SERIGEN

Serioss®: Osteoconductive Silk-Protein Bone Void Filler

Bone Healing Technical Monograph

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Overview

Serioss® is a patented* next-generation, silk protein bone void filler designed for bone regeneration. It is a fully synthetic, biomimetic scaffold made from 100% silk protein, engineered to facilitate predictable bone healing through controlled resorption and superior structural support[1,2].

Serioss® functions as an osteoconductive scaffold, enabling cell attachment, proliferation, and guided bone formation, while gradually resorbing in sync with new bone formation[1,2,3]. Its porous microstructure and mechanical properties are designed to closely mimic cancellous bone, supporting both biological integration and load-bearing requirements[1,4].

*Patents: WO2016110873A9, WO2014125505A4[5,6]

What are bone void fillers?

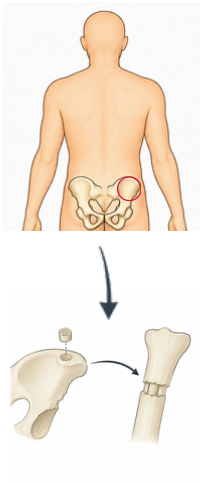
Bone void fillers are biomaterials used to fill, support, and promote healing in bone defects created due to trauma, tumor removal, cysts, infection, revision surgeries, or orthopedic procedures[7,8,9]. These materials act as temporary scaffolds that support new bone formation while maintaining structural integrity at the defect site[10,11].

They are widely used in orthopedic, trauma, spine, maxillofacial, and dental applications where restoration of bone continuity and regeneration is required[8,12].

BONE VOID FILLERS VS. BONE CEMENT

Feature	Bone Cement	Bone Void Fillers
Primary Purpose	Anchor implants to bone	Fill bone defects and gaps[8]
Main Function	Provides mechanical fixation	Acts as a scaffold for bone healing[11]
Biological Activity	Typically bioinert	Often osteoconductive
Resorption	Typically non-resorbable	Often resorbable
Strength	High immediate mechanical strength	Tunable mechanical properties
Use Case	Arthroplasty and implant fixation	Bone defects, trauma, and regenerative procedures[10,12]

History of bone void fillers

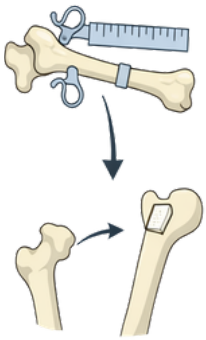


Autografts

Bone tissue from one part of a patient's body grafted at another site, eg., Iliac crest (pelvic bone), ribs, fibula (lower leg bone)

Gold standard: Live cells, natural scaffold, no rejection

Limitations: Two surgeries, donor site morbidity, painful for the patient, limited availability

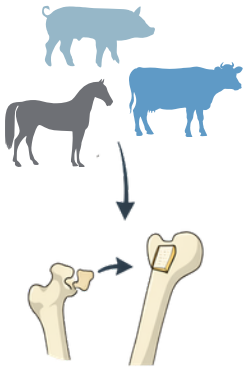


Allografts

Use of bone tissue from a human donor

Grafts are processed and sterilized

Limitation: Risk of infection transmission, risk of rejection, limited donors[10,13]



Xenografts

Grafting material is derived from animals, such as bovine (cow) or porcine (pig) sources, used to repair human bone defects

Limitation: Risk of infection transmission, risk of rejection, limited donors[10,13]

History of bone graft substitutes

Synthetic Bone Void Fillers

Man-made materials designed to mimic the natural properties of bone[11,12].

Commonly available bone void fillers:

- Ceramic: Calcium sulphate, calcium phosphate, Hydroxyapatite or composites[14,15,16]
- Bioglass[17]
- Polymers / Metals[17,18,19]

Ease of use, easily available

Limitation: Less-than-ideal mechanical or biological properties[1,10]

Desirable characteristics of bone void fillers

01

OSTEOCONDUCTIVITY

Providing a scaffold to support attachment, migration, and growth of bone-forming cells, enabling new bone formation[11,20]

02

BIOCOMPATIBILITY

Ensuring safe integration with host tissue without triggering inflammatory, immunogenic, or toxic responses[2,12]

03

OPTIMAL PORE SIZE & POROSITY

Facilitating cell infiltration, vascular ingrowth, and efficient transport of nutrients and signaling molecules[8,5]

04

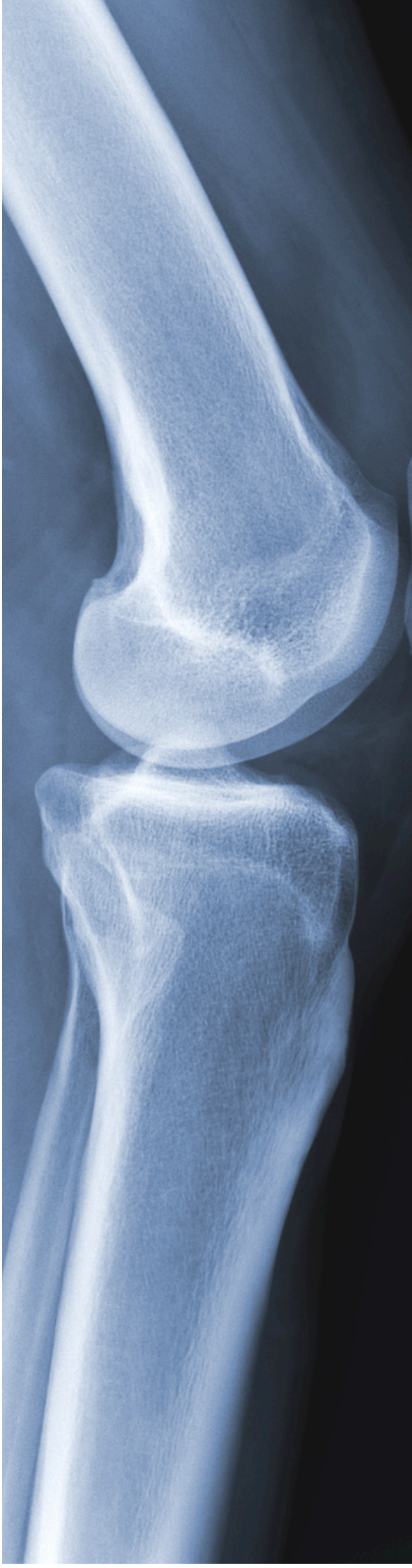
APPROPRIATE MECHANICAL PROPERTIES

Providing structural stability at the defect site while offering surface mechanical cues that support osteoblast activity and bone formation[1,3]

