An Analysis of Conformity Between Components in Modular Acetabular Cup Systems

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Summary: A number of studies have noted the importance of conformity and congruency between the components of modular acetabular cup systems.[1-4] A series of tests was conducted to examine the conformance of components in two modular acetabular cup systems in response to concerns of polyethylene wear raised in a comparative study at the UCLA Medical Center. The systems examined in this test series included components identical to those used in the UCLA study from the Richards Reflection Acetabular System and the Zimmer *Trilogy*™ Acetabular System*.

The tests included static and dynamic compression loading of cups to determine the area of contact between the outer dome of the liner and the inner surface of the acetabular shell. Contact was indicated by the transfer of nondrying Dykem ink from the inner shell surface to the liner.

The results of this test series show that all of the Reflection Microstable acetabular liners examined in this study failed to bottom in the mating metallic shell. Static loads of 150 pounds to 200 pounds were required to force contact between the modular components. The *Trilogy* liners bottom solidly and made good contact at all of the load levels tested.

The current scientific literature stresses the importance of conformity and congruency between components of modular acetabular cup systems. The UCLA study suggests many unanswered questions including the meaning of gold sputtering and its subsequent removal. The real significance may be better related to surface contact and congruency.

Background

A UCLA Medical Center study entitled *Deformation Patterns and Frictional Torque in Modular Acetabular Liners* was presented at the 1994 AAOS. According to this investigation, recent retrieval studies have noted polyethylene wear at the interface between the convex surface of the liner and the concave surface of the metal shell in modular acetabular components[5]

The purpose of that study was to determine the effect of cyclic compression on wear patterns at the liner/shell interface. To enhance visualization of the "wear" pattern, the investigators deposited a thin sputter coating of gold on the convex surface of the polyethylene liner. After cyclic compression testing to 10 million cycles (Mc), the liners were disassembled from the shell to examine the gold coated surface. Any detached gold coating was considered to be the result of wear between the two apposing surfaces.

The study found that, in the case of the *Trilogy* Acetabular Cup System, an average of 23 percent of the gold coating was removed. This compares to an average of 1 percent gold coating removal in the case of the Reflection Acetabular Cup System. There was no analysis of this raw data included in the report. Additionally, there was no data supplied to support the validity of gold coating removal as a measurement of wear or to define the proper test parameters.

Materials and Methods

Three Reflection cups and four *Trilogy* cups were submitted to the Zimmer Fatigue and Fracture Mechanics Laboratory for evaluation of the sputter coating test method used in the UCLA study. Both styles had screw holes in the superior aspect; three in the *Trilogy* shell and five in the Reflection shell. The four *Trilogy* cups consisted of two "older version" cups, identical to those used in the UCLA study, and two "newer version" cups. The new version of the *Trilogy* cup had a fine machine finish on the inner shell surface rather than a polished, reflective surface typical of the older version. The new version also had an added interference fit between the liner and shell. The liner diameter between the lip and locking ring groove was oversized to create the interference fit. The differences in the two cups were significant enough to warrant testing of both designs.

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U.S. Patent 5,383,938

The acetabular shells were potted in bone cement to a depth of approximately 0.75 inches above the pole. To determine the contact area between the components under a dynamic compressive load of 500 pounds a layer of non-drying Dykem ink paste was spread on the inner surface of the metal shell. The ink paste was spread very thin and transferred readily to any contacting surface. An attempt was made to measure the thickness of the ink paste coating using a Perthen SP8 perthometer (surface roughness measurement system) with a noncontacting Focodyne sensor. Scans of the transition from an uncoated to a coated surface revealed that the coating was too thin to measure. This indicates that the coating was much less than 5 micrometers thick. The liners were then pressed into the shell until they seated securely. In the case of the Reflection cup, a distinct "pop" was heard when the friction fit locking mechanism seated in the shell. In the case of the *Trilogy* cup, the locking ring tabs visibly closed as the ring slipped into the mating liner slot and a distinct "snap" could be heard as well.

