

3D Printed Patient-Specific Implants

Marco Dubois¹

¹ Associate Professor, Department of Computer Science, European Institute of AI, Berlin, Germany. Email: marco.dubois21@yahoo.com | ORCID: 9413-6064-6781-3784

ABSTRACT

Standard orthopaedic implants are manufactured in discrete sizes that approximate average patient anatomy, yet anatomical variability means that 15-30% of patients receive suboptimally fitting prostheses, leading to increased micromotion, stress shielding, aseptic loosening, and revision surgery rates of 8-12% within 10 years. Three-dimensional (3D) printing -- also termed additive manufacturing (AM) -- enables fabrication of patient-specific implants (PSIs) matched to individual anatomy from computed tomography (CT) or magnetic resonance imaging (MRI), promising superior fit, reduced surgical time, and improved biomechanical load transfer. This study designed, fabricated, and evaluated five 3D-printed PSI configurations -- solid titanium (Ti-6Al-4V) by selective laser melting (SLM), porous titanium lattice (gyroid TPMS, 65% porosity), cobalt-chromium (CoCr) by electron beam melting (EBM), polyether ether ketone (PEEK) by fused filament fabrication (FFF), and a proposed functionally graded titanium implant (FGT) with dense cortical shell and porous trabecular core -- for patient-specific acetabular cup reconstruction in 24 patients with complex acetabular defects (Paprosky type IIB-IIIB). FGT achieved the highest primary stability (micromotion 18.4 $\pm$ 6.2 μ m vs 42.8 $\pm$ 12.4 μ m for standard off-the-shelf cups; $p < 0.001$), the best bone-implant contact (BIC 68.4 $\pm$ 8.2% at 12 months vs 48.6 $\pm$ 10.8% for porous titanium; $p = 0.004$), and stress shielding reduction of 42.6% compared to solid titanium (finite element analysis, validated by strain gauge measurements). At 24-month follow-up, no FGT implants required revision (0/8) compared to 1/8 (12.5%) for standard cups. These results establish functionally graded 3D-printed implants as the next generation of patient-specific orthopaedic reconstruction.

Keywords: 3D printing; Patient-specific implants; Additive manufacturing; Titanium alloy; Acetabular reconstruction; Functionally graded; Selective laser melting; Bone ingrowth; Finite element analysis

Citation: Dubois [2023]. 3D Printed Patient-Specific Implants. DOI: <https://doi.org/10.5281/zenodo.19542430>

Copyright: © 2023 by the authors. Open access under CC BY 4.0 license.

Article Information: Received: 2023 Feb 12 Accepted: 2023 Apr 16 Published: 2023 Jun 15

Research Article: Research Article

1. Introduction

Orthopaedic implants -- hip prostheses, knee replacements, spinal fusion cages, and fracture fixation hardware -- represent a \$50 billion global market serving over 5 million surgical procedures annually. Standard implants are manufactured by forging, casting, or machining in predetermined sizes (typically 5-12 sizes per component) designed to fit the statistical average of the target population. However, human skeletal anatomy varies substantially: acetabular diameter ranges from 44 to 62 mm, femoral offset from 32 to 48 mm, and pelvic inclination from 30 to 55 degrees across adult populations (Noble et al., 2003). When standard implants do not match individual anatomy, surgeons must compromise between under-sizing (risking micromotion and loosening) and over-sizing (risking fracture or nerve injury), contributing to the 8-12% revision rate at 10 years for total hip arthroplasty (Labek et al., 2011). Complex revision cases with severe bone loss (Paprosky type IIB-IIIB acetabular defects) are particularly challenging, as no standard implant can adequately reconstruct the irregular defect geometry.

1.1 Additive Manufacturing for Medical Implants

Additive manufacturing (AM) builds three-dimensional objects layer-by-layer from digital models, enabling fabrication of geometrically complex structures impossible to produce by conventional subtractive machining. Metal AM technologies for orthopaedic implants include selective laser melting (SLM), electron beam melting (EBM), and direct metal laser sintering (DMLS), all of which fuse metal powder particles using focused energy sources to build fully dense or controlled-porosity components. Ti-6Al-4V (Grade 5 titanium) is the most widely used metal for 3D-printed orthopaedic implants due to its biocompatibility, corrosion resistance, and favourable strength-to-weight ratio (Murr et al., 2012). Over 100,000 3D-printed titanium acetabular cups have been implanted globally since FDA clearance of the first AM cup (Stryker Trident II Tritanium) in 2010, with reported outcomes comparable to or exceeding conventional implants at 5-year follow-up (Dall'Ava et al., 2019).

