

Review

Mechanical Design Maturity and Validation Pathways of Patient-Specific Subperiosteal Implants for Oral and Maxillofacial Rehabilitation: A Scoping Review

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Featured Application

This review appraises the maturity of mechanical design and validation evidence for patient-specific subperiosteal implants and provides an evidence map, a minimum reporting checklist, and an integrated validation pathway for future research and device development.

Abstract

Contemporary patient-specific subperiosteal implants (SPIs) have re-emerged as digitally planned, additively manufactured solutions for oral and maxillofacial rehabilitation when conventional endosseous implants are limited by severe atrophy, anatomical constraints, or reconstructive defects. Unlike conventional implants, SPIs behave as fixation-based skeletal frameworks whose performance depends on passive fit, screw fixation, anchorage, framework architecture, material properties, manufacturing accuracy, and prosthetic load transfer. This scoping review evaluated the maturity of mechanical design and validation evidence for contemporary SPIs. Following a predefined internal protocol and PRISMA-ScR, MEDLINE/PubMed, Scopus, Web of Science, Embase, and the Cochrane

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Library were searched from inception to 13 June 2026. Reference-list screening and citation tracking supplemented the electronic search. Two reviewers independently screened records against predefined eligibility criteria. Data were charted using a predefined extraction form and synthesized descriptively by evidence type, engineering domain, validation stage, and translational status. No meta-analysis was undertaken because of methodological heterogeneity, and no formal risk-of-bias grading was applied. Across 65 included records, the evidence was dominated by descriptive technical studies and comparative computational analyses, whereas direct mechanical testing, fatigue assessment, manufacturing verification, and clinical correlation were limited. Finite element analysis was useful for comparing design alternatives and identifying stress concentrations, but models were heterogeneous and often insufficiently validated. Design modifications generally redistributed stress across the implant–prosthesis–bone system rather than reducing it globally. Titanium and Ti6Al4V were the most established framework materials, whereas polymeric, ceramic, and scaffold-assisted strategies remained preliminary. The principal contribution of this review is a cross-domain appraisal of progression from anatomical feasibility and comparative modeling to manufacturing verification, experimental testing, and clinical validation. An evidence map, minimum reporting checklist, and integrated validation pathway are provided to support reproducible device development.

Keywords: patient-specific subperiosteal implants; finite element analysis; mechanical design; additive manufacturing; screw fixation; biomechanical validation; oral rehabilitation

1. Introduction

Severe maxillary and mandibular atrophy remains a major challenge for implant-supported oral rehabilitation. In advanced resorption patterns, conventional endosseous implant placement may be limited by insufficient bone volume, unfavorable prosthetic emergence, poor bone quality, or proximity to critical anatomical structures. Regenerative procedures and graftless alternatives, including sinus augmentation, distraction osteogenesis, nerve lateralization, and zygomatic or pterygoid implants, have expanded the available treatment options, but each involves specific anatomical, surgical, prosthetic, and complication-related limitations [1–4].

Subperiosteal implants were historically introduced for patients with severely resorbed jaws who were unsuitable for conventional implant placement. However, first-generation devices were fabricated primarily through direct bone impressions and analog casting procedures and frequently showed inadequate adaptation, limited fixation, micromotion, soft-tissue dehiscence, infection, and progressive framework exposure. These complications, together with the development of osseointegration-based implantology, led to their progressive abandonment [5–8].

Contemporary patient-specific subperiosteal implants (SPIs) differ substantially from these historical devices. Modern SPIs are digitally planned from CT or CBCT datasets, which can be integrated with intraoral scans, diagnostic wax-ups, and virtual prosthetic setups. Computer-aided design and additive manufacturing enable the production of individualized frameworks with planned fixation arms, screw trajectories, transmucosal abutments, and prosthetically driven emergence profiles. The resulting device is therefore defined not only by the external bone anatomy but also by prosthetic requirements, fixation strategy, manufacturing constraints, and the anticipated path of functional load transfer [9–13].

This evolution also requires a different mechanical interpretation. Unlike conventional endosseous implants, whose initial stability is obtained through engagement within bone, contemporary SPIs rely primarily on passive adaptation to the external cortical surface and rigid fixation with osteosynthesis screws. Occlusal forces are transferred from the prosthetic restoration through the abutments and framework to the fixation screws and supporting cortical bone. Consequently, their performance depends on the interaction among framework geometry, anatomical anchorage, screw configuration, abutment distribution, prosthetic cantilever, material properties, and manufacturing accuracy. Contemporary SPIs may therefore be more appropriately evaluated as fixation-based patient-specific medical devices than as conventional dental implants placed in an alternative anatomical position [14,15].

Finite element analysis (FEA) has become the principal computational method used to compare framework architecture, thickness, fixation, screw configuration, materials, anchorage, loading, and prosthetic variables. Because these factors interact across the bone-implant-prosthesis system, SPI performance should be evaluated using component-specific stress, strain, and displacement outcomes rather than a single mechanical endpoint [14,16–21].

The expanding range of materials and manufacturing strategies adds further complexity. Titanium and Ti6Al4V remain the most established framework materials, whereas polymeric and ceramic alternatives have mainly been investigated through computational or early preclinical studies. Similarly, surface treatments and scaffold-assisted approaches have been proposed to improve the biological interface, but their mechanical and clinical validation remains limited. Material selection must therefore be evaluated together with framework geometry, screw fixation, prosthetic design, manufacturing method, post-processing, and expected fatigue behavior rather than as an independent determinant of performance.

Despite the rapid growth of this field, evidence remains fragmented across computational, experimental, manufacturing, translational, and clinical studies, with substantial methodological heterogeneity preventing quantitative comparison. Previous reviews have predominantly addressed clinical outcomes and complications [22–29] or summarized finite element findings separately [30]. None provided a cross-domain appraisal linking anatomical and prosthetic inputs, mechanical design, manufacturing verification, experimental testing, and clinical correlation. This translational gap defines the specific focus of the present review.

The primary aim of this scoping review was to evaluate the maturity of the evidence supporting mechanical design and validation pathways for contemporary patient-specific SPIs. The review examined how engineering evidence progresses from anatomical and prosthetic definition through computational comparison, manufacturing verification, mechanical and fatigue testing, and correlation with clinical outcomes. Three secondary, evidence-derived outputs were developed: a structured map of the available evidence and interacting design variables, a minimum reporting checklist for computational and mechanical studies, and an integrated validation pathway for future device development. The overarching research question was: How mature is the evidence supporting the mechanical design and validation of contemporary patient-specific SPIs, and where are the principal gaps in translation from patient-specific design and computational prediction to manufactured-device verification, experimental testing, and clinical performance?

2. Materials and Methods

2.1. Review Design and Eligibility Criteria

This scoping review was conducted to map the available evidence on the mechanical design, computational modeling, materials, manufacturing, and validation of contemporary patient-specific SPIs used for oral and maxillofacial rehabilitation. The review was reported in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR) [31], and the completed checklist is provided in Table S1.

A written internal protocol specifying the review question, eligibility criteria, information sources, study-selection procedures, data-charting domains, and planned evidence synthesis was prepared before formal title-and-abstract screening and full-text study selection. The protocol was not prospectively registered or publicly posted. To improve transparency, it is now provided as Supplementary Document S1.

A scoping review design was selected because the available literature encompasses heterogeneous evidence, including finite element analyses, mechanical experiments, material and surface investigations, animal and translational studies, digital workflow reports, technical notes, clinical studies, and reviews with direct engineering relevance. The objective was not to estimate pooled clinical outcomes or compare treatment effectiveness, but to characterize the types of available evidence, identify the design variables and validation methods investigated, synthesize recurring or conflicting mechanical findings, and assess the maturity and translational limitations of the field.

Throughout this review, “patient-specific subperiosteal implant” (SPI) was used as the standardized umbrella term for contemporary digitally designed, patient-matched, screw-fixed frameworks positioned on the external bone surface. The term “juxta-osseous implant” was retained only when describing the search strategy, eligibility terminology, or wording used in the original publication. “Additively manufactured subperiosteal jaw implant” (AMSJI) was used only for studies explicitly referring to that specific device concept. Historical non-digital devices were identified separately as historical subperiosteal implants.

The review question was structured according to the Population–Concept–Context framework. The population and context comprised patients or anatomical models requiring oral or maxillofacial rehabilitation with patient-specific subperiosteal or juxta-osseous implants. The concept encompassed the engineering development of these devices, including image-based anatomical reconstruction, prosthetically driven planning, framework geometry, anchorage and screw configuration, finite element modeling, material selection, additive manufacturing, post-processing, surface engineering, mechanical testing, fatigue behavior, and validation. Dental, oral, maxillofacial, craniofacial, and post-ablative applications involving the maxilla or mandible were considered.

Records were eligible when they investigated contemporary patient-specific SPIs, including devices described in the source literature as custom-made, digitally planned, CAD/CAM-designed, additively manufactured, laser-sintered, laser-melted, or juxta-osseous implants, and provided information relevant to at least one predefined engineering domain. Finite element studies were included when they evaluated stress, strain, displacement, load transfer, framework geometry, anchorage, screw-related variables, material properties, prosthetic components, or loading conditions. Mechanical studies were eligible when they assessed static resistance, cyclic loading, fatigue, screw loosening, connection stability, manufacturing accuracy, or structural performance. Material, surface, and scaffold studies were included when their findings were directly applicable to the load-bearing, bone-facing, or transmucosal regions of an SPI.

Digital workflow and technical studies were eligible when they described image acquisition, segmentation, DICOM–STL registration, prosthetic reverse planning, CAD design, screw planning, surgical guide development, manufacturing, or quality-control procedures. Clinical studies, case series, and case reports were included only when they provided extractable information on device design, anchorage, screw configuration, materials, manufacturing, prosthetic planning, mechanical rationale, or validation. Reports describing only implant survival, complications, patient satisfaction, or prosthetic outcomes without relevant engineering information were excluded.

Historical cast subperiosteal implants were not considered primary evidence for contemporary design principles. Selected historical reports were retained only to contextualize the limitations of first-generation devices and the rationale for modern redesign. Studies exclusively concerning conventional endosseous, zygomatic, pterygoid, transnasal, transosteal, or blade implants and reconstructive plates were excluded unless they included a clearly identifiable patient-specific subperiosteal component or a direct mechanical comparison relevant to SPI design.

No restrictions were applied regarding anatomical site, material, manufacturing method, loading condition, or study design. Non-English records were considered when the information required for eligibility assessment and data charting could be reliably obtained from a translated full text or from sufficiently detailed English-language abstracts, tables, and figures.

2.2. Information Sources and Study Selection

A structured electronic search was conducted in MEDLINE/PubMed, Scopus, Web of Science, Embase, and the Cochrane Library from database inception to 13 June 2026. Reference lists of eligible articles, relevant reviews, technical reports, and finite element studies were also screened. Citation tracking was used to identify additional records, including online-ahead-of-print publications available by the final search date.

The search strategy was constructed using two concept blocks combined with the Boolean operator AND. The first block contained device-specific terms, including subperiosteal, juxta-osseous, patient-specific, custom-made, and additively manufactured subperiosteal implants. The second block contained database-adapted free-text terms representing the predefined engineering domains of the review: computational modeling, CAD/CAM and digital workflow, additive manufacturing, framework and screw design, biomaterials, fatigue, stress distribution, and mechanical validation. Broad terms such as titanium, zirconia, PEEK, fatigue, and CAD/CAM were never searched independently; a record could be retrieved only when an engineering or material term occurred together with at least one term from the device-specific block. The engineering terms were selected a priori to reflect the eligibility criteria and to capture the heterogeneous terminology used across computational, manufacturing, material, and clinically based SPI studies. This sensitivity-oriented strategy was considered appropriate for a scoping review because relevant studies are inconsistently indexed and may emphasize a material, manufacturing process, or mechanical variable rather than use a standardized engineering descriptor. Specificity was maintained through the mandatory device-related concept block, predefined eligibility criteria, and independent screening by two reviewers. The PubMed strategy was developed first and subsequently adapted to the syntax and searchable fields of the other databases. Complete database-specific strategies and the corresponding search yields are reported in Supplementary Table S2.

Retrieved records were imported into reference-management software and duplicates were removed before screening. Titles and abstracts were independently assessed by two reviewers. Potentially eligible reports then underwent full-text evaluation against the predefined criteria. Disagreements were resolved through discussion, with

consultation of a third reviewer when consensus could not be reached. Reasons for exclusion at the full-text stage were recorded and are summarized in the PRISMA-ScR flow diagram.

When multiple publications originated from the same research group or appeared to describe related devices or overlapping clinical cohorts, each record was evaluated according to its distinct contribution to the engineering synthesis. Duplicated clinical outcome data were not charted more than once. Companion publications were retained when they provided additional information on design evolution, computational modeling, manufacturing, surface treatment, prosthetic planning, mechanical testing, or device validation.

