A NEW APPROACH TO BEARING SURFACES FOR TOTAL HIP ARTHROPLASTY

by

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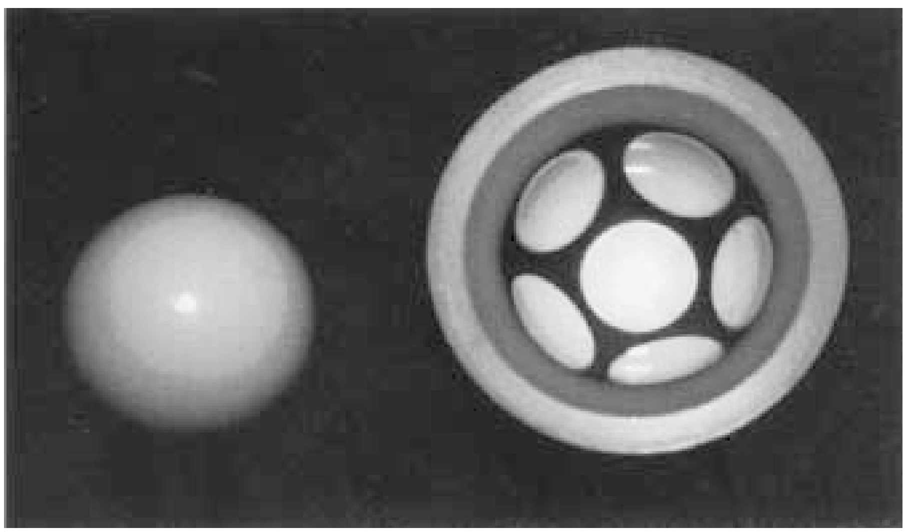

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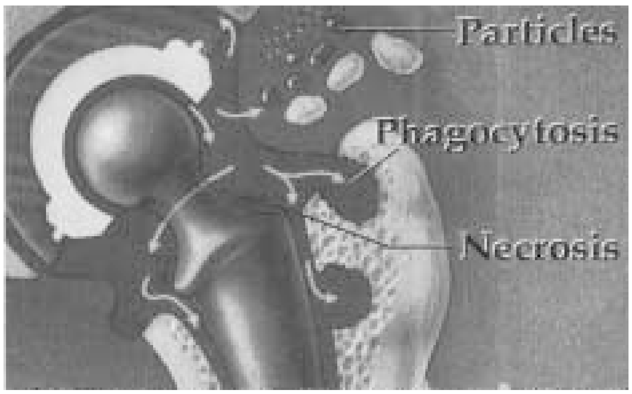
INTRODUCTION

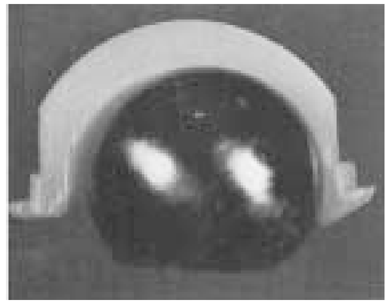
The most common cause of proximal femoral bone loss is due to osteolysis.' Although the specific cause of lysis in THA is not known, it has been attributed to a variety of factors, including motion of the implant and foreign body reaction to particulate debris, in particular to polymeric debris. It has been almost two decades since Willert first described the problem of polyethylene wear leading to



Osteolysis

periprosthetic inflammation, granuloma, bone resorption, and implant loosening.' Since then, many studies have documented the finding of particulate bone cement and polyethylene in periprosthetic tissues.[3,4]

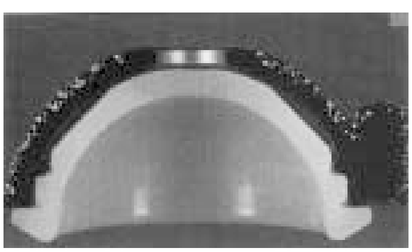
In normal wearing artificial joints, linear wear rates of 0.05-0.2mm per year result in the generation of about 25-100 mm 3(25 to 100 mg) of polyethylene debris annually. 5,1 On a basis of known dimensions of polyethylene particles found in tissues around hip prostheses, this equated to the annual production of tens to hundreds of billions of particles.



