Title: Personalized 3D-Printed Surgical Aiming Device for Precision Bone Allograft Shaping for Complex Bone Defect Reconstruction

Authors: Dr. Ron Burshtein[1], Dr. Yuval Peylan[1], Limor Haviv[2] and Dr. Ayelet Di Segni[1]
[1] Sheba Tissue and Cell Bank, Sheba Medical Center, Israel
[2] PlanNet, 3D Solution Center, Sheba Medical Center, Israel

Background
Critical-sized bone defects (CSD) resulting from trauma, tumors, or disease present complex challenges in reconstructive surgery and can profoundly impact the lives of patients. Current clinical approaches such as autologous grafts, bone allografts, and synthetic materials, are often limited by partial regenerative capacity, donor site morbidity, and availability constraints. Moreover, orthopedic and facial injuries cannot currently be fully reconstructed to restore patients to their pre-injury state, emphasizing the need for precision-based solutions. Aiming devices are specialized instruments designed to assist surgeons in accurately positioning and aligning surgical tools, implants, or fixation devices. These advanced surgical tools enable high-accuracy surgical execution and can leverage patient-specific 3D imaging to optimize outcome.

Hypothesis
We hypothesized that a novel workflow integrating patient-specific 3D modeling, bone allograft 3D modeling and custom-designed aiming devices could improve the precision of pre-operative bone graft processing and surgical interventions, thereby resulting in superior implant fit.

Methods
A novel workflow integrating patient-specific 3D modeling, bone allograft 3D modeling and custom-designed aiming devices was developed. This workflow enables precise graft cutting during the processing step, tailored to the patient's anatomy or specific bone loss, ensuring an optimal implant fit and potentially improved surgical outcomes

Results
The presented workflow enables the production of advanced implants with complex geometries, ensuring superior clinical fit while promoting biological integration and functional restoration. Moreover, this approach reduces operator risk and shortens surgical time. Two representative cases are highlighted: (1) patient-specific bone grafting for a malunited clavicular fracture, and (2) personalized graft design for tibial reconstruction using the Capanna technique following extensive segmental resection in a one-year-old infant.

Conclusions
This workflow represents a unique advancement in tissue banking functionality and reconstructive surgery practices by enabling the production of high precise bone implants with perfect anatomical fit. The approach will enable enhanced outcomes for patients with critical-sized defects. This platform exemplifies the power of personalized

medicine in surgical reconstruction and represents a significant step forward in functional bone restoration.

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Personalized 3D-Printed Surgical Guides for Precision Allograft Shaping in Complex Bone Defects Regeneration

Dr. Ron Burshtein[1], Dr. Yuval Peylan[1], Limor Haviv[2] and Dr. Ayelet Di Segni[1]

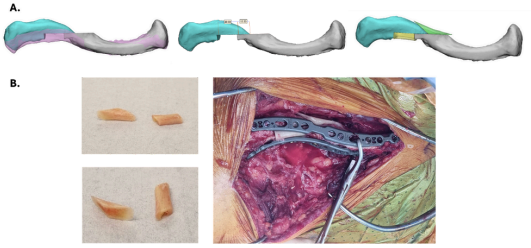
[1] Sheba Tissue and Cell Bank, Sheba Medical Center
[2] PlanNet - 3D Solution Center, Sheba Medical Center

Background

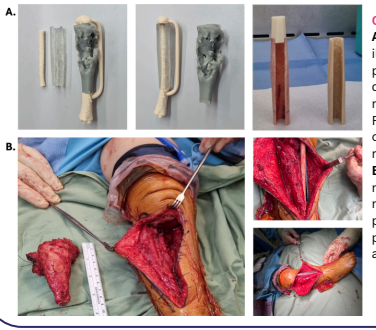
Critical-sized bone defects from trauma, tumors, or disease pose major challenges in reconstructive surgery. Existing solutions - autografts, allografts, and synthetics materials - are limited by regeneration potential, donor site morbidity, and availability. Current techniques often fail to fully restore function, especially in complex orthopedic and facial cases. Precision tools like surgical aiming devices, guided by patient-specific 3D imaging, can enhance surgical accuracy and improve outcomes.

Hypothesis

A novel workflow integrating patient-specific 3D modeling, bone allograft 3D modeling and custom-designed aiming devices can enhance precision of pre-operative bone allograft processing and improve implant fit during surgery.



Case Study #1: A.Modelling Conversion of the CT scan into a 3D model and definition of cutting planes using virtual planning tools that mirror the right and left clavicles.
B. Bone Shaping illustration of the precisely shaped, patient-specific bone allograft implant - shown before and during transplantation.



Case Study #2:
A. Modelling & Design illustration of the planned tumor dissection and reconstruction surgery. Right the final implant compered to the printed model.
B. Surgery Tumor resection and limb reconstruction using the precisely shaped, patient-specific bone allograft implant.

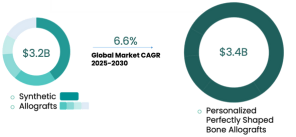
Impact

This innovation bridges precision engineering with regenerative medicine, positioning Sheba as a leader in next-generation personalized bone allograft manufacturing.

Work Flow

- Data Collection from CT scans ✓
- 3D Modeling ✓
- Surgical Design ✓
- Allograft Bone Design
- Allograft Bone Cutting — NEW

Bone Substitute Market, 2024



Advantages

- Enables true anatomical replication, including intricate curves
- Reduces operator risk
- Reduces surgery time
- Facilitates integration of regenerative biological components.