

# Independent Suture Tape Reinforcement of Small and Standard Diameter Grafts for Anterior Cruciate Ligament Reconstruction: A Biomechanical Full Construct Model

Samuel Bachmaier, M.Sc., Patrick A. Smith, M.D., Jordan Bley, B.A., and Coen A. Wijdicks, Ph.D.

**Purpose:** To compare the dynamic elongation, stiffness behavior, and ultimate failure load of standard with small diameter soft tissue grafts for anterior cruciate ligament (ACL) reconstruction with and without high-strength suture tape reinforcement. **Methods:** Both a tripled “small” diameter and a “standard” quadrupled tendon graft with and without suture tape reinforcement were tested using suspensory fixation ( $n = 8$  each group). The suture tape was passed through the suspensory fixation button on the femur and tibia to ensure independent (safety belt) fixation from the graft in vitro. The testing of the constructs included position-controlled cyclic loading, force-controlled cyclic loading at 250 N and 400 N as well as pull to failure (50 mm/min). **Results:** Reinforcement of a small diameter graft significantly reduced dynamic elongation of 38% ( $1.46 \pm 0.28$  mm vs  $2.34 \pm 0.44$  mm,  $P < .001$ ) and 50% ( $2.55 \pm 0.44$  mm vs  $5.06 \pm 0.67$  mm,  $P < .001$ ) after the 250 N and 400 N load protocol, respectively. Reinforcement of a standard diameter tendon graft decreased dynamic elongation of 15% ( $1.59 \pm 0.34$  mm vs  $1.86 \pm 0.17$  mm,  $P = .066$ ) and 26% ( $2.62 \pm 0.44$  mm vs  $3.55 \pm 0.44$  mm,  $P < .001$ ). No significant difference was found between both reinforced models. The ultimate failure loads of small and standard diameter reinforced grafts were  $1592 \pm 105$  N and  $1585 \pm 265$  N, resulting in a 64% ( $P < .001$ ) and 40% ( $P < .001$ ) increase compared with their respective controls. **Conclusions:** Independent suture tape reinforcement of soft tissue grafts for ACL reconstruction leads to significantly reduced elongation and higher ultimate failure load according to in vivo native ACL function data without stress-shielding the soft tissue graft. **Clinical Relevance:** If in vitro results are translational to human knees in vivo, the suture tape reinforcement technique for ACL reconstruction may decrease the risk of graft tears, particularly in the case of small diameter soft tissue grafts.

See commentary on page 500

**A**nterior cruciate ligament (ACL) reconstruction is one of the most commonly performed orthopaedic surgical procedures, with between 100,000 and

150,000 performed annually in the United States.<sup>1,2</sup> Recent studies have shown the rate of ACL graft rupture can be as high as 23% in patients below the age of 20 years.<sup>3</sup> In addition, articles have shown failure rates as high as 35% after the use of allograft tissue in young (10-25 years) patients.<sup>4,5</sup> This is of particular concern considering multiple studies have shown that the clinical results of revision ACL reconstruction are inferior to primary reconstruction.<sup>6,7</sup>

Hamstring (HS) tendons allow limited size prediction before surgery because of a large variability in graft length and diameter.<sup>8</sup> Previous studies have shown that shorter, lighter-weight patients have an increased risk of “small diameter” HS grafts ( $<8$  mm).<sup>9,10</sup> These small diameter grafts are associated with higher revision rates in young patients.<sup>11-13</sup>

Augmentation for ACL grafts is historically not a new concept and was introduced back in 1980.<sup>14</sup>

From the Arthrex Department of Research & Development (S.B., C.A.W.), Munich, Germany; and Department of Orthopaedic Surgery, University of Missouri (P.A.S., J.B.), Columbia, Missouri, U.S.A.

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Address correspondence to Coen A. Wijdicks, Ph.D., Arthrex Department of Research & Development, Erwin-Hielscher-Strasse 9, 81249 Munich, Germany. E-mail: [coen.wijdicks@arthrex.de](mailto:coen.wijdicks@arthrex.de)

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Augmentation techniques for clinical and functional outcome data showed a high failure rate and consequently were not recommended to be used any longer.<sup>15,16</sup> ACL reinforcement is an alternative method for supporting an ACL graft in a synergistic load-sharing manner with primary tension on the graft and a high-strength suture tape reinforcement as a protective “safety belt.” The goal is to provide improved mechanical properties for ACL reconstruction without stress-shielding the soft tissue graft.<sup>17,18</sup>

Although HS autografts have shown a higher failure rate than patellar tendon autografts,<sup>19,20</sup> biomechanical studies show that even small-sized quadrupled HS tendons have sufficient or better tensile strength than patellar tendon.<sup>21,22</sup> These results suggest that failure of small diameter grafts in vivo is not caused by low failure strength of the HS material itself, but perhaps by the insufficient mechanical stability of the entire ACL graft construct (graft plus fixation devices) during the time of biological healing. No previous studies have reported on the potential beneficial effect of independent suture tape reinforcement on the biomechanical stability of HS tendon graft constructs for ACL reconstruction.

