The Dangers of Big Femoral Heads on Thin Polyethylene: The Missing Part of the Equation

INTRODUCTION

In today's total hip arthroplasty market there is a trend of increasing femoral head size in bearing couples including ceramic-on-ceramic, metal-on-metal and either metal- or ceramic-on-polyethylene. A larger femoral head has many potential advantages such as increased stability and increased range of motion (ROM), which reduces the risk of impingement and dislocation.[1] However, these advantages are only one part of the equation.

A significant reduction in wear rate (10-95 percent) has been reported for a given head size with the introduction of highly crosslinked polyethylene (HXLPE) materials versus conventional polyethylene articulations (PE).[2,3,4] The improvements in stability and observations of lower wear rates with large heads on HXLPE, as compared to a 28mm head on standard PE, has led to the increased acceptance of these bearings.[5] Unfortunately, the appeal of decreased wear and increased stability has led to the trend of implanting larger-diameter heads in smaller-diameter acetabulae without full regard for the resulting very thin HXLPE liners. For example, Figure 1 shows the resultant thickness of a PE liner in a 48mm outer diameter cup with a 36mm femoral head. The resultant PE thickness is approximately 2.5mm, which is significantly less than widely accepted PE thicknesses and thus poses new risks for the construct.

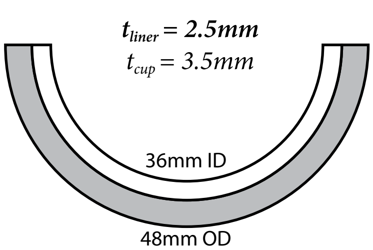

Figure 1: Schematic of 36mm ID liner in a 48mm OD cup

Exactech's position is to develop products that maximize range of motion, stability and longevity through materials and design while not sacrificing other important desirable attributes in total hip arthroplasty.

HISTORY

Attention to geometry and materials is key to kinematic performance and longevity. Much has been learned over time regarding these matters.

Polyethylene Thickness:

In 1985, Bartel and Burstein published a paper defining the minimum thickness of conforming (hip) and non-conforming (knee) polyethylene components.[6] Based on finite element analysis, they concluded that for conforming surfaces, polyethylene with thicknesses <4mm can result in excessively large contact stresses. Additionally, the International Standards Organization (ISO) recommends a minimum PE thickness of 6mm.[7] When contact stresses increase, wear rates and risk of mechanical fracture increase. This classic paper and the ISO standard are widely used and referenced for implant design.

Wear Rates:

Highly crosslinked polyethylenes were developed to reduce the incidence of wear-particle induced osteolysis with wear reductions of up to 95 percent being reported. This crosslinking is achieved with increased dosage of Gamma Radiation. Unfortunately, the increase in Gamma dose and associated decrease in wear rate is associated with the degradation of other mechanical properties including a decrease in tensile yield strength and fracture toughness.[5]

Polyethylene Fracture:

Design and material properties greatly affect the potential for fracture. Fracture toughness (the ability of a material to resist crack propagation and fracture), load application, and PE thickness and the resulting stresses seen in the component are all very important to implant performance. Designs must accommodate the reduction in fracture toughness and thickness limitations. For example, fully supported (i.e., non-rim loaded) liner designs of adequate thickness and sufficient fracture toughness are less likely to fracture because they will not be subjected to stress "risers" along the rim under physiologic loading. Figure 2a shows schematics of a rim-loaded and rim-locked design and Figure 2b shows Exactech's fully conforming, non rim-loaded design with apical locking mechanism.

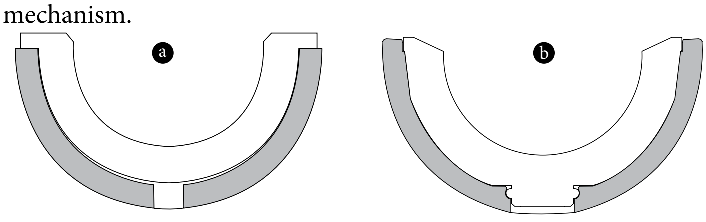

Figure 2: (a) Representative rim-loaded and rim-locked design. (b) Exactech's fully conforming, non rim-loaded design with apical locking mechanism.

Exactech's design provides an apical locking mechanism and fully conforming liner to cup interface. The rim of the liner does not experience excessive loading. In rim-loaded designs, the rim of the liner is carrying most of the load, and cracks initiate and propagate at the rim/cup interface (*Figure 3*). The rim crack will propagate to failure quicker as the thickness of the liner decreases.[8,9]

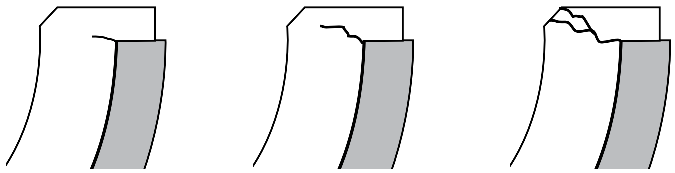

Figure 3: Detailed schematic of rim-loaded crack initiation and propagation to failure

What have we learned to help us understand improving implant longevity? Geometry **AND** material properties are key.

↑ head size = ↑ wear rates

↓ thickness = ↑ wear rates

↑ crosslinking = ↓ wear rates

↑ crosslinking = ↓ mechanical properties

The Industry Equation becomes:

Highly Crosslinked PE = *Lower Wear Rates* ➔ *Larger Diameter Heads on Thin Polyethylene*

The thought is that in smaller cups, a bigger head can be used because the significant decrease in wear rate makes up for the increase in head size and decrease in liner thickness.

The industry logic is missing part of the equation. Only one factor is considered and the other factors are assumed negligible or ignored. When Exactech analyzed thin PE liners, it was determined that the risks of wear and fracture were increased. The "Missing Part of the Equation" shows that when **ALL** the variables are considered, new risks for the construct arise.

Missing Part of the Equation:

Highly Crosslinked PE = *Lower Wear Rates* + *Reduced Mechanical Properties* ➔ *Larger Diameter Heads on Thin Polyethylene* ➔ *Potentially Higher Wear Rates and Increased Risk of Catastrophic Fracture*

CONCLUSION—THE EXACTECH SOLUTION

Exactech utilizes proven principles and design concepts that have been clinically successful. We believe that by maintaining these proven concepts (an appropriately sized femoral head, enhanced material and component design), our products for THA will allow the surgeon to get the stability, range of motion and longevity they expect from a modern-day implant while not introducing variables that may have undesirable effects on their patients.

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