Three-dimensional-printed customized prosthesis for pubic defect: Clinical outcomes in 5 cases at a mean follow-up of 17 months

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Research article

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Abstract

Background

This study is to present and evaluate the short-term clinical outcomes and associated complications of 3D-printed customized prostheses for pubic defect reconstruction.

Methods

5 patients receiving type III hemipelvectomy and three-dimensional-printed customized prosthesis reconstruction at our institution between 2017 and 2019 were retrospectively analyzed in this study. The operation time and blood loss during operation were recorded. The local and functional recovery was assessed by the physical examination and Musculoskeletal Tumor Society (MSTS) score. The prosthetic position and Osseointegration were evaluated by imaging examination. Oncology result and complications were recorded. Functional comparisons with MSTS score of patients grouped by resection extent were done.

Results

Of 5 cases, the prosthese consist of the type with stem (3, 60%) and the type without stem (2, 40%). Mean follow-up period was 17.6 months (range, 10–26 months). All 5 patients were alive with no evidence of disease. No deep infection and local recurrence occurred. The mean blood loss and mean intraoperative time was 1680 ml (range, 300 to 3700 ml) and 294 min (range, 180 to 430 min). The mean functional MSTS score at the final follow-up was 29.8 (range, 29–31). 1 male patient complained erectile dysfunction. Fretting wear around prosthetic stem was found in 3 patients while bone wear on the normal side pubis was found in 2 patients. Osseointegration was observed in all patients.

Conclusion

3D-printed customized prostheses could be a feasible option to reconstruct the pubic bone defects after type III hemipelvectomy. The good outcomes are inseparable from precision prostheses design and strict surgical procedures.

Background:

Surgical reconstruction of bone tumor defects of the pelvis is a complex procedure due to the complexity and irregularity of pelvis. According to the Enneking and Dunham classification(1), type III hemipelvectomy involves resection of either a portion of the pubis or the entire pubis from the symphysis to the lateral margin of the obturator foramen. But this type of hemipelvectomy is uncommon, accounting for only about 11% (2–4). Most defects after type III hemipelvectomy were usually not reconstructed because the weight-bearing axis, which goes through the proximal femur, acetabulum, sciatic buttress, and spine, is preserved (4–6).

However, lots of complications were reported after type III hemipelvectomy without reconstruction. Hernia and sacroiliitis were the most common complications and frequently reported as late complications in patients without reconstruction after type III hemipelvectomy(7, 8). Firstly, bony reconstruction provides an anchor for mesh and suture attachments, which adding to the integrity of pelvic floor soft tissue reconstructions. That's the reason why some surgeons who do not reconstruct the bone defect still try pelvic floor repair(9). Secondly, according to Tile(10), the anterior pelvic ring structure and the posterior ring structure accounts for 40% and 60% of the stability of the entire pelvic ring, respectively. And study shows that patients developed stress fractures without reconstruction after type III internal hemipelvectomy because the residual pelvic bones become unstable and distorted during walking and running(6). So the integrity of anterior pelvic ring should not be ignored, although the continuity of the weight-bearing axis was preserved. Thus, reconstruction after type III resection is becoming more and more accepted.

Currently, some reconstruction methods have been reported after type III hemipelvectomy, including allograft, mesh and artificial ligament (11, 12). However, large amount of studies revealed various limitations of these reconstruction options. Although allograft could provide a bony reconstruction, high operative infection rate was frequently reported by some researches(2). Researches showed that the infection rate of allograft after type III hemipelvectomy is as high as 20% (12, 13). Soft tissue reconstruction like mesh and artificial ligament is easy and convenient, but the mechanical stability of the pelvis is ignored which results in changes of pelvic structure and mechanics causing complications like acetabular shift and sacroiliitis. In addition, the prosthesis is also a choice to reconstruct pelvis and has good initial stability, early weight bearing and relatively rapid restoration of function, it has not been applied in reconstruction after type III resection.

Three-dimensional (3D) printed customized prosthesis with porous surface might be a solution for irregular bone defects especially for pelvis. Nowadays, 3D-printed customized prostheses in pelvis are mainly applied in hemipelvectomy including type I and type II hemipelvectomy with or without partial pubis (14, 15). However, there is no relative 3D-printed customized prosthesis for bone reconstruction after pure type III hemipelvectomy so far.

