CUP/LINER CONFORMITY OF METAL-BACKED ACETABULAR DESIGNS

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INTRODUCTION

Metal backed polyethylene cups have gained widespread use in total hip arthroplasty. As continued optimization of mechanical design and surgical technique have diminished the frequency of short-term failure of these systems, considerable attention has focused on long-term survivorship. In particular, debris generated from polyethylene components has been implicated as a factor prompting progressive osteolysis, leading to long-term implant instability[1,2].

In a metal backed acetabular component, lack of conformity between a polyethylene liner and its acetabular shell limits the surface area available for load transfer and concentrates the surface and subsurface stresses in regions of contact. A high degree of conformity between the liner and shell not only maximizes the area for load transfer, but reduces "gap-closure" deformation and its associated stresses under load. In addition, it has been shown that the stress state throughout the polyethylene is highly sensitive to liner/shell interface geometry[3], suggesting the need for careful interface design.

This study examines the degree of conformity between the polyethylene liner and metal shell of six modular and one factory pre-assembled metal-backed acetabular design, and discusses the relationship between conformity and polyethylene wear.

MATERIALS AND METHODS

Seven acetabular cup systems were analyzed for metal-cup/polyethylene-liner conformity. The liner dimensions for each system studied were approximately 52 mm OD and either a 32 or 28 mm ID. Cups representing all available hole configurations for each system were obtained for analysis. Regions of nonconformity were attributed to holes and gaps. According to the following protocol, three cups representing the minimum hole configuration for each system were analyzed for gap information.

In order to eliminate possible component migration during section preparation and testing, cyanoacrylate adhesive was used to bond the liner to the shell. Liquid self-curing cyanoacrylate was applied to the inner surface of each shell. The liner was inserted into the shell and a 10 lbf load was applied to the liner through a matching femoral head component for 24 hours. Each assembly was sectioned with a diamond wire saw and

MATERIALS AND METHODS *(cont.)*

subsequently inspected under a dissecting microscope at a magnification of 45x. An ocular micrometer was used to measure the thickness of the acrylic layer throughout 180 degrees of the face of each section. Based on reasonable machining tolerances, regions of contact were defined as gaps less than 0.20 mm.

As shown in Figure 1A, gap dimensions were recorded through ranges of approximately ±90 degrees relative to the central axis. In areas of complex geometry and in areas where gap dimensions approached the 0.20 mm gap criterion, readings were taken at 1 degree intervals. Otherwise, readings were taken every 5 degrees. When no gaps were present at any $\pm\theta$, the polyethylene circumference, swept in a plane normal to the central axis, was assumed to be entirely supported. Conversely, when gaps were present at both $\pm\theta$**,** the polyethylene circumference was assumed to be entirely unsupported. However, if supported polyethylene was indicated at any θ and unsupported at the opposite angle, the polyethylene and metal circumferences were modeled to resemble a circle of radius R_1 offset within a circle of radius R_2, where R_1 is less than R_2, as shown in Figure 1B. Subsequently, at this angle, the supported length around the circumference up to the location of 0.20 mm separation was determined.

Utilizing a custom computer program employing numerical integration, surface maps of gaps and holes were constructed separately, assembled and duplicate data removed. Gap information obtained from the minimum hole configuration for each system was applied directly to the multiple hole configurations. The total percent of unsupported polyethylene was determined by the sum of gap and hole regions. The total area of polyethylene/metal contact was determined in a similar manner in order to provide an absolute comparative basis for all the designs tested.

