Combination of an Annulus Fibrosus Repair with a Mechanically Interlocked Patch and a Nucleus Pulposus Augmentation with Acid-Tyramine Hydrogel in an *Ex Vivo* Model

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Objective

The current gold-standard treatment for lumbar disc herniation is discectomy, which provides symptomatic relief, but does not prevent re-herniation. Our approach combines (i) annulus fibrosus (AF) repair using a mechanically interlocked patch (iPatch) comprising polyethylene terephthalate (PET) fibers[1] (Fig.1), and (ii) nucleus pulposus (NP) augmentation with hyaluronic acid-tyramine hydrogel (HA-Tyr). The aim of the study was to test the influence of the viscosity of the HA-Tyr hydrogel on the mechanical function of the repaired disc after experimental herniation.

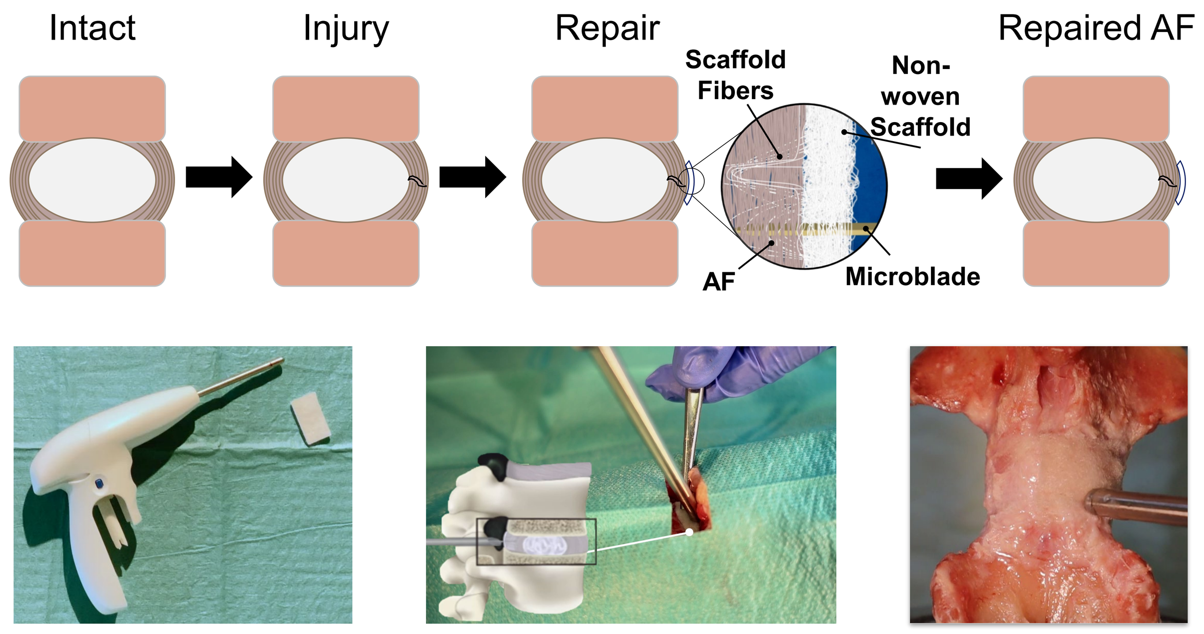

Fig.1: Mechanically interlocked patch affixed to the disc via fibers inserted into the soft tissue.

Methods

Bovine caudal intervertebral disc segments (N=23) underwent an induced injury through annulotomy and partial nucleotomy (NP volume removal of ~20%) and were divided into three treatment groups (n=6) and one control group (n=5). The treated groups were repaired with iPatch and HA-Tyr injection with different viscosities. Control group segments remained unrepaired to simulate discectomy. Matched mixed-effects model analysis with Tukey's post-hoc was used to statistically compare the groups. Significance level was α = 0.05. The protocol was separated in two parts:

(1) Biomechanical parameters under compressive-tensile cycles for intact, injured, and repaired intervertebral disc conditions (Fig.2).

