ACCSCIENCE PUBLISHING

International Journal of Bioprinting

RESEARCH ARTICLE

Personalized 3D-printed tantalum-coated titanium alloy pelvic reconstruction prosthesis for complex pelvic defects: A prospective randomized controlled trial

Zhaoyang Ran[1,2,3†], Boran Pang[1,2,3†], Yulin Tian[4], Dinghao Luo[1,2,3], Junxiang Wu[1,2,3], Lei Wang[1,2,3], Kai Xie[1,2,3], Jingke Fu[1,2,3], Liang Deng[1,2,3*], Wei Li[4*], and Yongqiang Hao[1,2,3*]

[1]Shanghai Key Laboratory of Orthopaedic Implants, Department of Orthopaedic Surgery, Shanghai Ninth People's Hospital, Shanghai Jiao Tong University School of Medicine, Shanghai, China

[2]Clinical and Translational Research Center for 3D Printing Technology, Shanghai Ninth People's Hospital, Shanghai Jiao Tong University School of Medicine, Shanghai, China

[3]Shanghai Engineering Research Center of Innovative Orthopaedic Instruments and Personalized Medicine, Shanghai Ninth People's Hospital, Shanghai Jiao Tong University School of Medicine, Shanghai, China

[4]School of Materials Science and Engineering, Shanghai Jiao Tong University, Shanghai, China

[†]These authors contributed equally to this work.

***Corresponding authors:**
Yongqiang Hao (hyq_9hospital@hotmail.com)

Wei Li (weilee@sjtu.edu.cn)

Liang Deng (676471883@qq.com)

Citation: Ran Z, Pang B, Tian Y, *et al.* Personalized 3D-printed tantalum-coated titanium alloy pelvic reconstruction prosthesis for complex pelvic defects: A prospective randomized controlled trial. *Int J Bioprint.* 2025;11(5):371-384. doi: 10.36922/IJB025310312

Received: July 7, 2025
Revised: August 2, 2025
Accepted: August 21, 2025
Published online: August 25, 2025

Abstract

The functional reconstruction of complex pelvic defects remains a global challenge. To address this, a personalized 3D-printed tantalum-coated titanium alloy pelvic reconstruction prosthesis was independently developed to enhance the osteogenic activity of existing titanium alloy prostheses. This prospective randomized controlled trial evaluated its efficacy, safety, and early clinical outcomes in 21 patients with complex pelvic defects. The patients were randomly assigned to an experimental group (11 cases of tantalum-coated prostheses) or a control group (10 cases of uncoated prostheses). The coated prostheses were designed using preoperative imaging data and coated with an approximately 15-μm tantalum coating through plasma immersion ion implantation. After post-treatment and sterilization, the prostheses were implanted during surgery. Operation time, intraoperative blood loss, and laboratory indices were recorded and compared between groups. Postoperative follow-up assessments included imaging assessments, complication monitoring, bone ingrowth analysis at the prosthesis–bone interface, and functional evaluation with the Harris Hip Score. All 21 surgeries achieved primary wound healing without early complications. Mean follow-up time was 15.1 ± 7.1 months. There was no significant difference in operation time, intraoperative blood loss, and abnormal laboratory indices. The prosthesis shape matched well with the bone defects, ensuring good stability. In the experimental group, one periprosthetic infection and one artificial femoral head dislocation occurred, compared to two periprosthetic infections and one dislocation in the control group. At final follow-up, the experimental group demonstrated significantly higher Harris Hip Scores ($p < 0.01$) and bone ingrowth rates (90.9% vs. 30.0% in control; $p < 0.001$). In conclusion, the personalized 3D-printed tantalum-coated titanium alloy pelvic

reconstruction prosthesis effectively promotes bone ingrowth, enhances prosthesis stability, and improves lower limb function, representing an effective approach for reconstructing complex pelvic defects.

Keywords: 3D printing; Complex pelvic defect; Pelvic reconstruction prosthesis; Tantalum coating; Titanium alloy

1. Introduction

Complex pelvic defects caused by trauma, tumor resection, inflammation, or infection remain a global orthopedic challenge due to irregular morphology, extensive bone loss, and the high mechanical demands of pelvic reconstruction. While autologous and allogeneic bone grafts serve as conventional clinical solutions for bone defect repair, they exhibit inherent limitations, including inadequate initial mechanical strength, limited donor availability, risks of disease transmission, and immunological rejection.[1–3]

Metal implants have gained attention as alternative reconstruction materials due to their abundance, favorable mechanical properties, and corrosion resistance. However, early-generation metal prostheses, such as saddle-shaped prostheses and ice-cream cone prostheses, demonstrated suboptimal clinical outcomes, primarily limited by conventional design concepts and manufacturing techniques.[4] Recent advancements in computer-aided design and metal additive manufacturing (3D printing) have enabled the development of patient-specific prostheses that simultaneously satisfy both biomechanical requirements and anatomical compatibility for pelvic reconstruction. These technological innovations have substantially improved the precision of defect restoration while maintaining essential load-bearing capacities, thereby advancing clinical management of complex pelvic defects.

Since 2014, pioneering clinical implementation of metal 3D printing technology for fabricating patient-specific pelvic prostheses has been reported.[5,6] A titanium alloy pelvic prosthesis featuring an anatomically adaptive design and surface structure optimization was developed through additive manufacturing. Animal experiments confirmed that the diamond-like porous structure facilitates trabecular bone ingrowth within 3–6 months post-implantation, achieving long-term osseointegration and mechanical stability.[5] Furthermore, a retrospective clinical study conducted by our group revealed that personalized 3D-printed titanium alloy pelvic prostheses for limb-salvage reconstruction in pelvic tumor patients yielded favorable early postoperative outcomes. The intervention was associated with reduced complication rates, satisfactory short-term functional recovery, and promising prosthesis survival rates.[6]

Osseointegration at the prosthesis–host bone interface is a fundamental determinant of long-term implant survival. Accelerating this interfacial osseointegration through material innovation and structural optimization has become a shared objective for both materials scientists and clinicians. Rapid prosthesis–bone interface integration offers two critical clinical advantages: (i) expedited achievement of biological fixation, thereby reducing dependence on mechanical fixation (primarily screw-based stabilization) during the early postoperative phase and minimizing stress-related failure risks; (ii) decreased susceptibility to periprosthetic infection. However, Ti-6Al-4V alloy is inherently bioinert and lacks osteoinductive capacity at the bone–implant interface. Current limitations persist regarding the insufficient osseointegration depth within porous titanium structures fabricated via 3D printing, with bone ingrowth typically restricted to superficial regions of the porous matrix.[7,8] These biological constraints highlight the urgent need for advanced modifications to existing 3D-printed pelvic prostheses. Enhancing both the velocity and depth of bone–implant interface integration represents a crucial research direction with significant clinical implications, particularly for improving prosthesis longevity and reducing revision surgery requirements in complex pelvic reconstructions. Therefore, there is an urgent need to develop a surface-modified titanium alloy prosthesis that simultaneously satisfies mechanical-performance requirements and actively promotes osseointegration.

Tantalum exhibits moderate hardness, exceptional wear resistance, and chemical inertness, conferring excellent biocompatibility and corrosion resistance.[9] Notably, tantalum demonstrates lower bacterial adhesion propensity and enhanced osteoinduction and bone regeneration compared to titanium alloys, making it a promising functional material for orthopedic implants.[10,11] *In vitro* studies by Guo *et al.*[12] demonstrated tantalum's capacity to enhance the proliferation, adhesion, and osteogenic differentiation of bone marrow mesenchymal stem cells. Corresponding *in vivo* evaluations revealed that tantalum scaffolds significantly promote new bone formation and osseointegration.

However, clinical application of bulk tantalum implants faces substantial limitations. The high density (16.6 g/cm^3) of tantalum increases prosthesis weight, particularly problematic for large-scale bone defects, while elevating manufacturing costs. Furthermore, pure tantalum's elastic modulus (180 GPa) dramatically exceeds that of human bone (10–30 GPa), predisposing implants to stress-shielding effects.

