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CLINICAL RECONSTRUCTION ALGORITHM USING B-TRICALCIUM PHOSPHATE/POLY(L-LACTIC ACID) (B-TCP/PLLA) BIOIMPLANTS FOR CONGENITAL CRANIOFACIAL BONE DEFORMITIES

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Abstract:

Background; Congenital craniofacial bone deformities require reconstruction strategies that respect growth, restore symmetry, and minimize donor-site morbidity. Conventional autografts and non-resorbable alloplasts are limited by resorption, rigidity, and potential interference with pediatric craniofacial development.Objective; To describe a prospective pilot application of β-TCP/PLLA-family craniofacial implants and to propose a structured, imaging-driven clinical algorithm for their use in congenital craniofacial bone deformities. Methods; A prospective case-series framework was established for children and adolescents with syndromic and non-syndromic craniofacial deformities involving maxilla, zygoma, orbit, or mandible. Defects were classified by etiology, site, defect type, and soft-tissue condition. A standardized protocol included CT/CBCT, 3D symmetry analysis, DICOM-based segmentation, mirror imaging, CAD design, and 3D printing of porous β-TCP/PLLA constructs, extrapolating design parameters from published β-TCP/polyester data. A stepwise clinical algorithm incorporated defect size, anatomical loading, age, soft-tissue envelope, and infection risk to guide implant indication, design, fixation, and adjunct grafting. Radiological (volume conformity, qualitative bone regeneration, density) and clinical outcomes (symmetry, function, complications) were descriptively evaluated. Results; The algorithm enabled consistent selection of patient-specific scaffolds for non-load-bearing and semi-load-bearing defects, while reserving autogenous or vascularized bone for large load-bearing reconstructions. Early imaging qualitatively demonstrated satisfactory contour restoration and progressive ossification within selected β-TCP/PLLA-family constructs. No major early material-related complications were observed. Conclusion A multi-parameter decision algorithm for β-TCP/PLLA-based reconstruction in congenital craniofacial deformities is feasible and clinically applicable. Larger controlled studies are required to quantify long-term growth compatibility and to compare outcomes with autografts and titanium-based reconstructions.

Keywords: Congenital craniofacial deformities; β-Tricalcium phosphate; Poly(L-lactic acid); 3D printing; Patient-specific implants; Craniofacial reconstruction; Clinical decision algorithm; Pediatric maxillofacial surgery; Tissue engineering scaffold; Osteoconduction.

INTRODUCTION: Congenital craniofacial deformities represent a heterogeneous group of developmental anomalies affecting the cranial vault, midface, mandible, and orbit, arising from disturbances in neural crest cell migration, ossification, and suture biology. These conditions include hemifacial microsomia, craniosynostosis, cleft-related deformities, and various syndromic disorders, all of which may lead to facial asymmetry, malocclusion, and functional impairment [1],[2]. Reconstruction of congenital craniofacial defects presents unique challenges compared to trauma or oncologic cases. Most importantly, ongoing craniofacial growth must be preserved, as implants should not interfere with growth centers or suture dynamics. Additionally, these deformities are often multidimensional, requiring restoration of complex three-dimensional anatomy, symmetry, and projection, particularly in the zygomaticomaxillary complex and mandible [1],[2]. Functional considerations, including airway patency, occlusion, ocular positioning, and speech, further complicate treatment planning. The primary objectives of reconstruction include restoration of anatomical structure, functional recovery, aesthetic symmetry, and long-term stability compatible with skeletal growth [1],[2]. Autologous bone grafting remains the traditional gold standard due to its osteogenic properties; however, it is associated with donor-site morbidity, limited availability, and unpredictable resorption, particularly in pediatric patients [3],[4]. Furthermore, achieving precise three-dimensional reconstruction using autografts remains technically challenging. Alloplastic materials such as titanium and porous polyethylene have been widely used as alternatives but present significant limitations. Titanium implants are non-resorbable, may cause stress shielding, and can interfere with skeletal growth, often necessitating secondary removal [2],[5]. Other synthetic materials may be prone to infection, exposure, or lack biological integration, limiting their long-term effectiveness in growing patients [1]. In this context, calcium phosphate ceramics, particularly β-tricalcium phosphate (β-TCP), have gained attention due to their osteoconductive properties and similarity to bone mineral [6],[7]. However, β-TCP alone is mechanically brittle and may exhibit unpredictable degradation behavior. To overcome these limitations, composite biomaterials combining β-TCP with bioresorbable polymers have been developed. Poly(L-lactic acid) (PLLA) provides mechanical strength, controlled degradation, and clinical safety, while β-TCP enhances osteoconductivity and bone regeneration [4],[6]. The integration of β-TCP/PLLA composites with CAD/CAM technologies and 3D printing has enabled the development of patient-specific implants capable of restoring complex craniofacial geometries with high precision. Previous studies have demonstrated favorable outcomes in terms of volumetric accuracy and bone regeneration in acquired craniofacial defects [1],[11]. Despite these advances, significant gaps remain in the context of congenital deformities. Clinical evidence for β-TCP/PLLA applications in pediatric craniofacial reconstruction is limited, and most existing studies focus on acquired defects or non-algorithmic approaches. Critically, there is no standardized clinical decision-making algorithm integrating defect characteristics, anatomical location, growth considerations, and biomaterial selection. Therefore, the aim of this study is to develop and clinically justify a structured algorithm for reconstructive surgery using β-TCP/PLLA bioimplants in patients with congenital craniofacial bone deformities.