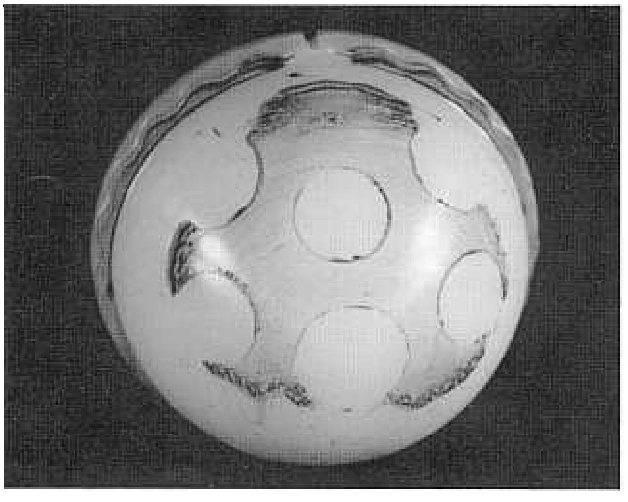

FIGURE 1

Reflection Liner with Dykem Impression From the Shell After Dynamic Loading to 100,000 Cycles

The assembled cup was then mounted in the test frame at an angle of 23° to the axis of the 28 mm femoral head used to apply the cyclic load. The cup was also oriented such that the screw holes were in line with the applied load. In accordance with the UCLA study, the load was cycled at 12 Hz from 50 pounds to 500 pounds. The test was run for only 100,000 cycles since the goal was only to obtain the estimated contact area between the components. The 100,000 cycles was subjectively selected to allow time for settling of the liner. Upon completion of the test, the components were disassembled to document the contact pattern obtained.

After completing a dynamic test of each cup system, the liner and shell were reassembled in the same manner as before and a static load of 50 pounds was applied as in the dynamic test (through a 28 mm femoral head at an angle of 23° to the axis of the articulating surface). The load was held for two minutes to allow for settling of the liner and then removed. The components were again disassembled to document the liner-shell contact pattern. This analysis was repeated at successive static loads of 100, 150, 200, 250, and 500 pounds with disassembly and documentation of the contact pattern after each static load.

Results

The contact area impression for the Reflection liner dome, shown in Figure 1, was estimated from hand measurement and calculation to be approximately 0.682 square inches. A computer controlled image analysis system calculated the dome contact area to be approximately 0.728 square inches. The latter value was accepted as more accurate. These estimates and all subsequent estimates of contact areas on the liner domes represent projected areas. As such, small errors due to curvature of the dome surface were neglected. A single circular contact impression was

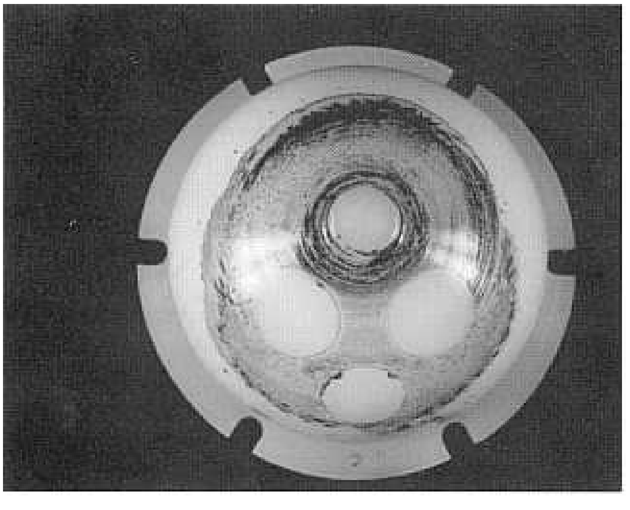

FIGURE 2

Trilogy Liner with Dykem Impression After 100,000 Cycles (polished shell)

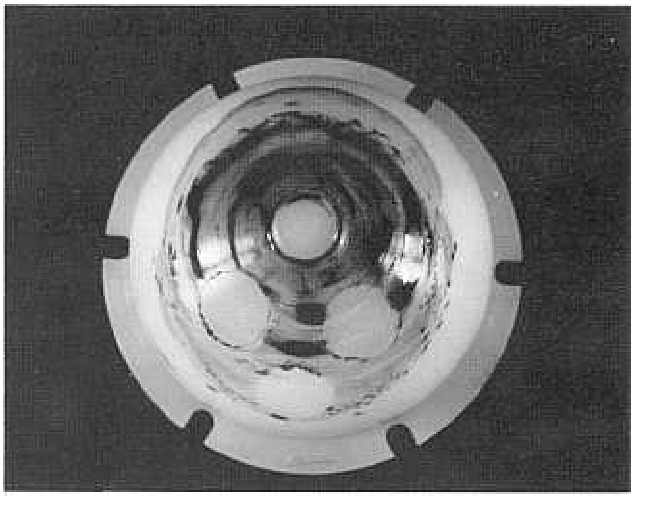

FIGURE 3

Trilogy Liner with Dykem Impression After 100,000 Cycles (machined shell) observed on the Reflection liner centered about an axis 23° off the pole and coincident with the axis of loading.