05

CONTROLLED RESORPTION

Where the resorption rate aligns with new bone formation to enable gradual load transfer and effective remodeling[1,7]



Serioss®- an ideal bone void filler

MEETING EVERY CRITICAL PARAMETER OF BONE REGENERATION

i) Superior Osteoconductivity
The interconnected porous architecture of Serioss® supports osteoblast attachment, migration, proliferation, and vascular ingrowth, guiding new bone formation and seamless integration with surrounding tissue[1,8].

ii) Biocompatibility
Made from high-grade silk protein with a long clinical history, Serioss® is non-cytotoxic, non-immunogenic, and integrates seamlessly with host tissue, minimizing inflammatory response. It is tested safe and biocompatible as per ISO 10993 standards[2].

iii) Optimal pore size and interconnected porosity
Engineered with an interconnected porous architecture (~40% porosity and ~800 µm pore size), Serioss® enables effective cell infiltration, vascularization, and nutrient exchange[1,2].

iv) Appropriate mechanical strength
Designed to mimic cancellous bone, Serioss® provides bone-like compressive strength, ensuring defect stability while supporting osteoblast activity and new bone formation[1].

v) Controlled resorption
Silk's controlled resorption allows Serioss® to resorb gradually in sync with new bone formation, enabling progressive load transfer and natural remodeling[1,2].

vi) Versatility in forms and sizes
Available in multiple shapes and sizes (e.g., pellets, cylinders), Serioss® allows surgeons to easily adapt and conform the scaffold to a wide range of defect geometries.

Preclinical Findings

Biocompatability Testing

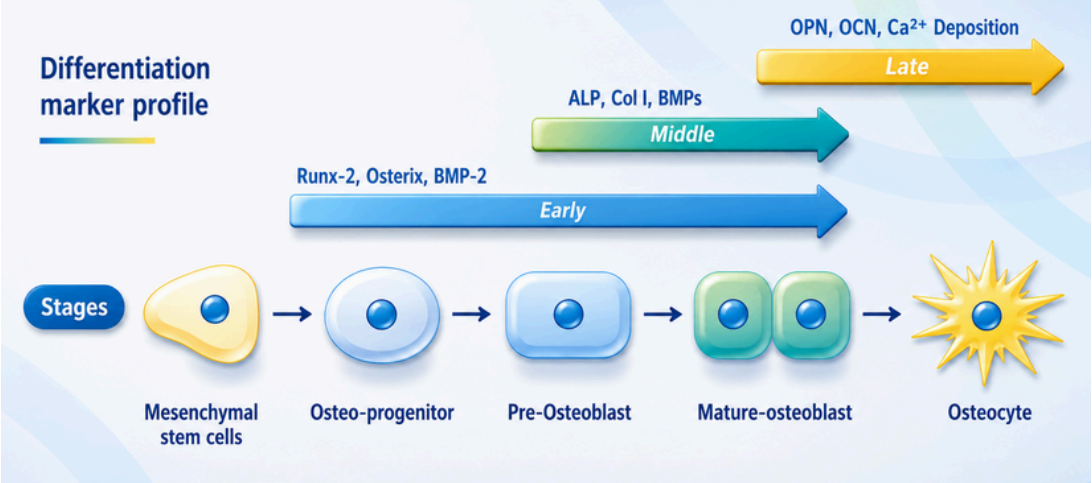
SERIOSS® IS BIOCOMPATIBLE AND SAFE AS PER ISO 10993 STANDARDS

In vitro and in vivo biocompatibility studies conducted by third party GLP-certified lab demonstrated that Serioss® is non-cytotoxic, non-genotoxic, non-sensitizing, non-pyrogenic and non-irritant as per ISO 10993 guidelines.

Test	Standard used	Conclusion
Cytotoxicity	ISO 10993-5:2010	Serioss® is non-cytotoxic
Ame's test (Mutagenicity)	OECD Guideline No. 471 and ISO 10993-3:2014	Serioss® is non-mutagenic
Chromosomal aberration	OECD Guideline No. 473 and and ISO 10993-3:2014	Serioss® is non-clastogenic
Irritation tests-ICT	ISO 10993-10:2010	Serioss® is non-irritant
Sensitization test (GPMT)	ISO 10993-10:2010	Serioss® does not induce sensitization
Material mediated pyrogenicity testing	ISO 10993-11:2017 (EN)	Serioss® is non-pyrogenic
Acute systemic toxicity	ISO 10993-11:2017 (E)	
Sub-acute systemic toxicity	ISO 10993-11:2006 and ISO 10992-12:2012	Serioss® does not induce systemic toxicity
Sub-chronic systemic toxicity	ISO 10993-11:2006 and ISO 10992-12:2012	
Bone implantation	ISO 10993-6:2017 (E)	Serioss® supports new bone formation

In vitro testing
Preclinical Findings

Human mesenchymal stem cells (hMSCs) were cultured on Serioss® and commercial calcium ceramic scaffolds, such as calcium sulphate, beta-tricalcium phosphate, beta-tricalcium phosphate-hydroxyapatite (60:40), for 21 days in osteogenic media. Molecular marker analysis was performed to assess the differentiation of hMSCs into osteoblasts.