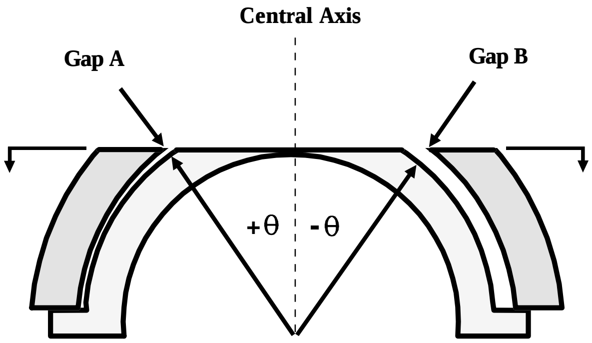


Figure 1A

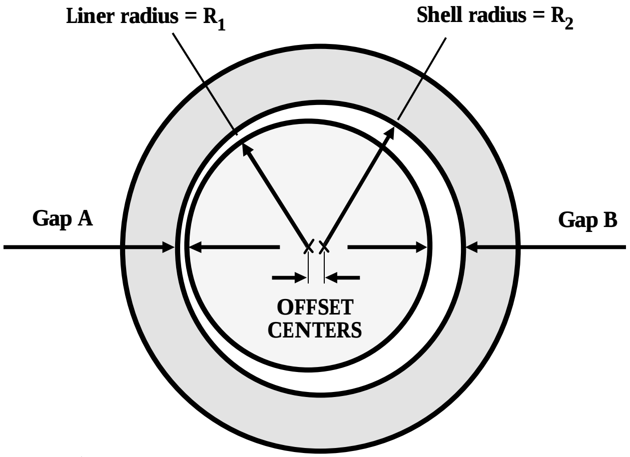
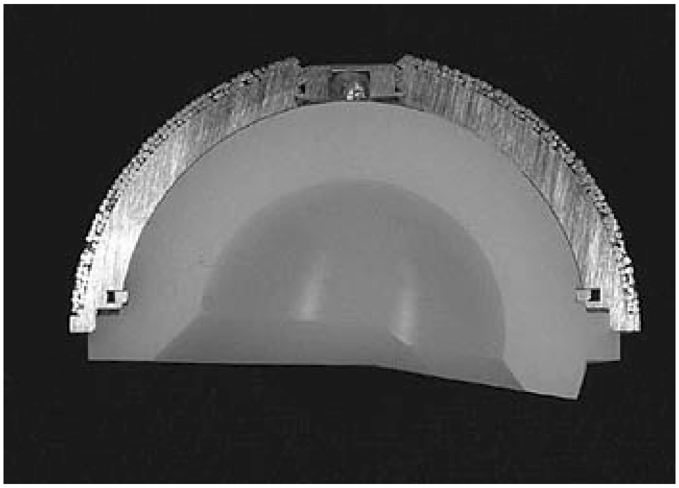


Figure 1B

Figure 1A. A cup section indicating locations for gap measurements. 1B. A section through a cup in a plane normal to the central axis, illustrating polyethylene offset within the metal shell.

