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Research paper

Wear study of Total Ankle Replacement explants by microstructural analysis

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ABSTRACT

The implantation of Total Ankle Replacement (TAR) prostheses generally gives satisfactory results. However, a high revision rate is associated with the Ankle Evolutive System (AES) implant, due to periprosthetic osteolysis that generates significant cortical lesions and bone cysts in the periprosthetic region. Radioclinical and histological analyses of peri-implant tissues show the presence of numerous foreign particles that may come from the implant. It is known that a precocious wear of materials may lead to an important rate of foreign body in tissues and may generate osteolysis lesions and inflammatory reactions. Thus the objectives of this retrospective study of 10 AES TAR implants (recovered after revision surgeries) are to understand how the prostheses wear out, which part is the most stressed and to determine the nature and size of foreign body particles. A better understanding of friction mechanisms between the three parts of the implant and of the nature and morphology of foreign particles generated was needed to explain the in vivo behavior of the implant. This was achieved using microstuctural and tomographic analysis of both implants parts and periprosthetic tissues.

1. Introduction

Today, Total Ankle Replacement (TAR) is a generally accepted treatment for advanced ankle joint disease of whatever cause but mainly post-traumatic osteoarthrosis, secondary osteoarthrosis to chronic ligament instability or rheumatoid arthritis (Besse et al., 2009; Koivu et al., 2012). It is a valid alternative to ankle arthrodesis. Indeed it allows the preservation of the ankle mobility, has satisfactory clinical results and potentially provides a better quality of life (Dalat et al., 2014) despite poor results compared to other joint replacements such as hip or knee. This procedure concerns 500 patients yearly in France. The Ankle Evolutive System implants (AES, Transystem) is one of the few accepted implants designed for

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this surgical procedure. However, in spite of technically successful implantation and satisfactory short-term results, (23% of complications for 5 years according to Gougoulias et al. (2010)) the intermediate and long-term results of AES implants are compromised compared to other implants. Several reports (Besse et al., 2009, 2013; Dalat et al., 2013; Koivu et al., 2009; Kokkonen et al., 2011; Rodriguez et al., 2010; Yoon et al., 2014) have shown that for AES TARs, corrective operations were made necessary by the appearance of tibial and talar osteolytic lesions evidenced by radiology examinations. Osteolysis is a biological cell-mediated process that results in the loss of bone as a direct response, in this clinical situation to the macrophagic granulomatous inflammatory reactions induced by the contact with foreign particles such as wear debris (Koivu et al., 2012). This study aims to understand the origin of these foreign particles, so as to limit their quantities in the future. To reach this objective, explanted AES TAR prosthesis have been studied by an analysis of the microstructure of different components, of debris in periprosthetic tissues and by an histologic study of these tissues. The goal is to get a better understanding of the underlying features responsible for oesteolysis (nature, morphology, size of wear particles as well as their provenance).

2. Materials and methods

2.1. AES prosthesis

This paper focuses on the AES TAR implant, which is manufactured by Transysteme (Nimes, France) and marketed by Biomet (Valence, France). The design was developed based on the Buechel Pappas TAR, with three non-stressed non-cemented parts: a talar and a tibial components made from a cobalt-chromium (Co–Cr) alloy (1 and 2 in Fig. 1) and a mobile bearing in ultra-high molecular weight polyethylene inserted between the two metallic components (3 in Fig. 1). A double hydroxyapatite/titanium coating (HA–Ti/TiO_2) is deposited on the surfaces of the talar and tibial components in contact with bone. The titanium coating is realized by Atmospheric Plasma Spraying, generating a coating with titanium oxide area in the core. Covering the alloy with Ti coating, acting as a chemical barrier that hinders the release of metal ions from the implant, led to promising in vivo corrosion behavior (Kurzweg et al., 1998; Nie et al., 2000). However, the chemical bond with the living bone in the body is relatively weak (Li et al., 1998). Therefore a double layer HA–TiO_2 coating on the Co–Cr alloy is used, which combines biochemical stability with appropriate mechanical properties, provided that there is a good adhesion between the different layers. This is particularly true when the interfacial adhesion uses HA as the porous and bioactive top layer while a dense Ti/TiO_2 film acts as the corrosion resistant inner layer.

2.2. Samples and surgical procedure

In this study, 6 AES TAR implants, which had undergone revision for osteolysis are studied and compared to 3 non-implanted TAR implants (1 AES, 1 SALTO (Tornier, Montbonnot Saint Martin, France) and 1 HINTEGRA (Integra, Saint-Priest, France)) and to 1 explanted GOELAND Total Knee Replacement implant (Landanger, Chaumont, France) (TKR) (Table 1). This last knee prosthesis was implanted between 1995 and 1997 and also necessitated a revision surgery due to osteolysis. The SALTO and HINTEGRA TAR implants belong to the most recent generations of TAR implants, currently used in France. The AES TAR implants were implanted by a single senior surgeon between 2004 and 2008 and remained in vivo during 5–9 years, which is short compared to the expected life time of such prostheses (around 20 years). When presenting results, the different parts of the TAR implants will be designated 1, 2 and 3 for tibial components, talar components and mobile bearings respectively (Fig. 1).

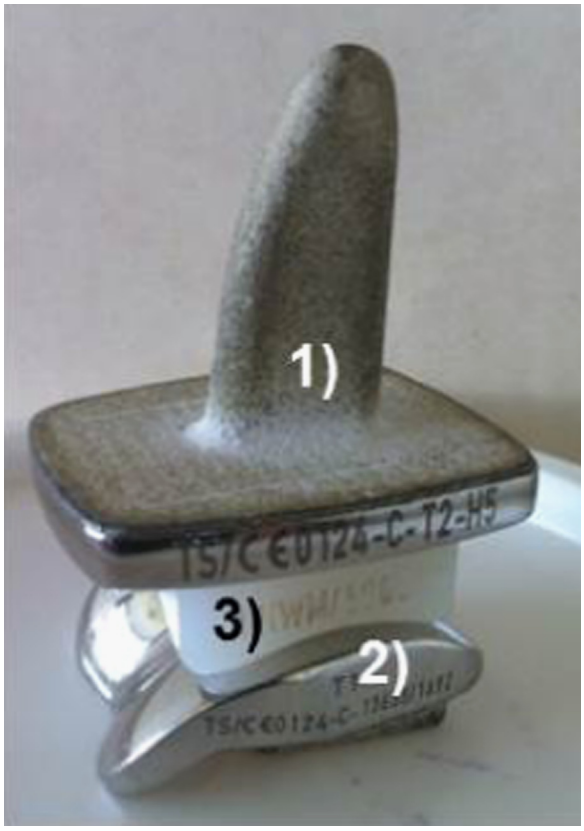

Fig. 1 – AES TAR implant.

Revision surgery used the anterior approach. Systematic tissue sampling of synovium and periprosthetic tissues was performed for histological and bacteriological analyses. Curettage of periprosthetic cystic lesions was performed under visual control helped by a mini-image intensifier, and guided by 3D cyst assessment on preoperative helical CT. Cysts were accessed via the cotical lysis, when present; otherwise, a cortical bone window was performed under CT guidance. The biological samples taken during surgery, upon removal, were immediately placed in a buffered formaldehyde solution or in ethanol 70 and stored at 4 °C/RT.

After dehydration, tissue samples in formol were paraffin embedded and analyzed by X-ray tomography.

Others samples (in ethanol) were fixed in ethanol 70°, dehydrated in absolute ethanol and xylene then included in methylmethacrylate resin (MMA). Slices of 7 μm thickness were performed using a microtome with tungsten knife.