Therefore, the purpose of this study was to compare the dynamic elongation and stiffness behavior as well as ultimate failure load of standard to small diameter soft tissue grafts for ACL reconstruction with and without high-strength suture tape reinforcement of the entire ACL graft construct in vitro. It was hypothesized that small diameter soft tissue grafts would show greater elongation at reduced stiffness and that independent reinforcement of soft tissue grafts with suture tape would significantly reduce construct elongation by increasing construct stiffness and ultimate failure loads.

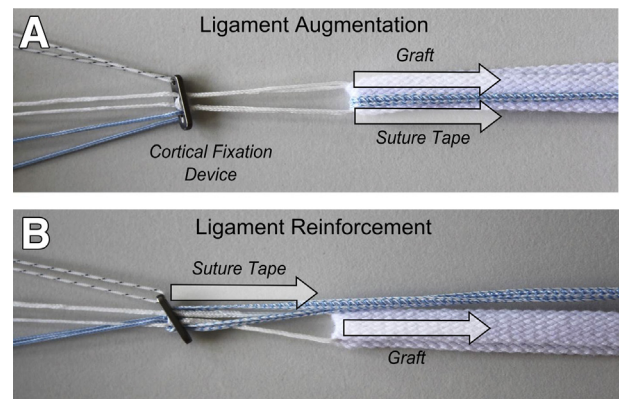
## Methods

### Testing Groups

Tripled and quadrupled all-inside graft construct groups ( $n = 8$  per group, total = 32) without (8 mm/9 mm) and with suture tape reinforcement (8 mm + ST/9 mm + ST) were prepared using adjustable loop-length devices (ALDs) on both sides. Tripled and quadrupled grafts were used to simulate “small” (8 mm) and “standard” diameter (9 mm) soft tissue graft models.<sup>23</sup> Test results of an isolated suture tape group (ST,  $n = 8$ ) served as reference and baseline for comparison with soft tissue graft groups.

### Augmentation Versus Reinforcement

Compared with other augmentation methods (Fig 1A) combining augmentation and graft material by stitching both together or securing both within the same fixation device,<sup>24</sup> the actual used reinforcement technique (*InternalBrace*, Arthrex, Naples, FL) is based on a synergistic load-sharing concept between graft and suture



**Fig 1.** Illustration of an (A) augmentation and (B) reinforcement technique with high strength suture tape for anterior cruciate ligament reconstruction leading to a combined and synergistic based load distribution with the independent fixed suture tape as protective “safety belt.”

tape with independent fixation points and tension options (Fig 1B). Primary tension on the soft tissue combined with a slack suture tape allows for creating a protective “safety belt” for soft tissue grafts.