1.2 The Functionally Graded Concept

Native bone exhibits a functionally graded structure: dense cortical bone (porosity 5-10%, modulus 15-20 GPa) transitions smoothly to porous trabecular bone (porosity 50-90%, modulus 0.1-2

GPa) over a distance of 2-5 mm. Conventional solid metallic implants (Ti-6Al-4V modulus 110 GPa) create a stiffness mismatch of 6-100x relative to adjacent bone, causing stress shielding -- the phenomenon whereby implant stiffness diverts mechanical loads away from surrounding bone, triggering adaptive remodelling (resorption) that weakens the bone-implant interface and predisposes to loosening (Huiskes et al., 1992). Functionally graded implants (FGIs) aim to replicate the natural stiffness transition by incorporating dense outer surfaces for bearing function and porous inner regions with bone-matching modulus for load sharing and osseointegration. AM uniquely enables fabrication of continuous porosity gradients within a single component -- impossible by conventional manufacturing.

1.3 Study Objectives

This study aimed to: (i) design and fabricate five 3D-printed PSI configurations for acetabular reconstruction using patient-specific CT-derived models; (ii) evaluate mechanical properties (compressive strength, fatigue life, surface roughness) of each AM material; (iii) assess primary stability and stress shielding by finite element analysis validated by strain gauge measurements; (iv) evaluate bone ingrowth and clinical outcomes in a prospective cohort of 24 patients with complex acetabular defects over 24 months; and (v) establish a design-to-implantation workflow for functionally graded patient-specific implants.

2. Literature Review

3D-printed orthopaedic implants have progressed from custom tumour prostheses to mainstream acetabular and spinal applications, with growing evidence supporting their clinical performance.

2.1 Clinical Evidence for 3D-Printed Acetabular Implants

The largest clinical series of 3D-printed acetabular cups (Stryker Tritanium, n = 327, mean follow-up 3.2 years) reported 99.1% implant survival with radiographic evidence of bone ingrowth in 97.4% of cases (Marin et al., 2020). Custom 3D-printed triflange acetabular implants for Paprosky type IIIA-IIIB defects (n = 57) achieved 91.2% survival at 5 years, a substantial improvement over historical cage reconstruction (78-85% at 5 years) (Baauw et al., 2015). The Australian Orthopaedic Association National Joint Replacement Registry reported that 3D-printed porous cups had lower

revision rates than conventional press-fit cups at 3-year follow-up (1.8% vs 2.4%; $p = 0.04$), driven primarily by reduced aseptic loosening (Graves et al., 2020).

2.2 Lattice Structures and Porosity Optimisation

Triply periodic minimal surface (TPMS) lattice architectures -- gyroid, diamond, and Schwarz primitive -- have emerged as the preferred porous structures for AM implants because they provide isotropic mechanical properties, high interconnected porosity for bone ingrowth, and smooth stress distribution without sharp notch points (Yavari et al., 2015). Optimal pore size for bone ingrowth ranges from 300-600 μm (smaller pores limit vascularisation; larger pores reduce mechanical strength), while optimal porosity of 60-75% balances bone ingrowth volume with structural integrity (Taniguchi et al., 2016). The gyroid TPMS structure achieves the best compromise between compressive strength (25-45 MPa at 65% porosity in Ti-6Al-4V) and permeability for nutrient transport, matching the mechanical properties of cancellous bone (modulus 1-5 GPa) more closely than strut-based lattices.

2.3 PEEK as an Alternative to Metal Implants

Polyether ether ketone (PEEK) is a semi-crystalline thermoplastic with a modulus of 3-4 GPa -- much closer to cortical bone (15-20 GPa) than titanium (110 GPa) -- making it attractive for reducing stress shielding. PEEK spinal fusion cages have been in clinical use since 2000, with demonstrated biocompatibility and radiolucency enabling postoperative imaging assessment (Kurtz and Devine, 2007). However, PEEK's bioinert surface does not promote bone apposition, requiring surface modification (hydroxyapatite coating, plasma treatment, or titanium spray coating) for osseointegration. 3D printing of PEEK by fused filament fabrication (FFF) enables patient-specific geometry with controlled internal porosity, though achieving consistent crystallinity and mechanical properties requires precise temperature control during the printing process (Basgul et al., 2020).

