

Research Article

Collagen Co-Braids Demonstrate Equivalent or Superior Physical Properties to Conventional Orthopedic Sutures

Kyle Christensen, PH.D.^{1a}, Rohith Nair^{1b}, Riya Palikonda^c, Victoria Stagnaro^{1d}, Amanda Carey^{1e}, Andrew Howell^{1f}, Nardos Sori, PH.D.^{1g}, Amrita Dasgupta, PH.D.^{1h}, Yas Maghdouri-White, PH.D.¹ⁱ, Kevin Bonner, M.D.^{2j}, Gregory DiFelice, M.D.^{3k}, Nicholas Sgaglione, M.D.^{4l}, Matthew Havener^{1m}

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- a Kyle Christensen's research and product development experience has focused on furthering advanced manufacturing technologies to create novel regenerative implants and devices. He has worked extensively with additive manufacturing and textile-based processes utilizing collagen as a biomaterial. Kyle's work has resulted in several first-author journal articles, multiple patented technologies, and clinically used products that improve patient healing.

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- b [Connect with Rohith Nair on LinkedIn](#)

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- c Riya Palikonda has extensive experience in the medical device industry, laboratory research, and patient care. With a special interest in innovative medical technologies, she is passionate about improving patient outcomes and enhancing care through cutting-edge solutions.

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- g [Conflicts of Interest Statement for Nardos Sori](#)

- h [Connect with Amrita Dasgupta on LinkedIn](#)

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- i Yas Maghdouri-White is a Biomedical Engineer with a PhD in this field. She has over 16 years of experience in the field of regenerative medicine and has been working in the medical device industry for about 9 years. Yas is an innovator and has had multiple patents on implantable devices and their manufacturing platform.

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- j Dr. Bonner is in practice at the Jordan-Young Institute in Virginia Beach, VA. He is also a Professor at Eastern Virginia Medical School where he enjoys both clinical teaching and participating in multiple research projects with students and colleagues. He also currently serves as Director of the Jordan Research Foundation. Dr. Bonner is principally focused on the treatment of problems prior to joint replacement surgery in the shoulder and knee. He has written numerous articles, medical textbook chapters and lectures on topics including arthroscopic shoulder surgery, arthroscopic rotator cuff repair, meniscus and articular cartilage treatment & repair, ligament reconstruction and other biologic treatments.

He is currently on the Presidential Line (2nd Vice President) and executive Board of Directors for the Arthroscopy Association of North America (AANA). He has also recently been on the Board of Trustees for the Arthroscopy Journal (JBOT) from 2022-2024. In the past several years he has been honored to serve as Program Chair or Co-Chair for the combined 2021 American Orthopaedic Society for Sports Medicine (AOSSM)/AANA Annual Meeting in Nashville, the AANA 2022 Annual Meeting in San Francisco and the Orthopaedic Summit & Evolving Techniques Conference in Las Vegas (2018-2021, 2024) and Boston (2022, 2023) as well as other national shoulder and knee courses. Participating as chairman, program director or expert faculty for many academic national and international orthopaedic conferences has allowed him to evaluate the latest techniques and devices that are being developed throughout the world at their earliest stages. In fact, Dr. Bonner has helped develop some of the implants, techniques and procedures currently used today.

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- k Dr. Gregory S. DiFelice is a fellowship-trained orthopaedic surgeon specializing in Sports Traumatology and Joint Reconstruction Surgery at Hospital for Special Surgery. He also holds an academic appointment as an Associate Attending Orthopaedic Surgeon. His main surgical focus is on the treatment of the knee, shoulder, and hip. Using both non-surgical and surgical methods, he strives to utilize the latest technologies to improve patient outcomes, while preserving their native tissues. He refers to his customized ap-

¹ Zimmer Biomet (United States), ² Jordan-Young Institute, ³ Hospital for Special Surgery, ⁴ Northwell Health

