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stryker®

Orthopaedics

Trident®
Ceramic Acetabular System
Technical Monograph

Introduction

Clinical research and laboratory testing have demonstrated the benefits of ceramic-on-ceramic bearings in THA. Among these benefits are the low level of gravimetric wear and higher resistance to scratching from third body particles.[1] Other benefits of ceramic-on-ceramic for hip replacement include biocompatibility and reduced friction.

The Trident® Acetabular System is Stryker Orthopaedics' flagship acetabular cup system. The Trident® Shell is a multi-bearing design, which allows it to accept either polyethylene or ceramic liners. This is accomplished by incorporating two independent locking mechanisms in the shell. In the specific case of ceramic inserts, a patented titanium sleeve encases the alumina. The titanium sleeve and shell have mating tapers, which allow the alumina insert to securely lock within the shell. In addition, there are anti-rotation tabs for rotational stability. This design, when coupled with Stryker stems, protects the alumina from impingement against the neck of the femoral stem, **Figure 1**.

The titanium sleeve provides many benefits to the System. The titanium sleeve:

- **Strengthens the insert by 50%** - The titanium sleeve keeps the alumina in compression, which strengthens it.
- **Protects the ceramic from impingement on the femoral stem –** Impingement on the stem may lead to ceramic fracture or scoring of the femoral neck.
- **Protects the ceramic from chipping during insertion** – The titanium sleeve has eliminated the intra-operative chipping that was observed in earlier generation ceramic inserts.*
- **Allows for liner exchanges**

The following pages present the research and development work behind the Trident® Acetabular System as it relates to the titanium sleeve of the Trident® Ceramic Insert.

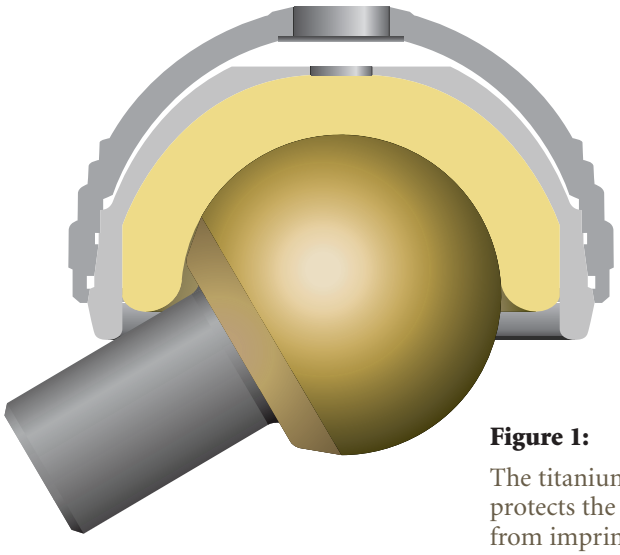


Figure 1:
The titanium sleeve protects the ceramic from impringement on the femoral neck.

Push-Out Testing of the Trident® Ceramic Insert

The Trident® Ceramic Inserts are unique in design. Induction-heating methods are used to assemble the ceramic liner to a titanium sleeve at the factory, thus allowing the insert and sleeve to be sold as a single unit. The induction-heating assembly method ensures an adequate press-fit and secure lock of the liner in the sleeve.

Push-out testing was performed to ensure the integrity of the component. Axial loads were applied at a rate of 1.27mm/minute to the ceramic insert through the apical hole in the sleeve. The ceramic insert began to slide at 10.2 kN +/- 1.9 kN. Once sliding began, loads in excess of 12 kN (2,300 lbs) were needed to keep the inserts sliding within the sleeve. **Figure 2** shows a typical set of data.

