Introduction: In December of 2000 Sulzer Orthopedics Inc. (Austin, TX) announced that a manufacturing process change appeared to have allowed a mineral oil contaminate to remain on the surface of the porous coating causing an adverse tissue response to the Inter-Op acetabular component.

One of the questions that concerned orthopedic surgeons was the viability of acetabular cancellous bone at the time of revision surgery. Another question asked was had the surgeon reamed to a depth of viable cancellous bone allowing for optimal fixation.

In order to address these questions, an Institutional Review Board (IRB) approved clinical protocol was developed. IRB approval had been obtained since it was not certain that reamings of cancellous bone from tetracycline labeled patients could be frozen sectioned for histological inspection and bone cores embedded in plastic may have been required. Treharne and Brighton bone viability can be confirmed by tetracycline double labeling. It was shown that after the first patient the reaming slurry of cancellous bone could be microtomized as a frozen section and no bone core biopsies were required. The hypothesis being addressed was that the host cancellous bone would be viable 1 millimeter (mm) beyond the region of the inflammatory tissue layer.

Materials and Methods: All patients provided informed consent in accordance with the IRB protocol prior to tetracycline labeling. Twelve patients with contaminated cups participated. Average patient age was 58 ± 11 years (range 35-78). Average in vivo time for the acetabular implant was 362 ± 104 days (range 207-521). In each case the revision was of a primary total hip arthroplasty using an Inter-Op acetabular component. Starting 21 days before the scheduled revision surgery, participating patients took 250 mg doses of oral tetracycline three times a day for three days. The same three day regimen was again repeated 7 days prior to surgery providing tetracycline double labeled trabeculae. This protocol for double tetracycline labeling is the same as has been used in other mineral apposition rate studies to measure bone metabolic activity. Following removal of the acetabular component, the acetabulum was reamed in 1mm increments in a standard fashion to remove sclerotic bone and the serial reamings saved for frozen section preparation. Unstained frozen section slides for each of the four serial reamings were then analyzed under a light microscope using a mercury florescent lamp. Mineral Apposition Rate (MAR) was calculated for each patient at each reaming level according to the published equation.

Preoperative and postoperative Harris Hip Scores (HHS) were obtained for each patient. Single tetracycline labels to double tetracycline labels was 1.7 ± 1.0 (range 0.3 – 3.0) for the initial reaming level and 2.2 ± 1.0 (range 0.3 to 1.0) for the final reaming level. An increase in the number of double tetracycline labeled bone fragments from the initial to final reaming was suggested although the difference was not statistically significant (p = 0.24).

Post-operative evaluation found none of the patients to demonstrate radiolucencies around their revision components at a mean follow up of 196 ± days (range 44 to 385). An average postoperative HHS of 86 ± 8 (range 66-96) was present at this time. When compared to a preoperative HHS of 45 ± 16 (range 16-66) this improvement was statistically significant (p<0.001).

Results: Tetracycline labeling (Figure 1) of the reamings demonstrated that viable double labeled bone existed within the first 1 mm reaming. Mean mineral apposition rates (MAR) for the initial reaming level was 1.31 ± 0.25 µm/day (range 1.02 to 1.83) in this twelve patient series while the final reaming level mean MAR was 1.49 ± 0.48 µm/day (range 0.97 to 2.44). Although a trend for the MAR to increase with greater distance from the initial reaming was exhibited, this difference was not statistically significant (p = 0.2231). The mean ratio of

Discussion: The tetracycline results are consistant with those reported by Bloebaum et. al. stating human bone has a mineral apposition rate of 1.25 µm/day at the interface of weight-bearing implants in the distal femur. The data also demonstrated that the surgeons placed the revision implants in viable bone with the clinical data complimenting the tetracycline data. This study shows that tetracycline labeling can be conducted on cancellous bone without need to embed bone core biopsies in plastic. This process allows for less invasive tissue collection and more rapid assessment of bone viability in future studies.