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While conventional high strength orthopedic sutures are made from synthetic materials, here we present a novel collagen co-braid with a unique composition of approximately 50 wt% type I collagen fibers and 50 wt% Ultra-High Molecular Weight Polyethylene (UHMWPE). Collagen is the most abundant protein in the human body and has been shown to have biostimulative properties including encouraging angiogenesis, stimulating new tissue formation, and enhancing biointegration. Here, we tested and compared critical physical properties of collagen-UHMWPE co-braids and industry-leading conventional high strength orthopedic sutures across several measures including knotted tensile strength, knot security, knot profile, and abrasiveness to tissue. In all of these assessments, collagen co-braids were shown to exhibit equivalent or superior performance characteristics, with a notably reduced abrasiveness to tissue, compared to conventional high strength UHMWPE sutures of corresponding sizes. This study

proach as Preservation First® and this guides his practice. His philosophy, developed over 20+ years in practice, is to use surgery as a last resort, and if surgery is absolutely necessary, to perform the most conservative surgery that will give the best, most long-lasting results for the patient. This delicate balancing of the risks and benefits of surgery for each individual is, in essence, the art of surgery.

His interest in collagen cobraid suture technology was a direct extension of his pioneering work and research into ACL Primary Repair. He has described multiple techniques that can be used to repair certain types of ACL injuries thereby greatly reducing recovery time for patients. His research team has published over 80 articles in the ligament preservation space.

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I Dr. Nicholas Sgaglione is Mauri Martocci Endowed Professor and Chair of the Northwell Health System Department of Orthopedic Surgery and at the Zucker School of Medicine at Hofstra / Northwell. He also serves as the Senior Vice President for Orthopaedics for the Northwell Health System and Executive Director of the Northwell Orthopaedic Institute in New York. Dr. Nicholas Sgaglione has been in clinical practice for 35 years in Great Neck, New York. He graduated from the Mount Sinai School of Medicine and completed his residency in orthopaedic surgery at the Hospital for Special Surgery in New York followed by a fellowship in sports medicine at the Southern California Orthopaedic Institute in Los Angeles. Dr. Sgaglione has been recognized in Best Doctors of New York State and Best Doctors of America since 2007. He served on the Board of Directors for the Arthroscopy Association of North America (AANA) beginning in 2008 and was President of AANA, the largest orthopaedic specialty society from 2012- 2013. Dr. Sgaglione was elected to the American Orthopaedic Association in 2006, a prestigious national society for leadership, education and research. He served as the chair of the Arthroscopy Association of North America Education Foundation as the chair of the Journal of Arthroscopy Board of Trustees. Dr. Sgaglione has also served as the New York State delegate for the American Orthopaedic Society of Sports Medicine and is an active member of the American Academy of Orthopaedic Surgeons, American Orthopaedic Society of Sports Medicine, International Cartilage Regeneration and Joint Preservation Society, International Society of Arthroscopy, Knee Surgery and Orthopaedic Sports Medicine and the New York Society of Orthopaedic Surgeons. He has served on the editorial board of several medical journals and is the editor of three orthopaedic textbooks and more than 100 published articles and book chapters on knee, shoulder, ankle and cartilage surgery. Dr. Sgaglione specializes in sports medicine and serves in numerous roles outside of Northwell Health, including the medical director for Hofstra University Athletics, an honorary police surgeon for the NYPD, and a consultant to the United States Ski Team and the US Professional Golf Association. He has also been the team physician for the United States Merchant Marine Academy for the past 35 years and the team medical director for the New York Lizards (2014 -2020).

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m Matthew Havener has a Bachelor's of Science in Biomedical Engineering from Lehigh University and a Master's of Science in Biotechnology Enterprise and Entrepreneurship from Johns Hopkins University. He has 18 years of experience in biomaterials and medical device research and product development, primarily in Orthopaedics, Spine, and Sports Medicine. His experience includes taking several novel biomaterial implants from concept to commercialization, including bone graft substitutes, bone cements, collagen and thrombin based surgical hemostats, and various fully or partially resorbable soft tissue repair and augmentation devices.

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concludes that collagen co-braids provide sufficient mechanical properties for the high demands of orthopedic procedures while incorporating a biological component.

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INTRODUCTION

More than 10 million orthopedic procedures are performed every year in the United States (AAOS Department of Clinical Quality and Value 2019). Common soft tissue procedures include repair of the rotator cuff, Achilles tendon, and ligaments of the elbow and knee (Elrod 2014; McElvany et al. 2015; Trofa et al. 2017; Bansal et al. 2021). Mechanical properties of orthopedic sutures designed to facilitate these procedures play a critical role in the success of soft tissue repair. The quality of repair can be adversely affected by utilizing materials with inadequate physical properties to support the repair construct at time zero as well as during the healing process (Najibi et al., n.d.). In particular, insufficient mechanical strength or excessive abrasion to surrounding tissue can lead to complications such as re-rupture at the site of injury, incomplete tissue repair, or overall failure of surgical repair (Açan, Hapa, and Barber 2018).

