enduron group. In addition, the incidence of osteolysis was lower in the Marathon group.

**Key words:** primary total hip arthroplasty, prospective clinical outcome study, cross-linked vs non-cross-linked polyethylene, radiographic wear, osteolysis, Marathon, Enduron.

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Particulate debris has been implicated in the development of osteolysis and prosthesis loosening among total hip arthroplasty (THA) patients. Among THAs performed with ultra-high-molecular-weight polyethylene (UHMWPE), bearing surface wear is considered to be the largest source of particulate debris. With the promise of substantially reducing in vivo wear based on in vitro hip simulator studies [1,2], several manufacturers have introduced highly cross-linked polyethylene liners. DePuy, a Johnson & Johnson Company (Warsaw, Ind), developed Marathon. Marathon is UHMWPE treated with 5 Mrad (50 kGy) of gamma irradiation



**Fig. 1.** The implant components for this prospective study consisted of an extensively porous-coated stem and a hemispheric Duraloc 100 cup with an apex hole plug that incorporated a positive stop. The cobalt-chrome alloy femoral heads had a diameter of 28 mm, and the center of the polyethylene liner was laterialized by 4 mm relative to the center of the shell, effectively increasing the dome thickness of the polyethylene by 4 mm. The polyethylene liner was secured in the Duraloc shell by a peripheral wire locking ring that engaged a groove machined into the liner and shell.

to induce cross-linking. The polyethylene is subsequently annealed above the melting temperature (150°C), which increases cross-linking and eliminates free radicals. The cross-linked polyethylene is machined and terminally sterilized with gas plasma, a non-cross-linking chemical surface treatment. The manufacturing process was designed to improve the component's resistance to wear through increased cross-linking and to eliminate residual free radicals that render the polyethylene

susceptible to oxidative degradation while maintaining other physical properties, such as ultimate strength and elongation to failure, above regulated minimum levels [1]. Since the introduction of Marathon, DePuy has continued to manufacture a conventional non-cross-linked UHMWPE terminally sterilized by gas plasma, which is marketed under the trade name Enduron.

Although Marathon has demonstrated superior wear properties during in vitro testing [3], history has taught us that the performance of a component can be different from that observed in the laboratory once implanted in the body [4]. As a result, in 1999, our institution began a randomized prospective study to compare the clinical outcome of THA patients randomized to cross-linked Marathon liners with that of patients randomized to conventional non-cross-linked Enduron polyethylene liners. We hypothesized that the clinical outcomes among the groups would be similar at 5-year follow-up but that the THAs randomized to Marathon liners would wear at a lower rate as compared with those randomized to Enduron liners.

## Materials and Methods

Between January 1999 and July 2000, 226 patients (236 hips) were enrolled in our prospective, randomized, and institutional review board-approved study. Patients enrolled in the study were

**Table 1.** Randomized Study Demographics

Variable	Marathon group	Enduron group	P
Liner material [n (%)]	116 (50.4)	114 (49.6)	NA
Sex [n (%)]			
Female	65 (56.0)	57 (50.0)	.36
Male	51 (44.0)	57 (50.0)	
Diagnosis [n (%)]			
Osteoarthritis	99 (85.3)	90 (78.9)	.54
Avascular necrosis	6 (5.2)	7 (6.1)	
Hip dysplasia	5 (4.3)	4 (3.5)	
Fracture/Trauma	5 (4.3)	8 (7.0)	
Rheumatoid arthritis	1 (0.9)	4 (3.5)	
Postseptic arthritis	0 (0.0)	1 (0.9)	
Age at surgery [y; mean $\pm$ SD (range)]	62.5 $\pm$ 10.6 (26-87)	62.0 $\pm$ 11.1 (34-84)	.70
Weight [lb; mean $\pm$ SD (range)]	186 $\pm$ 47 (113-329)	180 $\pm$ 40 (107-325)	.27
Body mass index [mean $\pm$ SD (range)]	28.6 $\pm$ 5.5 (19.9-47.3)	27.9 $\pm$ 5.1 (19.6-47.9)	.32

NA indicates not applicable.

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