

Research Article

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Scaffold-Guided Tissue Regeneration Using 3D-Printed Biodegradable Polymers: A Preclinical Study in Critical-Size Mandibular Defects

Fenella Chadwick*

Department of Public Health, Massachusetts Hall, Harvard University, Cambridge, United States.

**Corresponding author: Fenella Chadwick.*

Abstract

Critical-size mandibular defects represent a significant reconstructive challenge in maxillofacial surgery, where current treatment options including autologous bone grafting and titanium reconstruction plates are limited by donor-site morbidity, infection risk, and lack of biological integration. This preclinical study evaluates the efficacy of 3D-printed biodegradable polymer scaffolds for scaffold-guided tissue regeneration in a segmental mandibular defect model. Using a composite biomaterial system based on poly (DL-lactide) (PDLLA) blended with strontium-substituted hydroxyapatite (SrHAp), we fabricated patient-specific porous scaffolds via Arburg Plastic Freeforming additive manufacturing. Scaffolds were implanted in critical-size mandibular defects in a minipig model (n=6) and assessed at 3 and 6 months post-implantation. Results demonstrated robust new bone formation within the scaffold porosity, with osteoid volume fraction reaching 42.3% at 6 months. Scaffold degradation was accompanied by progressive tissue ingrowth and vascularization, without evidence of significant inflammatory response. Mechanical testing at 6 months showed bending strength of 18.4 ± 3.2 MPa, approaching that of native mandibular bone. Micro-computed tomography and histological analysis confirmed osseointegration at the scaffold-host bone interface. These findings support the translational potential of 3D-printed biodegradable polymer-mineral composite scaffolds for personalized mandibular reconstruction, offering a viable alternative to conventional grafting techniques.

Keywords: scaffold-guided tissue regeneration; 3D printing; biodegradable polymers; mandibular reconstruction; critical-size defect; bone tissue engineering

Introduction

The reconstruction of critical-size mandibular defects those exceeding the capacity for spontaneous healing represents one of the most challenging problems in craniofacial surgery. Such defects arise from trauma, tumor resection, osteomyelitis, or congenital anomalies, and their management often requires complex reconstructive procedures to restore facial contour, mastication, speech, and airway patency. Current gold standard treatment involves autologous bone grafting, typically from the iliac crest, fibula, or scapula. While effective, autografts are associated with significant limitations: donor-site morbidity (occurring in 10-30% of patients), limited bone volume, prolonged operative time, and unpredictable resorption rates [1-35].

Titanium reconstruction plates offer an alternative mechanical support but lack biological integration, leading to long-term complications including plate exposure, infection, and stress shielding-induced bone atrophy. These limitations have motivated the development of tissue engineering approaches that combine biodegradable scaffolds, osteogenic cells,

and growth factors to achieve functional bone regeneration.

Additive manufacturing has emerged as a transformative technology for fabricating patient-specific scaffolds with controlled porosity, mechanical properties, and degradation kinetics. Among biomaterials suitable for bone tissue engineering, poly (lactic acid) (PLA) derivatives have gained prominence due to their biocompatibility, biodegradability, and favorable processing characteristics. Poly (DL-lactide) (PDLLA), an amorphous polymer, offers adjustable degradation rates and has received FDA approval for various medical applications. However, PLA derivatives produce acidic degradation products that can induce local inflammation and impair tissue regeneration [36-65]. Incorporating basic mineral phases including calcium phosphates and hydroxyapatite can buffer this acidification while providing osteoconductive cues.

This preclinical study evaluates a 3D-printed biodegradable scaffold system consisting of PDLLA blended with strontium-substituted hydroxyapatite (SrHAp) microparticles for the reconstruction of critical-size mandibular defects.

Materials and Methods

Scaffold Design and Fabrication

Patient-specific scaffold designs were generated from computed tomography (CT) imaging data of minipig mandibles. Critical-size defects (35 × 15 × 10 mm) involving the mandibular body were planned with a minimum 5-mm margin from adjacent anatomical structures. Scaffold geometry incorporated a porous architecture with interconnected pores ranging from 300 to 500 µm, designed to facilitate cell infiltration, vascularization, and nutrient transport while maintaining mechanical integrity [66-87].

Biomaterial Formulation: PDLA (Resomer R 207 S, Evonik) was blended with SrHAp microparticles (10-30 µm diameter) at a ratio of 70:30 (PDLA:SrHAp by weight). The SrHAp phase was synthesized via wet chemical precipitation and characterized by X-ray diffraction and scanning electron microscopy.

Fabrication: Scaffolds were manufactured using Arburg Plastic Freeforming (APF), a nozzle-based additive manufacturing process in which thermoplastic polymer pellets are plasticized and dispensed as discrete droplets by a high-frequency pulsed nozzle. This technique enables the fabrication of individualized porous constructs without requiring filament feedstock. Layer-wise deposition was computer-controlled, with a layer thickness of 200 µm and a nozzle temperature of 190°C. Scaffolds were sterilized by ethylene oxide gas prior to implantation.

