

DEGRADATION OF CoCrMo HIP IMPLANTS – A CORROSION, WEAR AND CLINICAL ANALYSIS

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INTRODUCTION: A prerequisite to understanding the reasons that may lead to implant rejection, exemplified typically by aseptic loosening, is a clear insight of the processes occurring at the metal biological interface and the influences that each environment plays on the other. Considering the very different nature of the environments and the disparate interactions between these, it is essential to approach the problem from different directions corresponding to different competence fields. In this study, an animal model for interface tissue formation in cemented CoCrMo hip replacements [1] was exploited to investigate the processes occurring at the implant-biological interface. In contrast to most studies reported, in which the task in hand is approached from either a biological, clinical or material angle, here we seek to investigate the interaction of the different processes by combining competence from medicine, biology, corrosion and tribology. [2]

METHODS: The degradation of CoCrMo ASTM-F75-92 hip implants as a result of wear and dissolution processes was investigated. Total hip arthroplasty of the cemented type was carried out on 12 sheep and observed over a period of 8 1/2 months. Radiography was employed to analyse the stability of the implant and the presence of possible fractures in the cement mantle. Upon euthanasia, the explants were retrieved for analysis of the surfaces and evidence of degradation (optical stereomicroscopy, SEM and non-contact laser profilometry), whilst tissue from the interface regions was harvested for chemical analysis and evidence of Co, Cr and Mo content (ICP-MS). Histological analysis was also performed.

RESULTS: *Clinical analysis and histology.* The surgical procedure was successful in all 12 experimental animals. From the radiographs, differences in bone resorption and periosteal reaction were observed according to the clinical looseness of the implants. Severe cracks in the PMMA cement mantle were observed in cases where the implant was severely loose and could be

removed from the shaft with ease. During explantation of the bone and prostheses extraction procedures, the subjective clinical evaluation of the stability of the shaft of the implant within the femur showed differences between implants, and the degree of fixation was categorized as *well fixed*, *fixed* and *loose*. This classification reflected the degree of mobility of the prostheses within the cement mantle and the ease with which the latter could be removed at the time of euthanasia. Macroscopic analysis of transverse bone sections revealed an interface tissue with scar-like, dark red coloration between the PMMA mantle and the bone. The latter was considerably more prominent in sheep with clinically more loose implants. In the clinically fixed implants, an immediate contact between bone and cement was present without interposition of an interface tissue.

Metal release in tissue. In Figure 1 results of chemical analyses of tissue samples from the PMMA-cortex interface are shown, plotted as a function of the ranking of the implant stability within the cement mantle at the time of retrieval. In all experimental sheep tissue analysed, the metal concentrations measured exceeded those found in blank tissue, indicating that a release of metal from the prostheses took place in all cases.

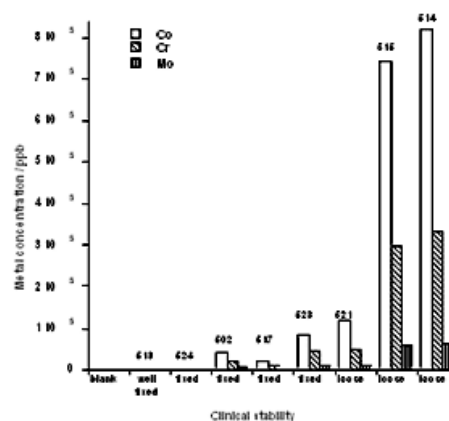


Fig. 1: Plot of absolute concentration of Co, Cr, Mo measured in interfacial membrane samples versus clinical stability of the implant within the bone at the time of retrieval.

In addition, the concentrations of all three metal elements measured increased with increasing clinical instability of the implant, as exemplified by sheep 513 with a very well fixed prosthesis, where the concentration of Co in the interface tissue was 141 ppb, and in sheep 514 with a very loose implant, where the concentration of Co reached a value of 820845 ppb. Of particular notice were the relatively constant concentration ratios of 1Mo:2Cr:100Co found, which do not reflect the composition of the alloy or that of the passive film, suggesting that the nature of the metal release process occurring could be a combination of cyclic mechanical de-passivation and chemical re-passivation.

Surface damage of implants. Optical and secondary electron (SEM) microscopies were used to identify surface modifications resulting from wear, such as scratches or presence of debris and from corrosion events such as pitting. SEM images of implant 514, compared to an as-received sterilized hip prosthesis, revealed a systematic mechanical flattening of the microscopic asperities forming the original surface topography, in addition to the observation of debris particles. This suggested that during clinical use repeated sliding conditions were locally established between the prosthesis and the PMMA cement mantle leading to wear of asperities.

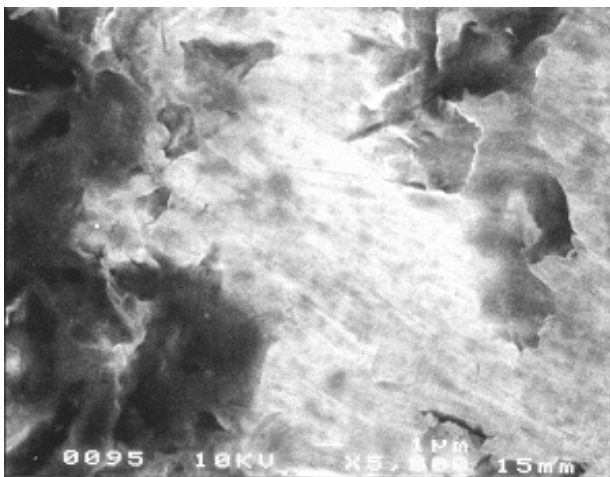


Fig. 2: SEM image of a flattened asperity observed on a loose implant (514) as the results of sliding wear events.

A variable length scale analysis of selected roughness profile lines measured using laser profilometry was carried out systematically on most of the implants to quantify the extent of asperities flattening and thus of wear damage. An influence of clinical use on surface structure was clearly noted when roughness was quantified over small interval distances ($<100 \mu\text{m}$) corresponding

to the typical size of the asperities. This was in agreement with SEM observations. However, no significant difference between fixed and loose implants could be identified, thus indicating that all the implants underwent similar wear damage.

DISCUSSION & CONCLUSIONS: From the results it was evident that a good degree of correlation exists between the clinical evaluation of the implant stability and the chemical analysis of the interface tissue. In particular, it was found that the quantity of interface tissue grown between the cement and the cortex closely reflected the degree of fixation of the implant shaft, and concomitantly the degree of metal release from the alloy. The presence of prominent interface membrane was often accompanied by more pronounced resorption and an abnormal new bone formation including increased vascularity within the bone cortex. Moreover, it was also found from measurements of the surface roughness along the stem that a certain degree of wear occurs in all implanted prostheses, irrelevant of the degree of fixation of the implant within the PMMA, indicating that fretting wear does take place.

In conclusion, it was clear from the collected explant surface- and retrieved tissue chemical-analysis data, that generation of metal particles, or alloy degradation mechanism, involving a mixture of wear and tribo-corrosion took place in all implanted hip prostheses. However, the absence of evident correlation between the surface morphology and roughness data with either the degree of fixation of the implants, or with the tissue chemical analysis classifications suggested that the modes of mass transport between the implant surface and the tissue play an as important role as the surface degradation mechanism of the metal. The mode and degree of mass transport might depend on the presence of cracks or defects in the bone cement as well as on the local physiological constitution.

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