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DEMONSTRATION OF BIOMECHANICAL SAFETY WHEN APPLYING A FLOWABLE HYDROGEL TENDON PROTECTOR: A CADAVER STUDY

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ABSTRACT

Injuries to tendons, including surgical trauma, can result in tethering scar formation which binds the tendon to surrounding tissues, thereby limiting joint mobility. Tendon protectors used today are available as meshes or films which the surgeon cuts to size before placing on the injured tissue. A flowable hydrogel tendon protector has been proposed to enable intuitive application; however, this creates an opportunity for the surgeon to apply an excessive volume of the hydrogel. The present study establishes a method to measure the mechanical forces required for joint mobility in cadaveric fingers and demonstrates that overapplication of the hydrogel does not result in unsafe conditions (i.e. impaired mobility) for the patient.

Keywords: tendon protector, tendon repair, flexor tendon, tendon biomechanics

NOMENCLATURE

DIP	distal interphalangeal
FDP	flexor digitorum profundus
MCP	metacarpophalangeal
ROM	range of motion

1. INTRODUCTION

Approximately 32M musculoskeletal injuries in the US cost nearly $322B annually [1]. Around 1.5M patients suffer flexor tendon injuries each year and as many as 30-40% of these individuals will subsequently have limited range of motion due to adhesions [2]. Current options to mitigate adhesions are limited and flawed, and there is an unmet need for a technology which can safely and effectively prevent adhesion formation to maintain normal joint function after tendon injury. They are composed of collagen-glycosaminoglycan (GAG) in the form of a membrane (TenoGlide, Integra LifeSciences) [3], a type I collagen fabric (TenoMend, Collagen Matrix) [4], or polysaccharide alginate film (VersaWrap, Alafair Biosciences) [5]. In practice, these products are difficult to deploy and often fail to prevent or limit adhesions as they can dislodge from natural tissue movement [6]. Furthermore, films and fabrics cannot be made to cover the entire surface area of tissues with irregular surfaces [7] and uncovered spaces remain at risk of adhesion formation. In orthopedic surgery, 7-17% of flexor tendon repairs require re-operation for lysing adhesions [8], and 17% of knee surgery patients suffer from severe loss of motion from adhesions [9].

TYBR Health has proposed a flowable gel barrier, which is designed to protect healing tendons and ligaments, and consists of two components: a collagen-based hydrogel, and a mixing system for application (Figure 1).

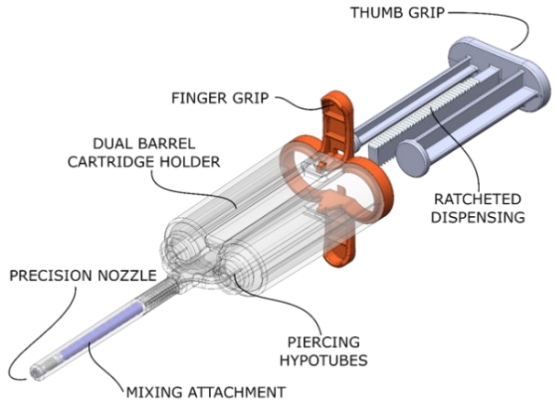

FIGURE 1: APPLICATOR FOR TYBR-GEL.

The hydrogel is provided in 2 parts: a solution of collagen and an activator solution in separate cartridges. The cartridges are inserted into a proprietary applicator designed to enhance the gel performance while minimizing loss volume.

This product can be used to treat both large tendons (e.g., rotator cuff) and small tendons (e.g., flexor tendons). To prevent surgeons from having insufficient volumes of hydrogel when coating large tendons or multiple small tendons, the product may be distributed in volumes which would be excessive for a single flexor tendon and could lead to overapplication in smaller tendons. This study aims to demonstrate safety in overapplication scenarios. Although no evidence to date suggests that overapplication of the natural gel poses a safety risk, if such a risk exists, mechanical impairment of tendon gliding would be the greatest concern, given that biocompatibility was already demonstrated in prior work. Therefore, this study evaluates the impact of gel application and overapplication on tendons gliding.

2. MATERIALS AND METHODS

Forces were measured in cadaveric fingers to determine the biomechanical effects of TYBR-GEL on flexor tendon mobility.

2.1 Selection of Cadaveric Test System

Though the biomechanical effects of tendon protector devices following flexor tendon repair can be assessed in preclinical animal models, human anatomy is necessary to accurately assess the effect of different hydrogel volumes dispensed into the synovial space. Because of these factors, computer modeling, in vitro studies, or in vivo animal studies would not provide meaningful clinical insight to establish the safety of overapplication of TYBR-GEL. Additionally, human hands have the same number of phalanges in 4 of the 5 digits (thumb excluded); this is not the case in commonly used bird models.

2.2 Experimental Groups and Sample Size

Gliding force was tested in three (3) conditions: untreated, treated, overtreated. Each digit served as its own control.

