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MESH WOVEN FROM PURE COLLAGEN THREADS FOR TREATMENT OF STRESS URINARY INCONTINENCE

<u>Hypothesis / aims of study</u>

SUI (Stress urinary incontinence) is a major problem affecting approximately 40% of women between 40 and 60 years. Sling operations are currently the gold standard of treatment for this condition [1]. Our novel construct is a pure collagen mesh woven from high strength collagen threads. Our aim is to test the biocompatibility and tissue integration of this mesh in a rat model.

<u>Study design, materials and methods</u>

Akkus and co-workers developed a novel electrocompaction process to transform pure collagen solution into highly dense aligned threads [2]. Our mesh is made of electrocompacted collagen threads which are woven to form macroporous meshes which are then cross-linked in a 2% genipin solution. Meshes were implanted suburethrallly into (2) female Sprague Dawley rats using the transvaginal technique. Meshes were then harvested at the two week and one month time points.

<u>Results</u>

Meshes were mechanically robust enough to travel smoothly through the abdominal muscles without tearing during the procedure. Both rats reacted well and survived until the planned time points. Histopathological evaluation at two weeks revealed excellent cellular infiltration, beginning of the healing response, focal chronic inflammation, neovascularization, tissue integration and granulation tissue deposition. No degradation was noticed. Evaluation of the one month time point revealed the same results with more neovascularization and tissue integration, minimal inflammation and new collagen deposition. No degradation was noticed at this point as well.

<u>Interpretation of results</u>

The most common slings are made from polyprolene; providing long-lasting mechanical support but erosions and extrusions are not uncommon. There are more than 40 slings on the market made from synthetic, autograft, allograft or xenograft materials which are used in SUI procedures. However, each maintains variable biocompatibility, some lack long term mechanical support and others present complications. Both material and design are affecting the fate of biomaterial. Our mesh showed early biocompatibility in the form of tissue integration and neovascularization with additional host collagen formation at one month.

<u>Concluding message</u>

Our novel mesh showed excellent early tissue response in the form of neovascularization and tissue deposition at 2 weeks with the addition of new collagen formation at one month. These results are promising as they indicate potential for complete remodelling and recipient tissue replacement. More long-term histological and mechanical testing in animal models are needed to fully assess success of the mesh.

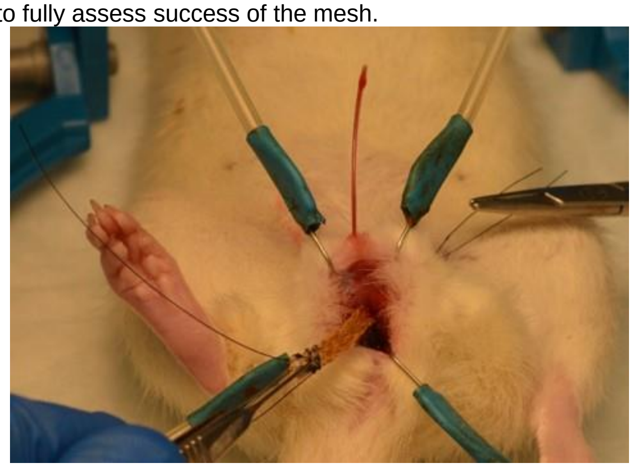
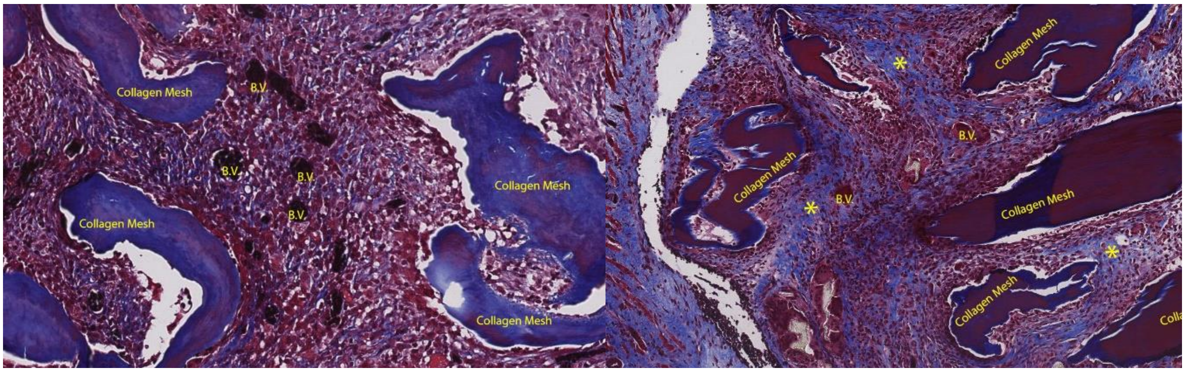


