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Cobalt from metal-on-metal hip replacements may be the clinically relevant active agent responsible for periprosthetic tissue reactions

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ABSTRACT

Some types of metal-on-metal (MOM) hip replacements have unacceptably high rates of failure, such as the Ultima TPS MOM hip, with 13.8% failure at 5 years. This has been attributed to an inflammatory reaction following the release of cobalt (Co) and chromium (Cr) from the bearing surfaces and modular junctions. There is in vitro evidence that Co is more important than Cr in the inflammatory process, but there are no reported human tissue studies of the analysis of implant-derived metals.

1. Introduction

The failure rates of some types of metal-on-metal (MOM) hips are unacceptably high and higher than many non-MOM hips [1,2]. This has been attributed to an adverse tissue response to material lost (the implants are made from an alloy of 60% cobalt, 30% chromium, and 7% molybdenum) from wear of either the bearing surfaces [3] or the modular (stem–head) junctions [4,5]. The risk of requiring further surgery, because of pain, is positively correlated with the levels of cobalt (Co) and chromium (Cr) in the blood [6].

A better understanding of the mechanism of the inflammatory response will help determine those patients most at risk and how to solve and avoid the problem. In vitro experiments suggest that Co is more reactive than Cr [7], but in vivo or ex vivo data is limited. Recently it was shown that the predominant implant-derived species in the tissues surrounding failed Non-Ultima MOM hips is Cr phosphate [8]. Previously Cr_2O_3 was thought to be the predominant species, but the use of synchrotron X-ray absorption spectroscopy (XAS) and X-ray absorption near edge spectroscopy (XANES) has enabled increased sensitivity and specificity over non-synchrotron techniques [9].

Agreement of the in vitro and ex vivo evidence may be explained if Co is more reactive and more soluble than Cr. The solubility of metals is dependent on the pH of the surrounding solution. Synchrotron XAS and XANES offer the best chance of detection of transitory Co and its chemical form, such as its oxidation state (zero for metallic and possible 2^+ or 3^+ valency).

The Ultima TPS modular MOM hip (DePuy, Leeds, UK) has very poor clinical results with a failure rate of 14% after 7 years [10] and a mode of failure that involves severe bone and muscle destruction. These hips frequently had severe femoral stem corrosion at revision surgery. Such changes are rarely seen with the current generation large diameter types. There are no studies on the analysis of implant-derived debris within the tissues for this type of hip implant.

We hypothesized that implant-derived debris in the periprosthetic tissue of Ultima hips was different to that derived from large diameter MOM hips. We had two research questions. First, was

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there a difference in the relative amounts of implant-derived metals in the tissues? Secondly, was there a difference in the chemical speciation of the debris?

2. Materials and methods

2.1. Study design

We performed an ex vivo analysis of periprosthetic capsular tissue taken during revision of MOM hips that failed without evidence of infection or a mechanical problem, such as dislocation or impingement. Our study inclusion criteria are shown in the experimental flow diagram (Fig. 1). The same sample preparation and X-ray spectroscopy analysis were performed on the tissues from both groups.

2.2. Patients recruited

The research ethics committee approved the study and all patients consented to the use of their tissue. More than one section per patient was examined optically and in all cases synchrotron X-ray fluorescence (XRF) elemental mapping was performed on

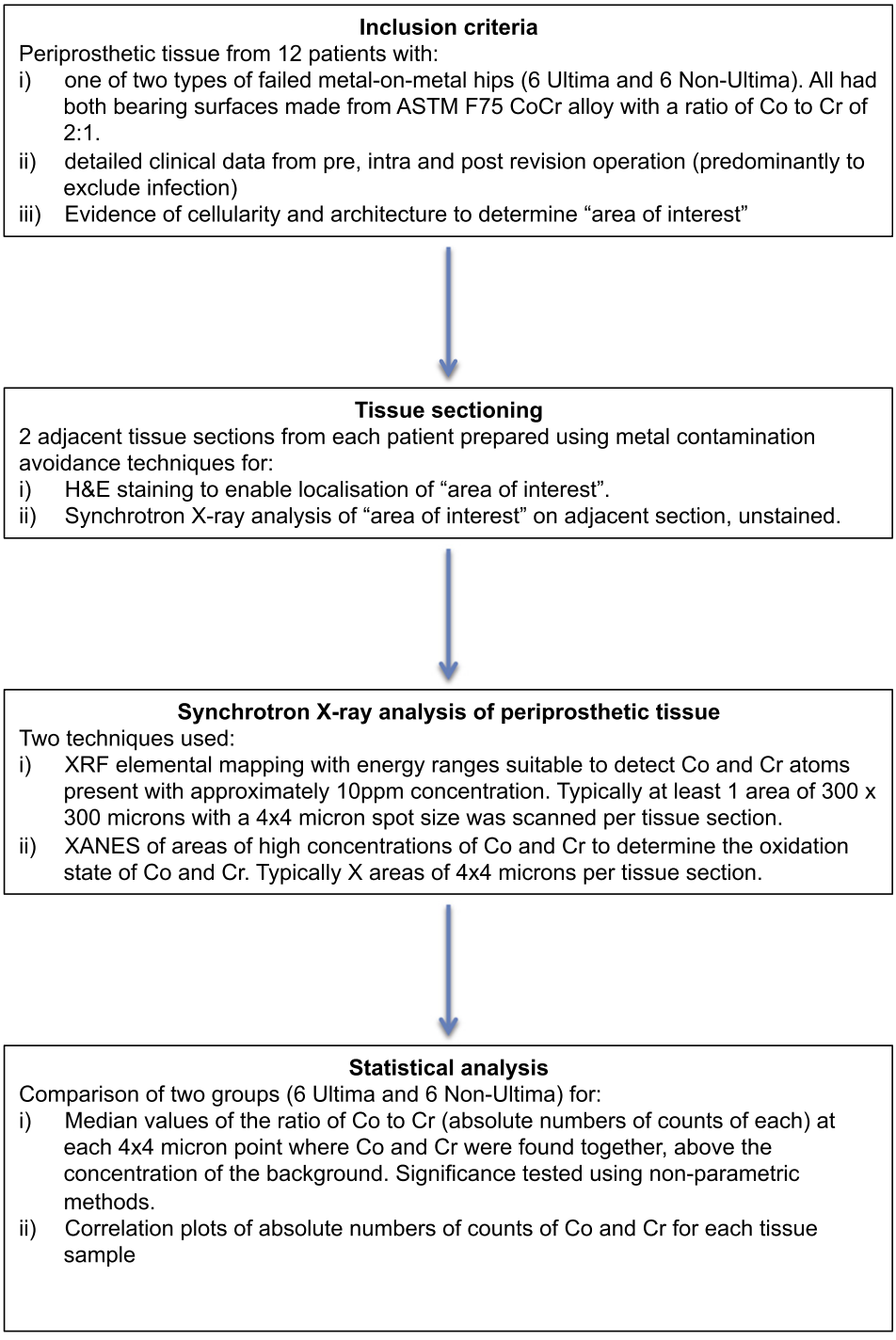

Fig. 1. Flow diagram to summarize the design of the study.