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Surgical technique

Custom titanium sleeve for surgical treatment of mechanically assisted crevice corrosion in the well-fixed, noncontemporary stem in total hip arthroplasty

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ABSTRACT

Adverse local tissue reaction associated with total hip replacement may occur when mechanically assisted crevice corrosion occurs at metal-metal modular junctions in which at least one of the components is fabricated from cobalt-chromium alloy. Complete removal of components may be associated with significant morbidity; when components are well fixed and in acceptable position, it may be appropriate to consider modular rather than complete revision. We have diagnosed mechanically assisted crevice corrosion in total hip arthroplasty patients with noncontemporary but well-fixed femoral components and found that modular conversion to a ceramic femoral head to remove a source of CoCr corrosion and fretting products was only possible by having a custom titanium sleeve manufactured. Surgical implantation with a revision style Biolox ceramic head (CeramTec, Plochingen, Germany) was then achieved.

Introduction

Serious adverse local tissue reactions (ALTRs) have become associated with metal-on-metal (MoM) joint failures, modular femoral neck components, and more recently, mechanically assisted crevice corrosion (MACC) at the taper interface of metal-on-polyethylene (MoP) total hip replacements [1-3]. Although some contemporary surgeries seem to have a higher prevalence of this issue [1], nonmodern implants may also fail in this manner, particularly after many years in service or after prior femoral head revision.

We present an approach to patients with MACC and noncontemporary total hip arthroplasties (THAs). When only "off-the-shelf" cobalt-chromium (Co-Cr) alloy femoral head options for revision of their well-fixed femoral components are available, we describe commissioning a custom titanium sleeve to be made that could be used with an already manufactured Biolox ceramic femoral head (CeramTec, Plochingen, Germany) to remove the source of Co alloy at revision. In our experience, metal ion levels decrease postoperatively, and patients are satisfied and improved at follow-up. This is the first report, to our knowledge, that describes the use of a custom titanium sleeve for surgical treatment of MACC in conjunction with a well-fixed nonmodern stem in THA.

Surgical technique

Once revision THA for MACC is contemplated, the exact implant is researched, preferably by obtaining the implant identification stickers. The manufacturer is then contacted to confirm the availability of a revision femoral head other than one made from a Co alloy (eg, ceramic with a titanium revision sleeve, BioBall Adapter System, and ceramic head [Merete, Germany] or zirconium alloy metal substrate that transitions into a ceramic zirconium oxide outer surface [Oxinium; Smith & Nephew, Inc., Memphis, TN]).

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Table 1
General process for obtaining manufacture of a custom titanium sleeve to allow implantation with a revision style Biolox ceramic head (CeramTec, Plochingen, Germany).

Confirm that ceramic or Oxinium (Smith & Nephew, Inc., Memphis, TN) revision femoral head component is not currently available for fixed femoral stem.
Request prosthesis trunnion specifications from femoral stem manufacturer.
Confirm that the custom titanium sleeve will work with implanted prosthesis (fixed femoral stem).
Obtain an assessment from a physician (orthopaedic surgeon) who is not biased concurring with plan to use the custom component.
Obtain compassionate use device documentation through hospital or practice IRB if indicated.
Submit device description including planned neck length and head size (Special products Implant Request Form).
Review manufacturing plan.
Forward purchase order to manufacturer for two devices (in case second urgent surgery is needed or the first implant is contaminated).
Obtain patient consent after reviewing risks, benefits, goals, and alternatives.
Sign informed risk document for surgery.
Proceed with surgery when device is available but have appropriate backup plan for revision if device is not suitable.

When no other options are available, in the case of a well-fixed and well-positioned femoral component, we have requested a custom titanium sleeve to be manufactured that works in conjunction with an "off-the-shelf" revision Biolox ceramic femoral head (Biolox Option; CeramTec, Plochingen, Germany). We have requested that the femoral stem manufactures make this product, as they have the exact specifications of the femoral trunnion. Table 1 summarizes the steps necessary to manufacture such a custom product. Note that if the company has made <5 such custom products in the last year, the Federal Food, Drug, and Cosmetics act was amended to allow the company to manufacture these for compassionate use without institutional review board approval. Our institutional review board, however, noted that the Food and Drug Administration recommends that physicians should follow as many of the patient protection procedures as possible (Table 2).

Of note, the surgeon should consider the exact femoral neck length that is being sought when manufacturing the custom sleeve. We choose the same or slightly longer length of the implanted neck if the leg length is acceptable to ensure stability at the time of revision. Also, we have had two sleeves per patient made, in case one is inadvertently contaminated during surgery or a repeat revision is needed.

