Dynamic and Load-to-Failure Testing of the DePuy Synthes FIBULINK™ Syndesmosis Repair System and Arthrex Syndesmosis TightRope® XP Implant System

DePuy Synthes Research and Development

Abstract

The FIBULINK™ Syndesmosis Repair System was compared to Arthrex Syndesmosis TightRope® XP (n=8 each) biomechanically in a poor-quality bone model in dynamic testing for 300,000 cycles and in load to failure (at both 2 mm displacement and construct failure). The FIBULINK Implant was statistically superior to TightRope XP in all comparisons (p-value ≤ 0.001), with, on average, less than a third of the overall displacement (0.61 mm vs 2.07 mm at maximum load) and 61% higher tiffness during dynamic cycling at 300,000 cycles (438 N/mm vs 273 N/mm at maximum load), as well as triple the fixation strength (394 N vs 129 N) at 2 mm displacement.

Objective

The objective of the test was to compare the mechanical performance of the FIBULINK System and TightRope XP using a bench-top test model. Testing was performed in a simulated poor-quality bone model to replicate worst-case clinical conditions for implant performance. The product was cyclically loaded to evaluate displacement over time as well as statically loaded to failure.

Materials and Methods

The FIBULINK Implant and TightRope XP implants were tested in polyurethane foam (per ASTM F1839) consisting of a 15 pcf cancellous core with a 1 mm, 20 pcf cortical layer. To provide syndesmotic reference, 14 mm and 41 mm thick blocks were used to approximate the fibula and tibia respectively, within readily available foam dimensions. Eight samples from each group were inserted per the manufacturer's specification and provided instrumentation. All test constructs were fabricated maintaining 2.5 mm of space between the tibia and fibula test blocks.

Per manufacturer's instructions and provided instrumentation,[1,2] each construct was pre-tensioned to a constant 20 N to preload the construct and ensure that the implant was appropriately tensioned and affixed. While under 20 N of tension, the displacement reading was zeroed. The constructs were then dynamically cycled from 20 N–113 N for 300,000 cycles. The loading scenario was derived from the loads that bones experience from the ligaments that make up the syndesmosis joint during healing.[3] The 300,000 cycles represent a conservative 8,000 steps per day on the affected limb for 10 weeks. Once fatigue testing was completed, static load-to-failure testing was executed at a speed of 5 mm/min to a maximum displacement of 5 mm. Load was measured at 2 mm of displacement[4] and the peak load prior to reaching 5 mm of displacement.

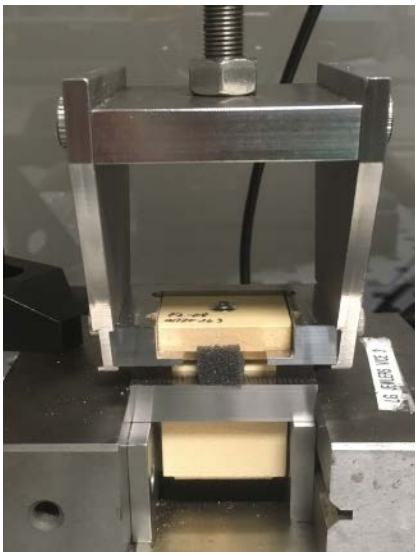

Figure 1 Representative Image of Test Fixture

Results

Assembly

The tensioning mechanism varies between the FIBULINK System and TightRope XP. TightRope XP required multiple, increasing tensioning steps that exceeded 100 N to achieve a steady 20 N preload. The FIBULINK Implant required fewer steps and more consistently maintained the 20 N pre-tension after application (Figure 2).

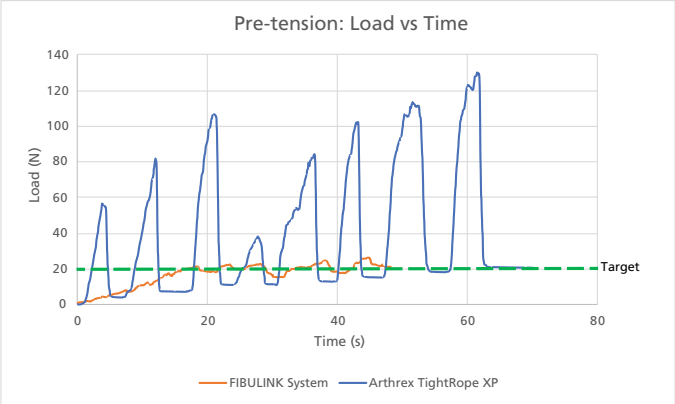

Figure 2 Force (N) relative to time (s) required to achieve 20N of pre-tension (representative graph).

Additionally, the FIBULINK Implant's stiffness was statistically superior with a 70% higher average stiffness at the first full cycle and a 61% higher average on the last cycle when compared to TightRope XP (366 N/mm vs 215 N/mm and 438 N/mm vs. 273 N/mm, respectively) (Figure 4).

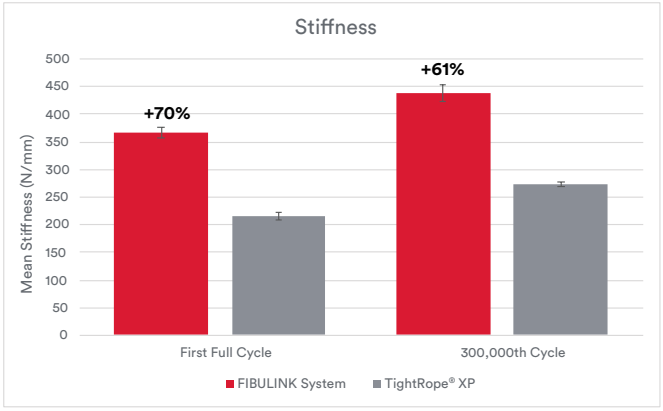

Figure 4 Mean (+/-SD) stiffness at first full dynamic cycle and 300,000th cycle. The FIBULINK Implant's stiffness was 61% higher than TightRope XP on the last cycle.

