Fatigue Test Comparison of Spiked Acetabular Implants

JACK JENNINGS, GREG STALCUP*

Investigation Performed at the Research Laboratories of Zimmer, Inc., Warsaw, Indiana

Summary: Sixty-two (62) spikes from twenty-nine (29) *Trilogy*® Acetabular System cups ranging in size from 44mm to 60mm were fatigue tested. In addition, nine spikes from three DePuy DURALOC spiked cups ranging in size from 50mm to 56mm were also fatigue tested. The spikes were loaded in cantilever bending to simulate bony resistance to rotation of the shell. The shells were tested to 10 million cycles or fracture, whichever occurred first. The 10-million cycle fatigue endurance strength of the spikes on the *Trilogy* cup is estimated to be 9.5 in-lbs. This is 35% higher than the DURALOC spiked cups which were estimated to have a fatigue endurance strength of 7.0 in-lbs (Figure 1).

Metallographic examination of the *Trilogy* spike/shell bond has shown that the spikes are well bonded to the shell in all cases. Examination of the DURALOC shells showed that the spike/shell bond was inconsistent. This may partially explain why the *Trilogy* spikes are significantly stronger.

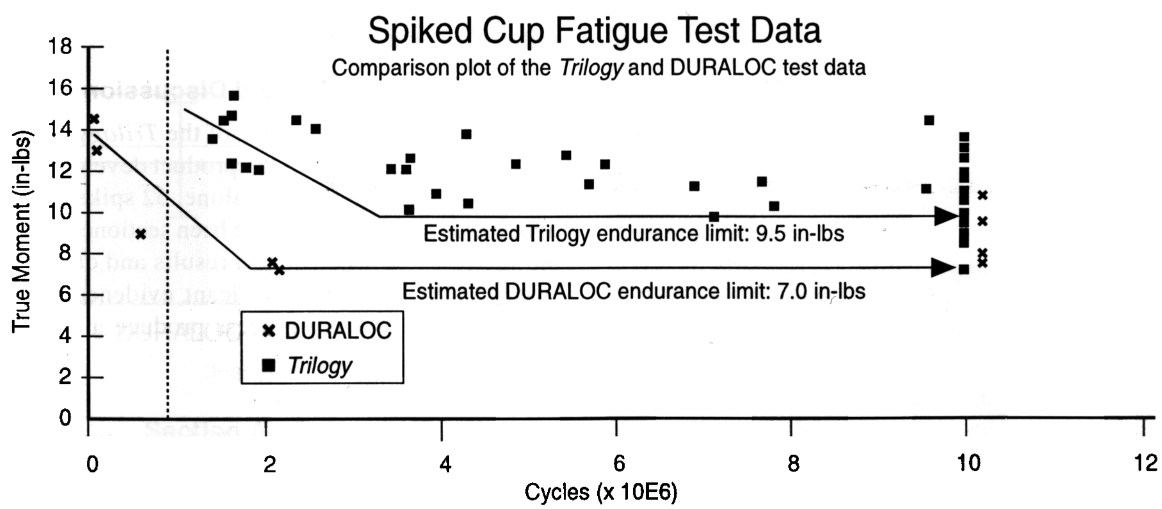

FIGURE 1

The *Trilogy* Spiked Acetabular Cup** is a line extension to the *Trilogy* Acetabular System. These cups have been designed with three spikes symmetrically located about the polar axis of the component. The DePuy DURALOC Spiked Acetabular cups also have three spikes symmetrically located about their polar axis. The primary difference between the *Trilogy* and DURALOC cups, relative to the spikes, is that the *Trilogy* spikes are smooth and the DURALOC spikes are porous coated.

*Greg Stalcup is a Senior Development Manager in Hip Systems at Zimmer, Inc. He is responsible for instrument and implant designs used in total hip and knee surgery. He holds a B.S. degree in Engineering and Management from Indiana/Purdue University. He has more than 14 years experience in design and management including more than 6 years experience in the medical field.

Jack Jennings is a Research Engineer working in the Fatigue and Fracture Mechanics Laboratory at Zimmer, Inc. He hold a B.S. degree in Materials Engineering from Purdue University. He is a member of the American Society of Metals, Society of Experimental Mechanics, and Society of Advanced Materials and Process Engineering.

The fact that the *Trilogy* spikes are smooth while the DURALOC spikes are porous coated suggests that bone will not grow onto the *Trilogy* spikes and that bone will in all probability grow into the DURALOC spikes. This further suggests that the DURALOC spikes are expected to carry loads throughout their life while the *Trilogy* spikes are not expected to carry the same type of load.