(2) Load capacity was determined until failure, defined as either NP herniation (control) or hydrogel extrusion (treatment groups).

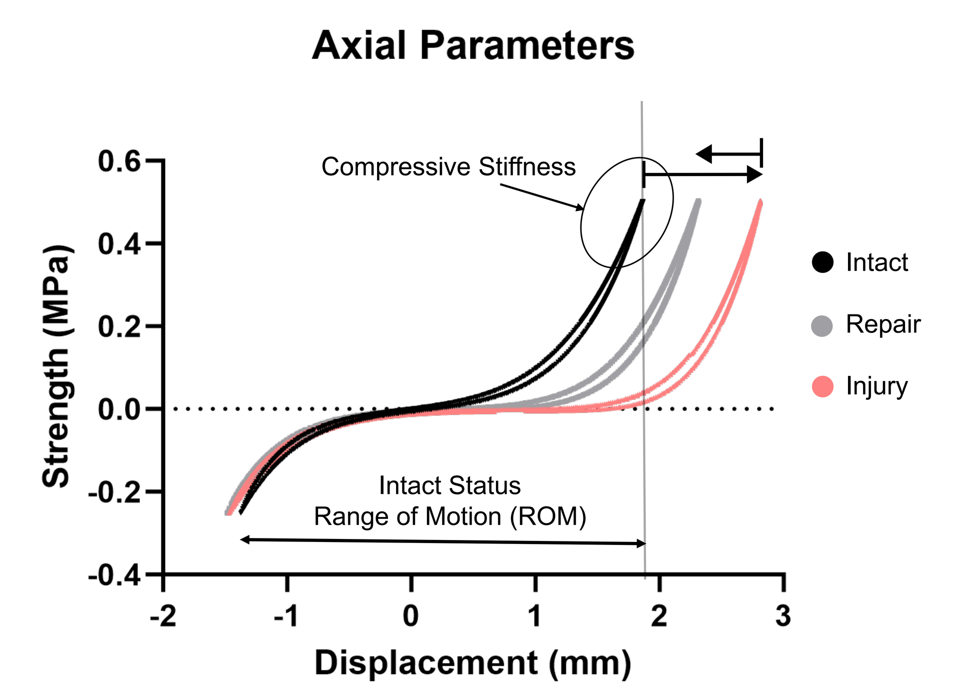

Fig.2: Strength-displacement curve with analyzed regions.

Results (1)

ROM for injury was significantly increased in all groups compared to intact disc segments (p<0.001) (Fig.3). ROM values in the high viscosity group were closest to the intact state (mean diff. to injury= +13.1%; p<0.001), while the low viscosity group remained mechanically similar to the injured disc (mean diff. to injury=+3.4%; p=0.48) (Fig.3).

Improvements from the injured condition were observed in all three treatment groups although none fully recovered compressive stiffness.