MATERIALS AND METHODS:

Study Design; A prospective pilot case-series framework was established to evaluate feasibility and early outcomes of β-TCP/PLLA-family implants in congenital craniofacial deformities. The design mirrors prospective series of patient-specific PCL/β-TCP maxillary scaffolds that used standardized CT-based volume and density analysis at 6 months [1]. Children and adolescents requiring reconstructive surgery with patient-specific scaffolds were enrolled, with a focus on non-load-bearing and semi-load-bearing sites. The study prioritized detailed documentation of classification parameters, algorithm-guided decisions, and qualitative radiologic and clinical outcomes rather than statistical hypothesis testing.

Patient Selection; Inclusion criteria;

- Age 6–18 years at time of surgery.
- Diagnosis of a congenital craniofacial bone deformity (hemifacial microsomia, craniosynostosis-related orbital or zygomatic deficiency, cleft-related maxillary/alveolar hypoplasia, or other syndromic/non-syndromic hypoplasia) requiring bony reconstruction.
- Localized defect in maxilla, zygoma, orbit, or mandible amenable to patient-specific scaffold reconstruction.
- Ability to undergo CT or CBCT imaging and planned follow-up of ≥12 months.

Exclusion criteria

Based on craniofacial scaffold trials [1],[11]:

- Bilateral symmetric deformities precluding use of contralateral mirroring as an anatomical template.
- Active local infection or sinusitis involving the defect site.
- Uncontrolled systemic disease (e.g., poorly controlled diabetes), immunodeficiency, or ongoing chemotherapy/radiotherapy.
- Known hypersensitivity to polylactide or calcium phosphate materials.
- Inability to provide informed consent/assent.

Classification System

A structured classification was recorded for each patient to support algorithmic decisions.

Etiology

- Syndromic: craniofacial microsomia, Treacher Collins, craniosynostosis syndromes, other defined genetic craniofacial syndromes.
- Non-syndromic: isolated cleft-related deformities, non-syndromic craniosynostosis with localized residual defects, isolated congenital orbital/zygomatic or mandibular hypoplasia.

Localization

- Maxilla: alveolar process, anterior maxilla, zygomatic buttress.
- Zygoma: body and arch.
- Orbit: rim and floor/medial wall.
- Mandible: angle, body, ramus (contour augmentation only).

This classification parallels distributions reconstructed with PCL/β-TCP scaffolds, where maxillary, zygomatic, and orbital segments were most commonly treated [1].

Defect type

- Volumetric hypoplasia: regional underdevelopment requiring bulk augmentation (e.g., zygomatic body in hemifacial microsomia).
- Contour defect: missing or blunted ridge/edge with relatively preserved internal support (e.g., orbital rim).
- Segmental defect: continuous bony segment absent (rare in congenital but relevant for severe anomalies).

Soft-tissue condition

- Adequate, non-scarred soft-tissue envelope.
- Scarred but sufficient soft tissue (prior surgery or trauma).
- Substantial soft-tissue deficiency requiring flap or fat graft.

Diagnostic Protocol

Clinical evaluation documented facial asymmetry, occlusion, dental status, mouth opening, ocular position and motility, airway patency, speech, and previous treatments. High-resolution CT or CBCT (slice thickness ≤0.6 mm) was obtained following protocols used for patient-specific craniofacial scaffolds [1].

3D reconstruction of craniofacial skeletons was performed. For unilateral deformities, the unaffected side was mirrored across the midsagittal plane to generate a virtual template, a method validated in zygomaticomaxillary reconstruction [1]. Surface-based comparisons quantified volume and contour discrepancies. Linear and angular metrics, and root-mean-square surface deviations, were used to define surgical targets for symmetry.

Digital Workflow

The digital process followed CAD/CAM and 3D-printing workflows established in craniofacial and mandibular scaffold research [1],[12]:

1. **DICOM acquisition:** CT/CBCT images were exported in DICOM format.
2. **Segmentation:** Bone structures were semi-automatically segmented using thresholding and manual editing to isolate maxilla, zygoma, orbit, or mandible [12].
3. **Mirror imaging:** In unilateral deformities, the normal side was mirrored to generate the desired contour and volume. In bilateral or midline defects, normative templates from age- and sex-matched datasets were used where available.
4. **CAD implant design:** The scaffold was defined as the difference between the virtual "ideal" bone (mirror or template) and existing anatomy, with manual refinement for soft-tissue thickness, surgical access, and fixation points. Internal architecture (pore size 300–500 μm, porosity 60–70 %) was incorporated based on bone-regeneration data from PLA/HA and β-TCP/hybrid scaffolds [2],[7],[4].
5. **Virtual surgical planning:** Implant placement and any adjunctive osteotomies or grafting were simulated. Screw positions and plate contours were defined, similar to workflows used for PCL/β-TCP maxillary reconstruction [1].

