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Case report

Implant fracture of the Regenerex® modular metal tibial component: A report of three cases

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ABSTRACT

Background: Implant fractures are a very rare complication in primary total knee replacement (TKR) surgery and with modern implant designs and improved metals these events have nearly been eliminated. In this case series we report three cases of tibial metal baseplate fractures in uncemented Regenerex® TKR.

Methods: Cases originated from a prospective case series of 80 patients operated between 2013 and 2016. Five patients were pilot cases and 75 were participants in a prospective randomized double-blinded clinical trial that evaluated different adjuvant bone anti-resorptive medical therapies. All patients were treated with an uncemented press-fit Regenerex® Porous Titanium Construct tibial tray and matching cemented (Refobacin Bone Cement R) patella and femoral components (hybrid implant).

Results: We report three cases of medial side metal baseplate fractures of a modular finned tibial stem. All three baseplate fractures were in male patients. Confirmed failure of the implant occurred after 10, 12 and 23 months, in situ, with a mean follow-up of 15 months (range 10-23).

Conclusions: Based on the current case series we cannot make any causal inferences. Failures may represent a multifactorial process with a cascade of events with implant failure as the result. However, like in most other case reports of metal failures in the literature, the implant fractures in this report were located on the medial side of the tibial component in male patients.

1. Introduction

Total knee replacement (TKR) is an effective and reliable treatment of degenerative joint disease, with improvement in the patient's pain and satisfaction levels, quality of life, and function [1]. The mean age for TKR in Denmark is 67.5 years, however patients requiring TKR are becoming younger, and 21.7% of the Danish TKR patients are below 60 years of age [2]. Survival rates of TKR have been high, over 90% at 10–19 years of follow-up [3,4]. However, implant survival is much better for older patients than for middle aged and young patients [1–4]. TKR components can be secured to the host bone through either cemented or uncemented fixation methods. New coating surfaces have been developed to improve fixation and bone ingrowth, and the use of uncemented fixation has been advocated in young patients with good bone-stock to improve the longevity of implants [5,6].

Although revision rates remain low in Denmark, counting approximately 10.8% of all knee arthroplasties performed in 2017, revision surgery has an extensive impact for both the patient and the healthcare system [2]. Failures of TKR include infections, aseptic loosening, polyethylene wear, joint instability, and alignment problems. Infection is the most common cause of early

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Table 1
Randomization groups.

Group 1	Vanguard cemented tibial tray (n = 25)	Cemented control group No adjuvant therapy
Group 2	Regenerex tibial tray (n = 25)	Uncemented control group No adjuvant therapy
Group 3	Regenerex tibial tray (n = 25)	Adjuvant 1 1.8 ml local Zolendronic Acid dissolved in 4.2 ml Sodium Chloride 9 mg/ml (total 6 ml) or just 6 ml of Sodium Chloride 9 mg/ml was applied to the tibia cut. It soaked for 60 s; then the bone was washed with saline and the tibia baseplate was press-fit into the bone
Group 4	Regenerex tibial tray (n = 25)	Adjuvant 2 Two days after surgery (before discharge) and again 6 months after surgery, Denosumab was administered subcutaneous (Prolia 60 mg)

revision (<2 years after primary TKR) and aseptic loosening of the tibial tray is the most common cause of late failure (>3 years after primary surgery) [3,7,8]. Implant fractures are a very rare complication in primary TKR surgery with a fracture rate of 129 per 100.000 implants in registries compared to 285 per 100.000 implants in clinical studies [9]. The Regenerex® tibial tray (Zimmer Biomet, Warsaw, Indiana, USA) is fairly new to the market; however, fracture of the Regenerex® tibial tray has already been reported in two cases by Stormont et al. [10].

In this case series we report three cases of tibial metal baseplate fractures in a series of 80 uncemented Regenerex® TKR.

2. Material and methods

The three cases described in this paper originated from a prospective case series of 80 patients, operated between 2013 and 2016, where five were pilot cases and 75 were participants in a prospective randomized double-blinded clinical trial (RCT) (EudraCT 2012-004046-15) that evaluated different adjuvant bone anti-resorptive medical therapies (Table 1). Inclusion criterion was primary knee osteoarthritis (OA) with indication for CR (cruciate retaining) TKR, in capable men and women with sufficient bone quality, aged between 18 and 66 years of age. Exclusion criteria were diseases affecting the bone metabolism (patients with osteoporosis were excluded on the basis of a pre-operative systemic bone mineral density measurement), patients with rheumatoid arthritis or renal failure (GFR <30 ml/min), severe bone defect or bone loss with the need of augmentation or stem-elongation, previous osteotomy, patients treated with radiation or chemotherapy or with sporadic or permanent need of systemic glucocorticoid treatment, and patients who could not refrain from postoperative use of non-steroid anti-inflammatory drug.