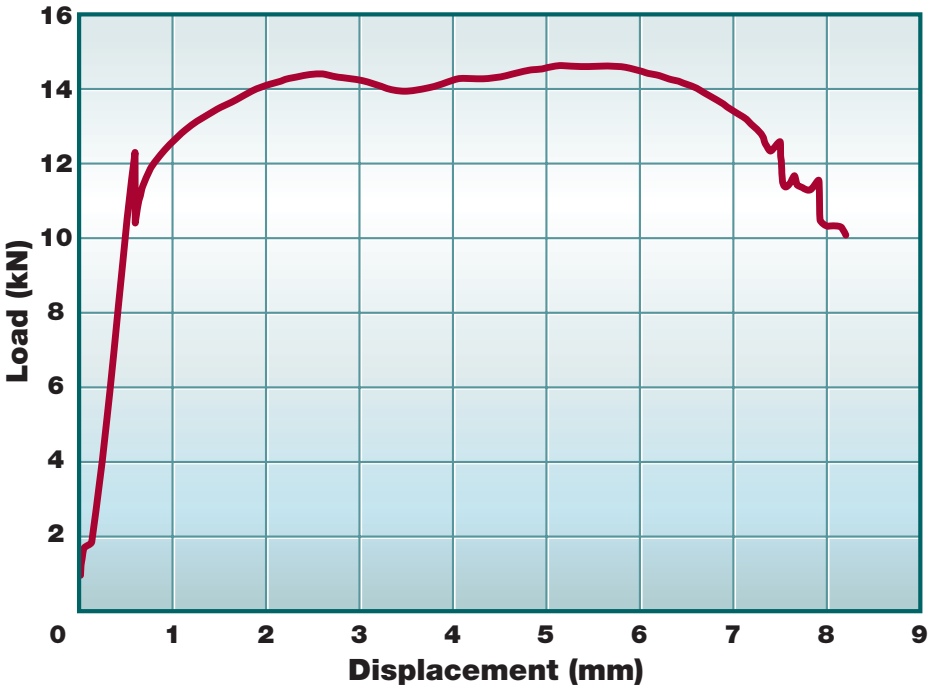


Figure 2:

A typical graph showing that a level in excess of 12kN was needed to slide the insert within the sleeve.

Push-Out Testing of the Trident® Ceramic Insert from the Shell

Modularity of orthopaedic implants is widely accepted and provides benefits including intra-operative flexibility. While rare, disassociation of a modular acetabular liner from a metal-backed acetabular shell has been reported in clinical literature.[2,3,4] While push-out testing does not re-create the *in-vivo* load environment, it does allow for comparison between locking mechanism designs.

Trident® Ceramic Inserts were assembled to Trident® Acetabular Shells using 450 lbs. of axial force. Testing was performed by applying direct compressive force to the ceramic insert to disassociate the components, **Figure 3**.

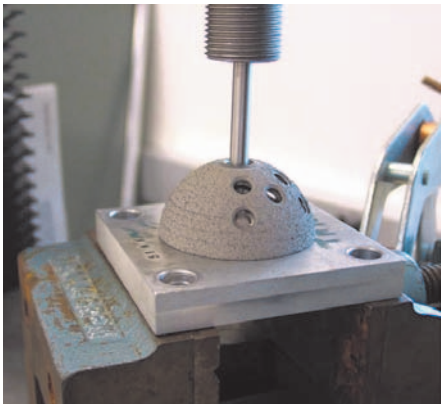
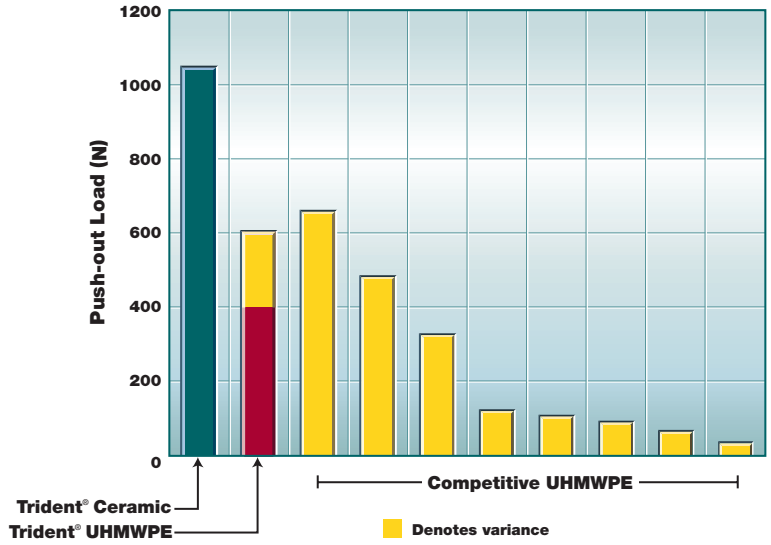