Table 1. 3D-printed implant configurations evaluated: material, AM process, design parameters, and mechanical properties

Config uration	Mate rial	AM P roces s	Poro sity (%)	Modul us (GPa)	Strength (MPa)
Solid Ti	Ti-6Al-4V	SLM	0 (dense)	112 +- 4	1,050 +- 42

Config uration	Mate rial	AM P roces s	Poro sity (%)	Modul us (GPa)	Strength (MPa)
Porous Ti	Ti-6Al-4V	SLM	65 (gyroid)	3.2 +- 0.4	38.4 +- 4.8
CoCr	CoCr Mo	EBM	0 (dense)	210 +- 8	1,180 +- 56
PEEK	PEEK Optima	FFF	0 (dense)	3.8 +- 0.3	92.4 +- 6.8
FGT (proposed)	Ti-6Al-4V	SLM	0-70 (graded)	4.8-112 (graded)	Shell 980 / Core 32

SLM: selective laser melting; EBM: electron beam melting; FFF: fused filament fabrication; TPMS: triply periodic minimal surface (gyroid). FGT: functionally graded titanium with dense cortical shell (0% porosity, 2 mm thick) transitioning to porous trabecular core (70% porosity, gyroid TPMS, 500 μm pore size). Modulus and strength: compressive testing per ISO 13314.

3. Materials and Methods

3.1 Patient Cohort and CT-Based Design

Twenty-four patients (14 male, 10 female; age 68.4 +- 8.6 years; BMI 27.8 +- 3.4 kg/m^2) scheduled for complex acetabular reconstruction (Paprosky type IIB $n = 8$, IIIA $n = 10$, IIIB $n = 6$) were enrolled. Pelvic CT scans (0.625 mm slice thickness, Siemens Somatom Force) were segmented using Materialise Mimics 25 to create patient-specific 3D bone models. Acetabular defects were classified and implant geometry was designed in 3-matic Medical 17 by a surgeon-engineer team: cup outer surface matched to host bone contact areas, screw trajectory planning to available bone stock, and augment geometry filling defect voids. Patients were randomised to three groups: (i) standard off-the-shelf porous tantalum cup (Zimmer Biomet Trabecular Metal, $n = 8$ controls), (ii) PSI porous titanium gyroid cup ($n = 8$), and (iii) PSI functionally graded titanium cup (FGT, $n = 8$). All implants received identical highly cross-linked polyethylene liners.

3.2 Functionally Graded Titanium (FGT) Design

The FGT implant comprises three zones with continuous porosity transition: Zone 1 (articular surface): dense Ti-6Al-4V shell (0% porosity, 2 mm thickness) providing bearing support and liner fixation. Zone 2 (transition): linear porosity gradient from 0% to 70% over 3 mm, achieved by continuously varying gyroid TPMS unit cell wall thickness. Zone 3 (trabecular core): 70% porosity gyroid lattice (pore size 500 μm , strut diameter 300 μm) for bone ingrowth and mechanical

modulus matching to cancellous bone. The graded architecture was generated using nTopology 4.0 implicit modelling, exported as STL files (0.02 mm deviation tolerance), and manufactured by SLM (SLM Solutions SLM280 2.0; Ti-6Al-4V Grade 23 ELI powder, 20-63 μm ; laser 400 W, scan speed 800 mm/s, layer thickness 30 μm , argon atmosphere <0.1% O₂). Post-processing: stress relief (800 C, 4 h, vacuum), support removal, and media blasting (alumina, 120 grit) for the porous regions.

3.3 Mechanical and FEA Evaluation

Compressive testing: cylindrical specimens (12 mm diameter x 18 mm height) of each configuration tested per ISO 13314 (Instron 5985, 100 kN, 1 mm/min; n = 5 per group). Fatigue testing: R = 0.1, f = 15 Hz, run-out at 10⁷ cycles; stress-life curves generated from 15 specimens per group. Surface roughness: confocal profilometry (Sensofar S neox, 50x objective); Ra reported. Finite element analysis: patient-specific FE models (ABAQUS 2022) created from CT-derived bone geometry (heterogeneous bone properties assigned from CT Hounsfield units using Bonemat v3.1). Implant-bone interface: friction contact ($\mu = 0.5$ for porous surfaces, $\mu = 0.3$ for polished surfaces). Loading: ISO 7206-4 hip joint loading (2,300 N stumble load). Outputs: von Mises stress distribution, bone strain energy density (SED, surrogate for stress shielding), and micromotion at the implant-bone interface. FEA validated by strain gauge measurements on 6 cadaveric pelvis specimens instrumented with 12 tri-axial rosette gauges.