2.3. Data Charting and Evidence Synthesis

Data were charted using a predefined extraction form. General variables included author, publication year, country, study design, implant system or concept, anatomical site, clinical or anatomical indication, study objective, material, manufacturing method, engineering domain, principal findings, and reported limitations. For descriptive counting, each included record was assigned to one primary evidence category according to its principal study design and contribution: computational modeling; experimental mechanical validation; digital workflow or technical development; material, surface, or scaffold investigation; clinically based engineering evidence; or secondary engineering synthesis and commentary. This primary-category assignment was used only to describe the composition of the literature and did not represent a hierarchy of evidence or imply direct comparability among study types. Because some records contributed to more than one engineering domain, cross-domain contributions were charted separately and were not treated as mutually exclusive.

For finite element studies, the extracted variables covered the anatomical model, segmentation method, implant architecture, framework thickness, and material properties. Additional variables included bone representation, boundary and contact conditions, screw modeling, mesh characteristics, convergence assessment, loading, the simulated clinical scenario, output measures, and the validation strategy. The principal outcomes of interest were stress, strain, displacement, safety factors, predicted failure regions, and load distribution among bone, framework, fixation screws, abutments, prosthetic screws, and prosthetic superstructures. Where directly comparable configurations and numerical results were reported within the same study, absolute values and relative differences were extracted. Relative differences calculated by the review authors were derived from the published values and were not pooled across studies because of differences in anatomy, loading, modeling assumptions, and outcome definitions.

For experimental mechanical studies, the extracted variables included specimen type, material and manufacturing process, post-processing, test configuration, static or cyclic loading protocol, load magnitude, number of cycles, fatigue criteria, screw-torque protocol, connection type, failure mode, and correspondence with clinically plausible conditions. For material, surface, and scaffold studies, information was collected on material composition, surface modification, scaffold architecture, post-processing, mechanical or biological endpoints, model type, and potential relevance to the bone-facing, transmucosal, or load-bearing regions of the device.

For digital workflow and clinically based technical reports, the charted variables included imaging modality, anatomical segmentation, and registration of anatomical and prosthetic datasets. We also recorded the reverse-engineering approach, abutment positioning, anchorage and screw planning, CAD workflow, surgical guide design, manufacturing method, fit verification, dimensional quality control, and rationale for the final device geometry.

Evidence integration was performed in two stages. First, findings were synthesized separately within each evidence type because the included study designs addressed different questions and supported different forms of inference. Digital workflow and technical reports were used to characterize design feasibility, data integration, manufacturing, and surgical transfer. Computational studies were used to identify mechanistic relationships and within-model comparisons among design variables. Experimental mechanical studies were used to evaluate structural resistance, fatigue, fixation, and connection behavior. Material, surface, scaffold, and animal studies were interpreted as preclinical or translational evidence. Clinical reports contributed only extractable information on device configuration, fixation, manufacturing, observed mechanical events, or clinical correlation. Secondary reviews and commentaries were used for contextualization and identification of evidence gaps and were not treated as independent confirmation of primary-study findings.

Second, evidence types were integrated at the level of shared engineering questions: digital workflow and manufacturing; anchorage and fixation; framework architecture and thickness; screw configuration and screw-to-bone interaction; abutment distribution, cantilever, and prosthetic load transfer; materials and prosthetic superstructures; and surface or scaffold-assisted strategies. Agreement across evidence types was described as convergence of observations rather than as increased certainty. Numerical results from fundamentally different study types were not directly compared, pooled, or subjected to vote counting.

No meta-analysis was undertaken because of substantial heterogeneity in anatomical models, implant geometries, material assumptions, screw representation, boundary conditions, loading protocols, output variables, experimental methods, and reporting units. The synthesis therefore focused on recurring mechanical relationships, conflicting findings, component-specific trade-offs, and gaps between computational prediction, experimental verification, manufacturing assessment, and clinical observation.

2.4. Operational Definition of Evidence Maturity and Validation-Pathway Synthesis

Consistent with the objectives of a scoping review, no formal risk-of-bias assessment, certainty grading, or comparative evaluation of clinical effectiveness was performed. In this review, evidence maturity was defined at the level of the overall body of literature as the extent to which the available evidence covered successive stages of mechanical validation. The term was not used as a methodological-quality grade for individual studies.

Four non-exclusive validation stages were defined for the descriptive synthesis. Descriptive feasibility comprised reports documenting anatomical reconstruction, digital planning, device design, manufacturing, or clinical implementation without quantitative mechanical comparison. Comparative computational assessment comprised studies comparing design variables, materials, fixation strategies, or loading conditions through FEA or another computational method without direct experimental validation. Experimental device verification comprised dimensional or fit assessment, static mechanical testing, cyclic or fatigue testing, screw-loosening evaluation, or comparison between predicted and measured mechanical behavior. Clinically correlated validation required an explicit relationship between design characteristics or mechanical predictions and spatially or mechanically relevant clinical outcomes.

Records could contribute to more than one validation stage. Mapping was based exclusively on explicitly reported methods and outcomes; information that was not reported was recorded as such and was not assumed to be absent. No numerical score, weighting system, pass-fail threshold, or overall ranking was assigned to individual studies. The four stages therefore describe the type of validation represented and not the methodological quality or risk of bias of a study.

To improve reproducibility and reduce subjectivity, methodological characteristics were charted using explicit descriptive domains. For finite element studies, anatomical realism covered dataset source, patient specificity, cortical and cancellous representation, segmentation, and defect or atrophy characterization. Material assumptions covered the source and justification of mechanical properties, homogeneity, isotropy, and bone-quality representation. Separate domains addressed boundary conditions and fixation constraints. Contact modeling covered bonded, frictional, sliding, threaded, or simplified screw-to-bone interfaces and any preload assumptions. Mesh and numerical verification included element type and size, local refinement, convergence testing, and solver reporting. Loading realism covered force magnitude, direction, and application site, together with unilateral, bilateral, oblique, cantilever, bruxism, trauma, and cyclic scenarios. The remaining domains addressed outcome and failure relevance, sensitivity or uncertainty analysis, and experimental, mechanical, or clinical validation. For mechanical studies, the descriptive domains additionally included specimen relevance, reproducibility of the test setup, loading justification, cyclic or fatigue assessment, screw-torque standardization, and predefined failure criteria. Material, surface, scaffold, workflow, and clinical studies were described according to model relevance, manufacturing characterization, endpoint selection, reproducibility, and the presence of experimental or clinical correlation. Each domain was interpreted only from explicitly reported information as adequately described, partially described, not reported, or not applicable. These descriptors reflected reporting completeness and interpretability rather than methodological quality or risk of bias. They were not weighted, combined into a numerical score, or used to rank individual studies, and absence of reporting was not assumed to indicate absence of the corresponding methodological procedure.

To distinguish clinically implemented applications from exploratory strategies, materials, manufacturing processes, surface modifications, and scaffold-assisted approaches were additionally classified according to their translational status. “Clinically implemented” indicated documented use in contemporary patient-specific SPIs. This classification reflected clinical adoption of the material, process, or strategy but did not imply mature mechanical validation, demonstrated superiority, standardized manufacturing tolerances, or established long-term reliability. “Preclinically supported” indicated direct mechanical, in vitro, or animal evidence without corresponding clinical validation. “Computational hypothesis only” indicated that the relevant performance claim was supported exclusively by computational comparison. “Emerging concept” indicated an isolated proof-of-concept without replicated preclinical or clinical evaluation. Classification was claim-specific and referred to the particular SPI application rather than to the general clinical use or regulatory status of the material.

To quantify the evidence supporting the proposed pathway, records were coded according to their contribution to digital workflow, computational simulation, formal or iterative design optimization, and quantitative manufacturing or fit verification. Additional stages comprised direct experimental mechanical validation, cyclic or fatigue testing, clinically based engineering observation, and direct correlation between computational predictions and clinical outcomes. These stage-specific counts were based on explicitly reported methods and were not mutually exclusive, because one record could contribute to more than one stage. A step was not counted when it was only mentioned as a recommended future procedure or when insufficient methodological information was provided.

Finally, the mapped validation stages and cross-domain gaps were used to construct an evidence-informed validation pathway for patient-specific SPI development. The pathway links clinical and prosthetic inputs, anatomical modeling, framework and fixation design, computational assessment, manufacturing verification, experimental testing, and clinical feedback. It is intended to show which validation stages are represented or

missing across the current evidence base, rather than to provide a validated clinical guideline or a hierarchy of study quality.

3. Results

3.1. Study Selection and Characteristics of the Evidence

The database searches identified 1828 records: 547 from PubMed, 701 from Scopus, 203 from Embase, 375 from Web of Science, and 2 from the Cochrane Library. After the removal of 932 duplicates, 896 records underwent title and abstract screening, of which 742 were excluded. The full texts of 154 potentially eligible reports were sought for retrieval; 9 could not be retrieved, leaving 145 reports for full-text eligibility assessment. Eighty reports were subsequently excluded because they did not address eligible patient-specific SPIs, including reports indexed or described using juxta-osseous terminology, lacked relevant engineering data, focused exclusively on clinical outcomes, represented historical or analog implant concepts, or provided insufficient or overlapping technical information. Expressed as descriptive screening proportions, 154 of the 896 unique records screened by title and abstract (17.2%) proceeded to full-text retrieval, while 742 records (82.8%) were excluded at this stage. Of the 154 reports sought, 145 (94.2%) were retrieved and assessed for eligibility. Sixty-five of the 145 full-text reports assessed (44.8%) met the eligibility criteria, corresponding to an overall inclusion yield of 7.3% among the unique records screened (Figure 1). The high title-and-abstract exclusion proportion was expected from the sensitivity-oriented search and was managed through predefined eligibility criteria and independent dual-reviewer screening.

When each record was assigned to a single primary evidence category, the included literature comprised 22 computational modeling studies, 1 stand-alone experimental mechanical study, and 11 digital workflow or technical development reports. The remaining evidence included 5 material, surface, or scaffold investigations, 21 clinically based reports containing extractable engineering information, and 5 secondary engineering syntheses or commentaries. One of the computational studies also included direct static and fatigue validation; therefore, direct experimental mechanical or cyclic testing was reported in two records overall.

The literature was strongly concentrated in the contemporary digital era. Only one included record was published before 2017, whereas most studies appeared between 2023 and 2026. The maxilla, particularly the severely atrophic edentulous maxilla, was the predominant anatomical setting. Fewer studies investigated the atrophic mandible, segmental rehabilitation, congenital conditions, or post-ablative maxillary defects. Computational modeling constituted the largest methodologically homogeneous evidence group, whereas experimental mechanical validation and translational surface or scaffold studies remained comparatively limited.

The distribution of evidence also differed across engineering domains. Computational studies primarily investigated framework architecture, thickness, screw configuration, anchorage, materials, and loading conditions. Digital and clinically based reports provided information on segmentation, prosthetic reverse planning, framework design, manufacturing, surgical transfer, and anatomical feasibility, but rarely quantified registration error, manufacturing deviation, passive fit, or design reproducibility. Surface and scaffold studies were predominantly preclinical, and only a small proportion of the overall evidence combined computational predictions with experimental or clinical validation. The characteristics and distribution of the included records are summarized in Table 1.