All 80 patients were treated with an uncemented press-fit Regenerex® Porous Titanium Construct tibial tray and matching cemented (Refobacin Bone Cement R) patella and femoral components (hybrid implant) from Zimmer Biomet Inc. Regenerex® is a novel porous titanium construct imitating normal trabecular bone with a high surface porosity and large pore size, which is believed to facilitate bone ingrowth and better fixation to the host bone [6,11]. As the Regenerex® tibial tray was new to the marked (launched in year 2008) the performance of the implant was compared to the well-documented cemented TKR, which was the standard in the department [12]. Therefore, 25 patients were treated with a cemented CR Vanguard total knee system in the study. In total 100 patients were randomized during surgery to one in four groups (Table 1). The study was double blinded in design to all patients (all four groups) and for all surgeons concerning the three uncemented Regenerex® tibial tray groups 2, 3 and 4. The surgeons could not be blinded to group 1 since the implant and the insertion were different. All patients in all groups were treated with soaking the tibia bone in a blinded substance (1.8 ml Zoledronic Acid four milligrams per five milliliters dissolved in 4.2 ml Sodium chloride nine milligrams per milliliter) or placebo (six milliliters sodium chloride nine milligrams per milliliter) for one minute before insertion of the tibia tray. On the second day after surgery and again six months after surgery all patients received an injection subcutaneously on the back-side of the left or right arm with a blinded substance (one milliliter Denosumab 60 mg/ml or placebo with one milliliter saline) (Table 1).

Operations were performed by three experienced Orthopedic Consultants at Aarhus University Hospital, Denmark. Standard operative procedure for cemented and uncemented TKA was used. Tantalum beads were inserted into the peri-prosthetic trabecular tibia bone during surgery for radiostereometric analysis (RSA) (cases 2 and 3). The patients in all four groups followed the same routine post-operative rehabilitation regime [13]. Conventional radiographs were obtained preoperative, on the first postoperative day and 12 and 24 months after surgery. Dual-energy X-ray absorptiometry (DXA) scans of the periprosthetic proximal tibia and stereoradiographs were obtained on the first postoperative day, and at six weeks, three, six, 12 and 24 months after surgery.

Table 2
Timeline of Regenerex tibial tray fractures.

	Included	Primary surgery	Confirmed failure	Revision surgery
Case 1	November 2013	December 2013	October 2014	November 2014
Case 2	June 2016	October 2016	November 2017	December 2017
Case 3	May 2016	June 2016	May 2018	July 2018

A Lunar iDXA Scanner from GE Healthcare and the investigational knee software (enCORE 11.40 or newer version Knee Mode, not FDA approved) was used, and we measured bone mineral density (BMD) in three regions of interest (ROIs) on AP and LA scans as previously described [14,15]. A standardized uniplanar RSA set-up for assessment of fixation of the tibial tray was used [15].

Postoperative radiographs were evaluated for tibial baseplate size compared to the resected tibial plateau. We used the ruler scale in the IMPAX imaging system and calibrated the measures according to the diameter of the proximal part of the stem trunnion on the tibial implant. We measured the distance from the tibial baseplate to the outer cortex line on the medial, lateral, anterior, and posterior side. Radiolucent lines (RLLs) below the tibial baseplate were measured in width (mm) and extent (%) on the medial and lateral side of the stem on screened AP radiographs. Visual bone resorption on screened AP radiographs was noted at last follow-up and supported by BMD measurements for cases 2 and 3. Visual implant migration on screened AP radiographs was noted on last follow-up screened AP radiographs and further measured with RSA as the subsidence of the geometric center of the tibial tray.

The clinical study was approved by the Central Denmark Region Committee on Biomedical Research (J. nr. 2012-004046-15) and the Danish Data Protection Agency (J. nr. 1-16-02-93-13).

3. Results

All three cases of fractured Regenerex® tibial baseplates were located on the medial side of the modular finned tibia stem. Confirmed failure of the implant occurred after 10, 12 and 23 months respectively, with a mean follow-up of 15 months (range 10–23) (Table 2**)**. Radiographic findings are listed in Table 3. All tibial trays were fully impacted to bone-contact on both the medial and lateral side at the postoperative radiographs but were in general under sized by two to three millimeters. RSA of the tibial tray showed progressive subsidence from six weeks until failure (Table 3**,** Fig 1). BMD increased during the follow-up especially in the medial proximal tibial plateau (Fig 2). Besides case 3 described below, there were two other cases of infection after primary surgery among the whole study group (n = 80). One patient had a superficial (extraarticular) wound infection treated with surgical wound debridement and locally administered antibiotics (gentamicin), and one patient had a deep intraarticular infection treated with a two-stage revision knee replacement.

