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CASE REPORT

Revision of a tibial baseplate using a customized oxinium component in a case of suspected metal allergy
A case report

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Materials currently used for total knee arthroplasty (TKA) are well known for their good biocompatibility, but corrosion of the implant and metal ion release may elicit an immune response in the periprosthetic tissue. Its role in the outcome of the implant remains a subject of discussion. Metal sensitivity after joint replacement is frequent, but few patients exhibit symptoms. Nickel, cobalt and chromium are the most common sensitizers, but allergic reactions to titanium and vanadium have also been described. We present a case of a 46-year old woman with persistent dermatitis following TKA revision with an oxidized zirconium (oxinium) femoral component and Ti6Al4V tibial baseplate. After revision with a customized oxinium tibial component, symptoms resolved completely.

Keywords : metal allergy ; dermatitis ; total knee arthroplasty ; oxinium.

INTRODUCTION

Total knee arthroplasty (TKA) has become a common procedure with predictable results at long-term follow-up. However, wear products and metal ions may elicit an immune response in the periprosthetic tissue. Its role in the outcome of the implant is not clear but cases of suspected loosening caused by an allergic reaction to metals have been reported (*2,4,5*).

Others doubt a direct cause-result relation between allergic reactions in periprosthetic tissues and loosening (*4,5,7,9*). Nickel, Cobalt and Chromium are known to be the most common sensitizers (*4,5,7*), but hypersensitivity reactions to titanium and vanadium have also been described (*4,9*). Ceramics are among the least reactive biomaterials. Oxidized zirconium (oxinium) has comparable hypoallergenic properties without the adverse material properties of ceramics. We report a case of local dermatitis and loosening of a Ti6Al4V tibial baseplate following TKA revision. After revision of the tibial baseplate with a customized oxinium component, symptoms resolved and dermatitis did not recur.

CASE REPORT

A 46-year-old woman presented with an end-stage osteoarthritis of the left knee. Over a 4-year period, three arthroscopic debridements were

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performed, with temporary relief of her complaints following each procedure. She felt like all conservative treatment options were exhausted and symptoms became severe enough to consider knee replacement surgery. She underwent primary TKA using an oxinium femoral component (Genesis II, Smith & Nephew, Memphis, Tenessee), given her relatively young age and high activity level. The patellar component was all-polyethylene and a Ti6Al4V tibial baseplate was used. A fixed bearing posterior stabilized design was used and all components were cemented using manually mixed gentamycin loaded bone cement (Palacos, Heraeus Medical). The early postoperative recovery was uneventful. At 6 weeks however, her knee became painful again and clinical examination revealed a diffuse swelling. There was no fever at that time and blood samples were not suspicious for infection. At this stage, she was treated with nonsteroidal anti-inflammatory agents. Over the next 3 months, pain increased and a skin rash appeared over the anterolateral side of the incision scar. Serological inflammatory tests remained slightly elevated with C-reactive protein (CRP) at 1.2 mg/dl (reference < 0.7 mg/dl) and erythrocyte sedimentation rate (ESR) at 17 mm/h (reference rate < 17 mm/h). White blood cell count at 6.9×10^9/L was normal, with the eosinophilic count being normal. A low-grade infection was suspected, but no organisms could be isolated from three separate joint aspirations. A progressive radiolucent line underneath the medial part of the tibial baseplate was noted on serial radiographs (Fig. 1). A 99mTc MDP bone scan showed an increased uptake at this level, in contrast with a white blood cell scan, which was normal. A decision was made to perform revision surgery, one year after primary TKA. At revision surgery, soft tissues appeared inflamed, synovial fluid was clear. The oxinium femoral component was well positioned and fixed, the tibial component was clearly loose with a contained defect in the medial part of the proximal tibia. After freshening of the tibial cut, the defect was filled with morcelized cancellous allografts and a cemented Ti6Al4V baseplate with an intramedullary stem was implanted. No bacteria could be isolated from several intra-operative tissue and joint fluid cultures. The early recovery was again uneventful. At 3 months however, dermatitis reappeared and the knee became painful and swollen again. CRP and ESR remained slightly elevated. Consecutive radiographs once more revealed a progressive loosening of the tibial baseplate. Resorption of the morcelized allografts was initially thought to be responsible for this finding, but an allergic reaction to the implant was considered more and more. At that time the patient recalled being treated for a humeral shaft fracture with a plate and screw osteosynthesis thirteen years earlier. Although the fracture healed well and she recovered a good range of motion, the upper arm remained very painful. Radiographs and CT-scan showed good callus formation and no signs of loosening of the material. One year postoperatively, the material was removed, whereafter her symptoms completely resolved. We referred our patient to the department of dermatology to investigate a possible allergic cause. Despite her history of metal sensitivity, patch tests could not reveal any cutaneous reactions to titanium, nor to nickel, chromium or cobalt. After reviewing the literature, we found conventional skin testing to metallic allergy to be quite unreliable. Given the recurrence of the inflamma-