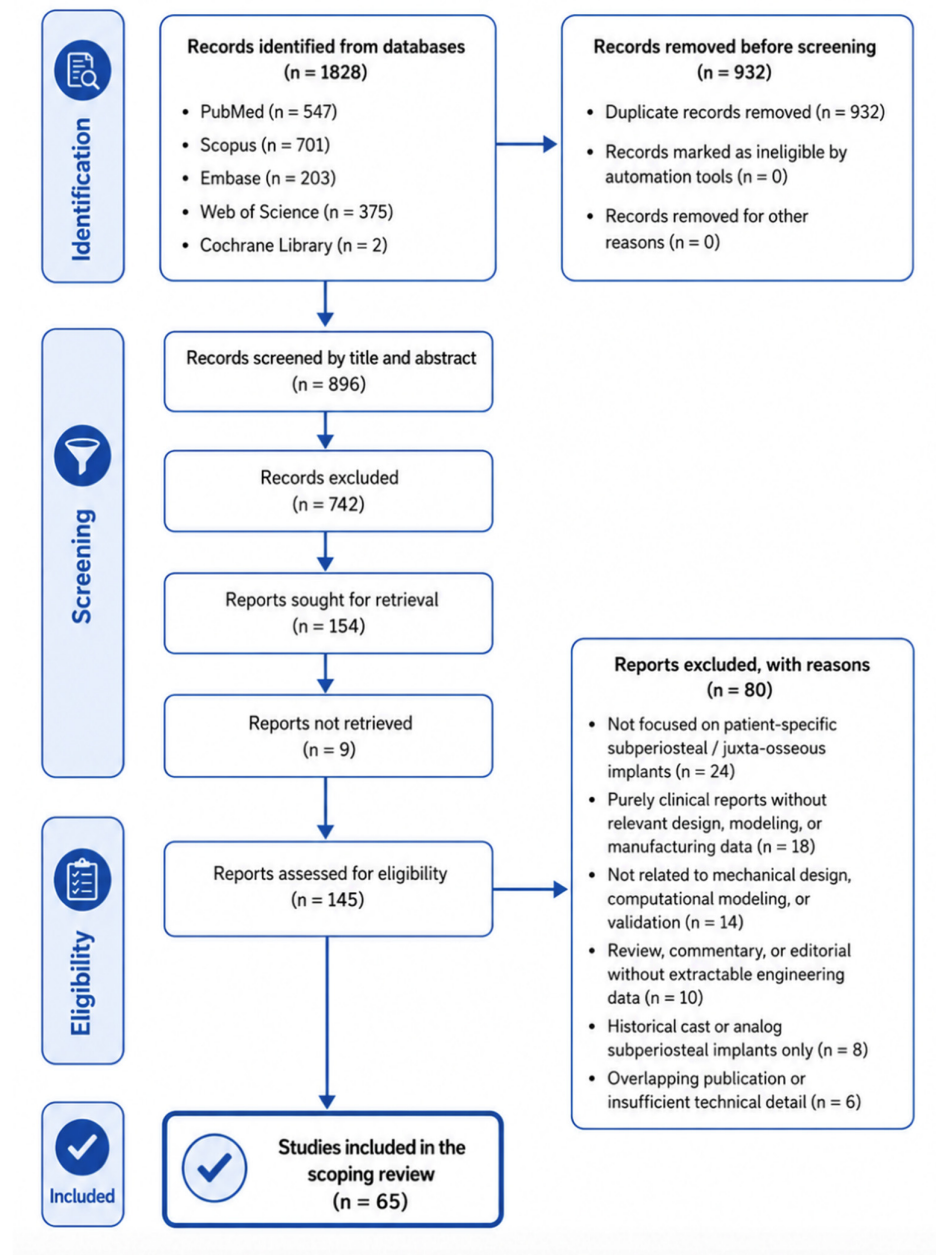


Figure 1. PRISMA-ScR flow diagram of the study-selection process.

Table 1. Evidence map of the 65 records included in the scoping review according to their primary evidence category.

Primary Evidence Category	Number of Records	Predominant Study Designs	Main Anatomical Settings
Computational modeling	22	Static FEA; comparative biomechanical analysis; topology or design optimization; integrated FEA and mechanical validation	Predominantly atrophic maxilla; fewer mandibular, unilateral maxillary, and post-maxillectomy models
Experimental mechanical validation	1	Cyclic screw-loosening and removal-torque testing	Connection-screw model

Digital workflow and technical development	11	Technical notes; design-development reports; digital workflow studies; patient-specific device descriptions	Atrophic maxilla, segmental maxillary defects, and post-ablative maxillary reconstruction
Material, surface, and scaffold investigations	5	In vitro cell studies; translational device development; surface characterization; animal scaffold study	Experimental titanium frameworks and subperiosteal models
Clinically based engineering evidence	21	Retrospective studies; cohort and pilot studies; case series; case reports; complication and management studies	Full-arch and segmental maxilla, posterior mandible, congenital defects, and oncologic reconstruction
Secondary engineering synthesis and commentary	5	Systematic, scoping, narrative, and literature reviews; meta-analysis; focused commentary	Multiple anatomical and clinical indications

3.2. Digital Workflow and Manufacturing Evidence

The included technical and clinically based studies described a broadly consistent digital workflow comprising anatomical image acquisition, segmentation, integration of prosthetic data, framework design, fixation planning, manufacturing, and surgical transfer. However, the level of technical reporting varied substantially. Most studies demonstrated the feasibility of producing an anatomically adapted device, whereas relatively few quantified the accuracy or reproducibility of the individual workflow steps [9,11–13,32].

CT or CBCT datasets were generally used to reconstruct the residual maxilla, mandible, or post-ablative defect. Segmentation extended beyond the alveolar ridge to identify cortical buttresses suitable for fixation and anatomical regions requiring protection. In maxillary applications, planning commonly incorporated the nasomaxillary and zygomaticomaxillary buttresses, palate, pterygoid region, or zygomatic structures, depending on the extent of atrophy or resection. Mandibular planning was constrained principally by the inferior alveolar canal, mental foramina, residual basal cortex, and available lateral cortical bone. Post-ablative cases required additional consideration of missing buttresses, resection margins, reconstructive flaps, scar tissue, and the relationship between the implant and the planned obturator or fixed prosthesis [26,33,34].

The studies consistently identified segmentation quality as a determinant of framework adaptation and screw safety, but quantitative reporting was limited. Cortical thickness, image artifacts, threshold selection, surface refinement, and the accuracy of the final anatomical model were not described uniformly. This is also relevant to computational studies because errors in reconstructed buttress geometry or cortical representation may influence both device fit and predicted stress distribution.

Prosthetically driven workflows combined the anatomical dataset with intraoral scans, diagnostic casts, wax-ups, or virtual prosthetic setups. DICOM–STL registration was used to define tooth position, occlusal plane, restorative space, and the emergence of transmucosal abutments. The prosthetic endpoint therefore determined where functional loads entered the framework, while the residual anatomy constrained the available anchorage and screw trajectories. This relationship was particularly important in segmental and single-tooth rehabilitation, where prosthetic emergence permitted limited positional flexibility, and in post-maxillectomy reconstruction, where the device could provide both skeletal fixation and prosthetic support [35–38].

Although most reports described the integration of anatomical and prosthetic datasets, registration accuracy and its propagation through the subsequent design steps were rarely quantified. Similarly, abutment selection was generally justified clinically, but few studies compared alternative abutment distributions or assessed their combined effects on load transfer, soft-tissue crowding, and hygiene accessibility. Available clinical

evidence suggests that close spacing between coupling elements and proximity to natural teeth may increase the risk of mucosal inflammation, emphasizing that prosthetic support and maintainability should be evaluated together [39].

CAD design translated the anatomical and prosthetic datasets into a framework incorporating the bone-facing surface, fixation arms, screw holes, transmucosal abutments, prosthetic connections, and relief areas. The literature described one-piece, bilateral, segmented, modular, and hybrid configurations. These alternatives were selected according to anatomy, surgical accessibility, insertion path, expected load transfer, and prosthetic requirements. Large one-piece frameworks offered structural continuity but could be more sensitive to cumulative fitting errors, whereas bilateral or segmented designs facilitated insertion and localized management but introduced additional interfaces.

Most contemporary titanium and Ti6Al4V frameworks were produced using laser-based additive manufacturing, including selective laser melting, direct metal laser sintering, or laser powder bed fusion. Reported post-processing steps included support removal, heat treatment, cleaning, polishing, surface differentiation, and sterilization. Bone-facing regions were generally designed to retain controlled roughness, whereas transmucosal and hygiene-critical regions required smoother surfaces. Nevertheless, build orientation, layer thickness, powder characteristics, dimensional tolerances, heat treatment, surface roughness, and the effects of polishing were inconsistently reported [12,13,17,40,41].

Surgical guides were described for osteoplasty, bone reduction, screw positioning, abutment seating, or reproduction of the planned implant position. Specific design criteria for vertical and horizontal osteotomy guides in terminal maxillary dentition have also been described, including the avoidance of acute angles in the buccal fixation arms [42]. Fit was commonly verified on a printed anatomical model or intraoperatively, but objective deviation analysis and predefined acceptance criteria were uncommon. This represents an important limitation because a geometrically optimized framework may develop non-uniform preload, local gaps, or uneven screw loading if manufacturing or seating inaccuracies prevent passive adaptation.

3.3. Computational Modeling and Mechanical Validation

The computational evidence was predominantly based on three-dimensional finite element analysis and focused mainly on the severely atrophic maxilla. The investigated variables included framework architecture, implant thickness, screw diameter and distribution, anatomical anchorage, cantilever, prosthetic superstructure, material properties, and loading direction. Maxillary applications included full-arch rehabilitation and alternative framework configurations [14,16–20,43,44]. Other studies investigated premaxillary, prosthetic-framework, mesh-type, and alternative buttress-supported configurations [21,45–50].

Fewer studies investigated mandibular applications, unilateral maxillary defects, total maxillectomy, or combined zygomatic–subperiosteal configurations. Mandibular models evaluated modular, single-piece, two-piece, titanium, and polymeric frameworks under functional or traumatic loading [51–53]. Defect-specific studies compared different implant-supported configurations and alternative framework extensions [54–56]. Other investigations evaluated designs applicable to both maxillary and mandibular rehabilitation or used topology optimization to reduce framework volume while maintaining structural performance [41,57].

Most anatomical models were reconstructed from CT or CBCT datasets obtained from an individual patient or anatomical source. This provided clinically recognizable geometries but limited generalizability across different degrees of atrophy, cortical thickness, buttress anatomy, sinus pneumatization, and defect morphology. Cortical and

cancellous bone were commonly represented as homogeneous, isotropic, and linearly elastic materials. Mucosa, periosteum, scar tissue, reconstructive flaps, and progressive changes in bone–implant contact were generally omitted. These models were therefore more suitable for relative comparison between predefined configurations than for establishing absolute clinical thresholds.

Representation of the fixation interface varied considerably. In several models, screws were represented through simplified geometries, bonded contacts, embedded elements, or idealized constraints. Explicit submodeling of threaded screw engagement demonstrated that the selected representation of the screw-to-bone interface could substantially modify predicted displacement and stress in the surrounding cortical bone [15]. The numerical values reported below are illustrative within-study examples selected to demonstrate component-specific mechanical trade-offs. They should not be interpreted as representative effect sizes or quantitatively compared across different implant systems, anatomical models, materials, or loading conditions. Studies investigating screw diameter, number, and distribution showed quantitatively different effects across components. Under a 250 N vertical load, increasing screw diameter from 1.5 to 2.0 mm reduced maximum residual bone stress from 22.15 to 19.86 MPa. This corresponded to a 10.3% within-model reduction. However, total implant displacement increased from 0.42 to 0.46 mm [19]. In a CFR-PEEK model with a 1.0 mm framework, the same increase in screw diameter reduced posterior tensile bone stress from 64.031 to 61.627 MPa. Under posterior vertical loading, implant von Mises stress decreased from 442.27 to 432.20 MPa. Under oblique loading, it decreased from 531.44 to 513.50 MPa [49]. Screw effects were therefore component-, material-, and loading-specific rather than uniformly favorable.

Loading protocols were heterogeneous. Most studies applied static vertical or oblique forces, commonly between approximately 100 and 250 N, to posterior, anterior, unilateral, or cantilevered regions. Oblique and cantilever loading generally produced greater displacement and less favorable stress concentrations than bilateral vertical loading. Some models investigated traumatic anterior forces, combined loading directions, or maxillectomy-specific conditions [17,20,50,52,54–56]. However, bruxism, progressive loss of screw preload, prosthetic misfit, bone remodeling, and long-term material degradation were rarely simulated.

Across the computational literature, no individual design modification produced a uniformly favorable response in every component. One-piece, two-piece, mesh-type, reinforced, modular, and extended frameworks redistributed stress differently among cortical bone, implant body, fixation screws, abutments, and prosthetic components [16,21,51,53–55]. Similarly, increased thickness or stiffness could reduce bone stress or displacement while increasing stress within the framework or metallic substructure [18,48,49]. Alternative framework and prosthetic materials also shifted stress among bone, implant, screws, and superstructure rather than producing a uniform reduction throughout the system [20,43,44,47]. The consistent cross-study finding was therefore redistribution, rather than global reduction, of mechanical stress. The comparative implications of these design variables are synthesized in Section 3.4.

Direct mechanical validation was uncommon. One investigation combined iterative FEA-guided optimization with static testing at 450 N and fatigue testing at 150 N for five million cycles, with the optimized laser-powder-bed-fused Ti6Al4V devices completing testing without failure [41]. A separate cyclic-loading study evaluated connection-screw stability and found that a tightening torque of 15 Ncm was insufficient to maintain stable removal-torque behavior, whereas 30 Ncm produced greater stability after cyclic loading [58]. These studies provided more advanced preclinical validation than isolated static simulations, although their findings remained specific to the tested device geometry, material, connection, and loading protocol.

