STABILIZORTHO

SPL® SCREW TECHNOLOGY

MICHAEL J GARDNER, MD
Stanford University School of Medicine
Changing construct stiffness over time creates an optimal environment for fracture healing. Stabiliz is the first technology to address this issue.

ANJAN R SHAH, MD
Florida Orthopaedic Institute
...this is different than everything on the market. The science behind it makes sense. The Stabiliz technology is truly a potential game-changer.

KENNETH KOVAL, MD
Memorial Hospital
Insertion of SPL screws has felt normal. There have been no complications with implant application or fracture healing. Postoperatively, all treated patients are progressing as expected.

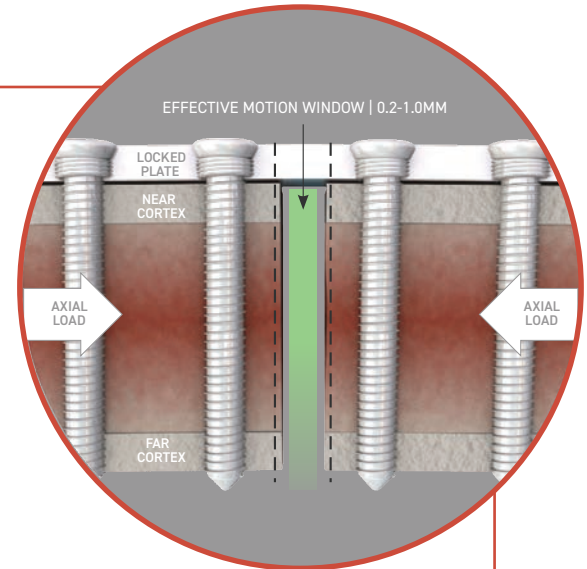
Rigid

ADJECTIVE: rig•id \'rij-əd\
- not able to be bent easily
- not easily changed
- not willing to change opinions or behavior

The Problem

Studies examining locked plating indicate reasons for concern due to the reported rates of non-unions and delayed unions. Recently, these healing difficulties have been reported in up to 23% of distal femur, 15% of distal tibia and 6% of proximal humerus fractures. [1, 2, 3]

Previous studies have shown that the high overall rigidity of locked plating can contribute to healing difficulties by inhibiting interfragmentary motion (IFM). [4] Under compression, rigid locking plates asymmetrically bend, limiting cortical motion. This rigidity may produce stress shielding across the fracture site, contributing to non-unions, which may result in implant fatigue and failure under repetitive loading. [4, 5]



Locked plating inhibits interfragmentary motion

Dynamic

ADJECTIVE: dy•nam•ic \di-'nam-ik\
- (of a process or system) characterized by constant change, activity, or progress
- (of or) relating to energy, motion, or physical force

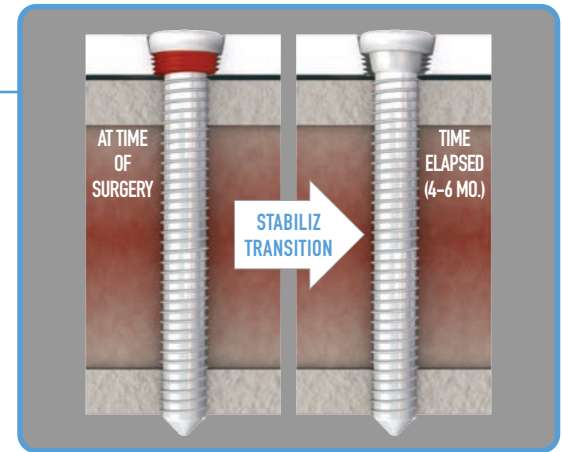
The Solution

Stabiliz Polymer Locking (SPL®) Technology

The first truly dynamic plate and screw technology:
A system that changes during the course of fracture healing

Concept

SPL® screws function in a manner similar to conventional locking screws at implantation and reduce construct stiffness over time, promoting interfragmentary motion. Delayed dynamization has shown enhanced healing when compared to constantly flexible fixation or early dynamization in animal models. [6, 7]



Clinically, favorable outcomes have been reported with dynamization of intramedullary nails between 3 - 5 months. [8, 9] In the presence of delayed unions, dynamization initiated between months 3 to 6 has been associated with higher bone union success rates. [10]

Technology

SPL® screws are stainless steel with a PLGA locking mechanism. The system is implanted using conventional plating techniques, including bi-cortical screw fixation. The polymer locking mechanism resorbs over four to six months, while the screw head remains in contact with the plate. Under load, the screw moves relative to the plate to create interfragmentary motion at the fracture site.