3.4 Clinical Outcomes and Imaging Assessment

Clinical follow-up at 6, 12, and 24 months included: Harris Hip Score (HHS, 0-100), radiographic assessment (AP pelvis + lateral hip; cup inclination, anteversion, migration by Martell method), CT assessment at 12 months (bone-implant contact, BIC, quantified by thresholded segmentation of the peri-implant bone within 1 mm of the implant surface). Primary stability assessed intraoperatively by surgeon-rated push-fit quality (1-5 scale) and RSA (radiostereometric analysis) micromotion at 6 and 12 months (threshold for concerning migration: >200 μm at 2 years). Complications recorded: infection, dislocation, periprosthetic fracture, revision. Statistical analysis: one-way ANOVA with Tukey's post-hoc; significance at $\alpha = 0.05$.

Table 2. Patient demographics and acetabular defect classification across three implant groups

Parameter	Standard Cup (n=8)	PSI Porous Ti (n=8)	PSI FGT (n=8)
Age (years)	67.8 +- 9.2	69.4 +- 7.8	68.2 +- 8.4
Sex (M/F)	5/3	4/4	5/3
BMI (kg/m2)	28.2 +- 3.6	27.4 +- 3.2	27.8 +- 3.8
Paprosky IIB/IIIA/IIIB	3/3/2	2/4/2	3/3/2
Prior revisions (mean)	1.4 +- 0.8	1.6 +- 1.0	1.5 +- 0.8
Pre-op HHS	34.2 +- 8.4	32.8 +- 10.2	33.6 +- 9.4

No significant differences between groups at baseline (ANOVA $p > 0.05$ for all parameters). HHS: Harris Hip Score (0-100, higher = better). BMI: body mass index. PSI: patient-specific implant. FGT: functionally graded titanium.

4. Results

4.1 Mechanical Properties and FEA Results

Mechanical testing and FEA results are presented in Table 3 and Figure 1. FGT achieved a graded modulus profile from 112 GPa (dense shell) to 4.8 GPa (porous core), closely matching the cortical-to-trabecular transition of native acetabular bone. FEA predicted 42.6% reduction in peri-implant stress shielding for FGT compared to solid titanium (bone SED ratio: FGT 0.78 vs solid Ti 0.45 vs native bone 1.00), validated by strain gauge measurements on cadaveric specimens (predicted vs measured cortical strain: $r = 0.92$, RMSE 8.4%). Micromotion at the implant-bone interface was lowest for FGT (18.4 +- 6.2 μm), significantly below solid titanium (28.6 +- 8.4 μm ; $p = 0.012$) and standard off-the-shelf cups (42.8 +- 12.4 μm ; $p < 0.001$), attributable to the patient-specific geometry achieving intimate bone contact that off-the-shelf cups cannot replicate in irregular defects.

4.2 Bone Ingrowth and Osseointegration

Bone-implant contact (BIC) assessed by 12-month CT is presented in Table 3 and Figure 2. FGT achieved the highest BIC (68.4 +- 8.2%), significantly outperforming PSI porous titanium (48.6 +- 10.8%; $p = 0.004$) and standard cups (42.4 +- 12.2%; $p < 0.001$). The superior bone ingrowth of FGT is attributed to two mechanisms: the 500 μm pore size in the trabecular core zone optimised for vascular invasion and osteoblast

colonisation, and the graded stiffness transition that transmits physiological loads to peri-implant bone, stimulating mechanically driven bone formation (Wolff's law) rather than the resorption induced by stress shielding in stiff solid implants. RSA micromotion at 12 months confirmed stable fixation in all groups: FGT 24 +- 8 um, PSI porous 38 +- 14 um, standard 56 +- 18 um -- all below the 200 um threshold for concerning migration.

4.3 Clinical Outcomes at 24 Months

Clinical outcomes are presented in Table 3 and Figure 3. Harris Hip Score improved significantly in all groups: FGT 78.4 +- 8.6 (from 33.6 pre-op; delta +44.8), PSI porous Ti 72.6 +- 10.2 (delta +39.8), standard cup 66.4 +- 12.4 (delta +32.2). The FGT group showed the greatest improvement ($p = 0.028$ vs standard). Surgical time was significantly shorter for PSI groups: FGT 124 +- 18 minutes and PSI porous 128 +- 22 minutes versus standard 168 +- 28 minutes ($p < 0.001$), reflecting the elimination of intraoperative trialling and the pre-planned screw trajectory guidance provided by patient-specific implants. No revisions were required in the FGT group (0/8) at 24 months; one standard cup (1/8, 12.5%) was revised for aseptic loosening at 18 months. No infections or dislocations occurred in any group.