Mesh convergence, sensitivity analysis, manufacturing verification, experimental confirmation, and clinical correlation were inconsistently reported. The common assumption of perfect passive fit may also underestimate preload and non-uniform screw loading. Current FEA findings should therefore be interpreted as design-specific comparative trends rather than as evidence of clinical superiority or universal safety thresholds.

The computational and experimental mechanical studies, together with their principal design variables, loading protocols, findings, and methodological limitations, are summarized in Table 2.

Table 2. Finite element and mechanical studies on contemporary patient-specific subperiosteal implants.

Author, Year	Anatomical Model/Indication	Design or Material Variables	Loading/Validation	Main Findings	Main Limitations
Carnicero et al., 2021 [57]	Severely atrophic maxilla; patient-specific SPI	Two-stage FEA-based topological optimization of Ti6Al4V framework	Five chewing and fixation-loss scenarios; computational fatigue estimation	Optimized design reduced framework volume by 27.7% and fixation requirements while maintaining acceptable stress distribution.	Single model; screws and bone not explicitly modeled; no experimental or clinical validation.
De Moor et al., 2022 [14]	Severely atrophic maxilla; AMSJI	AMSJI under functional loading	Functional loading simulation; mechanical evaluation	The implant appeared mechanically safe under average occlusal forces; higher stresses concentrated in the arms and may become critical in extreme atrophy, bruxism, or maximal loading.	Limited anatomical and loading scenarios; simplified assumptions; limited direct clinical validation.
Castrillo et al., 2023 [15]	Patient-specific SPI screw-fixation model	Screw-to-bone interaction and submodeling	Advanced FEA submodeling	Explicit modeling of the threaded screw-bone interface changed displacement and stress patterns; cortical bone was the most relevant region for stress concentration.	Focused on screw-interface modeling; not a full clinical design comparison.
Ayhan and Canakaya, 2023 [16]	Atrophic maxilla	Monoblock versus dual patient-specific SPI configurations	Static loading	Dual geometry produced lower stress values than monoblock designs; displacement remained low under static loading.	Static model; limited loading conditions; clinical validation lacking.
Zielinski et al., 2023 [17]	Edentulous maxilla; MAI implant	Single implant versus two implants connected by a bar; different load magnitudes and directions	Vertical and oblique load simulations	Displacement increased with higher loads and more oblique loading angles; stabilization and load direction strongly influenced mechanical behavior.	Simplified loading; limited validation; model-specific conclusions.
Cipollina et al., 2023 [45]	Severely atrophic maxilla/pre-maxillary region	Premaxillary patient-specific SPI or hybrid implant concept	FEA	Suggested favorable stress distribution on basal bone, with values within resistance limits of bone and titanium alloys.	Conceptual/pre-clinical model; limited clinical correlation.

Acar et al., 2024 [56]	Unilateral maxillary defect	Patient-specific SPIs versus zygomatic implant-Static FEA based configurations		SPI designs transmitted less stress to alveolar bone than zygomatic configurations; one-piece SPI design showed favorable distribution.	Specific defect model; static assumptions; limited validation.
Ari et al., 2025 [54]	Total maxillectomy defect	Quad zygoma, zygoma plus partial SPI frameworks, one-piece and two-piece SPI configurations	FEA under functional loading	Combined zygomatic–subperiosteal strategies, especially selected two-piece configurations, produced more balanced stress distribution in several components.	Highly specific model; clinical generalizability limited.
Kundakcioglu and Ayhan, 2024 [18]	Patient-specific SPI model under 250 N load	Framework thickness of 1.0, 1.5, and 2.0 mm	Static loading	The 1.0 mm design exceeded yield limits and showed plastic deformation; 1.5 mm appeared a more reasonable minimum thickness in the tested model.	Single design/model; static analysis; material and anatomy dependent.
Kundakcioglu and Gedik, 2024 [19]	Custom subperiosteal implant model	Fixation screws of 1.5 mm versus 2.0 mm diameter	Static FEA	Increasing screw diameter from 1.5 to 2.0 mm reduced residual bone stress from 22.15 to 19.86 MPa under 250 N loading (−10.3%) but increased implant displacement from 0.42 to 0.46 mm (+9.5%).	Screw diameter assessed in limited scenarios; clinical torque and bone quality not fully represented.
Parhiz et al., 2024 [51]	Severely atrophic mandible	Modular mandibular patient-specific SPI with inferior border cover and horse-shoe component	FEA	Stress concentrated mainly around screw sites; increasing number and distribution of fixation screws reduced loosening risk.	Preclinical design; limited validation; complex modularity.
Altiparmak et al., 2023 [43]	Atrophic maxilla; AMSJI	Titanium versus 60% carbon-fiber-reinforced PEEK	FEA	Titanium showed higher stress within the implant system, whereas stresses transmitted to cortical and cancellous bone were broadly similar between materials.	Material behavior simplified; no clinical validation of CFR-PEEK framework.
Canko and Doganay Ozyilmaz, 2025 [20]	AMSJI maxillary model	Framework material, cantilever presence, I-shaped versus Y-shaped wing design	Vertical and oblique loading	CoCr, I-shaped configuration, and absence of cantilever showed more favorable stress distribution; cantilevers increased displacement and stress; PEEK reduced framework stress but increased deformation/displacement.	Model-specific; static loads; material assumptions may not capture fatigue.
Demir and Caglar, 2025 [47]	Full-arch maxillary SPI	Prosthetic framework materials: CoCr-porcelain, Ti-porcelain, Ti-acrylic, Zr-porcelain, PEEK-composite	Functional loading	PEEK-composite produced higher stress in bone, implant, and screws; CoCr and zirconia showed more favorable biomechanical behavior; prosthetic screws were highest-stress areas.	Focus on prosthetic framework materials; static FEA; clinical validation lacking.
Deniz and	Totally edentulous	Conventional plus zygomatic	FEA	Zygomatic bone-anchored SPI design reduced stress in cortical and trabecular bone,	Comparative model; limited

Yurttu- tan, 2025 [46]	atrophic maxilla	implants versus maxilla-an- chored and zy- gomatic bone- anchored SPI de- signs		although implant, abutment, and screw stresses increased.	validation; clini- cal feasibility de- pends on anat- omy.
El-Sawy et al., 2025 [44]	Atrophic maxilla	Titanium, modi- fied PEEK/Bio- HPP, and PEKK combinations for framework and superstructure	Full-arch and anterior load- ing	Titanium framework transferred less stress to bone and screws and showed better stability under full-arch loading; PEEK/PEKK in- creased stress in selected components under anterior loading.	Multiple mate- rial assump- tions; limited clinical valida- tion.
Ari and Acar, 2025 [55]	Total maxil- lectomy de- fect, Liver- pool Class II	Conventional subperiosteal de- sign versus alter- native design with diagonal zygomatic bar	Oblique and vertical load- ing	Diagonal bar design did not provide a clear biomechanical advantage and showed higher stresses under oblique loading in some re- gions.	Defect-specific; static model; limited generali- zability.
Baş et al., 2025 [52]	Severely atrophic edentulous mandible under trau- matic ante- rior force	IAN lateraliza- tion plus six im- plants, All-on- four, PEEK SPI, titanium SPI	Traumatic an- terior loading	All-on-four and PEEK SPI behaved more fa- vorably under traumatic loading than tita- nium SPI and IAN lateralization models; PEEK showed more balanced stress on abut- ments and screws.	Traumatic model may not represent rou- tine loading; ma- terial behavior and fixation as- sumptions sim- plified.
Pelle- grino et al., 2025 [50]	Realistic models of atrophic jaws	Patient-specific SPI models with different screw and load-distri- bution configu- rations	FEA	Under 500 N loading, localized tensile stress around fixation regions exceeded 50 MPa. Adding a posterior screw reduced the spatial extent of the region exceeding 50 MPa, al- though paired peak values were not reported.	Heterogeneous indications; lim- ited direct ex- perimental vali- dation.
Roshdy et al., 2025 [53]	Atrophic edentulous mandible	Single-piece ver- sus two-piece ti- tanium SPIs	Functional loading	Bone, screw, and prosthetic stresses were sim- ilar, but two-piece frameworks showed more than double the framework stress compared with single-piece designs.	Specific mandib- ular model; static assump- tions; no long- term fatigue val- idation.
Vana- clocha et al., 2025 [41]	Maxillary and mandib- ular SPI de- signs	Iterative FEA op- timization plus static and fatigue mechanical test- ing	Static loading at 450 N and fatigue load- ing at 150 N for 5 million cycles	Optimized Ti6Al4V laser-powder bed fusion implants resisted static and fatigue testing without failure.	Preclinical me- chanical valida- tion; translation to broad clinical scenarios re- quires further evidence.
Vörös et al., 2025 [58]	In vitro me- chanical screw-loos- ening model	Tightening torque of M1.8 connection screws: 15 Ncm versus 30 Ncm after cyclic load- ing	Cyclic load- ing and screw-loos- ening assess- ment	15 Ncm did not provide sufficient stability and led to loosening after cyclic loading; 30 Ncm maintained better stability.	Connection screw model, not fixation screw model; clinical extrapo- lation should be cautious.

Dere and Findik, 2026 [21]	Atrophic edentulous maxilla	Six titanium designs; three single-piece and three two-piece configurations; mesh-type designs	Vertical 150 N and oblique 50 N at 30 degrees	Under 150 N vertical loading, mesh designs produced cortical tensile stresses of 12.6–13.7 MPa versus 14.9–25.2 MPa in non-mesh designs; abutment stresses were 34.0–34.6 versus 41.2–49.6 MPa, and prosthetic-framework stresses were 36.5–37.8 versus 45.8–48.5 MPa. Implant stress reached 153.6 MPa in the two-piece mesh model and 96.1 MPa in the single-piece mesh model.	Homogeneous, isotropic, linearly elastic assumptions; static loading; limited validation.
Etik and Keskin Yalcin, 2026a [48]	Atrophic maxilla	Titanium versus Y-TZP; 1.0 and 1.5 mm thickness; 1.5 and 2.0 mm screws	Bilateral vertical posterior loading, unilateral oblique loading, and anterior loading	Increasing thickness reduced bone stress but increased implant/framework stress; larger screws reduced bone and implant stress but increased stress concentration in metallic substructure; Y-TZP reduced bone stress but increased implant/framework stress.	FEA only; clinical applicability of Y-TZP requires in vitro, in vivo, and clinical validation.
Etik and Keskin Yalcin, 2026b [49]	Atrophic maxilla	60% CFR-PEEK; 1.0 and 1.5 mm thickness; 1.5 and 2.0 mm screws	Bilateral posterior vertical, unilateral oblique, and anterior loading	CFR-PEEK reduced bone stress but concentrated stresses in implant body and metal framework; thickness and screw diameter significantly influenced stability.	FEA only; single anatomical model; polymeric framework behavior requires experimental and clinical validation.

3.4. Comparative Synthesis of Design Variables

The included evidence showed that the mechanical behavior of patient-specific SPIs depends on interactions among anatomical anchorage, framework architecture, thickness, screw configuration, abutment distribution, and cantilever. None of these variables could be interpreted independently, and no configuration was consistently superior across bone, framework, screw, abutment, and prosthetic outcomes. Accordingly, the numerical comparisons presented in this section are study-specific illustrations of these interactions and not pooled or representative estimates of the magnitude of benefit associated with any design variable.

Anatomical anchorage determined the boundaries of the framework and the direction of load transfer. Maxillary designs generally transferred fixation away from the severely resorbed alveolar crest toward more stable cortical buttresses, palatal or pterygoid regions, and, in extensive defects, zygomatic or cranial landing zones. The available technical and computational evidence supported broad, multivectorial fixation, although more extensive frameworks increased surgical access requirements and soft-tissue coverage demands [9,10,14,27,33,46]. Mandibular designs instead relied on lateral or basal cortical support while remaining constrained by the inferior alveolar nerve, mental foramina, and limited soft-tissue thickness [51].

Framework architecture produced component-specific trade-offs. Monoblock and one-piece designs avoided modular interfaces and generally provided greater structural continuity, whereas bilateral or segmented devices could facilitate insertion and reduce cumulative fitting error. Computational comparisons did not establish universal superiority. Dual or two-piece configurations reduced stress transmitted to bone in some models but increased stress within the framework or connection regions in others [16,21,53–55]. The component-specific trade-off was quantified in the six-design comparison by Dere and Findik [21]. Under 150 N vertical loading, the two mesh-type models produced cortical tensile stresses of 12.6 and 13.7 MPa, compared with 14.9–25.2 MPa among the four

non-mesh designs. Abutment stresses were 34.0–34.6 MPa in the mesh models versus 41.2–49.6 MPa in the non-mesh models, and prosthetic-framework stresses were 36.5–37.8 versus 45.8–48.5 MPa, respectively. This reduction in secondary-component loading was accompanied by implant von Mises stresses of 153.6 MPa in the two-piece mesh design and 96.1 MPa in the single-piece mesh design, confirming redistribution rather than uniform stress reduction.