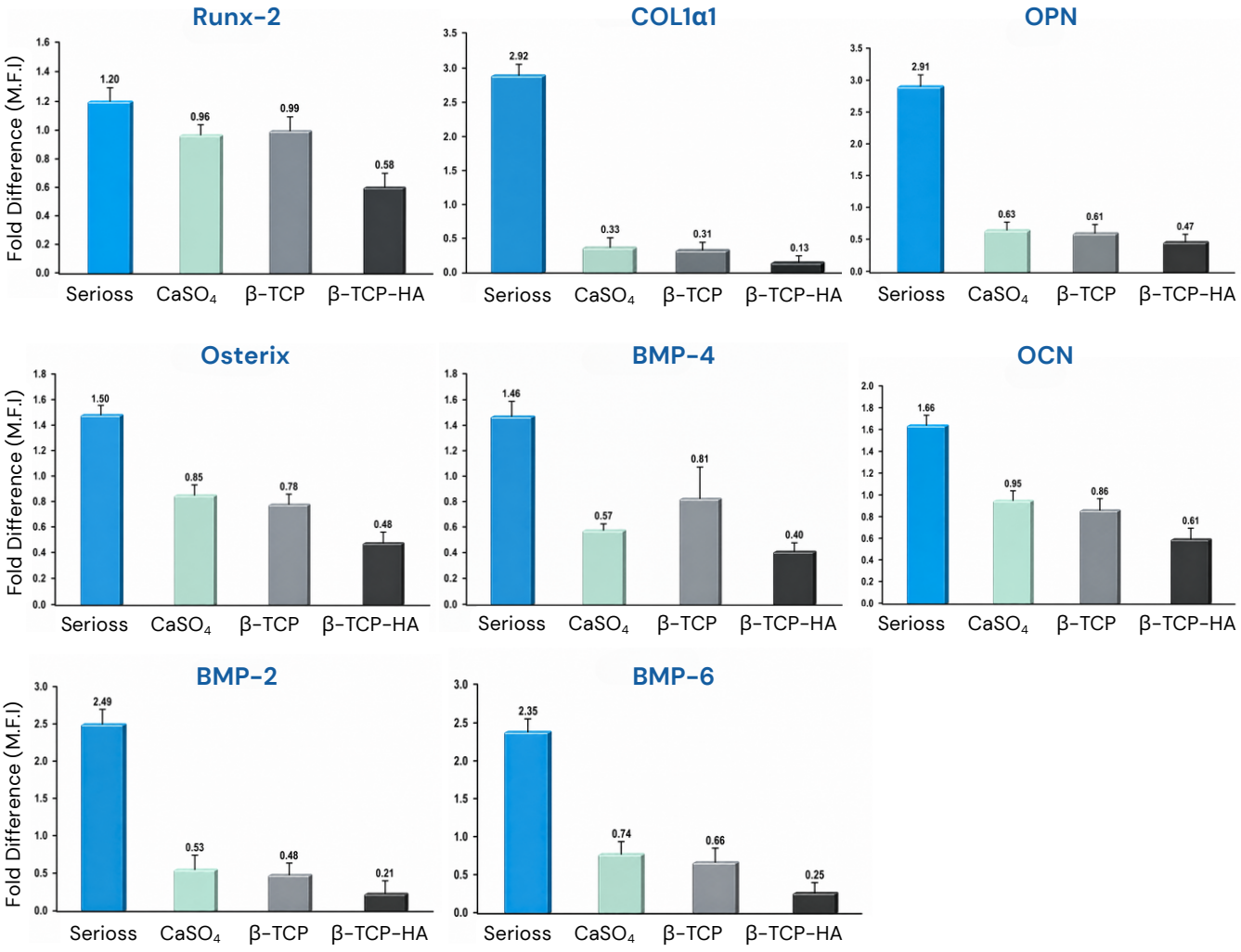


In vitro studies showed enhanced proliferation and differentiation of human mesenchymal stem cells into osteoblasts compared to conventional calcium ceramic scaffolds.

Serioss® exhibited significantly higher expression of osteogenic markers, including Runx-2, BMPs, osteocalcin, osteopontin, and collagen. The scaffold also promoted increased alkaline phosphatase activity and calcium deposition, indicating superior osteogenic potential. Its optimized pore architecture and mechanical properties provide structural support and a conducive environment for cell growth and differentiation.

In vitro testing
Preclinical Findings

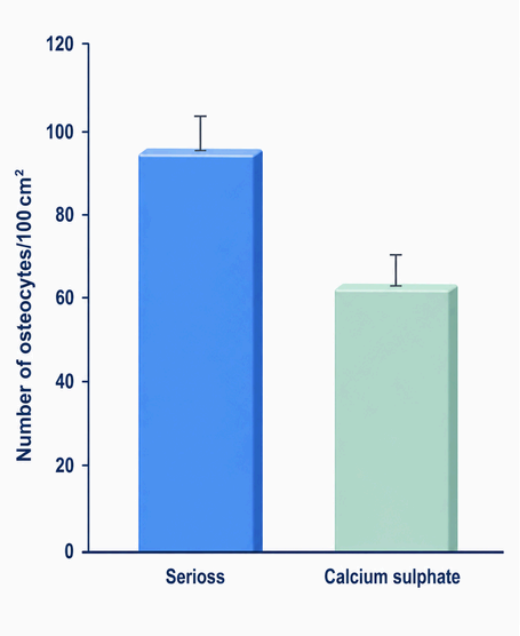
EARLY MARKERS | **EARLY TO LATE MARKERS** | **LATE MARKERS**



Comparison of expression of genes involved in osteoblast differentiation: Human mesenchymal stem cells (hMSCs) cultured on Serioss®, calcium sulphate (CaSO4), beta tricalcium phosphate (β-TCP), and beta tricalcium phosphate with hydroxyapatite (β-TCP-HA). Gene expression was analysed by RT-PCR. Panel shows the expression of early differentiation markers (Runx-2, Osterix, BMP-2), middle stage markers (Collagen type I, BMP-4, and BMP-6) and late differentiation markers (OPN, OCN)

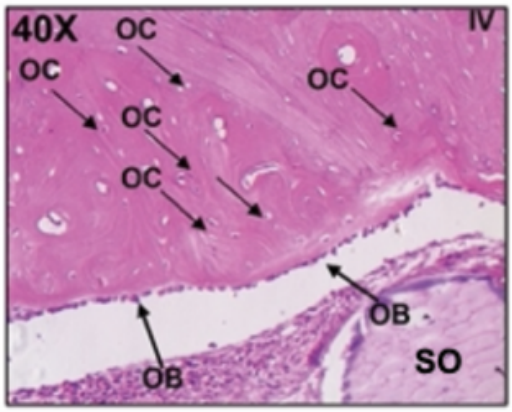
In vivo testing
Bone Implantation Studies

Serioss® and calcium sulphate scaffolds were implanted in rabbit femur. After 90 days of implantation, histopathological analysis was performed. Implantation studies in rabbit femur model showed excellent local tissue compatibility with no adverse reactions or systemic toxicity.

