Extractable Residue from Recalled Inter-Op™ Acetabular Shells

+Spiegelberg, SH; *Deluzio, KJ; **Muratoglu, OK
+Cambridge Polymer Group, Inc., Somerville, MA; School of Biomedical Engineering, *Dalhousie University Halifax, Nova Scotia, Canada;
**Massachusetts General Hospital, Boston, MA

Introduction: In 2000, Sulzer Orthopaedics Inc. (Austin, TX "SOI") experienced higher than normal rates of early revisions (within first year) of the acetabular component of its Inter-Op™ acetabular shell component. Changes in the manufacturing process were identified that could lead to mineral oil being introduced to the porous titanium coated surface during machining. Initially, all machining was conducted at Cycam. Commencing with approximately manufacturing lot number 1308068, SOI performed peg chamfering after receiving the machined parts from Cycam, and then washed the components (water-detergent) and passivated them in nitric acid. Commencing with approximately manufacturing lot number 1360759, SOI performed all machining. From approximately manufacturing lot number 1408266, the passivation in nitric acid step was removed. As of June 27, 2002, 1163 of the 1401 revisions (83.0%) came from the range of manufacturing lot numbers between approximately 1400000-1454000. It is recognized that machining of the final ID and peg chamfer by SOI could leave residual oil in the parts.

It had been suggested that the presence of excessive amounts of mineral oil inhibits bone in-growth and subsequent lack of implant fixation. The purpose of the analysis discussed here was to determine oil content as a function of manufacturing history for shelf-stored components, and to correlate manufacturing lot numbers with the rate of revision surgery and with various changes in the manufacturing process, including manufacturing location and cleaning steps.

Methods: Extractable residual mass data, which would include oil content, were gathered from shells with lot numbers 1281046 to 1449618 that correspond to a three-year period between June 1997 to September 2000. The residual oil data came from three sources (Carbomedics "Carbo", SOI, and Cambridge Polymer Group "CPG"). Both Carbo and SOI used a hexane extraction method to gravimetrically measure the residual non-volatile mass, while CPG used a carbon tetrachloride extraction followed by infrared spectroscopy. The data were also organized according to the manufacturing location of the shells (Cycam or SOI). During the time period in question, the manufacturing location and manufacturing process changed. The data were analyzed to determine if there was any correlation between manufacturing history and the quantity of residual material on the shells. In particular, the manufacturing steps following high temperature sintering of the porous titanium coating, which would pyrolize any organic residue, were carefully assessed, as shown in Table 1. These steps included additional machining steps, which may introduce more mineral oil, and cleaning procedures, including nitric acid passivation. The residue contents obtained from the shelf-stored components are also compared with lot numbers of explanted Inter-Op™ shells to identify any correlation between lack of implant fixation and manufacturing history.

Results: The extracted residual materials from the range of lot numbers discussed above are shown in Figure 1. The majority (95%) of the samples had less than 10 mg of residual material, while the remaining samples ranged from 10 to 67 mg. Normal probability plots of the mass data in the individual groups revealed that the data were not normally distributed. The data were transformed to normality with a square root transformation. Comparisons were made between the two manufacturing locations for each of the measurement methods. The CPG data revealed no difference between the manufacturing locations (p=0.16) while the hexane data revealed that the SOI manufactured parts had a 1.8 mg increase in residual mass (p=0.003). The latter finding does not supply good evidence that there is a significant difference in the quantity of residual material between the two manufacturing locations because: (i) the measurement accuracy of the hexane method is 1–2 mg, (ii) this small difference may not be of practical significance with regard to the lack of fixation in the explant, and (iii) there is a large difference in sample sizes between the two groups.

The second analysis performed was a correlation between the lot numbers and the revision surgeries known to date, also shown in Figure 1. Based on the data supplied, this analysis revealed that the revisions are associated with Group 4, a range of manufacturing lot numbers between approximately 1408266-1449618. These lots are characterized by the component having been manufactured at SOI *without* nitric acid passivation.

Table 1. **Manufacturing group numbers and description**

Group	Name	Description
1	Cycam 1	100% Cycam manufactured + nitric acid passivation[1]
2	SOI 1	Cycam final ID + SOI mill peg chamfer[2] + nitric acid passivation[1] (Approximately lot numbers 1308068-1393112)
3	SOI 2	SOI final ID + SOI mill peg chamfer[2] + nitric acid passivation[1] (Approximately lot numbers 1360759-1407611)
4	SOI 3	SOI final ID + SOI mill peg chamfer[2] + no nitric acid passivation[1] (Approximately lot numbers 1408266-1449618)

[1]Passivation: shells are soaked in 27 vol% nitric acid solution following water/detergent wash cycle for 1 hour.
[2]Final ID+mill peg chamfer: the shells are turned on a lathe to cut the inner diameter (ID) to its final size. Pegs located on the outer rim of the shell are cut to a 45° angle (chamfer) on a lathe. SOI= machined at Sulzer Orthopedics, Inc. Cycam= machined at Cycam.

Discussion: There was no statistical difference in residual oil content between any of the 4 manufacturing groups. In particular, the quantity of residual oil extracted in the lots manufactured at SOI without nitric acid passivation is not statistically higher compared to lots with the other manufacturing processes, while 83% of the revisions are associated with the lots lacking nitric acid passivation. Therefore, it appears that the principle cause of poor implant fixation is from the lack of nitric acid passivation, rather than excessive mineral oil as previously postulated.

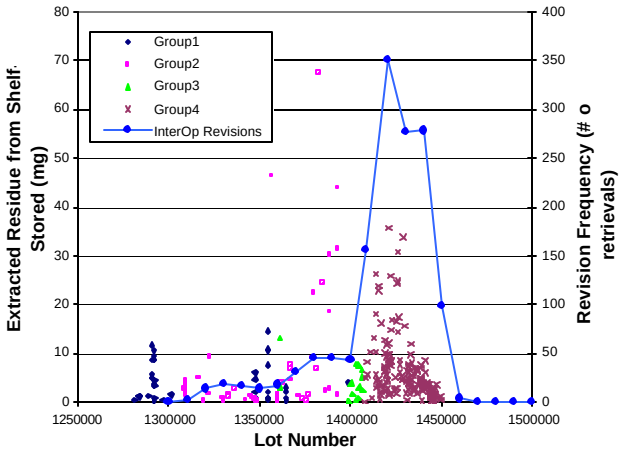

Figure 1. Residual mass data and revision frequency plot as of June 28, 2002. The line with the solid blue dots is a frequency plot of the revision data while the other points represent the residual oil extracted from the shelf-stored shells (mg) organized according to Groups 1 to 4. 83% of the explanted shells came from Group 4.