Topology and volume optimization offered a more individualized alternative to uniform framework reduction. A two-stage FEA-based optimization reduced framework volume by approximately 28% and decreased fixation requirements while maintaining stresses within predefined mechanical limits. However, these findings were obtained from a single patient-specific model and were not experimentally validated [57].

Framework thickness influenced rigidity, displacement, fatigue resistance, and soft-tissue bulk. In one model, a 1.0 mm titanium framework exceeded the material yield limit, whereas a 1.5 mm design maintained more favorable mechanical behavior. Other comparisons showed that increasing thickness could reduce bone stress while increasing stress within the implant or associated metallic substructure. Consequently, the available evidence does not support a universal minimum thickness independent of material, anatomy, fixation, and loading conditions [18,48,49].

Screw effects varied according to diameter, position, anatomical support, and the component evaluated. Explicit representation of threaded engagement altered predicted cortical stress and displacement compared with simplified fixation assumptions [15]. Under 250 N vertical loading, increasing screw diameter from 1.5 to 2.0 mm reduced residual bone stress from 22.15 to 19.86 MPa but increased implant displacement from 0.42 to 0.46 mm [19]. In the CFR-PEEK model evaluated by Etik and Keskin Yalcin [49], increasing screw diameter from 1.5 to 2.0 mm produced smaller, loading-dependent reductions in posterior bone and implant stress. Posterior fixation was evaluated directly by Pellegrino et al. [50]: under a 500 N load, addition of a posterior screw reduced the spatial extent of the region exceeding 50 MPa around the previously overloaded fixation site. Because paired peak values were not reported, a percentage reduction could not be calculated. These results support patient- and component-specific screw selection rather than a general recommendation that larger or more numerous screws are mechanically superior.

Abutment distribution and cantilever determined how prosthetic loads entered the framework. Posterior cantilever and oblique loading consistently increased displacement and stress concentration compared with non-cantilevered or more broadly supported configurations [17,20,50]. Increasing the number of abutments could improve prosthetic support but also created additional transmucosal interfaces. Clinically based evidence suggested that reduced spacing between coupling elements and proximity to natural teeth were associated with increased mucosal inflammation, indicating a trade-off between load distribution and maintainability [39].

Overall, apparently contradictory findings across studies largely reflected redistribution of stress within a coupled implant–prosthesis–bone system. A design that reduced cortical bone stress could increase framework or screw stress; segmentation could facilitate surgical placement while introducing connection vulnerability; additional fixation could improve stability while increasing anatomical and surgical demands; and greater thickness could reduce deformation while compromising framework bulk. The main design variables and their mechanical trade-offs are summarized in Table 3.

Table 3. Main design variables influencing the mechanical behavior of contemporary patient-specific subperiosteal implants. Quantitative values are illustrative findings from individual studies and should not be interpreted as pooled effect estimates or universal design thresholds.

Design Variable	Mechanical Rationale	Potential Advantages	Potential Risks or Trade-Offs	Key Evidence
Anchorage zone selection	Transfers load from resorbed crest to stable cortical buttresses	Improved fixation; reduced dependence on thin alveolar bone; better load distribution	More invasive design; difficult soft-tissue coverage; limited access for drilling; anatomical risk	[9,10,14,33]
One-piece/monoblock design	Increases structural continuity and reduces modular interfaces	Lower connection-related complexity; potentially reduced framework stress in selected models	More difficult passive seating; less modular management of complications; larger manufacturing tolerance sensitivity	[16,21,53]
Two-piece/segmented design	Reduces insertion difficulty and cumulative fitting error	Easier surgical handling; possible reduction in stress transferred to bone; independent side management	Higher stress at connectors or framework interfaces; possible fatigue risk	[21,53,54]
Mesh-type/lattice design	Distributes surface contact and may reduce bulk	In one six-design FEA, cortical tensile stress was 12.6–13.7 MPa in mesh models versus 14.9–25.2 MPa in non-mesh models; abutment and prosthetic-framework stresses were also lower	Implant stress remained design-dependent and reached 153.6 MPa in the two-piece mesh model; fatigue, polishing, and hygiene remain unvalidated	[21]
Topology optimization	Removes material from low-load regions while reinforcing critical areas	Reduced framework volume and fixation requirements	Model-specific results; manufacturing constraints; limited validation	[57]
Framework thickness	Controls rigidity, deformation, and load transfer	Increased thickness may reduce bone stress and deformation	Excessive bulk; difficult soft-tissue closure; increased implant/framework stress; thin designs may deform plastically	[18,48,49]
Screw diameter	Influences fixation stiffness and cortical engagement	Increasing diameter from 1.5 to 2.0 mm reduced residual bone stress from 22.15 to 19.86 MPa under 250 N loading	In the same model, displacement increased from 0.42 to 0.46 mm; effects varied by material, component, loading, and available cortical thickness	[19,48,49]
Screw number and distribution	Resists rotational and oblique forces	In one 500 N model, an additional posterior screw reduced the spatial extent of the region exceeding 50 MPa around the overloaded fixation site	No paired peak reduction was reported; additional drilling increases anatomical and surgical constraints	[15,25,51]
Abutment number and spacing	Determines entry points of prosthetic load into framework	Better prosthetic support; reduced cantilever when well distributed	More transmucosal interfaces; plaque retention; soft-tissue inflammation if too close	[39]
Cantilever reduction	Reduces bending moments and distal overload	Lower displacement and stress concentration	May require posterior extension; greater surgical complexity	[20,25]

3.5. Translational Status of Materials, Manufacturing, Surface Engineering, and Scaffold-Assisted Strategies

Application of the predefined translational categories showed a clear separation between clinically implemented materials and exploratory strategies. Titanium and Ti6Al4V frameworks and their principal additive-manufacturing routes were classified as clinically implemented, reflecting their documented use in contemporary SPIs rather than complete validation of individual designs, manufacturing protocols, dimensional tolerances, or fatigue performance. Polymeric and ceramic alternatives [59,60] were classified as computational hypotheses only because the relevant SPI performance claims were derived predominantly from FEA. Titanium surface modifications were classified as preclinically supported, whereas scaffold-assisted bone regeneration remained an emerging concept.

Within the clinically implemented category, titanium and Ti6Al4V were the reference materials most frequently documented in contemporary SPI frameworks because of their mechanical strength, biocompatibility, clinical use, and compatibility with additive manufacturing. Clinical and technical studies documented the use of these materials in full-arch, segmental, mandibular, and reconstructive applications [11–13,28,35,36,61]. Computational and mechanical investigations also evaluated their behavior under static and cyclic loading [41].

Nevertheless, titanium stiffness could shift stress toward the framework, fixation points, or prosthetic components, indicating that its clinical implementation does not eliminate the need for geometry- and fixation-specific optimization, manufacturing verification, or fatigue assessment.

Within the computational hypothesis-only category, polymeric alternatives produced heterogeneous findings across the available finite element models. PEEK, modified PEEK/BioHPP, and PEKK offered lower elastic modulus and reduced weight, but frequently showed increased displacement or stress in screws, bone, or prosthetic components. Titanium generally provided greater stability under full-arch loading, whereas the mechanical behavior of polymeric combinations varied according to loading direction and the material selected for both the SPI and prosthetic superstructure [43,44,47,60].

CFR-PEEK provided greater stiffness than unreinforced PEEK and reduced bone stress in some models. However, it also concentrated stress within the implant body or associated metallic framework, and its fatigue behavior, screw-interface performance, and clinical manufacturability remain insufficiently validated [43,49]. Y-TZP and zirconia similarly reduced bone stress or provided favorable prosthetic load distribution in selected simulations but increased stress within the implant or framework and introduced concerns regarding brittleness and long-term fatigue in screw-retained configurations [47,48].

Cobalt–chromium and zirconia showed favorable stress distribution in selected prosthetic and framework models because of their high stiffness. Conversely, PEEK-based configurations generally exhibited greater deformation or less favorable stress transfer under some loading conditions. These findings were specific to the simulated geometry and should not be interpreted as evidence of clinical superiority [20,47].

Laser powder-bed fusion was the principal additive-manufacturing family used for titanium and Ti6Al4V SPIs and was classified as clinically implemented, although quantitative process validation, dimensional verification, and characterization of manufacturing tolerances remained limited. Included studies variously described these processes as selective laser melting (SLM), direct metal laser sintering (DMLS), or laser powder-bed fusion (LPBF). However, the terminology was not applied consistently and generally referred to closely related powder-bed fusion processes rather than to manufacturing techniques evaluated through direct comparative testing. No included study provided a head-to-head comparison sufficient to establish the superiority of one named process over

another. One randomized clinical study compared milled and 3D-printed patient-specific mandibular SPIs, providing rare comparative clinical evidence across manufacturing strategies; however, it did not isolate the effects of individual laser powder-bed-fusion parameters or directly compare SLM-, DMLS-, and LPBF-labelled processes [62]. These approaches were therefore synthesized as a single manufacturing family. Their principal advantages included the production of complex patient-specific geometries, integrated screw holes and abutments, differentiated framework thicknesses, and topology-optimized structures. Nevertheless, material grade, powder characteristics, build orientation, layer thickness, heat treatment, support strategy, surface finishing, and dimensional tolerances were inconsistently reported across studies, limiting process reproducibility and comparative assessment [11–13,41,57].

Post-processing requirements differed according to the anatomical region of the device. Bone-facing surfaces could retain controlled roughness or receive osteogenic treatments, whereas transmucosal and hygiene-critical regions required smoother finishing to reduce plaque retention and mucosal irritation. Screw holes and prosthetic connections required dimensional stability during support removal and polishing. Despite their importance, polishing protocols, surface roughness, heat treatment, cleaning, and sterilization were reported inconsistently [13,35,63,64].

Within the preclinically supported category, *in vitro* investigations suggested that modified Ti6Al4V surfaces could influence osteogenesis-related gene expression, osteoblast-like cell proliferation, extracellular matrix deposition, and mineralization. These findings supported differentiated treatment of bone-facing surfaces but did not establish that increased *in vitro* osteogenic activity translates into clinically relevant bone coverage or reduced exposure risk [63,65–67].

Scaffold-assisted bone regeneration was classified as an emerging concept. In a single animal study, a three-dimensionally printed polycaprolactone scaffold placed over a titanium subperiosteal framework was associated with bone deposition, providing proof of concept for biological coverage rather than evidence of conversion to endosteal-like behavior [68]. Clinical translation remains uncertain because the available study did not establish scaffold degradation kinetics or the associated local tissue response, including the potential for aseptic inflammation and local acidification caused by degradation products. Infection risk, vascularization, and the long-term remodeling and mechanical competence of the newly formed bone under functional cyclic loading also remain uncharacterized. Consequently, whether this regenerated tissue can provide durable load sharing, reduce framework exposure, or improve implant survival remains unknown.

Overall, the available evidence does not establish a universally superior material. Material performance depended on framework geometry, fixation, loading, prosthetic design, manufacturing, and post-processing. Titanium and Ti6Al4V were the only framework materials classified as clinically implemented on the basis of documented use in contemporary patient-specific SPIs. Performance claims concerning polymeric and ceramic alternatives remained computational hypotheses; titanium surface modifications were preclinically supported; and scaffold-assisted bone regeneration remained an emerging concept.

These categories indicate translational status and documented level of implementation rather than mature mechanical validation, comparative material quality, proven reliability, or clinical superiority. The principal findings are summarized in Table 4.

Table 4. Translational status of materials, manufacturing processes, and surface or scaffold-assisted strategies investigated for contemporary patient-specific subperiosteal implants.