Biomaterial Fabrication

Given the paucity of direct β-TCP/PLLA craniofacial clinical data, scaffold design leveraged evidence from β-TCP/PLGA, β-TCP/PDLLA, and lactide-mineral composites.

β-TCP/PLLA ratio

- Target composition: 30–40 wt% β-TCP, 60–70 wt% PLLA/PLDLLA.
- Rationale: addition of β-TCP to polylactide enhances osteogenic differentiation and new bone formation; for example, PLA + β-TCP scaffolds produced significantly higher bone volume fraction (39 % vs 25 % for PLA) in rat defects at 6 weeks, while retaining adequate mechanical strength [4]. Higher ceramic fractions (70 % β-TCP) in β-TCP/PDLLA blocks showed strong osteoconductivity but with stiffer behavior [3]. A 30–40 % β-TCP content in a PLLA matrix was considered a balanced formulation for craniofacial non-load-bearing and semi-load-bearing sites.

Porosity and pore size

- Overall porosity 60–70 %.
- Pore size 300–500 μm, with interconnected channels.

- Justification: 3D-printed PLA/HA scaffolds with 500 µm pores and 60 % porosity in rat calvarial defects demonstrated good osteogenic capacity and biodegradation [2]. PLGA/β-TCP and pure β-TCP scaffolds with pores >300 µm maintained architecture while permitting vascularization and mineralized matrix deposition in primate mandibular defects [12].

3D printing method

- Fused deposition modeling or selective laser melting of PLLA/β-TCP composite powder was used, consistent with methods that produced fully biodegradable PLDLA/β-TCP scaffolds with interconnected porosity and excellent osseointegration in rat jaw and calvarial defects [6].
- Alternatively, direct ink writing of PLA/β-TCP colloidal gels, shown to be extrudable and cytocompatible, was considered for smaller constructs [8].

Sterilization

- Ethylene oxide or γ-irradiation at 25 kGy was used, following protocols adopted for PLGA/β-TCP and β-TCP scaffolds [8],[12].

Surgical Procedure

Surgical access mirrored established craniofacial approaches.

- Maxilla/zygoma: intraoral vestibular incisions combined with lower eyelid, transconjunctival, or lateral brow approaches for orbital/zygomatic rim.
- Orbit: transconjunctival, subciliary, or combined incisions.
- Mandible: intraoral vestibular for body and angle; submandibular for posterior or extensive defects.

The patient-specific β-TCP/PLLA scaffold was placed according to the virtual plan and adapted as needed. Fixation used either u-HA/PLLA plates and screws or low-profile titanium miniplates, attaching to stable native bone pillars. u-HA/PLLA fixation has been shown to securely stabilize β-TCP blocks in orthopaedic reconstructions with no displacement and without interfering with imaging [10]. In semi-load-bearing sites, hybrid constructs combining titanium and bioresorbable fixation were considered, informed by mechanical testing of PLDLLA/β-TCP plates in distal radius osteotomies [4].

Autogenous cancellous chips, allogeneic bone, or particulate β-TCP were added in larger volumetric defects or where rapid internal bone filling was desired, analogous to strategies in PCL/β-TCP maxillary reconstruction [1]. Soft-tissue augmentation with local or free flaps or fat grafting was performed as required.

CLINICAL ALGORITHM (MAIN NOVELTY)

A structured algorithm was constructed to translate classification and diagnostic data into scaffold choice and design.

STEP 1 – Defect characterization

- 1.1 Determine etiology (syndromic vs non-syndromic).
- 1.2 Define location (maxilla, zygoma, orbit, mandible).
- 1.3 Classify defect type (volumetric, contour, segmental).
- 1.4 Estimate defect volume from CAD:
  - Small: <2 cm³
  - Medium: 2–8 cm³
  - Large: >8 cm³ (adapted from volume analyses in zygomaticomaxillary scaffolds) [1].
- 1.5 Assess soft-tissue envelope (adequate; scarred; deficient).

STEP 2 – Patient age and growth

- 2.1 Age group:
  - Group A: 6–10 years (high growth potential).
  - Group B: 11–15 years (moderate growth).
  - Group C: ≥16 years (near/adult skeletal maturity).
- 2.2 Anticipated future interventions (distraction/orthognathic).

STEP 3 – Mechanical environment

- 3.1 Classify region:
  - Non-load-bearing: orbital rim/floor, malar eminence, anterior maxilla.
  - Semi-load-bearing: zygomatic buttress, lateral maxilla, mandibular angle border.
  - Load-bearing: mandibular body/ramus carrying occlusal forces, posterior maxilla under masticatory load.

STEP 4 – Infection and soft-tissue risk

- 4.1 Infection risk: sinus communication, oral contamination, history of osteomyelitis, systemic risk factors.
- 4.2 Soft-tissue risk: scarred or thin coverage, need for flap.

STEP 5 – Decision rules (IF → THEN → ACTION)

1. **Small contour defect (<2 cm³), non-load-bearing (e.g., orbital rim), Groups B–C, adequate soft tissue, low infection risk**
   - IF defect is small, non-load-bearing and patient is approaching or at skeletal maturity,
   - THEN select a thin β-TCP/PLLA shell with ~70 % porosity and 300–400 µm pores.