This white paper describes the fatigue test results of each of the aforementioned cups. The primary purpose of this study was to compare the fatigue strength of the *Trilogy* spikes to that of the DePuy DURALOC spikes.

Materials and Methods

Trilogy Spiked Cup

Sixty-two (62) spikes from twenty-nine (29) *Trilogy* spiked acetabular shells have been fatigue tested to evaluate the endurance strength of the *Trilogy* Spiked Cup System.

** U.S. Patent pending

Nine (9) spikes from three (3) DePuy DURALOC acetabular cups were fatigue tested in the same manner as the *Trilogy* shells.

Biomechanical Stress Analysis of the Spike

A biomechanical stress analysis of the *Trilogy* spike was conducted to evaluate the forces associated with bony resistance to cup rotation. The analysis showed that the highest spike stress was experienced by applying a force radially away from the polar axis of the cup as shown in Figure 2. The analysis assumed that the strength of the surrounding bone would limit the bending moment that could be applied to the spike. The cantilever fatigue test method described below was developed to load the spike in a manner consistent with this stress analysis.

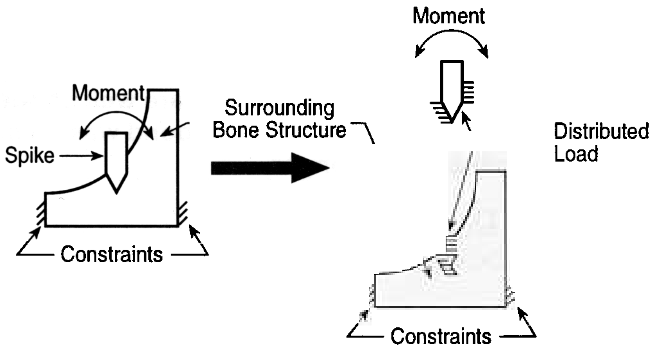

FIGURE 2

Fatigue Test Methods and Sample Preparation

The *Trilogy* spikes were prepared for loading by machining a small flat on the inner side of the spike with an end mill. The DURALOC spikes were prepared for loading by filing a recess 0.020 - 0.030 inch deep at the base of the tapered point (tip). This method of preparation was preferred on the DURALOC cups because the spike geometry and porous surface provided stability for the loading fixtures and also because there was some concern that machining could damage the spike/shell bond.

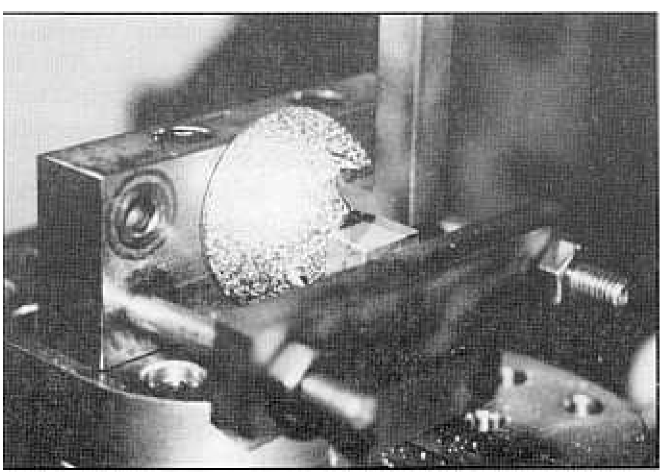

FIGURE 3

Fatigue testing was conducted on MTS closed-loop servo-hydraulic test frames. The cup was rigidly fixed to the test frame. A load was applied to the spike via a hook and clevis fixture. A typical test setup is shown in Figure 3. The load pulled the spike away from the axis of the shell placing the spike wall nearest the shell axis in tension and the outer spike wall in compression. The tests were run at 30 Hz in ambient laboratory air with an R ratio (min load/max load) of 0.1. Each test was run to 10 million cycles or fracture, whichever occurred first. All subsequent references to endurance strength relate to this 10-million cycle limit.

Post-Test Evaluation

Post-test evaluation of the spikes included measurement of the moment arm for determination of the true applied moment. The distance from the location of the applied load to the fracture initiation site was defined as the "true" moment arm length. This distance could only be estimated until the spike was fractured. Those samples which ran out to 10 million cycles were intentionally loaded to fracture to determine the true moment.

Several *Trilogy* and DURALOC cups were sectioned to analyze the weld as well as the microstructure of the spike, shell and weld zone.

Results and Discussion

The fatigue performance of the *Trilogy* spike has been well characterized during the product development process. In this final design iteration alone, 62 spikes have been fatigue tested and 25 spikes have been sectioned for analysis of the spike/shell bond. The test results and observations discussed below provide significant evidence that the spike design and fabricating process produce a device superior to the DURALOC cup.