3.1. Case 1

A 67-year-old man with painful OA of the right knee (Fig 3A) had a TKR with a 75 mm Regenerex® tibial tray and a 40 mm modular finned stem implanted (Batch number 869520) in December 2013 (Fig 3B), and since he was a pilot patient to the RCT he did not receive any adjuvant medical therapy. He was a former smoker (cessation in 1990), had an American Society of Anesthesiologists (ASA) score of 3 and a body mass index (BMI) of 41 kg/m^2. At his six-week postoperative follow-up he was pain free and had a knee range of motion (ROM) of 0–115°. In October 2014 (10 months after primary surgery) he was readmitted to the outpatient clinic due to pain in the medial part of the right knee that had developed over a period of 10–14 days. Radiographs revealed a fracture of the tibial baseplate (Fig 3C). At revision surgery a fracture of the medial side of the modular finned tibial baseplate was found (Fig 3D), the polyethylene component was intact. After removal of metallosis and the fractured tibial tray a stemmed tibia revision component was inserted. Cultures were negative for bacterial growth. Nine days after revision surgery the patient was readmitted due to suspicion of intraarticular infection. He was febrile (39.7 °C) and with elevated C-reactive protein (CRP) to 227 mg/l. Aspiration of the knee was positive and cultures showed *Staphylococcus*

Table 3
Postoperative radiographic evaluation of the Regenerex tibial baseplate.

	Case 1	Case 2	Case 3
Postoperative (date)	07.12.2013	12.10.2016	24.06.2016
Under sizing of the medial edge	2.6 mm	2.4 mm	2.0 mm
Under sizing of the lateral edge	None	1.7 mm	3.3 mm
Under sizing of the posterior edge	3.2 mm	None	5.3 mm
Under sizing of the anterior edge	None	None	1.7 mm
RLL[a]			
Medial	None	None	None
Lateral	None	None	None
Last follow-up (date)	17.10.2014	03.11.2017	18.05.2018
RLL[a] medial			
3 months	NA[b]	0.4 mm (70% medial)	0.1 mm (70% lateral)[c]
Last follow-up	Medial tibial tray fracture	Medial tibial tray fracture	Medial tibial tray fracture[c]
RLL[a] lateral			
3 months	NA[b]	0.6 mm (90% lateral)	0.2 mm (100%)
Last follow-up	0.5 mm (100%)	0.8 mm (90% lateral)	0.4 mm (100%)
Visual subsidence at last follow-up	Medial subsidence	Medial subsidence	Medial subsidence
RSA[d] measured subsidence at last follow-up	NA[b]	−3.12 mm	−1.8 mm

[a] Radiolucent line.
[b] Not available.
[c] Regenerex coating showed sign of coating separation from tibial tray.
[d] Radiostereometric analysis.

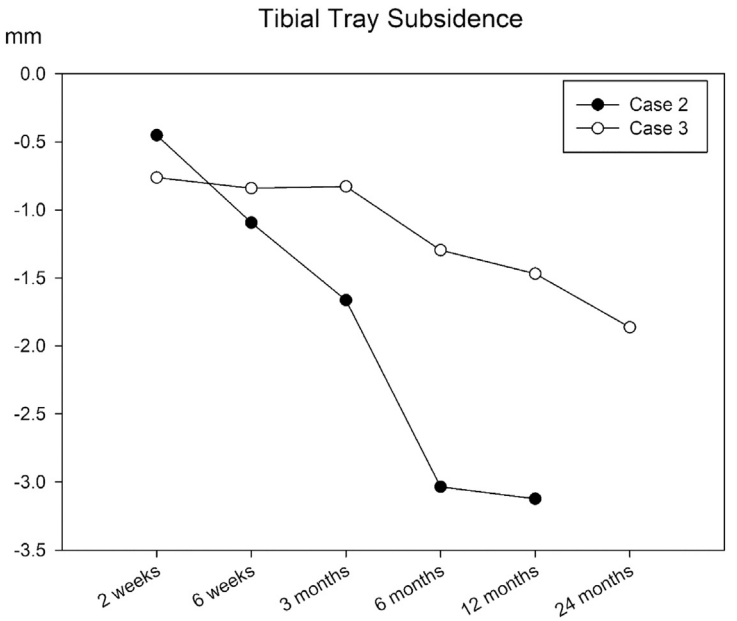

Fig 1. Radiostereometry measurement of tibial tray fixation expressed as subsidence in millimeter of the geometrical midpoint of the component. Cases 2 and 3 shown, data not available for case 1.

epidermidis. Revision surgery with debridement and exchange of the polyethylene component was done and he was treated with intravenous antibiotics (vancomycin) for two weeks and oral antibiotics (rifampicin and clindamycin) for further 10 weeks. At one-year follow-up in November 2015 he was pain free and with normal gait and knee ROM 0–120°.