While conventional high strength orthopedic sutures are made from synthetic materials, biostimulative materials, such as collagen, have been shown to promote angiogenesis, stimulate new tissue formation, and enhance biointegration (Lee, Singla, and Lee 2001; Mazzocca et al. 2007; Enea et al. 2013; Blackstone, Gallentine, and Powell 2021). Collagen is the most abundant protein in the body, comprising approximately 30% of all proteins and serving as building blocks for numerous tissues (Shoulders and Raines 2009; Kew et al. 2011). Though collagen coated synthetic sutures (e.g., Collagen Coated FiberWire® (Arthrex, Inc., Naples, FL, AR-7200B)) are commercially available, the surface coating is intended to improve handling characteristics (Arthrex Inc. 2014). As such, there remains an unmet need for an orthopedic suture with a unique composition offering an advantageous biointegrative component while maintaining the required mechanical strength for the high physical demands of orthopedic procedures.

Studies have shown that type I collagen can be additively manufactured into fibers by extrusion (Kato et al. 1989; Dunn, Avasarala, and Zawadsky 1993) and that extruded collagen fibers can be strengthened via crosslinking to improve strength, stability, and biocompatibility (Koob and Brown, n.d.; Zeugolis, Paul, and Attenburrow 2009; Reddy, Reddy, and Jiang 2015; Suesca et al. 2017). However, producing consistent, clinical-grade collagen fiber suitable for medical device manufacture at scale has remained a challenge (Zeugolis, Paul, and Attenburrow 2009; Reddy, Reddy,

and Jiang 2015; Enea et al. 2011; Delgado et al. 2015). In a previous study, we presented a method for the production of collagen fibers with high tensile strength, cytocompatibility, and low toxicity (Dasgupta et al. 2021). Briefly, a novel wet extrusion process was developed and used to produce strong, stable type I collagen fibers with diameters on the order of 150 μm . Since this study, we have further improved methodologies to produce high-strength collagen fibers at scales and costs suitable for medical device manufacturing with commercial textile processing equipment. These fibers offer immense potential as a component in medical textiles for numerous surgical applications, with one such application being biointegrative suture constructs for soft tissue repair.

The purpose of this study is to assess and compare key physical properties of novel co-braids consisting of approximately 50 wt% type I collagen fibers and 50 wt% Ultra-High Molecular Weight Polyethylene (UHMWPE) fibers to those of conventional orthopedic sutures. To ensure adequate mechanical properties for handling and maintaining tissue approximation, knotted tensile strength and knot security were determined. Knot profile and abrasiveness to tissue were also assessed as critical measures that may affect repair outcomes. In particular, suture pullout resulting from abrasion at the suture-tendon interface has remained a critical point of failure in orthopedic repairs (Kowalsky et al. 2008; Williams et al. 2016). We hypothesize that the unique composition of co-braids providing both structural and biological attributes will meet or exceed the physical properties of conventional suture while leveraging the biostimulative properties of collagen.

MATERIALS AND METHODS

COLLAGEN-UHMWPE CO-BRAID AND CONVENTIONAL HIGH STRENGTH SUTURE CONFIGURATIONS

Three commonly used orthopedic size configurations spanning a wide range of clinical applications are investigated herein for both collagen co-braids and conventional synthetic sutures: 2-0, #2, and tape. Sutures of corresponding sizes are plotted together throughout for comparison purposes. 2-0 collagen co-braid (Fig. 1) is compared to 2-0 FiberWire (Arthrex, Inc., Naples, FL, AR-7220). #2 collagen co-braid (Fig. 1) is compared to #2 FiberWire (Arthrex, Inc., Naples, FL, AR-7200). Collagen co-braid tape (Fig. 1) with

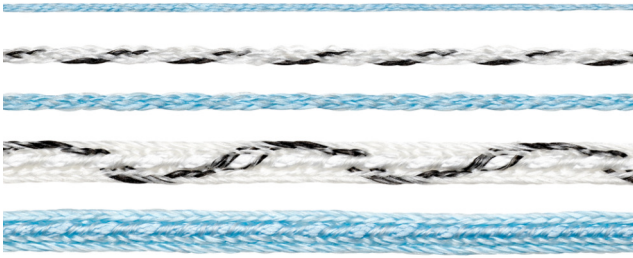


Figure 1. High strength collagen co-braids of different size configurations and colorations to facilitate suture management during arthroscopic use.

