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ORIGINAL PAPER

Early failures of porous tantalum osteonecrosis implants: a case series with retrieval analysis

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Abstract
Backgrounds Porous tantalum osteonecrosis implants have been used in femoral head necrosis for several years, while the clinical outcomes were mixed. As a joint-preserving surgery, early necrosis deterioration and conversion to total hip arthroplasty failed our expectation. We hence investigate an observational study with retrieval analysis to find out the underlying reasons.
Methods Thirteen patients were treated with core decompression and implantation of a tantalum rod. The cases were evaluated both functionally and radiologically. We retrieved and analyzed the micro-structural changes and the histopathologic features of four early failed femoral heads with scanning electron microscopy, histopathologic examination, and micro-CT scaning.
Results All implants were placed in proper positions. One-year survival rate was 64.29 % with a HSS score of 81.11 ± 15.62. Four patients converted to arthroplasty in a mean time of 305 days (0.84 years), with a HSS score of 43.75 ± 7.5 at the last follow-up. A liquid layer surrounded the tantalum implant was noted on MRI in all four failed cases. Volume render CT remodeling revealed interspace between the metal and bone. Scanning electron microscopy and histopathologic examination indicated sparse and isolated bone ingrowth into the implants. The remodeled trabecular bone and the increased density around the peri-implant area were illustrated with micro-CT scaning.
Conclusions The deterioration of early failed tantalum implant exceeds the nature of osteonecrosis progression. Rather than insufficient mechanical support resulting in improper position and invalid bone ingrowth, nullification of core decompression and consequential intra-osseous pressurization probably led to early failure of porous tantalum osteonecrosis implants.

Keywords Femoral head · Osteonecrosis · Porous tantalum osteonecrosis implant · Total hip arthroplasty

Introduction

Porous tantalum rod implantation has been widely applied to patients with early-stage osteonecrosis of femoral head (ONFH), in which neither collapse of the femoral head nor any crescent line is noted. Combined with core depression (CD), it is supposed to reduce the increased intra-osseous pressure and to provide structural support [1]. The reasons for the use of tantalum are its high porosity (75 to 80 %), fully interconnected pores, osteoconductivity, and an elastic modulus similar to that of cancellous bone. Hence it is able to provide mechanical support and to allow bone growth into the avascular femoral head [2, 3].

Aiming at postponing or avoiding total hip arthroplasty (THA), this technique succeeds in most of the human cases and the clinical efficacy and post-operative follow-ups have been well described [1, 4, 5]. Nevertheless, there are still some concerns regarding early failure and remedial THA surgery which occasionally happened within the first few post-

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operative years. The short survival time was in the contrary to the our purpose of joint-preserving and with low economic efficiency. It is suggested that early failures usually happen within the first two years, and make up the majority of clinical failures [6].

To date, there have been no specific report and analysis for the early failures in literature. In the present study, we presented a case series of patients receiving porous tantalum rod implantation, in which early failures were described and analyzed in an attempt to elicit reasons. We hope the lessons learned from the failed cases could help improve the treatments in future.

Patients and methods

Patients and surgical techniques

Prospectively, an observational cohort study was designed to evaluate the efficiency of femoral head necrosis (FHN) treatment with porous tantalum rod implantation. From 2013 to 2015, 13 patients who met the inclusion criteria were enrolled in our survey. Experimental subjects were taken from patients referred to a single surgeon for treatment of ACRO I and II unilateral or bilateral femoral head osteonecrosis. Only patients with non-traumatic aetiologies for the disease were considered for participation in the study. Exclusion criteria also included patients who were actively being treated with corticosteroids, had previous surgery to the affected hip, or were unwilling to have surgery at time of clinical presentation.