### Specimen Preparation

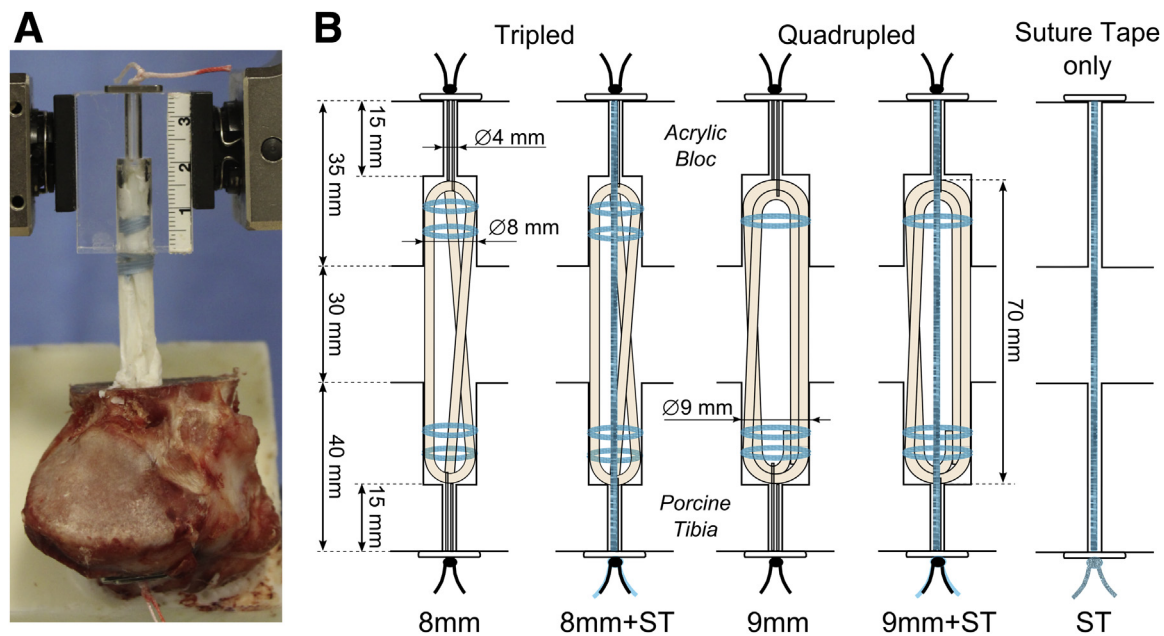
Transparent acrylic blocks were used to model the femoral side and to allow direct visualization during graft insertion and tensioning. Porcine tibias were selected to model the tibial side because of previously reported similarity to young adult humans.<sup>25</sup> A total number of 40 fresh porcine tibias (age 8 months) were collected from a local abattoir and removed of all soft tissue and cut 14 cm distal to the joint line. Embedding was carried out in line with the tibial tunnel axis by using RenCast (Huntsman Advanced Materials, Basel, Switzerland), a bicomponent embedding material. To allow sufficient space for ALD tensioning and a secure fixation of the tibias, a custom-made rectangular fixture was used to embed 2 cm distal to the predetermined exit of the tibial tunnel axis. To ensure a constant tunnel length of 40 mm, a sagittal bone saw was used to cut the lateral plateau of the tibia. The embedded bones were stored at  $-20^{\circ}\text{C}$  and thawed at room temperature overnight before biomechanical testing.

### Tunnel Preparation

For tendon groups, tibial bone tunnels with 8 mm (small) and 9 mm (standard) diameter were prepared by drilling 25 mm deep over a 4-mm spade-tipped guide pin, leaving a 15-mm bone bridge (Fig 2A). On the femoral side, in acrylic blocks with a total length of 35 mm, 20-mm tunnels were drilled with the same diameters as the graft. For isolated suture tape tests, 4-mm-diameter tibial and femoral tunnels were used.

### Graft Preparation

Bovine flexor tendons were harvested from adult bovine hind limbs because of their similar viscoelastic



**Fig 2.** (A) Final experimental setup and (B) schematic illustration of bone tunnel and graft-related definitions for tripled and quadrupled all-inside anterior cruciate ligament graft constructs as well as suture tape only configuration simulating a 30-mm joint space. (ST, suture tape.)

and structural properties to human HS tendons.<sup>26</sup> For tripled and quadrupled graft preparation, tendons were cut to a single-stranded length of 215 and 290 mm. Tendons were trimmed continuously in line with the fiber orientation to achieve an 8 mm tripled and 9 mm quadrupled graft diameter measured with a graft-sizing block and an overall length of 70 mm.

The quadrupled all-inside ACL graft was prepared according to Lynch and Anderson<sup>27</sup> using 2 ALDs (ACL TightRope RT, Arthrex). The 2 free ends were first sutured together and then the sutured part was placed inside of the construct near the tibial end. The graft was fixed in a preparation station and tensioned with 20 N using a spring-loaded tensioning device before suturing all limbs together on the tibial side with a circumferential stitch. Afterward, tension was increased to 80 N and one final stitching was performed on each graft end near the loops to create the final graft.

For tripled graft preparation, both tendon ends were whip-stitched 5 times at the last 20 mm and centrally positioned in the created graft loop on each side (see Fig 2B). An ALD was incorporated on each graft end, and the graft was installed in a preparation station and stitched together once on each side with 20 N tension applied. Preparation was finalized adding a second circumferential stitch on each end at 80 N tension. After preparation, tendons were stored at  $-20^{\circ}\text{C}$  and thawed at room temperature for 2 hours before biomechanical testing. All specimens were intermittently kept moist with a physiological saline solution during specimen preparation and testing.

### Device Insertion Techniques

The tibia and the acrylic block were secured to the base plate and actuator of a dynamic testing machine (ElectroPuls E10000, Instron, Norwood, MA) using custom clamps. Tensile load was applied on the entire ACL graft construct in line with the tunnel axis according to “worst case” loading for graft testing. Before device insertion and mechanical testing commenced, tendon grafts were subject to a spring-scale preloading of 80 N on the graft preparation board for 5 minutes.<sup>28</sup>

For groups using the high-strength suture tape (FiberTape, Arthrex), the reinforcement was inserted in the femoral ALD button (13 mm length) by passing it through the eyelets and creating a loop here with the 2 free ends on the tibial side.