Recently, we designed 3D-printed customized prostheses and applied them to treat patients with malignancies involving region III, and satisfactory outcome was observed. This study introduces the experience of using 3D-printed customized prostheses for reconstruction after type III hemipelvectomy, and evaluates the clinical outcomes and associated complications of 3D-printed customized prostheses for reconstruction.

Method:

Patients

Between June 2017 and February 2019, 5 patients receiving three-dimensional-printed customized prosthesis reconstruction after type III hemipelvectomy at our institution were retrospectively analyzed in this study. There were 3 males and 2 females with a mean age of 36.6 years (range, 26–46 years) at the time of surgery. 3 patients underwent one ramus of pubis resection while 2 patients underwent both pubic rami resection.

To determine local disease and assess the resectability, all patients receive three-dimensional computerized tomography (3D CT), magnetic resonance imaging (MRI), single-photon emission computed tomography (SPECT) or positron emission tomography/computerized tomography (PET/CT) and preoperative biopsy (Fig. 1). Diagnoses were chondrosarcoma in all cases. The characteristics of the patients are summarized in Table 1. Musculoskeletal Tumor Society (MSTS) scores were evaluated preoperatively (Rating scale is based on 7 items including pain, range of motion, strength, joint stability, joint deformity, emotional acceptance, and overall function. Each item is scored from 0–5 with a maximum possible score of 35.).

Table 1
– The demographics of the 5 patients treated with 3D-printed customized prosthesis

Case	Gender	Tumor location	Diagnosis	Follow-up (months)	IOT* (min)	Blood Loss (ml)
1	M	Entire pubis	Chondrosarcoma	10	290	1100
2	F	Entire pubis	Chondrosarcoma	12	180	300
3	M	Pubic superioris	Chondrosarcoma	19	370	2500
4	M	Pubic superioris	Chondrosarcoma	21	430	3700
5	F	Pubic superioris	Chondrosarcoma	26	200	800
mean				17.6	294	1680
*IOT, Intraoperative time.						

Table 2
– Detailed MSTS data.

Case	Motion		pain		Stability		Deformity		Strength		Functional Activity		Emotional Acceptance		MSTS		Oncologic outcome	Compli
	Pre.	Post.	Pre.	Post.	Pre.	Post.	Pre.	Post.	Pre.	Post.	Pre.	Post.	Pre.	Post.	Pre.	Post.		
1	5	5	3	5	5	5	5	5	3	3	5	3	3	3	29	29	NED*	ED
2	5	5	3	3	5	5	5	5	3	3	5	3	5	5	31	29	NED	
3	5	5	3	5	5	5	5	5	3	3	5	3	5	5	31	31	NED	
4	5	5	3	5	5	5	5	5	5	3	5	3	5	5	33	31	NED	
5	5	3	3	3	5	5	5	5	5	3	5	5	3	5	31	29	NED	
Mean	5	4.6	3	4.2	5	5	5	5	3.8	3	5	3.4	4.2	4.6	31	29.8		
*NED, No evidence of disease; ED, Erectile dysfunction;																		

This study was approved by the Ethical Committee of our institution. Written informed consent to participate in this study was obtained from all the patients.

Prosthesis Design And Fabrication

All prostheses were designed by our clinical team and fabricated by Chunli Co., Ltd., Tongzhou, Beijing, China. 3D CT files of all patients were imported to Mimics V20.0 software (Materialise Corp., Leuven, Belgium) to build three dimensional models of tumor and pelvis. The margin of tumor was determined by the combination of x-ray, MRI, SPECT and 3D CT on the basis of 3D model. Then the curative margin was obtained to determine the tumor resection part and residual bone part. According to shape of the tumor resection part and residual bone part, the preliminary shape of prosthesis was determined by mirroring normal corresponding part in Geomagic Studio software (Geomagic inc., Morrisville, United States). And the osteotomy guides were designed. After that, specific features were added to the prosthesis. Next, removing unnecessary features and smoothing the surface of prosthesis. In the end, porous structure was separated and generated in Magics V20 software (Materialise Corp., Leuven, Belgium). The porous structure was 600 μm-pore-size and 70%-porosity (Fig. 2, 3).

The prostheses were saved as stereolithography (STL) files and the size of prostheses were measured in Mimics. Prosthesis was fabricated by electron beam melting technology (ARCAM Q10plus, Mölndal, Sweden) and the osteotomy guides and the plastic trial model were fabricated by stereo lithography appearance technique (UnionTech Lite 450HD, Shanghai, China).

