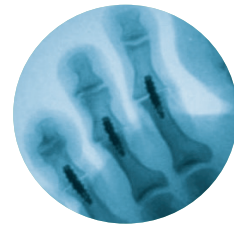




ToeMATE® Hammertoe Implant

Comparison of Biomechanical Strength



Background:

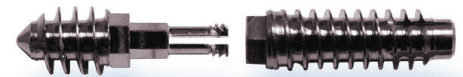
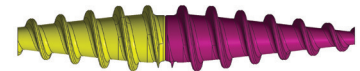
By some estimates, 7% to 20% Americans aged 31-60 years and 10% to 11% of Americans aged 60 years or older have hammertoe deformity.¹ Multiple implant devices are available for surgical treatment of a hammertoe deformity.² Comparative biomechanical testing between the Arthrosurface ToeMate® and a leading competitive hammertoe implant was conducted to assess the performance of these devices in the most clinically relevant attributes.

ToeMATE® (TM):

The ToeMate® implant device consists of two intramedullary bone screws and a taper lock pin, which provides a press-fit connection between the two screws. The implant is offered in two sizes with a straight (0 degree) and angled (10 degree) option.

StayFuse® (SF):

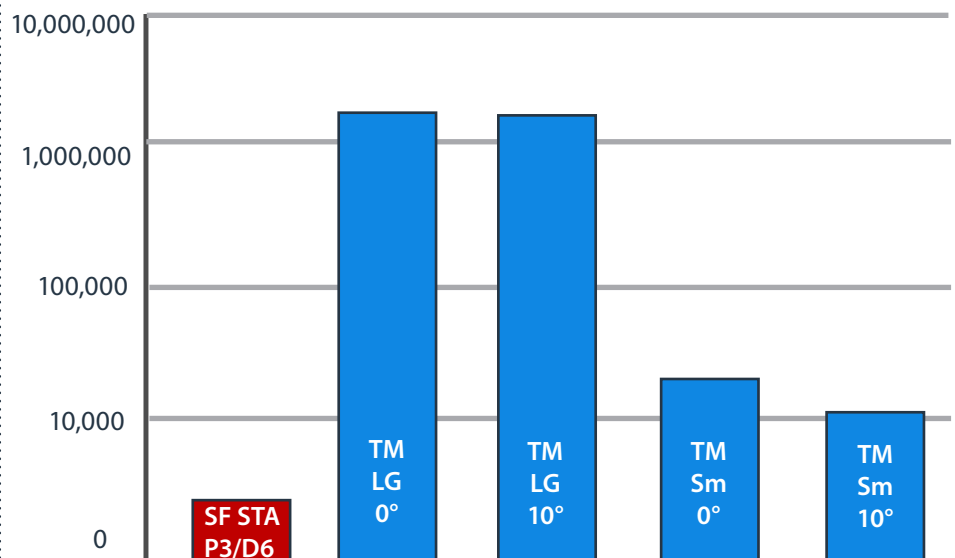
The StayFuse® implant device consists of two intramedullary bone screws that interlock via a ratcheted snap-in mechanism. The implant is offered in multiple sizes but only with a straight (0 degree) option.



Fatigue Test:

- This test was performed to simulate the repetitive loads that the toes might experience during normal, day to day activities prior to bony or fibrous union.
- Studies report that the load across the PIP joint can reach 169 N.³
- Representing a 1.3X safety factor, all devices were tested at an applied load of 228 N in the fatigue test setup.
- **The largest StayFuse® implant fractured @ 2,109 cycles; whereas the largest ToeMate® implant survived 2.5 million cycles with no observed failure. The smallest ToeMate® implant survived greater than 10,000 cycles before failure.**
- The smallest ToeMate® implant was at least 5X more durable and the largest ToeMate® implant was 1000X more durable than the largest StayFuse® implant.

