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Waghmare Vaibhav Sanjiv
Department of Physics, Sanjeevanee Mahavidyalaya, Chapoli, Chakur Taluka, Latur, Maharashtra, India

Corresponding Author:
Waghmare Vaibhav Sanjiv
Department of Physics, Sanjeevanee Mahavidyalaya, Chapoli, Chakur Taluka, Latur, Maharashtra, India

Physics-Guided Design of Low-Cost Biomaterials for Bone Repair

Waghmare Vaibhav Sanjiv

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Abstract
In developing countries, the costs of implant, the continuity of supply, and the ability to test in a standardized manner have a direct bearing on the results of the patients suffering from such conditions. Through physics-guided (mechanobiology-aware) biomaterial design, the reader can discover a principled route to developing low-cost solutions for bone repair which connects measurable physical stimuli (strain, stress, fluid flow) to differentiation outcomes and thus to performance targets for scaffolds/implants. The paper describes fundamental mechanobiological modelling and scaffold structure-property principles for a unified construct for designing low-cost bone substitutes that are clinically usable in India. A proposed workflow consists of several scales that deploy computational models based on mechanoregulation of defect microenvironments as the starting point. In converting the predicted healing trajectories into scaffold and or biomaterial architecture specifications (porosity, stiffness, degradation, and bioactivity), it streams the verification of product performance using a harmonized test matrix of mechanical and biological evaluation based on ISO or ASTM requirements baseline. Discussion takes place on material choices of calcium phosphate bioceramics, calcium phosphate cements, bioactive glasses, polymer/bioceramic composites with an affordability perspective for certain scalable processing routes. Lastly, design verification and risk management steps are mapped to MDR-2017 and bio-compatibility of medical devices in the Indian context. Relevant evidence packages have been suggested for clinically relevant indications such as traumatic loss of bone and fragility fracture defects. With the planning design framework helps in reduction in trial/error-based development.

Keywords: Mechanobiology, bone substitute, scaffold design, finite element modeling, calcium phosphate, bioactive glass, mechanical testing, ISO 10993, CDSCO, India

1. Introduction
Bone is a complex of materials whose functional performance depends on organization across many frequency scales. Trabeculae in cancellous bone and osteons in cortical bone are formed from the collagen fibrils and lamellae that are mineralized. Whole-bone geometry is further elaborated from the trabecular network or cortex formed in turn. One cannot understand bone's mechanical competence, or engineer it, based on chemistry alone (Currey, 2002; Rho *et al*., 1998) [23, 22].

Only in the right biological-mechanical environment, with constant adaptation of the loading and boundary conditions, can adequate repair of disturbed bone take place. Such disturbance can occur due to trauma, infection, tumor resection, or within a fragility fracture. Bone graft substitutes (Finkemeier, 2002; Giannoudis *et al*., 2005) [11, 8]. In many indications autograft remains the reference standard. Despite this however, limited availability, donor-site morbidity and additional operative burden raise concerns. Nonetheless, the clinical performance tends to be variable because many products are developed or positioned primarily as “materials” optimised for their composition, or their in vitro bioactivity rather than as players in a mechanobiological milieu where fixation stability, local strain states, and transport conditions regulate tissue differentiation and maturation.

National and academic reports on road traffic injuries identify them as a common cause of fractures and trauma disabilities, suggesting a sustained need for a treatment workflow and adjunctive care measures like reliable bone void fillers and defect management (MoRTH, 2023; TRIP Centre, IIT Delhi, 2023). Design specifications for contextually relevant protocols and biomaterials that can provide good and reliable functioning in a variety of clinical settings (ICMR, 2010, 2021) are provided by the fragile fracture care protocols and

Indian populations bone health references. In a scenario where low cost does not imply minimal, the low-cost devices and concoctions must be value-for-money, plausibly safe and effective with plausible mechanistic rationale, documented and standard mechanicobiological testing and documentation package for regulatory scrutiny and clinical uptake (CDSCO,2017, 2023). Physics-guided design provides a logical pathway to achieve this goal via strengthening development using three complimentary pillars. On the one hand, mechanoregulation concepts provide a causal link from loading to predicted healing outcomes (Claes & Heigele, 1999; Prendergast *et al*., 1997) [1, 3] through physically tractable stimuli local strain and stress states that drive tissue differentiation events during repair.