Fatigue Testing

The *Trilogy* and DURALOC fatigue test data have been plotted in Figure 1 for comparison. The fatigue endurance limit for the *Trilogy* spikes was subjectively estimated from the test data to be 9.5 in-lbs. This compares to a subjective estimate of 7.0 in-lbs for the DURALOC spikes. These values indicate that the 10-million cycle endurance strength of the *Trilogy* spikes is 35% higher than the DURALOC spikes.

The data plotted in Figure 1 also show a marked difference in the fatigue performance of the two cup designs shortly after the start of testing. None of the 62 *Trilogy* spikes tested fractured at cycle counts under 1 million cycles. In comparison, three of the nine DURALOC spikes fractured at cycle counts less than 1 million and samples tested at a peak moment greater than 11.9 in-lbs fractured at approximately 100,000 cycles.

The spikes that ran out were intentionally tested at 250 lbs until the spike fractured. This allowed for measurement of the moment arm so that the true applied moment could be calculated. This is three to four times (depending on the moment arm length) the estimated compressive yield strength of cortical bone surrounding this spike design. At these loads the *Trilogy* spikes were observed to run for 20,000 to 45,000 cycles before tripping the displacement limit on the test machine which stops the test. This suggests that if high loads are applied to the spikes the bone will most likely fail under the stress rather than causing the spike to fracture. The DURALOC spikes were observed to run between 8,000 and 20,000 cycles at the breaking load. (Figure 4)

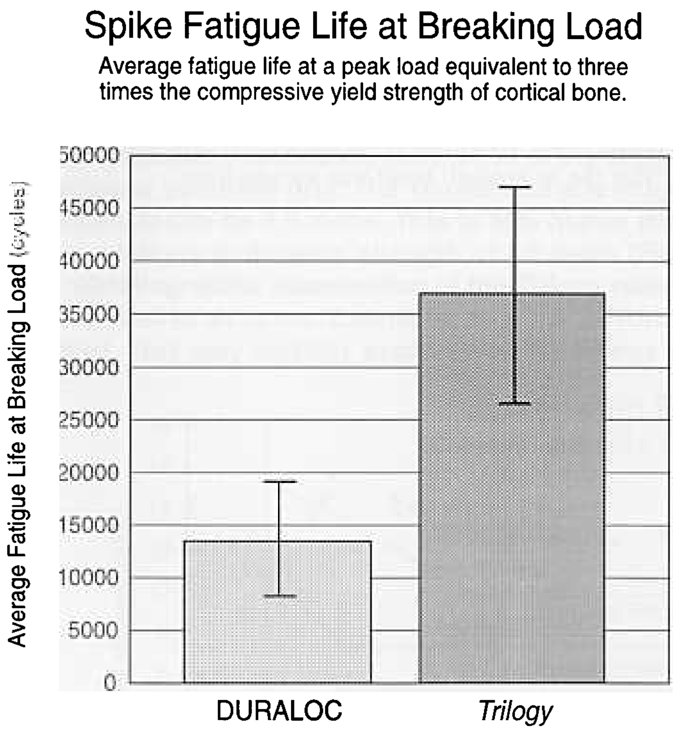

FIGURE 4

Section Analysis

Nine *Trilogy* cups (25 spikes) were sectioned for analysis of the microstructure and general evaluation of the spike/shell bond. Observations made during the course of this analysis have been recorded in the subsequent paragraphs. Collectively the section analysis observations suggest that the spikes were well bonded to the shell in all cases.

A typical section through a *Trilogy* spike is shown in Figure 5. The section analysis indicated that there was intimate contact between the spike and shell (in the weld zone) in all cups. This indicates that the pre-weld preparation as well as the welding process have produced the proper results. This intimate contact is beneficial because it provides mechanical support for the spike and because it facilitates producing a continuous weld between the two surfaces since the weld beam melts only a small area of metal.

The microstructure appeared to have been well homogenized by the post weld processing. Test data indicated that this was a significant factor in producing a consistently high fatigue strength.