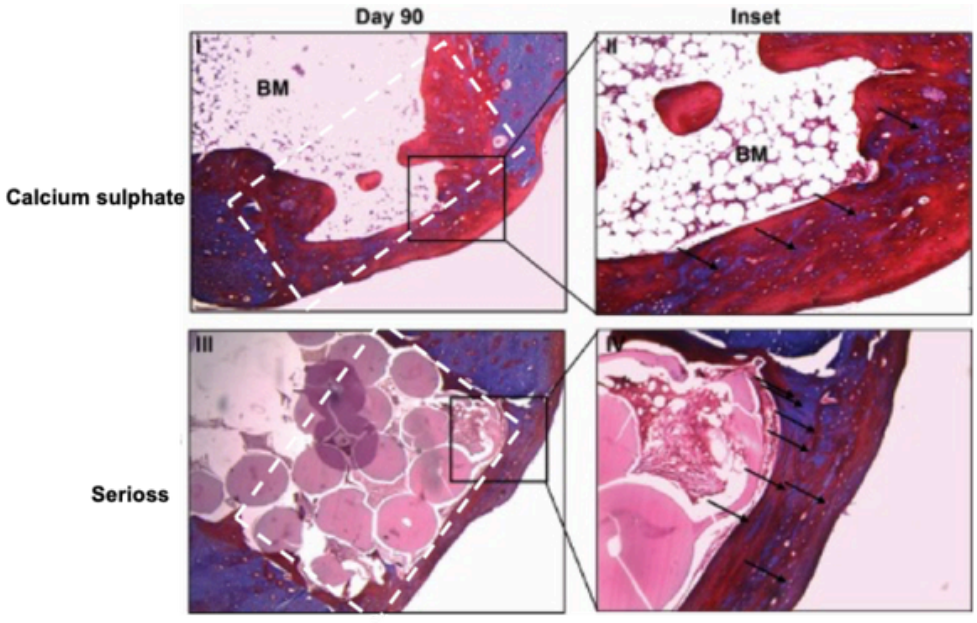


Serioss® supported osteoblast and osteoclast activity, enhanced new bone formation, resulting in higher osteocyte density and collagen deposition compared to commercial calcium sulphate scaffolds. Additionally, Serioss® implantation sites showed reduced incidence of secondary fractures during the 90-day evaluation period.

In vivo testing
Bone Implantation Studies



HE stained section of rabbit femur after 90-days of implantation. Serioss® (SO) implantaion sites depict osteoblast (OB) lining in the areas of new bone formation. OC - osteocytes; OB - osteoblasts; SO - Serioss®.



Modified Masson Tricrome staining on bone sections from rabbit femur implantation sites (white dotted line) of calcium sulphate and Serioss® after 90-days of implantation. Blue color indicates the presence of collagen. Newly formed bone near the Serioss® implantation site shows higher collagen deposition than the calcium sulphate implantation site.

Pilot Clinical Study

Pilot Clinical Study - Overview

Objective

To evaluate the safety of Serioss® in patients undergoing surgery for bone void filling

End Points

Incidence of occurrence of adverse events (AEs) (including infection)	**OR**	Serious adverse events (SAEs) during the study period	**OR**	Uneventful completion of the study

(*whichever is earlier)

Study Design

This is an open label pilot clinical study. Patients with depressed intra articular fracture of upper end of tibia, requiring bone grafting or use of bone void fillers will be invited for study participation.

Clinical Investigation Site	Principal Investigator
sancheti	**Dr. Chetan Pradhan** Assistant Medical Director of Sancheti Hospital; Consultant Trauma and Orthopaedic surgeon

Pilot Clinical Study - Overview

Inclusion Criteria

- Male and female subjects aged above 18 years, who had been scheduled for long bone surgery requiring bone void filler
- Patients with depressed intra-articular fractures of the upper end of tibia, proximal humerus, distal radius, distal femur, proximal femur, and calcaneus requiring bone grafting or use of bone void fillers

Exclusion Criteria

- Any clinically significant medical condition which may, in the judgment of the investigator, interfere with the subject's ability to participate in the study or may interfere with study results (e.g., active infections, cardiac, diabetes, psychiatric, neurological, pulmonary, or immunological conditions etc.)
- Pregnant women
- Known allergy to silk fibroin
- History of deep space/tissue infection (e.g., fasciitis, abscess, osteomyelitis) and infected prosthetic joint

Additional Safety Assessments Conducted At Pre-defined Time Points

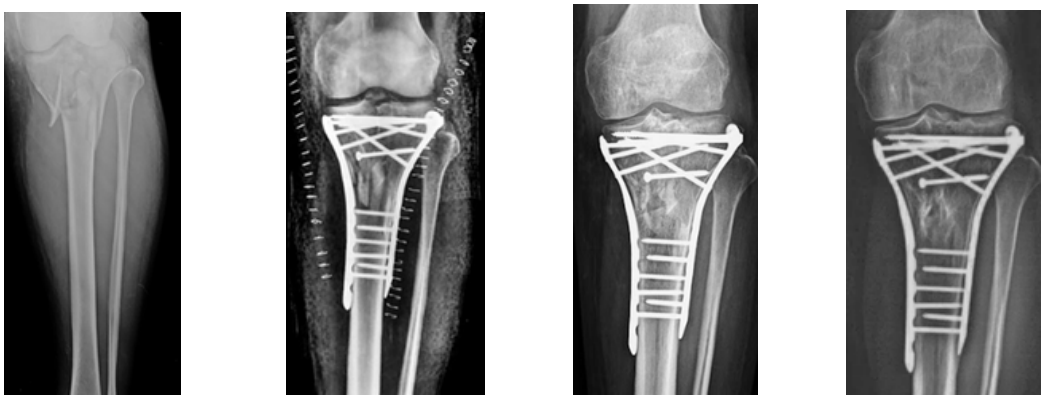
- Vital signs were assessed at Screening, Surgery, Discharge Day, and during follow-up visits at Month 1, Month 2, Month 3, Month 6, and Month 12
- Blood chemistry assessments, including CBC, CRP, calcium, phosphorus, renal function tests, liver function tests, and alkaline phosphatase, were performed at Screening, Discharge Day, Month 1, Month 3, Month 6, and Month 12
- Radiographic evaluation using X-ray imaging was conducted at Screening, Surgery, Month 1, Month 3, Month 6, and Month 12
- CT imaging of the affected joint was performed at Screening, Month 6, and Month 12 to assess bone regeneration and healing progression

Pilot Clinical Study
Follow up at 3 (+ 0.5) years

Case Study 1: Proximal tibia fibula

- Stable post-operative implant placement with maintained joint integrity
- Normal bone structure and surrounding soft tissues without abnormalities