Both the passing ALD tensioning sutures and suture tape strands were passed through the femoral sided acrylic block and the tibial bone tunnel from proximal to distal. The ALD buttons were flipped and passing sutures removed. On the tibial side, a 20 mm  $\times$  5 mm button extender from the same manufacturer was used to improve cortical fixation by reducing the risk of bone failure. Tibial cortical button loops were then manually adjusted by alternately pulling the shortening strands to allow for graft tunnel docking. All tibial ALDs were knotted at this point with 4 half-hitch suture knots using an arthroscopic knot pusher. All femoral ALDs remained loose with no tension on the graft at this stage.

### Construct Fixation

An ACL length over flexion angle relation was used to transfer the *in vivo* kinematics of the ACL during

weight-bearing knee flexion in an unidirectional motion to allow for incorporation into the test methodology.<sup>29</sup> It was found that the ACL experiences consistent length decreases of 1 and 3 mm at 30° and 90° respectively during flexion activity starting from full extension. In our knee model, a joint space of 30 mm would represent a knee in full extension, so that a 29-mm joint space represents 30° of flexion and a joint space of 27 mm a knee in 90° of flexion. Thus, the suture tape fixation was performed with 1-mm tape slackness (31-mm joint space) in reference to a knee in full extension (30-mm joint space).

For groups using the suture tape, a caliper was used to separate the acrylic block and tibia by a joint space of 31 mm at the beginning of the test. Suture tape fixation was performed first by tying 4 half-hitch knots on the tibial button using an arthroscopic knot pusher with 1-mm tape slackness (31 mm) in reference to a knee in full extension (30-mm joint space). To guarantee consistent and reproducible testing conditions, the test machine actuator moved successively after tape fixation to a load level of 10 N and further –2 mm to reach the graft fixation position. Graft fixation was performed at a position replicating 30° of knee angle flexion (29-mm joint space), which also served as reference for later elongation analysis. All tendon grafts were manually preloaded at this point by alternately pulling on the shortening strands to 50 N and then knotted on the femoral side by tying 4 half-hitch knots using an arthroscopic knot pusher. This is further illustrated in Figure 3.

### Test Protocol

All groups then underwent dynamic position-controlled cycling after primary fixation to replicate

the in vivo kinematics of the ACL during weight-bearing knee flexion, followed by 2 load control blocks at 0.75 Hz for 1,000 cycles per test block (Fig 3). Peak loads for force-controlled loading blocks were set to 250 N and 400 N simulating in vivo ACL loads during the early and late rehabilitation phase.<sup>30,31</sup> The valley load level was 10 N. Subsequently, grafts were further displaced during a load-to-failure test at 50 mm/min. Cyclic loading and load-to-failure data were recorded using the Wave-matrix software (Instron) with a sampling rate of 500 Hz.

### Outcome Data

Metrics for comparison included a decrease in the peak load level ( $F_D$ ), initial elongation ( $s_i$ ), dynamic elongation for the 250 N ( $s_{D,250}$ ) and 400 N load block ( $s_{D,400}$ ), total elongation ( $s_T$ ), and the final hysteresis width ( $HW_{F,400}$ ) at the end of the 400 N load block (Fig 4). The hysteresis width represents final construct loading situation and was calculated using the difference between valley and peak elongations. Note that obtained valley elongation values are quantifying the amount of plastic construct deformation and therefore the amount of laxity in the system during force-controlled loading. Furthermore, dynamic stiffness of the initial 250 N block load cycle ( $D_{L,250}$ ) and final load cycles for both load blocks ( $D_{F,250}$ ,  $D_{F,400}$ ) were calculated using hysteresis valley and peak values. Ultimate failure load ( $F_{UF}$ ) and stiffness ( $D_{UF}$ ) were determined during pull to failure. Stiffness was calculated within the linear portion of the load elongation curve between 200 N and 450 N.