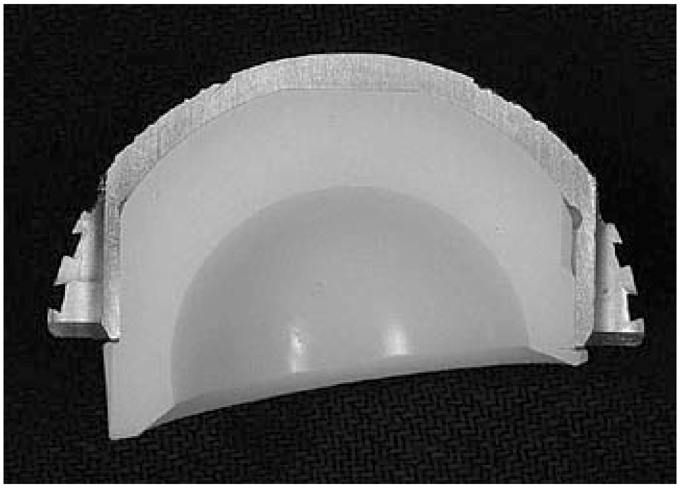
CUPS

Foundation



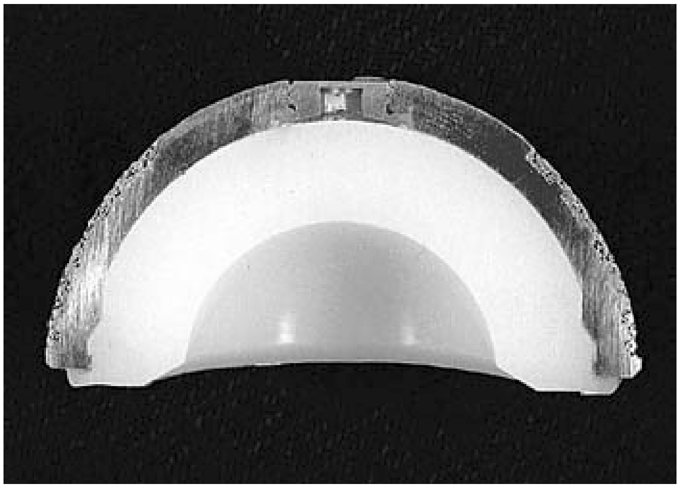
Minimum Hole Geometry:
(1) Apical Hole
Other Hole Geometries:
(4) Apical Hole + 3 Dome Holes

Elliptical



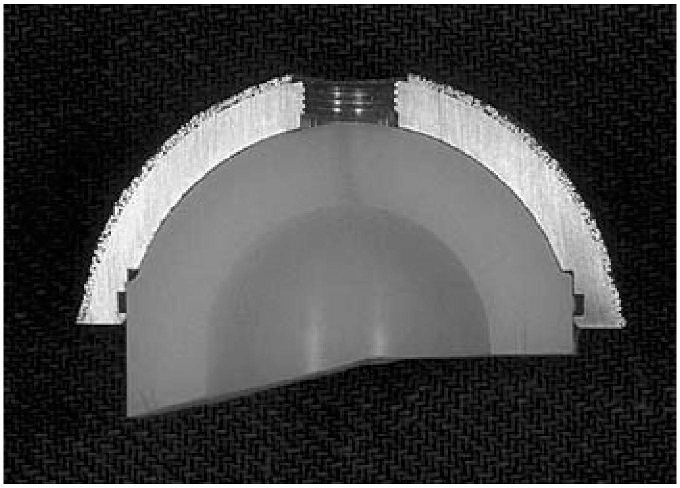
Minimum Hole Geometry:
(0) No Holes
Other Hole Geometries:
None
Factory Pre-assembled

Inter-Op



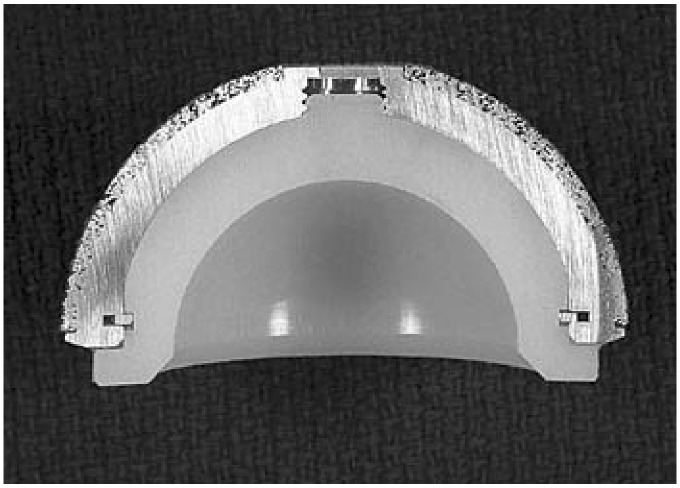
Minimum Hole Geometry:
(1) Apical Hole
Other Hole Geometries:
(3) Apical Hole + 2 Dome Holes