Surface tantalum coating technology emerges as an effective strategy to circumvent these limitations while preserving tantalum's bioactivity. This approach significantly reduces implant weight, production costs, and elastic modulus mismatch. Plasma immersion ion implantation (PIII) is a versatile surface modification technique with applications in precision manufacturing, aerospace, and biomedical engineering.[13] The PIII process utilizes active screen and hollow cathode coupling to generate high-density plasma, enabling bombardment of tantalum plasma onto heated substrate surfaces. Subsequent adsorption and diffusion processes form uniform surface alloy layers.[14] A key advantage of PIII is the complete immersion of substrates in plasma, enabling uniform coating deposition within complex geometries, including porous structures, making PIII particularly suitable for surface alloying of geometrically complex 3D-printed components.[15] The PIII technique induces metallurgical bonding between implanted ions and substrate particles, creating novel phase structures that preserve mechanical properties while enhancing surface characteristics. This technology achieves exceptional coating efficiency, cost-effectiveness, and environmental sustainability compared to conventional coating methods. These attributes position PIII as a transformative approach for developing next-generation tantalum-coated orthopedic implants with optimized biomechanical compatibility and enhanced osseointegration potential.

Therefore, this study developed a novel 3D-printed pelvic reconstruction prosthesis integrating porous titanium alloy substrates with PIII-derived tantalum coatings. This dual-phase design synergistically combines the structural–mechanical compatibility of porous titanium frameworks with the bioactive advantages of tantalum surface modifications. Through systematic clinical investigations, this study evaluated the safety profile and therapeutic efficacy of these customized prostheses in managing complex pelvic defects, demonstrating their potential to address both biomechanical requirements and biological integration challenges. The findings provide valuable insights into the development of functionally enhanced orthopedic solutions for critical bone defects.

2. Methods

2.1. Patient enrollment

This study was approved by the Ethics Committee of Shanghai Ninth People's Hospital affiliated to Shanghai Jiao Tong University School of Medicine (approval no.: SH9H-2020-T206-1). The clinical prospective randomized controlled trial was registered at the Chinese Clinical Trial Registry (www.chictr.org.cn) on September 25, 2020 (registration no.: ChiCTR2000037020). Patients were enrolled according to predefined inclusion and exclusion criteria. This study was conducted in accordance with the Consolidated Standards of Reporting Trials (CONSORT) guidelines.[16]

The inclusion criteria included:

(i) Chinese citizens aged 16–85 years;

(ii) Good systemic condition with surgical tolerance;

(iii) Absence of active infectious diseases (e.g., hepatitis A/B/C and tuberculosis);

(iv) Complex pelvic defects requiring prosthetic replacement surgery due to tumors, revision needs, or other indications;

(v) Normal hematological parameters and hepatic/renal function;

(vi) No participation in other clinical trials within three months;

(vii) Willingness to provide written informed consent; and

(viii) No contraindications for implantation.

The exclusion criteria included:

(i) Systemic or localized active infections;

(ii) Failure to undergo hemipelvic replacement surgery at our institution;

(iii) Incurable comorbidities with life expectancy ≤2 years;

(iv) Allergies to implant materials;

(v) Inability to accept innovative techniques in this trial; and

(vi) Poor compliance with follow-up or protocol requirements.

This randomized controlled trial enrolled 21 patients (10 males, 11 females) with complex pelvic defects who met the rigorous inclusion criteria. An independent third-party statistician, blinded to study implementation and data analysis, generated the 1:1 allocation sequence

using SAS® software (SAS, United States [US]) with block randomization methodology. Allocation concealment was ensured through sequentially numbered, opaque, sealed envelopes (SNOSE) containing group assignment information. Following completion of enrollment procedures and informed consent documentation, a designated independent staff member sequentially opened these sealed envelopes to disclose group assignments according to the predetermined randomization sequence, with participant blinding being rigorously maintained throughout this allocation process. Patients in the control group underwent pelvic defect reconstruction using personalized 3D-printed titanium alloy prostheses, while those in the experimental group received reconstruction with 3D-printed titanium prostheses with tantalum-coated surfaces. All surgical procedures were performed at our institution between September 2020 and August 2023. Participants had a mean age of 51.9 ± 13.3 years (range: 21–70 years), and all provided written informed consent. Detailed demographic and clinical characteristics are presented in Table 1.

2.2. Prothesis design

Following admission, all patients underwent preoperative evaluations, including complete blood count, coagulation profile, biochemical panels, and ancillary tests to assess surgical fitness. Standard radiographic assessment comprised pelvic X-ray and thin-slice pelvic computed tomography (CT) scans. Tumor patients received additional diagnostic workups: contrast-enhanced pelvic magnetic resonance imaging, chest CT, whole-body bone scintigraphy, and pathological examinations to evaluate tumor progression and metastasis, facilitating clinical decision-making regarding therapeutic strategies. Pelvic defect parameters were determined through 3D reconstruction of CT data using Mimics Medical 20.0 software (Materialise, Belgium; Figure 1), including defect area quantification and characterization of the acetabular center, dimensions, and orientation. Prosthetic design was executed in Unigraphics NX software (Siemens Digital Industries Software, USA), incorporating guidance positioning screws and locking screw channels within the implant structure. Bone–implant interface optimization was performed with porous trabecular structures (pore size: 600–800 μm, porosity: 60–80%). The finalized prosthetic model was exported in STL format and manufactured via electron beam melting additive manufacturing using Ti-6Al-4V titanium alloy powder.

The surface coating of prostheses was prepared using PIII technology, where tantalum was deposited via a high-energy plasma surface alloying system. Prior to coating, the prostheses were ultrasonically cleaned in anhydrous ethanol and deionized water, followed by drying. During this process, the cathode assembly consisted of the 3D-printed prosthesis combined with a tantalum mesh and rods, functioning as an active screen plasma device. The argon pressure was maintained at 22.5 Pa with other parameters adjusted accordingly. Throughout the coating process, the temperature remained more than 1000˚C for approximately 4 h. Subsequently, the vacuum pump was deactivated, and high-purity argon was introduced into the chamber to achieve rapid cooling to ambient temperature. Finally, the prostheses underwent 5-min ultrasonic cleaning in anhydrous ethanol, followed by standard sterilization protocols prior to surgical implantation. The surface morphology of the coated prostheses was examined using a high-resolution analytical scanning electron microscope (MIRA3, TESCAN, Czech Republic) at various magnifications, with elemental composition analysis performed by energy dispersive X-ray spectroscopy (EDS). Coating adhesion strength was evaluated using a micro-scratch tester (MFT-4000, Huahui, China) with a constant loading rate of 5 N/min.

2.3. Surgical process

Following general anesthesia induction, patients were positioned in the lateral floating orientation with the affected side elevated. The torso and unaffected limbs were immobilized on the operating table, followed by standard antiseptic preparation and draping. A classical ilioinguinal incision extending from the pubis to the sacroiliac joint was created, originating at the posterior superior iliac spine, coursing anteriorly along the iliac crest to the anterior superior iliac spine, then turning medially parallel to the inguinal ligament toward the lateral border of the pubic symphysis, with supplementary extensions

Table 1. Demographic data of the patients

Parameter	Experimental group (n = 11)	Control group (n = 10)	p-value
Gender			>0.05
Male	5 (45.5%)	5 (50%)	
Female	6 (54.5%)	5 (50%)	
Age (years)	47.9±13.6	56.2±11.4	>0.05