Fatigue Test ToeMATE v/s StayFuse

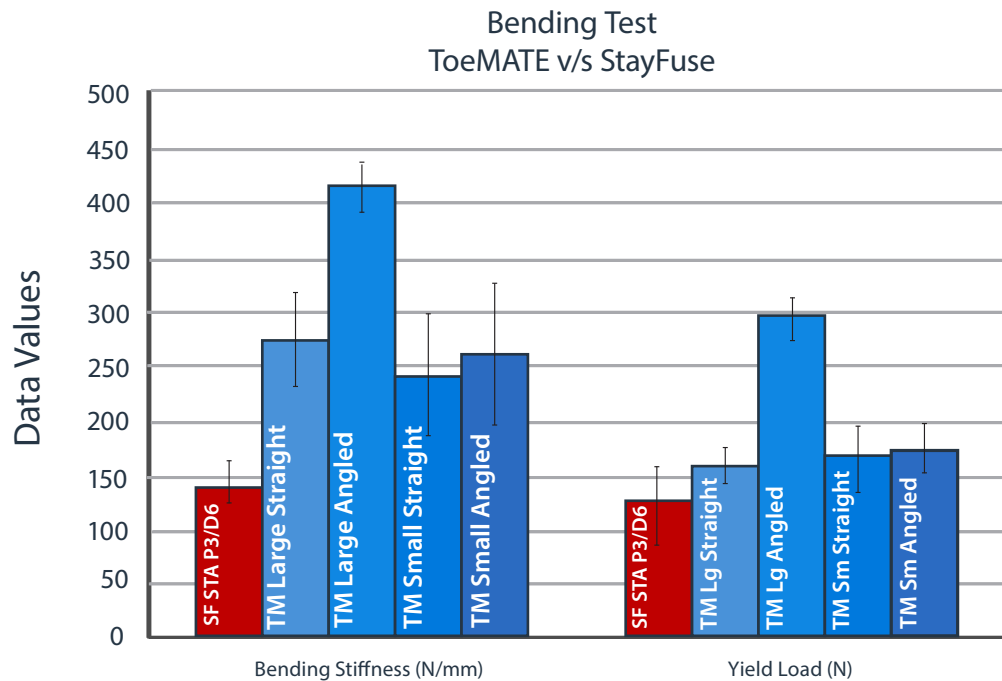


Number of cycles survived at a Load of 228 N.

*Data on file at Arthrosurface

Bending Test:

This test was performed to evaluate the rigidity of the implant construct and its ability to resist bending loads. **The bending stiffness (N/mm) or rigidity of the ToeMate® implant was at least 1.8X higher than that of the StayFuse® implant and the yield load (N) or resistance to bending was at least 1.3X higher.**



Load to failure in a single load application setting.

**Data on file at Arthrosurface*

Pullout Strength Test:

The axial pullout force required to pull or disengage the screw out of a 20 PCF sawbones model for the ToeMATE® small and large screws was higher by at least 35% compared to the largest StayFuse® screw.

Dissassembly Strength Test:

Both the ToeMate® and the StayFuse® hammertoe implants consist of two intramedullary screw components that are assembled intraoperatively resulting in a single connected intramedullary screw device. The disassembly strength of the ToeMate® and StayFuse® hammertoe implants was found to be within the same range of values, with no observed statistically significant differences between the means.

Summary:

The ToeMate® implant has superior mechanical properties compared to the StayFuse® implant, thus providing a biomechanical advantage for a stiff, strong and immobile PIPJ fixation. It is well accepted in orthopaedic medical literature that in vitro biomechanical performance of an implant determines its in vivo clinical performance. In a retrospective clinical review of the StayFuse® hammertoe implant in a series of 38 patients, only 60.5% patients showed a bony or fibrous union with a complication rate of 55.3%.⁴ Based on its superior mechanical properties, the ToeMate® implant is expected to provide improved clinical results.

References:

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- Moon, Jared L., et al. "Digital arthrodesis: current fixation techniques." Clinics in podiatric medicine and surgery 28.4 (2011): 769-783.
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