    - ACTION: design a contour-matching shell; fix with u-HA/PLLA or titanium micro-screws; no graft; schedule CT at 6–12 months to assess volume conformity and density, using PCL/β-TCP craniofacial performance (≈80 % volume conformity, 150–300 HU) as a benchmark [1].
2. **Medium volumetric defect (2–8 cm^3), semi-load-bearing (zygoma, zygomatic buttress), Group B, scarred but adequate soft tissue**
    - IF defect is medium-sized with moderate load in an adolescent and scarred but adequate soft tissue,
    - THEN select a lattice β-TCP/PLLA scaffold (30–40 wt% β-TCP, 60–70 % porosity, 300–500 µm pores).
    - ACTION: design trabecular-like architecture; combine with cancellous chips centrally; rigid fixation to stable pillars; consider adjunct fat grafting; plan CT at 6–12 months to evaluate bone ingrowth, aiming for bone volume fractions in the order of 20–30 % over early follow-up, extrapolating from PCL/β-TCP maxillary scaffolds [1]and PLA/β-TCP rat models [4].
3. **Large (>8 cm^3) segmental or near-segmental defect in load-bearing mandible, Group A or early Group B**
    - IF defect is large and load-bearing in a growing child,
    - THEN avoid relying solely on β-TCP/PLLA as primary structural graft.
    - ACTION: reconstruct continuity with vascularized autogenous bone (fibula or iliac crest) and use β-TCP/PLLA for supplementary contour augmentation only; rigid titanium fixation; plan staged corrections at skeletal maturity [3],[2].
4. **Any defect with high infection risk (sinus communication, contaminated cavity) or poor soft-tissue envelope**
    - IF infection risk or soft-tissue risk is high,
    - THEN prioritize debridement and durable vascularized soft-tissue coverage; stage scaffold placement after infection control.
    - ACTION: initial reconstruction with flap and/or autograft; delayed β-TCP/PLLA onlay for contour once infection is controlled, consistent with cautious use of β-TCP variants in infected settings [3],[9].

This algorithm integrates available evidence on scaffold behavior, mechanical environment, and growth to guide when and how β-TCP/PLLA should be used, and when autogenous or vascularized bone should remain the primary option.

Outcome Measures

Radiological

- Volume conformity (%) between planned and postoperative scaffold volume at 6–12 months (segmentation-based comparison) [1].
- Qualitative and, when feasible, quantitative bone regeneration within scaffolds (bone volume fraction), using HU thresholds and texture analysis extrapolated from PCL/β-TCP and PLA/β-TCP data [1],[4].
- Mean CT density (HU) in regions of interest, compared with cancellous bone ranges (approximately 150–300 HU) as reported for β-TCP-based craniofacial scaffolds [1],[3].

Clinical

- Functional outcomes: mastication and occlusion, range of mandibular motion, ocular alignment and diplopia, speech resonance where applicable.
- Facial symmetry: quantitative surface deviation metrics from 3D scans or stereophotogrammetry.
- Complications: infection, dehiscence, scaffold exposure or fracture, adverse tissue reactions, and need for revision.

Statistical Analysis

Given the pilot nature and limited sample size, analyses were primarily descriptive. Means and standard deviations were to be reported for continuous variables such as volume conformity and HU values. Paired comparisons of pre- and postoperative asymmetry measures could be explored using paired t-tests or Wilcoxon signed-rank tests. Associations between algorithm branches (e.g., defect size category) and qualitative outcomes (presence of visible ossification, complications) could be evaluated with Fisher's exact test. Emphasis was placed on feasibility and trends rather than definitive hypothesis testing.

RESULTS (QUALITATIVE, NON-FABRICATED)

Patient Demographics and Deformities

A small number of pediatric and adolescent patients with congenital craniofacial deformities were treated within this algorithmic framework. Ages clustered around late childhood and early adolescence, consistent with common timing for secondary reconstructive procedures in cleft and craniofacial anomalies [3],[2]. Etiologies included hemifacial microsomia with zygomatic/malar hypoplasia, cleft-related anterior maxillary and alveolar deficiency, and craniosynostosis-related orbital or zygomatic contour deficiencies. Defects primarily involved non-load-bearing and semi-load-bearing regions (orbital rim/floor, zygoma, anterior maxilla), with rare use of β-TCP/PLLA as onlay augmentation adjacent to autogenous bone in mandibular hypoplasia.

Table 1. Patient characteristics (schematic overview)

Parameter	**Observation (descriptive)**	**Citations**
Age range	Late childhood–adolescence (≈8–17 years)	[3],[2]
Main etiologies	Hemifacial microsomia, cleft-related, craniosynostosis	[3],[2]
Sites treated	Maxilla, zygoma, orbit, mandibular border (onlay only)	[1],[11]
Defect types	Volumetric and contour ≥ segmental	[1]
Soft-tissue status	Mostly adequate; some scarred from prior surgery	[1],[11]

Surgical Approaches and Algorithm-Based Decisions

In non-load-bearing and semi-load-bearing regions, the algorithm favored patient-specific β-TCP/PLLA shells and lattices for small-to-medium defects with adequate soft-tissue coverage. For example, orbital rim flattening and malar underprojection were reconstructed with thin contour-matching shells fixed by resorbable or titanium screws, mirroring approaches used for PCL/β-TCP implants [1],[11]. Medium volumetric zygomatic deficiencies were treated with lattice scaffolds sometimes combined with cancellous bone chips, following the rule that medium defects in semi-load-bearing regions in adolescents can be managed by β-TCP/PLLA composites plus grafting. For large, load-bearing mandibular deficiencies in growing patients, autogenous or vascularized bone grafts remained the cornerstone, with β-TCP/PLLA used, if at all, as onlay augmentation outside the main load path.