3.2. Case 2

A 50-year-old man (ASA score 2 and a BMI of 34 kg/m^2) was seen in the outpatient clinic in June 2016. He had a previous anterior cruciate ligament repair of the right knee and presented with years of global knee pain and radiographic OA (Fig 4A). He was a cigarette smoker (52.5 pack-years) and had a previous (before 2006) alcohol abuse (>14 drinks per week). A TKR with a 83 mm Regenerex® tibial tray and a 40 mm modular finned stem was implanted (Batch number 981810) in October 2016 (Fig 4B), and was randomized to the Zolendronic acid treatment group (Table 1). At his six-week postoperative follow-up he was mobilized without walking aids. At one-year follow-up (November 2017) he suffered from increasing knee pain and varus malalignment. Radiographs revealed a fracture of the tibial baseplate (Fig 4C). At revision surgery the polyethylene component was intact, but a tibial tray fracture was found on the medial side of the modular finned tibial stem (Fig 4D). The femoral component and the fractured tibial tray were removed, and a stemmed tibial and femoral revision component was inserted. Cultures were negative for bacterial growth. Six weeks after revision surgery he was readmitted to the hospital with signs of deep knee infection. He was afebrile but there were leaking from the wound on the knee and CRP was elevated to 415 mg/l. Aspiration of the knee was positive and cultures showed *Staphylococcus aureus*. Revision surgery with debridement, removal of the implants and insertion of a cement spacer was done in January 2018. He was treated with intravenous antibiotics (dicloxacillin). However, during hospitalization he went increasingly respiratory affected with bronchospasm and low oxygen saturation. A computed tomography (CT) angiography revealed segmental atelectasis in the left lung but no signs of pulmonary embolism and an echocardiography was normal. He was admitted to the intensive care unit and intubated and subsequently he had a tracheotomy. In the following days a radiograph of the thorax shoved bilateral pneumonia. He was treated with broad-spectrum antibiotics (vancomycin, ciprofloxacin and meropenem) without clinical or laboratory improvement. A bronchoalveolar lavage revealed a fungal infection with Aspergillus fumigatus and *Candida glabrata* and a PCR test was positive for influenza. Treatment with amphotericin and oseltamivir was started. There were no signs of active infection in the right knee. Forty days after the knee revision the patient had a bleeding from the tracheal tube with subsequent cardiac arrest. Cardiopulmonary resuscitation was started; however, the patient was not to save, and he was declared dead.

3.3. Case 3

A 68-year-old man, non-smoker, ASA score 3 and a BMI of 34 kg/m^2 presented with painful OA of the left knee in May 2016 (Fig 5A). He had a TKR with a 79 mm Regenerex® tibial tray and a 40 mm modular finned stem (Batch number 279140) implanted in June 2016 (Fig 5B) and was randomized to the Denosumab treatment group (Table 1). Seven days after primary surgery he was readmitted to the hospital with leaking form the knee wound. He was febrile (38.6 °C) and with an elevated CRP