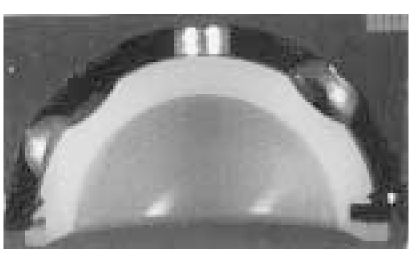
Excessive Wear

Variations of polyethylene wear rates probably relate to acetabular implant design,' femoral head size, 8 femoral head material,' and at least in part to the quality of the polyethylene used.. Wide variations are known to exist between i batches of polyethylene and between different polyethylene suppliers.

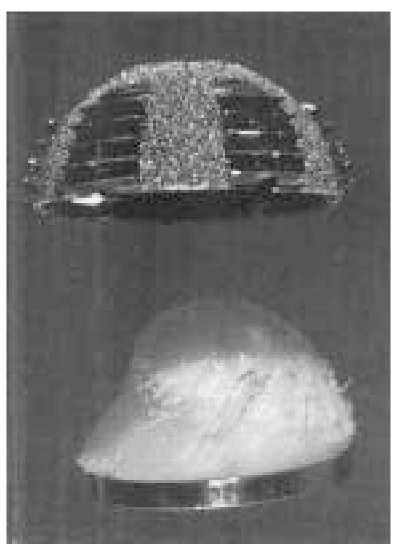
Examples of Design Flaws



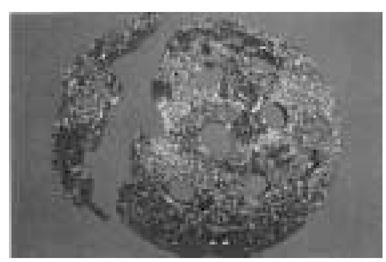
Examples of Poor Contact of Liner With Metal Cups



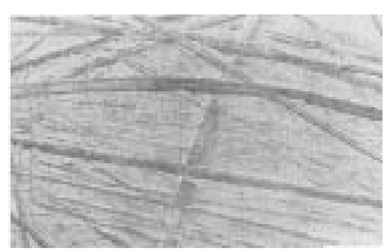
Examples of Failures



Constrained Socket



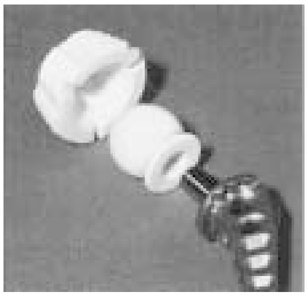
Fiber Mesh Cup



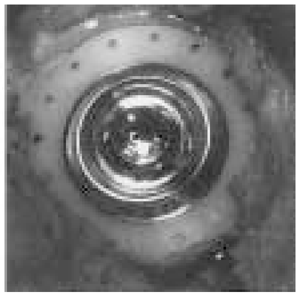
Increased Wear of Poly Cups

REVIEW

Based on favorable clinical trails in Europe during the past decade, improved ceramic-on-ceramic and metal-on-metal bearing combinations have been renewed as possible solutions to the problem of polyethylene wear.



Ceramic Articulation Mittlemeier Design

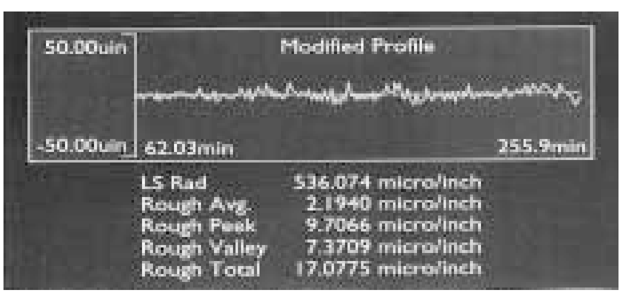


Metal Articulation Cup Design

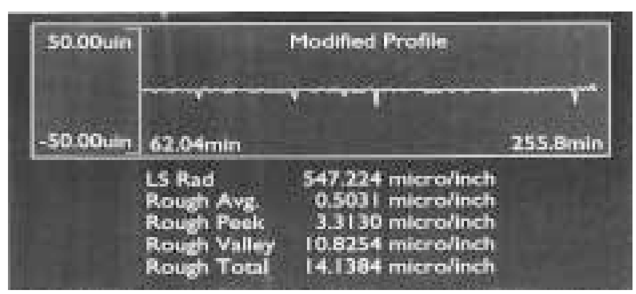
Ideally, the bearing surfaces for most sliding, rotating, or articulating bearing surfaces systems will be made from material having relatively high strength, high wear, and corrosion resistance, a high resistance to creep, and low frictional moments. However, in reality no one material presently exhibits all of these characteristics.