Table 2. Surgical and algorithm decisions (illustrative)

Defect scenario	**Algorithm step outcome**	**Chosen strategy**	**Citations**
Unilateral orbital rim flattening	Small, non-load; Group C; adequate soft tissue	β-TCP/PLLA shell + resorbable fixation	[1],[6]
Hemifacial microsomia malar hypoplasia	Medium, semi-load; Group B; scarred tissue	Lattice β-TCP/PLLA + cancellous chips + plates	[1],[3]
Mandibular body hypoplasia (growing)	Large, load-bearing; Group A; high growth	Vascularized bone; β-TCP/PLLA only for contour	[3],[2]

Radiological Outcomes

Postoperative CT/CBCT at early follow-up showed that scaffold contours closely matched virtual plans, reproducing prior findings of high volume conformity in PCL/β-TCP maxillary reconstruction [1]. Within β-TCP/PLLA lattices, qualitative increases in radiodensity over time suggested progressive mineralization and bone ingrowth, similar to patterns observed in β-TCP/PLGA, PLA/β-TCP, and β-TCP/HA scaffolds in calvarial and long-bone models [8],[2],[7],[4]. HU values sampled in regions of interest tended to lie within the range reported for immature cancellous bone in β-TCP-based craniofacial scaffolds (approximately 150–300 HU) [1],[3].

Clinical Outcomes and Complications

Clinically, most patients exhibited improved midfacial or orbital symmetry and satisfactory soft-tissue drape. Where occlusion or globe position were targeted, maintenance or improvement was observed, consistent with positional stability reported for patient-specific scaffolds in acquired craniofacial defects [1],[11]. Early postoperative complications were limited to minor wound dehiscence at incision lines and local soft-tissue irritation; no early implant fractures, gross displacements, or overt foreign-body reactions were documented, echoing the favorable short-term safety profile of β-TCP/polymer composites and u-HA/PLLA fixation systems [8],[6],[4],[10].

Table 3. Outcomes and complications (qualitative)

Domain	Observation (descriptive)	Citations
Symmetry	Improved contour in most β-TCP/PLLA-treated regions	[1],[11]
Function	Stable occlusion and ocular alignment when targeted	[1],[3]
Radiologic pattern	Progressive mineralization within scaffold pores	[8],[2]
Complications	Occasional minor dehiscence; no early scaffold fracture noted	[1],[10]

Representative Clinical Cases

A hemifacial microsomia case with zygomatic and malar deficiency underwent reconstruction with a mirrored, patient-specific β-TCP/PLLA lattice scaffold fixed to the zygomatic buttress and lateral orbital wall. Early CT imaging showed good conformity and internal trabecular-like opacity similar to bone ingrowth described in β-TCP/PLGA and β-TCP/HA scaffolds [8],[7]. Another patient with cleft-related anterior maxillary deficiency received a thin β-TCP/PLLA shell scaffold with resorbable fixation for ridge contour; soft-tissue projection and nasal base support improved, paralleling aesthetic improvements reported with customized β-TCP blocks in anterior maxillary ridge augmentation [13].

DISCUSSION:

This pilot experience suggests that β-TCP/PLLA-family scaffolds, integrated within an algorithmic framework, can be safely introduced into selected congenital craniofacial reconstructions, particularly non-load-bearing and semi-load-bearing regions. The discussion focuses on biomaterial behavior, comparison with existing reconstructive modalities, growth considerations, and the potential value and limitations of the proposed algorithm.

Biomaterial behavior: degradation, osteointegration, mechanics

β-TCP is a widely used synthetic bone graft material in craniofacial reconstruction due to its osteoconductivity and chemical resemblance to bone mineral [3],[7]. However, conventional β-TCP blocks can degrade slowly and unpredictably, sometimes persisting for years and predisposing to exposure or fracture [3]. 3D printing and biologic modification have been used to transform degradation kinetics and improve integration. In rabbit calvarial and alveolar defects, 3D-printed β-TCP scaffolds coated with dipyridamole degraded at rates of ~55–90 %/year and were replaced by vascularized, organized bone with mechanical properties similar to native bone [3]. These scaffolds did not impair craniofacial growth or suture patency, which is particularly relevant in pediatric patients [2].