### Native ACL Functional Zone

Final construct loading situation and dynamic stiffness were referenced to available native ACL data from

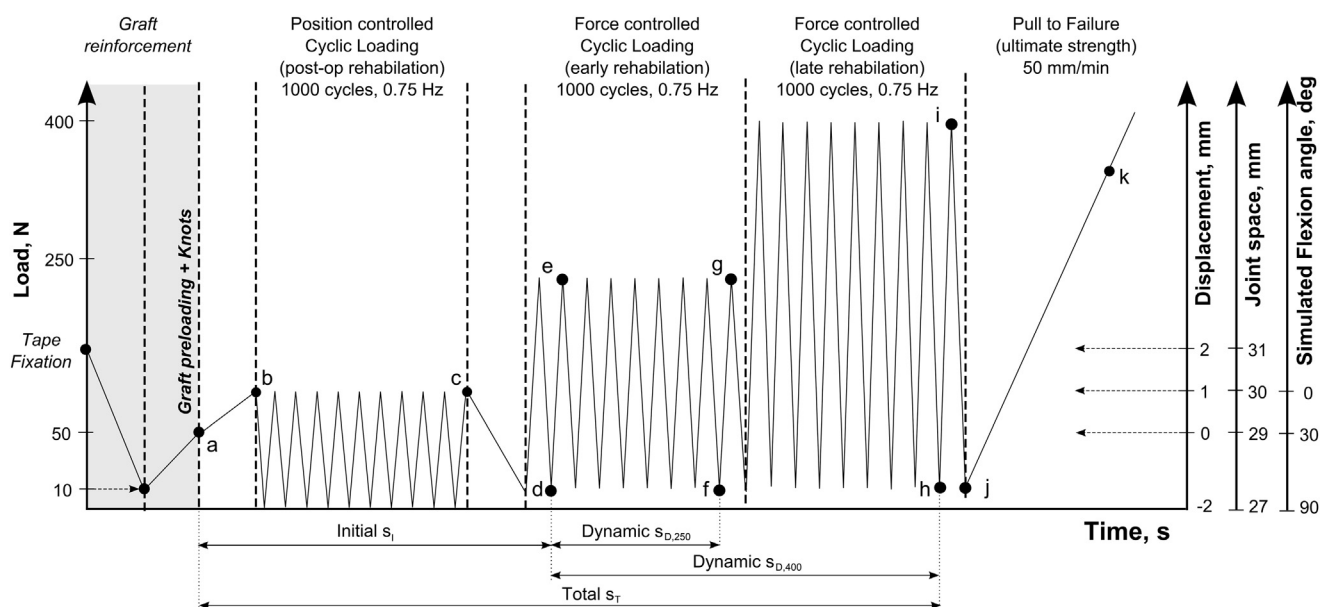
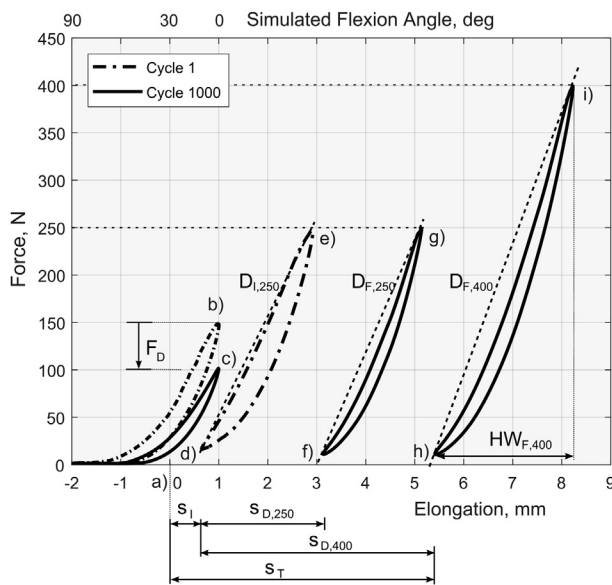


Fig 3. Testing protocol with points of data analysis.





**Fig 4.** Selected hysteresis curves with points of data analysis. Metrics for comparison included the peak load level change  $F_D$  ( $\Delta bc$ ), initial elongation  $s_1$  ( $\Delta ad$ ), dynamic elongations  $s_{D,250}/s_{D,400}$  ( $\Delta df/\Delta dh$ ) and total elongation  $s_T$  ( $\Delta ah$ ), initial  $D_{I,250}$  ( $\Delta de$ ) and final stiffness  $D_{F,250}$  at 250 N ( $\Delta fg$ ), final stiffness  $D_{F,400}$  and hysteresis width  $HW_{F,400}$  ( $\Delta hi$ ) at the end of the 400 N block as well as ultimate load and stiffness during pull to failure ( $\Delta jk$ , not shown). (HW, hysteresis width.)