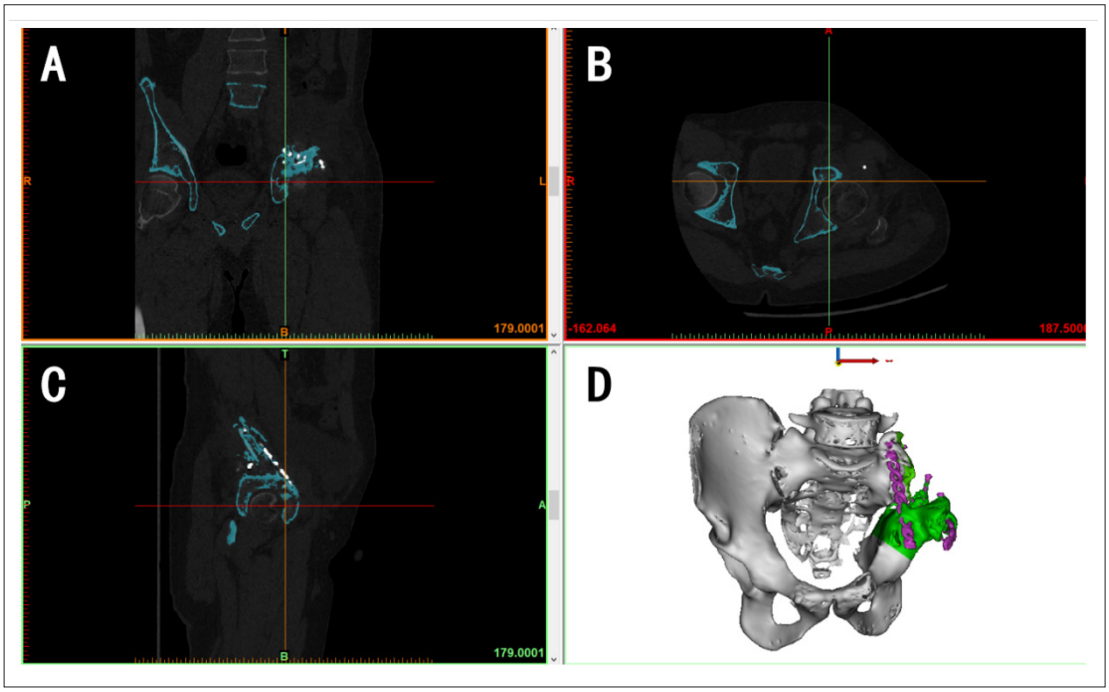

Figure 1. Three-dimensional pelvic model reconstruction utilizing patient computed tomography (CT) data. (A) CT coronal view. (B) CT axial view. (C) CT sagittal view. (D) 3D-reconstructed pelvic model.

as required. Layered dissection of skin and soft tissues exposed the osteotomy site, enabling precise implantation of the customized 3D-printed pelvic prosthesis secured through conventional and locking screws via pre-designed screw channels, supplemented by bone cement augmentation at the acetabular interface. Intraoperative fluoroscopy confirmed proper prosthesis alignment. The surgical site was irrigated, a closed suction drainage system was placed, and closure was achieved through layered fascial approximation (Figure 2). Operative duration and intraoperative blood loss were systematically recorded.

2.4. Postoperative management

Patients were maintained on strict bed rest with continuous vital sign monitoring. Affected limbs were immobilized using anti-rotation boots for 14 days. Surgical drains were removed when daily output fell below 50 mL. Thromboembolism prophylaxis included daily compression stockings. Prophylactic third-generation cephalosporins were administered according to institutional protocols. Hematological monitoring (complete blood count, coagulation profiles, and hepatic/renal function) was performed on postoperative days 1, 7, and 14, with laboratory deviations >50% from preoperative baselines flagged as abnormal. Clinical significance was assessed in the context of surgical blood loss or wound infection for parameters such as erythrocyte/leukocyte counts. Dietary intake was gradually resumed following bowel function recovery. Pelvic radiography and CT scans were conducted on postoperative day 14. Patients meeting discharge criteria (afebrile status, wound stability, and normalized inflammatory markers) were discharged with customized rehabilitation protocols. Progressive hip joint functional training was initiated at 2 months postoperatively.

2.5. Follow-up

All patients underwent regular postoperative follow-up consisting of clinical consultations, physical examinations, pelvic radiography, CT scans, and lower extremity functional assessments. Safety evaluations included monitoring of laboratory parameters (complete blood count, hepatic/renal function, and coagulation profiles); detection of mechanical complications (prosthesis loosening, dislocation, and periprosthetic fractures); and identification of non-mechanical complications (periprosthetic infections, surgical site infections, and systemic infections). Mechanical complications were radiologically assessed through pelvic X-ray and CT imaging, while non-mechanical complications were evaluated using combined laboratory and imaging data. Physicians conducted comprehensive assessments through medical history review and physical examination.

Lower extremity functionality was quantified using the Harris Hip Score system. Osseointegration

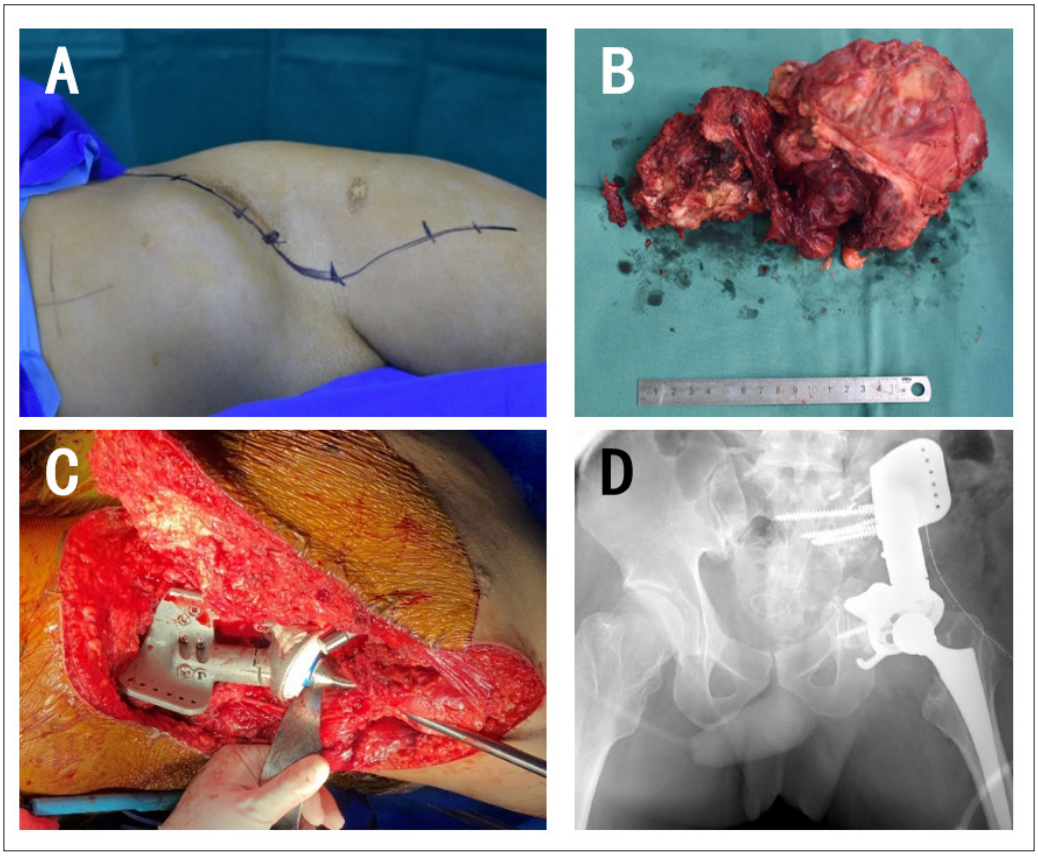

Figure 2. Limb salvage surgery for pelvic tumors. (A) Incision. (B) Pelvic tumor resection. (C) Personalized 3D-printed prosthesis implantation. (D) Intraoperative fluoroscopy of the prosthesis.

at the prosthesis–bone interface was analyzed through 0.625-mm-thin-slice CT reconstructions during final follow-up, with bone ingrowth criteria defined as:

- Excellent: Trabecular bone ingrowth >80% at perpendicular prosthesis–bone interface.
- Good: Partial trabecular integration (20–80%).
- Fair: Minimal ingrowth (0–20%).
- Poor: No detectable osseous incorporation.