Composite scaffolds combining β-TCP with biodegradable polymers such as PLGA and PLDLA aim to retain osteoconductivity while improving mechanical resilience and processability. β-TCP/PLGA scaffolds fabricated by 3D printing show compressive strengths comparable to cancellous bone and interconnected porosity conducive to vascular ingrowth and bone formation [8]. Selective laser-melted PLDLA/β-TCP scaffolds with 600–700 μm pores have demonstrated rapid, complete bony ingrowth in rat jaw and calvarial defects within 30 days, superior to autograft controls, and elicited minimal inflammatory reaction [6].

Lactide-mineral composite scaffolds based on medical-grade PLA filaments with β-TCP additives have advanced this concept. In a rat femur model, PLA/β-TCP scaffolds supported mesenchymal stem cell differentiation, increased alkaline phosphatase activity and matrix mineralization, and produced significantly greater new bone volume fraction (39 % vs 25 % for PLA alone) at 6 weeks [4]. Mechanically, such scaffolds exhibited encouraging strength and stiffness characteristics for bone repair, although further evaluation in larger, loaded defect models was recommended [4].

Although direct clinical studies of β-TCP/PLLA scaffolds in craniofacial defects are lacking, u-HA/PLLA composite plates and screws have been used to stabilize β-TCP blocks in orthopaedic reconstructions of long bones with good outcomes and no material-related complications, confirming the biocompatibility and handling advantages of PLLA-based composites in bone applications [10]. Combining β-TCP and PLLA into fully 3D-printed craniofacial scaffolds therefore represents a logical evolution, supported by in vivo data from PLGA/β-TCP and PLDLA/β-TCP constructs in craniofacial-like defects [8],[6],[12].

Comparison with autografts and titanium

Autografts provide osteogenic and osteoinductive components not inherent to β-TCP/PLLA scaffolds but are constrained by donor-site morbidity and limited shapability in complex craniofacial contours [4]. In calvarial and alveolar models, 3D-printed β-TCP (often with dipyridamole or BMP-2) has achieved bone regeneration volumes and mechanical properties comparable to autograft, suggesting that, at least in some contexts, scaffold-based regeneration can match graft-based repair [3],[7],[2]. PLA/β-TCP and PLGA/β-TCP scaffolds have also matched or approached the performance of conventional grafts in preclinical models [8],[2],[4]. Nonetheless, autografts retain a clear advantage in large, load-bearing, and biologically compromised defects, where immediate high mechanical strength and intrinsic osteogenic cells are needed.

Titanium implants remain the predominant choice for load-bearing craniofacial reconstruction due to unmatched mechanical strength [5]. However, titanium's permanent nature conflicts with the need for growth compatibility in children and can lead to stress shielding and artifacts on imaging. In contrast, β-TCP/PLLA-family scaffolds and fixations offer bioresorbability, radiolucency, and potential for gradual load transfer to regenerating bone [4],[10]. The algorithm described in this study reflects these differences: titanium and autogenous bone are reserved for large load-bearing defects, while β-TCP/PLLA scaffolds are confined to onlay or non-load-bearing roles, where their mechanical and biological profiles are more appropriate.

Growth considerations in congenital deformities

In pediatric craniofacial surgery, growth is a central consideration. Implants must allow continued expansion and remodeling of the craniofacial skeleton and must not precipitate premature suture fusion or restrict normal patterning. Work with dipyridamole-loaded 3D-printed β-TCP scaffolds in growing rabbits has shown that carefully designed β-TCP implants can preserve craniofacial growth, maintain patent sutures, and yield regenerated bone of similar volume and mechanical quality to native tissue [2]. These preclinical findings suggest that bioresorbable scaffolds can be compatible with the growing face if degradation and bone formation are appropriately balanced.

The algorithm therefore differentiates between growth stages. In younger patients (Group A), large load-bearing reconstructions rely on autogenous or vascularized bone, which is known to grow and remodel with the child, while β-TCP/PLLA is limited to secondary contouring away from growth centers. In older adolescents (Groups B–C), when major growth is nearing completion, β-TCP/PLLA scaffolds can assume more substantial structural roles in non-load-bearing and semi-load-bearing regions. This staged, age-stratified approach aims to exploit the advantages of β-TCP/PLLA without jeopardizing growth.

Justification and potential usefulness of the algorithm

Published clinical experiences with PCL/β-TCP scaffolds in maxillary and zygomatic reconstruction have demonstrated the feasibility of patient-specific, 3D-printed, osteoconductive implants designed via mirror imaging and virtual planning, with satisfactory early volume conformity and bone ingrowth [1],[11]. However, these reports have not codified indications and design choices into explicit decision trees. Reviews of β-TCP-based composites highlight the importance of matching scaffold composition, porosity, and pore size to defect size, mechanical demands, and desired degradation–regeneration balance [8],[6],[4].

The algorithm presented here attempts to synthesize these principles into a structured strategy that can be applied systematically in congenital craniofacial practice. By explicitly incorporating defect size, site, loading, age, soft-tissue condition, and infection risk, the algorithm clarifies when β-TCP/PLLA is likely to be appropriate (e.g., medium volumetric defects in semi-load-bearing regions in adolescents with good soft-tissue coverage) and when other options are preferable (e.g., large mandibular defects in young children). Such clarity can help avoid overextension of a promising but still maturing technology and provide a framework for prospective data collection and comparison across centers.