the literature.<sup>32,33</sup> A native ACL reference model was established to quantify and qualify the stabilization potential of the ACL reconstruction.<sup>33-36</sup> The biomechanical tensile behavior of the native ACL was used for the actual used knee model with a 30-mm joint space (Fig 5). According to the in vivo behavior of the ACL during weight-bearing knee flexion with a 3-mm ACL length decrease from 0° to 90° and ACL slackness during mid-flexion angles, the transition from a strained to an unstrained ACL occurs between a mean flexion angle from 35° to 48° during active motion.<sup>29,37-42</sup>

### Statistical Analysis

In this study, a tendon model (8 mm/9 mm) and incorporation of the suture tape (8 mm + ST/9 mm + ST) were independent variables. All metrics for the comparison parameter were dependent variables. Ultimate failure load, dynamic elongation, stiffness, and total elongation were defined as primary outcome variables. Statistical analysis was performed using Sigma Plot Statistics for Windows, version 13.0 (Systat Software, San Jose, CA).

The Shapiro-Wilk test was used to ensure that outcome variables were normally distributed. Groups were compared using the 2-tailed Student *t*-test. The significance level was set at  $P < .05$ .

The observed post hoc average power value for statistically significant findings was 0.98, which is much

higher than the standard value of 0.8 and leading us to conclude that our sample size was sufficient. Data analysis was performed with MATLAB, version R2015b (MathWorks, Natick, MA).

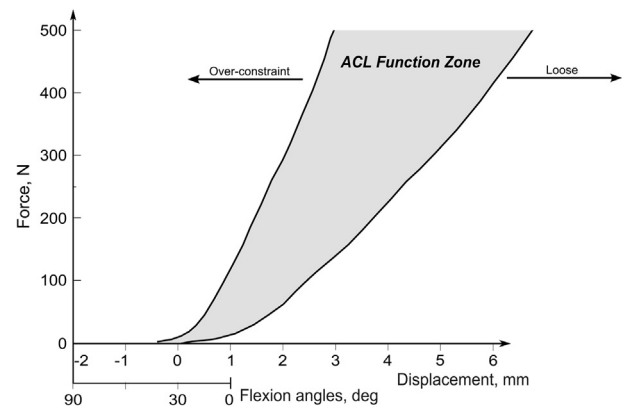
## Results

The mean and standard deviation results across all testing variables for defined groups are shown in Table 1. For isolated suture tape, no peak load level change ( $\Delta bc$ ) was assessed because of a complete unloading of the slack suture tape. *P* values and power values for the groupwise statistical analysis of ultimate failure load, dynamic stiffness, and elongation as well as total elongation are reported in Table 2. No significant difference could be found between reinforced groups (8 mm + ST/9 mm + ST) and between both quadrupled groups for dynamic elongation at 250 N peak load. All other analyzed parameters were statistically significant ( $P < .05$ ).

### Elongation

The isolated suture tape group starts load bearing at an increased elongation value of  $2.53 \pm 0.21$  mm compared with all other groups. The 8 mm + ST group revealed a dynamic elongation decrease of 38% and 50% after the 250 N and 400 N force block compared with the 8 mm group. The 9 mm + ST group showed a dynamic elongation decrease of 15% and 26%, respectively.

The final cumulative valley ( $s_T$ ) and peak elongation (sum of  $s_T$  and  $HW_{F,400}$ ) during the last load cycle at 400 N for 8 mm + ST were 59% and 53% decreased compared to the 8 mm group. The 9 mm + ST group revealed an analogous decrease of 39% (valley) and 36% (peak) (Fig 6). Final peak elongations at 400 N for both control (8 mm/9 mm) and suture tape only (ST) groups showed increased values compared with native



**Fig 5.** Typical range of the native ACL tensile force versus displacement and flexion angle for a knee model with a 30-mm joint space indicating its function zone (shaded) with overconstraint and loose regions. (ACL, anterior cruciate ligament.)