Figure 1: Transvaginal suburethral implantation of the novel pure collagen mesh



A : Histology at 2 weeks **B :** Histology at one month

* refer to new collagen formatiom , **B.V.** refer to de novo blood vessels formation

Figure 2: Showing tissue integration and neovascularization at two weeks' time point with additional new collagen deposition (the blue areas) in-between threads of at one month time point.

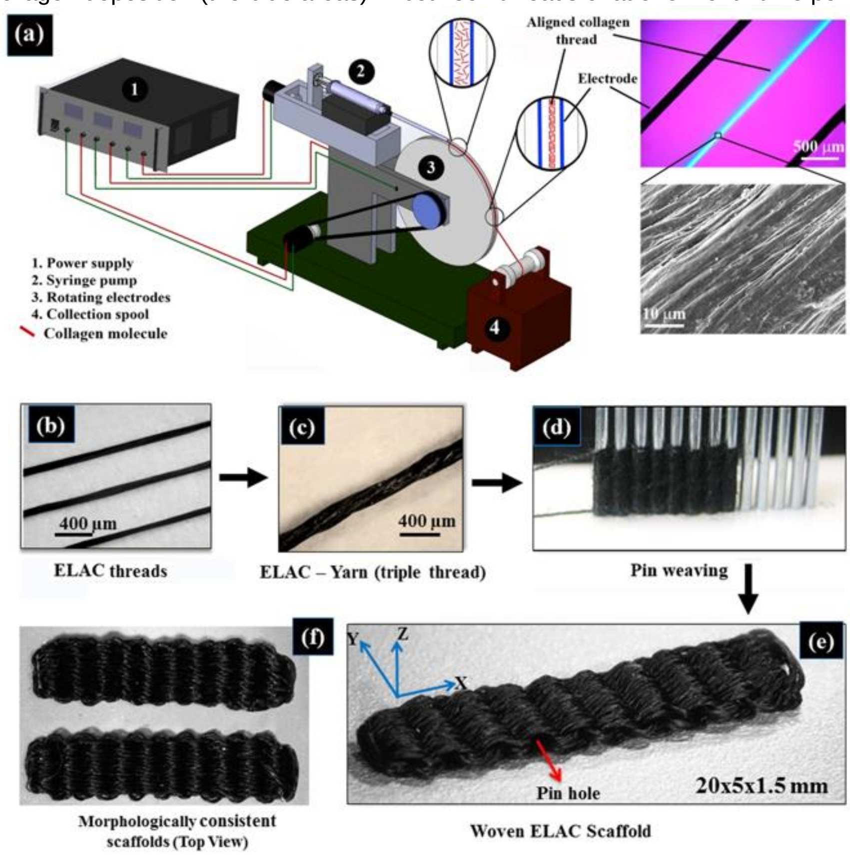


Figure 3 : Schematic of the rotating electrode electrochemical alignment device (REEAD) used to produce compact collagen threads
(a) Main components of the device. Compensated polarized images in the top left insert show the aligned collagen molecules between electrodes. The closely packed and aligned topography of the fiber surface is evident from the electron microscopy image.
(b) Individual collagen threads made by REEAD
(c) Yarns made by twisting multiple collagen threads together
(d) Pin- setup for weaving collagen scaffolds.
(e) The resulting woven collagen scaffold
(f) Two scaffolds to demonstrate the consistency of fabrication

N.B. We are currently running study of biocompatibility and mechanical specifications of our novel sling at large number of animals with different crosslinking materials and longer duration. The results will be available before the meeting dates.

References

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2. Cheng, X., et al., An electrochemical fabrication process for the assembly of anisotropically oriented collagen bundles. Biomaterials, 2008. 29(22): p. 3278-3288.

Disclosures

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