	STABILIZ SPL	ZIMMER MOTIONLOC	METAL LOCKING
MICROMOTION	✓	✓	
DELAYED MICROMOTION	✓		
USES ANY SCREW IN ANY HOLE	✓		✓
BI-CORTICAL FIXATION	✓		✓
FOLLOWS TRADITIONAL PROCEDURE STEPS	✓		✓

Reduced Stiffness

Axial stiffness decreased up to 57% after resorption of the SPL® locking mechanism. Decreases in fixation stiffness from 29-86% have improved rates of fracture healing and remodeling in animal models. [4, 6, 13]

Tested

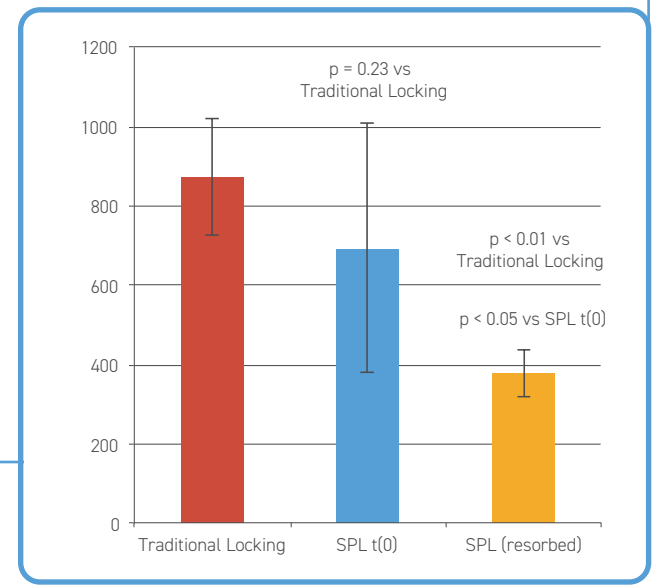
ADJECTIVE: test•ed \'tes-təd\

- subjected to or qualified through testing
- the presence, quality, or genuineness of anything having been determined by means of trial

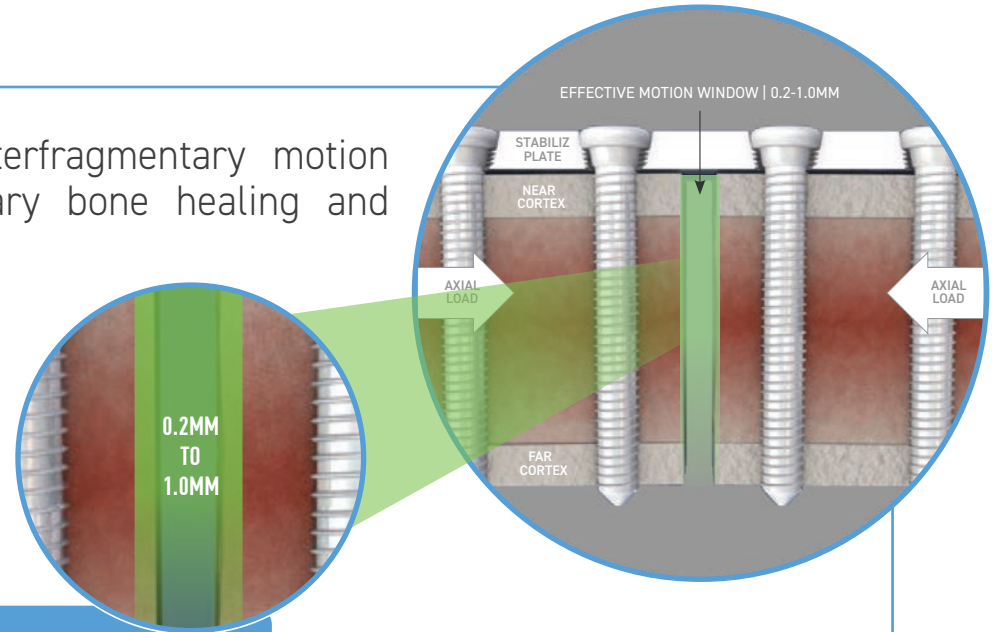
	Metal Locking Screws	SPL (t0) (% reduction compared to metal locking)	SPL (resorbed) (% reduction compared to metal locking)
Axial Stiffness (N/mm)	873 ± 146	694 ± 314 (21%)	379 ± 59 (57%)

SPL® screws were compared to standard metal locking screws using validated synthetic bone models in a diaphyseal bridge-plating construct.

SPL® screws created significant increases in micromotion at the near and far cortices after resorption. Interfragmentary motion between 0.2 to 1 mm has been shown to promote secondary bone healing and remodeling. [13, 14]



SPL® screws allow the interfragmentary motion shown to promote secondary bone healing and remodeling.