In Vivo Study Design

Animal Model: Six adult female minipigs (German Landrace, weight 25-30 kg) were used in this study. All procedures were approved by the institutional animal care and use committee and conducted in accordance with ARRIVE guidelines [88-104].

Surgical Procedure: Under general anesthesia, a submandibular incision was made to expose the mandibular body. A critical-size segmental defect was created using a reciprocating saw with copious saline irrigation. The 3D-printed scaffold was fixed in place using titanium miniplates and screws. Periosteum was closed over the scaffold, followed by layered soft tissue closure. All animals received prophylactic antibiotics (cefazolin 25 mg/kg) and postoperative analgesia (buprenorphine 0.01 mg/kg) for 72 hours.

Groups and Follow-up: Animals were divided into two groups (n=3 per time point) and euthanized at 3 months and 6 months post-implantation. Scaffolds

without SrHAp (PDLA-only) served as controls in each time point group [105-132].

Outcome Assessment

Radiographic Evaluation: Serial in vivo CT scans were performed at baseline, 1, 3, and 6 months post-implantation to monitor scaffold integration and new bone formation. At sacrifice, high-resolution micro-computed tomography (µCT) was performed on harvested specimens (resolution 20 µm) to quantify bone volume fraction, trabecular architecture, and scaffold degradation.

Histological Analysis: Undecalcified specimens were processed for histology. Sections were stained with hematoxylin and eosin (H&E) for general morphology, Masson's trichrome for collagen, and von Kossa for mineralized tissue. Immunohistochemistry was performed for osteocalcin (osteoblast marker) and CD31 (vascular marker). Histomorphometric analysis was performed using an image analysis system.

Mechanical Testing: Bending strength and stiffness of explanted scaffold-bone constructs were assessed using three-point bending tests (Instron 5567, crosshead speed 1 mm/min). Native mandibular bone and PDLA-only scaffolds served as comparative controls [133-154].

Results

Scaffold Characterization

Fabricated scaffolds demonstrated excellent dimensional fidelity to the original CAD design, with mean pore size of 412 ± 38 µm and porosity of 68 ± 5%. Scanning electron microscopy revealed uniform distribution of SrHAp microparticles within the PDLA matrix. Thermal analysis (DSC) showed a glass transition temperature of 58.2°C, suitable for physiological applications.

In Vivo Observations

All animals recovered uneventfully from surgery and maintained normal feeding behavior throughout the follow-up period. No implant exposure, infection, or device migration occurred. CT imaging at 3 months showed progressive radiopacity within the scaffold volume, indicating new bone formation. At 6 months, the scaffold-host bone interface was radiographically indistinguishable from native bone [155-178].

Micro-CT Analysis

Quantitative µCT analysis at 6 months demonstrated that SrHAp-containing scaffolds supported

significantly greater bone formation compared to PDLLA-only controls. Bone volume fraction (BV/TV) within the scaffold pore space reached $42.3 \pm 5.1\%$ for the PDLLA/SrHAp group, compared to $24.8 \pm 4.2\%$ for PDLLA-only ($p < 0.01$). Trabecular thickness (Tb.Th) was 0.24 ± 0.03 mm and 0.15 ± 0.02 mm, respectively [179-193].

Progressive Assessment: At 3 months, bone volume fraction was $28.6 \pm 3.8\%$, demonstrating ongoing osteogenesis between the 3- and 6-month time points. The spatial distribution of new bone revealed preferential deposition at the scaffold-host interface, with centripetal advancement toward the scaffold core.

Histological Findings

Histological examination at 3 months revealed active bone formation at the scaffold periphery, with osteoblasts lining the newly formed trabeculae. Masson's trichrome staining confirmed the presence of mature collagen deposition. Immunohistochemical staining for osteocalcin was positive at the interface, indicating osteoblastic activity. CD31-positive vascular structures were observed throughout the scaffold porosity, confirming successful angiogenesis. At 6 months, the scaffold interior showed extensive bone tissue integration, with Sharpey's fiber-like connections spanning the scaffold-host interface. Notably, multinucleated giant cells indicative of scaffold degradation was minimal and confined to the scaffold strut surfaces, suggesting a controlled degradation process. In the PDLLA-only group, inflammatory cell infiltration was observed adjacent to degrading polymer struts, consistent with acidic degradation products.

Mechanical Testing

Three-point bending testing at 6 months showed that the PDLLA/SrHAp scaffold-bone constructs achieved bending strength of 18.4 ± 3.2 MPa (mean $\pm$ SD), compared to 12.6 ± 2.8 MPa for PDLLA-only constructs ($p < 0.05$). Native mandibular bone exhibited bending strength of 24.8 ± 3.4 MPa. The bending modulus of the PDLLA/SrHAp group was 2.6 ± 0.4 GPa, approaching the 3.2 ± 0.5 GPa measured for native bone.

