

ORTHOLOX® UHMWPE BAND SYSTEM MECHANICAL PROPERTIES

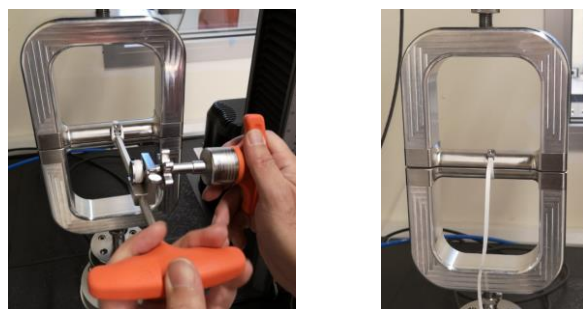
Ortolog Research & Development

Objective

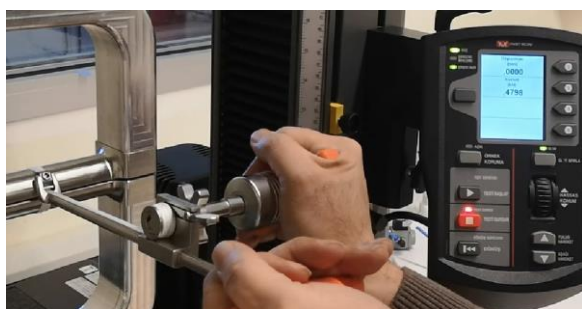
The purpose of this study was to define the mechanical properties of an Ortholox® UHMWPE Band construct in a clinically relevant test setup. Additionally, these results were then benchmarked against both a competitor’s polymer tape and an 18 ga monofilament stainless steel wire (1.0mm Dia.) which is commonly used in cerclage procedures.

Materials and Method

The test environment temperature was measured as 25.3°C. The test samples were secured around a pair of semicircular fixtures spaced **2 mm** apart. The combined outer diameter of the fixtures was approximately **32mm** and the **circumferential length was approximately 100mm**, simulating the approximate circumference of the proximal humerus or diaphysis of the femur. Ortholox® UHMWPE Band System constructs were wrapped **twice** around the fixture and locked according to the recommended technique. (Picture 1) Load applied by Band to fixtures during final tightening of the band by using torque limiting T-Handle was measured as 479N. (Picture 2).



Picture 1. Application of the Ortholox® UHMWPE Band System to the test rig and general view of test setup



Picture 2. Final tensioning of the Ortholox® UHMWPE Band System around the fixture with the special torque limiting T-Handle

Testing was carried out using an INSTRON 5965 Universal Testing System (INSTRON, Norwood, MA). Five samples per group in four different groups (a total of twenty samples) were cycled at 50 to 500N for 50 cycles with a subsequent pull to failure of 4000N at a speed of 40N/s.

Same method was applied to competitor Polymer Tape and 18 ga stainless steel wire. Testing was carried out using an INSTRON ElectroPuls Dynamic Testing System (INSTRON, Canton, MA) (*). The Polymer Tape was secured around a pair of semicircular fixtures spaced **2 mm** apart. The combined outer diameter of the fixtures was approximately **100 mm (the circumference being 314 mm)**. The Polymer Tape constructs were looped **twice** around the fixture and secured

with half-hitches after tensioning. The 18 ga wire was secured by twisting the wire tails **7 times** using a pair of pliers.

Total cyclic displacement, as well as cyclic displacement at cycles 1 and 50 were calculated using the resulting load vs displacement curve of each sample. Cyclic displacement was defined as the unrecoverable movement experienced by each sample over the course of cycling. The mode of failure and maximum load was recorded for each sample. T-tests were run to determine if outcome metrics differed significantly between the groups.

Results

Measurement ± standard deviation testing metrics for Ortholox® UHMWPE Band System, Polymer Tape construct and stainless steel cerclage groups are presented in Table 1.

Table 1

Group	Ortholox® UHMWPE Band ¹	Polymer Tape	18 ga Stainless Steel Wire
Displacement at Cycle 1 (mm)	0.17 ± 0.05	0.15 ± 0.05	0.39 ± 0.04
Displacement at Cycle 50 (mm)	0.37 ± 0.08	0.31 ± 0.12	0.61 ± 0.05
Total Cyclic Displacement(mm)	0.33 ± 0.13	0.32 ± 0.17	0.75 ± 0.07
Maximum Load (N)	6950.42 ± 1103.93	4359.66 ± 463.23	935 ± 143.31

Conclusion

An Ortholox® UHMWPE Band System construct produced less than half the displacement compared to 18 ga stainless steel wire cerclage and almost the same displacement with Polymer Tape. The Ortholox® UHMWPE Band System construct carried more than 50% load compared to Polymer Tape and 7.5 times as much the ultimate tensile load compared to 18 ga stainless steel wire. The Ortholox® UHMWPE Band System construct offers a viable alternative to both a Polymer Tape cerclage construct and commonly used 18 ga stainless steel wire for cerclage procedures with regards to strength and cyclic stability. Where fatigue strength and ultimate tensile strength of a cerclage construct is paramount, Ortholox® UHMWPE Band System would be safe option.

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¹ Fixture outer diameter used in Polymer Tape test is specified as 10cm (100mm). 314mm Polymer Tape was wrapped on a cylinder of said diameter. Ortholox® UHMWPE Band System fixture outer diameter is 32mm. 100mm tape can be wrapped around a cylinder of said diameter. Since the load distribution is 3.14 times more per mm in Ortholox® UHMWPE Band System, the comparison is made accordingly. Test results are available on file at Ortolog Medikal AS.