Surgical Techniques

All surgeries were performed by the same senior surgeon (Chongqi Tu). The patients were placed in the oblique supine lithotomy position. Ilioinguinal incision was mostly used. Osteotomy was performed with the help of osteotomy guides and specific bone structures. Besides the tumor resection, subfascial dissection with the removal of all of the muscles in the compartment was done. At the level of the bone osteotomy, the muscles were severed. Then the plastic trial model with the same proportion of the prosthesis was used first to confirm perfect match between the defect and the prosthesis. The next step is the prosthesis implantation. Prosthesis fixation ways are different in different prostheses. For the patient underwent superior ramus of pubis resection and reconstruction with prosthesis with plate and intramedullary stem, the stem was insert into the normal pubis firstly, then the plate was fixed on the medial side of pelvis by screws which went through superior side of acetabulum and another screw fixed prosthesis to the inferior pubis. For the patient underwent entire pubis resection and reconstruction with prosthesis without plate and intramedullary stem, prosthesis was fixed firstly by two screws passing through the anterior and medial side of acetabulum and one screw inserting to the ischial ramus, then tied to the contralateral pubis with rivet string. Afterwards, the preserved muscles such as musculus pectineus and musculus adductor longus were reconstructed either before stitching (Fig. 4).Intraoperative time and blood loss were recorded.

Postoperative Management

For patients who received prosthesis with stem replacement, bed rest and movement limiting of the affected limb for three-four weeks were undertaken. Meanwhile, the flexion, extension and internal rotation of hip joint were executed with adductor relaxation and contraction. Passive adduction and external rotation were allowed within 30° before week four, and gradually changed to positive movement at week five to prevent the failure of adductor reconstruction. Walking with crutches began at week five and weight-bearing of the affected limb increased gradually. Two month postoperatively, walking on flat ground without crutches was allowed. Three-four days bed rest was recommended for those patients who received prostheses without stem replacement. The movement of hip joint and adductor relaxation and contraction were undergone with the passive adduction and external rotation during the first week. And during the second week, walking with crutches with gradually increasing weight-bearing was undergone. The positive abduction and external rotation began at the third or fourth week. Patients could walk on flat ground without crutches a month later after surgery.

Patients were followed monthly in first three month after operation, then trimonthly in first year, and every year after one year. The physical examination and Musculoskeletal Tumor Society (MSTS) score was used to assess the local and functional recovery. Complications were recorded according to Henderson et al. CT of chest was used to determine metastasis. Prosthetic position was evaluated by imaging examination including x-ray, tomosynthesis-shimadzu metal artefact reduction technology (T-SMART) of pelvis. Osseointegration was evaluated by T-SMART. Oncologic results were evaluated according to local recurrence, metastasis, or death.

Statistical analysis

Statistical analyses were performed using IBM SPSS Statistics software, version 22 (IBM SPSS, Armonk, NY). Descriptive statistics including proportion and mean value were calculated. The normality of the continuous data was checked by the one sample Kolmogorov-Smirnov test. Preoperative and postoperative data were compared using Wilcoxon signed-rank test. A $p < 0.05$ was considered statistically significant.

Results:

Combined with postoperative histology result, the final pathology of all patients was chondrosarcoma. Two patients were chondrosarcoma Grade 2 and three patients were chondrosarcoma Grade 3. And for tumor stage according to Enneking, one patient was stage IIa and four patients were IIb. All operations were R0 resection.

The mean blood loss was 1680 ml (range, 300 to 3700 ml) and mean intraoperative time was 294 min (range, 180 to 430 min). The mean daily drainage of 1,2,3,4 day after operation was 400 ml (range, 380 to 430 ml), 278 ml (range, 330 to 190 ml), 174 ml (range, 110 to 260 ml), 56 ml (range, 30 to 90 ml), respectively.

At the time of the last follow-up, all 5 patients were alive with no evidence of disease (NED). Local surgical incision was healed well without infection, sinus during follow-up. 1 male patient complained erectile dysfunction after operation and function recovery gradually after 5 months. Overall survival was 100%. No local recurrence was observed.

Mean follow-up period was 17.6 months (range, 10–26 months). The mean functional MSTS score was 29.8 (range, 29–31). No significant difference compared with preoperative MSTS score. No dislocation and infection of prosthesis was found until the last follow-up. Fretting wear around prosthetic stem was found in 3 patients undergoing superior ramus of pubis resection and prosthesis with stem reconstruction after postoperative 6 months without any subjective discomfort (Fig. 5). Bone wear on the normal side pubis was found in 2 patients undergoing both pubic rami resection and prosthesis without stem reconstruction after postoperative 4 months without any subjective discomfort (Fig. 6). T-SMART showed absence of interfacial gap between prosthesis and bone six months postoperatively (Fig. 7).