All postoperative CT datasets were anonymized by an independent technician who removed patient identifiers and group labels, replacing them with unique randomized codes. All imaging assessments underwent dual independent evaluation by two senior orthopedic surgeons. They were both blinded to group allocation. Final grading determinations were achieved through consensus evaluation, thereby ensuring assessment reliability within the study's methodological constraints. Clinical classifications were determined through consensus review, integrating radiographic findings, physical examination data, and patient-reported functional outcomes.

2.6. Statistical analysis

Statistical analyses were conducted using SPSS version 29.0 software (IBM, US). Continuous variables are presented as means ± standard deviations and were compared via independent *t*-tests. Repeated-measures ANOVA was applied to compare outcomes at different time points. Categorical data are expressed as percentages (%) and were analyzed via the Chi-square test. Differences between groups were considered statistically significant at $p<0.05$.

3. Results

The surface morphology of personalized 3D-printed pelvic prostheses with tantalum coating is shown in Figure 3. Low-magnification scanning electron microscopy (SEM) images confirmed well-bonded tantalum coatings prepared through PIII technology, demonstrating no visible defects such as cracks or peeling. High-magnification SEM observations revealed numerous honeycomb-like microporous structures on the coating surface, with these fine pores increasing surface roughness to facilitate cellular adhesion and promote early osseointegration at the prosthesis–bone interface. EDS analysis further indicated

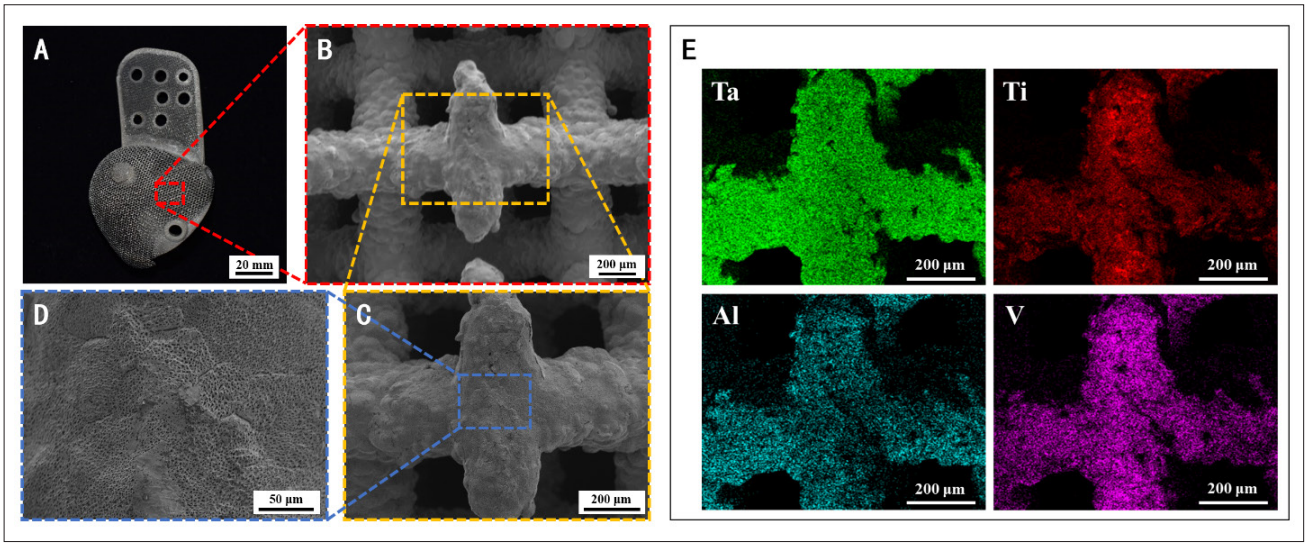

Figure 3. Macro/micromorphology and energy dispersive X-ray spectroscopy (EDS) analysis of a tantalum-coated prosthesis. (A) Macroscopic view of a tantalum-coated prosthesis (scale bar: 20 mm; magnification: 1×). (B–D) Scanning electron microscopy images at different magnifications: (B) magnification: 100× (scale bar: 200 μm), (C) magnification: 250× (scale bar: 200 μm), and (D) magnification: 1000× (scale bar: 50 μm). (E) EDS analysis (scale bar: 200 μm; magnification: 250×).

uniformly distributed high tantalum content across the coating surface, confirming the homogeneous nature of the prepared coating and its potential to enhance tantalum's osteogenic biological functions. Scratch testing revealed an adhesion strength of 123 MPa for the PIII-deposited tantalum coating, indicating robust bonding between the coating and the substrate.

Figure 4 illustrates the complete workflow encompassing personalized prosthesis design, manufacturing, implantation, and postoperative follow-up. In accordance with established inclusion/exclusion criteria, 21 patients with complex pelvic defects were enrolled, assiging to an experimental group (n = 11; 5 males [45.5%] and 6 females [54.5%]; mean age: 47.9 ± 13.6 years) or a control group (n = 10; 5 males [50.0%] and 5 females [50.0%]; mean age: 56.2 ± 11.4 years), with no significant differences in gender distribution or age between groups ($p > 0.05$), as detailed in Table 1.

All 21 participants successfully underwent pelvic defect reconstruction, with the experimental group demonstrating a mean operative duration of 306.6 ± 118.7 min and an intraoperative blood loss of 1886 ± 854 mL, compared to 297.1 ± 30.4 min and 2810 ± 1524 mL in controls. No significant differences were observed in operative duration or hemorrhage volume ($p > 0.05$), confirming the comparable intraoperative safety profile of tantalum-coated prostheses.

Safety assessments of tantalum-coated prostheses were conducted through hematological tests, hepatic/renal function, and coagulation profiles on postoperative day 14, revealing no significant differences in abnormal laboratory parameters between the experimental and control groups ($p > 0.05$). Prosthesis-related complications included one incision infection and one prosthetic femoral head dislocation in the experimental group, compared to two incision infections and one dislocation in controls. All three cases of incision infections (one experimental and two controls) resolved completely with antibiotic therapy, while both dislocated cases underwent successful open reduction without recurrence. The absence of significant differences in complication rates ($p > 0.05$) confirmed the postoperative safety equivalence of tantalum-coated prostheses. The detailed safety evaluation metrics are presented in Table 2.

At final follow-up, all patients survived, with one case of tumor recurrence in each group, maintaining survival with recurrent tumors. As shown in Figure 5, the experimental group demonstrated stable prosthesis positioning on postoperative X-rays at 1, 3, 6, and 22 months, with significant improvement in hip inclination from preoperative pathological elevation to near-symmetrical alignment by 6 months. This group showed a median follow-up of 15 months (range: 3–29 months) and significantly higher Harris Hip Scores (81.8 ± 5.7 vs. 69.8 ± 7.0 in controls, $p < 0.001$). Thin-slice CT evaluations by two surgeons revealed 4 excellent, 6 good, 1 fair, and 0 poor osseointegration cases (90.9% excellent/good rate) in the tantalum group versus 0 excellent, 3