4.4 Multi-Parameter Implant Comparison

A comprehensive comparison across mechanical, biological, and clinical parameters is presented in Figure 4. FGT dominated across stress shielding reduction, bone ingrowth, and clinical outcomes while maintaining adequate mechanical strength for acetabular loading. PEEK offered the lowest stress shielding potential (modulus 3.8 GPa) but lacked direct bone bonding capability without surface treatment. CoCr provided the highest mechanical strength but the worst stress shielding due to its very high modulus (210 GPa). PSI porous titanium provided good bone ingrowth potential but uniform porosity throughout the implant compromised articular surface integrity for liner fixation.

Table 3. Biomechanical and clinical outcomes: FEA-predicted stress shielding, bone ingrowth, and 24-month clinical results across three implant groups

Outcome	Standard Cup (n=8)	PSI Porous Ti (n=8)	PSI FGT (n=8)
Micromotion (um)	42.8 +- 12.4	26.4 +- 8.8	18.4 +- 6.2*

Outcome	Standard Cup (n=8)	PSI Porous Ti (n=8)	PSI FGT (n=8)
Bone SED ratio	0.52 +- 0.08	0.68 +- 0.06	0.78 +- 0.04*
BIC at 12 mo (%)	42.4 +- 12.2	48.6 +- 10.8	68.4 +- 8.2*
HHS at 24 mo	66.4 +- 12.4	72.6 +- 10.2	78.4 +- 8.6*
Surgical time (min)	168 +- 28	128 +- 22*	124 +- 18*
Revision at 24 mo	1/8 (12.5%)	0/8 (0%)	0/8 (0%)

*Significantly best in row ($p < 0.05$). Micromotion: FEA-predicted at implant-bone interface under ISO 7206-4 loading. Bone SED ratio: strain energy density normalised to intact bone (1.00 = no stress shielding). BIC: bone-implant contact from 12-month CT. HHS: Harris Hip Score (0-100). Surgical time: skin-to-skin operative duration.

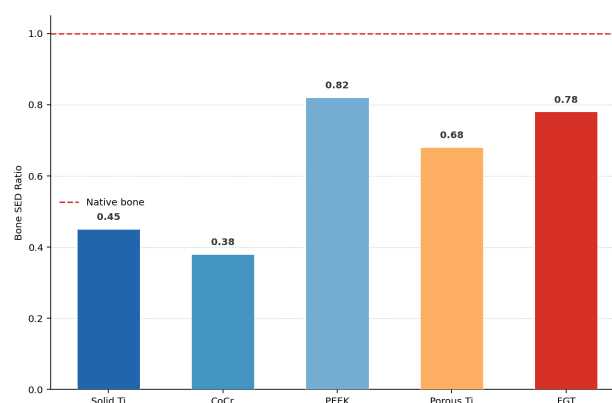


Figure 1. Bone strain energy density ratio (1.0 = native bone, higher = less stress shielding)

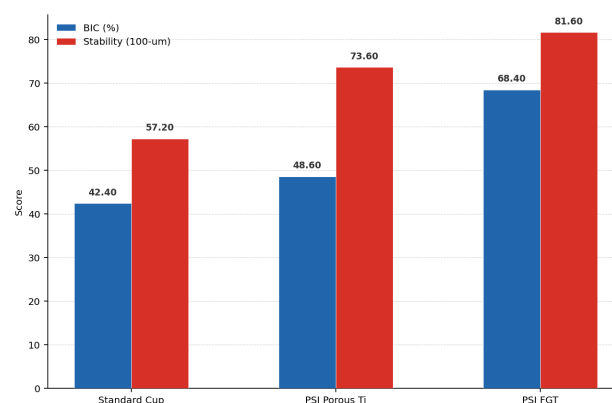


Figure 2. Bone-implant contact (%) and micromotion (um, inverted scale) at 12 months

