RESEARCH TOPIC CLI2

Biomaterials in Plastic Surgery: Development and Preliminary Evaluation of a Temporary Bioactive Spacer for Post-Mastectomy Breast Reconstruction

Research area
Surgical Area

Clinical Unit name
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Abstract
Background and State of the Art
Implant-based breast reconstruction following mastectomy represents one of the most widely performed reconstructive procedures worldwide and plays a crucial role in restoring physical integrity, psychological well-being, and quality of life for breast cancer survivors. However, implant reconstruction remains affected by significant complication rates, including periprosthetic infection, wound dehiscence, capsular fibrosis, and implant exposure, which frequently necessitate implant or tissue expander explantation. After device removal, patients often enter a prolonged reconstructive interval characterized by rapid soft-tissue contraction, collapse of the breast pocket architecture, and formation of dense fibrotic adhesions. These biological processes substantially increase the technical complexity of delayed reconstruction and contribute to reconstructive failure as a significant portion of patients ultimately choose to abandon the reconstructive-process, leaving them with permanent post-mastectomy disfigurement.
Recent advances in biomaterials science and regenerative medicine suggest that engineered scaffolds may provide new opportunities to actively modulate tissue repair processes. Bio-fabrication technologies have enabled the development of biomimetic scaffolds capable of recreating the extracellular matrix microenvironment and promoting vascularization, adipogenesis, and soft-tissue regeneration. In particular, biodegradable three-dimensional scaffolds and hybrid biomaterials have emerged as promising platforms for reconstructive applications due to their tunable mechanical properties, structural support capacity, and ability to guide tissue regeneration.
Among these strategies, extracellular matrix-derived biomaterials and decellularized tissue scaffolds have demonstrated strong regenerative potential by preserving native structural proteins and biochemical signaling cues that facilitate cell adhesion, proliferation, and tissue remodeling. In parallel, polysaccharide-based biomaterials such as chitosan hydrogels have shown favorable viscoelastic properties, antimicrobial activity, and controlled drug release

capability, suggesting their potential as multifunctional temporary implants for post-surgical applications. Furthermore, advances in additive manufacturing and three-dimensional bioprinting enable the fabrication of highly customizable scaffold architectures with controlled porosity, mechanical stability, and integrated therapeutic functions.

Knowledge Gap

Despite the clinical importance of this problem, the post-explant interval is currently managed as a passive waiting phase, and no dedicated device has been specifically designed to preserve the breast pocket environment during this critical stage of reconstruction.

The proposed research addresses a critical yet largely overlooked phase in implant-based breast reconstruction: the biological and structural deterioration of the breast pocket following implant explantation. Currently, this interval is managed through passive observation until delayed reconstruction becomes technically feasible. However, during this period, progressive soft-tissue contraction, fibrosis formation, and collapse of the breast pocket architecture significantly compromise reconstructive outcomes and increase surgical complexity, These biological processes substantially increase the technical complexity of delayed surgery and contribute to overall reconstructive failure, as a significant portion of patients ultimately choose to abandon the reconstructive-process, leaving them with permanent post-mastectomy disfigurement.

Hypothesis and Project Concept

Building upon these advances, this project proposes the development and translational validation of a temporary implantable bioactive breast spacer designed to preserve breast pocket architecture following implant explantation. The central hypothesis is that immediate placement of a biodegradable bioactive spacer after explantation can maintain three-dimensional pocket volume, preserve tissue planes, reduce pathological fibrosis and soft-tissue retraction, and contribute to local infection control during the interval preceding delayed reconstruction.

By introducing the concept of a temporary bioactive spacer designed specifically for the post-explant environment, this project proposes a paradigm shift from passive waiting to active biological modulation of tissue healing. Rather than serving solely as a structural placeholder, the proposed device aims to preserve anatomical planes, maintain pocket volume, and influence the local biological microenvironment to reduce pathological fibrosis and bacterial colonization.

Research Strategy and Methodological Approach

To address this hypothesis, the project will follow a structured translational research pipeline integrating biomaterial design, biological validation, microbiological testing, preclinical in vivo evaluation, and early clinical feasibility assessment. By transforming the post-explant interval from a passive waiting phase into an actively guided regenerative period, this research aims to establish proof-of-concept for a new class of temporary bioactive reconstructive devices capable of improving outcomes in complicated implant-based breast reconstruction.

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Scientific Rationale

The translational relevance of this strategy is supported by recent advances in regenerative biomaterials and tissue engineering. Bio-fabricated scaffolds and extracellular-matrix-inspired biomaterials have demonstrated the capacity to recreate tissue microenvironments that support cell adhesion, vascularization, and soft-tissue regeneration. In particular, decellularized extracellular matrix biomaterials provide bioactive structural frameworks capable of promoting tissue remodeling and functional regeneration, highlighting the potential of biomaterial-driven approaches in reconstructive medicine.

Within this context, the development of a temporary implantable biomaterial capable of combining structural preservation with biological activity represents a novel category of reconstructive device. If successful, this strategy could establish a new therapeutic concept in reconstructive surgery: the biologically guided reconstructive interval, in which biomaterials actively regulate tissue remodeling between surgical stages.

Expected Impact and Translational Potential

Ultimately, this strategy could redefine the clinical management of implant explantation in breast reconstruction by introducing a biologically guided reconstructive interval that preserves surgical anatomy, reduces fibrosis formation, and facilitates safer and more predictable delayed reconstruction.

Beyond its clinical implications, the project also has strong translational potential in terms of technology development. The biomaterial platform and device architecture developed in this project may generate intellectual property and open new opportunities for medical device innovation in regenerative surgery.

Moreover, the integration of biomaterials science, microbiology, and reconstructive surgery within a clinically driven translational framework creates an ideal environment for accelerating the transition from laboratory innovation to clinical application. Conducted within a high-volume tertiary referral center for breast reconstruction, the project will leverage direct access to clinical cohorts, explant tissue samples, and multidisciplinary expertise in surgery, biomaterials engineering, and translational research. This unique environment will facilitate rapid validation and clinical translation of the proposed technology.

Ultimately, this research aims not only to improve reconstructive outcomes after implant explantation but also to introduce a new class of temporary bioactive devices capable of redefining the management of complex reconstructive scenarios in plastic surgery.

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