From top to bottom: 2-0 blue, #2 white/black, #2 blue, 2.5 mm tape white/black, and 2.5 mm tape blue.

a nominal width of 2.5 mm is compared to FiberTape (Arthrex, Inc., Naples, FL, AR-7237).

KNOTTED TENSILE STRENGTH

Knotted tensile strength of configurations 2-0 and #2 were assessed by tying a single overhand knot in the midsection, followed by tensile testing to failure (n=30 per configuration). Collagen co-braid tape and FiberTape were not assessed due to the absence of knotting in standard clinical use. Suture ends were firmly clamped using pneumatic bollard grips (Instron Corporation, Norwood, MA, 2714-040 series) mounted to an electromechanical test system with a 1000 N load cell (MTS Systems Corporation, Eden Prairie, MN, Criterion Model 42) with the knotted portion positioned approximately centered between the clamps. Per FDA-recognized United States Pharmacopeia (USP) <881> “Sutures – Tensile Strength”, a gauge length of 200 mm and crosshead displacement rate of 5 mm/s were used. The peak load of each knotted specimen was recorded as the knotted tensile strength. All specimens were tied by the same experienced user to eliminate user-to-user variability.

KNOT SECURITY LOAD

Knot security load of configurations 2-0 and #2 were assessed by forming a loop held by a knot, followed by tensile testing to 3 mm crosshead displacement (n=30 per configuration). Collagen co-braid tape and FiberTape were not assessed due to the absence of knotting in typical clinical use. Per established protocols (Lo et al. 2004; Hassinger, Wongworawat, and Hechanova 2006; Shah et al. 2007; Baums et al. 2015), each looped specimen was formed by tightly tying a surgeon’s knot with three reversing half hitches on alternating posts onto a 30 mm circumference rod. All samples were tied by the same user to eliminate user-to-user variability. Prior to testing, loops were removed from the rod and hydrated in a Dulbecco’s phosphate-buffered saline (DPBS) bath for 30-40 minutes to simulate physiological conditions. Prepared loops were mounted to custom fixtures using S-hooks to apply tension to the loops on an electromechanical test system with a 1000 N load cell (MTS Systems Corporation, Eden Prairie, MN, Criterion Model

42). A 5 N pre-load was applied followed by crosshead displacement at 0.5 mm/sec to a displacement of 3 mm. Knot security load is defined as the load at which 3 mm displacement of the loop occurs, the displacement representative of a clinical repair failure (Lo et al. 2004; Hassinger, Wongworawat, and Hechanova 2006; Shah et al. 2007). If the maximum load occurred prior to 3 mm displacement, this was instead recorded as the knot security load. All specimens were tied by the same experienced user to eliminate user-to-user variability.

KNOT PROFILE HEIGHT

Knot profile height of configurations 2-0 and #2 were assessed by tying and measuring the height of a surgeon’s knot (n=30 per configuration). Collagen co-braid tape and FiberTape were not assessed due to the absence of knotting in typical clinical use. For each specimen a single surgeon’s knot was tied tightly onto a 12.7 mm diameter shaft and the height of the knot stack was measured using a material thickness gauge (Rex Gauge, Buffalo Grove, IL, MTG-D #2322) and recorded as the knot profile height. All specimens were tied by the same experienced user to eliminate user-to-user variability.