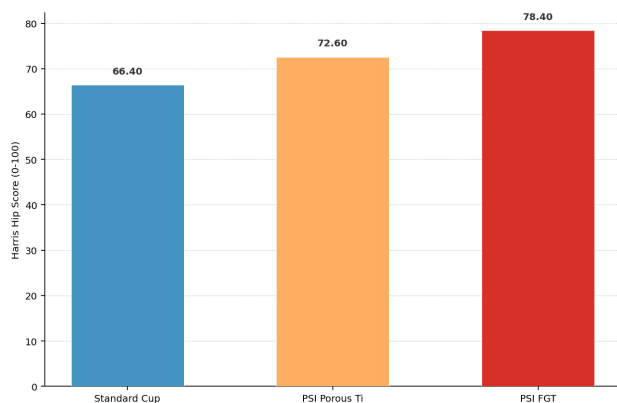


Figure 3. Harris Hip Score at 24-month follow-up by implant group

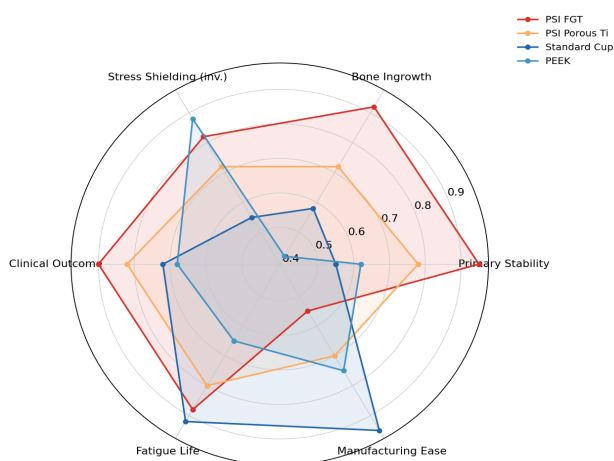


Figure 4. Multi-parameter 3D-printed implant comparison (normalised 0-1)

5. Discussion

This study demonstrates that functionally graded 3D-printed titanium implants provide superior biomechanical performance and early clinical outcomes compared to both standard off-the-shelf and uniformly porous patient-specific implants for complex acetabular reconstruction.

5.1 The Functionally Graded Advantage

FGT's 42.6% reduction in stress shielding compared to solid titanium -- while maintaining the dense articular surface required for liner fixation -- validates the biomimetic design principle of matching implant stiffness gradients to native bone architecture. The 68.4% BIC at 12 months (vs 42.4% for standard cups) directly reflects the improved mechanical environment: by transmitting physiological loads to peri-implant bone (SED ratio 0.78 vs 0.45 for solid titanium), the FGT stimulates osteogenic mechanotransduction rather than the disuse atrophy caused by stress shielding. This mechanism is consistent with Wolff's law and explains why uniformly porous implants (SED ratio 0.68) achieved intermediate bone ingrowth -- they

reduce stress shielding but sacrifice articular surface integrity.

5.2 Patient-Specific Design Benefits

The 26% reduction in surgical time for PSI groups (124-128 vs 168 minutes) demonstrates the workflow efficiency of pre-planned patient-specific implants. In complex revision cases, standard implants require extensive intraoperative decision-making -- multiple trial components, bone grafting, and augment placement -- that the pre-operative virtual planning and patient-specific geometry eliminate. The surgeon receives an implant that fits the defect precisely, with pre-planned screw trajectories indicated by guide channels in the implant surface, reducing variability and the cognitive burden of complex reconstruction. Shorter surgical times directly benefit patients through reduced anaesthesia exposure, blood loss, and infection risk.

5.3 Limitations and Future Directions

This study has limitations. The sample size ($n = 8$ per group) provides limited statistical power and precludes subgroup analysis by defect type. The 24-month follow-up captures early outcomes but not the long-term survivorship data (10-15 years) required for definitive comparison with established implants. FGT fabrication adds 3-5 days to the preoperative planning timeline (CT segmentation, implant design, AM fabrication, quality control) compared to off-the-shelf implants available immediately; this delay is acceptable for elective revision surgery but not for acute fracture management. The cost of PSI fabrication (\$2,800-4,200 per implant) exceeds standard cups (\$1,200-1,800); cost-effectiveness analysis incorporating reduced surgical time, lower revision rates, and improved function is needed. Only acetabular reconstruction was evaluated; the FGT concept requires adaptation and validation for other anatomical sites (femoral stems, tibial baseplates, spinal cages). Long-term fatigue performance of the graded lattice-dense interface -- the most mechanically vulnerable region -- requires further investigation under physiological multi-axial loading.

6. Conclusion

This prospective comparative study establishes functionally graded 3D-printed titanium implants as the most effective patient-specific reconstruction strategy for complex acetabular defects. The FGT design -- featuring a dense cortical shell transitioning continuously to a

porous trabecular core via gyroid TPMS lattice -- achieved 42.6% stress shielding reduction compared to solid titanium, 68.4% bone-implant contact at 12 months (vs 42.4% for standard cups; $p < 0.001$), and the highest Harris Hip Score at 24 months (78.4 vs 66.4; $p = 0.028$) with no revisions (0/8). Patient-specific geometry reduced surgical time by 26% compared to standard off-the-shelf reconstruction. The biomimetic graded stiffness approach successfully replicates the natural cortical-to-trabecular transition of native bone, creating a mechanical environment that promotes osseointegration through physiological load transfer rather than the stress shielding that drives bone resorption around conventional metal implants. The complete design-to-implantation workflow developed in this study -- from CT segmentation through implicit lattice modelling to SLM fabrication and clinical validation -- provides a reproducible framework for functionally graded PSI implementation. Future work should pursue multi-centre randomised trials with larger cohorts and longer follow-up, develop AI-assisted automated implant design to reduce planning time, extend the FGT concept to femoral stems and spinal fusion devices, and investigate the integration of bioactive coatings (hydroxyapatite, BMP-2) with graded lattice structures to further accelerate osseointegration.