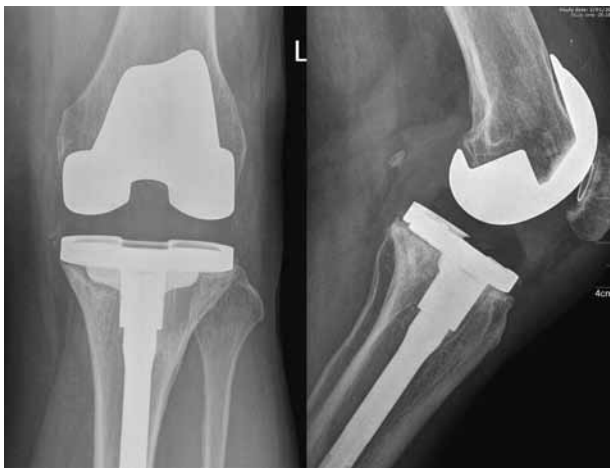

Fig. 1. — Anteroposterior and lateral view 3 months after first revision of the tibial component. An osteolytic clearance underneath the medial part of the implant was observed on serial radiographs and symptoms of dermatitis and swelling reappeared. The lateral view shows absence of cement behind the anterior flange of the femoral component, which did not change over time. At revision, the femoral component appeared well-fixed.

tory signs and of tibial component loosening, we decided to perform a second revision. A stable tibial baseplate with an intramedullary stem was needed, which ruled out the use of an all-polyethylene tibial component. A customized oxinium tibial baseplate and stem were manufactured, matching the sizes of the previous component. Although such an implant has not been reviewed or FDA approved, its hypoallergenic properties were thought to warrant its use in this case. At revision surgery, a rectus snip approach was used. Again, a loose tibial component was found. The femoral component was still well fixed. The contained defect in the proximal medial tibia was filled again with morcelized allografts. The oxinium tibial baseplate was fully cemented and a posterior stabilized tibial insert was used. In both revisions, antibiotic loaded cement was used (Palacos, Heraeus Medical). The intra-operative tissue and fluid cultures were negative for infection. The patient made an excellent recovery after the second revision. The skin rash resolved in 3 weeks and did not recur. At latest follow-up of 18 months, she had minimal pain and good range of motion, dermatitis did not recur. Serial radiographs showed a good position of the components and a thin radiolucent line underneath the medial part of the tibial component, which did not progress over time (Fig. 2).

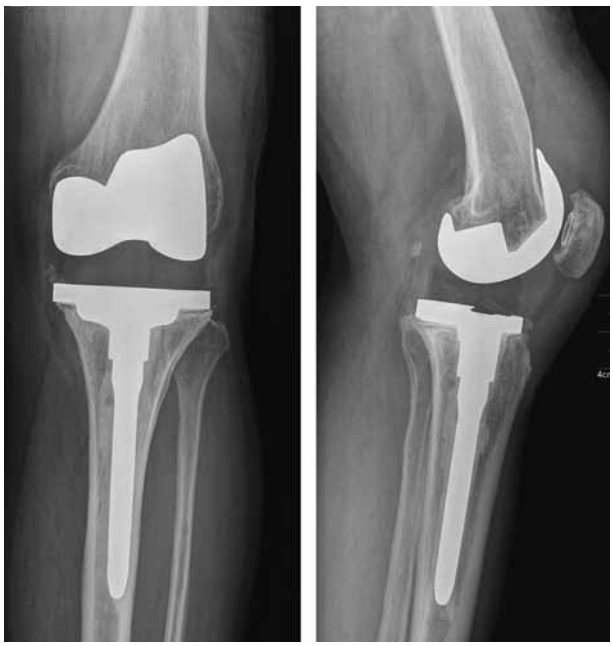

Fig. 2. — Anteroposterior and lateral view 18 months after the second revision of the tibial component with a customized oxinium implant. A thin radiolucent line has developed under the tibial tray ; it remained stable over time. The patient was free of allergic symptoms at this time.