**Table 1.** Mean and Standard Deviation Test Results of All Test Variables

| Groups   | 8 mm             | 8 mm + ST        | 9 mm             | 9 mm + ST        | ST              |
|--|------------------|------------------|------------------|------------------|-----------------|
| Load decrease $F_D$ , % ( $\Delta bc$ )              | 22.2 $\pm$ 6.6   | 19.2 $\pm$ 4.2   | 26.7 $\pm$ 4.2   | 19.9 $\pm$ 3.7   | 0               |
| Initial elongation $s_I$ , mm ( $\Delta ad$ )        | 0.85 $\pm$ 0.21  | -0.11 $\pm$ 0.29 | 0.36 $\pm$ 0.42  | -0.23 $\pm$ 0.47 | 2.53 $\pm$ 0.21 |
| Dynamic elongation $s_{D,250}$ , mm ( $\Delta df$ )  | 2.34 $\pm$ 0.44  | 1.46 $\pm$ 0.28  | 1.86 $\pm$ 0.17  | 1.59 $\pm$ 0.34  | 0.90 $\pm$ 0.12 |
| Dynamic elongation $s_{D,400}$ , mm ( $\Delta dh$ )  | 5.06 $\pm$ 0.67  | 2.55 $\pm$ 0.44  | 3.55 $\pm$ 0.44  | 2.62 $\pm$ 0.44  | 2.14 $\pm$ 0.38 |
| Total elongation $s_T$ , mm ( $\Delta ah$ )          | 5.91 $\pm$ 0.76  | 2.44 $\pm$ 0.29  | 3.91 $\pm$ 0.74  | 2.39 $\pm$ 0.28  | 4.67 $\pm$ 0.30 |
| Hysteresis width $HW_{F,400}$ , mm ( $\Delta hi$ )   | 3.02 $\pm$ 0.21  | 1.77 $\pm$ 0.09  | 2.49 $\pm$ 0.17  | 1.71 $\pm$ 0.22  | 1.18 $\pm$ 0.02 |
| Dynamic stiffness $D_{I,250}$ , N/mm ( $\Delta de$ ) | 96.6 $\pm$ 9.0   | 136.5 $\pm$ 5.6  | 114.6 $\pm$ 8.9  | 150.5 $\pm$ 18.1 | 241.3 $\pm$ 10  |
| Dynamic stiffness $D_{F,250}$ , N/mm ( $\Delta fg$ ) | 115.2 $\pm$ 8.8  | 182.0 $\pm$ 8.7  | 136.4 $\pm$ 8.5  | 194.1 $\pm$ 23.2 | 303 $\pm$ 6.4   |
| Dynamic stiffness $D_{F,400}$ , N/mm ( $\Delta hi$ ) | 129.4 $\pm$ 8.9  | 219.7 $\pm$ 10.7 | 156.9 $\pm$ 10.4 | 231.2 $\pm$ 29.8 | 329.4 $\pm$ 5.9 |
| Ultimate failure load $F_{UF}$ , N ( $\Delta jk$ )   | 968 $\pm$ 103    | 1,592 $\pm$ 105  | 1,131 $\pm$ 89   | 1,585 $\pm$ 265  | 865 $\pm$ 81    |
| Ultimate stiffness $D_{UF}$ , N/mm ( $\Delta jk$ )   | 166.7 $\pm$ 12.0 | 296.0 $\pm$ 23.3 | 205.0 $\pm$ 9.2  | 298.2 $\pm$ 29.8 | 327.7 $\pm$ 6.5 |

HW, hysteresis width; ST, suture tape.

ACL behavior during walking at late rehabilitation loads (400 N).<sup>32</sup>

For each soft tissue graft group, hysteresis curves of a representative test sample at the end of each force control block were used and referenced to native ACL

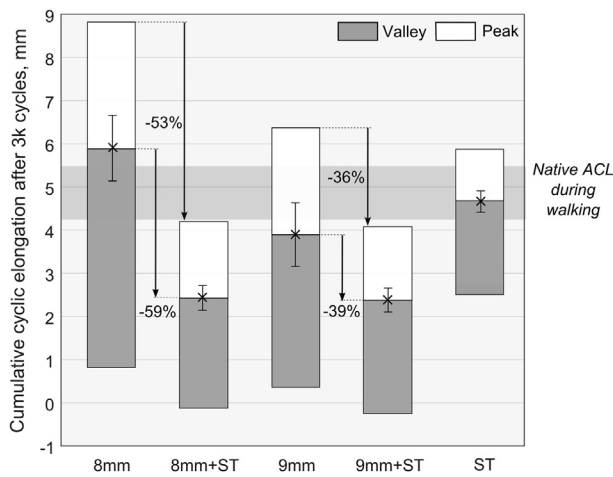
behavior and the isolated ST group (Fig 7). All hysteresis curves for reinforced groups are within the defined native ACL function zone. A complete loose state was assessed for the 8 mm control group at the end of both loading levels.