Due to the increasing use of medical implants, the demand for ideal implant material is more urgent than ever. Titanium alloys have been widely used for over a century in orthopedic, dental and craniofacial implants. The material is aptly named "the implant metal" thanks to its helpful properties. What makes titanium so ideal and how does it compare with other implant materials? In the following article we will discuss all these questions and also see the common applications of titanium alloy in medical sectors.

2. Conceptual Framework: Physics-Guided Bone Repair Design

2.1 Mechanobiological basis of bone healing

Many factors interfere during the healing of fracture bone and critical-size defects. The mechanical and biological environment impact the healing of fracture or bone defect. This setting comes into being for the interactions occurring between mechanical stimuli with cellular and further chemical processes. Thus, it can be deduced that such tissue differentiation is directed by these stimuli.

Moreover, we can observe their ongoing impact on the recovery of fractures. We can observe this through the computational modeling of fracture healing in various ways. Initially, we will review the foundational mechanoregulation theories. Theories that latent fluid and macrophage signaling are together a latent possible source of inflammation.

They promote the differentiation of mesenchymal lineage cells into fibrous tissue, cartilage, or bone. For example, we have the original proposition of Prendergast *et al*. in 1997 [3] that looks into a dual phase continuum with the solid mesenchymal composite phase. We also observe the impact of incompressible interstitial fluid action on the phase's surface.

We further study lowers magnitude of these biophysical stimuli result in intramembranous ossification. Intermediate levels aid in developing a cartilage intermediate along with endochondral bone formation. On the other hand, fibrous tissue develops with high magnitude.

There is substantial experimental and clinical evidence support for the notions outlined in the previous section. Claes and Heigele successfully showed in 1999 that local stress-strain.

2.2 Scaffold architecture as a mechanical-biological "controller"

The scaffold serves as a mechano-biological controller inside a bone defect. It regulates the transfer of loads, which affects the cells' local environment. The porosity, pore size distribution, interconnectivity, and effective stiffness of an architectural feature all influence the permeability, nutrient and oxygen transport, and local mechanical stimuli. Many researchers have emphasized that these attributes regulate tissue growth pathways (Hollister, 2005, Karageorgiou and Kaplan (2005)). [3, 20]

A key challenge in scaffold design is the conflict between biological and mechanical demands. When porosity is increased, it will make mass transport easier and leave some space for vascular and tissue ingrowth. According to Gibsson and Ashby (1997) [25], increasing porosity lowers stiffness and strength. That is the reason for the need to balance.

If the scaffold is made too stiff, this will give rise to stress shielding and consequent problems in remodelling. When stiffness is inadequate, the issue is insufficient mechanical stimulus and, more significantly, the inability to develop stable implant-tissue interface, particularly in load bearing applications. The design requirement is that we should obtain mechanical compatibility and not strength. Consequently, our goal is not to optimize strength, but instead to select stiffness values that will maintain stability and allow physiological loading to stimulate bone formation. The approach of employing a scaffold architecture that varies in density (or porosity) in a spatially heterogeneous manner is called graded architecture.

2.3 Material classes for cost-effective bone substitutes

The choice of material is important for designing cost-effective bone repair materials relying on mechanobiological principles. Calcium orthophosphates are bioceramics class of material which is osteoconductive and has a chemical similarity to natural bone's mineral particle (Dorozhkin, 2010) [26]. The usefulness of calcium phosphates is also extended to calcium phosphate cements which offer injectability and moldability functionalities. The advantages allow small defect fillings minimally invasively (the formulation can be injected and set in place within the tissue defect). Achieving intimate contact of defect filling with defect surrounding bone.