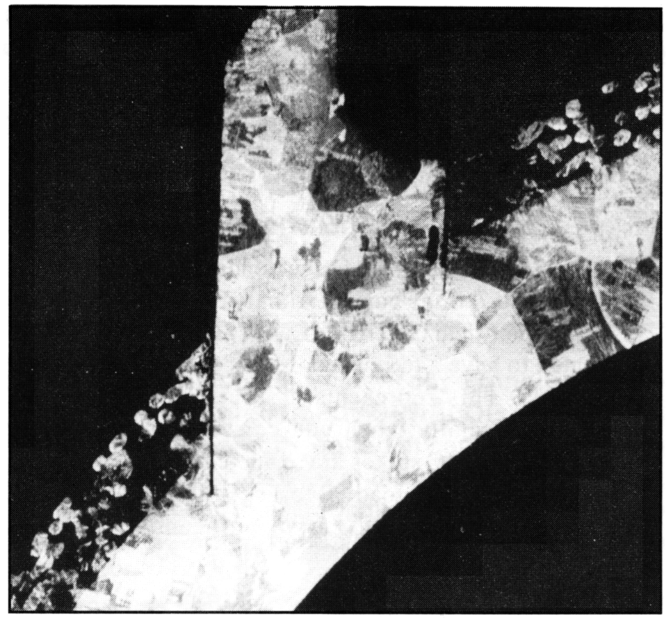

FIGURE 5

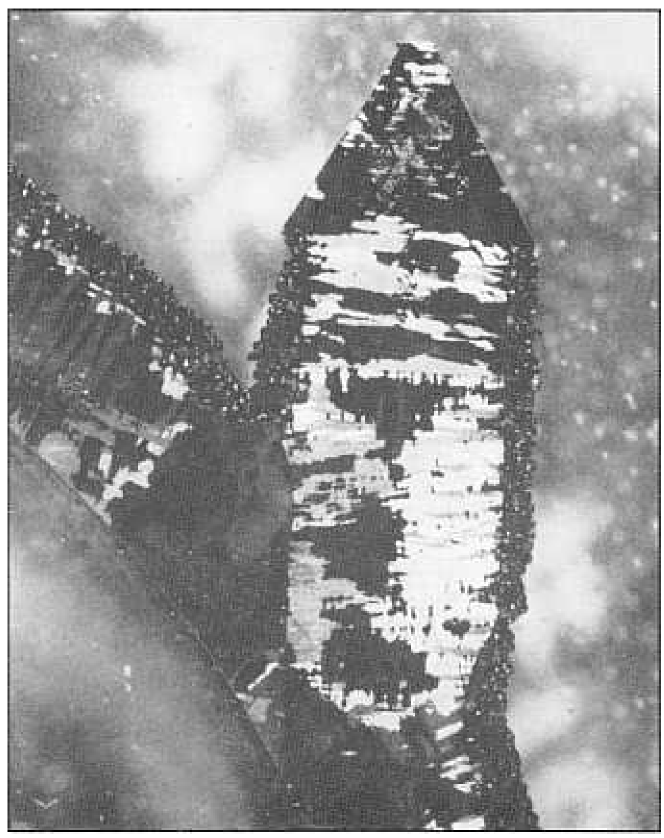

FIGURE 6

A typical section through a DePuy DURALOC spike is shown in Figure 6. Sections of the DURALOC spikes provided some information on the process by which the spikes are fixed within the cup. The analyses suggest that three blind holes are drilled symmetrically around the perimeter of the cup. The spike is positioned within the hole and a weld bead is formed between the spike wall and the outside diameter of the shell. The cup is subjected to a sinter heat cycle to bond beads to the shell OD. In some cases the sinter cycle also bonded the spike wall to the shell. Of the nine DURALOC spikes tested, four were bonded only by the perimeter weld at the shell OD.

Conclusions

The 10-million cycle fatigue endurance strength of the spikes on the *Trilogy* cup is estimated to be 9.5 in-lbs. This is 35% higher than the DURALOC spiked cups which were estimated to have a fatigue endurance strength of 7.0 in-lbs (Figure 1). This represents a significant difference in strength, especially when you consider the fact that the DePuy DURALOC spikes are expected to ingrow bone and therefore share more load. Because of this the DURALOC spikes can be expected to carry significant loads throughout their life while the *Trilogy* spikes are not expected to carry the same type of load.

Fatigue testing observations indicate that none of the *Trilogy* spikes fractured under 1 million cycles. Three of the nine DURALOC spikes tested fractured under 1 million cycles. The test observations also indicate that the *Trilogy* spikes can survive several thousand cycles at loads exceeding three times the compressive yield strength of the surrounding cortical bone. At these loads the *Trilogy* spikes were observed to run for 20,000 to 45,000 cycles. The DURALOC spikes were observed to run between 8,000 and 20,000 cycles at this load. (Figure 4)

Metallographic examination of the *Trilogy* spike/shell bond has shown that the spikes are well bonded to the shell in all cases. Examination of the DURALOC shells showed that the spike/shell bond was inconsistent.