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The customization paradox: Why geometric precision is no substitute for biological integration?

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Abstract

Three-dimensional metal printing has made anatomical perfection readily achievable in orthopaedic reconstruction. Yet, as patient-specific implants transition from salvage solutions to routine applications, a critical question emerges: Does geometric precision improve long-term outcomes, or merely perfect existing problems? The article argues that customization defined by shape alone fails to address fundamental biological constraints, including stiffness mismatch, stress shielding, vascular compromise, and the inevitability of revision surgery. While additive manufacturing enables porous architectures and tailored mechanics, unchecked integration and over-conformity may jeopardize bone preservation and future surgical options. The article further highlights the professional and economic costs of patient-specific workflows and the limitations of static digital planning. True innovation, it is argued, lies not in achieving the "perfect fit," but in designing implants that participate in bone biology and remain surgically defensible decades after implantation.

Keywords

patient-specific implants, 3D printing, stress shielding, mechanobiological integration, revision surgery

Three-dimensional (3D) printing—spanning metal powder bed fusion as well as high-performance polymer processes—has transitioned from a niche salvage tool for extreme anatomical defects into a routine consideration for complex orthopaedic reconstructions [1]. What began as a technical necessity after major oncological resections or severely compromised anatomy (for example, revision surgery) is now increasingly accessible in many centres [2, 3]. High-resolution imaging, automated segmentation, and mature design-to-manufacture workflows allow the production of implants and instruments with exceptional geometric fidelity [4]. However, this achievement has exposed a persistent disconnect: Technical feasibility does not equate to clinical superiority [5]. In current discussions of patient-specific implants (PSIs), success is frequently defined by immediate postoperative metrics such as anatomical fit, initial stability, and radiographic appearance. These parameters are important, but they are foundational rather than definitive. Implantation marks the beginning of a prolonged interaction between biomaterial

and living bone, not its conclusion. As customization migrates from exceptional cases into routine practice, evaluation must extend beyond the moment of implantation to encompass biological and surgical consequences that unfold over decades [6, 7].

Importantly, standardized off-the-shelf implants remain highly effective for many indications. They benefit from decades of iterative design, broad clinical registry evidence, predictable instrumentation, and well-characterised revision pathways. Additive manufacturing can add value—particularly in rare anatomy, oncological reconstruction, and complex revision—but it does not automatically outperform modular systems. A balanced appraisal therefore requires us to state not only where customization can solve unmet needs, but also where it may introduce new risks or opportunity costs [5]. The core trade-offs between these two approaches are summarized in Table 1.

Table 1. Practical comparison points when choosing off-the-shelf versus patient-specific additively manufactured implants (AM).

Domain	Off-the-shelf (strengths/typical limits)	Patient-specific/AM (potential gains/new risks)
Evidence base	Large registries; established survivorship; predictable instrumentation	Smaller series; indication creep; often mid-term parity
Biomechanics	Well-characterised stiffness; known stress-shielding patterns	Stiffness tuning via lattices; fatigue/process variability
Biological integration	Proven surface finishes/coatings; predictable osseointegration	Porosity/graded structures; vascular barrier risk; assessment heterogeneity
Revision strategy	Standardised explant tools; modular exchange	Over-conformity and deep ingrowth complicate removal; must design exit strategy
Workflow & cost	Short planning time; lower unit cost	Virtual surgical planning (VSP)/design iterations; manufacturing lead time; higher unit cost; QA burden
Regulatory & liability	MDR/FDA cleared for broad use; manufacturer liability	“Custom-made” exemption status; increased institutional & surgeon liability for design

From salvage to routine: the opportunity cost of parity

The earliest clinical use of custom implants was driven by necessity. In cases of massive bone loss, where standardized modular systems could not achieve fixation, patient-specific designs offer the only viable reconstructive option [1]. In those salvage scenarios, restoring continuity and enabling limb preservation are considered successful outcomes. Custom implants are now increasingly deployed where high-quality off-the-shelf systems already provide reliable long-term outcomes [5]. This shift demands a higher evidentiary threshold than before. To date, mid-term data for patient-specific knee instrumentation and custom femoral components have demonstrated, at best, clinical parity with standardized alternatives [5]. Improvements in alignment accuracy or intraoperative workflow have not consistently translated into superior patient-reported outcomes or implant survival. The problem with clinical parity in this setting is the associated opportunity costs. When a custom solution replaces a standardized implant that already performed reliably, the burden of proof shifts. If increased planning time, manufacturing complexity, and institutional resources do not translate into demonstrable long-term benefits, then customization becomes an exercise in refinement rather than improvement [4, 5]. We are effectively choosing a more expensive and complex path to reach the same destination. Recent single-centre series in complex oncological reconstructions (e.g., hemipelvic and upper cervical spine tumor cases) illustrate both the promise and the ongoing need for rigorous long-term evaluation of patient-specific workflows [8, 9].