The dome contact area impression for the two *Trilogy* cup systems shown in Figures 2 and 3 was essentially equivalent. The impression area was estimated from hand measurement and calculation to be approximately 1.07 square inches. The image analysis system was not effective in estimating the *Trilogy* contact area impression because two distinct, intersecting, circular contact impressions were obtained. One circular contact impression was centered about the polar post of the liner. The second was centered about an axis 23° from the polar post and coincident with the axis of loading. The former impression was due to initial "zero load" contact between the components after they were pressed together. The latter impression was due to the cyclic load. These two areas could be separated with hand measurement of the diameter but accurate separation the two areas with the image analysis system was not possible without increasing the errors in calculation due to the curvature of the dome.

The static load testing results confirmed the observation made in the dynamic test results: the Reflection liners did not bottom in the mating shell when no load was applied. The results obtained from all three of the submitted Reflection cups were similar. Documentation, shown in Figures 4, 6, 8, and 10, from only one of the Reflection cups has been included in this report. The results from the three Reflection cups show that the liner does not make contact with the mating shell until 150 to 200 pounds of force is applied through the femoral head. In the successive static loads one cup, the one which had already been dynamically tested to 100,000 cycles showed no contact

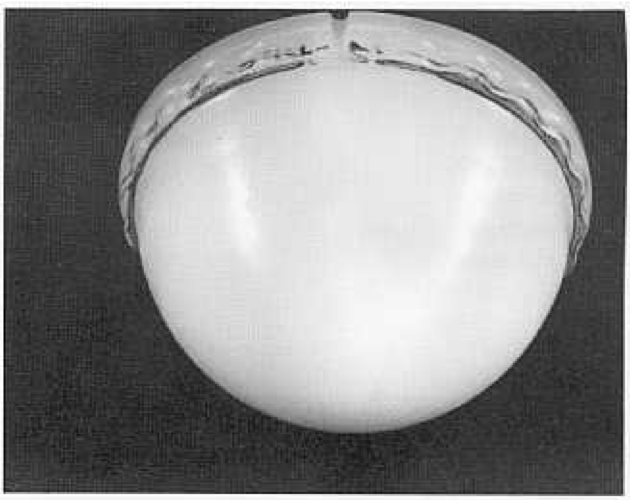

FIGURE 4

Reflection Liner with Dykem Impression After Being Pressed into the Shell

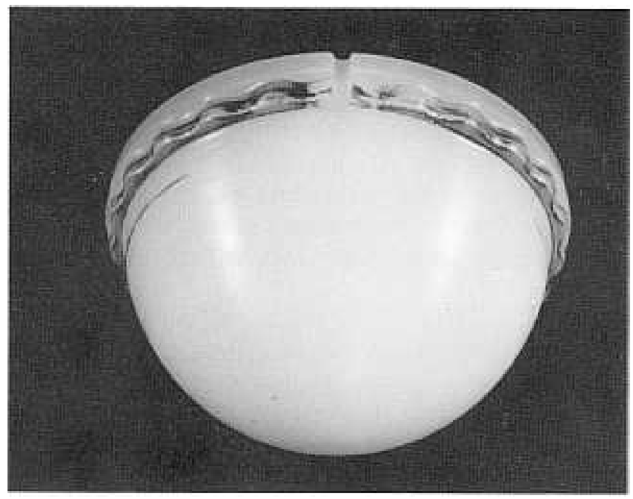

FIGURE 6

Reflection Liner with Dykem Impression After Static Load to 100 Pounds

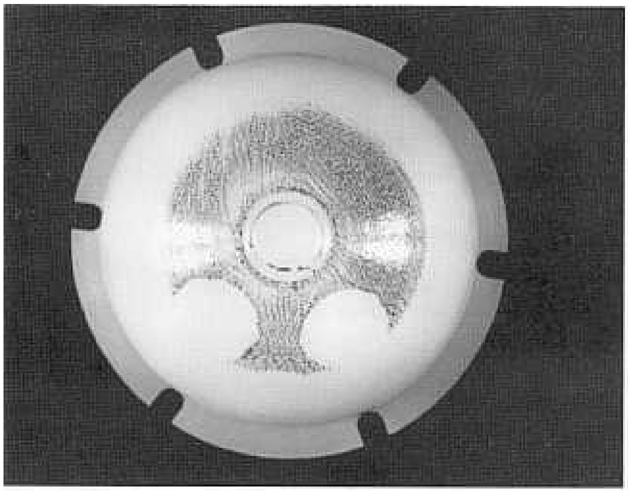

FIGURE 5

Trilogy Liner with Dykem Impression After Being Pressed into the Shell

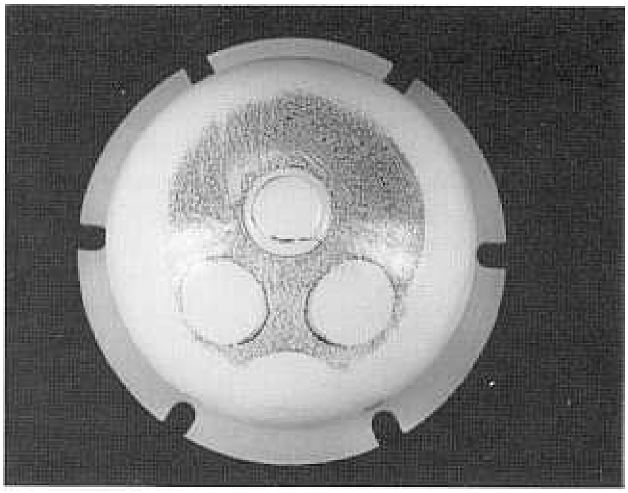

FIGURE 7

Trilogy Liner with Dykem Impression After Static Load to 100 Pounds

FIGURE 8

Reflection Liner with Dykem Impression After Static Load to 200 Pounds

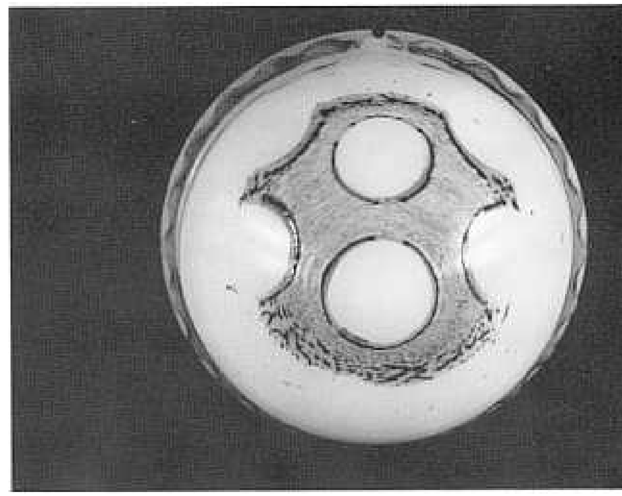

FIGURE 10

Reflection Liner with Dykem Impression After Static Load to 500 Pounds

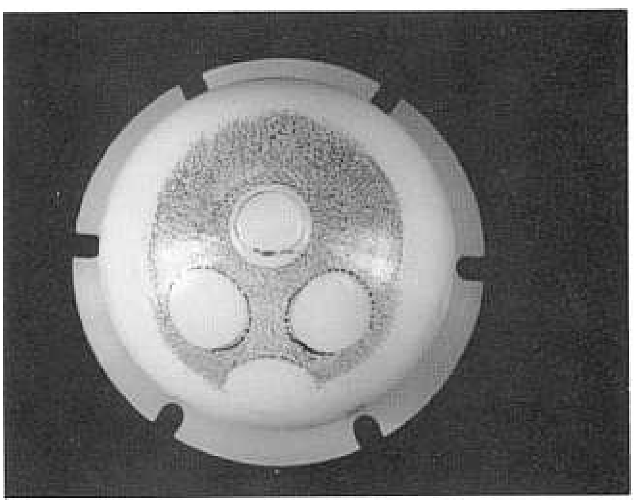

FIGURE 9

Trilogy Liner with Dykem Impression After Static Load to 200 Pounds

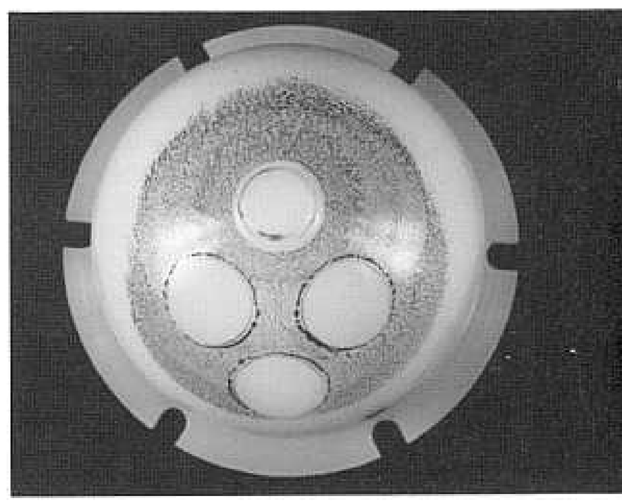

FIGURE 11

Trilogy Liner with Dykem Impression After Static Load to 500 Pounds

