Clinical Monograph

arthrosurface®

ToeMATE® Hammertoe Implant

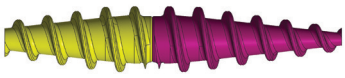
Comparison of Biomechanical Strength

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.

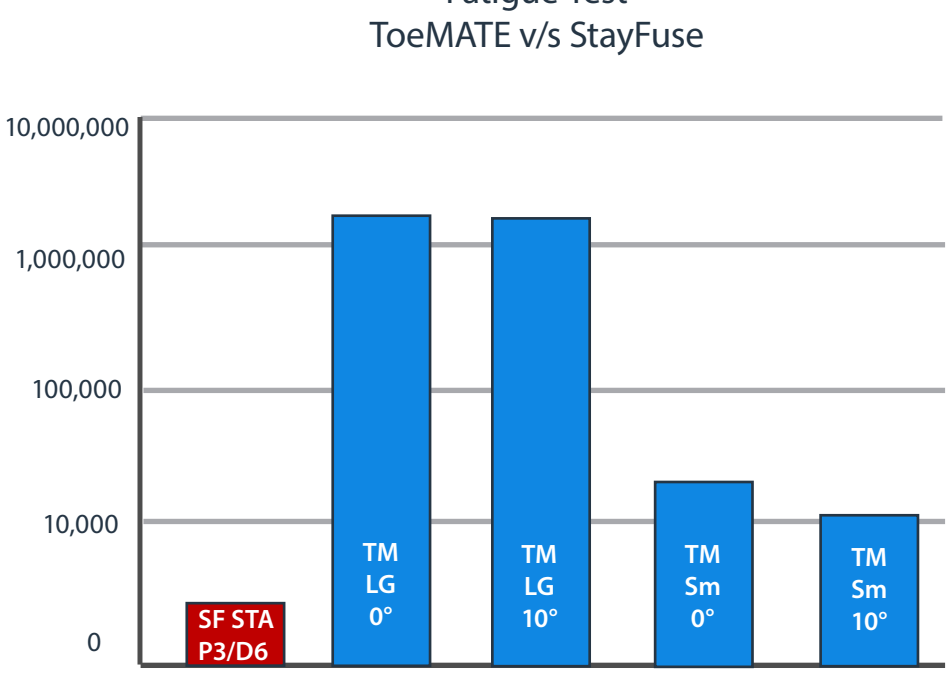


StayFuse® (SF):

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 repetitve 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.



Number of cycles survived at a Load of 228 N.

**Data on file at Arthrosurface*

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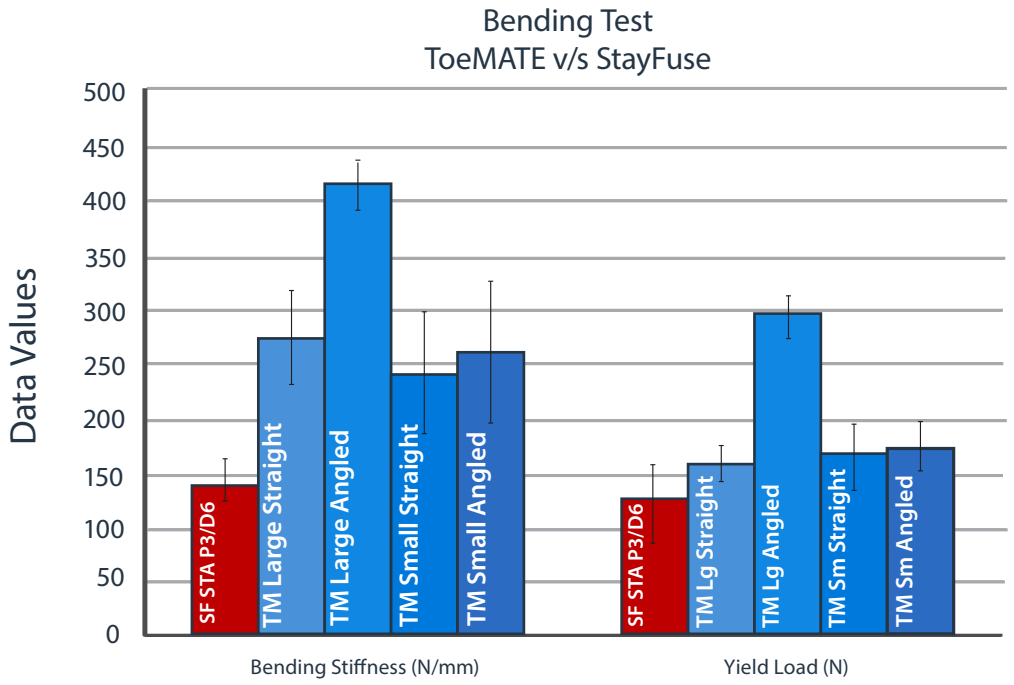
Bending Test:

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.

Dissasembly 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:

1. Schuberth, John M. "Hammer toe syndrome." The Journal of foot and ankle surgery 38.2 (1999): 166-178.
2. Moon, Jared L., et al. "Digital arthrodesis: current fixation techniques." Clinics in podiatric medicine and surgery 28.4 (2011): 769-783.
3. Stokes, I. A., W. C. Hutton, and J. R. Stott. "Forces acting on the metatarsals during normal walking." Journal of anatomy 129.Pt 3 (1979): 579.
4. Ellington, J. Kent, et al. "Radiographic analysis of proximal interphalangeal joint arthrodesis with an intramedullary fusion device for lesser toe deformities." Foot & ankle international 31.5 (2010): 372-376.