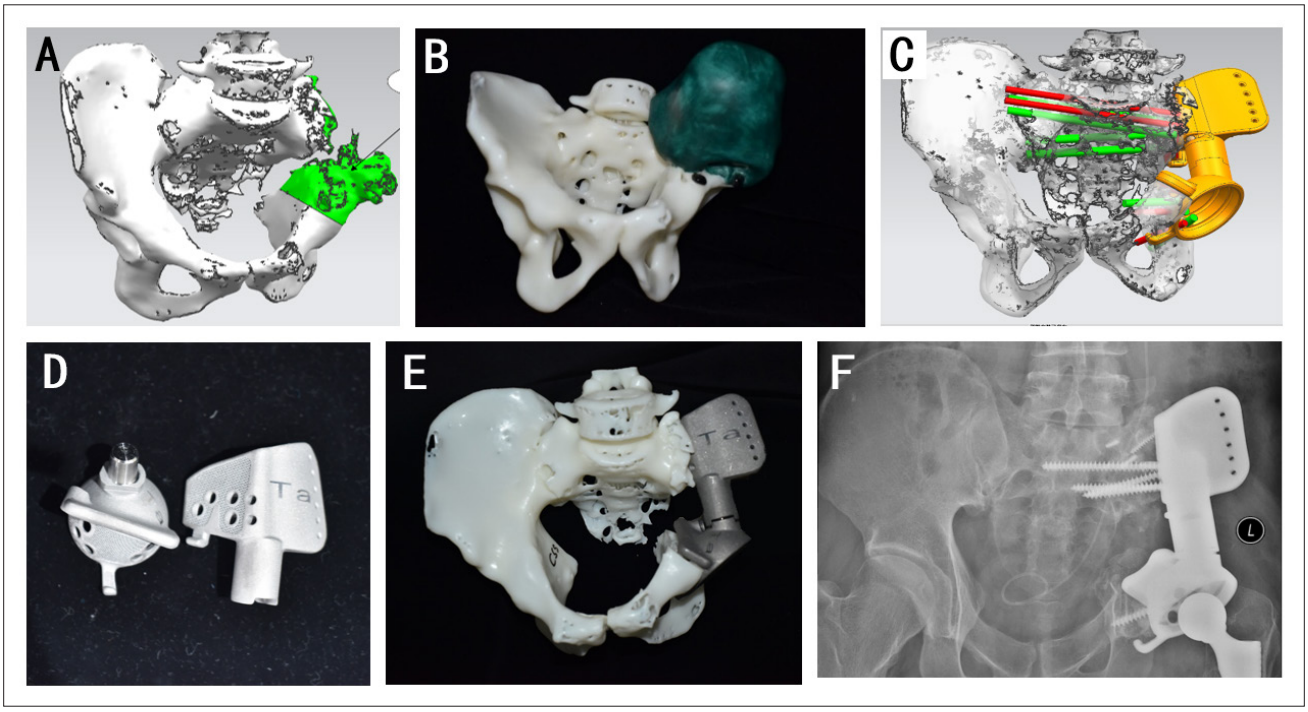

Figure 4. The entire process of personalized prosthesis design, preparation, and implantation. (A) 3D reconstruction of the lesion model. (B) 3D-printed pelvic lesion model. (C) Personalized prosthesis design. (D) 3D-printed personalized tantalum-coated titanium alloy pelvic reconstruction prosthesis. (E) *In vitro* simulation installation. (F) X-ray images at 3 months after the implantation of the 3D-printed personalized tantalum-coated titanium alloy pelvic reconstruction prosthesis.

good, 6 fair, and 1 poor (30.0% excellent/good rate) in controls. As shown in Figure 6, CT imaging confirmed enhanced trabecular bone formation at the prosthesis–bone interface, consistent with prior animal studies.[17] The detailed effectiveness data are provided in Table 3.

4. Discussion

Reconstructing complex pelvic defects necessitates both anatomical restoration and functional rehabilitation, requiring implants that not only restore bone continuity but also replicate native bone tissue to regain biomechanical stability and biological function. Therefore, implants must possess sufficient mechanical strength, excellent biocompatibility, and most critically, the ability to accelerate bone defect repair and osseointegration. Traditional bone defect treatments, such as autologous or allogeneic bone grafting, fail to meet the high weight-bearing demands of pelvic defect reconstruction or to provide early mechanical stability. Although 3D-printed porous titanium alloy pelvic prostheses manifest adequate mechanical strength

Table 2. Safety evaluation indices

Parameters	Experimental group (n = 11)	Control group (n = 10)	p-value
Operative duration (min)	306.6 ± 118.7	297.1 ± 30.4	>0.05
Intraoperative blood loss (mL)	1886 ± 854	2810 ± 1524	>0.05
Abnormal laboratory findings			
Blood tests	1 (9.1%)	2 (20%)	0.587
Liver function	1 (9.1%)	2 (20%)	0.587
Renal function	0 (0.0%)	1 (10%)	0.474
Postoperative complications			
Peri-incisional infection	1 (9.1%)	2 (20%)	0.587
Prosthetic femoral head dislocation	1 (9.1%)	1 (10%)	1.000

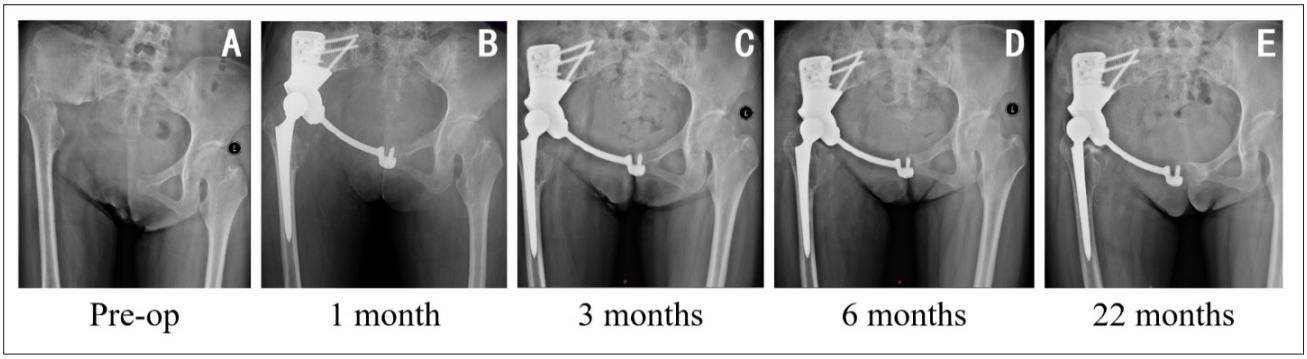

Figure 5. X-ray images of a middle-aged female with a pelvic defect at different time points (A) before and (B–E) after surgery: (B) 1 month, (C) 3 months, (D) 6 months, and (E) 22 months. The tantalum-coated prosthesis remained stable within a year after surgery. Abbreviation: Pre-op, preoperation.

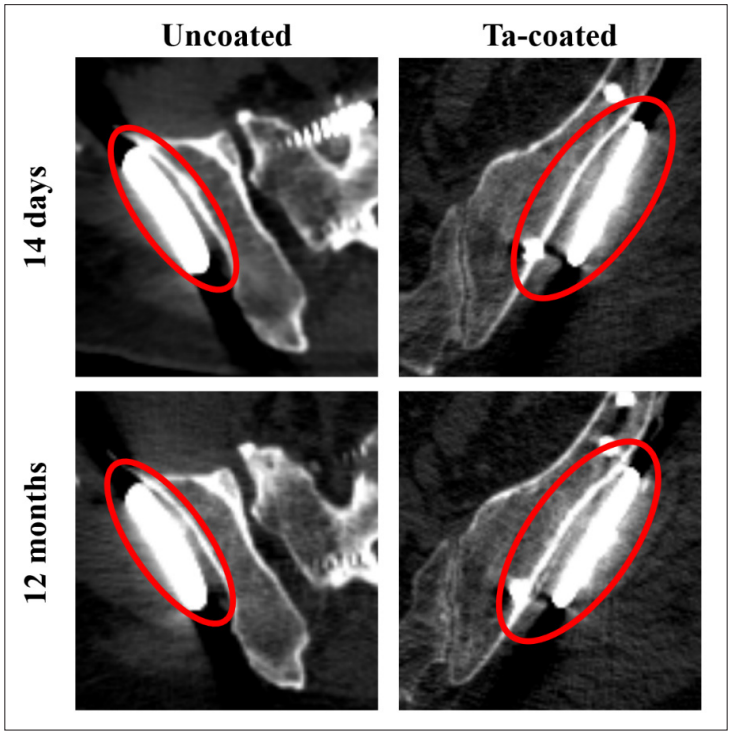

Figure 6. Computed tomography images of patients in the experimental (Ta-coated) and control (uncoated) groups on the 14th day after surgery and 12 months of follow-up. The red circles represent the bone trabeculae formed at the prosthesis–bone interface.