The operation was conducted in supine position. Fluoroscopy was used to detect the centre of the necrotic lesion and the point immediately superior to the lesser trochanter. A 4~6 cm skin incision was made along the lateral thigh. The subcutaneous soft tissue, the fascia lata, and the vastus lateralis muscle were then split in the direction of the fibres to expose the lateral proximal femur. A guide pin hole was drilled from the proximal lateral femur into the centre of the necrotic lesion, and reamed along the path. After measurement, a porous tantalum rod (TaBw01, Zerun, Chongqing, SC, PRC), with length of 70–130 mm, 10 mm diameter, and 14 mm threads, was inserted into the proper position. After fluoroscopic confirmation, the incision was closed in layers. Patients remained in hospital for an average of three days for post-operation care and were limited weight-bearing in hospital, with progression to full weight bearing as tolerated thereafter.

Clinical evaluation and conversion to THA

Post-operatively, patients were evaluated clinically using the Harris hip score (HHS) and radiologically using post-operative X-ray. MRI scans were done in all cases at first, third, sixth, 12th to document the progression of necrosis, to reveal its space relationship with inserted tantalum rod and to evaluate the supporting effect on the subchondral bone.

The indications for conversion to THA were either clinically with persistent hip pain interfering with the daily activity and deterioration of the hip score or radiological collapse of the femoral head and intra-articular penetration of the tantalum rod. The technique of conversion to total hip arthroplasty after a failed tantalum rod included femoral neck osteotomy and cutting of the implantation, both done using the power saw with an excision of the trochanteric part by a special core reamer. The procedure was completed as a straightforward hip arthroplasty using a cementless prosthesis with ceramic on a highly cross-linked polyethylene-bearing surface.

Analyses of bone-implant specimens

In vitro CT scan was performed for each specimen to further confirm the position relationship between the bone and implant, to determine the location of the implant with respect to the osteonecrotic areas. Volume rendering technique (VRT thin collection, SIEMENS SOMATOM definition) was applied to highlight the interspace between materials.

Bone density measurements of the cancellous bone were made using micro-CT technique. A preliminary scan of specimens from case 5 was done with porous tantalum implants inside. Other specimens were cut into approximately 8 mm thick sections and the implants were removed with trepan to avoid metal artifact. The X-ray source voltage was set at 70 kV and beam current at 200 mA using filtered Bremsstrahlung radiation. Acquisition times were approximately four hour/specimen.

Scanning electron microscope (SEM) was performed at 20 kV accelerating voltage, 50× to 1000× magnification (S-3000 N, Hitachi). The microstructures of the samples were observed, to confirm the tissue ingrowth into the tantalum pores, and to evaluate the tightness of bone-metal interaction.

The bone-implant specimens were then fixed in 10 % buffered formalin and prepared for undecalcified thin-section histological analysis [7]. The sections were mounted to a glass slide, progressively thinned with petrographic grinding techniques, HE and Masson stained respectively, and examined with transmitted light microscopy. This enabled qualitative assessment of the tissue response to the tantalum implant, including the identification of calcified and fibrous tissue, the formation of new bone, and the vascularity and cellularity of the femoral head.

Results

Up to July 2015, an average 19-month follow-up was made. We compared the pre-operative, six months post-operative, and one and two years post-operative HHS (Table 1). At