Ceramics have characteristics which are very desirable for use in sliding, rotating, and articulating bearing systems.”,” In addition to high compressive strength, they exhibit high wear and corrosion resistance with relatively low frictional moments. However, use of such ceramic materials in bearing systems has been inhibited because such materials are susceptible to fracture due to their relatively low tensile and shear strengths. This weakness of ceramic materials is one reason Why metal and/or polymeric materials have been used for many bearing surfaces.

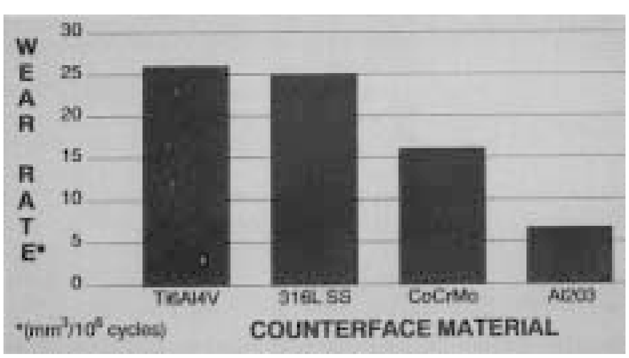
Compared to bearing ceramics, bearing metals and polymers typically have lower wear and corrosion resistance or resistance to creep and higher frictional moments. In bearing -systems where ceramics have been used, their low tensile and shear strengths often force the adoption of costly design compromises. Thus, one design compromise has been to make the entire bearing component rather than just a portion thereof out of solid ceramic, thereby



Surface Roughness: CoCr

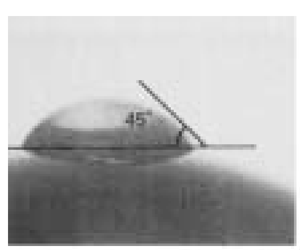


Surface Roughness: Ceramic

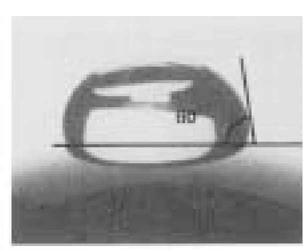


Wear Rates

Ceramic

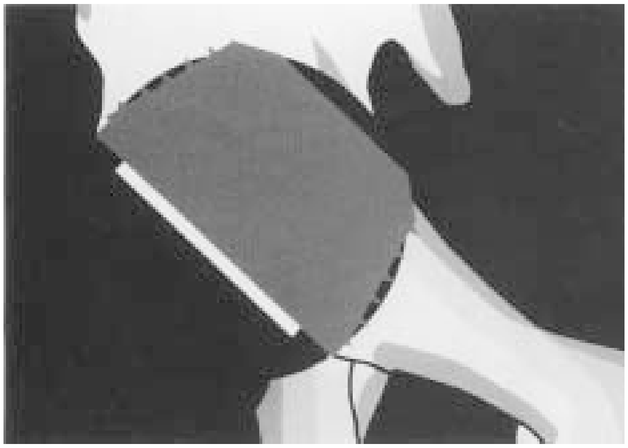


Metal



Surface Wettability

increasing the amount of ceramic used and, therefore, effectively increasing the structural strength of the bearing surface .12 Such a solid ceramic bearing component can be larger and bulkier than its metal and/or polymeric counterpart.



Ceramic Truncated Cone Design

Making an entire bearing component, like the acetabular cup, out of solid ceramic helps to compensate for the relatively poor tensile and shear strength typically found with ceramics. Also, because bearing ceramics are typically inflexible, additional manufacturing quality control of the geometry of both articular surfaces must be maintained in order to maximize the contact area between the two surfaces. If tight control is not maintained, point contacts may develop between the bearing surfaces. As the contact area between two bearing surfaces decreases, the stress that is transmitted between the surfaces increases. This can result in greater wear and increased possibility of fracture of one or both surfaces.