Another significant group is bioactive glasses which allow for the creation of a strong chemical bond with the bone. The excellent osteogenic and angiogenic stimulation properties of bioactive glasses are thought to arise from the release of biologically active ions. The presence of brittleness, which jeopardizes the use in mechanically loaded regions, reflects their excellent bioactivity. Composite materials that involve either polymers with bioactive ceramics or ceramics with bioactive polymers can modify the bioactivity of materials while simultaneously enhancing other properties such as toughness, processability, damage tolerance etc. (Rezwan *et al*., 2006) [21]. Natural polymers chitosan and silk fibroin are convincing material choices within low- and middle-tech applications.

3. Methods: A Physics-Guided Workflow for Low-Cost Biomaterial Design

This section presents a *research-ready workflow* (computational + experimental) that can be implemented as an academic study or a translational R&D program.

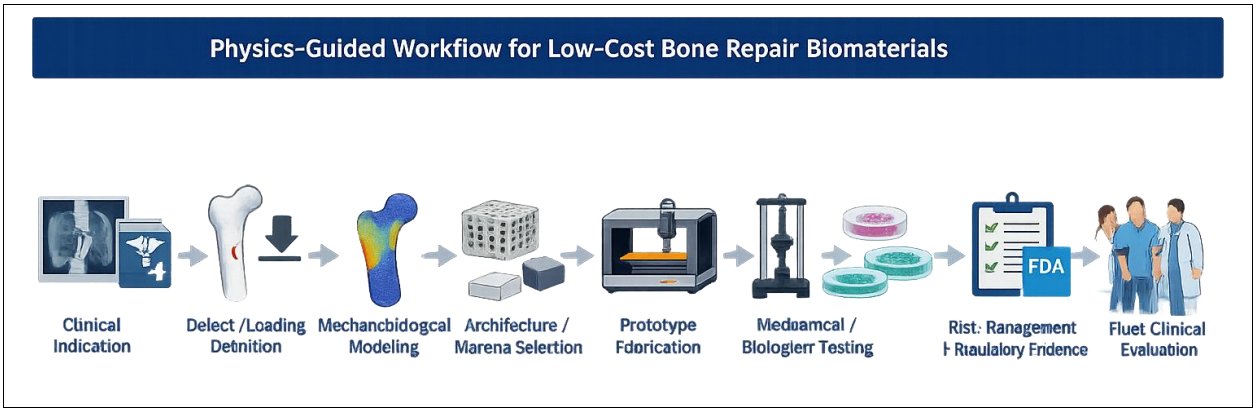

Fig 1: Physics-Guided Workflow

3.1 Step 1: Clinical indication and defect environment specification

According to Giannoudis *et al*., the design always starts with an indication such as metaphyseal void filler, segmental defect adjunct, non load bearing craniofacial defect (Grado *et al*., 2018) [14]. The kind of fixation type, gap size and anticipated loading or patient factors will determine the biomechanics of a defect. In India, it is better to select things based on commonality and high-impact injuries (e.g. trauma defects) and fragility fracture voids.

3.2 Step 2: Mechanobiological computational model

The finite element model of the defect region and fixation estimates provides spatial fields of strain/stress and potentially fluid flow. Subsequently, according to a mechanoregulation law, a predicted tissue phenotype (Prendergast *et al*., 1997; Lacroix & Prendergast, 2002) [3, 2] is arrived at through time from the local stimuli. The results from the modeling will aid in deciding the stiffness and architecture of the scaffold to direct the stimuli into windows which "foster bone formation". Literature reviews on the subject discuss dependable parameterisation and validation or control to avert conclusions that are too confident. (Ghiasi *et al*., 2017; Carlier & Geris, 2015) [4, 5].

At a minimum, the projected modeling outputs are: The distribution of Interfragmentary strain, the predicted tissue differentiation fibrous cartilage bone map, the Sens.

