

# Gap formation analyses

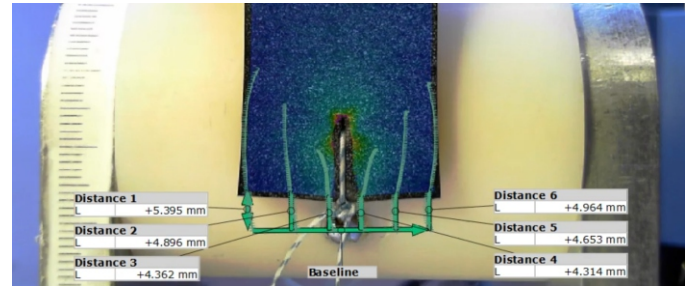
## ZipE® Knotless Tissue Repair Devices



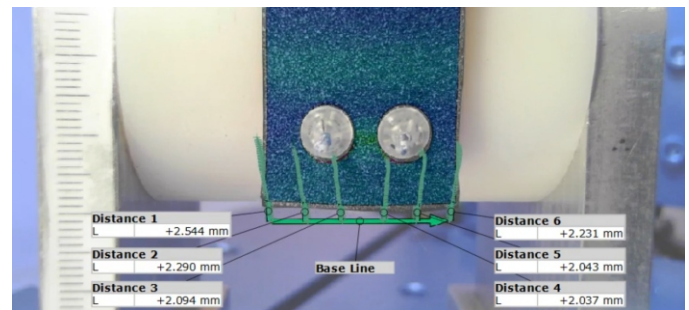
Present arthroscopic surgical constructs rely on a direct suture-tendon interface repairing method; this induces high mechanical stress concentrations around the suture zone that may lead to progressive tissue damage causing earlier rip-through failure. Moreover, the thin strands of suture can only distribute the holding loads in a small area of contact. ZipE® Knotless Tissue Repair devices function by distributing evenly the loads through a capture button over a larger area. Because of this load distribution, the holding forces act in a more uniform fashion and thus enhance the surgical construct to protect the tissue against rip-through effects. The larger contact area reduces the relative displacement of the tendon edge when muscle contraction occurs, a condition called gap formation.

An in-vitro mechanical study was conducted for simulation of the gap formation effect of the different surgical constructs using UHMWPE suture. All tests were conducted using current surgical constructs as well as ZipE® Knotless Tissue Repair devices. Displacement measurements were performed by computer image analyses using Digital Image Correlation methods. The software was able to track and measure the vertical displacement of all the individual points in the specimen and then gap formation was calculated as the average displacement of those points.

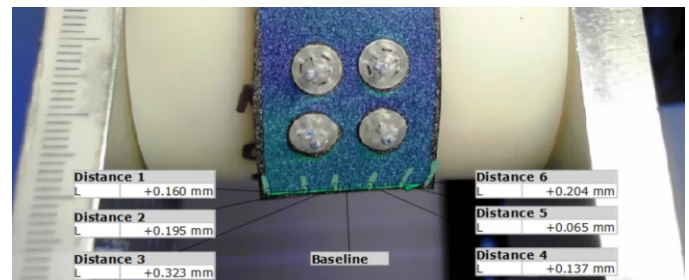
The average gap formation for the ZipE® constructs resulted in a lower displacement than the non-ZipE® counterparts. This suggests that a more even load distribution of the holding forces can result in a lower relative displacement of the repaired tissue edge. A lower gap formation may improve clinical outcomes in terms of repaired tissue strength, quality of repair and re-tear rates.



Simple Loop configuration (#2 suture with 1 anchor)



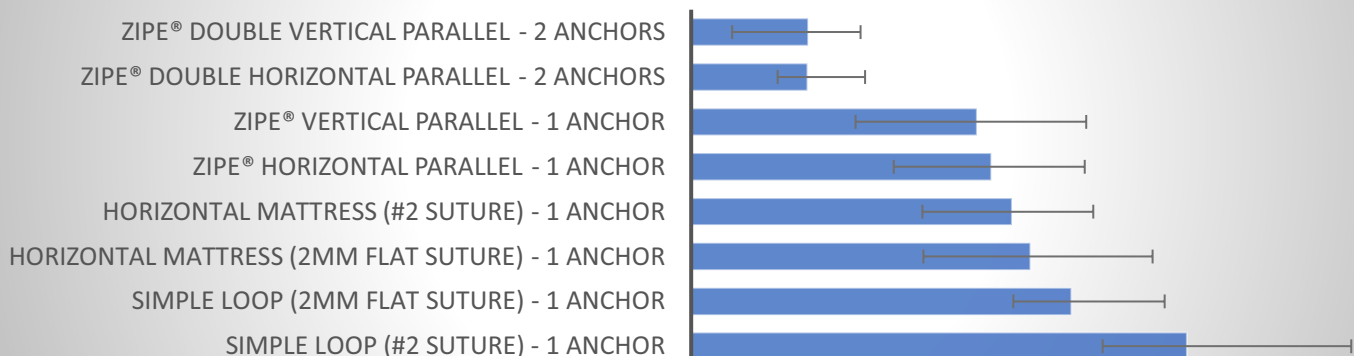
ZipE® Horizontal Parallel configuration (#2 suture with 1 anchor)



ZipE® Double Parallel configuration (#2 sutures with 2 anchors)

### Average Gap Formation (mm) @ 80 N

Lower is better



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