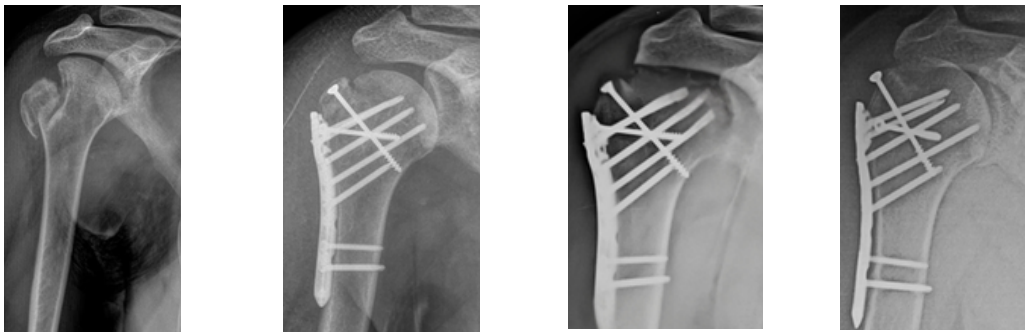
Pre operative **Post operative** **6 Months** **3 years**



Case Study 2: Proximal humerus

• Cortical regeneration and defect bridging
• Anatomical restoration with unrestricted upper limb mobility at 3-year follow-up

Pre operative **Post operative** **6 Months** **3 years**



Summary of pilot clinical study

01

SAFETY PROFILE

Established over the 3-year observation period

02

RADIOLOGICAL SUCCESS

Definitive evidence of osteointegration and progressive bone remodelling

03

STRUCTURAL RECONSTRUCTION

Successful cortical regeneration with complete bridging of the defect, demonstrating sustained mechanical and structural integrity

04

HEALING OUTCOMES

Resolution of the primary defect with achievement of optimal anatomical restoration

Pivotal Clinical Study

Pivotal Clinical Study - Overview

Primary Objective

To evaluate bone formation and integration at the site where Serioss® is used; and to establish non- inferiority of Serioss® in comparison with Tri Calcium Phosphate bone void filler.

Secondary Objective

• Evaluation of extent of bone healing/regeneration by CT (via radiological analysis by expert) at 6 months.

• Surgical outcomes like operative time, length of hospital stay, complications etc., functional outcomes of the operated limb/area as determined by post-operative movement.

Primary Endpoint

> Establishment of non-inferiority of Serioss® by evaluation of the extent of bone healing/regeneration, through a comparative investigation with other TCP bone void filler, through an independent assessment done by PI and expert radiologist (using X-ray at all visits).

Secondary Endpoint

> • Incidence of occurrence of related adverse events (AEs) (including infection) OR serious adverse events (SAEs) during the investigation period.
>
> • Evaluation of extent of bone healing/regeneration through an independent assessment done by PI and expert radiologist.

Pivotal Clinical Study - Overview

Comparator study with total 80 patients

8 sites, 3 states, 5 cities

Clinical Investigation Sites

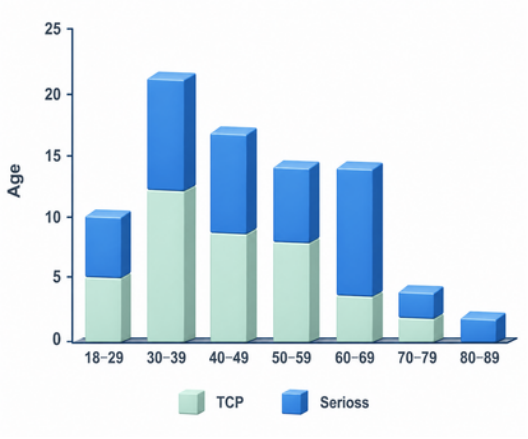
- Sancheti Hospital, Pune
- Dr R N Cooper General Hospital, Mumbai
- PGIMER, Chandigarh
- Sahyadri Super Specialty Hospital, Pune
- Kasturba Medical College, Manipal
- Synergy Multispecialty Hospital, Miraj
- Dr D Y Patil Medical College, Hospital and Research Centre, Pimpri
- Sainath Hospital, Moshi

Pivotal Clinical Study Overview

Inclusion Criteria

- Male and female participants aged above 18 years
- Patients with any bone void in the extremities (both upper and lower) that requires surgical reconstruction using autografting/ allografting*
- Full comprehension, willing to give informed consent, and willing to comply with all the study requirements

Patient Age Distribution Across Study Groups



Exclusion Criteria

- Patients with clinically significant medical conditions such as hepatorenal failure, uncontrolled diabetes, long-standing steroid intake, etc.
- Patients with active infections of bone or HIV/Hepatitis B/C, or pathological fractures
- Patients with known allergy to silk fibroin

Additional Safety Assessments Conducted At Pre-defined Time Points

- Complete haemogram with ESR, including haemoglobin, PCV, total blood count, platelet count, neutrophils, lymphocytes, monocytes, eosinophils, and basophils
- Clinical chemistry evaluations including calcium, phosphorus, Vitamin D3, serum creatinine, alkaline phosphatase, renal function tests, and liver function tests
- C-reactive protein (CRP) testing for inflammatory monitoring
- Urine pregnancy testing (UPT), performed when indicated by the Principal Investigator
- CT imaging for selected cases, including intra- and peri-articular fractures, based on investigator assessment
- Serial radiographic evaluations performed during follow-up visits to assess healing progression and post-operative outcomes

