CLINICAL REPORT

Bilateral simultaneous metal inlay dissociation from the polyethylene liner of a metal-on-metal hip replacement

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Accepted: 3 July 2009

KEYWORDS
Total hip arthroplasty; Composite polyethylene liner failure; Prosthetic components dissociation; THR mechanical failure

Summary

Introduction: Hard-on-hard bearings for total hip replacement may require a modular acetabular inlay for which polyethylene is often used in a sandwich-type configuration. However, differences in the elastic modulus of the materials make fixation of this metal insert uncertain. The aim of this study is to report a case of bilateral separation of the metal insert from the polyethylene sandwich in a metal-on-metal bearings prosthesis.

Materials and methods: A bilateral total hip arthroplasty was performed in two operations, four months apart, in a 53-year-old woman following a corticosteroid-induced osteonecrosis. The total hip replacement system included a cementless stem, and a press-fit hemispheric cup containing a polyethylene sandwich with a metallic insert (Sikomet\textsuperscript{TM}).

Results: Three years later, the patient consulted because of abnormal noise in her right hip which appeared normal on conventional X-ray. Three months later she consulted again for persistent noise. Separation of the metal insert from the polyethylene sandwich was diagnosed and an acetabular revision was performed selecting a metal-on-polyethylene articulation system. The postoperative course, for this revision, was uneventful, but the patient returned with the similar symptoms in her left hip four months later, resulting in the same type of revision. During the revisions, osteolysis secondary to metallosis was diagnosed, requiring synovectomy and acetabular reconstruction with morcelized allograft impaction. The left side postoperative course included three dislocations in nine months which were conservatively treated and have not since recurred.

Discussion and conclusion: This is the first reported case recording an almost simultaneous bilateral dissociation of a hard-on-hard inlay from its polyethylene sandwich. This bilateral case suggests that the fixation of the metal insert inside the polyethylene was probably defective. This case is also a reminder that mechanical complications (separation, implant fracture)
should be searched for in presence of any abnormal noise occurring after hard-on-hard bearings prosthetic implantation. This confirms the necessity of periodical follow-up of hip arthroplasties and the importance of knowing their radiological features. The low carbon content of the Sikomet™ bearing may have been the cause of this failure by increasing frictional torque on the bearing surface, causing metallosis which has already been described in the literature in this type of hip replacement system.

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Introduction

The introduction of the second generation of metal-on-metal bearings for total hip arthroplasty was facilitated at the end of the 1980s by the use of a polyethylene sandwich [1]. Indeed, direct cementing of a metallic cup into the acetabulum was one of the reasons for loosening in the McKee implants [2,3]. To avoid this type of failure, it seemed logical to use a sandwich system which would allow fixation similar to that of conventional implants. The failure of directly cementing a metal insert onto bone was only recognized later in the middle of the 1990s [4], then confirmed by association with the cementing of small diameter Metasul™ sandwich-cups [5,6] and the analysis of mechanical and clinical data [7,8]. After the study by Weber [1], a cementless system was developed for the Metasul™ bearing system at the beginning of the 1990s with a polyethylene sandwich [9] attached to a metal back with a treated surface to favour osseointegration. The reliability of this type of fixation has been confirmed with 10 years of follow-up [10,11] and has favoured the development of implants with a polyethylene sandwich for metal-on-metal [12] or ceramic-on-ceramic bearing systems [13,14]. In the latter system, the difference in the elastic modulus of ceramic and polyethylene has been blamed for loosening and fractures in ceramic inserts [13,14]. As a result, orthopaedic specialists have been warned about defective sandwiches in ceramic inserts. [15]. On the other hand, to our knowledge, reports on the separation of metal-on-metal articulations are rare, and usually entail manufacturing problems with the devices rather than the design of the sandwich itself [16,17]. We report our experience with a metal-on-metal Sikomet™ articulation system. The bilateral nature of this report provides new information about this complication.

Clinical case

Bilateral total hip arthroplasty was performed in two operations four months apart in 1999 in a 53-year-old woman with Arlet and Ficat stage III bilateral osteonecrosis [18]. The patient had been treated with corticosteroids for a benign brain tumor (meningioma) diagnosed three years before. She weighed 63 kg and was 1 m 68 tall, had a position in sales, exercised at a gym and practiced horseback riding and modern dance; her activity level was rated as 4 according to Devane et al. [19]. Bilateral hip mobility at arthroplasty was: 110/10, 40/20, 40/30.

The total hip arthroplasties, performed by posterolateral approach, included a cementless stem (SL+, Endoplus/Smith and Nephew), a press-fit hemispheric cementless cup (EP-Fit, Endoplus/Smith and Nephew) with a polyethelene sandwich housing a low-carbon metallic insert which is industrially welded to the plastic (Sikomet™). The head of the articulation was 28 mm in diameter (with a long neck requiring a skirt adapted to the Sikomet™ bearing on the left hip for stability). The postoperative follow-up was uneventful and the patient went back to work three months after the second total hip arthroplasty. She was not seen again after the 12th month of follow-up when hip function was evaluated at 18 points according to Merle D’Aubigné [20]. Plain X-rays were normal. She gradually took up her different athletic activities again (swimming, biking) and her level of activity was rated as 3 according to Devane et al. [19].