Table 1 Demographic data of enrolled patients

Case	Name initials	Age	Sex	Etiology	Affected side	ARCO grade	Location of lesion*	HSS				Days before conversion to THA	Comments
								Pre-op	Post 6 months	Post 1 year	Post 2 year		
1	C.LJ.	60	F	Idiopathic	R	II	A	56	86	90	90		
2	J.LH.	37	M	Idiopathic	L	III	A	58	84	80	–		
3	X.XJ.	36	M	Idiopathic	R	II	C2	54	80	80	–		
4	L.ZG.	27	M	Alcoholic	L	II	C1	32	85	90	–		
5	C.W.	57	M	Alcoholic	L	II	C2	40	55	THA	THA	227	Right PTR[a] /bilateral THA
6	L.F.	27	F	Cortisone	L	III	C1	61	THA	THA	THA	21	Postoperative infected
7	Z.ZH.	27	M	Idiopathic	L	III	C2	30	80	80	–		
8	Z.DS.	39	M	Idiopathic	L	II	A	44	55[b]	85	88		
					R	II	C2	44	40	THA	THA	317	
9	S.HY.	34	M	Idiopathic	R	II	C1	55	88	88	88		
10	S.SFS.	48	M	Idiopathic	R	II	C1	64	88	–	–		
11	L.NP.	47	M	Idiopathic	R	II	C1	50	58	40	THA	478	
12	Y.HJ.	44	M	Idiopathic	R	III	C1	46	85	88	–		
13	Z.SJ.	38	M	Idiopathic	L	II	C2	34	40	THA	THA	196	Left PTR[a] /b ilateral THA

*Lesion location partition was performed according to the guideline of Japanese Investigation Committee (JIC) [9]: Type A: lesion located in interior 1/3 of weight-bearing area; Type B: middle 1/3; Type C1: lateral 1/3, not exceed acetabulum limbus; Type C2: over the acetabulum

[a] *PTR* Porous tantalum rod (implantation)

[b] The symptoms were much improved in the left hip, while the right hip progression influenced the HSS in gait, daily activity, etc.

six months follow-up, the mean HHS score improved from 47.71 ± 10.93 pre-operatively to 71.08 ± 18.55 ($p < 0.05$). The survival rate was 100 % at six months. Between six post-operative months to one year, three cases had persistent pain and unsatisfactory outcome (HHS score was 55, 40, and 40) and were converted to total hip arthroplasty. The remaining nine hips (64.29 %) were still doing well at one year with a mean score of 81.11 ± 15.62. All three patients who had a hip survival time longer than two years, were still doing well with good functional score (88.67 ± 1.15) and unchanged radiological appearance.

As for the early failed cases specially, four patients (besides one infected case, the same hereinafter) turn to THA for early deterioration and failure of implants. Two cases had obvious radiological progression and the other two were with persistent hip pain interfering with daily activity. Clinical symptoms began to progress after a mean time of 5.3 months (ranging from 3 to 7 months). The last HSS score before THA was 55, 40, 40, and 40. Conversion to THA occurred after a mean time of 305 days (0.84 years).

Post-operative radiology revealed proper position of implanted tantalum rod in all hips. Conventional MRI confirmed the distal portion was inserted into the centre of necrotic area correctly, even in the necrosis progressed femoral heads. Osteonecrotic lesion progression were present in six (46 %) of 13 hips. Fracture of the subchondral bone of the femoral head was present in all cases and two (15 %) of 13 femoral head collapses were identified in the MR images. The osteonecrosis affected the superolateral portion of the femoral head in all six progressed cases. A liquid layer surrounded the tantalum implant (Fig. 1) was noted in nine (69 %) of 13 hips in which five (56 %) disappeared at the next follow-up, the remaining 4 progressed gradually and finally turned to THA.

In vitro CT scan with 3D remodeling simulated the space relationship between bony structure and the implants. Cavity was found in all four specimens retrieved from failed cases using volume rendering technique (Fig. 2). In one case the cavity was only found around the distal part of the rod, while in the three diffused around the whole implants. Therefore, questions were raised for the extent of the supposed osteointegration.

Retrieval scanning electron microscopy confirmed the presence of tissue ingrowth into the porous structure with full extent (Fig. 3a). Even though interfered by grease on the surface of the tantalum, obvious cell-shape morphology was found under 100× magnification (Fig. 3b and c). However, An obvious gap at the interface was found, which indicates a weak connection between the bone and metal (Fig. 3d). The average distance was 0.27 mm (ranging from 0.16 to 0.34 mm).

