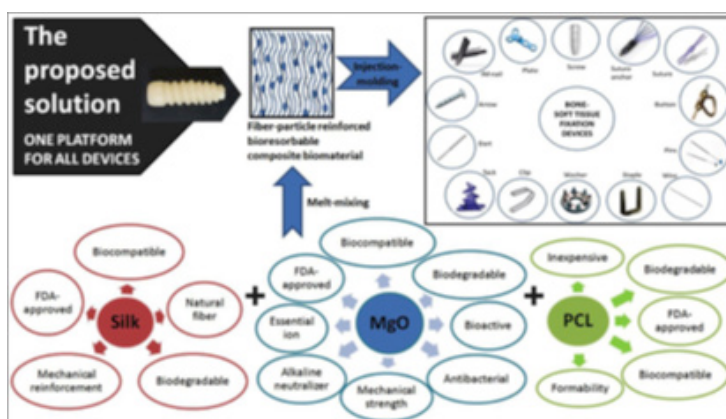


# Low-cost indigenously developed bioresorbable bone screw for bone and soft-tissue fixation applications

Our research work focuses on indigenous development of low-cost bioresorbable medical bone screw for bone-soft tissue Fixation applications. There is a huge demand for orthopedic devices in India and worldwide. It is estimated that more than 100 million screws are used for bone or soft-tissue fixations per year globally.

To demonstrate proof-of-concept of bioresorbable bone screw prototype composed of novel composite biomaterial with advanced functionality:

- Development of novel biomaterial composite of n-MgO/Silk/PCL melt mixed in different ratio for tunable properties and its in-vitro physicochemical, mechanical, biological characterisation
- Development of injection molding molds according to reference screw design using machine tool workshop facility
- Fabrication of bone screw prototype using micro compounding and injection molding and its *in vitro*, *ex vivo* biological and mechanical evaluation
- *In vivo* evaluation of as-developed composite bone screw for biocompatibility and toxicity by subcutaneous implantation in SD rats



Novel composite biomaterial (MgO - silk fiber reinforced in Polycaprolactone) was developed achieving advanced functionalities with variable filler concentration:

- a. Tunable mechanical properties (tensile strength = 15-30 MPa and modulus = 0.2-1.2 GPa) matching that of cancellous bone, tendon and ligaments;
- b. Enhanced in-vitro biological properties (biodegradation, biomineralisation and biocompatibility);

Sr. No.	Smith & Nephew	RCI	BIO-RCI	BIO-RCI-HA	Our Product
	Composition	Ti alloy	PLLA	HA-PLLA	Silk-MgO-PCL
	Characteristics				
1	Biodegradable/ no revision surgery	X	✓	✓	✓
2	Bioactivity	X	X	✓	✓
3	Tunable mechanical strength	X	X	X	✓
4	Inherent antibacterial property	X	X	X	✓
5	Anti-resorption property	X	X	X	✓
6	Stress-shielding	✓	✓	✓	X
7	Screw driver design specificity	✓	✓	✓	X
8	Per unit cost (INR)	5,000-10,000	10,000-15000	10,000-15000	2000
9	Regulatory approvals (USFDA, DCGI, CE)	✓	✓	✓	✓
10	Marketing (brand name, distributor network, track-record)	✓	✓	✓	✓

Green: Desirable, Red: Undesirable, Orange: In-between/to be achieved

- c. *Ex vivo* hemocompatibility studies with human blood revealed no interference with normal blood cell viability, count, coagulation process, etc.;
- d. *In vivo* biosafety studies showed minimal inflammatory response by 8 weeks in tissue surrounding implant with no adverse effect on vital organ functions.

Presently, our research team is working on ex-vivo biomechanical studies (pullout test):

1. In-house injection molding capability was developed in terms of custom-manufactured molds with pocket-pin assembly to fabricate bone screw of desired shape and size
2. Proof-of-concept was demonstrated by fabricating PCL and MgO-silk-PCL bone screws (cannulated and non-cannulated) fitting regular hexagonal Allen keys of different head diameters (3 mm and 4 mm).