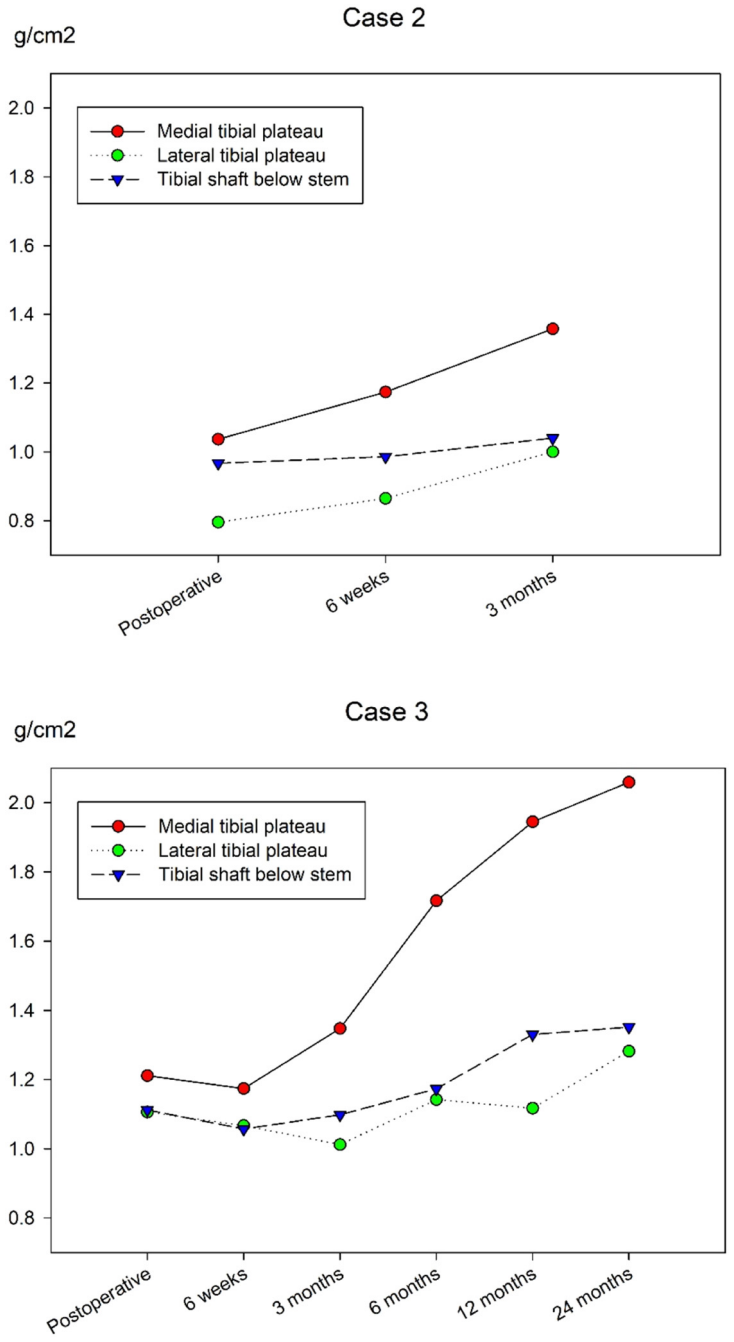

Fig 2. Bone mineral density measurements of the periprosthetic medial and the lateral proximal tibial plateau of cases 2 and 3. Data not available for case 1.

(244 mg/l). Revision surgery with debridement and exchange of the polyethylene component was done. Cultures showed *S. aureus*. He was treated with intravenous antibiotics (cefuroxime) for two weeks and oral antibiotics (dicloxacillin) for further 8 weeks. At 1-year follow-up in August 2017 the patient was doing well. He was nearly pain free and had a knee ROM of five to 100°. In May 2018 (23 months after primary surgery) he was readmitted to the outpatient clinic due to increasing knee pain and varus malalignment. Radiographs revealed a fracture of the tibial tray (Fig 5C). At revision surgery the polyethylene component was intact but a fracture of the tibial tray on the medial side of the modular finned tibia stem was found (Fig 5D). There were massive metallosis and the medial tibial condyle was accompanied by osteolysis with a contained bony defect. After removal of the fractured tibial tray a stemmed tibia revision component was inserted. Cultures were negative for bacterial growth. Ten days after revision surgery the patient was readmitted due to leaking form the wound. He was febrile (38.8 °C) and