Interseal



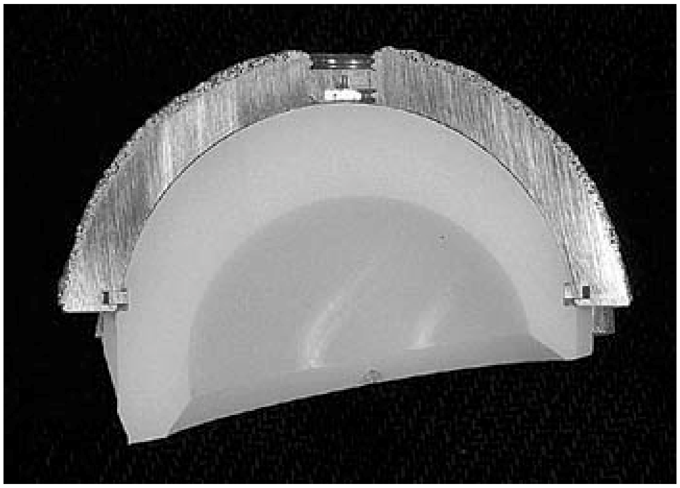
Minimum Hole Geometry:
(1) Apical Hole
Other Hole Geometries:
(4) Apical Hole + 3 Dome Holes
(13) Apical Hole + 12 Dome Holes

Trilogy



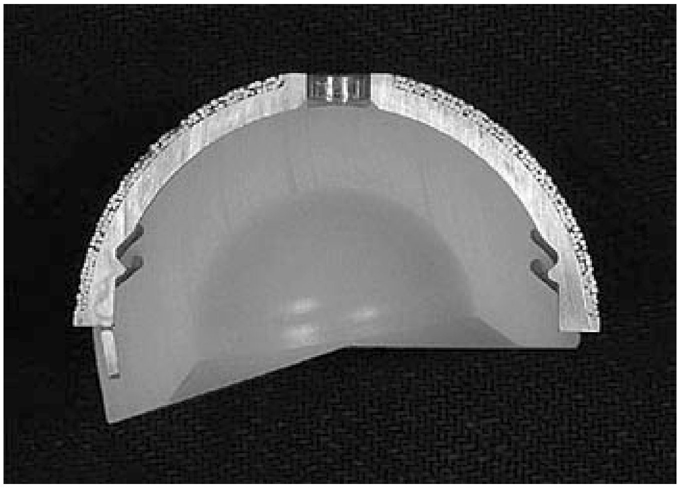
Minimum Hole Geometry:
(0) No Holes
Other Hole Geometries:
(3) No Apical Hole + 3 Dome Holes
(11) No Apical Hole + 11 Dome Holes

BiomEX



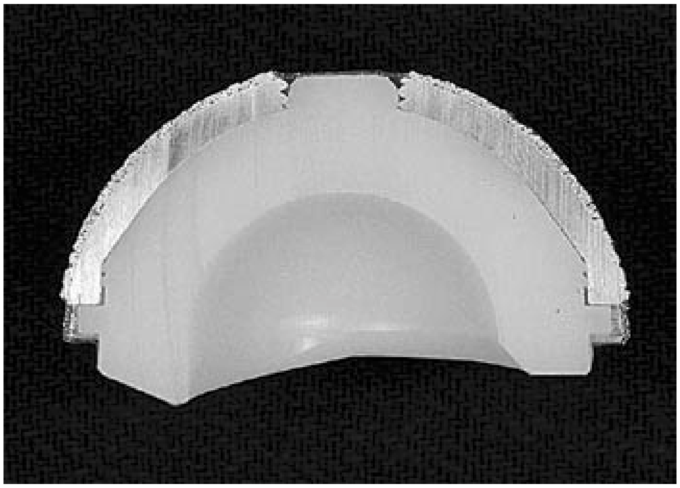
Minimum Hole Geometry:
(1) Apical Hole
Other Hole Geometries:
None

Consensus



Minimum Hole Geometry:
(1) Apical Hole
Other Hole Geometries:
(5) Apical Hole + 4 Dome Holes

Micro-Seal



Minimum Hole Geometry:
(7) Apical Hole + 6 Dome Holes
Other Hole Geometries:
None

RESULTS

The cup sections presented are of the minimum hole configuration of each system. Figure 2 describes the median percent of unsupported polyethylene in each cup, covering the outer polyethylene surface up to, but not including the rim. Hole and gap information are presented separately for each acetabular cup design. The range of unsupported polyethylene in the cups studied was 3.3% to 41.8% as evidenced in Figure 2. Supported regions of polyethylene were characterized by the area of conformity up to, but not including the rim. Figure 3 demonstrates median areas of contact for each system, which ranged between 29.7 cm^2 and 16.2 cm^2 for the designs evaluated.