Figure 3: Push-Out test setup.

Results of the testing indicated that the force necessary to remove the ceramic liner from the shell was 1.1 kN (247 lbs.). This represents 55% of the insertion force. For Trident® UHMWPE liners, the average recorded push-out loads range from 400 to 600 N (90 to 135 lbs). In the case of the Trident® Ceramic Insert, the push-out load required to disassociate the liner from the shell was greater than that of several commercially available acetabular cup systems, **Figure 4**.[5,6] This data supports that the use of the dual locking mechanisms incorporated in the Trident® Acetabular System ensure the integrity of both the alumina ceramic and UHMWPE inserts.

Figure 4: Push-Out test comparison.

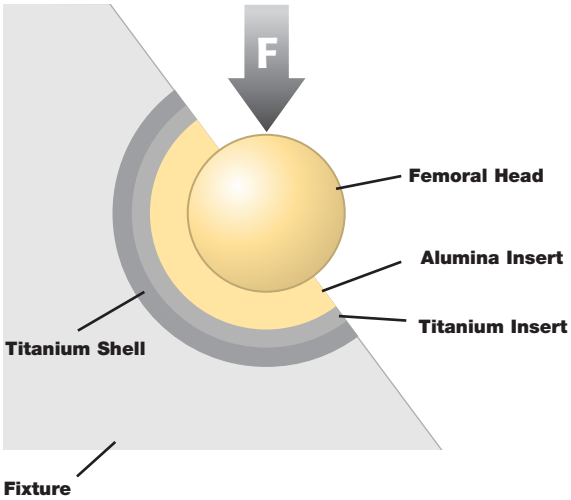


Anatomic Fatigue Strength Testing of the Trident® Ceramic Insert

Gait studies typically predict hip joint loads of two to four times body weight for healthy subjects during normal daily activities.[7,8] Academic literature on THA suggests that the typical patient body weight averages 76 Kg (168 lbs), with a maximum of 130 Kg (287 lbs)[9,10,11,12,13] while our in-house data indicates that the average weight for patients receiving THA ranges from approximately 45 Kg (100 lbs) to 118 Kg (260 lbs). Using this data, the expected minimum loads during normal daily activities should range from 1494 to 2987 N (336 to 672 lbs) and maximum loads should range from 2,551 to 5,103 N (574 to 1,148 lbs).