The histological examination confirmed the bone ingrowth into the porous system (Fig. 4a and b). Furthermore, it also revealed tissue that ingrows into porous structure to be not only migrated bone cell (Fig. 4c) but also fibrocyte-formed connective tissue (Fig. 4d). The implant surface was in contact

Fig. 1 MRI follow-up of case 5 showed persistent bone marrow oedema and complete regression after insertion of a tantalum implant: **a**. Pre-operative (stage ARCO II with tendency to ARCO III). **b**. 1 month post-operative. **c**. 2 months post-operative. **d**. 6 months post-operative

with sparse and disconnected islands of bone. The tissue ingrowth extends from 1 to 4 mm from the implant periphery. Normal cell morphology was observed of osteocyte in the pores besides dead marrow tissue with fat necrosis (Fig. 4e) and infiltration of chronic inflammatory cells (Fig. 4f). Well re-formed bony trabeculae was identified around the peri-implant area, in contact with extending tissue from the implant periphery (Fig. 4g and h). In two cases the ingrowth occurred in portions of the implant within the femoral neck and head region, while in the other two cases it occurred only in the neck region.

The micro-CT image confirmed remodeled trabecula and messy topographic structure around the area of metal implantation. Obvious fibroplasia and strong sclerosis was found. Areas of peri-implant sclerosis and comparatively normal trabecula could be easily recognized in the single tomographic film. A low-density region was found in the sclerosis portion beside the implant drill hole in case 11. It was thought be the appearance of a bone cyst secondary to high intramedullary pressure and marrow edema around the tantalum implantation (Fig. 5).

Discussion

The development of porous tantalum rod intervention was supposed to improve the treatment of precollapse, to delay final arthroplasty as long as possible. The design of this surgery were thought to include the advantages of the core decompression (CD): reduction of the intra-osseous pressure, structural support, and reperfusion with the possibility of regeneration [5]. However, early conversion to THA failed our expectation.

Studies had recently pointed out the reason of these unsatisfactory results. Retrospective analyses suggest that the hips with lateral lesions were more prone to early failure, especially the type C-2 lesions because it was difficult for the metal implants to achieve proper positions and further to provide necessary mechanical support [5]. In this study, osteonecrosis progression in the superolateral portion of the femoral head was found in all six progressed cases. It was hypothesized that improper implantation position was one of the causes that result in early failures [8]. However in this study, all of the tantalum rods including the failed ones were implanted with fitness, proved by the postoperative X-ray and additional MRI follow-up. Additionally, for each implant, the distal portion was inserted right through the centre of necrotic area. In a recent study, Osman et al. also found that implantation of a porous tantalum metal rod for early-stage osteonecrosis of the femoral head did not add a significant advantage to CD alone even with the proper position in relation to the necrotic area, 60 % of the cases turned to THA finally [8].

In contrast to most of the previous studies, an MRI scanning was conducted in our study. In a few cases, a liquid layer surrounding the tantalum implant was seen. Also, in vitro CT

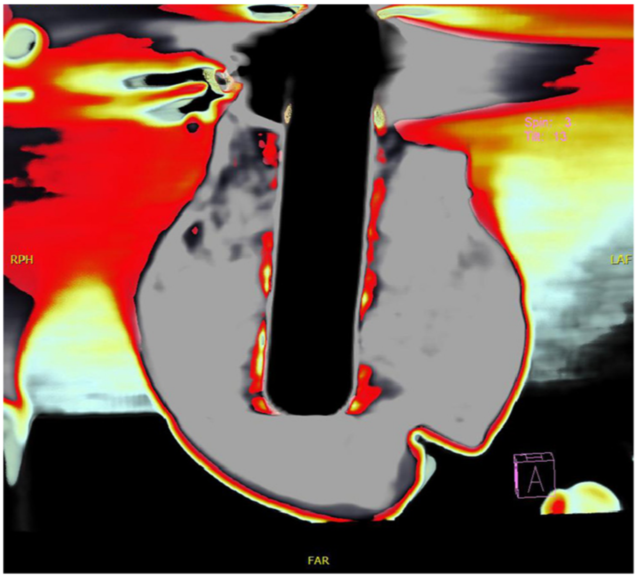

Fig. 2 3D remodeling CT of case 13, which was fetched after 6.5 months in situ. Diffused cavities were found around the implantation