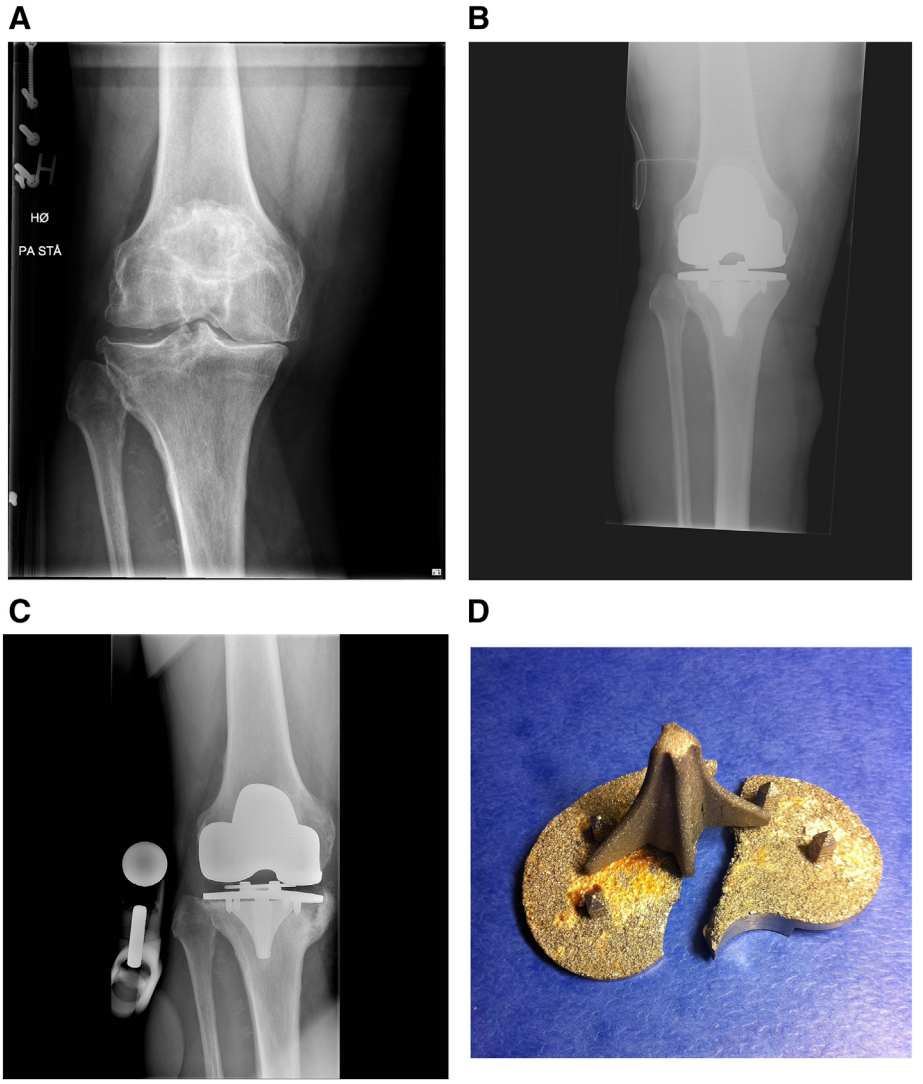

Fig 3. Case 1: Antero-posterior radiograph of the right knee, (A) preoperative, (B) postoperative, (C) 10 months after primary surgery, and (D) picture of retrieved tibia component with fracture of the metallic baseplate.

with an elevated CRP (356 mg/l). Re-revision surgery with debridement and exchange of the polyethylene component was done. Cultures showed *S. aureus* sensitive to penicillin, and he was treated with intravenous antibiotics (benzylpenicillin) for two weeks and oral antibiotics (phenoxymethylpenicillin) for further eight weeks. The patient is still followed. After five months he was afebrile, pain free and with a knee ROM 0–110°.

4. Discussion

Modes of failures in TKR surgery have generally shifted from implant related problems to more surgical related problems like instability and or malalignment [8,16]. Implant fractures are a very rare complication and with modern implant designs and improved metals these events have nearly been eliminated [9]. In a literature review Gilg et al. found that implant fracture rates were reported from 0.2 to 2.5% in clinical studies and from 0.02 to 0.17% in registries with the highest incidence of implant breakage among unicompartmental knee arthroplasty prostheses implanted before 2000, constrained primary or revision TKR and patellar replacements [9]. In the current report we describe three male cases of metal baseplate fractures, all on the medial side of the modular finned tibial stem, in a series of 80 uncemented Regenerex® tibial replacements. Confirmed failure occurred at 10, 12 and 23 months after primary surgery. There has been one previous report in the literature of similar fractures of the Regenerex® tibial trays [10]. Stormont et al. described two cases, both males, of aseptic failures in a serial of 43 uncemented Regenerex® tibial trays. Fractures were also located on the medial side of the modular finned tibial stem, and occurred 17 and 37 months after