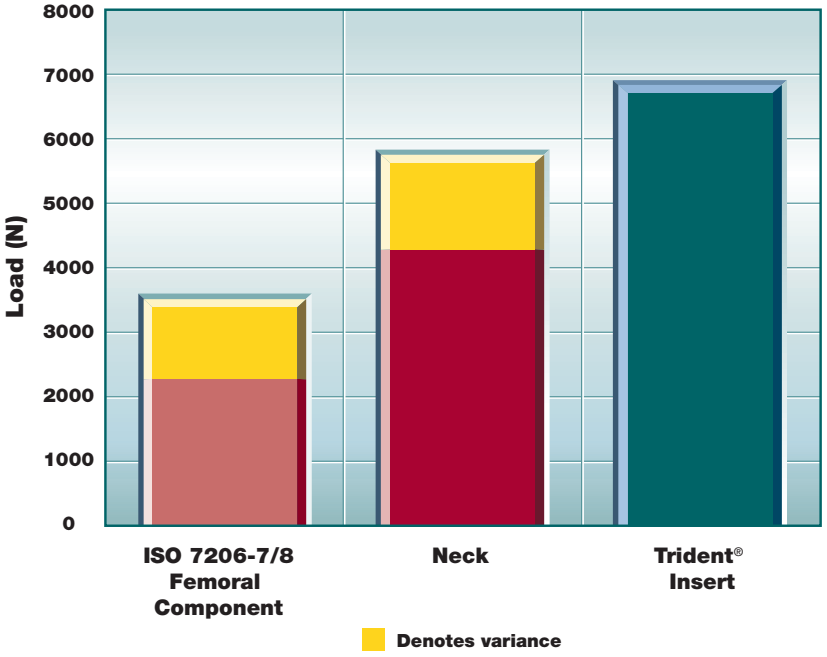
ISO Standards (7206-7 and 7206-8)[14,15] for fatigue testing of stemmed femoral components specify that a stem should be tested with joint loads of 3300N (742 lbs) and 2300N (517 lbs), respectively. Fatigue testing was performed on the Trident® Ceramic Insert to evaluate the strength and structural integrity of the component, **Figure 5**. Axial compressive force was applied at a rate of 10 Hz. Testing began at 5338N(1,200 lbs). All tests were run for 10,000,000 cycles in saline.

Figure 5: Schematic showing test setup.



Test results showed that the fatigue strength of the Trident® inserts is greater than 6,668 N (1,500 lbs). This result, when compared to expected physiological load levels as observed in the literature and present performance standards for metallic femoral components, indicates that this design has exceeded requirements for safe implantation, **Figure 6**.

Figure 6: Fatigue Strength Comparison



Strength Testing of the Trident® Ceramic Insert

In accordance with ISO[16] and the present ASTM draft standard for the evaluation of ceramic femoral heads, the test methods used include Ultimate Compression Strength Testing (UCS), Axial Fatigue Strength Testing, and Post-Fatigue Ultimate Compression Strength Testing. The Trident® Ceramic Insert was developed to meet and/or exceed these performance criteria.

UCS Testing:

UCS testing was first performed with the ceramic insert assembled within the Trident® Acetabular Shell, **Figure 7**. A second test of the ceramic inserts in test nests was also performed, **Figure 8**. The results yielded UCS values ranging from 55 kN to 70 kN (12,370 to 15,750 lbs).

Results of UCS testing in the Trident® Acetabular Shells yielded insert strength values greater than 80 kN (18,000 lbs), **Figure 9**. The UCS testing was stopped due to a breakage of the steel plate on the machine that supported the acetabular shell.

Axial Fatigue Strength Testing/ Post-Fatigue UCS Testing:

Axial fatigue testing was performed with loads ranging between 1.5 to 15.6 kN (350 to 3500 lbs.). All heads and inserts tested in axial fatigue survived ten million cycles of loading in a test nest (**Figure 8**).

All ceramic inserts that passed the fatigue test were UCS tested per above. Post-fatigue UCS values were all greater than 46 kN (10,350 lbs).

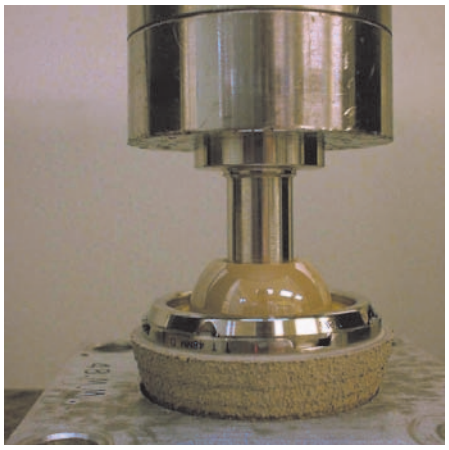


Figure 7:
UCS test setup in Trident® Shell.