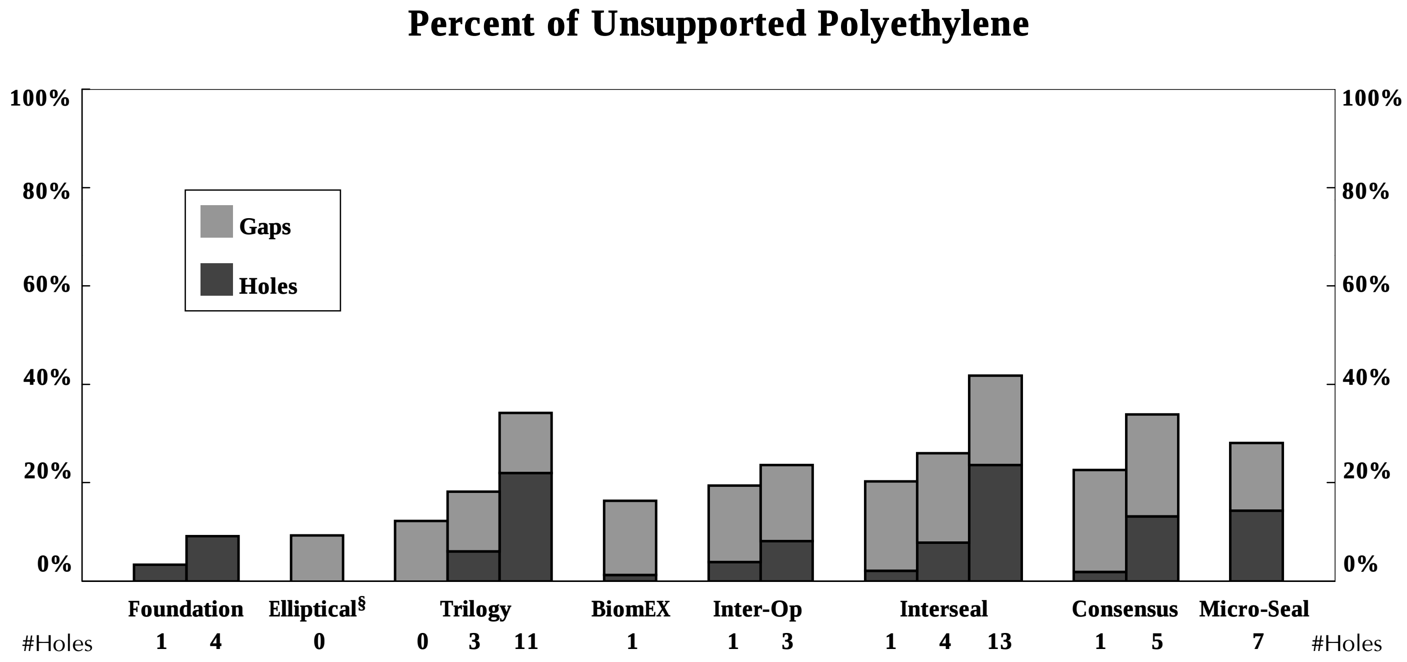


Figure 2. Median percent of unsupported polyethylene for two piece acetabular designs.