scan and 3D remodel confirmed the existence of interspace. Questions were raised of the extent of the supposed osteointegration. A finite element analysis reveal a less superior performance for tantalum rod implantation than simple CD presumably due to the lack of complete bone ingrowth of the implanted tantalum [9]. In this study, SEM data of retrieved FHN proved full ingrowth of tissue into the porous structure other than what is said to be dead marrow tissue packed in [7]. We found under higher magnification, cell-sharp structure distributed evenly on the inner surface of the pores. To our disappointment, HPE revealed only isolated, sparse regions of real bone ingrowth into porous tantalum implants. Cytocompatibility studies had confirmed vivid migration and proliferation of osteocyte on tantalum materials before [2], while according to our observation fibrocytes anticipate to occupy the porous surface maybe even earlier in a much better bioactivity with the tantalum material. The compactness and mechanical strength might therefore be influenced.

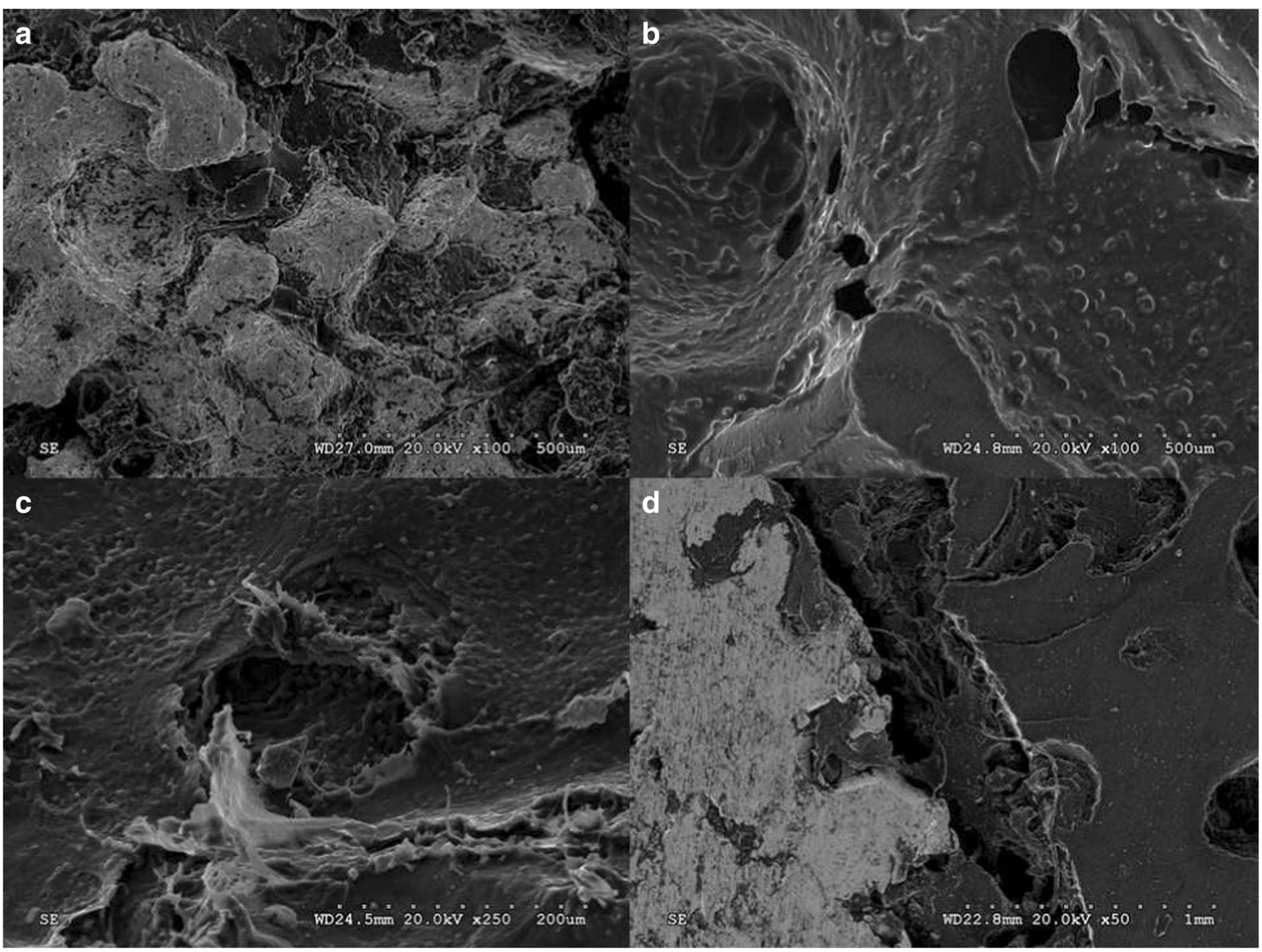

Fig. 3 Scanning electron micrograph of specimen taken from case 5. **a**. Full tissue ingrowth on the tantalum surface (100×). **b & c**. Cell migration into/around the porous structure. **d**. Interspace between metal (*left*) and bone (*right*)

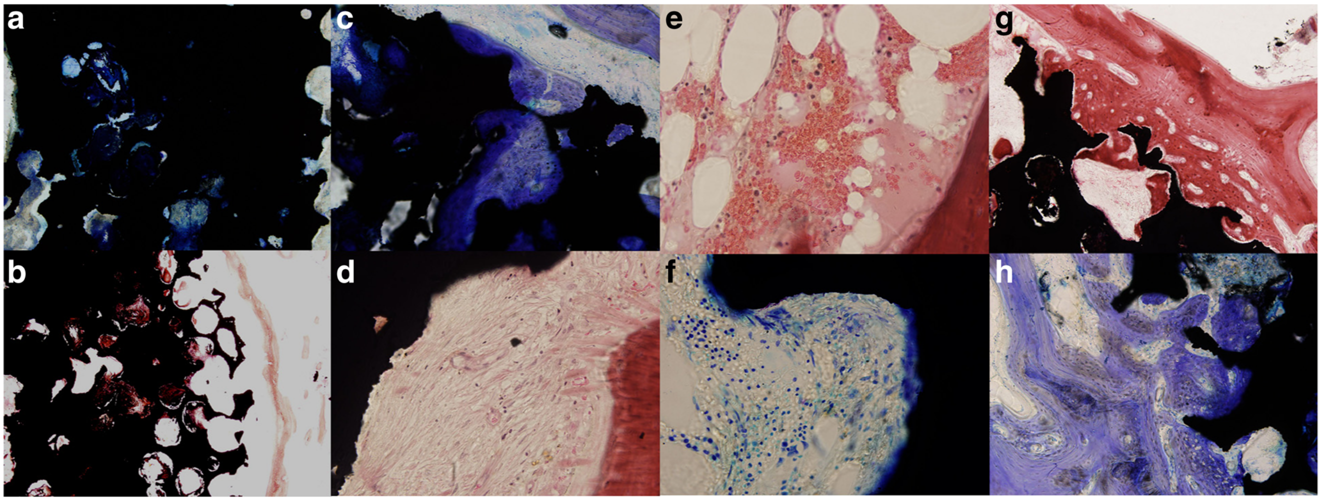

Fig. 4 Specimens from case 5 (**b**, **d**, **e**, **g**) and case 11 (**a**, **c**, **f**, **h**). **a & b**. Bone growth deeply into the porous system (left the center, right the periphery). **c**. Osteogenesis in the micro pores. **d**. Fibrous scars attached on the metal. **e**. Dead marrow tissue with fat necrosis **f**. Chronic inflammatory cells around the implant. **g & h**. Trabeculae remodeling and connecting to the host bone