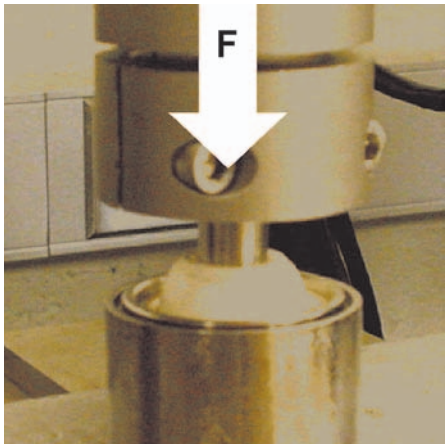


Figure 8:
UCS test setup in testing nests.

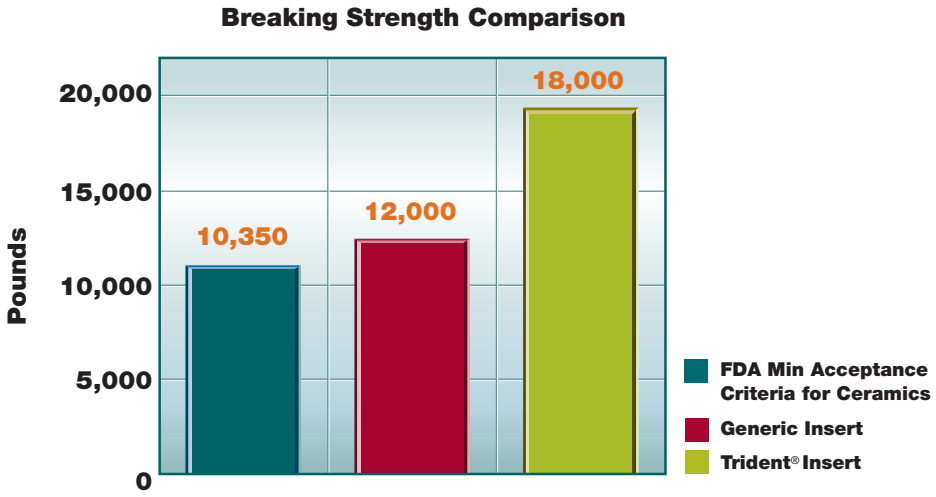


Figure 9:
The Trident® Ceramic Insert is 50% stronger than a ceramic insert without the titanium sleeve.

Fretting Fatigue and Corrosion Testing of the Trident® Acetabular System

Recent laboratory studies have shown that implant material and implant design play a key role in the amount of fretting and therefore corrosion that occurs at the modular interfaces.[17, 18, 19] Design features that minimize the amount of motion, and subsequently fretting, at the taper interface should reduce the corrosion potential.

The Trident® Acetabular System was tested to evaluate the metal/metal interface taper lock when the shell is coupled with the ceramic liner. Testing included high cycle/short timeframe fatigue testing to evaluate fretting and high cycle/long timeframe fatigue testing to evaluate corrosion at the metal/metal interface.

All samples, in all tests, successfully completed 10,000,000 cycles of fatigue loading without failure in a saline environment. Inspection of both the fretting and corrosion fatigue components showed minimal amount of fretting to have occurred in all components.[20, 21, 22] All components were easily disassembled using Trident® instrumentation. In addition, no indication of galling (cold weld) was present.

These results indicate that for up to ten million cycles, or ten years of simulated clinical use, a stable interface exists between liner and shell.

Components were further evaluated for corrosion and fretting damage using a scanning electron microscope (SEM) and energy dispersive spectroscopy unit. Typical photographs of the acetabular liners are shown in **Figure 10**. The microscope evaluation indicated that regions of damage were minimal. In general, machining lines were undamaged. Where damage was found, it was generally of small regions consisting of scratching and smearing of the material. In no case was there evidence of corrosion.