until 150 pounds was applied. The only contact impression observed at the lower loads was a ring around the protruding liner rim at the friction fit locking mechanism. A contact impression was also observed on the underside of the protruding liner rim where a small shelf extends back to the hemispherical liner surface. The remaining two components, which were tested immediately after removal from the package, showed no contact until 200 pounds was applied. Failure of the liner dome to bottom in the shell explains why no circular contact impression was observed to be centered around the pole of the Reflection cup liners.

Since the dynamic test results obtained on the two *Trilogy* cup designs were identical, only one of the two versions was statically tested. The older design was chosen for testing because the absence of an interference fit between the components facilitated assembling and disassembling the components. The results of this test were consistent with those of the dynamic testing. The liner dome made good uniform contact with no applied load (see Figure 5). As the off-axis load was increased the contact area shifted under the load as shown in Figures 7, 9, and 11. At no time, in the static tests or in the prior dynamic tests, was the *Trilogy* liner not making significant solid contact with the mating shell.

Discussion

A number of reports and studies have been written about the importance of conformity and congruency between the components of modular acetabular cup systems. A study specifically addressing the implications of incongruity in the generation of polyethylene debris was discussed recently at the 24th Annual Harris Hip Course.[6]

This study, conducted by scientists at the Mt.Sinai Medical Center, concluded that the significance of modular component conformity rests in understanding that high contact and subsurface stresses in polyethylene lead to wear and debris formation. They noted that the most active mechanisms in polyethylene wear are pitting and delamination which are more appropriately referred to as forms of surface fatigue failure. They point out in their analysis that loading of unsupported polyethylene may generate permanent residual stresses in the polymer due to plastic deformation and weaken the polymer's resistance to surface fatigue failure.

The results of the static tests described above show that the entire domed area of all three Reflection cups tested were completely unsupported until a load of 150 to 200 pounds was applied through the femoral head. This indicates that during the course of dynamic testing the Reflection liner was being cyclically fatigued in tension as it oscillated between increased contact at 500 pounds and no contact at 50 pounds. As described in the Mt. Sinai Medical Center study, sustained cyclic loading of the polymer may lead to fatigue related debris generation and ultimately to fatigue failure.