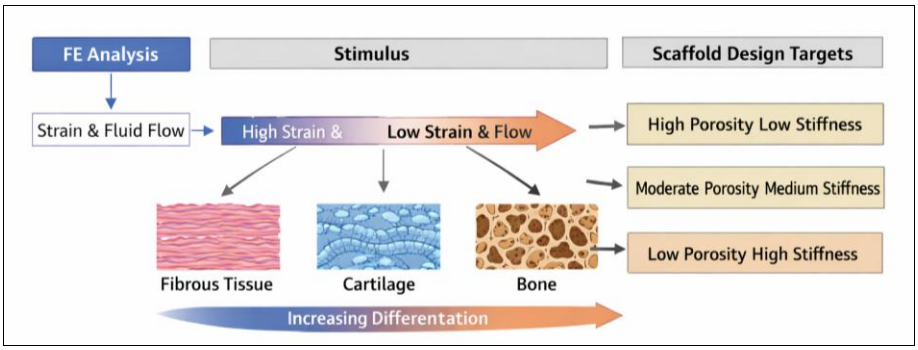

Fig 2: Mechanoregulation Model Schematic

3.3 Step 3: Scaffold architecture selection using structure-property relations: Theoretical examination of cellular solids (Gibson & Ashby, 1997) [25] shows that the compressive modulus and compressive strength scale with relative density, while porosity is a trade-off on stiffness. The design features (such as porous layers, lattice strurs, or foamy microstructures) can be designed in such a way that stability gets localized

Table 1: Physics-guided design requirements for low-cost bone repair scaffolds

Requirement	Physical/biological rationale	Practical target (illustrative)	Evidence basis
Mechanical stability	Excessive strain risks fibrous tissue/non-union	Architecture tuned to reduce high-strain hotspots	Claes & Heigele (1999); Lacroix & Prendergast (2002) [1, 3]
Interconnected porosity	Enables vascularization + transport	Controlled pore interconnectivity	Karageorgiou & Kaplan (2005); Hollister (2005) [20, 3]
Bioactivity	Surface supports bone bonding/mineralization	CaP / bioactive glass surfaces	Dorozhkin (2010); Hench (2006) [26, 30]
Controlled degradation	Maintains support during early healing; avoids premature loss	Matched to expected healing timeline	Rezwan *et al*. (2006) [21]; Oryan *et al*. (2014) [9]
Manufacturability & cost	Scale-up feasibility and affordability	Scalable sintering/cement processing; local supply	Ginebra *et al*. (2010) [28]; Bohner (2010) [27]
Regulatory readiness	Risk-based biocompatibility and testing	ISO/ASTM aligned evidence	ISO 10993-1 (2018); CDSCO (2017)

Note: Targets should be customized per indication and validated experimentally.

3.4 Step 4: Material selection with affordability and scalability constraints

Research is focused on low cost materials that can be upscaled for processing: calcium orthophosphates (HA/β-TCP) with high osteoconductivity and compositional affinity (Dorozhkin, 2010) [26]; injectable CPCs able to conform a defect that is likely to require less surgical time (Ginebra *et al*., 2010; Bohner, 2010) [28, 27]; Bioactive glasses which bond with bone and provide ionic signalling (Hench, 2006; Jones, 2013) [30, 31]; composites of polymers with ceramics showing improved toughness and handling (Rezwan *et al*. 2006) [21].

Table 2: Candidate material classes for cost-effective bone repair: physics-guided comparison

Material class	Strengths	Key limitations	Typical "low-cost" pathway
Calcium phosphates (HA/β-TCP)	Osteoconductive; bone-like mineral	Brittleness; limited toughness	Powder processing + sintering; ceramic granules/blocks
CPCs	Injectable; conformal filling	Lower tensile strength; washout risk	CPC formulation optimization; setting control
Bioactive glass	Bone bonding; ionic dissolution benefits	Brittleness; processing sensitivity	Melt-derived or sol-gel; particles in composites
Polymer/CaP composites	Better toughness; tunable degradation	Requires process control; variability	Extrusion/solvent casting; particulate composites
Chitosan/silk composites	Biocompatible; potentially affordable	Weak mechanically alone	Reinforced composites + crosslinking; hybrid scaffolds

Note. Selection should follow the modeled mechanical environment and defect indication (Hollister, 2005; Dorozhkin, 2010; Jones, 2013) [20, 26, 31].

