ENHANCED CROSS-LINKED POLYETHYLENE MODULAR ACETABULAR DESIGNS: PERFORMANCE CHARACTERISTICS

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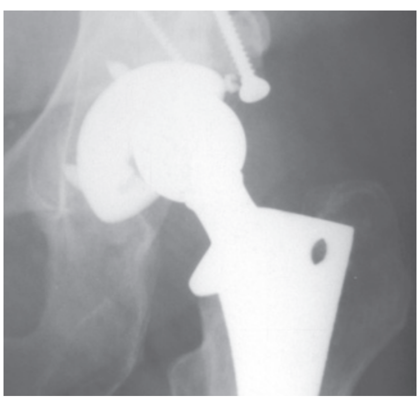
INTRODUCTION

Modular acetabular designs enjoy widespread use in THA procedures. Their mechanical performance has continually increased through improved locking mechanism assemblies.[10-12]

Recently, a number of enhanced cross-linked polyethylenes have emerged whose commonly heralded benefit is a reduction in polymer wear due to increased cross-linking concurrent with minimized oxidation.[7,9] These processes, however, change the chemical structure of the polymer affecting both static mechanical and fatigue properties, including a decrease in the resistance to crack propagation.[1,3,7] This has significant ramifications on the long-term clinical integrity of modular acetabular components where enhanced cross-linked polyethylenes are employed and reduced liner thicknesses are advocated.



One year retrieval from a 50-year old female who underwent THA for degenerative arthritis. This patient experienced left hip pain for two months prior to revision surgery. Separation and fracture of the conventional polyethylene liner are observed along with significant galling of the cup interface.

This study evaluated the locking mechanism integrity for three, contemporary, modular acetabular designs, which employ both conventional and enhanced cross-linked polyethylene liners. The designs presented in this study are the Converge® (Centerpulse†, Austin, Texas) with Sulene and *Durasul® liners, the Duraloc® (DePuy Orthopaedics, Warsaw, Indiana) with Enduron and *Marathon™ liners, and the Pinnacle™ (DePuy Orthopaedics, Warsaw, Indiana) with GVF and *Marathon™ liners.

† Acquired by Zimmer, Inc. in 2003
* Enhanced cross-linked polyethylene

ACETABULAR CUP DESIGNS

CONVERGE®	DURALOC®	PINNACLE™
		
		

Sulene™	*Durasul®	Enduron	*Marathon™	GVF	*Marathon™
GUR 1020 Compression Molded	GUR 1050 Compression Molded	GUR 1050 Extruded Rod	GUR 1050 Extruded Rod	GUR 1020 Extruded Rod	GUR 1050 Extruded Rod
Machined to part	9.5 Mrad electron beam radiation with remelt then machined to part	Machined to part	5 Mrad gamma irradiation with remelt then machined to part	Machined to part	5 Mrad gamma irradiation with remelt then machined to part
Sterilized by gamma irradiation in Oxygenless Packaging™	EtO sterilized	Gas plasma sterilized	Gas plasma sterilized	Sterilized by gamma irradiation in vacuum/barrier packaging	Gas plasma sterilized

** Enhanced cross-linked polyethylene*[7]

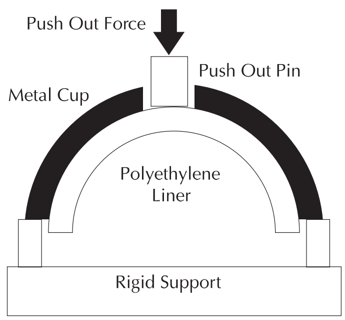
The Converge® acetabular system locking mechanism incorporates twelve, rectangular notches circumferentially located around the rim of the liner. The shell has four rectangular pegs on its rim, which fit into the liner notches to provide rotational constraint. There are fifteen polyethylene tabs located circumferentially and below the liner rim, which engage a recess in the shell to define the locking mechanism.

The Duraloc® acetabular system locking mechanism uses six, circumferential wedges located below the shell rim to facilitate rotational capture of the liner. A circumferential groove is located 2mm below the rim of the liner. A retaining wire supported in the shell wall snaps into this circumferential groove to define the locking mechanism.

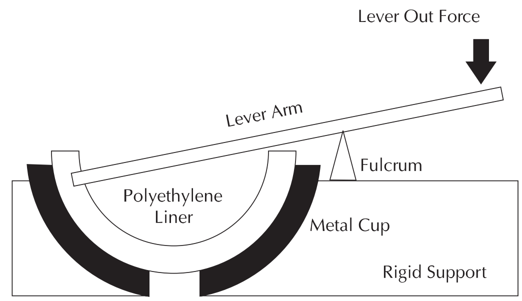
The Pinnacle™ acetabular system locking mechanism facilitates rotational capture by seating six radial pegs, located slightly below the rim of the liner, into notches in the shell. There are six additional polyethylene tabs located circumferentially and below the radial pegs, which engage a recess in the shell to define the locking mechanism.