Table 3. Effectiveness evaluation index

Parameters	Experimental group (n = 11)	Control group (n = 10)	p-value
Harris Hip Score	81.8 ± 5.7	69.8 ± 7.0	0.001
Bone ingrowth grade			
Excellent	4	0	
Good	6	3	
Fair	1	6	
Poor	0	1	
Excellent/good rate (%)	90.9	30.0	

and favorable biocompatibility, their capacity to promote osteogenesis remains unsatisfactory. To address this limitation, this study applied PIII technology to deposit a tantalum coating on the surface of 3D-printed porous titanium alloy prostheses, thereby endowing them with osteogenic biological functionality. Clinical studies have substantiated that the personalized 3D-printed tantalum-coated titanium alloy pelvic reconstruction prostheses, independently developed by our research team, significantly enhance new bone ingrowth at the prosthesis–bone interface, thereby improving prosthesis stability, restoring lower limb function in patients, and ultimately representing a more effective approach for managing complex pelvic defects.

Aseptic loosening of orthopedic implants can lead to significant complications, including pain, functional impairment, and ultimately implant failure requiring revision surgery. A primary contributor to aseptic prosthetic loosening is inadequate osseointegration between the implant and host bone.[18,19] While robust osseointegration is paramount for implant success, conventional titanium alloys widely used in clinical orthopedic implants inherently lack the biological capacity to promote neo-osteogenesis. Substantial research efforts have been devoted to enhancing the osseointegration efficiency of existing titanium alloy prostheses to combat implant loosening.

Hydroxyapatite (HA) coating on implant surfaces has a well-established history, with studies as early as 1991 demonstrating that plasma-sprayed HA coatings on titanium alloys induced greater intramedullary neo-osteogenesis, thereby enhancing implant osseointegration.[20] Multiple clinical investigations have confirmed that plasma-sprayed HA coatings on titanium surfaces can stimulate cancellous bone formation.[21,22] However, HA coatings deposited via plasma spraying undergo progressive degradation *in vivo*, potentially leading to inflammatory reactions, coating disintegration, and subsequent implant loosening.[23]

Chemical surface modifications through sandblasting, acid-etching, or their combination have been clinically proven to enhance osseointegration, improve implant stability, and reduce healing duration.[24–26] Nevertheless, these techniques are predominantly applied to smaller oral/dental implants in maxillofacial regions rather than orthopedic clinical implants. In summary, although rational surface modifications and coating technologies can effectively improve titanium alloy osseointegration performance, current methodologies exhibit respective limitations, urgently necessitating the development of novel approaches to address the persistent clinical challenge of suboptimal osseointegration efficiency in titanium alloy prostheses.

Tantalum manifests significant potential for enhancing osseointegration due to its exceptional biocompatibility and corrosion resistance. The remarkable osteogenic capacity of tantalum has gained international recognition, positioning it as a promising novel material for orthopedic implants. While pure tantalum exhibits several limitations as an implant material, current strategies focus on fabricating porous tantalum prostheses or depositing tantalum coatings onto implant surfaces.[27–29] For example, Ying *et al.*[30] employed 3D-printed tantalum acetabular augments to address acetabular defects during total hip arthroplasty revision, achieving effective acetabular reconstruction with restored hip rotation center and improved hip function. Similarly, Li *et al.*[31] reported successful reconstruction of massive pelvic defects following iliac chondrosarcoma resection using 3D-printed tantalum prostheses, with the patient achieving ambulation at 1 month postoperatively and maintaining tumor-free status without implant loosening or mechanical failure during 12-month follow-up. Nevertheless, widespread clinical implementation of 3D-printed porous tantalum prostheses remains constrained by the prohibitively high cost of raw spherical tantalum powder required for fabrication.[32]

Tantalum coatings enhance surface roughness and microtopography, creating a favorable microenvironment for cell adhesion and promoting early osseointegration. Our research team previously fabricated 3D-printed porous tantalum scaffolds, with cellular and animal experiments confirming their exceptional osteogenic activity and biosafety in bone regeneration.[12] Zimmer Biomet (USA) developed a porous tantalum material through chemical vapor deposition technology, featuring 40–60-μm-thick tantalum coatings deposited on low-density vitreous carbon scaffolds.[33] This porous tantalum has achieved widespread clinical application for bone defect filling with documented economic and therapeutic benefits.[34,35] However, three critical limitations persist: First, its low elastic modulus prevents customization of patient-specific porous tantalum reconstruction prostheses.[17] Second, the inherent mechanical weakness of the carbon scaffold substrate becomes particularly problematic when applied to weight-bearing regions such as the pelvis.[36] Third, the mechanical properties of porous tantalum primarily hinge on the thickness of the tantalum coating on its surface. To guarantee the prosthesis's mechanical strength, the tantalum coating on the surface typically needs to exceed 40 μm in thickness, which necessitates a prolonged coating duration and incurs higher manufacturing costs.

Our research team pioneered the application of PIII technology to uniformly deposit tantalum coatings on personalized 3D-printed titanium alloy prostheses, with coating thickness maintained below 20 μm. This methodology simultaneously fulfills prosthetic morphological requirements, maintains structural integrity under mechanical loading, and preserves tantalum's biological functionality, thereby enabling functional reconstruction of complex pelvic defects. The coatings fabricated through PIII technology demonstrate exceptional density and uniformity while maintaining robust adhesion to the substrate.[37,38] Compared with solid pure tantalum implants, our surface-modified prostheses exhibit a significantly reduced elastic modulus closer to bone tissue, substantial weight reduction, and improved cost-effectiveness. The PIII-derived coatings completely cover all internal and external surfaces of porous prostheses without compromising osseous ingrowth into the porous architecture.[39,40] Our preliminary investigations demonstrated that 3D-printed titanium alloy implants maintained comparable mechanical properties before and after PIII deposited tantalum coating, with no significant changes in elastic modulus or compressive strength.[41] These findings suggest that the observed clinical improvements are principally attributable to tantalum's inherent osteoinductive capacity and bioactive properties that potentiate bone regeneration.

Through synergistic interaction with porous structures, tantalum further enhances osseointegration at the prosthesis–bone interface, thereby reducing the incidence of postoperative aseptic loosening of the prosthesis and ensuring a more secure union between the implant and the bone. Owing to its non-line-of-sight deposition characteristics and excellent adaptability, PIII tantalum-coating technology should be broadly compatible with various types of 3D-printed titanium implants—including acetabular cups, spinal fusion cages, and dental fixtures—while its process characteristics guarantee conformity with complex topologies and lattice architectures. Compared with conventional hydroxyapatite or micro-arc oxidation coatings, this technique demonstrates superior osseointegration-promoting capacity, while simultaneously enabling synergetic enhancement of mechanical adaptability and biological activity through topology-optimization strategies. Although the high-temperature process may increase manufacturing costs, batch processing and parameter optimization can effectively contain cost increments, thereby ensuring seamless integration into both clinical and commercial workflows.

Regarding safety considerations, tantalum-coated prostheses maintain identical design principles, manufacturing processes, surgical techniques, and perioperative management compared to conventional titanium alloy implants. The only distinction lies in the surface coating modification, which does not increase surgical complexity or procedural requirements, thereby ensuring equivalent intraoperative safety. Postoperative safety was evaluated through monitoring biochemical parameters and complication rates. In this study, no significant differences were observed between preoperative and postoperative indicators in the experimental group, with no severe complications reported. Both the experimental and control groups showed comparable prosthesis stability and equivalent patient survival rates. These results confirm that tantalum-coated prostheses exhibit favorable postoperative safety and are clinically applicable for complex pelvic reconstruction.