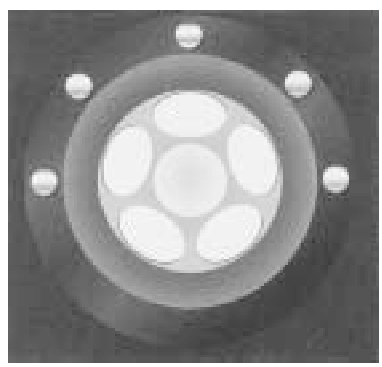
In the past one solution to this problem has been to manufacture prosthesis with matching pairs of heads and cups. However, this solution is not only costly due to maintaining the quality levels required, but are additional inventory costs while making surgical intervention more difficult.

INTRINSIC™ SEGMENTED CERAMIC CUP DESIGN

This paper will review one such concept of ceramic-on-ceramic articulation for use in total hip arthroplasty

In an attempt to address these real life problems, a segmented ceramic bearing system has been developed. This segmented bearing system provides ceramic surfaces for mechanical bearings that would apply loads over a greater bearing surface area, resulting in i reduced bearing stresses and, in turn, reduce creep, wear, and likelihood of fracture of the bearing surfaces.

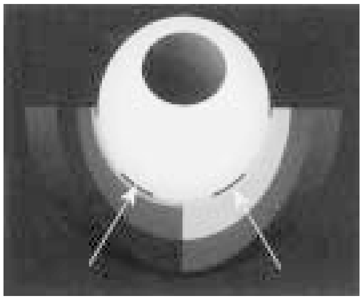
The acetabular component is designed with several ceramic articular segments that are backed and held in a pre-determined pattern and configuration by either polyetheretherketone or polyethylene. Both of these materials, have a lower elastic modulus than the segmented ceramic material. In addition, the polymeric material is reduced in height so that only the segmented ceramic material articulates with a ceramic femoral head.



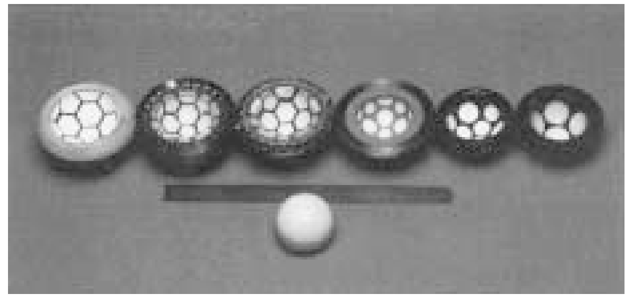
lntrinisic™ Segmented Ceramic Cup

Because of its resilience and lower elastic modulus, the polymeric material flexes as loads are transmitted between bearing surfaces while the shape of the surfaces of the segments remain relatively unchanged. This freedom of movement of the segments, under an applied load, allows for greater contact area between bearing surfaces because the segments as a group are able to conform to the geometry of the opposing bearing surface. Thus, rather than having highly localized stress concentrations typically occurring in bearing systems, any applied load is shared by a number of segments which result in lower stress being applied to the bearing surfaces and each segment.

An additional feature of this design is the formation of channels generated by locating the polymeric material slightly below the surface of the ceramic segments for lubrication and for allowing debris that finds its way into the bearing to either pass between the segments or be trapped in the polymeric material.



Lubrication Channels

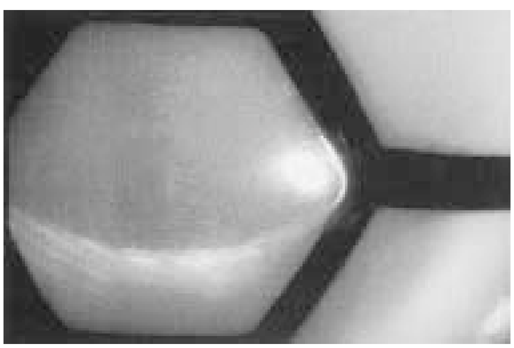


Segmented Evolution

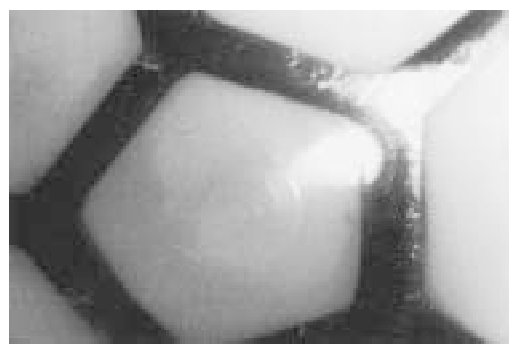
This concept has evolved over the past five years from the ceramic in a hex shape imbedded in polysulfone to a current design that is circular imbedded in either polyetheretherketone or polyethylene."

