SPL Locking Screw

FOR USE WITH STABILIZ FIXATION SYSTEM | TECHNICAL INFORMATION
THE PROBLEM: LOCKED PLATING MAY BE CONTRIBUTING TO FRACTURE HEALING COMPLICATIONS

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. [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]
THE SOLUTION: STABILIZ POLYMER LOCKING (SPL) TECHNOLOGY

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

CONCEPT
SPL locking 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 locking 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.

HIGHLIGHTS & UNIQUE BENEFITS
SPL screws provide bi-cortical fixation. Bi-cortical locking screws increase resistance to all applied forces, most notably torsion. [11, 12]

SPL screws do not require additional procedure steps: No shims, No locking caps.

SPL screws can be used in any plate hole: No minimum number of screws required, not limited to placement in diaphyseal bone only.

After resorption, SPL motion is constrained within the screw hole of the plate, not the screw hole in the near cortex.

Fig. 2 Illustration depicting Stabiliz Polymer Locking (SPL) Screw changing over time.
SPL Locking Screws were compared to standard metal locking screws using validated synthetic bone models in a diaphyseal bridge-plating construct under static axial compression and dynamic cyclic axial load to failure.

**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]

<table>
<thead>
<tr>
<th></th>
<th>Metal Locking Screws</th>
<th>SPL (t0) (% reduction compared to metal locking)</th>
<th>SPL resorbed (% reduction compared to metal locking)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Axial Stiffness (N/mm)</td>
<td>873 ± 146</td>
<td>694 ± 314 (21%)</td>
<td>379 ± 59 (57%)</td>
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</tbody>
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**INTERFRAGMENTARY MOTION**

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]
**Interfragmentary Motion (mm)**

<table>
<thead>
<tr>
<th></th>
<th>Near Cortex</th>
<th>Far Cortex</th>
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<tbody>
<tr>
<td>Metal Locking Screws</td>
<td>0.06 ± 0.02</td>
<td>0.20 ± 0.07</td>
</tr>
<tr>
<td>SPL t(0)</td>
<td>0.09 ± 0.04</td>
<td>0.30 ± 0.01</td>
</tr>
<tr>
<td>SPL, resorbed</td>
<td>0.32 ± 0.08</td>
<td>0.76 ± 0.07</td>
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**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 end-screw, 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]

<table>
<thead>
<tr>
<th></th>
<th>Non-Locked [16]</th>
<th>SPL t(0)</th>
<th>SPL resorbed</th>
</tr>
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<tbody>
<tr>
<td>Load at Failure</td>
<td>370 N</td>
<td>1277 N</td>
<td>912 N</td>
</tr>
</tbody>
</table>

Fig. 3
Illustration depicting how, with time, SPL Locking Screws promote interfragmentary motion at both near and far bone cortices.


CLAES, ET AL. Late dynamization by reduced fixation stiffness enhances fracture healing in a rat femoral osteotomy model J Orthop Trauma. 2011;25:169-174


FULKERSON, ET AL. Fixation of diaphyseal fractures with a segmental defect: A biomechanical comparison of locked and conventional plating techniques. J Trauma. 2006;60:830-835