All patients were divided into two groups according to resection extent, including 3 patients with one ramus of pubis resection and 2 patients with entire pubis resection. No significant differences was detected in MSTS score ($p = 0.875$).

Discussion:

For the treatment of bone defects after type III hemipelvectomy, more and more surgeons tend to reconstruct defect because of the reported complications. Up to now, allograft, mesh repair and artificial ligament repair are the main choices for reconstruction after type III hemipelvectomy(11, 12, 16). Recent reconstruction ways after type III resection were listed in Table 3. Artificial ligament (ligament advanced reinforcement system,LARS), marlex mesh and soft tissue flap were common used relatively to reconstruct the bone defect and could prevent incisional hernia effectively(2, 9, 17). However, its soft tissue reconstruction cannot restore the pelvic ring which leads to hip joint displace and sacroiliac joint stress concentration. And allograft can provide a pelvic bony reconstruction and restore the stability of pelvis. Although better function outcomes and pain relief were observed in studies compared with non-reconstruction, more complications occurred including high infection rate, nonunion, and fracture. Karim, S.M.'s research reported that complications of reconstruction for type III defect with allograft included infection in two, symptomatic hernia in one, hip instability in one, dislocated total hip arthroplasty in one, and graft failure in one among 14 patients(12).

Table 3
Recent reconstruction ways after type III resection

First author	Year	Type of reconstruction	Number of patients	Follow-up time	MSTS
Laurel, A.	1989	No reconstruction	12	0.75-15 years	N/A*
Timothy Jorden	2002	Marlex mesh	9	0.75-12 years	N/A
Reddy, S.S.	2012	Marlex mesh	8	9.5years(average)	N/A
Courtney E. Sherman	2011	No reconstruction	8	N/A	N/A
Nikolaos Arkoulis	2012	No reconstruction	1	N/A	N/A
Jungo Imanishi	2015	No reconstruction, fascia lata	2	N/A	100
Rosyane, R. D. F.	2015	Fibular graft	2	N/A	N/A
		No reconstruction	3	N/A	N/A
Albert, H.	2015	Mesh, Soft tissue flap	14	N/A	N/A
Karim, S.M.	2015	Allograft	5	0.58-6 years	N/A
Zhang J	2018	LARS ligament	25	1.33-4 years	88
RĂZVAN ENE	2018	No reconstruction	1	N/A	N/A
*: N/A means not available					

Recently, modular hemipelvic prosthesis has been frequently used for different pelvic bone defects due to its high adaptability. But no proper prosthesis matches the defect well after pure type III hemipelvectomy. 3D-printed customized prostheses are increasingly being used in the pelvic defect reconstruction thanks to its precise matching and have been reported with good early results(18). But 3D-printed customized prosthesis has not been applied in defect reconstruction after type III hemipelvectomy. This study described detailed clinical outcomes after 3D-printed customized prosthesis reconstruction in type III hemipelvectomy.

With the advantages of additive manufacturing, 3D-printed customized prosthesis could add porous bone trabecular-like structures to promote bone ingrowth and promote bone and prosthesis interface integration, which play an important role in bone defect reconstruction and repair. Previous studies showed that the porous structures with 300 to 800 μm pore-size and 70% porosity can enhance bone ingrowth (19–23). So porous structures with porosity of 70% and poro-size of 600 μm were applied in this study, and osseointegration was well observed in patients. What's more, the precise forming technology of 3D-printing allows 3D-printed prosthesis to match the shape of the defect perfectly, that can reduce the difficulty of prosthesis implantation. But conversely, it increased the difficulty in intraoperative osteotomy, which means osteotomy guides assist and preoperative simulating is necessary.