The technique itself is exactly as for the Biolox Option (CeramTec, Plochingen, Germany) technique [4]. The ceramic femoral head is placed on the head adapter, and pressure is applied until resistance is felt. The ceramic femoral head must be placed straight down on the sleeve. The system components are then assembled on the femoral stem; no washing or cleaning is necessary.

Case example

The patient is a 52-year-old man who reported newly onset groin and buttock pain of the left hip 18 years after total hip replacement surgery for osteonecrosis and 5 years postrevision total hip replacement for instability. A 36-mm, medium-plus Co-Cr head was used on the 6° taper of the patient's titanium fiber metal ingrowth stem (Zimmer, Inc., Warsaw, IN). Physical examination of the patient demonstrated no gait impairment, and abductor strength was found to be satisfactory. Medical history was positive for diabetes mellitus, type 1.

Radiographic examination showed no obvious evidence of osteolysis or loosening and that hip components were satisfactorily positioned. The calcar osteolysis associated with his prior surgery had not increased (Fig. 1). Laboratory tests conducted approximately 3 months after the onset of hip pain revealed serum Co (2.2 ppb; normal, <0.3 ppb) and Cr (2.4 ppb; normal, 0.0-0.9 ppb) ions in the blood. Complete blood count revealed a white blood cell count of 5600 cells/mm^3 (normal, 4200-9900); C-reactive protein was found to be normal at 0.9 mg/L (normal, 0.0-8.0 mg/L), as was erythrocyte sedimentation rate at 8 mm/h (normal, 0-10 mm/h). Axial, coronal, and sagittal sequencing performed using metal artifact reduction sequence magnetic resonance imaging found no

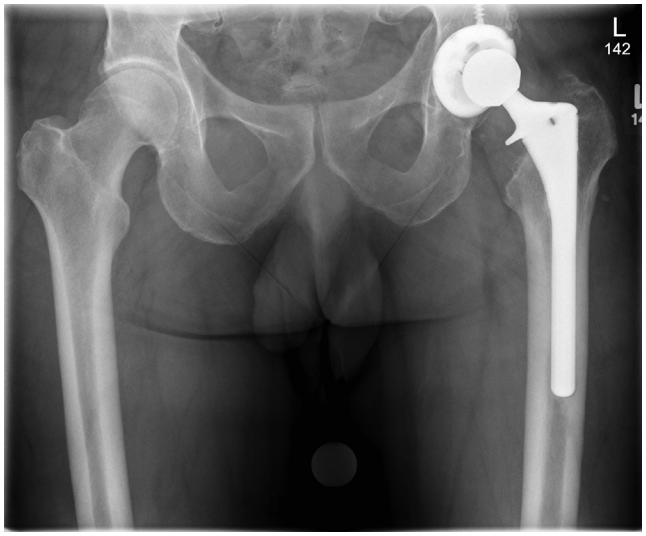

Figure 1. Anteroposterior pelvis radiograph of a 52-year-old man with a revision metal-on-polyethylene bearing surface THA and new diagnosis of MACC. The acetabulum and femoral stem appear to be well fixed. Osteolysis associated with his prior surgery has not increased over time.

Table 2
Patient protection procedures recommended by the Food and Drug Administration for use of a custom device in joint replacement surgery.

Informed consent from the patient or a legal representative.
Clearance from the institution as specified by institutional policies.
Concurrence by the IRB chairperson.
Assessment from a physician (orthopaedic surgeon) who is not biased concurring with plan to use the custom component.
Authorization from the investigational device exemption (IDE sponsor) if an IDE exists for the device.

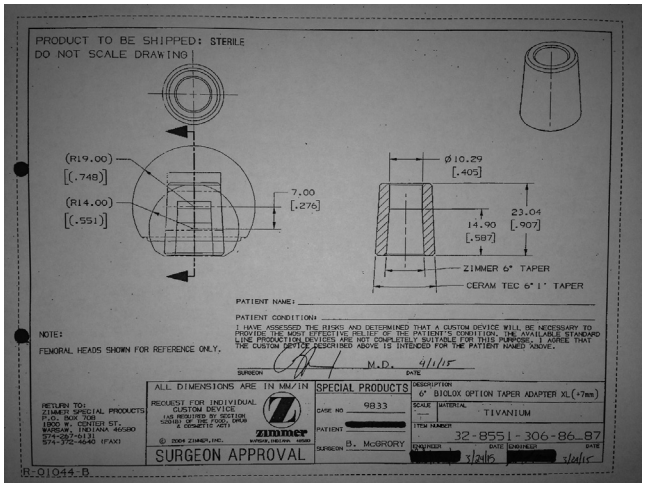

Figure 2. Drawing sent for surgeon approval of a custom titanium sleeve.