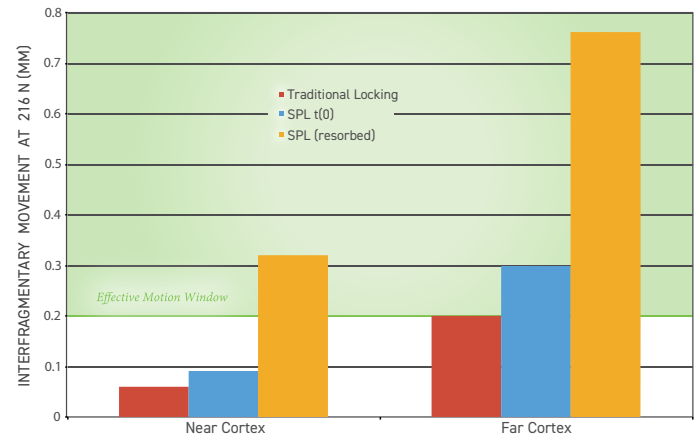


IFM between 0.2 - 1.0mm promotes bone healing

	Interfragmentary Motion (mm)	
	Near Cortex	Far Cortex
Metal Locking Screws	0.06 ± 0.02	0.20 ± 0.07
SPL t(0)	0.09 ± 0.04	0.30 ± 0.01
SPL (resorbed)	0.32 ± 0.08	0.76 ± 0.07

Interfragmentary motion evaluated via linear transducer at 216 N axial compression

SPL® screws demonstrated significantly increased IFM at both near and far cortices.



	Non-Locked [16]	SPL t(0)	SPL (resorbed)
Load at Failure	370 N	1277 N	912 N

Load Distribution

SPL containing constructs may provide more evenly distributed load sharing among screws with SPL end-screws functioning similar to standard cortical or cancellous screws, after resorption of the polymer locking mechanism. By contrast, standard locking screws may induce stress risers when used as an endscrew, resulting in reduced construct strength in torsion and bending. [15]

Load at Failure

SPL constructs tolerated higher loads than those reported for traditional non-locked implants. SPL loads exceeded forces seen with early, full weightbearing at 1x body weight (800N). [4]

Implant

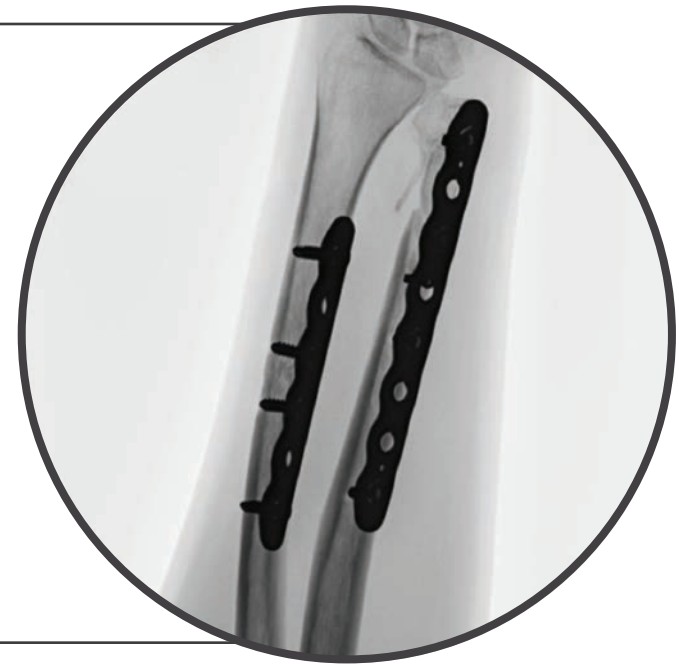
VERB: im•plant \im-'plant\
• to fix or set securely or deeply
• to insert in living tissue

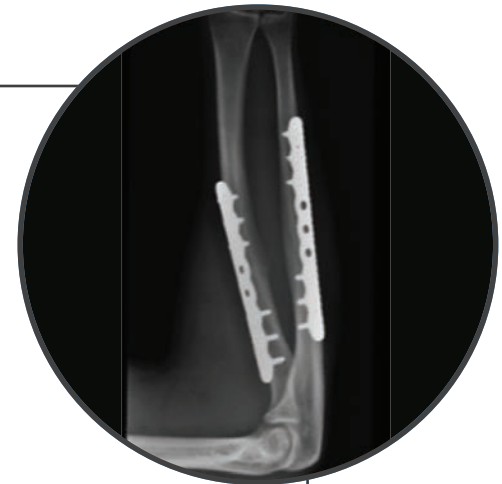
NOUN: im•plant \'im-,plant\
• device implanted in tissue

Patient: 27 yo male with mid-shaft radius & distal ulnar fractures.

Treatment: (Radius) 6-hole Stabiliz SSL plate, 4 non-locking screws. (Ulna) 9-hole SSL plate, 2 SPL® screws in comminuted segments. No bone grafting or biologics.

Results: Increasing callous formation with resolving fracture lines at 20 weeks.





Patient: 17 yo male with mid-shaft radius & ulnar fractures.

Treatment: (Radius) 8-hole Stabiliz SSL plate, 6 Stabiliz SPL® screws. (Ulna) 9-hole Stabiliz SSL plate using 6 Stabiliz SPL® screws. No bone grafting or biologics.

Results: Bridging bone healing at 24 weeks with full range of motion.

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[16] PATEL R ET AL. Crutch weightbearing on comminuted humeral shaft fractures: a biomechanical comparison of large versus small fragment fixation for humeral shaft fractures. J Orthop Trauma. 2011;25:300-305