It can be concluded that fretting and corrosion damage to the Trident® metal interfaces should not be an issue clinically.

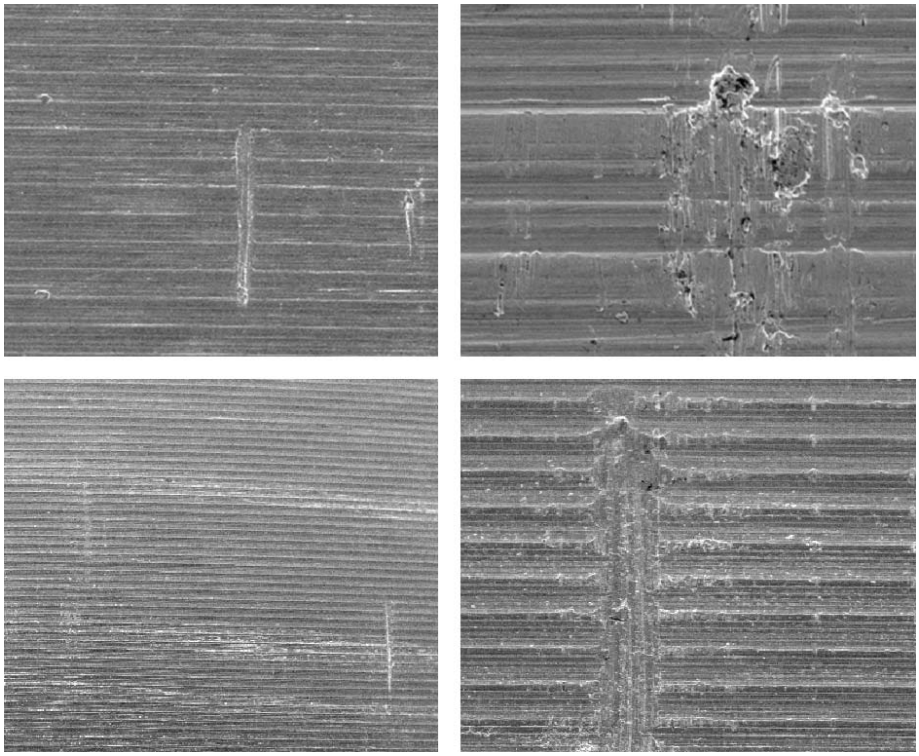


Figure 10:

The Trident® Ceramic Inserts show minor scratching and smearing of material. No corrosion degradation is visible.

Neck Impingement Study

The intent of the titanium sleeve surrounding the ceramic insert is to protect the ceramic insert and the femoral neck should any impingement occur clinically. Ceramic is an extremely hard material and may damage the femoral neck of the stem after repeated contact.

Testing was performed to determine the amount of damage sustained by the neck region of a titanium alloy implant if metal/metal or metal/ceramic impingement occurred. To determine the potential clinical damage to the femoral neck, a series of fatigue tests were performed. The fatigue testing subjectively evaluated the damage to the neck region of a titanium alloy femoral component when coupled with a Trident® (metal/metal impingement) insert. Additionally, testing was performed to determine the damage to the neck region when metal/ceramic impingement occurs. A photograph of the test set-up is shown in **Figure 11**.

The acetabular insert was mounted directly to the base of the lower holding fixture. An alumina femoral head was assembled to a femoral component. The femoral head was mounted between the upper and lower holding fixtures and clamped to the base of the test machine. A load of 1334N (300lb) was applied. This load equates to a 2669N (600lb) load at the neck impingement point. A total of 10,000,000 cycles were applied to all components.

Upon completion of testing, the damage to the neck region of the femoral components was assessed using visual and microscopic (SEM) evaluation. While the results of metal/metal contact show marking on the femoral neck, **Figure 12a**, the ceramic/metal contact shows more severe damage to the femoral neck, **Figure 12b**.