3.5 Step 5: Mechanical testing matrix aligned to standards

Mechanical testing must represent likely loading mode (compression s for cancellous-like scaffolds, fatigue tests for load bearing constructs). Standardized testing will make the Table 3. Mechanical Testing Plan and Relevant Standards

Table 3: Mechanical testing matrix for bone repair biomaterials

Test	Purpose	Standard / reference
Compressive modulus/strength	Scaffold stiffness and failure resistance	ISO 13314 (2016); ASTM D695 (2015)
Bone cement mechanical properties	Handling and strength for cements	ISO 5833 (2019); ASTM F451 (2021)
Plate/construct mechanical testing (if applicable)	Construct behavior under bending	ASTM F382 (2021)
Construct testing in vertebrectomy model (spine constructs)	System-level stability	ASTM F1717 (2020)

Note. Choose tests based on indication and device type.

3.6 Step 6: Biocompatibility and risk management for India translation

Evaluation of biocompatibility should fundamentally be risk-based but should also correlate with the contact type and duration intended, per 10993-1(2018).

In India, all devices and IVD development must comply with the Medical Devices Rules and meet the evidence, labelling and quality systems expectations of CDCO (CDSCO 2017, 2023). A practical way to approach and build evidence in one dossie is the following:

- Materials characterization,
- Sterilization validation,
- Mechanical performance,
- Biocompatibility.

Table 4: Translation-focused checklist: evidence package for India context

Domain	Evidence item	Reference anchor
Regulatory pathway	Device classification + compliance plan	CDSCO (2017, 2023)
Biocompatibility	Risk-based evaluation plan	ISO 10993-1 (2018)
Mechanical performance	Standardized tests matched to indication	ISO 13314 (2016); ASTM standards
Clinical need linkage	Indication rationale (fragility fractures/trauma)	ICMR (2021); MoRTH (2023)
Post-market considerations	Usability, cost, supply continuity	Bone substitute clinical reviews (Giannoudis *et al*., 2005; Campana *et al*., 2014) [8, 15]

4. Results: Illustrative Modeling-to-Design Outputs

The present paper is a research synthesis with a proposed workflow; "results" are presented as illustrative outputs that a typical study would generate, using established mechanobiological principles and tissue engineering scaffold theory.

4.1 Mechanobiological modeling outcomes: stability windows and non-union risk

Models that base predictions on mechanoregulation propose that excessive IFM and/or stimulus regimes may favour the formation of fibrous tissue and non-union (Prendergast *et al*., 1997; Lacroix & Prendergast, 2002) [3, 2]. The impact of local mechanical conditions on the prediction of healing course was studied by Claes and Heigele (1999) [1]. This additional point highlights the necessity of joint design of scaffold stiffness and fixation stability. Most computational analyses of non-unions perform parameter sensitivity and boundary condition investigation. Proxies of insufficient stability and insufficient vascularity/transport frequently appear as risk factors (Carlier & Geris, 2015; Ghiasi *et al*., 2017) [5, 4]. Meaning (Interpretation) of design. If stresses in hotspot regions are predicted to be higher than bone-favouring conditions, then locally increase stiffness (e.g. denser struts near fixation).