The patient consulted three years later for abnormal noise in the right hip. She was not seen by the surgeon and X-ray results were normal. Three months later, she consulted the surgeon because of persistent noise. Separation of the metallic insert from the polyethylene sandwich was diagnosed (Fig. 1) requiring unilateral acetabular revision with a metal-on-polyethylene articulation component (with a change in the size of the 28 mm head). A 2 mm deep notch was found in the neck of the implant caused by prolonged displacement of the insert. The surgeon considered changing the femoral component because of this notch, but the notch, un cemented stem could not be removed even with the proper instruments. Because of this difficulty and also in consideration of potential medicolegal issues in case of iatrogenic femoral bone lesions, the surgeon decided to revise the acetabular component only. After an uneventful postoperative course, the patient arrived for both revisions requiring a long head with a skirt for stability. The postoperative follow-up was uneventful and the patient went back to work three months after revision was performed. As a result, a report was made to the appropriate medical device vigilance authorities. During both revisions, acetabular osteolysis secondary to metallosis was diagnosed requiring extensive synovectomy and acetabular reconstruction by impaction allograft. A traditional metal-on-polyethylene articulation was used for both revisions requiring a long head with a skirt for revision of the left side. The postoperative course included three dislocations in nine months on the left side which were treated conservatively. There was no recurrence after this date. Five years later, there are no complications at the level of the notch in the neck of the right implant and there is no sign of separation or osteolysis in either of
Bilateral simultaneous metal inlay dissociation

Figure 1  A: X-ray of the pelvis, frontal view, three months after the development of noise in the right hip. Slipping of the insert is suspected because the acetabular component and the head of the stem are no longer concentric. Slipping is confirmed by the presence of a groove in the lower edge of the stem (arrow). The left hip is normal; B: schematic slice of the entire metal back (black), the polyethylene sandwich (white), and the metallic insert (grey). The metallic insert has become separated from the polyethylene at the interface indicated by the arrows.

the arthroplasties (Fig. 3). The patient lost her job, and negotiated compensation while waiting to find employment.

Discussion

This is the first report of nearly simultaneous separation in this type of implant. The nearly simultaneous and bilateral nature of these separations suggests that there is a defect in fixation of the insert rather than a surgical error because the initial orientation of the implants was correct (Fig. 1). Three factors must be evaluated in this case report:

- the use of a skirted head in the left hip replacement, which might favour cam-impingement and could have caused loosening of the metal insert. However, the complications first occurred in the right side, the second to be operated on, and in the implant without the skirt;
- an indication of osteonecrosis, which would not affect mobility and might suggest the presence of cam-impingement, favouring movement of the metal insert, although the patient did not notice anything until the complications occurred. However, from this point of view, the left hip arthroplasty with the skirt should have been more vulnerable and since it was the first to be operated on, should have been the first to develop this complication;
- the use of a low-carbon (Sikomet™) articulation system. An increased frequency of osteolysis and loosening has been found with this articular system by Korovessis et al. [12] and Milosev et al. [21].

These authors have suggested that a breakdown in the tribiological properties of the articulation system, causing metallosis as in our case, and increased frictional torque in the bearing could result in separation [12,21]. This latter
hypothesis associated with a defect in the design for fixation of the metallic insert into the plastic, played a role in the development of this bilateral complication in our report.

This type of complication has not been observed in vivo with the Metasul™ systems even after 10 years of follow-up in active patients [10], confirming the importance of the mechanical and chemical properties of metal-on-metal bearings. Saito et al. [22] reported a case of unclipping of the polyethylene from the metal back (InterOp cup) without mechanical failure of the Metasul™ bearing. Saikko et al. [23] reported in vitro separation of a Metasul™ insert from a 28 mm polyethylene sandwich following a sudden increase in frictional torque of the bearings after 1.66 million cycles. A similar case was reported by Cazenave [17] with another metal-on-metal bearing (Ellistra™, Stratec). Cazenave [17] reported osteolysis secondary to metallosis and described another case of abnormal motion between the metal insert and its polyethylene backing. This author concluded that the design for fixation of the metal insert was defective but not the metal-on-metal bearing itself. Both our case and that of Cazenave [17] suggest that a defective metal-on-metal bearing, besides causing metallosis, may also cause separation of a sandwich or a cup by increasing frictional torque in the bearing, thus emphasizing the importance of the design of this type of bearing. In our report, metallosis was probably caused by the use of the Sikomet™ [12,21] articulation and from the contact between the stem and the insert after it loosened.

Our case confirms the importance of close follow-up of innovative implants and the importance of knowing their radiological features because, in our case, diagnosis was delayed by three months, favouring the development of a notch on the metallic stem and a risk of fatigue fracture. Maintaining the femoral stem was debatable, but excision included a risk of bone complications which the surgeon preferred to avoid because of the medicolegal risks. Short-term conciliation with the patient, despite the favourable course of the revisions, and the absence of complications in the notched component five years after surgery, confirms that this was the best choice. The risk of stem fracture might have been greater if the groove had been craniolateral rather than inferior. This case shows that a mechanical complication (dissociation, fracture of one of the ceramic components, instability, cam-impingement) should be looked for in case of any abnormal noise in a hard-on-hard bearing.

References