An appropriate sample size, determined via a priori power calculations, was employed to power the study for significant statistical outcomes. The primary outcomes of this study included force at 10 mm of excursion. Secondary findings included work of flexion and range of motion. Published data from a cadaveric finger study employing similar methods was used to conduct a sample size analysis [10], wherein the mean force at 10 mm excursion was 120 ± 2.8 g. Therefore, a sample size of 8 digits would power the study to an 80% chance of detecting a 20% difference in force compared to the control group. The 8 digits were harvested from a single cadaver and tested in random order, though treatment groups were tested in order of untreated, treated, then overtreated.

Untreated is defined as 0 mL of hydrogel applied; treated is defined as 0.2-0.4 mL of hydrogel applied; overtreated is defined as 0.8-1.0 mL applied. Treatment volume was determined in prior studies wherein the volume required to completely coat the tendon was measured, and overtreatment was at least doubled.

2.3 Surgical Model

The flexor profundus tendon (FDP) to each of the fingers was sharply cut approximately 90% using a scalpel. A 90% rupture was chosen over a complete rupture because it would minimize any potential variability which may have been induced by misalignment of the free tendon ends. It was then repaired using a 3-0 Ethibond suture with a double modified Kessler technique plus an epitendinous running suture (Figure 2A). The skin was closed with skin staples to enable easy repeat access and closure throughout the study.

Each digit was dislocated at the metacarpophalangeal (MCP) joint (i.e. where the finger bone meets the hand bone). Each flexor and its corresponding extensor tendon was tied off with a loop of suture to be used when applying load during testing. Each proximal phalange was drilled so the bone could receive an anchor pin by which to hold the digit during testing. A 1.1 mm K-wire was driven into the distal tip of the distal phalange into the middle phalange to immobilize the distal interphalangeal (DIP) joint (Figure 2B).

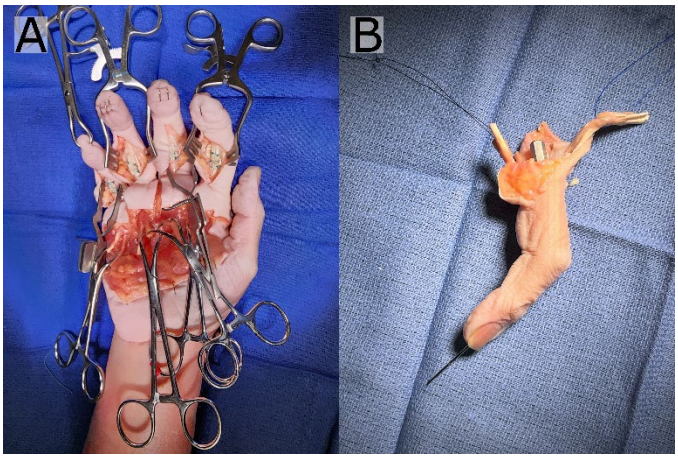

FIGURE 2: (A) FLEXOR TENDONS AFTER RUPTURE & REPAIR. (B) FINGER PREPARED FOR TESTING WITH TIED FLEXOR AND EXTENSOR TENDONS, IMMOBILIZED DIP, AND SPIKED PROXIMAL PHALANGE.

2.4 Biomechanical Testing

All digits were tested for functional metrics by mounting into a purpose-built fixture on an Instron using a 5 N load cell [11], Figure 3. A 100 g mass was attached to the extensor tendon. The FDP was pulled at a rate of 2 mm/s to a maximum excursion of 10 mm. A camera recorded video of the motion.

From this test, force at 10 mm excursion, work of flexion, and range of motion were reported [12]. To make these data applicable and comparable across groups, all data were normalized by the average of the untreated group.

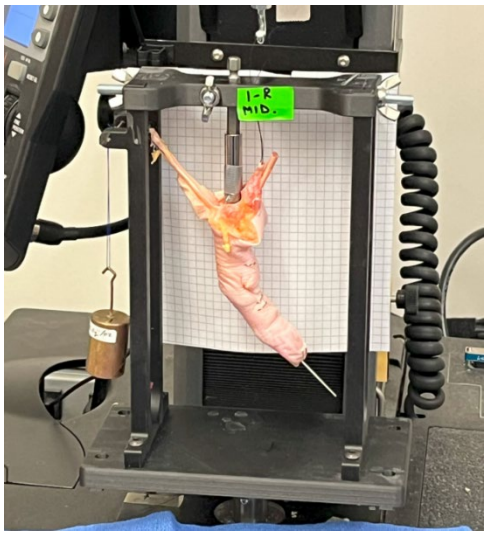

FIGURE 3: CADAVERIC FINGER MOUNTED TO A FRAME ATTACHED TO THE INSTRON.

2.5 Method Validation

To validate the method's sensitivity to gliding resistance, one digit was randomly selected, and a band was applied (Figure 4) to induce resistance to gliding, as measured by force at 10 mm excursion, work of flexion, and range of motion (ROM).