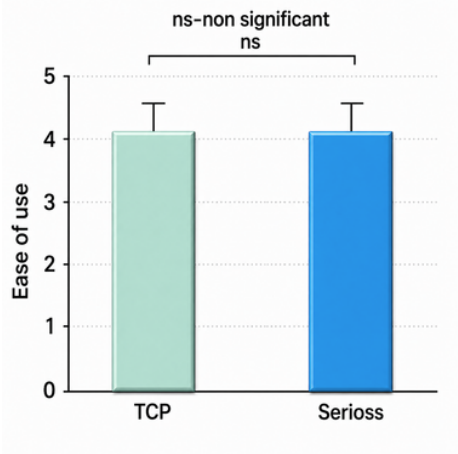
Pivotal Clinical Study Overview

***Surgical interventions were performed across the following upper and lower extremity sites:**

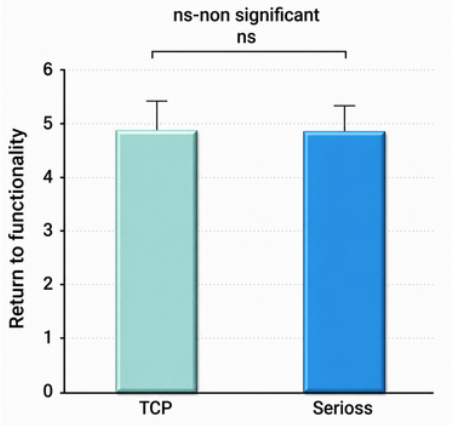
Anatomical Location	Serioss®	TCP
Tibia	12	18
Humerus	17	5
Femur	7	1
Radius	5	10
Metatarsal	0	1
Middle phalanx middle finger	0	1
Lateral condyle	0	1
Clavicle	1	1
Calcaneus	0	2
Total	**42**	**40**

Pivotal Clinical Study
Assessment of Surgical and Functional Outcomes

Ease of Use

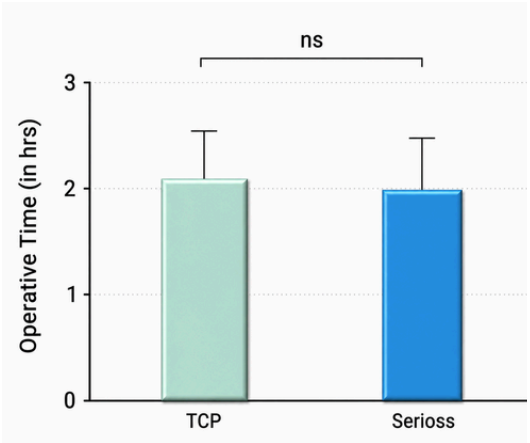


Return to Functionality

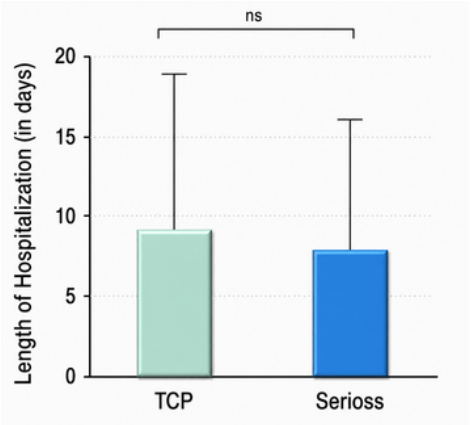


Surgical handling characteristics, intra-operative usability & functional recovery comparable to TCP

Operative Time



Length of Hospital Stay



Serioss® is non-inferior across surgical outcomes

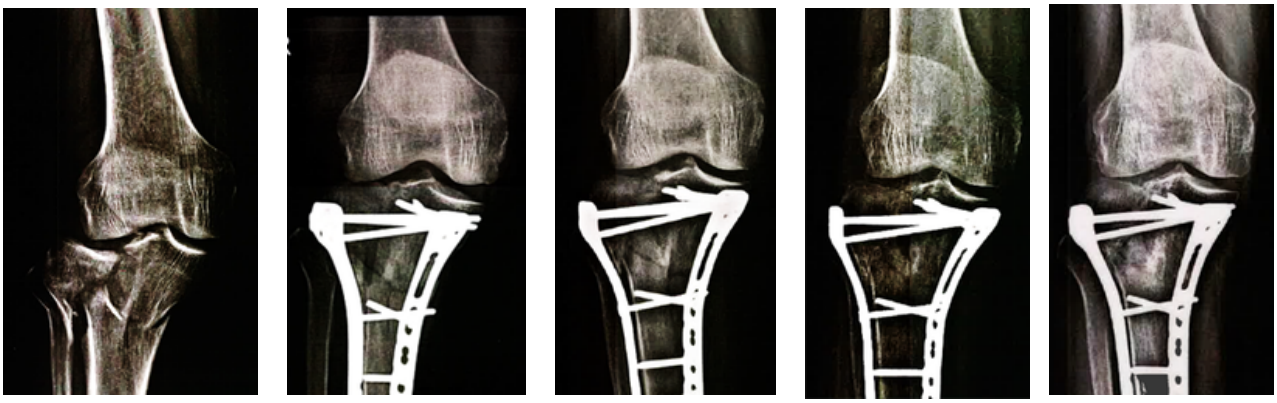
Pivotal Clinical Study

Bone formation after 6 months: Fresh Fracture

Case Study 3:

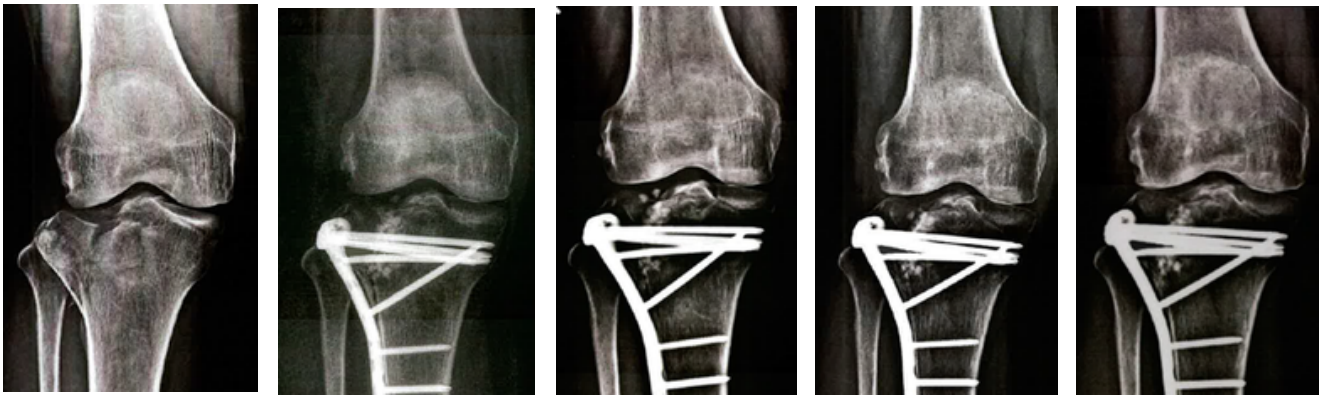
Serioss® : Proximal tibia

Visit 1 Pre operative	Visit 2 Post operative	Visit 4 6 weeks	Visit 5 3 months	Visit 6 6 months