Results show that during ceramic/metal impingement, the neck of the femoral component is indented by the ceramic component. The shape of the indentation matches the geometry of the ceramic component. This result was expected, as the ceramic acetabular insert is significantly stiffer than the femoral component. For the metal/metal impingement areas of contact are visible, but little to no indentation is seen in either the femoral component or acetabular insert.

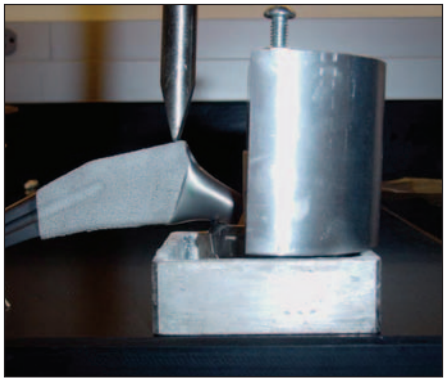


Figure 11:

Photograph of Neck Impingement Test Set-up

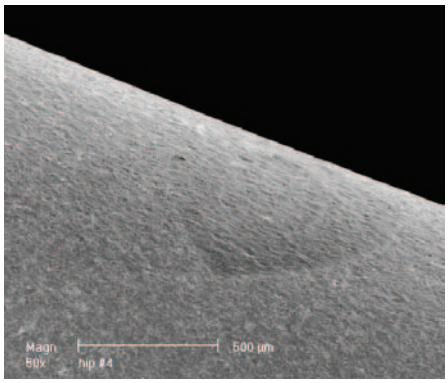


Figure 12a:

Femoral neck after impingement with Trident® Sleeve (magnified 50X)

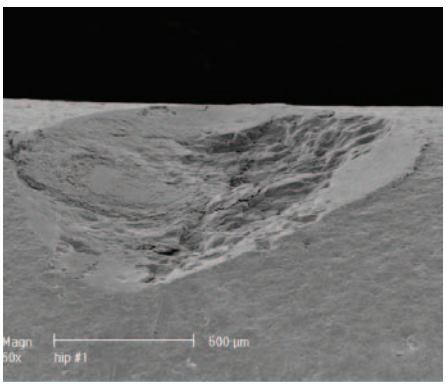


Figure 12b:

Femoral neck after impingement with ceramic (magnified 50X)

Acetabular Shell/Bone Interface Stresses

The Trident® Acetabular System accepts both polyethylene and alumina ceramic liners. To investigate the effect of liner material on shell/bone interface, a two-dimensional axi-symmetric finite element analysis was performed. Additionally, the effect of using a stiffer CoCr alloy acetabular shell was investigated. The finite element model is shown in **Figure 13**. Maximum principal stress contour plots were also charted for the Trident® Acetabular System. For all cases, the stress magnitude and distribution in the bone remained consistent, **Figure 14**.