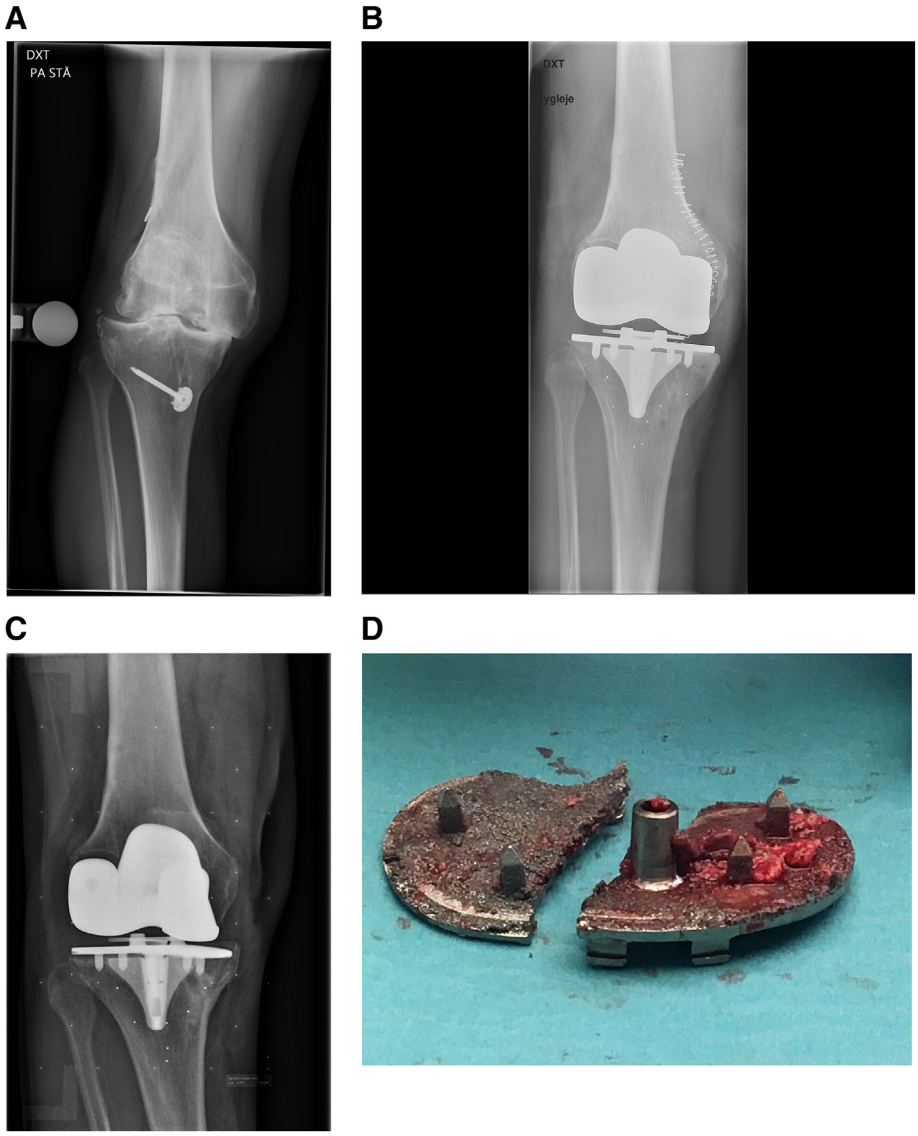

Fig 4. Case 2: Antero-posterior radiograph of the right knee, (A) preoperative, (B) postoperative, (C) 12 months after primary surgery, and (D) picture of retrieved tibia component with fracture of the metallic baseplate.

surgery, with a mean follow-up of 65 months (range 44–47). Different from the current study, patients had a compatible uncemented femoral component and an uncemented patellar resurfacing component (39 of 43 knees). Furthermore, 40 knees including both failures, were implanted using the Signature (ZimmerBiomet) system with custom femoral and tibial positioning guides, whereas three knees were implanted using a standard manual instrument technique. The authors suggest that the underlying mechanism of failure in their two cases were metallurgical caused by a high stress concentration and subsequent metal fatigue at the junction of the central portion of the modular stem with the medial plateau. Tibial tray components among failures in our study were derived from different Batch numbers and failures because of a poor single production seems unlikely.

Review of the Annual Report 2018 from the Australian Orthopedic Association National Joint Replacement Registry (AOANJRR) revealed a higher than anticipated rate of revision of the Vanguard PS/Regenerex prostheses, with a cumulative percent revision of 5.3% at five years follow-up (compared with approximately 3.5% in other TKR), and a hazard ratio for revision within the first six months after surgery of 4.19. The cause of TKR revision is unfortunately not given in the AOANJRR [17].

Source of failures due to implant fractures in primary TKR have been attributed to specific implant designs, malalignment and lack of bone stock [9]. Persisting varus malalignment following TKR with eccentric loading and displacement of the mechanical axis to the medial side of the tibial implant may be a risk factor in implant fracture [18]. The tibiofemoral joint is affected by a significant mechanical impact during daily activities and contact forces across the knee joint increases during ambulation