ABRASIVENESS TO TISSUE

Abrasiveness to tissue of configurations 2-0, #2, and tape (n=6 per configuration) were assessed by cycling suture through a bovine tendon specimen under a constant load using a custom cycling device and measuring tendon cut-through. Using a FastPass Scorpion SL Suture Passer (Arthrex, Inc., Naples, FL, AR-13999MF) with MultiFire Scorpion Needle (Arthrex, Inc., Naples, FL, AR-13995N), sutures were passed through bovine calf distal deep flexor tendons (Lampire Biological Laboratories, Pipersville, PA). Tendons were selected to be free of defects, have uniform thickness between 4 mm and 8 mm, and tendon thickness was measured at the point of insertion. Adapted from established protocols (Williams et al. 2016; Owens et al. 2019), suture specimens and tendons were mounted to a custom-built cycling device which applied a constant load of 4.9 N to a suture end while repeatedly drawing the suture midsection through the tendon for 30 cycles with a cycle draw distance of 120 mm. Tendons were kept hydrated prior to and during testing. 100 uL of 0.9% saline solution (Molecular Biologicals, LLC, Pasadena, TX, MSDW-1000) was applied to the point of insertion immediately prior to testing to ensure that both the portion of suture being cycled through the tendon and the cut-through region of the tendon remained hydrated. Tendon cut-through occurred in a direction parallel to the tendon grain as is often observed in clinical use. Applied load, number of cycles, and cycle distance were selected to create measurable tendon cut-through to investigate the abrasiveness of the collagen co-braid compared to conventional UHMWPE sutures. Following cycling, tendon cut-through was measured using digital calipers on the top and bottom surfaces of the tendon. This cut-through was then averaged, normalized to the thickness of the tendon to account for varying tendon thickness,

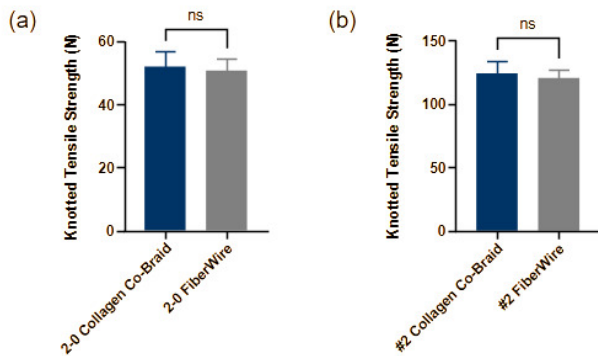


Figure 2. Knotted tensile strength of collagen co-braid and conventional orthopedic suture of corresponding configurations (a) 2-0 and (b) #2.

Error bars represent SD. n=30 for each configuration.

and presented in results herein for a tendon thickness of 6 mm to enhance data readability (as opposed to presentation in mm cut-through per mm tendon thickness).

STATISTICAL METHODS

Where appropriate, data sets were analyzed for statistical differences in mean using unpaired parametric t tests with Welch's correction. All tests were conducted with n=30 samples (with the exception of abrasiveness to tissue with n=6) for each configuration tested for enhanced statistical significance. Results are plotted showing mean with error bars representing standard deviation and statistical significance is determined as follows: ns $p > 0.05$, * $p < 0.05$, ** $p < 0.01$, *** $p < 0.001$, **** $p < 0.0001$. Statistical analysis was conducted in Prism (GraphPad, San Diego, CA).

RESULTS

KNOTTED TENSILE STRENGTH

2-0 collagen co-braid and 2-0 FiberWire showed no significant difference in knotted tensile strength (52.1 ± 4.7 and 50.8 ± 3.8 N, respectively) (Fig. 2a). #2 collagen co-braid and #2 FiberWire also showed no significant difference in knotted tensile strength (124.3 ± 10.1 and 120.6 ± 6.9 N, respectively) (Fig. 2b). All failures occurred as expected at the knotted region within the gauge length.

KNOT SECURITY

2-0 Collagen co-braid and 2-0 FiberWire showed no significant difference in knot security load (67.0 ± 12.3 and 66.6 ± 11.8 N, respectively) (Fig. 3a). #2 collagen co-braid and #2 FiberWire also showed no significant difference in knot security load (110.3 ± 22.3 and 112.0 ± 18.0 N, respectively) (Fig. 3b). Extension of all suture loops occurred as expected due to pull-through at the knotted region.

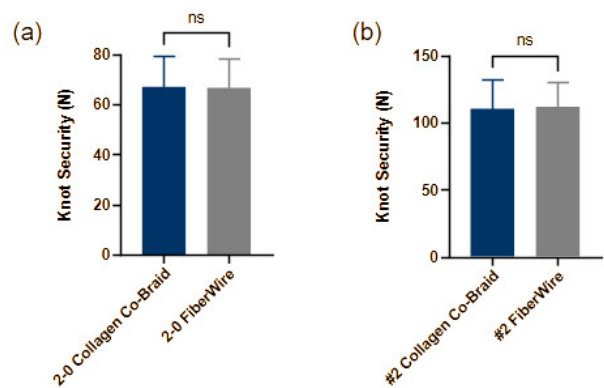


Figure 3. Knot security load of collagen co-braid and conventional orthopedic suture of corresponding configurations (a) 2-0 and (b) #2.