Variable	Translational Category	Current Role	Potential Advantages	Main Concerns	Key Evidence
Titanium/Ti6Al4V	Clinically implemented	Most frequently documented clinical framework material	High strength-to-weight ratio; biocompatibility; manufacturable by laser-based additive manufacturing; compatible with surface treatments	Stress concentration in rigid frameworks; need for design optimization; surface finishing required	[12,13,28,35,36]
PEEK/PEKK/BioHPP	Computational hypothesis only	Alternative or prosthetic materials investigated mainly in FEA	Lower modulus; reduced weight; radiolucency; possible shock absorption	May increase displacement or stress in screws, bone, or framework depending on design	[43,44,47]
CFR-PEEK	Computational hypothesis only	Fiber-reinforced polymeric framework material investigated in FEA	Higher stiffness than unfilled PEEK; may reduce bone stress	Stress concentration in implant body or metallic substructure; limited experimental and clinical validation	[49]
Y-TZP/zirconia	Computational hypothesis only	Experimental high-stiffness framework or prosthetic material	Reduced bone stress in some FEA models; favorable esthetic and biological properties in other dental applications	Higher implant/framework stress; brittleness; uncertain fatigue behavior in screw-retained SPI frameworks	[47,48]
Cobalt–chromium	Computational hypothesis only	Prosthetic superstructure material in FEA	High stiffness; favorable stress distribution in selected prosthetic models	Weight, stiffness-related stress transfer, prosthetic-specific role rather than SPI framework standard	[20,47]
Laser powder-bed fusion, reported as SLM, DMLS, or LPBF	Clinically implemented; comparative process validation incomplete	Principal additive-manufacturing family for Ti/Ti6Al4V patient-specific frameworks; the terminology was inconsistently applied across studies	Complex patient-specific geometries; integrated screw holes and abutments; differentiated framework thicknesses; topology-optimized structures	No direct comparative evidence establishing the superiority of SLM-, DMLS-, or LPBF-labelled processes; inconsistent reporting of powder characteristics, build orientation, layer thickness, support strategy, heat treatment, surface finishing, and dimensional accuracy	[11–13,28,41,57]
Post-processing and polishing	Clinically implemented; incompletely standardized	Required after additive manufacturing	Improves transmucosal smoothness, fit, and plaque control	May alter geometry or surface properties; underreported in many studies	[13,35,63]
Surface treatments	Preclinically supported	Preclinical strategy for bone-facing regions	May improve osteogenic maturation, matrix deposition, and mineralization	Requires in vivo validation; rough surfaces may be unfavorable if exposed orally	[63]
PCL scaffold overlay	Emerging concept	Animal proof-of-concept only	Preclinical bone deposition over the	Single animal study; degradation-related inflammation and local acidification, infection	[68]

titanium frame-
work risk, and long-term bone re-
modeling under functional
loading remain unknown

Abbreviations: CFR-PEEK, carbon-fiber-reinforced polyetheretherketone; FEA, finite element analysis; PCL, polycaprolactone; PEEK, polyetheretherketone; PEKK, polyetherketoneketone; SPI, patient-specific subperiosteal implant; Ti, titanium; Ti6Al4V, titanium–aluminum–vanadium alloy; Y-TZP, yttria-stabilized tetragonal zirconia polycrystal.

3.6. Cross-Domain Validation Coverage and Evidence Gaps

Cross-domain mapping showed that evidence was concentrated in descriptive feasibility and comparative computational assessment. Digital planning and additive manufacturing were widely documented, but quantitative evaluation of registration, manufacturing deviation, and passive fit remained uncommon. Computational studies predominantly compared selected variables within single anatomical models and did not support direct aggregation of absolute stress values.

Only two records included direct experimental or cyclic mechanical testing, and no study prospectively linked patient-specific computational predictions with spatially corresponding clinical outcomes. The available evidence therefore does not support universal thresholds for framework dimensions, screw configuration, cantilever length, manufacturing deviation, or acceptable stress, nor does it allow reliable prediction of framework exposure, screw loosening, or fracture [69–71].

The explicit methodological domains used for descriptive appraisal are summarized in Table 5, together with the minimum information required to improve reproducibility. The framework covers anatomical realism, material assumptions, boundary and contact conditions, screw modeling, mesh convergence, loading realism, uncertainty analysis, and validation. These domains were used to identify recurrent reporting and interpretive limitations but were not combined into a methodological-quality score. The table distinguishes exploratory simulation from progressively stronger manufacturing, experimental, and clinically correlated validation without prescribing a single modeling method.

Table 5. Explicit methodological domains used for descriptive appraisal and minimum reporting of finite element and mechanical validation studies on patient-specific subperiosteal implants.

Methodological Domain	Explicit Descriptive Criteria and Minimum Reporting Items	Interpretive Relevance
Study objective and context of use	Primary mechanical question; clinical indication or anatomical scenario; intended use of the model; exploratory, comparative, optimization, or validation purpose; design variable tested; prespecified hypothesis when applicable.	Clarifies the intended use of the study and the strength of the conclusions that can reasonably be drawn.
Anatomical realism	Source of CT/CBCT or anatomical dataset; patient-specific or generic model; segmentation method and software; cortical and cancellous distinction; cortical-thickness representation; anatomical site; degree of atrophy or defect classification.	Determines whether the model represents the intended patient population and whether findings can be generalized beyond a single anatomy.
Prosthetic setup	Virtual wax-up; occlusal scheme; number and position of abutments; prosthetic material and geometry; restorative space; emergence profile; cantilever length; location and distribution of load-entry points.	Prosthetic design determines load entry into the SPI framework.
Implant design	Framework architecture; one-piece, two-piece, modular, or segmented design; framework thickness; mesh or solid regions;	Defines the geometry responsible for load transfer and stress distribution.

	fixation arms; abutment design; coupling elements; anchorage zones; posterior extension; topology or geometry optimization.	
Screw configuration and modeling	Number, diameter, length, location, and insertion angle of screws; cortical engagement; thread geometry or simplified representation; screw–bone interface; screw material; torque or preload assumptions; friction; justification of the selected configuration.	Screw fixation represents the principal bone–device interface and strongly influences stability, peri-screw stress, and load transfer.
Material assumptions	Material type and grade; source of mechanical properties; elastic modulus; Poisson ratio; yield strength; fatigue properties when available; homogeneous or heterogeneous representation; isotropic, orthotropic, or anisotropic assumptions; representation of cortical and cancellous bone quality.	Material assumptions directly influence predicted stress, strain, displacement, and the comparative ranking of competing designs.
Boundary conditions and constraints	Anatomical regions constrained; degrees of freedom restricted; representation of skeletal continuity and remote anatomical supports; fixation constraints; justification of boundary conditions; assessment of their influence on model stiffness.	Artificial or insufficiently justified constraints may alter global stiffness and produce non-physiological load-transfer patterns.
Contact and interface modeling	Bone–implant contact; screw–bone contact; framework–abutment contact; implant–prosthesis contact; bonded, frictional, sliding, separating, or interference assumptions; friction coefficients; contact separation; interface slip; representation of passive fit or initial gaps.	Contact definitions determine interface load transfer and the model's ability to represent micro-motion, separation, preload loss, and screw loosening.
Mesh and numerical quality	Element type and order; global and local element size; mesh density; refinement around screws, holes, contacts, abutments, and stress concentrations; mesh-convergence assessment; software and version; solver settings; numerical tolerances; verification against benchmark or analytical solutions when applicable.	Supports numerical reliability and distinguishes mechanically meaningful results from mesh-dependent stress peaks or solver artifacts.
Loading realism	Load magnitude, direction, location, duration, and distribution; unilateral or bilateral loading; vertical, oblique, anterior, posterior, and cantilever scenarios; muscle-force representation when applicable; justification using clinical or experimental data; bruxism, trauma, or cyclic loading when relevant.	Determines whether the predicted mechanical response is applicable to clinically plausible functional or parafunctional conditions.
Uncertainty and sensitivity analysis	Plausible ranges or distributions for bone properties, loading, contact parameters, screw fixation, and manufacturing deviation; sensitivity or probabilistic method; effect on outputs and design ranking.	Establishes whether conclusions remain robust when uncertain patient-specific and modeling inputs are varied.
Output variables	Component-specific stress and strain; displacement; peri-screw stress, strain, or micromotion; contact pressure; contact separation; interface slip; screw preload loss; prosthetic displacement; passive-fit gap; fatigue damage or predicted life; safety factor; probability of failure or other reliability measures.	Multi-component and failure-relevant outputs reduce the risk of drawing misleading conclusions from a single peak-stress value.
Decision criteria and limit states	Component-specific acceptance criteria; source and justification of thresholds; bone strain or damage limits; framework yield or fatigue limits; screw-loosening or interface-slip criteria; prosthetic displacement limits; passive-fit tolerances; safety or reliability targets; treatment of manufacturing variability and uncertainty.	Defines how computational outputs are converted into design decisions and prevents unsupported claims of mechanical safety or superiority.
Validation strategy	Analytical or benchmark verification; comparison with experimental strain, stress, displacement, or deformation measurements; static mechanical validation; fatigue testing; screw-loosening or removal-torque testing; dimensional or fit validation; comparison with intraoperative or clinical observations; level of agreement and acceptance criteria.	Distinguishes hypothesis-generating comparative models from quantitatively verified or clinically correlated predictions.

Mechanical and fatigue-testing protocol	Specimen and device configuration; number of specimens; control or comparator; test fixture; support conditions; load magnitude and rate; loading frequency; number of cycles; torque standardization; environmental conditions; run-out definition; predefined failure criteria; failure location and mode; reproducibility of the test setup.	Determines whether experimental findings are reproducible and representative of expected clinical loading and failure mechanisms.
Manufacturing details	Additive-manufacturing or milling technology; machine and process parameters; material grade; powder characteristics when applicable; build orientation; layer thickness; support strategy; post-processing; support removal; polishing; heat treatment; surface treatment; cleaning and sterilization; manufacturing-specific material properties.	Manufacturing and post-processing affect dimensional accuracy, passive fit, fatigue resistance, surface characteristics, and reproducibility.
Dimensional accuracy and passive-fit assessment	Comparison between the original CAD model and manufactured device; digital deviation analysis; signed or absolute deviation maps; local deviations at fixation arms, screw holes, and abutment platforms; printed anatomical model; intraoperative seating method; rocking or gap assessment; bone-reduction guide; predefined region-specific acceptance criteria.	Passive adaptation is essential for fixation-based stability because local gaps or seating errors may produce non-uniform preload and screw loading.
Biological interface considerations	Mucosal thickness; soft-tissue coverage; framework prominence; transmucosal surface finish; bone-facing surface characteristics; hygiene access; plaque-retentive regions; vascular and anatomical constraints; exposure-prone regions; relationship between mechanical design and biological complications.	Mechanical optimization must account for soft-tissue protection, hygiene accessibility, framework exposure, and other clinically relevant biological consequences.
Reporting completeness and reproducibility	Availability of anatomical and CAD models; description of pre-processing and analysis workflow; software and version; sources of material properties; explicit reporting of assumptions; access to input data, meshes, code, or supplementary files when possible; sufficient methodological detail to reproduce the analysis.	Complete reporting permits independent reproduction, comparison across studies, and identification of whether conflicting findings arise from design or methodological differences.
Limitations	Simplified anatomy or material assumptions; single anatomical model; idealized contacts; simplified screw threads or absent preload; static rather than cyclic loading; missing mesh convergence; missing sensitivity or uncertainty analysis; missing fatigue assessment; absence of experimental or clinical validation; uncertainty in clinical translation.	Makes the scope, credibility, and translational limitations of the conclusions transparent.

Abbreviations: CBCT, cone-beam computed tomography; CT, computed tomography; FEA, finite element analysis; SPI, patient-specific subperiosteal implant.

Evidence maturity differed substantially across engineering domains. Table 6 provides an analytical matrix combining the operational definition of each stage, the number of contributing records, the corresponding level of evidence maturity, and the principal remaining gap. Unlike the mutually exclusive primary-category counts reported in Table 1, these stage-specific counts identify validation activities that could occur within more than one study type. They are therefore not mutually exclusive and should not be summed.

Table 6. Cross-domain evidence-maturity matrix for the mechanical validation of patient-specific subperiosteal implants.

Engineering Domain or Stage	Operational Definition	Number of Records	Evidence Maturity	Principal Remaining Gap
Digital workflow or technical development	Primary focus on imaging, segmentation, data integration, CAD design, manufacturing workflow, guides, or surgical transfer	11	Descriptive feasibility	Registration error, dimensional deviation, passive fit, and workflow reproducibility rarely quantified
Computational simulation	FEA or another computational method used as the primary study design	22	Comparative computational evidence	Predominantly static, single-model analyses with limited sensitivity, experimental, or clinical validation
Formal or iterative design optimization	Explicit topology optimization or iterative redesign informed by computational results	2	Limited optimization evidence	Few studies evaluated robustness to anatomical, loading, material, or manufacturing uncertainty
Quantitative manufacturing and fit validation	Complete protocol combining dimensional or deviation measurement with predefined mechanical or clinical acceptance criteria	0	Evidence gap	No complete tolerance-validation protocol linking manufactured deviation with passive fit or mechanical consequences
Direct experimental mechanical validation	Static testing, cyclic testing, screw-stability testing, or comparison between predicted and measured mechanical behavior	2	Very limited experimental verification	Available findings are specific to individual devices, materials, connections, and test protocols
Cyclic or fatigue testing	Repeated loading used to assess framework fatigue or screw-connection stability	2	Very limited fatigue evidence	No standardized fatigue protocol or validated relationship with expected clinical service conditions
Clinically based engineering evidence	Clinical report with extractable information on design, fixation, manufacturing, complications, or device-specific technical behavior	21	Descriptive clinical evidence	Technical variables and spatial complications were rarely linked with mechanical predictions
Direct computational–clinical correlation	Patient-specific computational prediction explicitly compared with spatially corresponding mechanical or clinical outcomes	0	Evidence gap	No prospective model-to-outcome validation
Material, surface, or scaffold investigation	Primary in vitro, translational, surface-characterization, or animal investigation	5	Preclinical or early translational evidence	Limited device-level mechanical, fatigue, and clinical correlation

Note: Validation stages were non-exclusive, and individual studies could contribute to more than one stage. Therefore, these counts should not be interpreted as cumulative progression, mutually exclusive evidence levels, or independent sample sizes.