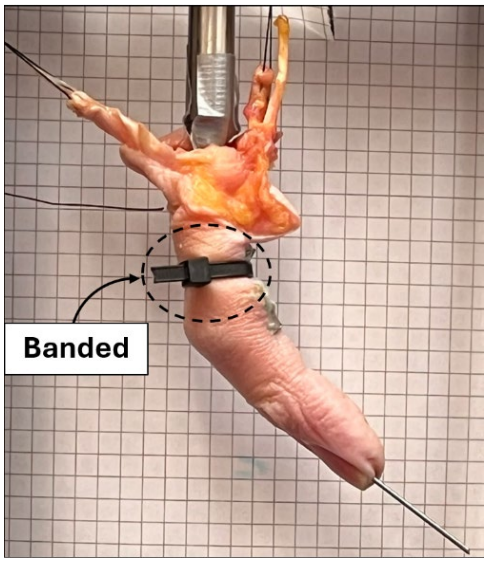

FIGURE 4: BANDED DIGIT, MECHANICALLY TESTED TO CONFIRM METHOD SENSITIVITY.

It was observed that force at 10 mm excursion and work of flexion were the most sensitive metrics for detecting changes in gliding resistance, as demonstrated by the high force and work values in the banded digits compared to the untreated digits.

Conversely, the comparison of the ROM between banded and untreated digits indicates that ROM is not sufficiently sensitive to changes in gliding resistance using the test system and method used in the present study and, therefore, may not provide meaningful results.

3. RESULTS AND DISCUSSION

Each digit was tested three (3) times (untreated, treated, and overtreated) and evaluated for force at 10 mm excursion, work of flexion, and range of motion.

3.1 Force at 10 mm Excursion

The comparison of force at maximum excursion results (Figure 5) indicate no significant difference in gliding resistance between the treatment groups.

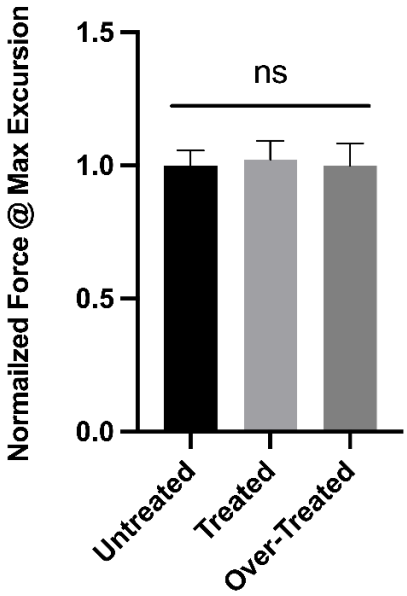

FIGURE 5: FORCE AT MAXIMUM EXCURSION.

3.2 Work of Flexion

The work of flexion results (Figure 6) indicate no significant change in gliding resistance in the treated and overtreated groups compared to each other or to the untreated group.

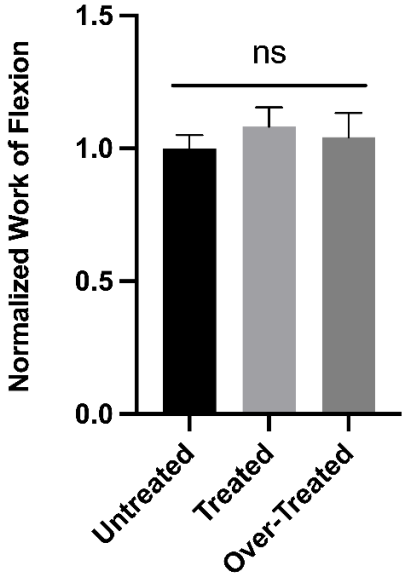

FIGURE 6: WORK OF FLEXION

3.3 Range of Motion

As observed while conducting method validation, the range of motion is not sensitive to changes in gliding resistance when using these testing conditions. There is no statistically significant change in range of motion across treatment groups (Figure 7). Though these results are not meaningful in isolation, they further support the force and work of flexion data above.

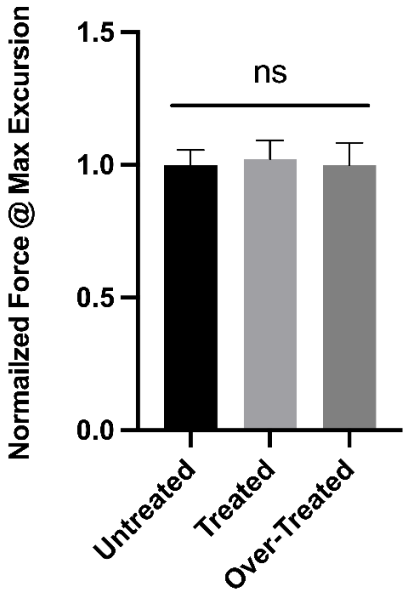

FIGURE 7: RANGE OF MOTION.

3.4 Study Limitations

The greatest weakness of this study was that cadaver fingers may be stiff from being chilled for transport. This was addressed by warming the fingers to body temperature. Additionally, all the digits tested came from a single donor; this was unavoidable, since donors free from injury or arthritis narrow the availability.

4. CONCLUSION

The method used in this study was validated for sensitivity to changes in gliding resistance when measuring force at maximum excursion and work of flexion.

Since no change was detected in either force at maximum excursion or work of flexion, TYBR-GEL does not impair gliding resistance, even when it is overapplied. This indicates that it is mechanically safe to use on tendons, independent of user variability in application volumes.

ACKNOWLEDGEMENTS

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