Error bars represent SD. n=30 for each configuration.

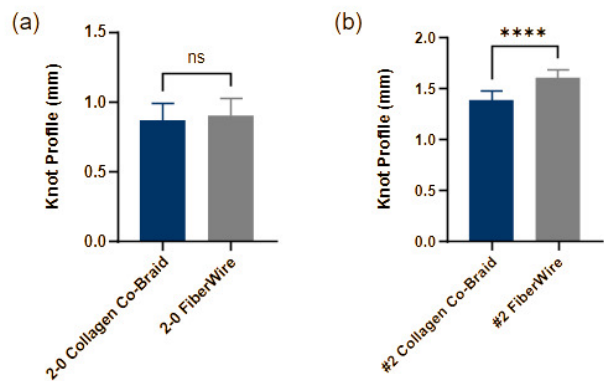


Figure 4. Knot profile height of collagen co-braid and conventional orthopedic suture of corresponding configurations (a) 2-0 and (b) #2.

Error bars represent SD. ****Signifies p -value < 0.0001 . n=30 for each configuration.

KNOT PROFILE

2-0 Collagen co-braid and 2-0 FiberWire showed no significant difference in knot profile height (0.87 ± 0.12 and 0.90 ± 0.12 mm, respectively) (Fig. 4a). #2 collagen co-braid showed a moderately smaller but significantly different knot profile compared to #2 FiberWire (1.38 ± 0.09 and 1.60 ± 0.08 mm, respectively) (Fig. 4b), with #2 collagen co-braid having a 14% smaller knot profile. Despite this difference being statistically significant, knot profile varied only by fractions of a millimeter and was nearly equivalent between sutures of corresponding sizes.

ABRASIVENESS TO TISSUE

2-0 collagen co-braid showed significantly lower abrasiveness to tissue compared to 2-0 FiberWire (5.08 ± 0.65 and 16.39 ± 3.40 mm, respectively) (Fig. 5a), with 69% less tendon cut-through. #2 collagen co-braid also showed signif-

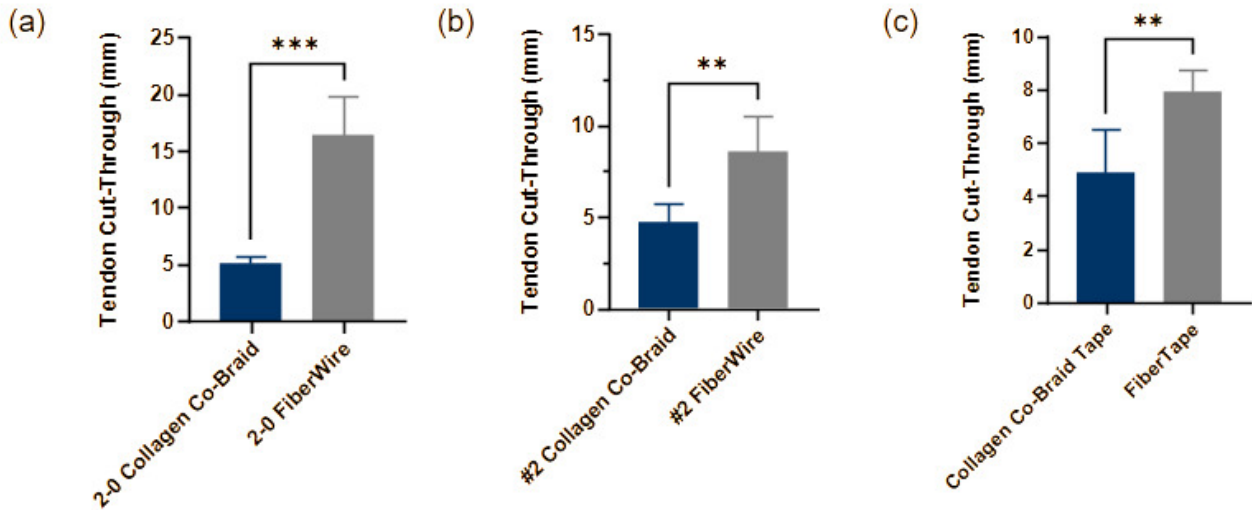


Figure 5. Abrasiveness to tissue of collagen co-braid and conventional orthopedic suture of corresponding configurations (a) 2-0, (b) #2, and (c) tape.