The design of prosthesis was very important for stability. In the 3 patients undergoing superior ramus of pubis resection, we designed prosthesis with an arcuated stem fitting the normal side pubic medullary cavity and fixed the prosthesis by plates, screws and the stem inserting into the normal side pubic medullary cavity. And during the follow-up, we found fretting wear around prosthetic stem, which means the prosthesis was not stable as we thought. We inferred the pubic symphysis and sacroiliac joint with low mobility resulted in the fretting wear. Because the pelvic is a closed ring, and the sacroiliac joint with low mobility could affect the pubic symphysis. As long as the sacroiliac joint is fretting, so is the pubic symphysis. Based on that, we design the prosthesis without stem to try to reconstruct the pubic symphysis. Then, bone wear was found on the normal side pubis instead of fretting wear because the elastic modulus was ignored. The direct contact between the alloy prosthesis and the bone can lead to the bone wear. And this wear gradually stabilizes through our observation.

On the other hand, intraoperative precise osteotomy, proper endoprosthesis implantation and correct screws insertion are critical in operation of 3D-printed prosthetic reconstruction. Osteotomy guides were applied for providing desired osteotomy plane with less exposure and instrument requiring during operation. Specific anatomy features should be the location point of the guides, such as the angle of the superior and inferior pubis. Additionally, due to complex anatomy of pelvis and severe displacement of residual pelvic bone after resection, proper placement of prosthesis is technically demanding: (1) plastic trial model should be used to assess whether the prosthesis matches the defect, and plastic trial model should be with a smaller stem or without stem for avoiding affecting the stability of prosthesis and provide convenience for implantation; (2) bone surface in contact with prosthesis should remove partially cortex to expose cancellous bone to promote bone ingrowth; (3) conformation of well placement should be done before inserting screws by checking pelvic continuity near osteotomy plane; (4) the order of prostheses fixation is critical for implantation. For prosthesis with stem, intramedullary stem should be inserted into the medullary cavity first and then fixing the prosthesis to the acetabular side bone. While for prostheses without stem, fix the prosthesis to the acetabular side bone first and then reconstruct the pubis symphysis.

Compared with allograft reconstruction, 3D-printed customized prosthesis significantly reduced infection rate and prosthesis related complications. Mankin,H.J.'s research(13) showed that 2 of the 14 patients undergoing allograft reconstruction after partial hemipelvectomy of pubis had infection and 1 had hardware failure with nonunion. In Shao's review(24), the allograft reconstruction group reported a wound infection rate ranging from 7.7 to 37.5% and an implant breakage or displacement rate that ranged from 7.7 to 12.5%. In our study, No dislocation and infection of prosthesis was found until the last follow-up. Preoperative high temperature sterilization of prosthesis, intraoperative repeated pulse flushing and iodophor immersion could be significant to avoid infection. Multilayer stitching and postoperative wound care may be helpful to avoid incision infection. Porous structures enhance bone ingrowth and increase stability of prosthesis. Precise matching of the defect and the prosthesis reduced the chance of dislocation. In addition, postoperative MSTS score had no significant difference compared with preoperative MSTS score which suggested reconstruction with 3D-printed customized prosthesis was no effect on the function recovery.

Erectile dysfunction (ED) was first reported in type-III hemipelvectomy. It has been reported that 3% of cases of ED may result from pelvic fractures or perineal blunt trauma(25). It is assumed that ED caused by such reasons is due to lesions of the cavernous nerves or branches of the internal pudendal arteries that pass in close proximity to the pelvic bones and posterior urethra (26). Combined with this study, tumor resection involved with inferior ramus of pubis could probably affect the branches of the internal pudendal arteries. For prevent ED after type-III hemipelvectomy, resection of inferior ramus of pubis should be careful, especially when dealing with the medial side. Pay attention to the protection of blood vessels and nerves in this area and do not stretch too much. Although symptom was relieved after 5 months, surgeon should be more careful. Because of the few samples, whether the never or artery was damaged then the normal side nerve compensation or gradually recovered after nerve traction injuries was unknown.

Our study has some limitations. First, this is a retrospective case series of a small number of patients with a short-term follow up, it is possible that more complications or problems might arise as long-term follow-up. Second, because of small numbers, different extents of resection and disease processes, it's difficult to make a control group to compare with. In addition, there is no biomechanical analysis in our study, so finite element analysis should be down in the next step. Therefore, further study should be continued and multi-institutional study is needed. And we will continue follow-up of these patients.

Conclusion:

3D-printed customized prosthesis for the bone defects reconstruction after type III could be a feasible option to reconstruct the pubic bone defects. The good outcomes are inseparable from precision prosthesis design and strict surgical procedures. Despite favorable outcomes, we observed some imperfections in preoperative design and surgical applications, more works and long-term follow up are required in further study.