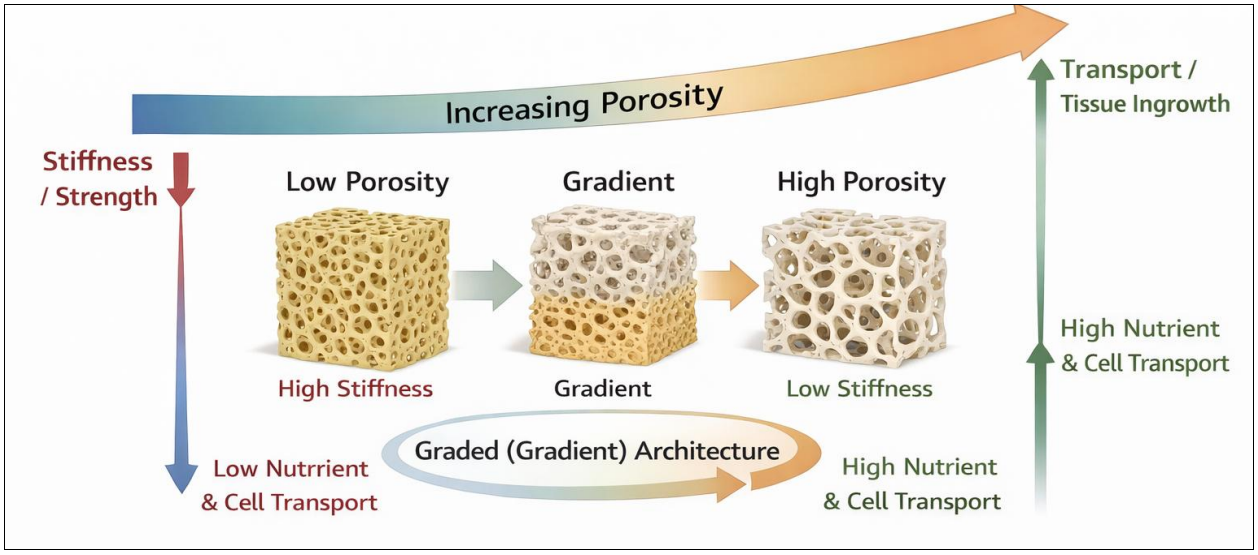

Fig 3: Architecture-Property Trade-off Map

4.2 Material selection implications: ceramics, cements, and composites

Calcium orthophosphates due to their osteoconductivity and long term use on clinic makes one of the most studied bioceramics (Dorozhkin, 2010; Giannoudis *et al*., 2005) [26, 8] (Fig. 3.8). CPCs and similar materials can aid and direct new bone formation. The authors have argued that CPC shape adaptability might lead to close contact with the host bone, as well as reduced surgical complexity (Ginebra *et al*., 2010; Bohner, 2010) [28, 27]. Despite the CPC forming a non-adhesive low-strength bone cement, it nonetheless needs mechanical integrity, in vivo setting control and phase conversion (Bohner 2010) [27]. Bioactive glasses (BG) can bond chemically with bone and deliver bone-growing agents.

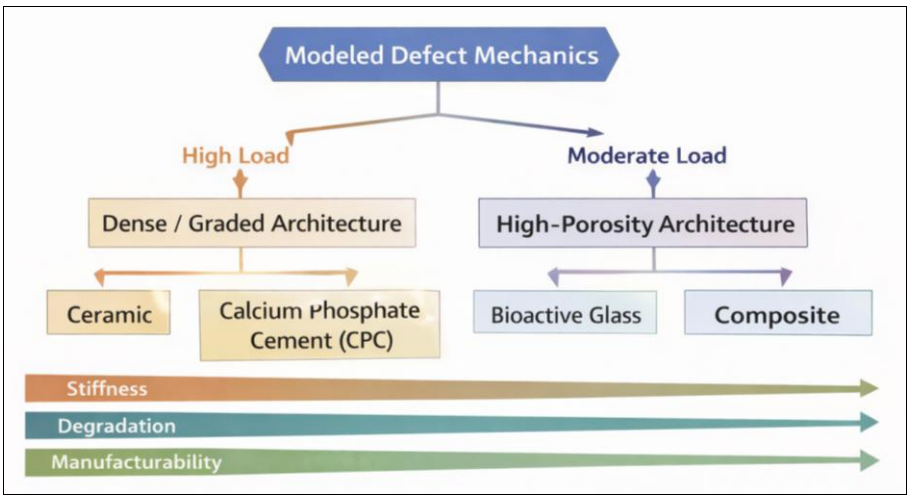

Fig 4: Materials Decision Tree

4.3 Testing outcomes: linking mechanical data to design targets

One cannot simply determine the suitability of the bone scaffold performance based on the architecture alone. Mechanical testing for strength and processing property of scaffolds recommends mechanical testing. In addition, we can obtain data related to cellular, porous behaviour through compressive testing of modulus and collapse behaviour. As the load of natural bone so is cancellous (ISO 13314) Bone Cements Specific Strength and Processing Property.