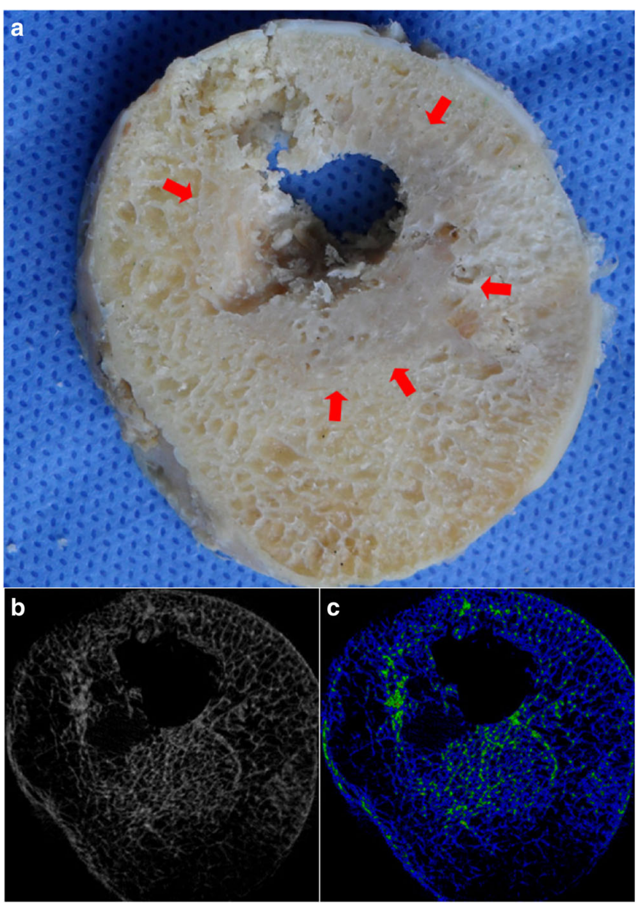

Fig. 5 Specimen retrieved from case 11. **a**. A compact layer of bone around the tantalum implant was noted on the gross section. **b & c**. Micro-CT revealed sclerosis around the peri-metal area with bone cyst formation (increase of bone density in the sclerosis area highlighted in *green*)

Augmentation has also been explored for the role of bone ingrowth and how much bone graft transplantation could contribute to it. Zhao et al. reported a five year joint-preserving success rate of 87.5 % for entire group treated with tantalum rod implantation and vascularized iliac grafting, 95 % for ARCO stage II hips, 92 % for ARCO stage III hips [10]. Liu et al. found among the tantalum implant failed hips, 35/79 (44.3 %) did not undergo bone-grafting, whereas only 8/59 (13.6 %) of those undergoing bone grafting failed [6]. The advocates of vascularized bone grafting believe that vascularized grafts should enhance its incorporation with the host bed, maintain the viability and provide perfusion and osteoformative cells to the osteonecrotic area [11]. However, in a histopathologic study of free vascularized bone grafting, Gonzalez Del Pino et al. found the invalid function of anastomosed vascular, and the new bone in the femoral head was originated mainly from the host bones rather than the grafts [12]. We presume similar deduction could be used here in our analysis. Reasons for unsatisfactory early results need further investigations.

As reported previously [4], the operation results may differ from patient to patient. In contrast to previous encouraging studies, this study showed only 64.29 % satisfactory results at one year follow-up, the conversion to THA occurred after a mean time of 305 days (0.84 years). Although in successful cases the survivors had improved symptoms and almost unchanged radiological appearances over two years, yet in the failed ones the incidence and time of the early conversions to THA was embarrassing comparing with the published data about outcomes of CD alone [13, 14]. Despite the uncertainty and varying long-term effect of CD due to a lack of mechanical support, the short-term result was well established. The design of this tantalum implant insertion were thought to include the advantages of the CD. However the result especially the early failures revealed a worse outcome than that described previously in the literature [5, 12, 15] and no better outcomes than simple CD surgery [16].