The biomechanical mismatch: periprosthetic stress-shielding

The central biological limitation of permanent metallic implants remains the stark elastic modulus mismatch between alloy and bone. While native cortical bone typically exhibits a Young’s modulus (E) between 10–20 GPa, conventional alloys like CoCr or Ti6Al4V exceed this by nearly an order of magnitude (E ≈ 110–210 GPa) [10]. This disparity dictates that the implant bears a disproportionate share of

physiological forces, leading to the 'stress-shielding' effect and subsequent periprosthetic bone mineral density loss [7, 11]. Clinical and experimental work consistently links this mismatch to adverse remodeling, including periprosthetic bone mineral density loss and endosteal resorption around cementless components [7]. Recent simulation-based design studies further illustrate that lattice-enabled stiffness reduction can meaningfully decrease predicted stress shielding compared with solid stems (e.g., ~30% reductions reported for β-titanium lattice hip designs), although these findings still require robust long-term clinical validation [12, 13]. Customization that reproduces external anatomy without addressing internal mechanics therefore risks replicating the same biomechanical disparity with higher geometric precision [14].

Internal architecture as a mechanobiological intervention

Additive manufacturing offers a transformative approach to mitigating stress shielding by decoupling external geometry from internal stiffness. Unlike conventional subtractive methods, powder bed fusion enables the design of implants where load transfer occurs volumetrically rather than across a superficial interface [15]. Lattice-based architectures, such as gyroid or diamond topologies, allow the effective modulus to be tailored to the surrounding host bone. By modulating parameters like pore size, strut thickness, and graded porosity, both stiffness and permeability can be co-tuned to facilitate physiological load sharing and osseointegration [16–18]. Early experimental data support the premise that such designs can promote physiological load sharing and enhance osseointegration [16, 17]. However, structural porosity introduces significant mechanical risks. Every strut within the lattice represents a potential site for fatigue initiation, where manufacturing-induced defects—such as surface roughness or lack-of-fusion porosity—can accelerate crack propagation under the millions of cycles inherent to human locomotion [15]. Crucially, designs that satisfy initial static strength criteria may still succumb to long-term cyclic failure. Validation must therefore extend beyond peak load capacity to include fatigue behaviour, process qualification, and post-processing control.

Defining and assessing "biological integration"

Throughout this article, we use "biological integration" to mean more than radiographic apposition. It refers to a coupled state of (i) structural fixation (bone ingrowth/ongrowth and interfacial shear strength), (ii) biological homeostasis (vascular supply, immunologic equilibrium, and absence of chronic inflammation), and (iii) mechanobiological function (physiological strain transfer that supports remodeling rather than disuse) [6, 16]. Because no single test captures this construct, evaluation typically relies on surrogate markers such as micro-CT or histology in preclinical models, radiostereometric analysis (RSA) for early migration, serial DEXA for periprosthetic bone density changes, advanced imaging (e.g., contrast-enhanced MRI/CT for perfusion), and—still experimentally—biomarkers of bone turnover and inflammation [6, 7, 16]. Importantly, these tools have limitations (cost, radiation, lack of standardized thresholds, and imperfect correlation with long-term failure), which should be acknowledged when claims of "enhanced integration" are made.

The vascular constraint: mitigating ischemic risk in high-fidelity implants

One of the more nuanced risks associated with high-fidelity customization is the potential disruption of local vascularity. Bone remodeling and interfacial maintenance are metabolically intensive processes that remain fundamentally dependent on an uninterrupted blood supply. Implants engineered to maximize surface conformity and contact area may inadvertently compromise periosteal or endosteal circulation [6, 19]. Such extensive surface coverage can induce a 'barrier effect', obstructing microcirculation and potentially leading to ischemic compromise at the bone-implant interface [6, 16, 19].

To ensure long-term clinical success, future design iterations must transcend purely mechanical objectives. Incorporating vascular clearance zones or designated perfusion channels is essential to preserve the homeostasis of the underlying bone. To move beyond a mere 'barrier effect', designers must prioritize

interconnected porosity with pore diameters exceeding 300–400 μm, which are critical for effective angiogenesis and the maintenance of deep-seated osteocytes [18]. The interface should be regarded not only as a mechanical junction, but as a metabolically active boundary requiring sustained nutrient exchange.

Time as a design variable: resorbable metallic implants

While permanent scaffolds address load transfer in space, resorbable metals introduce the critical dimension of time into the healing process. Magnesium- and zinc-based alloys offer a fundamentally different strategy, particularly relevant in trauma and pediatric reconstruction, where long-term hardware retention is often undesirable [20]. These constructs provide robust mechanical support during early healing, then gradually degrade into biocompatible ions as bone regeneration progresses. This controlled transfer of load back to the native skeleton aligns more closely with physiological repair than permanent fixation. However, the success of this strategy depends on a precise synchronization between material degradation kinetics and individual osteogenic capacity—shifting the focus of customization from spatial geometry to biological timing.

Materials and manufacturing: Why "printability" is not performance?