TCP: Proximal tibia

Visit 1 Pre operative	Visit 2 Post operative	Visit 4 6 weeks	Visit 5 3 months	Visit 6 6 months



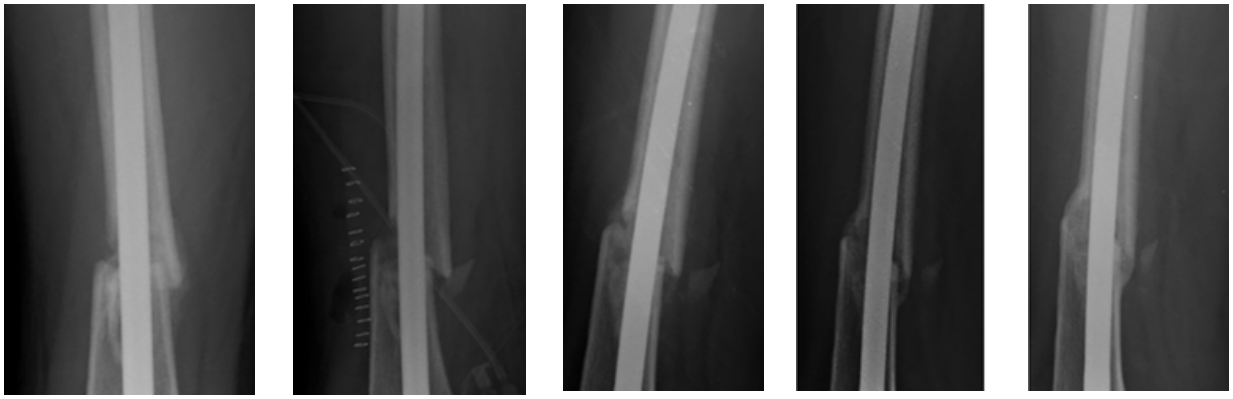
Pivotal Clinical Study

Bone formation after 6 months: Non-Union

Case Study 4:

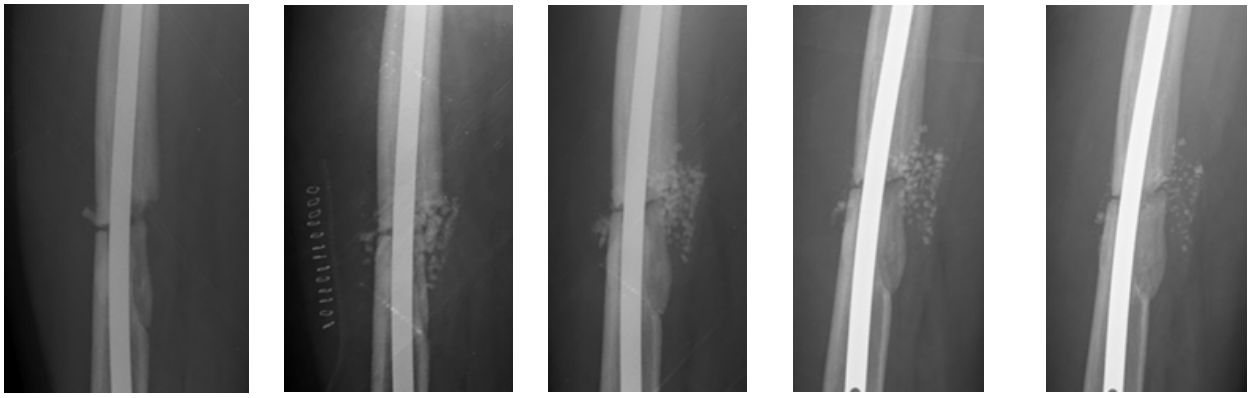
Serioss® : Femur

Visit 1 Pre operative	Visit 2 Post operative	Visit 4 6 weeks	Visit 5 3 months	Visit 6 6 months



TCP: Femur

Visit 1 Pre operative	Visit 2 Post operative	Visit 4 6 weeks	Visit 5 3 months	Visit 6 6 months



Pivotal Clinical Study
Robust Validation Across Parameters

Across all follow-up time points, Serioss® demonstrated progressive and consistent bone formation, as assessed by both treating surgeons and independent radiologists. Radiographic scoring showed clear improvement over time, indicating effective defect bridging, cortical regeneration, and remodeling.

Non-Inferiority with Evidence of Superior Outcomes

Statistical analysis using mixed-effects regression models established that:

- Serioss® met all primary endpoints for non-inferiority vs TCP
- Adjusted mean scores for bone healing were consistently higher for Serioss® across both X-ray and CT assessments
- Differences between Serioss® and TCP were statistically significant in key evaluations, indicating a measurable advantage in bone regeneration outcomes

High Data Reliability and Agreement

Assessment consistency between the Principal Investigator and independent radiologist showed strong agreement (ICC ~0.80).

Safety and Functional Outcomes

- No device-related serious adverse events were reported
- Clinical chemistry and inflammatory markers remained within normal ranges
- Return to functionality and surgical handling were comparable or favorable versus TCP
- Operative time and hospital stay remained aligned with standard of care

Longitudinal analysis across follow-up visits demonstrated a clear upward trajectory in healing scores, reflecting:

- Progressive bone formation and integration
- Consistent remodeling across patient cohorts
- Comparable or improved performance relative to TCP at each time point

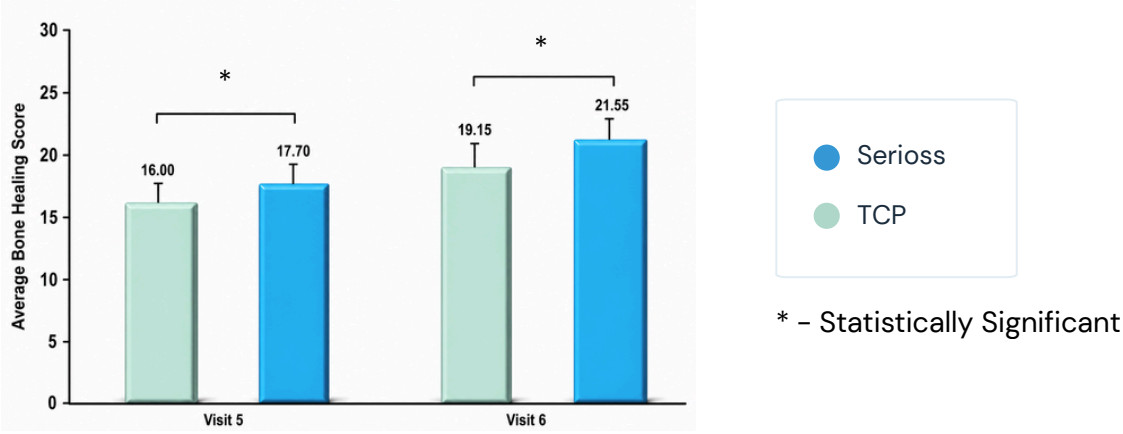
Pivotal Clinical Study
Robust Validation Across Parameters