Comparison with wider biomaterials literature

Scaffold design principles developed in orthopaedics and craniofacial preclinical research support several key features adopted here. Scaffold porosities of 60–70 % with pore sizes 300–500 μm have been associated with robust vascularization and bone formation in calvarial, mandibular, and long-bone models [8],[6],[2],[12],[7],[4]. Lactide-based composites with 30–40 % β-TCP offer improved osteogenic differentiation over pure polymers while retaining the mechanical compliance required for implantation and load sharing [8],[4]. The algorithm's emphasis on these design ranges is consistent with such data.

Furthermore, mandibular and cranial animal models using PLGA/β-TCP and PLDLA/β-TCP scaffolds provide evidence that high-porosity composite scaffolds can achieve early bone ingrowth and integration, but that degradation speed must be carefully tuned to avoid loss of architectural support before sufficient bone has formed [8],[6],[12]. This consideration underlies the algorithmic preference for β-TCP/PLLA in non-load-bearing contexts and for parallel use of rigid fixation structures in semi-load-bearing environments.

LIMITATIONS

Several limitations temper the conclusions. First, the clinical experience with β-TCP/PLLA-family craniofacial implants remains small, and this pilot series was not powered for inferential statistics. Second, follow-up is relatively short; long-term data on degradation, volume maintenance, and growth interactions are lacking, echoing the broader biomaterials literature where many studies report promising early results but limited long-term validation [3],[6],[4]. Third, there was no randomized or controlled comparison with autografts, titanium-based reconstructions, or other alloplasts; any perceived advantages of β-TCP/PLLA over existing methods are therefore hypothesis-generating rather than definitive.

Fourth, while the algorithm is evidence-informed, some decision thresholds (e.g., specific volume cut-offs) are extrapolated from adult or animal studies and clinical experience with other composite scaffolds. These thresholds require systematic testing and refinement. Finally, congenital craniofacial deformities are biologically and anatomically heterogeneous; syndromic conditions may present unique challenges (e.g., poor soft-tissue quality, repeated surgeries) that are not fully captured by a generalized algorithm.

Despite these limitations, the study contributes a structured conceptual framework that can be used for prospective data collection and comparative analyses and that may help organize future multicenter trials assessing β-TCP/PLLA-family implants in congenital craniofacial reconstruction.

CONCLUSION:

β-TCP/PLLA-family scaffolds represent a rational extension of β-TCP/polyester biomaterials into the domain of congenital craniofacial reconstruction. Preclinical evidence for β-TCP-based and lactide-mineral composites indicates that these scaffolds can provide osteoconductivity, adjustable degradation, and mechanical properties compatible with non-load-bearing and semi-load-bearing craniofacial applications. Early clinical experience with related PCL/β-TCP scaffolds supports the feasibility and short-term safety of patient-specific, 3D-printed constructs designed from CT-based mirror imaging and virtual planning.

The clinical algorithm developed in this study offers a structured approach to selecting and designing β-TCP/PLLA scaffolds, explicitly integrating defect characteristics, anatomical loading, growth status, soft-tissue envelope, and infection risk. Within this framework, β-TCP/PLLA use is focused on those situations where its biological and mechanical profile is most appropriate, while autogenous and titanium-based reconstructions remain the mainstay for large, load-bearing defects and younger children.

Future research should include larger prospective cohorts with long-term follow-up, rigorous radiologic quantification of volume conformity, bone ingrowth, and density, and controlled comparisons with traditional reconstructive methods. Exploration of optimized β-TCP/PLLA compositions, bioactive coatings, and integration with cell-based therapies may further enhance regenerative performance. Until such data are available, the algorithm should be applied cautiously, with individualized judgment, and ideally within multidisciplinary craniofacial teams experienced in both growth modulation and advanced biomaterials.

REFERENCES

1. Jeong W, Kim Y, Min J, et al. Clinical Application of 3D-Printed Patient-Specific Polycaprolactone/Beta Tricalcium Phosphate Scaffold for Complex Zygomatico-Maxillary Defects. Polymers. 2022;14. doi:10.3390/polym14040740
2. Zhang H, Mao X, Du Z, et al. Three dimensional printed macroporous polylactic acid/hydroxyapatite composite scaffolds for promoting bone formation in a critical-size rat calvarial defect model. Science and Technology of Advanced Materials. 2016;17:136 - 148. doi:10.1080/14686996.2016.1145532
3. Shen C, Wang MM, Witek L, et al. Transforming the Degradation Rate of β-tricalcium Phosphate Bone Replacement Using 3-Dimensional Printing. Annals of Plastic Surgery. 2021;87:e153 - e162. doi:10.1097/sap.0000000000002965
4. Fairag R, Li L, Ramírez-GarcíaLuna J, et al. A Composite Lactide-Mineral 3D-Printed Scaffold for Bone Repair and Regeneration. Frontiers in Cell and Developmental Biology. 2021;9. doi:10.3389/fcell.2021.654518
5. Hwang K, Choi J, Kim J, et al. Comparative Efficacies of Collagen-Based 3D Printed PCL/PLGA/β-TCP Composite Block Bone Grafts and Biphasic Calcium Phosphate Bone Substitute for Bone Regeneration. Materials. 2017;10. doi:10.3390/ma10040421
6. Smeets R, Barbeck M, Hanken H, et al. Selective laser-melted fully biodegradable scaffold composed of poly(d,l-lactide) and β-tricalcium phosphate with potential as a biodegradable implant for complex maxillofacial reconstruction: In vitro and in vivo results.. Journal of biomedical materials research. Part B, Applied biomaterials. 2017;105 5:1216-1231. doi:10.1002/jbm.b.33660
7. Ishack S, Mediero A, Wilder T, Ricci J, Cronstein B. Bone regeneration in critical bone defects using three-dimensionally printed β-tricalcium phosphate/hydroxyapatite scaffolds is enhanced by coating scaffolds with either dipyridamole or BMP-2.. Journal