Abbreviations

3D
three dimensional
CT
computerized tomography
MRI
magnetic resonance imaging
SPECT
Single-photon emission computed tomography
PET/CT
positron emission tomography/ computerized tomography
T-SMART
tomosynthesis-shimadzu metal artefact reduction technology
MSTS
Musculoskeletal Tumor Society
NED
no evidence of disease
ED
erectile dysfunction

Declarations

Ethics approval and consent to participate

This study was performed in accordance with the Declaration of Helsinki as revised in 2008 and was authorized by the Ethics Committee of West China Hospital. All patients or their families signed the informed consent form before surgery and provided consent to publish and report individual clinical data.

Consent for publication

Not applicable.

Availability of data and materials

The data and materials are available from the medical records department of the West China Hospital. The datasets used and analyzed during the current study are available from the corresponding author on reasonable request.

Competing interests

The authors declare that they have no competing interests.

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Author contributions

YQ Zhang, L Min, MX Lu and CQ Tu were involved with the concept and design of this manuscript. J Wang, Y Luo, YT Wang and Y Zhou were involved with the acquisition of subjects and data. YQ Zhang, MX Lu and CQ Tu were involved in the design of the prosthesis. L Min, Hong Duan and CQ Tu were involved in postsurgical evaluation of the patients. All authors contributed toward data analysis, drafting and critically revising the paper, gave final approval of the version to be published, and agree to be accountable for all aspects of the work.