Radiological Outcome Trends

- Radiological healing was assessed using a composite scoring system evaluating bone formation, total radiographic union, bridging, fracture lines, implant resorption, bone void filler–host bone junction, and remodelling across serial follow-up visits[2].
- Independent radiologist assessments demonstrated progressive improvement in healing scores over time.
- Across all evaluated visits, Serioss® demonstrated radiological outcomes comparable to or better than TCP, with statistically significant advantages observed in key bone regeneration assessments[2,8].
- These results confirm non-inferiority and support the clinical effectiveness of Serioss®.

Superior Performance of Serioss® vs. Tricalcium Phosphate (TCP) in Pivotal Clinical Study

Average Bone Healing Score over Time - Independent Radiologist Assessment



* – Statistically Significant

Summary of pivotal clinical study

01

NON-INFERIORITY

Serioss® is non-inferior to the TCP bone void filler

02

BONE FORMATION

Serioss® enables effective new bone formation and functional restoration

03

SAFETY

Clinical data confirms the safety profile of Serioss®

04

SUITABILITY

Serioss® is suitable across population above 18 years of age for for clinical use in various orthopaedic applications

Conclusion

Serioss® represents a significant advancement in bone void management by combining the biological advantages of natural materials with the consistency and usability of synthetic materials. Its silk-based, biomimetic design addresses the fundamental requirements of bone healing—biocompatibility, structural support, porosity, and controlled resorption—enabling predictable and effective regeneration.

Supported by strong preclinical and clinical evidence, Serioss® demonstrates reliable bone formation, functional recovery, and long-term integration across a range of orthopedic applications. With its surgeon-friendly handling and scientifically engineered performance, Serioss® offers a dependable solution for treating bone defects and improving patient outcomes.

References

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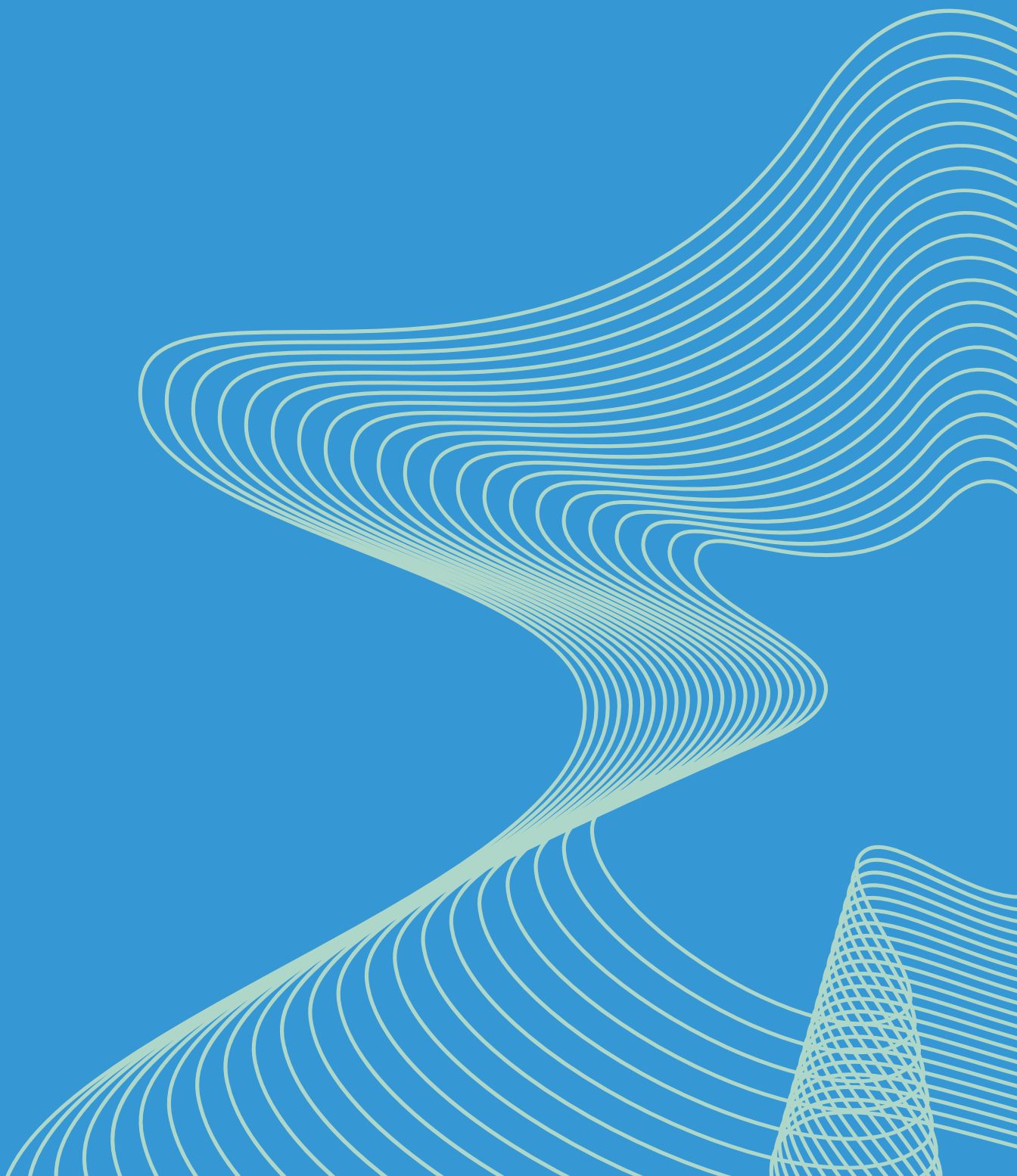

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