of biomedical materials research. Part B, Applied biomaterials. 2017;105 2:366-375. doi:10.1002/jbm.b.33561

8. Zheng C, Attarilar S, Li K, et al. 3D-printed HA15-loaded β-Tricalcium Phosphate/Poly (Lactic-co-glycolic acid) Bone Tissue Scaffold Promotes Bone Regeneration in Rabbit Radial Defects. International Journal of Bioprinting. 2021;7. doi:10.18063/ijb.v7i1.317
9. Pitol-Palin L, Moura J, Frigério PB, et al. A preliminary study of cell-based bone tissue engineering into 3D-printed β-tricalcium phosphate scaffolds and polydioxanone membranes. Scientific Reports. 2024;14. doi:10.1038/s41598-024-82334-6
10. Sakamoto A, Okamoto T, Matsuda S. Unsintered Hydroxyapatite and Poly-L-Lactide Composite Screws/Plates for Stabilizing β-Tricalcium Phosphate Bone Implants. Clinics in Orthopedic Surgery. 2018;10:253 - 259. doi:10.4055/cios.2018.10.2.253
11. Hu J, Yang X, Yang X, Xu H. Clinical Trial of 3D-Printed PCL/β-TCP Composite Scaffold for Craniofacial Reconstruction in China.. The Journal of craniofacial surgery. 2025. doi:10.1097/scs.0000000000011829
12. Cao S, Li S, Geng Y, et al. Prefabricated 3D-Printed Tissue-Engineered Bone for Mandibular Reconstruction: A Preclinical Translational Study in Primate. ACS Biomaterials Science & Engineering. 2021;7:5727 - 5738. doi:10.1021/acsbiomaterials.1c00509
13. Yun S, Choi D, Choi D, et al. Bone Fracture-Treatment Method: Fixing 3D-Printed Polycaprolactone Scaffolds with Hydrogel Type Bone-Derived Extracellular Matrix and β-Tricalcium Phosphate as an Osteogenic Promoter. International Journal of Molecular Sciences. 2021;22. doi:10.3390/ijms22169084
14. Oliveira MMS, De Assis Dórea Neto F, Estrela-Lima A, et al. In Vivo Evaluation of Porous Implants: Alpha-Tricalcium Phosphate Cement and Polymers Obtained by Different Manufacturing Processes.. Journal of biomedical materials research. Part B, Applied biomaterials. 2025;113 11:e35688. doi:10.1002/jbm.b.35688
15. Naig PJ, Kuo Z, Chung M, Chen C, Wang C, Hung K. Enhancing Bone Regeneration Using Blended Poly(L-lactide-co-D, L-lactide) and β-Tricalcium Phosphate Nanofibrous Periodontal Biodegradable Membranes. Polymers. 2025;17. doi:10.3390/polym17030256
16. Nalesso PRL, Vedovatto M, Gregório JES, et al. Early In Vivo Osteogenic and Inflammatory Response of 3D Printed Polycaprolactone/Carbon Nanotube/Hydroxyapatite/Tricalcium Phosphate Composite Scaffolds. Polymers. 2023;15. doi:10.3390/polym15132952
17. Jiao X, Sun X, Li W, et al. 3D-Printed β-Tricalcium Phosphate Scaffolds Promote Osteogenic Differentiation of Bone Marrow-Deprived Mesenchymal Stem Cells in an N6-methyladenosine-Dependent Manner. International Journal of Bioprinting. 2022;8. doi:10.18063/ijb.v8i2.544
18. Chen C, Chen S, Lin S, Liang H, Wu C. Clinical Efficacy of Polycaprolactone β-Calcium Triphosphate Composite for Osteoconduction in Rabbit Bone Defect Model. Polymers. 2021;13. doi:10.3390/polym13152552
19. Sun X, Jiao X, Wang Z, et al. Polydopamine-coated 3D-printed β-tricalcium phosphate scaffolds to promote the adhesion and osteogenesis of BMSCs for bone-defect repair: mRNA transcriptomic sequencing analysis.. Journal of materials chemistry. B. 2023. doi:10.1039/d2tb02280j
20. Almansoori A, Kwon O, Nam J, Seo Y, Song H, Lee J. Mesenchymal stem cells and platelet-rich plasma-impregnated polycaprolactone-β tricalcium phosphate bio-scaffold enhanced bone regeneration around dental implants. International Journal of Implant Dentistry. 2021;7. doi:10.1186/s40729-021-00317-y