TESTING

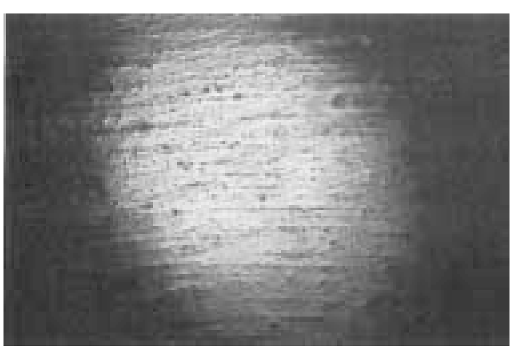
Post-fatigue testing (10 million cycles) has demonstrated no significant mechanical failures of the grout material (polysulfone) or of the ceramic bearing. SEM evaluations did demonstrate a small micro fracture within the grout and a polishing effect on the ceramic bearing surface.



Hex Design Pre-Test



Hex Design Post-Test



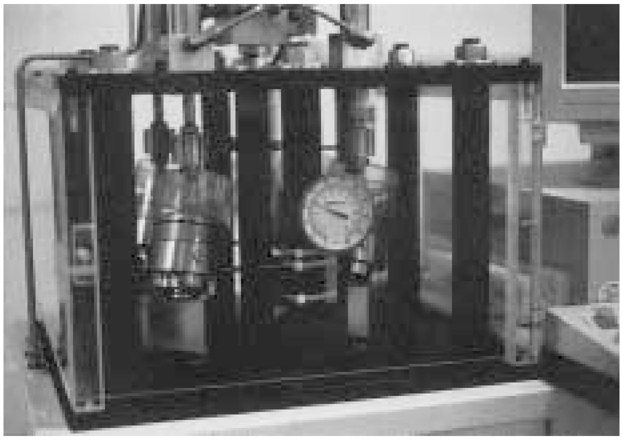
500X Pre-Test

500X Post-Test

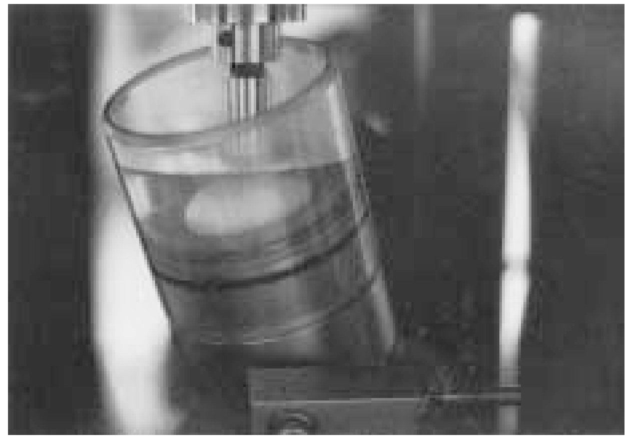
This test suggests that the bearing surface might benefit from pre-cycling to reduce initial ceramic debris.

Ongoing wear testing comparing different grout materials (peek and poly) on a P.M. state-of-the-art wear tester in conjunction with contact area and finite element analysis studies will help to determine the value of this design.

To date we are optimistically encouraged by the preliminary work concerning this unique approach. However, only additional solid basic science results can justify in-vivo clinical evaluation.



P.M. Wear Tester



Cup Being Tested

SUMMARY

Intrinsic™
Segmental Ceramic Bearing Surface

Hemispherical Design
High Wear Resistance
Low Friction
High Compression Strength
Greater Bearing Surface Area
Self-Adjusting Design (Lower Surface Stress)
Lubrication Channels
Cost Effective

Note: This device is not available for commercial use.

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