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Figures

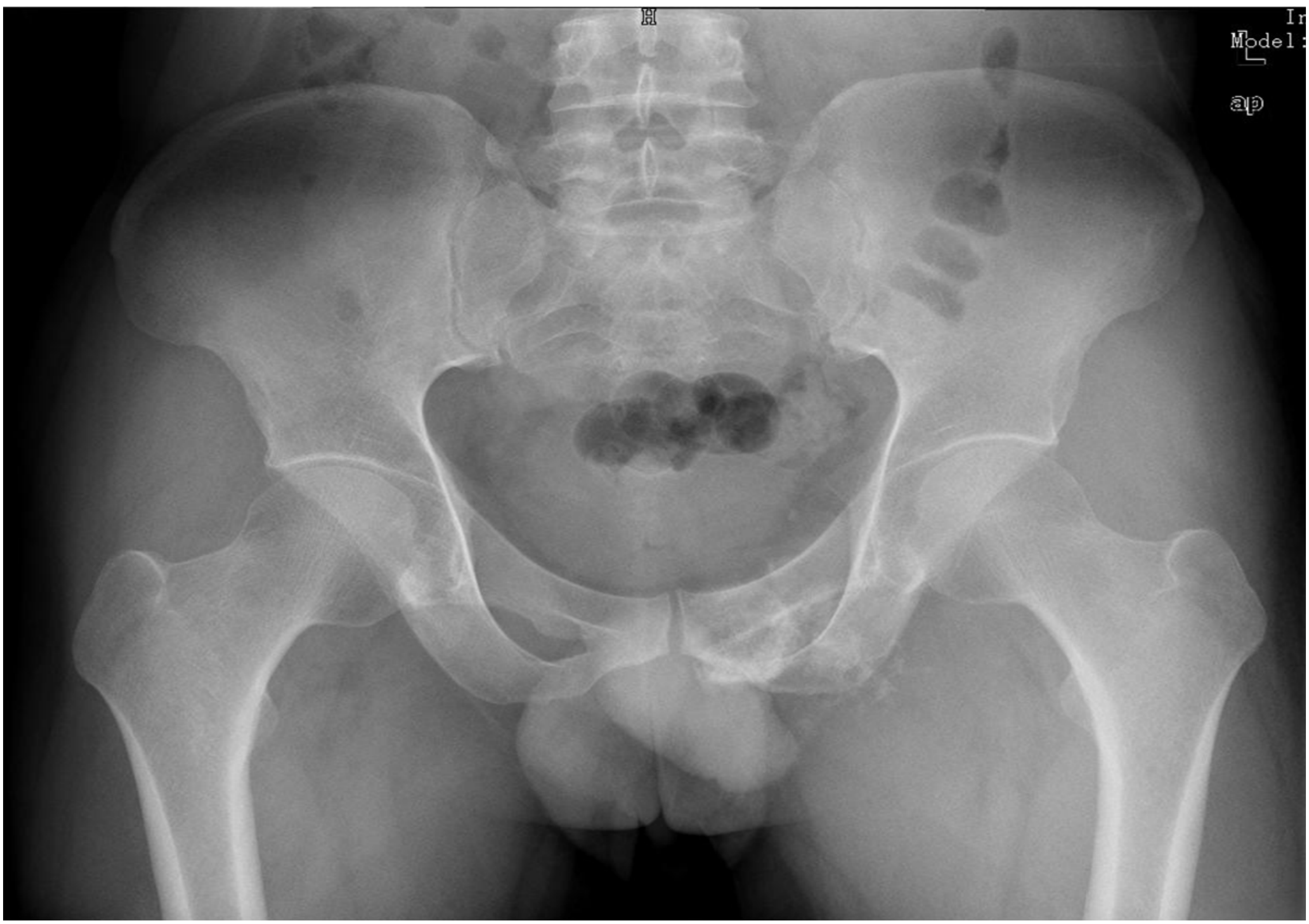

Figure 1

Pelvic X-ray in a patient with a osteosarcoma (after biopsy) involving the superior and inferior pubis.

Figure 2

Prosthesis without stem

Figure 3

Prosthesis with stem

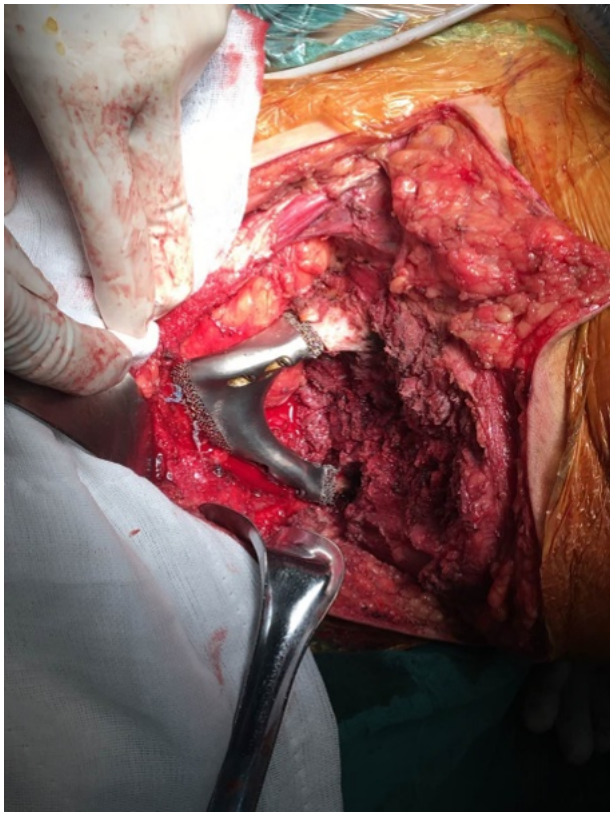

Figure 4

The prosthesis was implanted and fixed with screws.