5. Discussion

5.1 Why physics-guided design improves reproducibility and translation

The bone substitute literature is plagued by heterogeneity between scaffolds and studies, representing an enduring barrier to translation. Not only chemistry, but also architecture and mechanics. When the same base material is being utilized, the pore size distribution and/or interconnectivity, strut thickness, processing-induced defects, etc. can vary significantly creating large shifts in the permeation, stiffness and the fatigue behaviour. As a result, biological outcomes in this far-distant-Halcyon zone are variable. Even worse, whatever the base chemistry, its choice or formulation also often rests on instances of underspecified design targets. For instance, use of terms such as “highly porous and bioactive, ”which perhaps refers to an elastic modulus in the MPa range, or “osteoimmunomodulatory” connect to biology but do not anchor scaffold properties in the actual mechanical environment at the defect.

Design based on physics.

Physics-driven design methodologies tackle these issues by treating the defect environments as generators of specification. The main aim is to eliminate the issue of under specification and explicitly state the mechanical boundary conditions. It is used as basis on which rational performance targets are then derived. This is done by examining the mechanical behaviour of the living healing defect and the implanted substitute.

The mechanoregulation models provide an antecedent example of a specification generator. These models offer a mechanistic-type mapping of local mechanical stimuli (often strain and fluid flow or related stimulus measures derived from finite element fields).

The theory of cellular solids is established, and scaffold design frameworks enable controllable stiffness-strength trade-offs. These trade-offs can scale in a predictable manner between architecture and mechanical properties and are consistent with and enable designs that are manufacturable. It is important to mention that different chemistries may lead to the generation of very different local strain/fluid flow patterns. Thus one scaffold and the other scaffolds may result in very different mechanobiological signals and tissue trajectories (Prendergast *et al*., 1997; Lacroix & Prendergast, 2002) [3, 2]. In a more general sense, by explicitly linking "what the defect needs" and "what the scaffold delivers."

5.2 Low-cost does not mean "minimal" it means cost-effective and testable

The term "low-cost" should not suggest low testing or diluted evidence. It means efficient performance obtained through testing to a specified standard. According to the clinical review in orthopedic reconstruction, the specifications that a graft substitute must meet varies by indication, and as a result, they must be chosen and assessed on criteria relevant to their indication. In other words, void filling vs segmental defects, load vs non-load bearing sites, and risk factors intrinsic to the patient themself (Campana *et al*., 2014; Giannoudis *et al*., 2005) [15, 8]. The "cheap" material that doesn't provide evidence for its mechanical consistency or biocompatibility may end up costing far more, down the line: revision, infection, prolonged immobility, loss in productivity and variable outcomes reduce clinician confidence (Campana *et al*. 2014; Giannoudis *et al*., 2005) [15, 8]. Affordability should therefore come from scalable processing + disciplined testing, not reduced verification. Routes that can be scaled up involve formulations based on CPCs that allow for consistent processing and packaging, ceramic granules and putties that are suitable for being manufactured at volume, and composite processing routes that give improved toughness and handling without losing bioactivity. Each of these routes needs acceptance criteria and test methods defined a priori, linked to already-used standards, so that even "low-cost" devices become testable, comparable.

In this area, biocompatibility assessment to ISO 10993-1 increases translation by ensuring biological risk and biological response assessment and testing is related to the device contact type, duration and intended use rather than ad hoc assays (ISO 10993-1 2018). Similar to this, the mechanical and handling standards for polymeric components for orthopaedic applications enable consistent claims for materials selection and quality ISO 5833 2019). To avoid preventable failures and reducing uncertainty, standardisation has been an essential means since it lowers total systems cost at the point of clinical adoption and not an optional luxury.