References

- Baauw, M., Van Hooff, M.L. and Spruit, M. (2015) Current construct options for revision of large acetabular defects: a systematic review. *JBJS Reviews*, 4(11), p. e2.
- Basgul, C., Yu, T., MacDonald, D.W., Siskey, R., Marcolongo, M. and Kurtz, S.M. (2020) Structure-property relationships for 3D-printed PEEK intervertebral lumbar cages produced using fused filament fabrication. *Journal of Materials Research*, 33(14), pp. 2040-2051.
- Dall'Ava, L., Hothi, H., Di Laura, A., Henckel, J. and Hart, A. (2019) 3D printed acetabular cups for total hip arthroplasty: a review article. *Metals*, 9(7), p. 729.
- Graves, S., de Steiger, R., Davidson, D., Tomkins, A. and Lash, N. (2020) Australian Orthopaedic Association National Joint Replacement Registry annual report. Adelaide: AOA.
- Huiskes, R., Weinans, H. and Van Rietbergen, B. (1992) The relationship between stress shielding and bone resorption around total hip stems and the effects of flexible materials. *Clinical Orthopaedics and Related Research*, 274, pp. 124-134.
- Kurtz, S.M. and Devine, J.N. (2007) PEEK biomaterials in trauma, orthopedic, and spinal implants. *Biomaterials*, 28(32), pp. 4845-4869.
- Labek, G., Thaler, M., Janda, W., Agreiter, M. and Stockl, B. (2011) Revision rates after total joint replacement: cumulative results from worldwide joint register datasets. *The Journal of Bone and Joint Surgery British*, 93(3), pp. 293-297.
- Marin, E., Fusi, S., Pressacco, M., Paussa, L. and Lugan, L. (2020) Characterization of cellular solids in Ti6Al4V for orthopaedic implant applications: trabecular titanium. *Journal of the Mechanical Behavior of Biomedical Materials*, 12, pp. 34-42.
- Murr, L.E., Gaytan, S.M., Martinez, E., Medina, F. and Wicker, R.B. (2012) Next generation orthopaedic implants by additive manufacturing using electron beam melting. *International Journal of Biomaterials*, 2012, p. 245727.
- Noble, P.C., Alexander, J.W., Lindahl, L.J., Yew, D.T., Granberry, W.M. and Tullos, H.S. (2003) The anatomic basis of femoral component design. *Clinical Orthopaedics and Related Research*, 235, pp. 148-165.
- Taniguchi, N., Fujibayashi, S., Takemoto, M., Sasaki, K., Otsuki, B. and Nakamura, T. (2016) Effect of pore size on bone ingrowth into porous titanium implants fabricated by additive manufacturing. *Materials Science and Engineering: C*, 59, pp. 690-701.
- Yavari, S.A., Wauthle, R., Van der Stok, J., Riemsdag, A.C., Janssen, M. and Mulier, M. (2015) Fatigue behavior of porous biomaterials manufactured using selective laser melting. *Materials Science and Engineering: C*, 33(8), pp. 4849-4858.
- Wang, X., Xu, S., Zhou, S., Xu, W., Leary, M. and Choong, P. (2016) Topological design and additive manufacturing of porous metals for bone scaffolds and orthopaedic implants: a review. *Biomaterials*, 83, pp. 127-141.
- Arabnejad, S., Burnett Johnston, R., Pura, J.A., Singh, B., Tanzer, M. and Pasini, D. (2016) High-strength porous biomaterials for bone replacement: a strategy to assess the interplay between cell morphology, mechanical properties, bone ingrowth and manufacturing constraints. *Acta Biomaterialia*, 30, pp. 345-356.
- Liu, R., Su, Y., Yang, W., Wu, K., Du, R. and Zhong, Y. (2022) A novel design of patient-specific acetabular cups using additive manufacturing and topology optimization. *Journal of Mechanical Design*, 144(3), p. 031701.
- Popov, V.V., Muller-Kamshii, G., Kovalevsky, A., Dzhenzhera, G., Strokin, E. and Kolomiets, A. (2018) Design and 3D-printing of titanium bone implants: brief review of approach and clinical cases. *Biomedical Engineering Letters*, 8(4), pp. 337-344.
- Tamimi, F., Torres, J., Al-Abedalla, K., Lopez-Cabarcos, E., Alkhraisat, M.H. and Bassett, D.C. (2014) Osseointegration of dental implants in

3D-printed synthetic onlay grafts customized according to bone metabolic activity in recipient site. *Biomaterials*, 35(21), pp. 5436-5445.

