HISTOPATHOLOGY OF TISSUES FROM INTER-OP ACETABULAR SOCKETS

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Introduction:
Beginning in late August, 2000, several specimens of failed Inter-Op acetabular components with Metasul (metal-on-metal) bearings were submitted to our institute for implant retrieval analysis. The cause for failure was not immediately clear. The implants had been in vivo less than 6 months. The patients reported ongoing pain and the implants apparently lacked fixation, despite the previous clinical success of the socket design and porous coating. The patients with failed sockets did not have clinical evidence of infection. It was initially suspected by the surgeon that insufficient clearance of the metal bearings had caused mechanical loosening. The components were examined using a coordinate measuring machine and found to be within normal tolerances. Investigations by Sulzer Orthopaedics identified a change in the manufacturing process that may have resulted in the contamination of the porous coating with an oily residue. The aim of this study was to determine if the histopathology of these and subsequent cases was consistent with this proposed cause of Inter-Op socket failure.

Materials and Methods:
Over 400 cases have been reviewed. The first 113 retrievals with tissue available for histology were examined using a histopathology scoring method designed for the purpose. Almost half of these had UHMWPE bearings, approximately 20% had Metasuls and the remainder were unknown. The average time to revision in 91 cases was 4.7 ± 2.5 months (1 to 16 months); the remainder of the cases (20%) had Metasuls and the remainder were unknown. The average time to revision in 91 cases was 4.7 ± 2.5 months (1 to 16 months); the remainder were unknown. The specimens submitted for analysis were highly variable, ranging from as little as a single, small fragment of tissue to multiple components (socket and/or insert and/or femoral ball) and substantial samples of periprosthetic tissues. Each specimen was accessioned, photographed, examined grossly, and the presence and characteristics of any adherent tissue was determined if the histopathology of these and subsequent cases was consistent with this proposed cause of Inter-Op socket failure.

Results:
"Early scar" showed modest amounts and "late scar" showed abundant granulation tissue vascularity, bone formation, bone resorption, bone debris, hemorrhage, fibrin, hemosiderin, necrosis, necrobiosis, granulomas, granulation tissue vasculature, bone formation, bone resorption, bone debris, synoviocyte hyperplasia and unusual globular spaces that may represent colonies of common contaminants.

"Intermediate scar" showed modest amounts and "late scar" showed abundant granulation tissue vascularity, bone formation, bone resorption, bone debris, hemorrhage, fibrin, hemosiderin, necrosis, necrobiosis, granulomas, granulation tissue vasculature, bone formation, bone resorption, bone debris, synoviocyte hyperplasia and unusual globular spaces that may represent colonies of common contaminants.

Discussion and Conclusions:
The intensity of the chronic and acute inflammations in these cases was more typical of septic failures. However, given the absence of consistent bacterial cultures, the observations of granulomatous (histiocyte-rich) inflammation, features consistent with presence of oil (such as cell-lined spaces, vacuoles in giant cells, and foamy macrophages), metal-like debris associated with silica-like crystalloids not seen in conventional prosthesis failures, fit best with the hypothesis that these implants were contaminated with an oil-based residue admixed with debris & other substances at the time of manufacturing. The inflammatory response was not limited to tissues in immediate contact with the socket, since similar findings were also noted in the capsule. This indicates that the joint as a whole is involved in the inflammatory response to contaminants on the Inter-Op sockets. The severity of the response suggests that some substance or substances in the residue, rather than mineral oil per se, is responsible for the inflammation and subsequent lack of bone ingrowth. The identity of these substances is currently being investigated by Sulzer and its team of outside research consultants.

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Fig. 1. Typical failed Inter-Op socket with minimal attached tissue, revised after 4 months. Fig. 2. Typical appearance of tissue from a failed socket showing early scar, intense chronic inflammation, granulation tissue, 200X.

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