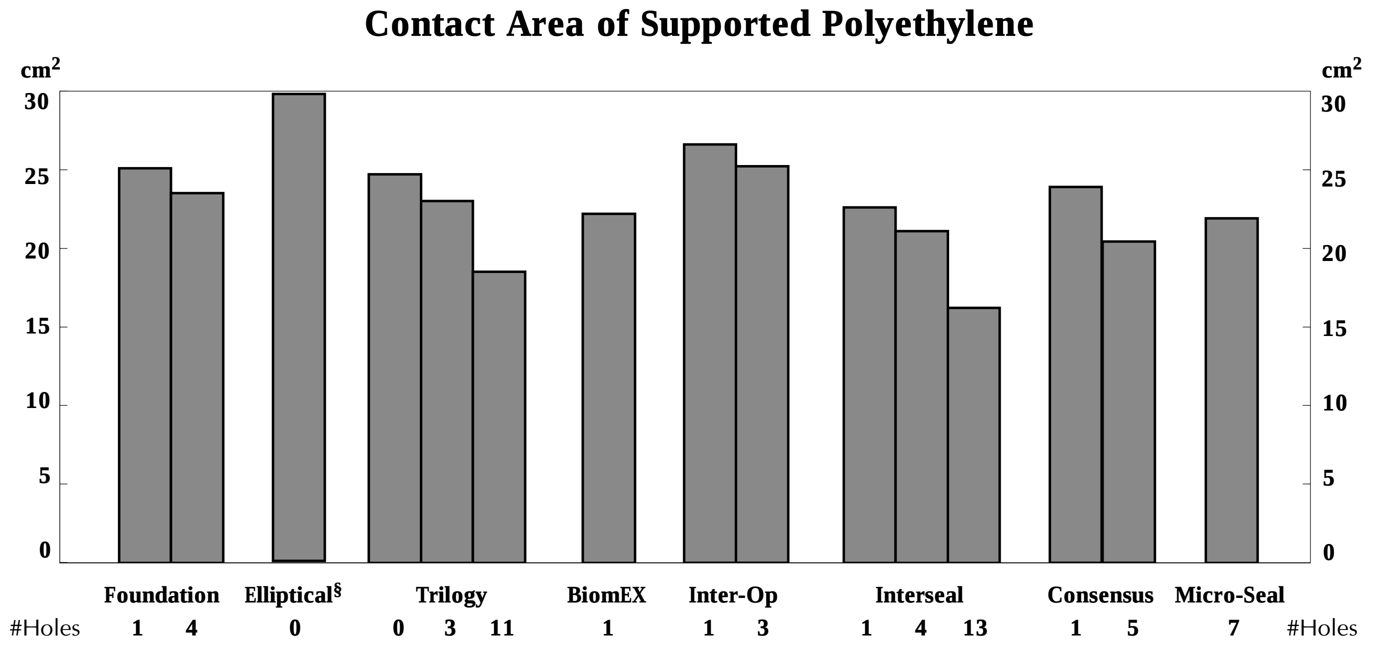


Figure 3. Median contact area of supported polyethylene for two piece acetabular designs.

[§] Factory Pre-assembled

DISCUSSION

The significance of polyethylene/metal conformity rests in the understanding that high contact and subsurface stresses in polyethylene contribute to polyethylene damage through creep, wear and fracture. Polyethylene/metal conformity not only decreases the potential for polyethylene deformation, but it reduces contact stress concentrations by increasing the surface area available for load transfer.

In general, gaps account for a considerable amount of nonconformity as noted in Figure 2. Gaps may be attributable to locking mechanism geometries, poor machining tolerances, or simply interface design. In many of the multiple hole cups, lack of support attributable to the holes themselves is considerable. Thus, selective placement of a minimal number of holes is strongly recommended as an effective means of achieving greater conformity.

While it is valuable to understand the causes of nonconformity, the areas of conformity, shown in Figure 3, suggest an absolute context by which stress transfer may be inferred. The goal to increase conformity is synonymous with the goal to increase contact area. Although certain locales of contact will be of much greater relevance than others for stress transfer in any single loading condition, dynamic loading in common activities such as gait suggest the necessity for contact over a relatively wide range. An increase in contact area will reduce stress-induced redefinition of the polyethylene surface, as well as inhibit the catalysis of wear mechanisms.

CONCLUSION

In comparison to previous studies[4], the results of these current evaluations strongly reflect the evolving trend of improved design conformity. They are indicative of attempts to increase congruity in metal-backed acetabular components.

Polyethylene wear is a multi-factorial problem. The increased shell/liner conformity realized in the designs studied is a factor which will contribute to debris reduction in metal-backed acetabular components.

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

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