4. Evidence-Informed Mechanical Validation Pathway

4.1. Purpose and Scope

The proposed pathway is an author-developed, evidence-informed conceptual model derived from the evidence mapped in this scoping review. Its individual domains and validation stages were identified from the included computational, experimental, manufacturing, translational, technical, and clinically based studies, while their organization into an integrated development sequence required interpretive synthesis by the authors. The pathway therefore combines evidence synthesis with author interpretation; it does not represent a formal expert-consensus statement, an empirically validated

development model, a prescriptive engineering standard, or a practical clinical recommendation. Its purpose is to organize the available evidence, identify missing transitions, and illustrate the validation activities required to progress from anatomical feasibility and comparative computational assessment toward manufacturing verification, experimental device testing, and clinically correlated validation. The stages describe coverage and gaps within the current evidence base rather than the methodological quality of individual studies.

4.2. Design Inputs and Candidate Generation

Development begins with definition of the clinical, prosthetic, anatomical, and maintenance requirements. CT or CBCT data provide the skeletal model, while intraoral scans, diagnostic casts, facial scans, or virtual wax-ups define the prosthetic envelope. Registration should identify potential anchorage regions, protected anatomical structures, soft-tissue constraints, and the intended abutment positions (Figure 2). Maintenance requirements, including hygiene access, prosthetic retrievability, abutment spacing, and management of possible framework exposure, should be considered from the outset [72,73].

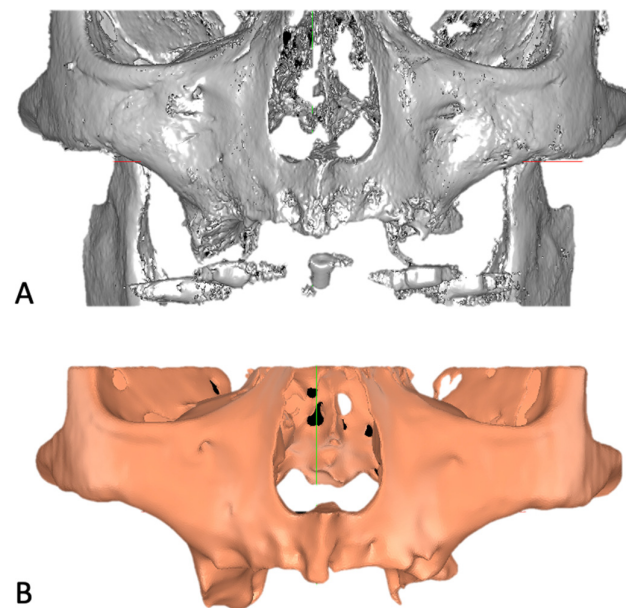


Figure 2. Image-based anatomical reconstruction and segmentation for patient-specific subperiosteal implant planning. (A) Three-dimensional reconstruction of the maxillofacial skeleton from CT/CBCT data before digital refinement. (B) Segmented and digitally processed maxillary model after anatomical reconstruction and surface refinement.

The prosthetic setup defines tooth position, occlusal plane, restorative space, emergence profiles, and functional load-entry points. The framework must therefore reconcile the planned restoration with anatomically available regions for stable multivectorial fixation (Figure 3) [9,11,27].

These inputs should generate alternative candidate designs rather than a single definitive geometry. Candidates may differ in anchorage, framework architecture or thickness, screw configuration, abutment distribution, segmentation, posterior extension, or cantilever length, allowing design choices to be compared before manufacturing (Figure 4).

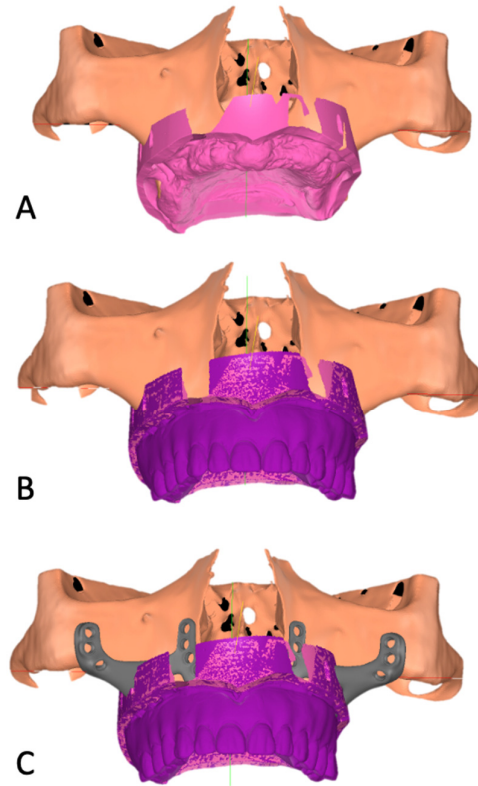


Figure 3. Prosthetically driven reverse planning and initial framework design. (A) Superimposition of the gingival scan onto the segmented maxillary anatomy. (B) Refined digital prosthetic setup after DICOM–STL integration, defining tooth position, occlusal plane, restorative space, and the ideal emergence profile of the transmucosal abutments. (C) Initial patient-specific subperiosteal implant framework designed according to the prosthetic plan and residual maxillary anatomy, with fixation arms extended toward stable buttress areas and screw holes positioned to support multivectorial fixation.

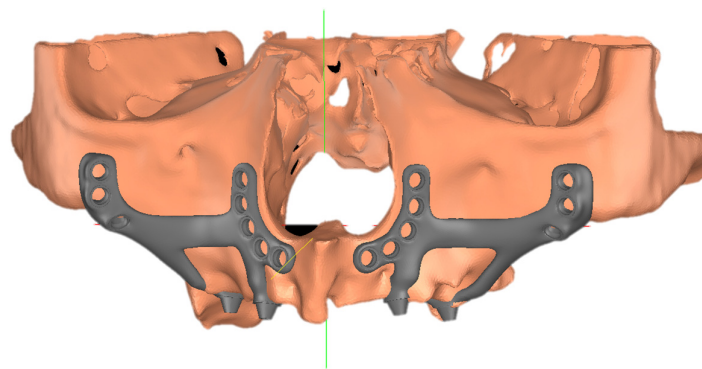


Figure 4. Patient-specific subperiosteal implant framework after CAD design.

4.3. Iterative Optimization, Manufacturing, and Validation

Candidate designs should be compared under clinically plausible vertical, oblique, unilateral, cantilever, parafunctional, or traumatic loading, as appropriate to the indication. Evaluation should include component-specific stress, strain, displacement, fixation behavior, and fatigue-relevant outputs across the framework, peri-screw bone, screws,

abutments, connections, and prosthetic components. Modeling and reporting should follow Table 5.

Computational findings should guide targeted modifications of fixation, local reinforcement, framework volume, screw geometry, abutment position, cantilever, or architecture. Topological optimization and detailed screw–bone modeling may be appropriate when framework efficiency or fixation behavior is the primary outcome [15,57]. Optimization should balance bone response, framework and connection resistance, screw stability, prosthetic displacement, passive fit, manufacturing tolerance, soft-tissue coverage, surgical access, and maintainability rather than minimize a single peak-stress value.

The selected design should undergo manufacturing and fit verification before mechanical testing proportionate to its novelty and intended use. Quality control should assess dimensional deviation, screw holes, prosthetic connections, seating, and region-specific surface finishing. Novel architectures, fixation systems, or materials require stronger verification through sensitivity analysis, static testing, cyclic or fatigue assessment, screw-stability testing, and comparison between predicted and measured behavior. Vanaclocha et al. [41] and Vörös et al. [58] provide the limited current examples of this progression.

4.4. Clinical Implementation and Feedback

Surgical transfer should document framework seating, screw sequence and torque, intraoperative adjustments, and concordance between planned and achieved prosthetic positioning. Surgical or bone-reduction guides may be used according to device complexity.

Follow-up should record mechanical, biological, and prosthetic events according to their anatomical location. Where computational data are available, these events should be compared with predicted critical regions, fixation characteristics, and soft-tissue constraints. Figure 5 presents an author-developed, evidence-informed conceptual model derived from the validation stages and cross-domain gaps identified in the included literature. It is not intended to represent a validated clinical guideline, regulatory standard, or prescriptive sequence for device development. The pathway should therefore be interpreted as a research and reporting framework rather than as a recommended clinical workflow.

Figure 5 visualizes both the concentration of evidence in descriptive and computational stages and the discontinuities toward manufacturing, experimental, and clinical validation. The zero counts for complete tolerance validation and direct model–outcome correlation identify evidence gaps rather than an absence of clinical or manufacturing activity. Accordingly, these stages represent priorities for future validation and not established components of current SPI development.

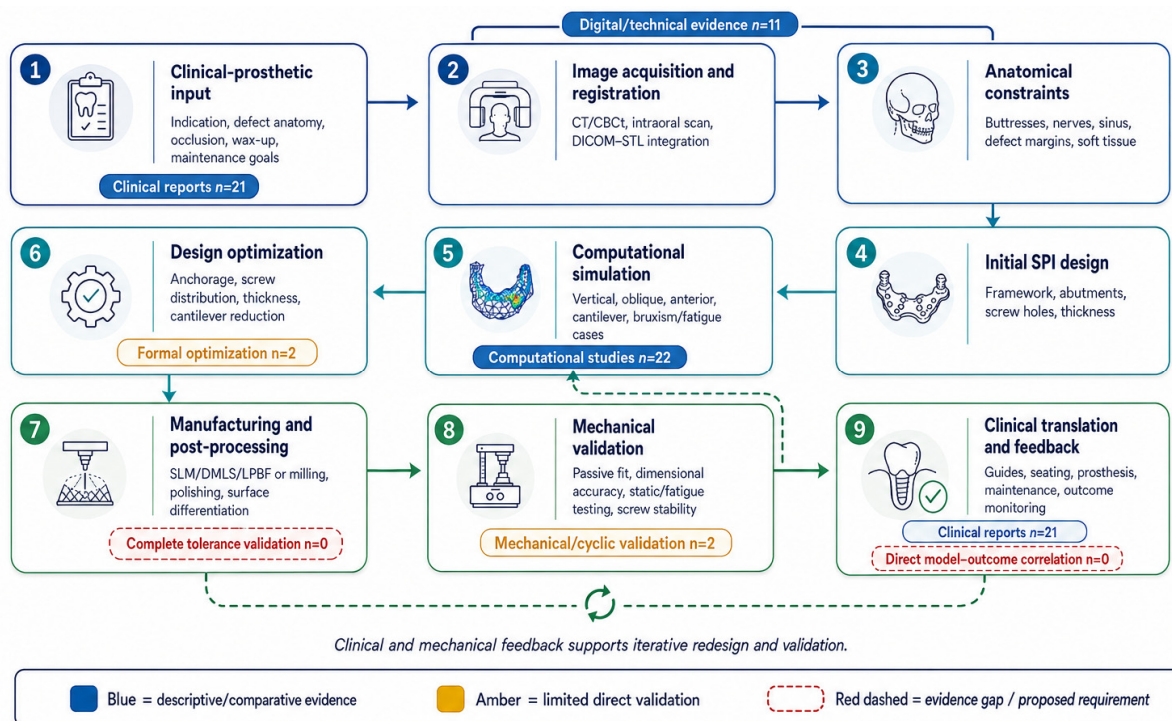


Figure 5. Author-developed, evidence-informed conceptual model of the mechanical validation pathway for patient-specific subperiosteal implant development. The model was constructed by integrating the engineering stages identified in the scoping-review evidence synthesis and should not be interpreted as a validated clinical guideline, consensus statement, or prescriptive design standard. Numbers indicate records explicitly contributing to each non-mutually exclusive engineering stage. Blue labels identify descriptive or comparative evidence, amber labels identify limited direct validation, and red dashed labels identify stages for which no qualifying study was found.