EVALUATION

Locking mechanism integrity was evaluated by measuring the forces required to push out or lever out a fully seated 28mm polymer liner from a 52mm cup (ASTM F1820-97(2003)). Three liners were tested in each mode (n=3). The test set-ups depicted were mounted in an Instron Testing Machine. A loading rate of 0.2in/min was utilized for the push out test. For the lever out test, a 1.3rad/min angular velocity was applied at a fulcrum 1.9 ± 0.1in from the liner.



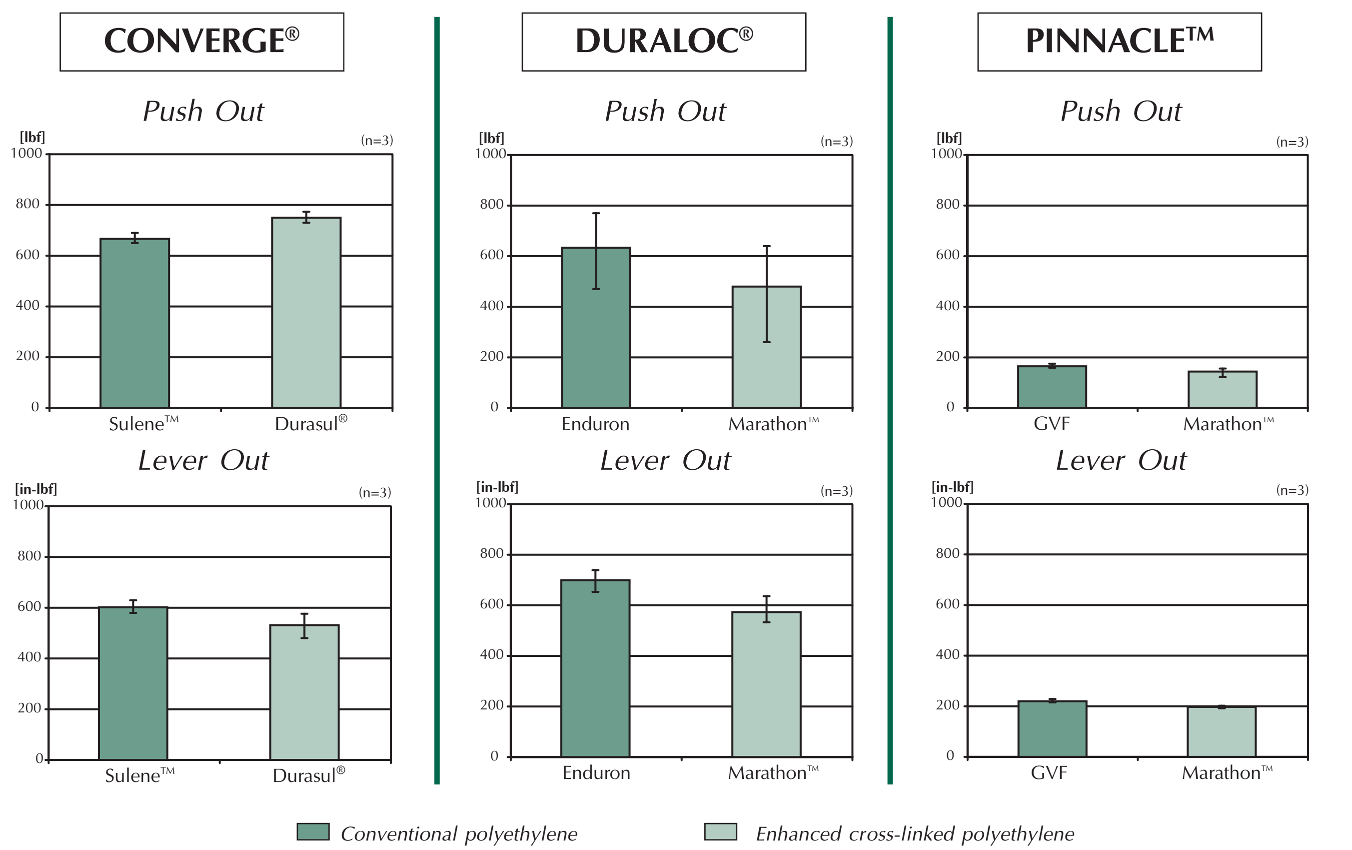
PUSH OUT TEST ASSEMBLY



LEVER OUT TEST ASSEMBLY

RESULTS

The bar graphs depict the forces and torques required to dislodge the conventional and enhanced cross-linked polyethylene liners. These results are interpreted as a measure of the efficacy of the particular retention mechanism provided by each cup design with different liner materials. As the *in vivo* loading of these systems is complex and the mechanism of liner disassembly not fully understood, the results do not infer the clinical advantage of any one design, but rather provide a basis for comparative assessment of conventional and enhanced cross-linked polyethylenes.



DISCUSSION

Modular acetabular cup designs enjoy increasing use for cementless and hybrid THA application. However, problems of short-term liner separation and polyethylene fracture in the absence of normal wear have led to at least one system's recall and a more careful scrutiny of two piece cup performance.