The Mt. Sinai study also suggested that high contact stresses are significant in polyethylene wear and debris formation. As can be seen in the successive static loading photographs, the load is carried entirely by the rim of the Reflection liner in the initial 150 to 200 pounds. A small area of contact is observed thereafter which becomes increasingly larger as the load increases. This indicates that, up to 300 pounds, large loads are being supported by the rim and relatively small areas on the dome. Distribution of these loads over such small contact areas generates high contact stresses in the polymer which could result in plastic deformation. At the maximum load of 500 pounds, the contact area of the *Trilogy* components is 48 percent larger than that of the Reflection cups. After factoring out the loss of contact due to the presence of screwholes in the shell, the contact area observed in the *Trilogy* components is still 25 percent larger.

Further analysis of these cups will be necessary to evaluate the validity of polyethylene wear studies, such as those conducted at the UCLA Medical Center, which base their analysis of polyethylene wear on the detachment of a gold sputter coating. As the results of the above testing show, the coated surface of Reflection cups used in such a study may not have been making constant contact with the metal backing. If no contact or inconsistent contact occurred then there would most likely be very little gold coating removed. There are a number of other parameters such as coating thickness and surface roughness which need to be evaluated before the validity of such tests can be determined.

Conclusions

The results of this test series show that all of the Reflection Microstable acetabular liners examined in this study failed to bottom in the mating metallic shell. Static loads of 150 pounds to 200 pounds were required to force contact between the modular components. In dynamic compression tests, the Reflection cup pistoned in the metallic shell with contact between the liner dome and metal back occurring only at higher loads. The nonconformity appears to be related to the design of the cup system. Independent studies have suggested that nonconformity could lead to fatigue related wear debris and potential failure of the device.

The results of this test series indicate that the *Trilogy* liner and shell make solid contact at all loads from zero to 500 pounds. In dynamic tests, the *Trilogy* liner dome was always in contact with the metal shell and the contact area was observed to vary only slightly across the range of loads.

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