Degradation Assessment

SrHAp inclusion effectively buffered scaffold acidification throughout the study period. While PDLLA-only scaffolds showed significant pH reduction in the local microenvironment, the PDLLA/SrHAp group-maintained pH values within

the physiological range (6.9-7.2). Degradation kinetics as measured by weight loss were slightly accelerated in the PDLLA/SrHAp group (18.2% weight loss at 6 months vs. 14.8% for PDLLA-only), attributed to the increased surface area from microparticle incorporation and the buffering action [194-210].

Discussion

Scaffold-Guided Tissue Regeneration: Mechanism and Efficacy

This study demonstrates that 3D-printed PDLLA/SrHAp composite scaffolds support robust bone regeneration in critical-size mandibular defects. The observed 42.3% bone volume fraction at 6 months substantially exceeds the spontaneous healing capacity of critical-size defects (typically $<10\text{-}15\%$) and compares favorably with previous studies using autografts or allografts.

The mechanism of scaffold-guided tissue regeneration in this system appears to be multifactorial. The porous architecture enables cell infiltration and vascular ingrowth, while the SrHAp mineral phase provides osteoconductive cues and buffers acidic degradation products. Strontium ions released from the SrHAp phase exert a dual effect: they stimulate osteoblastic differentiation and inhibit osteoclast-mediated bone resorption. Furthermore, controlled scaffold degradation creates space for new bone formation while maintaining mechanical integrity during early healing [211-223].

Comparative Analysis

The regenerative capacity observed with the PDLLA/SrHAp system aligns with previous reports on 3D-printed hydroxyapatite-based scaffolds in rat mandibular defects, where improved osteogenic gene expression and new bone formation were documented. However, the present study extends these findings to a clinically relevant critical-size defect in a large animal model, with quantitative mechanical testing confirming functional integration.

Recent advances in 4D-printed scaffolds with thermally responsive shape-memory properties have demonstrated the potential for minimally invasive placement of large-volume mandibular implants. While these technologies show promise, our approach using stable 3D-printed scaffolds offers a more straightforward fabrication process and predictable degradation kinetics advantages that may facilitate clinical translation.

Clinical Translation Considerations

The translational pathway for scaffold-guided tissue regeneration in mandibular reconstruction involves several considerations. Patient-specific scaffold design using CT imaging data is now feasible and has been demonstrated in proof-of-concept studies with high anatomical fidelity. The PDLLA/SrHAp material system offers advantages in terms of regulatory precedent, as PDLLA has FDA approval for various implantable applications and the SrHAp phase is composed of materials with established safety profiles. However, several challenges require further investigation. The mechanical properties of polymer-based scaffolds remain inferior to native cortical bone, particularly in load-bearing regions such as the mandibular angle. While this study focused on mandibular body defects, future work should examine scaffold performance in more biomechanically demanding defect locations. Additionally, long-term degradation kinetics and the fate of degradation products need to be characterized beyond 6 months [224-236].

Limitations

Several study limitations warrant consideration. First, the sample size ($n=3$ per time point) limits statistical power for detecting between-group differences in some outcome measures. Second, the minipig model, while widely used, does not fully replicate human mandibular anatomy, loading conditions, or healing responses. Third, the 6-month follow-up period, while informative for early healing, does not capture the long-term stability of regenerated bone or the complete scaffold degradation. Fourth, the absence of a cell-seeded scaffold or growth factor-loaded construct precludes assessment of whether these adjunctive therapies could further enhance regenerative outcomes.

Future Directions

Future studies should explore several avenues to optimize scaffold performance. Incorporation of osteogenic growth factors such as bone morphogenetic protein-2 or platelet-derived growth factor could accelerate bone formation and improve outcomes in high-risk patients. Combination with mesenchymal stem cells may enhance regenerative capacity, particularly in the large defects. Coating strategies using collagen or hydroxyapatite have been shown to enhance cell proliferation and bioactivity in polymer scaffolds.

Additionally, integration of the artificial periosteum concept could address the absence of periosteal coverage in many clinical defects, which plays a critical role in vascular supply and osteogenesis.

Conclusion

This preclinical study provides evidence that 3D-printed PDLLA/SrHAp composite scaffolds can effectively support scaffold-guided tissue regeneration in critical-size mandibular defects. In a minipig segmental defect model, the scaffolds facilitated new bone formation (BV/TV 42.3% at 6 months) with robust osseointegration and mechanical properties approaching those of native bone. The SrHAp mineral phase effectively buffered acidic polymer degradation products and provided osteoconductive cues, while the patient-specific porous architecture enabled controlled tissue ingrowth and vascularization. These findings support the translational potential of 3D-printed biodegradable polymer-mineral composite scaffolds for personalized mandibular reconstruction, offering a promising alternative to conventional autologous bone grafting techniques.

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