Material choice and process parameters strongly dictate whether a patient-specific design can translate its geometric promise into clinical performance. While Ti6Al4V remains the workhorse of the field, its high modulus necessitates the use of lattice-based porosity to prevent stress shielding. Conversely, high-performance polymers (e.g., PEEK/PEKK) offer bone-mimetic stiffness but require advanced surface modifications to overcome their inherent bio-inertness [21].

Furthermore, additive manufacturing introduces complex process–structure links: build orientation, scan strategy, and post-processing (e.g., hot isostatic pressing) fundamentally alter anisotropy and fatigue life. Ultimately, "same CAD, different process" can yield disparate mechanical and biological outcomes—an argument for rigorous standardized quality assurance and detailed reporting of manufacturing parameters in clinical studies.

The surgical exit strategy: addressing potential explantation

As additive manufacturing capabilities expand, so does the temptation to pursue increasingly complex designs. However, every orthopaedic surgeon must contend with the reality that revision surgery is an eventual likelihood. Whether due to late hematogenous infection, periprosthetic fracture, wear-related osteolysis, or mechanical failure, the feasibility of hardware removal must be a primary design consideration rather than an afterthought [10, 20, 22].

Consider a massive, patient-specific triflange acetabular component used for a type III Paprosky defect [14, 23, 24]. Through additive manufacturing, the implant may achieve deep biological integration into a porous mesh. Should a chronic infection occur years later, the very features that ensure stability—extensive porosity and high conformity—can make explantation extraordinarily destructive. In this setting, removal is no longer a matter of simple hardware extraction but requires an extensive resection, often resulting in a bone stock deficiency more severe than the initial pathology [20, 23].

To bridge the gap between initial stability and eventual retrieval, a revision-oriented design strategy must incorporate specific technical features:

Planned Extraction Interfaces: The inclusion of solid "break planes," retrieval slots, or accessible strike points to facilitate controlled disassembly [22]. Specifically, incorporating CAD-defined 'notches' or structural thinning in non-load-bearing areas can allow for targeted osteotome access without risking uncontrolled fragmentation of the host bone.

Fracture Management Zones: Preservation of cortical windows for cerclage passage and specific zones for plate/cable fixation, ensuring that the implant does not obstruct future fracture care [25].

Modularity and Access: Designing for modular exchange of wear components (e.g., liners) and maintaining access corridors for debridement without sacrificing host bone.

The professional burden and the limits of static planning

Patient-specific workflows impose a substantial, often unacknowledged professional burden. Virtual surgical planning (VSP), segmentation review, and iterative design consultations require significant amounts of surgeon time and intensive multidisciplinary coordination [3–5]. Furthermore, current digital planning tools remain largely static. They optimize for a single point in time, yet fail to forecast how bone, fixation, and patient activity will interact over years. A static CAD model is, in essence, a snapshot of a moving target.

The next meaningful advance lies in the development of predictive digital twins. To transcend static CAD limitations, these models must integrate longitudinal data to forecast mechanobiological remodeling—the process by which bone adapts its density in response to the altered strain environment over years. This shifts the implant from a static structure toward an active component of long-term biological adaptation [13, 26]. By utilizing finite element-based simulations that are continuously updated as loading conditions change, we can begin to anticipate bone loss or failure before it becomes radiographically evident [27, 28]. Until these models undergo rigorous verification and validation, surgeons must remain cautious stewards of customization, recognizing that the responsibility for long-term outcomes cannot be delegated to software algorithms.

The health-economic reality

In a global healthcare system focused on value-based care, the price difference between a custom-made implant and a modular off-the-shelf system must be justified by more than just "intraoperative comfort". True innovation must reduce the "total cost of care" by decreasing revision rates and shortening recovery times. Without this economic justification, customization risks becoming a luxury for the few rather than a standard for the many.

Conclusion

The transition from modular off-the-shelf implants to high-fidelity, patient-specific interventions represents a paradigm shift in orthopaedic surgery. However, as this analysis demonstrates, geometric conformity must not be mistaken for clinical success. The pursuit of a "perfect fit" introduces a triad of complex challenges that transcend traditional engineering: the mechanical risk of long-term fatigue in porous architectures, the biological constraint of maintaining periosteal perfusion, and the logistical necessity of a viable surgical exit strategy.

To move beyond the current limitations of static CAD modeling, the field must embrace temporal design variables. This requires a shift toward resorbable materials that synchronize with the body's healing kinetics and the development of predictive digital twins that treat the implant-bone interface as a dynamic, metabolically active boundary. Ultimately, customization should not be used to bypass the principles of bone biology, but to honor them. As additive manufacturing evolves, the goal remains clear: to provide interventions that combine long-term mechanical integrity with durable biological integration.

Declarations

Author contributions

FT: Conceptualization, Validation, Writing—original draft, Writing—review & editing. BJ: Investigation, Writing—review & editing. TB: Investigation, Writing—review & editing. ED: Investigation, Writing—review & editing. FW: Conceptualization, Validation, Writing—original draft, Supervision. All authors read and approved the submitted version.

Conflicts of interest

The authors declare that they have no conflicts of interest.

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