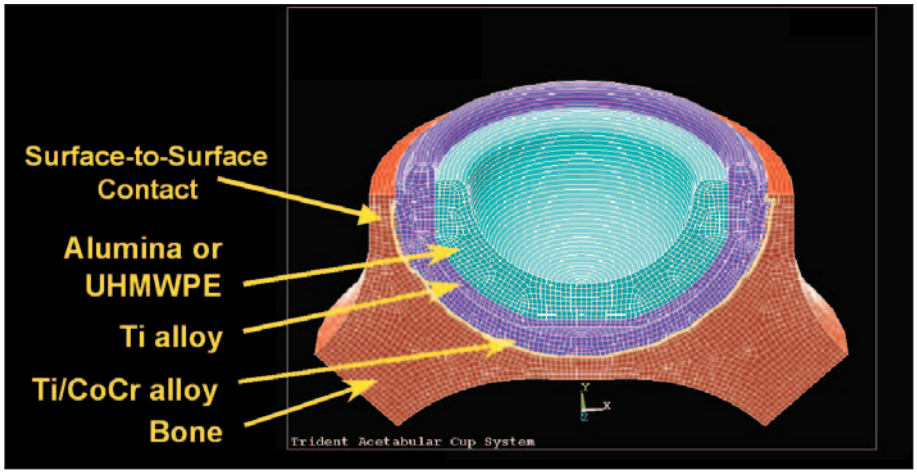


Figure 13: Finite Element Model

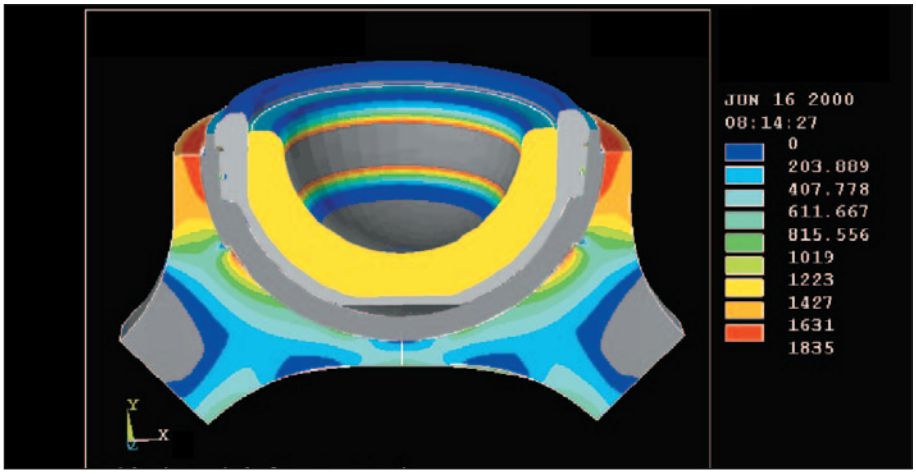


Figure 14: Stress distribution for Trident® Acetabular System

Figure 15 shows a comparison of the highest maximum principal bone stress calculated for each cup configuration. From this chart, it can be seen that there is little difference between UHMWPE and ceramic inserts on the shell/bone interface. It can therefore be concluded that neither of the variables significantly affect the stress in the underlying bone. The outer geometry of the Trident® shell design is the most significant design factor when looking at bone interface stress. Changes in the overall stiffness of the cup had little effect on bone stress magnitude and distribution.

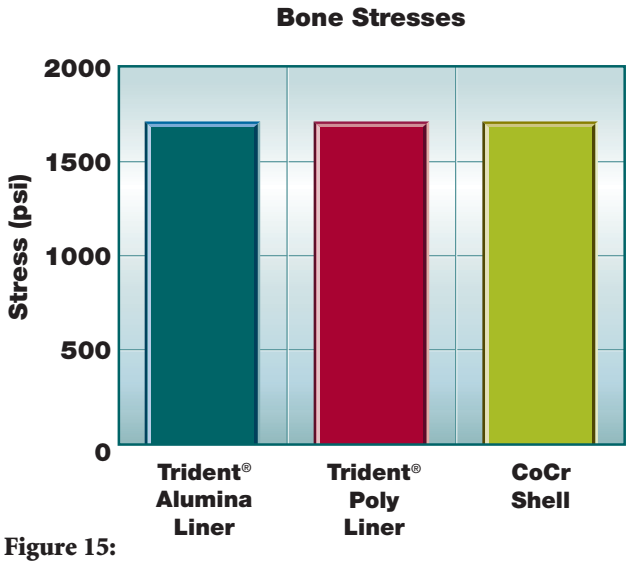


Figure 15:
The maximum principal stress was the same for the entire Trident® Acetabular System.

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U.S. Pat. 6,475,243

* In the U.S. IDE Clinical Study there were no instances of intra-operative chipping with the Trident® Ceramic Insert.

Notes

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