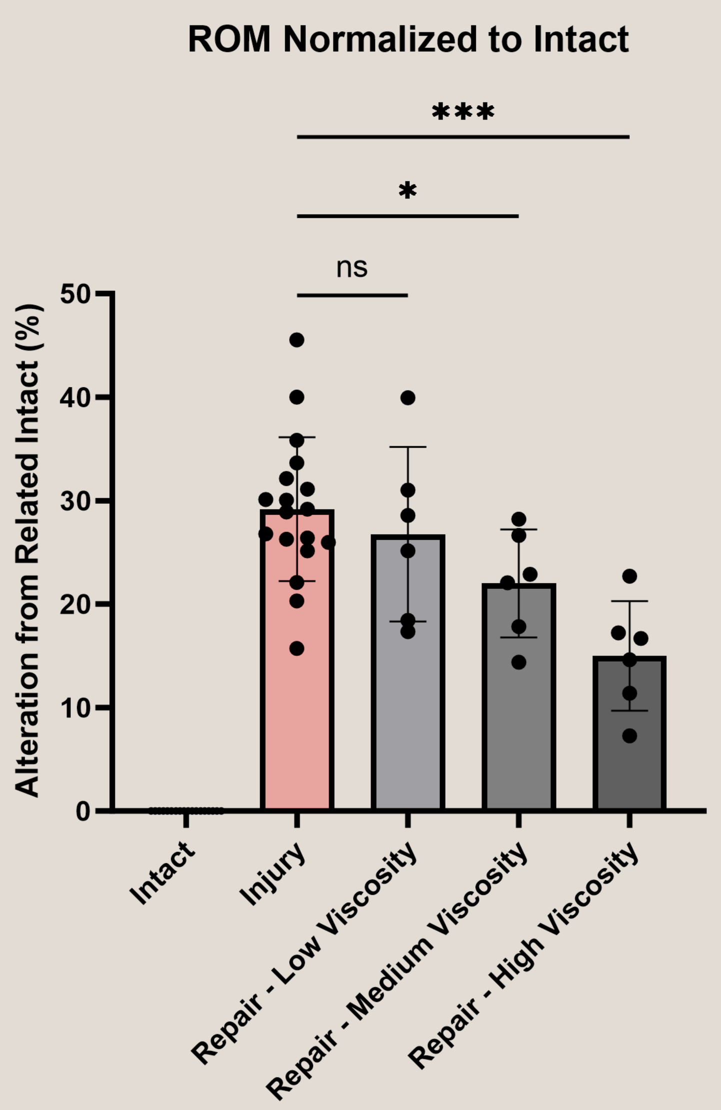

Fig. 3: : Calculated range of motion from strength-displacement curve.*: p < 0.05, ***: p < 0.001.

Results (2)

During the failure strength test, the low viscosity group had a favorable lower herniation rate (33%) compared to the control group (80%) (Fig.4). The medium viscosity group had intermediate herniation frequency (50%), while high viscosity (83%) resembled discectomy (Fig.4). Both the low viscosity and medium viscosity groups reported either herniation over the human physiological stress level or no herniation (Fig.5). All treated groups showed higher failure strength compared to control group, with highest difference in low viscosity (mean diff.=+4.1 MPa; p=0.256) (Fig.6).