Dynamic Testing

Both systems completed 300,000 cycles of dynamic loading, however, one TightRope XP exceeded the 2 mm overall displacement threshold during testing. The FIBULINK System was found to be statistically superior in total displacement throughout the entire dynamic cycle. The average displacement at the first full amplitude cycle while fully loaded (113 N) was 230% higher for TightRope XP when compared to the FIBULINK Implant (1.48 mm vs 0.45 mm). Additionally, at the final, 300,000th cycle, TightRope XP's average displacement while fully loaded was 240% higher when compared to the FIBULINK System (2.07 mm vs 0.61 mm) (Figure 3).

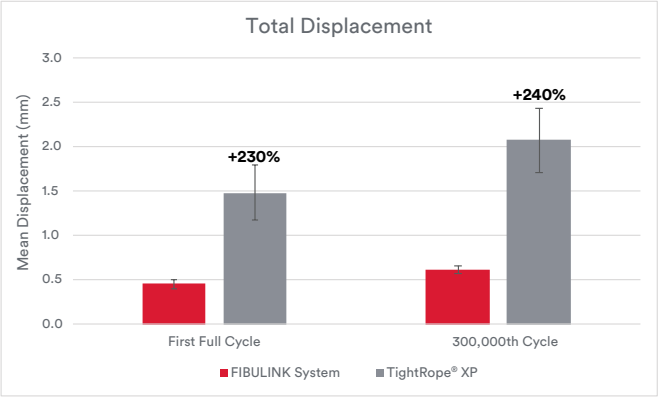

Figure 3 Mean (+/- SD) total displacement at first full cycle and 300,000th cycle. At the final cycle, TightRope XP's average displacement was 240% higher than the FIBULINK Implant.

Static Testing

A comparison of the static load-to-failure results shows statistical superiority in average tensile load at 2 mm displacement and ultimate load (peak load prior to reaching 5 mm of displacement) between the FIBULINK Implant and TightRope XP (Figure 5). The average load at 2 mm of displacement was 206% higher for the FIBULINK Implant (394 N vs 129 N). In addition, the FIBULINK Implant resisted, on average, a 62% higher ultimate load (424 N at 2.42 mm vs 261 N at 3.84 mm). The failure mode for the FIBULINK Implant was screw pullout (n=7) and suture failure (n=1) while the failure mode for TightRope XP was the button subsiding in the foam (n=8).

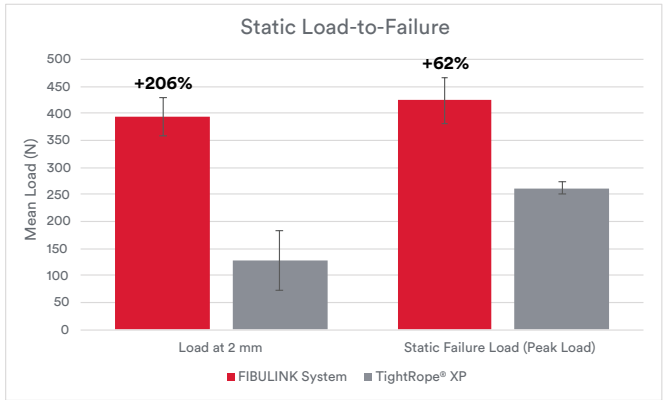

Figure 5 Mean (+/-SD) static load failure after fatigue testing. The average load at 2 mm was 206% higher for the FIBULINK Implant.

Discussion

From a clinical perspective, the fibula displacement difference of 2 mm or more medial to lateral is considered to be pathologic.[5-9] This is primarily due to 2 mm lateral displacement equating to articulation on just 40% of the tibiotalar surfaces. Such an offset can lead to a mismatch in congruency of the surfaces, resulting in instability and chronic osteoarthritis.[10-12]

While the TightRope XP test constructs were pre-tensioned per the surgical technique, the tension significantly dropped once the sutures were released. This demonstrates that the implant may not maintain the same level of manually applied tension. In contrast, the FIBULINK System achieved and retained tension more consistently with the variable tensioning knob.

During dynamic testing, TightRope XP constructs, on average, displaced 1.48 mm from this initial pre-tensioned position after the first full amplitude, cyclic load to 113 N. Additionally, half of the TightRope XP constructs exceeded 2 mm of total displacement within 300,000 cycles while at peak load (113 N). Movement from the initial tensioned position may equate to immediate postoperative syndesmotic widening. Excessive displacement of the tibiofibular joint post-operatively may become symptomatic. In contrast, the FIBULINK Implant only displaced an average of 0.61 mm in total after 300,000 cycles allowing for precise, anatomic syndesmotic fixation.[13,14]

During static load-to-failure, the FIBULINK Implant had higher load at 2 mm total displacement and at ultimate failure. The testing demonstrates that even in a poor quality bone model, the FIBULINK Implant provides superior fixation strength.

Conclusion

In the dynamic and load-to-failure testing of the DePuy Synthes FIBULINK Syndesmosis Repair System and Arthrex Syndesmosis TightRope XP Implant System, the FIBULINK System was shown to be statistically superior to TightRope XP in all biomechanical performance comparisons.[15]*

References

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*Bench testing may not be predictive of clinical performance. Sample size of n=8. Percentages and ratios based on averages.

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