CD is able to relieve hip symptoms and prevent further necrosis by reducing the intra-osseous pressure and enhancing reperfusion. In this study, a compact layer of bone around the tantalum implant was noted. Compared with surrounding cancellous bone, the topographic structure seemed messy and the bone density was higher; this is mighty because the micro-fracture of trabecular bone induced during femoral drilling [17]. It seems that this continuous shell of bone and fibrous tissue accretion might have nullified the effect of core decompression, by blocking the porous tantalum. Although the implant provided good structural support to the articular cartilage and helped maintain the integrity of the articular surface, the pressure-relief pores were blocked completely soon after surgery, probably leading to a fast increase in the intramedullary pressure and causing symptoms before radiological progression. Oh et al. reported an early clinical failure of porous tantalum rod with proper position and vivid bone ingrowth [18]; the patient suffered hip pain again at six weeks after the tantalum implant surgery and had to convert to THA after four months. The development of symptom was much similar to two of our failure cases (cases 11 & 13). Serial reactions might happen after the overrun of intramedullary pressure, which would cause bone marrow oedema (the most significant risk factor and strong prognostic sign for worsening hip pain [19]), micro-vascular compression, bone ischemia, and finally femoral head necrosis. In case 5, a large lesion area of consequential cystic degeneration around the implant was observed. Thus, insufficient mechanical strength could be provided, which might result in femoral head collapse finally.

The reason for precocious trabecula reconstruction was undiscovered, but clues have pointed to probably early weightbearing. The post-operative weight-bearing protocol after tantalum rod insertion remained debatable in published literature. Shuler et al. instructed their patients on six weeks of protected weight bearing [12], while Aldegheri et al. allowed their patients immediate full weight bearing due to the additional structural support provided by the rod in comparison to CD alone [20]. Floerkemeier et al. observed a less encouraging outcome and attributed it to unlimited weightbearing [4]. Interestingly, a later finite element analysis he conducted found fracture risk was not elevated after surgery and suggested unrestricted weightbearing instead [9]. In this current study, the post-operative load bearing was not restricted and the results lag behind the mainly encouraging outcomes [5, 12, 15, 19]. Other than potential fracture risk and mechanical support, the reason might be the adaptive changes in internal architecture of the trabecula. To respond to the increased stress between the metal-bone interface, the peri-implant trabecular bone might undergo structural remodeling and result in continuous blockage around the implant, which nullified the decompression effect. Further studies deeply analyzing the outcomes are still necessary to confirm the hypothesis.

Several limitations in this study should be acknowledged. First, the number of included subjected was very small; but still the few failed cases have already demonstrated their own developing pattern of quick progressing and early conversion to THA, suggesting the fast elevation of intramedullary pressure. The other limitation of our study is that we could only speculate based on the pathological procedure with serial radiological information and histopathologic retrieval examination indirectly. Direct methods such as successive intra-osseous pressure measurement in animal models could further confirm the histological response to the implant and to illuminate the real pathological changes that led to failure in these hips.

To conclude, using porous tantalum osteonecrosis implants does not add much improvement to the survival rate and to delay of conversion to total hip arthroplasty. Early failures could happen following precocious bone remodeling and decompression nullification. The suggested advantage of an earlier load bearing may have a negative influence on the early outcome of the treatment. Further studies analyzing the outcomes are necessary.

Compliance with ethical standards All procedures performed in the study were in accordance with the ethical standards of the institutional and national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.
Informed consent Informed consent was obtained from all individual participants included in the study.

Conflict of interest The authors declare that they have no competing interests.

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