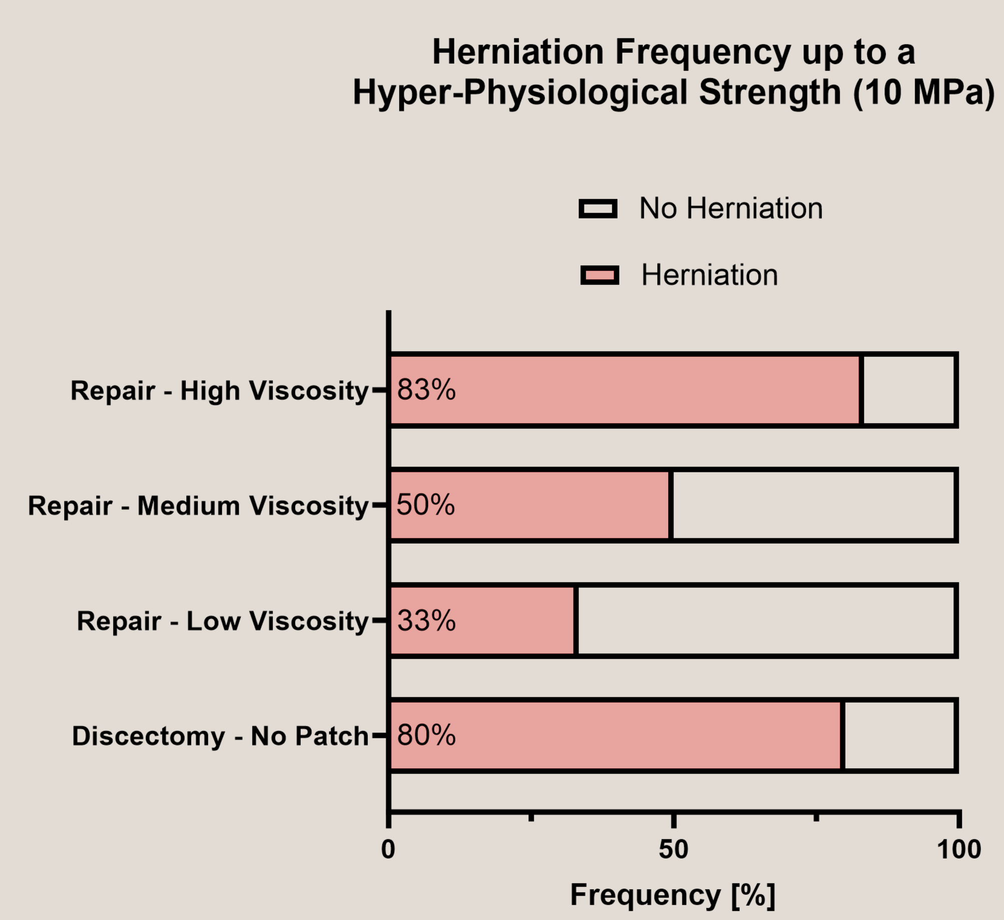

Fig.4: Frequency of herniation up to 10 MPa (hyper-physiological load) expressed in percentage.

