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PULLOUT FORCE OF POLYPROPYLENE MESH DEPLOYED BY ENDOFAST RELIANT FASTENER - A COMPARATIVE STUDY IN A SHEEP MODEL

Hypothesis / aims of study

EndoFast Reliant™ is a minimally invasive system designed for vaginal mesh reinforcement using four soft- tissue stainless steel fasteners (Fig. 1), avoiding the use of trocars or needles, and requiring a single vaginal incision. Other options are based on tunneling of mesh straps through the obturator membrane (tunnel technique), or mesh cover over the defect without sutures (pocket technique).

Fig.1 - Schematic drawing of a fastener.

The aim of this study was to evaluate and compare the mechanical pullout force needed to detach mesh straps deployed by different techniques in a sheep model over time.

Study design, materials and methods

A comparative study assessing the mechanical pullout forces that were needed to detach monoflilament polypropylene mesh straps (Biomedical Structures Ltd) from the tissue. The study included three techniques for deployment: Mesh starps deployed by the EndoFast Reliant™ fastener vs. mesh straps deployed in a tissue pocket or in a tissue tunnel. The tunneling technique mimics the trans obturator mechanism for mesh overlay and the pocket technique is comparable to mesh overlay in connective tissue without suturing. The inserted mesh straps size were 4.5 X1.5 cm for the fastener and the pocket deployment and 6.5X1.5 cm for the tunneling deployment technique. This difference was due to the longer arms of the straps in the tunneling deployment technique in the current used kits. All straps were implanted in the muscular area of the sheep thigh.
Mechanical pullout forces were assessed at the following time points: 0, 3, 7, 15, 30 and 45 days after deployment. The sheep were under general anesthesia during mesh straps insertion and pullout examinations. Continuous horizontal traction at an average speed of 0.15 m/sec was applied until the strap was detached from the tissues and mobilization occurred. At each time point a force gauge (TSCALE IQ-20) was used to measure the pullout force in grams. In each sheep, a total of 15 mesh straps were deployed (5 for each deployment technique). At each designated time point, one sheep was tested for measurements of the pullout forces of the mesh straps.

Results

At days 0 and 3, we observed significant higher pullout forces of the EndoFast Reliant™ system compared to the other methods ($p<0.01$). At day 7 this trend continued without reaching statistical significance (Table 1). At day 15 we observed breaking of the mesh without detaching it from the tissue, so the pullout forces were similar in all straps. We continued to observe this phenomenon also at days 30 and 45. Accordingly, the average tearing force of the same mesh straps in vitro was found to be 3936 gr, similar to the average pullout forces of all straps from day 15.

		Day 0	Day 3	Day 7	Day 15	Day 30	Day 45
EndoFast Reliant	Min	1420	930	2240	3330	2720	3660
	Max	1730	2000	3310	5600	4600	4650
	Mean	1604*	1512.5*	2805	4112.5	3247.5	4220
Pocket	Min	80	630	430	2930	3020	2150
	Max	170	1180	3810	5610	4880	5590
	Mean	112	900	1906	4344	4310	4030
Tunnel	Min	170	440	1700	3050	3420	3230
	Max	320	820	3240	5300	3900	4350
	Mean	282	637.5	2390	4457.5	3617.5	3787.5

Table 1: Mesh pullout force in grams during surgery (day 0) and post operative period (* $p<0.01$).

Interpretation of results

During early post-operative phase (0-7 days) the pullout forces needed to detach the mesh straps with the fastener were significantly higher than the other insertion modalities (pocket and tunnel). Forces increased progressively in all techniques up to Day 15 to plateau, where the pullout force was reaching the mesh tearing forces. Similar results of early plateau were demonstrated in other pullout model (1).

Concluding message

We conclude that in a sheep model the EndoFast Reliant method of deployment generates better holding force in soft tissue compared to mesh deployed in a pocket or by tunneling technique. This may imply to a better immediate post operative support during mesh overlay with fasteners in pelvic organ prolapse repair.

References

1. Int Urogynecol J Pelvic Floor Dysfunct. 2008 Mar;19(3):397-400

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Is this a clinical trial?	**No**
What were the subjects in the study?	**ANIMAL**
Were guidelines for care and use of laboratory animals followed or ethical committee approval obtained?	**Yes**
Name of ethics committee	**Assaf Harofe Medical Center IRB**