Given the inability to obtain prosthesis–bone interface specimens for histological or cellular analysis, the osteogenic capacity of tantalum coatings was evaluated exclusively through radiographic assessment. Currently, no established imaging criteria exist for quantifying bone ingrowth at prosthesis–bone interfaces. In this study, pelvic CT scans were utilized to evaluate trabecular bone formation perpendicular to the interface as the primary indicator of osseointegration. Comparative analysis revealed that the tantalum-coated group exhibited significantly higher bone ingrowth grades and superior clinical success rates compared to uncoated controls, thereby confirming the coating's enhanced osseointegration potential, findings consistent with previous cellular and animal experimental outcomes. The enhanced osseointegration observed with the tantalum coating may be attributed to its superior bioactivity, surface energy, and potential to modulate osteoblast behavior, as suggested in prior studies.[41] Furthermore, patients with tantalum-coated prostheses exhibited superior postoperative lower limb function scores and sustained implant positional stability, thereby confirming the enhanced postoperative stability and biomechanical performance characteristics of the tantalum-coated implants.

In summary, personalized 3D-printed tantalum-coated titanium alloy prostheses, fabricated through PIII, demonstrate clinical safety in the treatment of complex bone defects while exhibiting promising efficacy in promoting bone regeneration and restoring lower limb function. Its remarkable bone integration potential suggests the likelihood of long-term prosthesis stability, potentially leading to a significant reduction in long-term loosening rates and ultimately contributing to sustained improvements in patients' limb function and mobility. Nevertheless, potential long-term complications, such as late-onset infections, coating fatigue, and wear debris

reactions, necessitate further evaluation through extended observation periods.

This study has several limitations. First, the relatively small sample size, inherent to the rarity of complex pelvic defects requiring such reconstruction, may limit the statistical power and generalizability of the findings. Second, heterogeneity in follow-up durations among patients introduces potential bias in the assessment of complications and functional outcomes, particularly for long-term effects. Third, the lack of long-term follow-up data precludes definitive conclusions regarding the durability and long-term clinical efficacy of the prosthesis. Consequently, there is a need for long-term, multicenter studies with a larger cohort to comprehensively assess the long-term safety and effectiveness of a tantalum-coated prosthesis in treating complex bone defects, and to validate its potential in enhancing patients' long-term quality of life.

5. Conclusion

The personalized 3D-printed tantalum-coated titanium alloy pelvic prostheses fabricated via PIII demonstrate clinical safety and efficacy in reconstructing complex pelvic defects. These prostheses enhance osseointegration at the bone–implant interface, improve mechanical stability, and effectively restore lower limb function. Collectively, these advantages establish this technology as a superior therapeutic strategy for complex pelvic reconstruction. The findings confirm the significant clinical potential of functional tantalum-coated prostheses for orthopedic applications.

Acknowledgments

None.

Funding

This work was financially supported by the National Key Research & Development Program of China (2024YFB3814700), National Key Research & Development Program of China (2022YFC2406000), National Natural Science Foundation of China (52401056), Shanghai Municipal Commission of Economy and Informatization (2024-GZL-RGZN-01023), Domestic Science and Technology Cooperation Projects of Shanghai Municipal Science and Technology Commission (24010701700), Key Research & Development Programs of Ningxia, China (2020BCH01001), Shanghai Engineering Research Center of Innovative Orthopedic Instruments and Personalized Medicine (19DZ2250200), Biomaterials and Regenerative Medicine Institute Cooperative Research Project, Shanghai Jiao Tong University School of Medicine (2022LHA01), 3-year Action Plan of Shenkang Development Center (SHDC2020CR2019B) and Shanghai Pujiang Program (23PJ1421600).

Conflict of interest

The authors declare they have no competing interests.

Author contributions

Conceptualization: Yongqiang Hao, Wei Li, Liang Deng
Formal analysis: Zhaoyang Ran
Investigation: Zhaoyang Ran, Boran Pang, Junxiang Wu, Lei Wang, Jingke Fu
Methodology: Zhaoyang Ran, Boran Pang, Yulin Tian, Dinghao Luo
Writing–original draft: Zhaoyang Ran, Boran Pang
Writing–review & editing: Yongqiang Hao, Liang Deng, Wei Li, Kai Xie

Ethics approval and consent to participate

The study was approved by the Ethics Committee of Shanghai Ninth People's Hospital affiliated to Shanghai Jiao Tong University School of Medicine (approval no.: SH9H-2020-T206-1). Written informed consent to participate was obtained from all participants and/or their legal guardian(s)

Consent for publication

We confirmed that written informed consent for publication was obtained from all the subjects and/or their legal guardian(s).

Availability of data

The datasets used or analyzed during the current study are available from the corresponding author upon reasonable request.

References

1. Dimitriou R, Mataliotakis GI, Angoules AG, Kanakaris NK, Giannoudis PV. Complications following autologous bone graft harvesting from the iliac crest and using the RIA: a systematic review. *Injury*. 2011;42(Suppl 2):S3-S15. doi: 10.1016/j.injury.2011.06.015

2. Campana V, Milano G, Pagano E, *et al*. Bone substitutes in orthopaedic surgery: from basic science to clinical practice. *J Mater Sci Mater Med*. 2014;25(10):2445-2461. doi: 10.1007/s10856-014-5240-2

3. Ran ZY, Wang Y, Li JX, *et al*. 3D-printed biodegradable magnesium alloy scaffolds with zoledronic acid-loaded

ceramic composite coating promote osteoporotic bone defect repair. *Int J Bioprinting*. 2023;9(5):401-417. doi: 10.18063/ijb.769

4. Wang J, Min L, Lu M, *et al*. Three-dimensional-printed custom-made hemipelvic endoprosthesis for primary malignancies involving acetabulum: the design solution and surgical techniques. *J Orthop Surg Res*. 2019;14(1):389. doi: 10.1186/s13018-019-1455-8
5. Li GY, Wang L, Pan W, *et al*. In vitro and in vivo study of additive manufactured porous Ti6Al4V scaffolds for repairing bone defects. *Sci Rep*. 2016;6:34072. doi: 10.1038/srep34072
6. Wu JX, Xie K, Luo DH, *et al*. Three-dimensional printing-based personalized limb salvage and reconstruction treatment of pelvic tumors. *J Surg Oncol*. 2021;124(3):420-430. doi: 10.1002/jso.26516
7. Xue T, Attarilar S, Liu SF, *et al*. Surface modification techniques of titanium and its alloys to functionally optimize their biomedical properties: a thematic review. *Front Bioeng Biotechnol*. 2020;8:603072. doi: 10.3389/fbioe.2020.603072
8. Souza JCM, Sordi MB, Kanazawa M, *et al*. Nano-scale modification of titanium implant surfaces to enhance osseointegration. *Acta Biomater*. 2019;94:112-131. doi: 10.1016/j.actbio.2019.05.045
9. Wang X, Liu WT, Yu XD, *et al*. Advances in surface modification of tantalum and porous tantalum for rapid osseointegration: a thematic review. *Front Bioeng Biotechnol*. 2022;10:983695. doi: 10.3389/fbioe.2022.983695
10. Schildhauer TA, Robie B, Muhr G, Köller M. Bacterial adherence to tantalum versus commonly used orthopedic metallic implant materials. *J Orthop Trauma*. 2006;20(7):476-484. doi: 10.1097/00005131-200608000-00005
11. Wang Q, Qiao YQ, Cheng MQ, *et al*. Tantalum implanted entangled porous titanium promotes surface osseointegration and bone ingrowth. *Sci Rep*. 2016;6:26248. doi: 10.1038/srep26248
12. Guo Y, Xie K, Jiang WB, *et al*. In vitro and in vivo study of 3D-printed porous tantalum scaffolds for repairing bone defects. *ACS Biomater Sci Eng*. 2019;5(2):1123-1133. doi: 10.1021/acsbiomaterials.8b01094
13. Li WY, Li XY, Dong HS. Effect of tensile stress on the formation of S-phase during low-temperature plasma carburizing of 316L foil. *Acta Mater*. 2011;59(14):5765-5774. doi: 10.1016/j.actamat.2011.05.053
14. Ueda M, Silva C, Marcondes AR, Reuther H, de Souza GB. Recent experiments on plasma immersion ion implantation (and deposition) using discharges inside metal tubes. *Surf Coat Technol*. 2018;355:98-110. doi: 10.1016/j.surfcoat.2018.05.009
15. Zhang LC, Chen LY, Wang LQ. Surface modification of titanium and titanium alloys: technologies, developments, and future interests. *Adv Eng Mater*. 2020;22(5): 1901258. doi: 10.1002/adem.201901258
16. Schulz KF, Altman DG, Moher D; CONSORT Group. CONSORT 2010 statement: updated guidelines for reporting parallel group randomised trials. *J Clin Epidemiol*. 2010;63(8):834-840. doi: 10.1016/j.jclinepi.2010.02.005
17. Li X, Wang L, Yu XM, *et al*. Tantalum coating on porous Ti6Al4V scaffold using chemical vapor deposition and preliminary biological evaluation. *Mater Sci Eng C Mater Biol Appl*. 2013;33(5):2987-2994. doi: 10.1016/j.msec.2013.03.027
18. Agarwal R, Garcia AJ. Biomaterial strategies for engineering implants for enhanced osseointegration and bone repair. *Adv Drug Deliv Rev*. 2015;94:53-62. doi: 10.1016/j.addr.2015.03.013
19. Bohara S, Suthakorn J. Surface coating of orthopedic implant to enhance the osseointegration and reduction of bacterial colonization: a review. *Biomater Res*. 2022;26(1):26. doi: 10.1186/s40824-022-00269-3
20. Jansen JA, van de Waerden JP, Wolke JG, de Groot K. Histologic evaluation of the osseous adaptation to titanium and hydroxyapatite-coated titanium implants. *J Biomed Mater Res*. 1991;25(8):973-989. doi: 10.1002/jbm.820250805
21. D'Antonio JA, Capello WN, Jaffe WL. Hydroxylapatite-coated hip implants: multicenter three-year clinical and roentgenographic results. *Clin Orthop Relat Res*. 1992;285:102-115 doi: 10.1097/00003086-199212000-00015
22. D'Lima DD, Walker RH, Colwell CW Jr. Omnifit-HA stem in total hip arthroplasty: a 2- to 5-year follow-up. *Clin Orthop Relat Res*. 1999;363:163-169.