Error bars represent SD. **Signifies p -value $< .01$. ***Signifies p -value $< .001$. $n=6$ for each configuration.

icantly lower abrasiveness to tissue compared to #2 FiberWire (4.71 ± 1.06 and 8.58 ± 1.97 mm, respectively) (Fig. 5b), with collagen co-braid averaging 45% less tendon cut-through. Similarly, collagen co-braid tape showed significantly lower abrasiveness to tissue compared to FiberTape (4.88 ± 1.64 and 7.92 ± 0.83 mm, respectively) (Fig. 5c), with collagen co-braid averaging 38% less tendon cut-through.

DISCUSSION

The most significant finding in this study is that co-braids comprised of approximately 50 wt% collagen fiber provide physical properties and strengths equivalent to or exceeding those of conventional orthopedic sutures of corresponding sizes. Knotted tensile strength, knot security, and knot profile are not compromised with collagen co-braids, and abrasiveness to tissue was decreased compared to conventional suture. Conventional high-strength sutures possess adequate mechanical properties for soft tissue repair, but historically lack the benefits of a biologic element and integrative properties. In this study we have shown that a novel co-braid consisting of type I collagen fibers co-braided with UHMWPE fibers provides the physical properties necessary for demanding orthopedic applications, while offering a biologic augmentation element within the construct itself.

Knotted suture properties are traditionally preferred as the most meaningful measures of an orthopedic suture's mechanical strength and performance as these measures adequately represent clinical use. Knotted tensile strength is the only property investigated herein with an FDA-recognized standard, USP <881> "Sutures – Tensile Strength", and no significant difference was found between collagen co-braid and conventional high strength sutures of corresponding sizes. Additionally, collagen co-braids were found

to greatly exceed minimum knotted tensile strength requirements, with sizes 2-0 and #2 offering strengths 3.7 times and 3.6 times greater, respectively, than those indicated in USP <881>. Knot security has also often been investigated, as the extension of a looped suture closely mimics clinical use where a specified loop elongation represents a failure of the repair (Lo et al. 2004; Hassinger, Wongworawat, and Hechanova 2006; Shah et al. 2007; Baums et al. 2015). Again, no significant difference was found for knot security load between collagen co-braid and conventional high strength sutures of corresponding sizes, indicating that their performance is substantially equivalent. Knot profile height is associated with patient satisfaction and was also assessed, with #2 collagen co-braid resulting in a smaller knot profile compared to traditional corresponding suture.

Abrasiveness to tissue was assessed using a custom setup adapted from established protocols (Williams et al. 2016; Owens et al. 2019). Collagen co-braids were found to have significantly lower tendon cut-through than conventional suture for sizes 2-0, #2, and tape. This suggests that the unique composition and structure of collagen co-braids results in reduced friction with the tissue, likely due to the surface texture of the UHMWPE and collagen fibers and/or co-braid manufacturing parameters such as number of constituent strands and picks per inch. Reduced abrasiveness is of particular relevance, as soft tissue cut-through at the suture-tendon interface resulting in suture pullout remains a critical point of failure in orthopedic repairs (Kowalsky et al. 2008; Williams et al. 2016).

This study was limited to benchtop testing of physical and functional properties of orthopedic suture including collagen-UHMWPE co-braid configurations. While the biostimulative properties of collagen are widely accepted, further studies are needed to investigate the *in vivo* perfor-

mance and clinical outcomes related to the use of collagen co-braids for orthopedic repairs.

bioactivity, and potential for improved patient outcomes facilitated by the orthopedic use of collagen co-braids.

CONCLUSIONS

Collagen co-braids with a unique proprietary structural composition providing the biostimulative properties of collagen offer mechanical properties suitable for the high demands of orthopedic procedures. Across several assessments of physical properties including knotted tensile strength, knot security, knot profile, and abrasiveness to tissue, collagen co-braids were shown to exhibit equivalent or superior performance characteristics to conventional UHMWPE sutures. Future work will include benchtop, animal, and clinical studies investigating the biocompatibility,

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