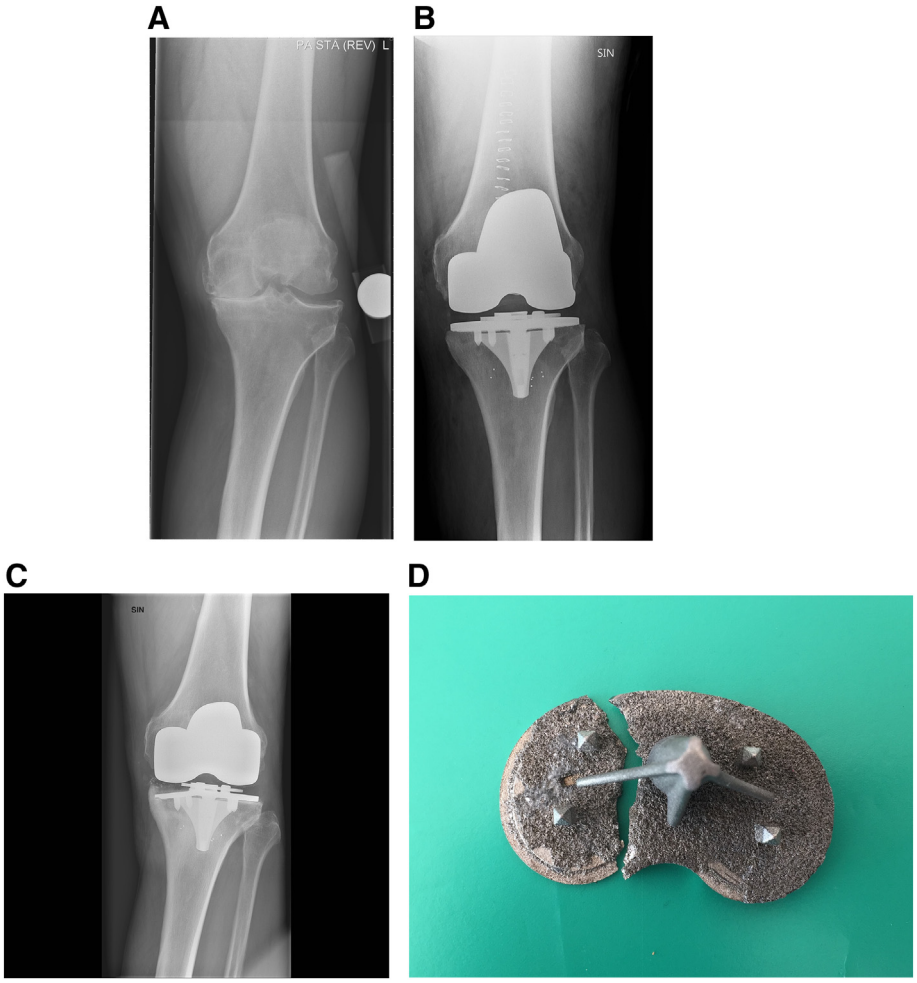

Fig 5. Case 3: Antero-posterior radiograph of the left knee, (A) preoperative, (B) postoperative, (C) 23 months after primary surgery, and (D) picture of retrieved tibia component with fracture of the metallic baseplate. Note that the Regenerex coating has separated from the tibial tray on the medial edge.

especially in the medial compartment [19,20]. Higher stress in the medial compartment especially in TKR with malalignment may theoretical create osteolysis and cyclic overload of the tibial baseplate resulting in fatigue fractures of the implant. This could explain why case reports in the literature describing fractures of the tibial baseplate in TKR, generally report the fracture site on the medial side of the implant [10,18,21]. We did not have long extremity radiographs and do not use them routinely in our clinic; however, review of the postoperative radiographs did not indicate any malalignment problems.

Lack of bone stock may be caused by stress shielding. It has been shown that altered biomechanical loading at the bone-implant interface influence the BMD in the proximal part of the tibia after TKR [15]. Most studies have demonstrated a decrease in BMD, but Winther et al. found a significant increase in BMD of the lateral proximal tibial plateau and unchanged BMD values in the medial region at follow-up after Regenerex® tibial tray [22]. BMD measures did not indicate any stress shielding among cases in the current report. BMD generally increased especially in the medial proximal part of the tibial plateau. Whether this is a sign of bone compression or bone preservation due to the adjuvant bone anti-resorptive medical therapy is uncertain. In general, bisphosphonates have shown improved implant fixation in the literature (with no mentioned cases of implant fractures) [23]. Different adjuvant medical treatments with bone anti-resorptive therapy were given in two of our three cases, but not in the last case and in none of the two cases described by Stormont et al. [10]. Therefore, a correlation between the bone anti-resorptive therapy and the tibial tray fractures in the current case series seems unlikely.

Another issue may be the sizing of the tibial component relative to the host bone with optimal cortical contact or coverage. Under-coverage of the tibial baseplate has been correlated with implant migration and subsequent aseptic loosening and implant fracture [24,25]. Review of our postoperative radiographs revealed no significant under sizing of the tibial components.

Infection may be another cause of altered bone stock. The revision rate for deep infection after implant knee surgery in Denmark is 2.4% and in the present study 2.5% (two out of 80) [2]. Periprosthetic joint infection (PJI) was confirmed in one of the cases after primary surgery, but all three cases were complicated with PJI after revision surgery. These events were however

interpreted as an acute PJI as tissue biopsies taken during revision surgery were negative. We do not believe that infection was the primary cause of failure in our cases, but we cannot exclude that a slow and silent PJI could be a contributory factor in the underlying mechanism of failure. In the article by Stormont et al. the Regenerex® tibial baseplate fractures did not have infection.

The limitations of the current report include the small number of cases, the lack of long extremity radiographs, as well as the lack of postoperative metallurgical examination of the retrieved components as these were destroyed after revision surgery.

5. Conclusion

In summary, we report three cases of metal baseplate fractures of the modular finned tibial stem, in a series of uncemented Regenerex® tibial replacements. Implant fractures are a very rare complication in primary TKR surgery, although the incidence of these failures might be underrepresented, due to different systems used to classify complications. Based on the current case series we cannot make any causal inferences. Failures may represent a multifactorial process with a cascade of events with implant failure as the result. However, like most other case reports in the literature concerning metal failures, implant fractures in this report were located on the medial side of the tibial component in male patients.

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Declaration of Competing Interest

None.

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