5. Discussion

5.1. Principal Findings and Interpretation

The central contribution of this review is a cross-domain mapping of mechanical-design maturity rather than another description of the SPI digital workflow. Table 6 demonstrates the mismatch between broad descriptive and computational activity and limited validation: 22 records used computational simulation, only two included direct experimental or cyclic testing, and none directly correlated patient-specific computational predictions with corresponding clinical outcomes. The proposed pathway therefore represents both available evidence and missing transitions rather than an empirically validated universal workflow.

Contemporary SPIs function as anatomically adapted, screw-fixed load-transfer devices whose performance depends on the coupled behavior of the prosthesis, abutments, framework, fixation, and supporting cortical anatomy. The computational evidence indicates that design changes redistribute mechanical demand across these components rather than improving all outcomes simultaneously. Consequently, device performance cannot be inferred from survival, a single peak-stress value, or the response of one component alone. The comparison between one-piece and modular or two-piece frameworks illustrates why apparently conflicting findings require component- and context-specific interpretation. In a static maxillary model, a dual configuration produced lower reported stress values than the corresponding monoblock design [16]. Conversely, in an atrophic mandibular model under functional loading, bone, screw, and prosthetic stresses were similar

between the configurations, whereas the two-piece framework developed more than twice the framework stress of the single-piece design [53]. In the six-design maxillary comparison by Dere and Findik [21], mesh-type frameworks reduced cortical tensile stress to 12.6–13.7 MPa under 150 N vertical loading, compared with 14.9–25.2 MPa in non-mesh designs. However, within the mesh configurations, implant stress was 153.6 MPa in the two-piece design and 96.1 MPa in the single-piece design. Selected two-piece configurations also produced more balanced component-level stress distributions in a total-maxillectomy model, but these findings were specific to an anatomically discontinuous defect and its associated fixation and loading conditions [54]. These differences arise because segmentation does not act as an isolated variable. A continuous one-piece framework increases global rigidity and distributes load without connector discontinuities, which may reduce framework and interface stress, but it can transfer a greater proportion of mechanical demand to the fixation sites or supporting bone and is more sensitive to cumulative manufacturing and seating errors. Segmenting the framework can facilitate insertion, reduce the consequences of global misfit, and allow each side to adapt or be managed independently, but it interrupts structural continuity and may concentrate stress at connectors, junctions, or locally loaded framework regions. The observed outcome therefore depends on anatomical continuity, anchorage distribution, connector geometry, passive fit, load direction, and whether the reported endpoint concerns bone, framework, screws, abutments, or prosthetic components. Current evidence consequently does not identify a universally preferable clinical configuration. When accurate passive seating and surgical insertion of a continuous framework are feasible, a one-piece design may be mechanically preferable because it avoids connector-related stress and fatigue vulnerability. Modular or segmented designs may be preferable in anatomically complex or asymmetric defects, restricted insertion pathways, or situations requiring independent component management, provided that connector strength, preload stability, and fatigue behavior are specifically verified. These conditional preferences represent an engineering interpretation of the available evidence rather than validated clinical recommendations.

Methodological heterogeneity limits comparison of absolute FEA outputs across studies, and most simulations remain most defensible as within-model comparisons [14,15,41,50]. Clinical and computational evidence also remain disconnected: clinical reports rarely include patient-specific mechanical or manufacturing measurements, while computational studies rarely correlate predicted critical regions with subsequent complications. Neither evidence stream alone therefore establishes mechanical superiority.

5.2. From Finite Element Outputs to Decision-Relevant Design Criteria

The translation of FEA results into clinical or design decisions requires a clearly defined context of use. A model used to screen candidate geometries does not require the same level of predictive credibility as a model used to justify a patient-specific design without experimental testing. Model verification, validation, uncertainty characterization, and the consequences of an incorrect decision should therefore be proportional to the intended use of the simulation [74]. The principal assumptions used in current SPI models directly restrict their clinical interpretation [14,15,50]. Homogeneous and isotropic bone models suppress spatial variations in cortical thickness, density, anisotropy, and local screw purchase and may therefore obscure mechanically vulnerable regions in severely atrophic or reconstructed jaws. Bonded or otherwise simplified screw–bone interfaces prevent simulation of thread engagement, frictional slip, contact separation, loss of preload, progressive cortical damage, and screw loosening. Static loading represents an instantaneous mechanical condition but cannot reproduce accumulated fatigue damage, time-dependent preload loss, repeated parafunctional loading, or progressive interface deterioration. Ideal fixation and perfect bone–framework adaptation disregard

manufacturing deviation, incomplete seating, local gaps, surgical repositioning errors, and non-uniform screw tightening, all of which may substantially alter load transfer in the implanted device. Consequently, the absolute stress, strain, or displacement values generated by these models should not be interpreted as patient-specific safety thresholds or direct predictors of exposure, screw loosening, framework fracture, or clinical survival. Most current SPI models are most defensible for relative within-model comparison of design alternatives. Stronger clinical interpretation requires sensitivity analysis, uncertainty quantification, manufacturing and mechanical verification, and correlation with spatially corresponding clinical outcomes [74,75].

Uncertainty in bone properties is a major obstacle to absolute interpretation. Predicted peri-screw stress and strain depend on cortical thickness, local density, elastic modulus, anisotropy, cancellous support, and the representation of screw purchase [14,15,76]. These variables are particularly uncertain in severely atrophic, irradiated, reconstructed, or previously operated jaws. Current SPI studies rarely quantify how variation in these inputs affects either the magnitude of the predicted response or the ranking of competing designs. Future studies may evaluate anatomically justified ranges or probability distributions through sensitivity analysis or probabilistic methods to determine which inputs most strongly influence model outputs [75,77]. Such analyses could help determine whether comparative design findings remain stable across plausible combinations of bone properties and loading conditions.

A universal clinically relevant threshold for manufacturing deviation cannot currently be derived from the SPI literature. Global mean or root-mean-square deviation alone may be misleading because the mechanical consequence of an error depends on its location and direction. A deviation may be relatively inconsequential in an unloaded framework region but critical if it produces rocking, loss of passive seating, screw-axis mismatch, a gap beneath a fixation arm, altered abutment position, or non-uniform preload during screw tightening [13,41]. More informative manufacturing studies would report signed deviation maps and region-specific deviations at fixation arms, screw holes, abutment platforms, and other load-bearing regions. Any future acceptance criteria would need to be device- and region-specific and supported by tolerance, seating, and mechanical verification [74]. Until such relationships are validated, no single deviation value should be presented as a universal clinical tolerance.

Conversion of FEA outputs into practical design thresholds also requires component-specific limit states. Relevant criteria may include principal strain or strain-energy measures in cortical bone, equivalent stress and fatigue damage in the metallic framework, loss of screw preload or interface slip, peri-screw micromotion, prosthetic displacement, connection deformation, and passive-fit gaps [41,58]. Each threshold should be justified using appropriate material data, mechanical testing, manufacturing-specific properties, or clinical correlation. Comparing a peak von Mises stress with a nominal material yield strength is insufficient when fatigue, surface condition, additive-manufacturing defects, residual stress, stress gradients, or connection behavior may govern failure [78,79].

Current FEA studies are not capable of reliably predicting the principal clinical failure modes of SPIs. Framework fracture could potentially be estimated when validated material properties, manufacturing defects, residual stresses, stress concentrations, cyclic loading, and fatigue-life models are incorporated, but these elements are rarely combined. Screw loosening requires explicit representation of preload, friction, thread engagement, contact separation, cyclic loading, and loss of cortical purchase; static bonded-interface models cannot reproduce this process [15,58].

Framework exposure is even less amenable to prediction from mechanical stress alone because it also depends on mucosal thickness, vascularity, flap design, surface finish, hygiene access, infection, scar tissue, radiotherapy, and framework prominence

[72,80,81]. Current simulations can therefore identify mechanically vulnerable regions and generate hypotheses, but they cannot assign reliable patient-specific probabilities of exposure, loosening, or fracture.

Potential future developments include multi-objective optimization, uncertainty quantification, and reliability-based design, which may help evaluate trade-offs among bone protection, framework fatigue resistance, screw stability, prosthetic requirements, device volume, and soft-tissue constraints [57,74,75]. However, these approaches remain largely conceptual in the SPI field and require validated mechanical inputs, experimentally supported limit states, and prospective clinical data. Patient-specific risk prediction should therefore be regarded as a longer-term research direction rather than an immediately applicable design or clinical tool. These approaches are presented as potential research directions and not as currently validated or immediately feasible components of routine SPI development.

5.3. Implications for Research and Translation

The translational classification reinforces the distinction between documented clinical implementation and computational plausibility. Titanium and Ti6Al4V frameworks and their established additive-manufacturing pathways were categorized as clinically established, although this designation does not imply that individual designs, manufacturing tolerances, fixation configurations, or fatigue performance have been comprehensively validated. In contrast, performance claims concerning PEEK, PEKK, CFR-PEEK, zirconia, Y-TZP, and alternative prosthetic materials were categorized as computational hypotheses only [20,43,44,47–49]. These studies demonstrate material-dependent redistribution of stress but do not establish equivalent fatigue resistance, connection reliability, manufacturability, or clinical durability. Alternative materials should therefore be regarded as design hypotheses requiring experimental qualification rather than as clinically interchangeable substitutes.

Titanium surface modifications were categorized as preclinically supported because their potential benefits were derived principally from in vitro evidence [63,66,67]. Scaffold-assisted bone regeneration was categorized as an emerging concept because the available evidence was limited to an animal proof-of-concept [68]. Biological activity or bone deposition in a preclinical model does not demonstrate protection against framework exposure or long-term mechanical stability. Further preclinical evidence is required before these strategies can be linked to reduced framework exposure or improved long-term mechanical stability.

Clinical translation will require prospective studies linking computational predictions and manufacturing measurements with spatially corresponding mechanical, prosthetic, and soft-tissue outcomes. Standardized multicenter data collection may subsequently help distinguish patient-specific events from recurrent design-related failure patterns.

5.4. Strengths and Limitations of the Review

A strength of this review is the integration of computational, experimental, manufacturing, biological, technical, and clinically derived evidence within a single engineering-oriented synthesis. This broad scope was necessary because no individual evidence stream adequately represents the complete development pathway of a patient-specific SPI. Separating the evidence by methodological domain also made it possible to distinguish clinical feasibility from computational plausibility and experimental validation.

Several limitations should be considered. Consistent with the scoping-review design, no formal risk-of-bias assessment or certainty grading was performed [31]. The inclusion of heterogeneous study types allowed broad evidence mapping but prevents direct

comparison of methodological quality and clinical effectiveness. Quantitative pooling was not appropriate because anatomical models, implant designs, material assumptions, loading conditions, numerical methods, validation strategies, and outcome measures differed substantially.

The number of publications should also not be interpreted as an equivalent number of independent device concepts or patient populations. Some reports originated from related research groups, implant-development pathways, or potentially overlapping clinical cohorts. Although companion publications were retained when they contributed distinct engineering information, this clustering may give a greater impression of independent replication than the evidence supports.

Terminological inconsistency between “subperiosteal,” “juxta-osseous,” “patient-specific,” “custom-made,” and system-specific implant names may have affected retrieval despite the broad search strategy and supplementary citation tracking. In addition, incomplete technical reporting frequently limited extraction of geometry, screw, contact, mesh, manufacturing, and validation parameters. Publication bias toward favorable computational or clinical outcomes cannot be excluded.

Accordingly, the proposed reporting checklist and engineering framework should be interpreted as structured outputs of evidence mapping, not as validated design standards or clinical recommendations. Their purpose is to make assumptions explicit, improve comparability, and define the evidence required to progress from patient-specific feasibility to reproducible mechanical and clinical validation.

6. Conclusions

Contemporary patient-specific SPIs should be regarded as fixation-based medical devices whose performance depends on the interaction of prosthetic loading, anatomical anchorage, framework architecture, screw fixation, material behavior, manufacturing accuracy, soft-tissue conditions, and maintenance. Current computational evidence supports comparison of design relationships within defined models but not universal prescriptions or patient-specific prediction of clinical failure.

Titanium and Ti6Al4V remain the only clinically implemented framework materials identified in the contemporary SPI literature, although this documented clinical use should not be interpreted as evidence of complete mechanical validation or established long-term reliability. Alternative materials and biological strategies remain at computational, preclinical, or emerging stages.

This review maps the discontinuities between anatomical feasibility, computational comparison, manufacturing verification, experimental testing, and clinical correlation. Its evidence map, reporting checklist, and evidence-informed pathway are research tools intended to improve reproducibility and progression toward validated device development; they are not prescriptive design standards or clinical guidelines.

Supplementary Materials: The following supporting information can be downloaded at <https://www.mdpi.com/article/10.3390/app16157721/s1>, Supplementary Document S1: Internal protocol for the scoping review; Table S1: PRISMA-ScR Checklist; Table S2: Electronic search strategies.

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