Recently, a number of enhanced cross-linked polyethylenes have been introduced as a solution for decreasing acetabular liner wear. [7,9] However, the material processing protocols utilized ultimately change the chemical structure of the polymer and influence its static mechanical properties and fatigue characteristics.[1,3,7]

It is not known how much force a cup-liner assembly should be able to tolerate to prevent separation, but it seems logical that the higher the resistance to dislocation the higher the degree of safety. While it is unlikely that pure push out forces represent a component of *in vivo* hip loading, they do, by comparison, provide a measure of system integrity. This is better appreciated when a statistically significant correlation is drawn with the lever out tests, which could arise in a varus or valgus anatomical orientation, ($p<0.05$).[10-12]

The push out and lever out strengths measured for the enhanced cross-linked polyethylene acetabular liners in this study indicate that short-term disassociation of these components is no more likely than that for the conventional polyethylene liners of each design. Student t-tests confirmed the null hypothesis. In addition, when compared to the strengths of clinically successful modular designs[10-12] none of the systems evaluated presents any great risk of short-term disassociation.

The predominant failure mechanisms of modular acetabular cups are fatigue related.[2,4,5,6] The reduction in crack propagation resistance which enhanced polyethylenes evidence suggests that further laboratory evaluation as well as mid- to long-term clinical monitoring is important. Short-term case reports of *in vivo* liner fracture have been attributed to component positioning.[8] However, whether existing acetabular shell designs are acceptable vessels assuring the long term performance of enhanced polyethylenes requires further study.

These ongoing laboratory evaluations[10-12] assist an understanding of the anticipated performance of contemporary modular acetabular cup designs. The results are intended to aid the surgeon in device selection when considering patient factors. Further, they provide the manufacturer with design criteria and assist regulatory agencies in determining the safety and efficacy of specific cup designs.

REFERENCES

1. Baker DA, Hastings RS and Pruitt L: Study of Fatigue Resistance of Chemical and Radiation Crosslinked Medical Grade Ultrahigh Molecular Weight Polyethylene. *J Biomed Mater Res* 46(4):573-81, 1999.
2. Bradford L, Baker DA, Graham J, Chawan A, Ries MD and Pruitt LA: Wear and Surface Cracking in Early Retrieved Highly Cross-Linked Polyethylene Acetabular Liners. *J Bone Joint Surg [Am]* 86(6):1271-82, 2004.
3. Bradford L, Baker DA , Ries MD and Pruitt LA: Fatigue Crack Propagation Resistance of Highly Crosslinked Polyethylene. *Clin Orthop Rel Res* 429:68-72, 2004.
4. Currier BH, Currier JH, Mayor MB, Lyford KA, Collier JP and Van Citters DW: Evaluation of Oxidation and Fatigue Damage of Retrieved Crossfire Polyethylene Acetabular Cups. *J Bone Joint Surg [Am]* 89(9):2023-9, 2007.
5. Fosco DR and Buchanan DJ: The Importance of Fatigue Loading When Assessing Liner/Shell Distraction Resistance and Congruency for Modular Acetabular Components in Modularity of Orthopaedic Implants, ASTM STP 1301 (Marlowe DE, Parr JE and Mayor MB [eds.]), *American Society for Testing and Materials, Conshocken, PA, 1997*.
6. Furmanski J, Gupta S, Chawan A, Kohm A, Lannutti J, Jewett B, Pruitt LA and Ries MD: Aspherical Femoral Head with Highly Cross-Linked Ultra-High Molecular Weight Polyethylene Surface Cracking. *J Bone Joint Surg [Am]* 89(10):2266-70, 2007.
7. Greenwald AS, Bauer TW and Ries MD: New Polys for Old: Contribution or Caveat?. *J Bone Joint Surg [Am]* 83(Suppl. 2, Part 1):27-31, 2001.
8. Halley D, Glassman A and Crowninshield RD: Recurrent Dislocation After Revision Total Hip Replacement with a Large Prosthetic Femoral Head: A Case Report. *J Bone Joint Surg [Am]* 86(4):827-30, 2004.
9. Jacobs CA, Christensen CP, Greenwald AS and McKellop H: Clinical Performance of Highly Cross-Linked Polyethylenes in Total Hip Arthroplasty. *J Bone Joint Surg [Am]* 89(12):2779-86, 2007.
10. Postak PD, Tradonsky S, Froimson AI and Greenwald AS: Performance Characteristics of Two Piece Acetabular Cups - Series II. *Orthopaedic Transactions* 20(1):182, 1996.
11. Postak PD, Ratzel AR and Greenwald AS: Highly Cross-Linked Polyethylene Modular Acetabular Designs: Performance Characteristics. *Proceedings of the American Academy of Orthopaedic Surgeons Annual Meeting* 5:650, 2003.
12. Tradonsky S, Postak PD, Froimson AI and Greenwald AS: A Comparison of Disassociation Strength of Modular Acetabular Components. *Clin Orthop Rel Res* 296:154-60, 1993.