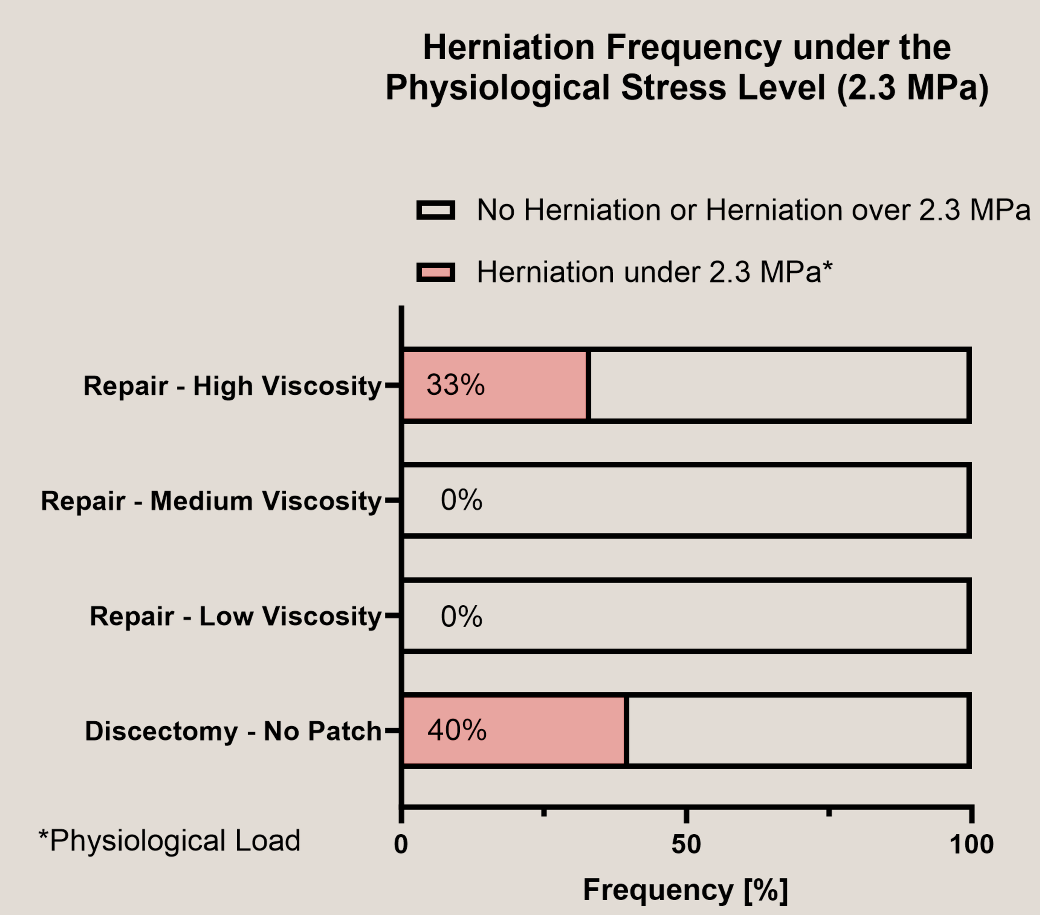

Fig.5: Frequency of herniation under 2.3 MPa (physiological load) expressed in percentage.

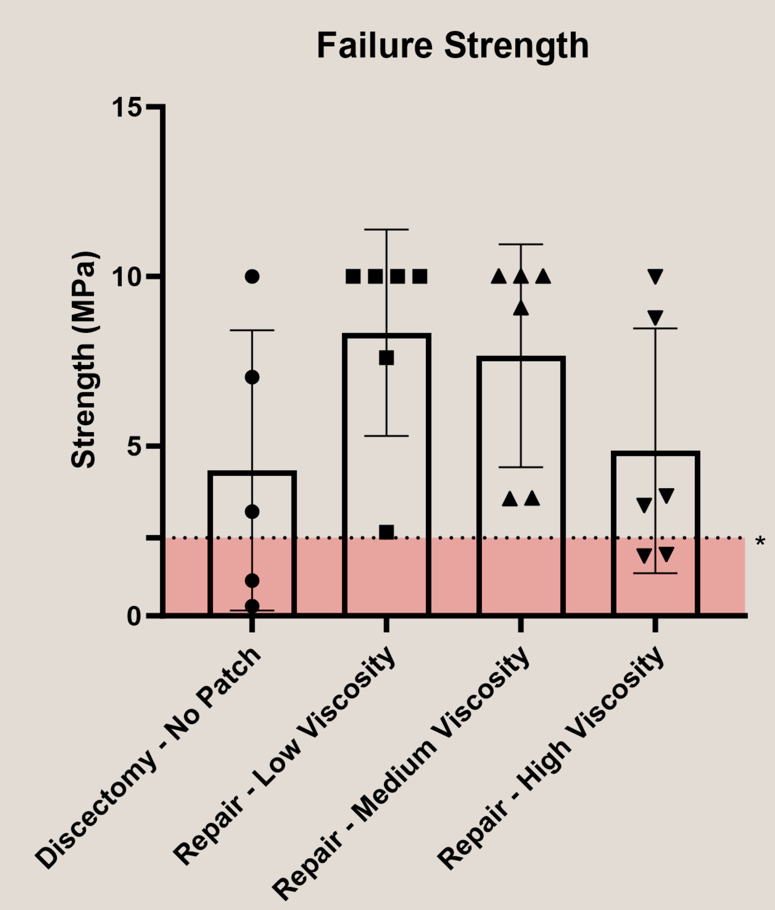

Fig.6: Quantitative data of failure strength. The red area represents the physiological stress level (2.3 MPa).

Reference

1. Meyer DC, Bachmann E, Darwiche S, et al. Rotator Cuff Repair and Overlay Augmentation by Direct Interlocking of a Nonwoven Polyethylene Terephthalate Patch Into the Tendon: Evaluation in an Ovine Model. *American Journal of Sports Medicine*. Published online October 1, 2023. doi:10.1177/03635465231189802

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Discussion

- Lower herniation risk if annulus defect is repaired with iPatch.
- Samples combining an iPatch repair with either low or medium viscosity hydrogel successfully withstood physiological stresses (2.3 MPa).
- This study showed the importance of an optimized viscosity of an injectable hydrogel for the restoration of NP biomechanical parameters.
- A limitation of this study is that lateral bending, flexion, and extension were not tested.
- Conclusion: combining iPatch with a HA-Tyr hydrogel of low-to-medium viscosity strongly reduces herniation frequency and partially restores range of motion.

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