    doi: 10.1097/00003086-199906000-00021
23. Landor I, Vavrik P, Sosna A, Jahoda D, Hahn H, Daniel M. Hydroxyapatite porous coating and the osteointegration of the total hip replacement. *Arch Orthop Trauma Surg*. 2007;127(2):81-89. doi: 10.1007/s00402-006-0235-1
24. Bornstein MM, Hart CN, Halbritter SA, Morton D, Buser D. Early loading of nonsubmerged titanium implants with a chemically modified sand-blasted and acid-etched surface: 6-month results of a prospective case series study in the posterior mandible focusing on peri-implant crestal bone changes and ISQ values. *Clin Implant Dent Relat Res*. 2009;11(4):338-347. doi: 10.1111/j.1708-8208.2009.00148.x

25. Schatzle M, Mannchen R, Balbach U, Hammerle CH, Toutenburg H, Jung RE. Stability change of chemically modified sandblasted/acid-etched titanium palatal implants: a randomized-controlled clinical trial. *Clin Oral Implants Res*. 2009;20(5):489-495.
doi: 10.1111/j.1600-0501.2008.01694.x

26. Markovic A, Colic S, Scepanovic M, Misic T, Ethinic A, Bhusal DS. A 1-year prospective clinical and radiographic study of early-loaded bone level implants in the posterior maxilla. *Clin Implant Dent Relat Res*. 2015;17(5):1004-1013.
doi: 10.1111/cid.12201

27. Zhang C, Chen H, Fan H, *et al*. Carpal bone replacement using personalized 3D printed tantalum prosthesis. *Front Bioeng Biotechnol*. 2023;11:1234052.
doi: 10.3389/fbioe.2023.1234052

28. Girerd D, Parratte S, Lunebourg A, *et al*. Total knee arthroplasty revision with trabecular tantalum cones: preliminary retrospective study of 51 patients from two centres with a minimal 2-year follow-up. *Orthop Traumatol Surg Res*. 2016;102(4):429-433.
doi: 10.1016/j.otsr.2016.02.010

29. Shi LY, Wang A, Zang FZ, Wang JX, Pan XW, Chen HJ. Tantalum-coated pedicle screws enhance implant integration. *Colloids Surf B Biointerfaces*. 2017;160:22-32.
doi: 10.1016/j.colsurfb.2017.08.059

30. Ying J, Cheng L, Li J, *et al*. Treatment of acetabular bone defect in revision of total hip arthroplasty using 3D printed tantalum acetabular augment. *Orthop Surg*. 2023;15(5):1264-1271.
doi: 10.1111/os.13691

31. Li Z, Chen G, Xiang Y, *et al*. Treatment of massive iliac chondrosarcoma with personalized three-dimensional printed tantalum implant: a case report and literature review. *J Int Med Res*. 2020;48(10):300060520959508.
doi: 10.1177/0300060520959508

32. Wei XW, Zhao DW, Wang BJ, *et al*. Tantalum coating of porous carbon scaffold supplemented with autologous bone marrow stromal stem cells for bone regeneration in vitro and in vivo. *Exp Biol Med (Maywood)*. 2016;241(6):592-602.
doi: 10.1177/1535370216629578

33. Levine BR, Sporer S, Poggie RA, Della Valle CJ, Jacobs JJ. Experimental and clinical performance of porous tantalum in orthopedic surgery. *Biomaterials*. 2006;27(27):4671-4681.
doi: 10.1016/j.biomaterials.2006.04.041

34. Rajgopal A, Panda I, Yadav S, Wakde O. Stacked tantalum cones as a method for treating severe distal femoral bone deficiency in total knee arthroplasty. *J Knee Surg*. 2019;32(9):833-840.
doi: 10.1055/s-0038-1669789

35. Liu GH, Wang J, Yang SH, Xu WH, Ye SN, Xia TA. Effect of a porous tantalum rod on early and intermediate stages of necrosis of the femoral head. *Biomed Mater*. 2010;5(6):065003.
doi: 10.1088/1748-6041/5/6/065003

36. Chalkin B, Minter J. Limb salvage and abductor reattachment using a custom prosthesis with porous tantalum components: case report. *J Arthroplasty*. 2005;20(1):127-130.
doi: 10.1016/j.arth.2004.09.029

37. Zhou Y, Li M, Cheng Y, Zheng YF, Xi TF, Wei SC. Tantalum coated NiTi alloy by PIIID for biomedical application. *Surf Coat Technol*. 2013;228:S2-S6.
doi: 10.1016/j.surfcoat.2012.11.002

38. Lu T, Wen J, Qian S, *et al*. Enhanced osteointegration on tantalum-implanted polyetheretherketone surface with bone-like elastic modulus. *Biomaterials*. 2015;51:173-183.
doi: 10.1016/j.biomaterials.2015.02.018

39. Bobyn JD, Stackpool GJ, Hacking SA, Tanzer M, Krygier JJ. Characteristics of bone ingrowth and interface mechanics of a new porous tantalum biomaterial. *J Bone Joint Surg Br*. 1999;81-B(5):907-914.
doi: 10.1302/0301-620X.81B5.9283

40. Bobyn JD, Poggie RA, Krygier JJ, *et al*. Clinical validation of a structural porous tantalum biomaterial for adult reconstruction. *J Bone Joint Surg Am*. 2004;86-A (Suppl 2):123-129.
doi: 10.2106/00004623-200412002-00017

41. Tian YL, Jiang WB, Deng L, *et al*. A fractal-like hierarchical bionic scaffold for osseointegration. *Adv Funct Mater*. 2025;35(8):2415880.
doi: 10.1002/adfm.202415880