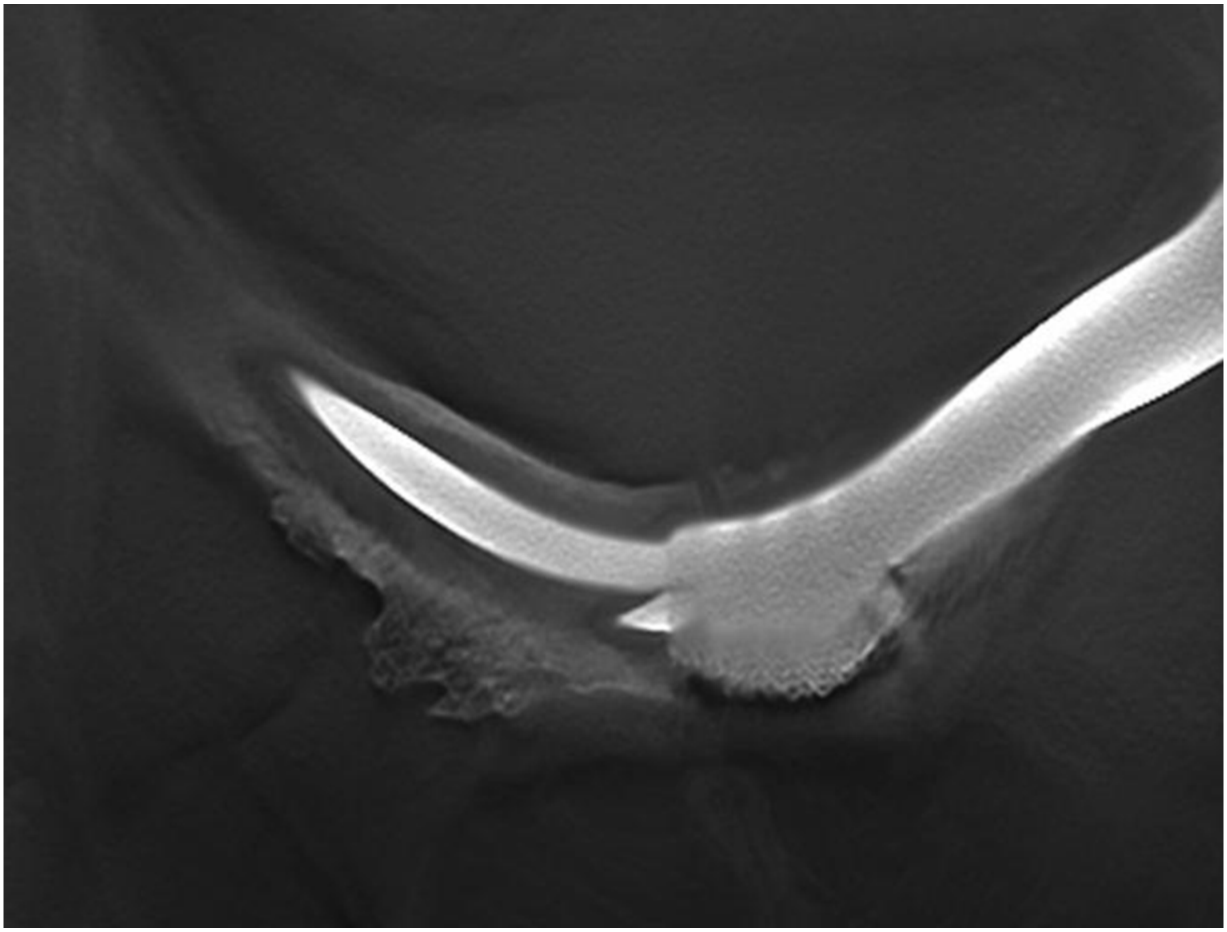

Figure 5

Six months after operation, T-SMART showed fretting wear appeared around prosthetic stem.

Figure 6

Four months after the operation, X-ray showed bone wear on the normal side pubis.

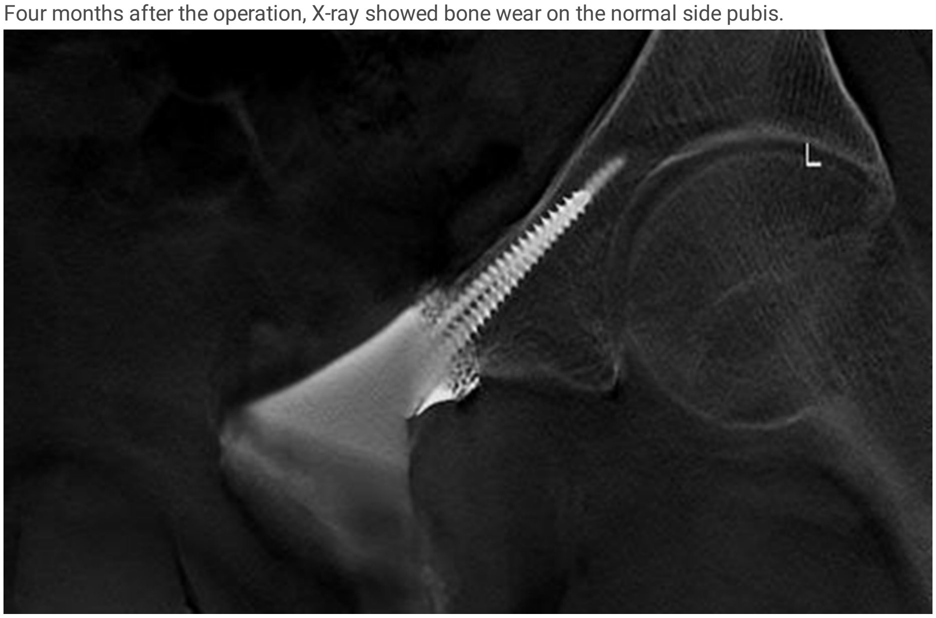

Figure 7

Six months after the operation, T-SMART showed preliminary osseointegration