5.3 Indian clinical needs: burden, pathways, and regulatory realism

Due to the high load of road traffic injuries and fractures in India, orthopaedic reconstruction options at various hospital tiers are required (MoRTH, 2023; TRIP Centre, IIT Delhi, 2023) Model of care and device compatibility are particularly relevant for older persons and those at risk of metabolic bone disease (ICMR 2010 2021). In this scenario, their translation is most likely when device form and indication matches the realities of operating time and surgeon workflow, sterilization infrastructure and supply chain robustness. The physics-guided method encourages alignment by forcing developers to prioritize solutions that align with common clinical use-cases. As an example, void fillers for metaphyseal (around joint surface) defects may favour osteoconductivity and controlled resorption under moderate loading. Injectable CPCs are of interest when handling, set time and conformation to irregular defects are important and time constraint in surgery is significant. Composite scaffolds interest moderate mechanical needs so that enhanced toughness and reduced brittleness increase robustness to both implantation and early rehabilitation. It is also necessary to use regulatory realism.

Indian rules which are solely medically based, deals with classification, licensing, and so on also give us a guideline regarding what sort of proof will be relied upon on a checking stage. Having regular updates means that there are strong forces which drives us all to early planning for quality system and quality dossier makeup (CDSCO, 2017, 2023). Even a prototype, coming out from academic institute, if developed with "regulatory-ready" mindset helps to mature a batch traceability, pre-defined performance specification for PMA and or standard test methods for PMA, which can later on be migrated into selection of design approval and verification procedures and ultimately into design control and QMS documentation.

5.4 Limitations and research agenda

The first limitation is that our paper presents a framework as opposed to the findings of a new trial. To begin with, mechanobiological models are strong but they need calibration and validation. The uncertainty of parameters may be huge. Results produced by the model can be sensitive to the assumptions made about the properties of tissues and organs, the nature and distribution of, boundary conditions and initiation criteria, as well as the form and kinetics of figures of biological regulation. Moreover, we are focusing on a particular stimulus range and translating that to a scaffold that delivers these local strains and flow. However, to actualize gradients of stimulus, there must be scaffold in which architecture is tightly controlled point to point. As a result of processing differences, local mechanical environments will differ from those predicted. As a result, there should be four practical steps for future work. To begin with, predictions can be validated by carrying out longitudinal imaging and mechanics measurements, and still more directly, healing trajectories can be compared with imaging as predicted (Quinn *et al*., 2022) [6]. Secondly, research should measure the consequence of changes in architecture gradients upon local

mechanoregulation outcome, for example, can graded stiffness and porosities produce spatial patterns of strain/flow that preferentially stimulate bone formation in a reliable manner within a heterogenous defect (Hollister, 2005; Prendergast *et al*., 1997) [20, 3] Thirdly, low cost.
Because of this, priorities established in burden-of-disease studies must be linked through India-focused translational pipelines to feasible procurement, training, and post-market monitoring pathways to deliver affordable innovation replicable in practice.

6. Conclusion

In-depth understanding of bone biology can enable the design of low-cost biomarkers to promote their application for fancy tests and diagnostic procedures. By fusing tissue strain-regulated mechanobiological modeling with scaffold structure-property relations and standardized mechanical test methods, developers will adjust scaffold stiffness, porosity and bioactivity to promote bone formation while ensuring stability. In India, affordability is key as trauma and fragility fracture need is large. Such a framework would facilitate rational selection of scalable material classes, calcium phosphate ceramics/cements, bioactive glasses, polymer -ceramic composites, combined with ISO/ASTM aligned verification and CDSCO aware evidence planning. Use this workflow as a template for research studies, these projects, and translational R&D to speed-up economics/verification and proof of concept towards safe, cost-effective bone repair.

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