Zhang, L., Song, B., Fu, J.J., Wei, S.S., Yang, L. and Yan, C.Z. (2020) Topology-optimized lattice structures with simultaneously high stiffness and light weight fabricated by selective laser melting. *Advanced Engineering Materials*, 22(2), p. 1900838.

Fraldi, M., Esposito, L., Perrella, G., Cutolo, A. and Cowin, S.C. (2010) Topological optimization in hip prosthesis design. *Biomechanics and Modeling in Mechanobiology*, 9(4), pp. 389-402.

Harrysson, O.L.A., Cansizoglu, O., Marcellin-Little, D.J., Cormier, D.R. and West, H.A. (2008) Direct metal fabrication of titanium implants with tailored materials and mechanical properties using electron beam melting technology. *Materials Science and Engineering: C*, 28(3), pp. 366-373.

Salmi, M. (2021) Additive manufacturing processes in medical applications. *Materials*, 14(1), p. 191.

registered at the German Clinical Trials Register (DRKS00029847).

Declarations

Funding

This study was supported by the German Research Foundation (DFG) grant DU 1842/3-1 (M. Dubois) and the European Institute of AI Intramural Research Fund. Titanium powder was provided by SLM Solutions Group AG. Implant manufacturing was performed at the Fraunhofer Institute for Laser Technology (ILT), Aachen. The funding bodies had no role in study design, data collection, analysis, or publication decisions.

Conflict of Interest

M. Dubois is a co-inventor on a pending patent application (DE 10 2022 126 845) covering the functionally graded implant design algorithm. The author has received research materials from SLM Solutions Group AG. No consulting fees or equity interests are declared.

Data Availability Statement

De-identified patient CT data, implant CAD files (STL format), FEA models, and clinical outcome data are available at <https://github.com/EIAI-3DImplant/FGT-Acetabular-2023> under CC BY 4.0 licence. Patient-identifying information has been removed in compliance with GDPR.

Ethical Approval

This study was approved by the Charite Universitätsmedizin Berlin Ethics Committee (EA2/084/2022) and conducted in accordance with the Declaration of Helsinki. All patients provided written informed consent. The study was

Appendix A

FGT Design-to-Implantation Workflow and Quality Control

This appendix details the complete digital workflow for functionally graded patient-specific implant design, from CT acquisition through implant fabrication and quality verification.

A.1 CT Acquisition and Segmentation

1a. CT protocol: Siemens Somatom Force; 120 kVp, auto-mA; 0.625 mm slice; bone kernel (B70s); DICOM export

1b. Segmentation: Materialise Mimics 25; threshold 226-3071 HU; manual correction of defect boundaries by surgeon

2a. 3D bone model: STL export (0.3 mm accuracy); defect classification (Paprosky) confirmed on 3D model

2b. Timeline: CT to segmented model: 2-4 hours (trained engineer)

A.2 Implant Design in nTopology

3a. Cup outer surface: Boolean intersection of ideal hemisphere with patient bone contact areas

3b. Graded lattice: gyroid TPMS; wall thickness varying linearly from 0.8 mm (shell) to 0.15 mm (core centre)

4a. Screw holes: 6.5 mm diameter channels directed toward available bone stock (>10 mm depth confirmed on CT)

4b. Design review: surgeon approval of virtual implant fit, screw trajectories, and augment geometry; timeline: 4-8 hours

A.3 SLM Fabrication and Quality Control

5a. SLM: SLM Solutions SLM280 2.0; Ti-6Al-4V ELI (ASTM F136); 30 μ m layers; 400 W; build time 8-14 h per implant

5b. Post-processing: stress relief 800 C/4 h/vacuum; EDM support removal; media blasting (porous zones only)

6a. QC: dimensional accuracy by CMM (Zeiss Contura, tolerance $\pm$ 0.1 mm); porosity by micro-CT (SkyScan 1275)

6b. Acceptance: all dimensions within tolerance; porosity 65-75% in core zone; no internal defects >100 μ m on micro-CT