DISCUSSION

Materials used for TKA are well known for their good biocompatibility, but corrosion of the implanted components and metal ion release may elicit an immune response in the periprosthetic tissue. Nickel, cobalt and chromium are known to be the most common sensitizers, but hypersensitivity reactions to Titanium, Vanadium and PMMA have also been occasionally reported (*3,9,11*). The possible correlation between implant failure and hypersensitivity has been previously investigated, but the question about a direct cause-result relationship has not yet been answered (*4,5,13*). Symptomatic metal sensitivity presenting as eczematous dermatitis, is rare and is currently estimated to occur in less than 1% of patients undergoing TKA (*3,6*). Implant-induced dermatitis and sensitization has raised concern whether it is clinically useful to screen for metal sensitized patients preoperatively.

Theoretically, skin tests may provide a clear advantage in the preoperative planning of TKA, as the most appropriate composition of the implant can be chosen. However, their usefulness in predicting hypersensitivity to metal implants remains unclear (*6*). Skin tests have certain limitations when used to determine deep tissue hypersensitivity. Skin is an excellent barrier sealing the immune system from direct environmental contact and short exposure of the skin to potential allergens does not represent the constant exposure of the periprosthetic environment to the implant (*4*). Alternatively, there are several *in vitro* tests for metal sensitivity detection based on leukocyte migration or proliferation (*3*). These tests are assumed to be more reliable but there are limitations to their large scale clinical application, including high costs and the

need for qualified laboratories (*4*). Another problem is that the issue of metal sensitivity is often addressed retrospectively, after the onset of symptoms like pain, effusion and dermatitis. A patient presenting with these symptoms should raise suspicion for infection in the first place. When thorough work-up has ruled out infection, diagnosis of metal allergy is often one of exclusion. When confronted with a case of suspected metal allergy, the surgeon should consider the use of alternative materials, eliminating the sensitizing metal. Titanium is known for its excellent biocompatibility and resistance to corrosion, while its low mechanical resistance and poor wear properties make it inappropriate to use as a bearing surface.

Ion implantation improves the wear resistance of titanium-based implants (*1,16*) and the use of femoral components entirely made of Ti6Al4V has been described with good early results. A higher failure rate at long-term remains an important issue of concern. Alternatively, patients with metal allergy can be treated with a Ti(Nb)N-coated knee implant made of cobalt-chrome (*14*). Surface coating prevents direct contact of the sensitizing material with the surrounding tissue. Good results at medium term and less wear on knee simulator have been reported (*14*). The use of ceramics, combined with an all polyethylene tibial component can eliminate metal from TKA. Both aluminum and zirconium are among the least bioreactive materials.

There is significantly less experience with ceramic bearings in TKA than in THA.

Concerns persist about the brittle nature of ceramics and their inability to withstand high-impact forces. Ceramic components in TKA have been in use in Japan for some time (*8,14*).

Laboratory wear studies demonstrated significantly less wear of the polyethylene and the ability to withstand high forces in the knee without fracturing (*14*). Oxinium implants can be used as well in patients with metal allergy. Oxinium is a metal/ceramic (97.5% zirconium – 2.5% niobium) composite with a surface coating of $\geq 5\ \mu$m of oxidized zirconium (*12*). Its hypoallergenic properties are comparable to ceramics, without the adverse biomechanical features. Oxinium femoral components have been in use for some time, mainly in younger patients, when polyethylene wear and long-term failure is a concern (*10,15*). Significantly reduced wear properties on knee simulator have been reported (*10,15*). In this case, an oxinium femoral component was chosen, given the young age of the patient. The first revision for early loosening of the tibial component failed to resolve the inflammatory symptoms. Since chronic dermatitis appeared after insertion of the implant and infectious work-up was negative, metal sensitivity to Titanium or Vanadium was assumed to be the most likely aetiology. Skin tests though, could not reveal any allergic reaction to the most common sensitizing metals. At the second revision, a customized oxinium tibial component was used to take advantage of its hypo-allergenic properties. After the second revision the skin reaction completely resolved and the patient remained free of symptoms. Some clearance appeared again underneath the medial part of the tibial baseplate. This radiographic finding was seen following both revisions, localized at a tibial defect which was filled with morcellized cancellous allografts. The lack of progression beyond the initial defect on serial radiographs was reassuring since resorption of cancellous allografts is a common radiographic finding. However difficult or impossible to prove, we are not convinced that the clearance following the second revision was caused again by an allergic reaction since symptoms did not recur.

The present case indicates that the use of an oxinium tibial baseplate can be a good alternative in total knee revision cases with sensitivity to Titanium or Vanadium. Especially when a stable implant with an intramedullary stem is needed, oxinium appears to be a good option. The indications should however be seriously balanced against the very high cost of such custom oxinium components. This case further illustrates that skin tests are not reliable in detecting metal sensitivity. The question whether to screen preoperatively for metal sensitivity remains a subject of discussion. We believe that certainly in cases with a history of metal sensitivity, screening should be performed and the use of alternative materials should be considered.

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