**Table 2.** *P* Values and Power Values of Primary Outcome Variables When Each Group Was Compared With All Other Groups

|  | 8 mm         | 8 mm + ST         | 9 mm              | 9 mm + ST         |
|--|--------------|-------------------|-------------------|-------------------|
| Dynamic elongation $s_{D,250}$ , mm ( $\Delta df$ )  |              |                   |                   |                   |
| 8 mm   | —            | <.001 (.99)       | .012 (.76)        | <.001 (.98)       |
| 8 mm + ST  | <.001 (.99)  | —                 | .004 (.90)        | <b>.394 (.13)</b> |
| 9 mm   | .012 (.76)   | .004 (.90)        | —                 | <b>.066 (.46)</b> |
| 9 mm + ST  | <.001 (.98)  | <b>.394 (.13)</b> | <b>.066 (.46)</b> | —                 |
| Dynamic elongation $s_{D,400}$ , mm ( $\Delta dh$ )  |              |                   |                   |                   |
| 8 mm   | —            | <.001 (1.00)      | <.001 (.99)       | <.001 (1.00)      |
| 8 mm + ST  | <.001 (1.00) | —                 | <.001 (.99)       | <b>.723 (.06)</b> |
| 9 mm   | <.001 (.99)  | <.001 (.99)       | —                 | <.001 (.99)       |
| 9 mm + ST  | <.001 (1.00) | <b>.723 (.06)</b> | <.001 (.99)       | —                 |
| Total elongation $s_T$ , mm ( $\Delta ah$ )          |              |                   |                   |                   |
| 8 mm   | —            | <.001 (1.00)      | <.001 (.99)       | <.001 (1.00)      |
| 8 mm + ST  | <.001 (1.00) | —                 | <.001 (1.00)      | <b>.728 (.06)</b> |
| 9 mm   | <.001 (.99)  | <.001 (1.00)      | —                 | <.001 (1.00)      |
| 9 mm + ST  | <.001 (1.00) | <b>.728 (.06)</b> | <.001 (1.00)      | —                 |
| Dynamic stiffness $D_{I,250}$ , N/mm ( $\Delta de$ ) |              |                   |                   |                   |
| 8 mm   | —            | <.001 (1.00)      | .001 (.96)        | <.001 (1.00)      |
| 8 mm + ST  | <.001 (1.00) | —                 | <.001 (1.00)      | <b>.057 (.49)</b> |
| 9 mm   | .001 (.96)   | <.001 (1.00)      | —                 | <.001 (1.00)      |
| 9 mm + ST  | <.001 (1.00) | <b>.057 (.49)</b> | <.001 (1.00)      | —                 |
| Dynamic stiffness $D_{F,250}$ , N/mm ( $\Delta fg$ ) |              |                   |                   |                   |
| 8 mm   | —            | <.001 (1.00)      | <.001 (.99)       | <.001 (1.00)      |
| 8 mm + ST  | <.001 (1.00) | —                 | <.001 (1.00)      | <b>.189 (.25)</b> |
| 9 mm   | <.001 (.99)  | <.001 (1.00)      | —                 | <.001 (1.00)      |
| 9 mm + ST  | <.001 (1.00) | <b>.189 (.25)</b> | <.001 (1.00)      | —                 |
| Dynamic stiffness $D_{F,400}$ , N/mm ( $\Delta hi$ ) |              |                   |                   |                   |
| 8 mm   | —            | <.001 (1.00)      | <.001 (1.00)      | <.001 (1.00)      |
| 8 mm + ST  | <.001 (1.00) | —                 | <.001 (1.00)      | <b>.323 (.16)</b> |
| 9 mm   | <.001 (1.00) | <.001 (1.00)      | —                 | <.001 (1.00)      |
| 9 mm + ST  | <.001 (1.00) | <b>.323 (.16)</b> | <.001 (1.00)      | —                 |
| Ultimate failure load $F_{UF}$ , N ( $\Delta jk$ )   |              |                   |                   |                   |
| 8 mm   | —            | <.001 (1.00)      | .005 (.878)       | <.001 (1.00)      |
| 8 mm + ST  | <.001 (1.00) | —                 | <.001 (1.00)      | <b>.948 (.05)</b> |
| 9 mm   | .005 (.878)  | <.001 (1.00)      | —                 | .001 (.99)        |
| 9 mm + ST  | <.001 (1.00) | <b>.948 (.05)</b> | <.001 (.99)       | —                 |

NOTE. *P* values > .05 were considered not statistically significant and are denoted in bold and italics.

HW, hysteresis width; ST, suture tape.



**Fig 6.** Cumulative cyclic valley elongation (10 N) with hysteresis width ( $HW_{F,400}$ ) as a peak elongation value and indicator for the final construct loading situation of all groups at the end of force-controlled cyclic loading with native ACL elongation behavior during walking as reference.<sup>32</sup> (ACL, anterior cruciate ligament; ST, suture tape.)

### Dynamic Stiffness

The 8 mm + ST group exhibited a 41% increased initial dynamic stiffness ( $D_{1,250}$ ) compared with the 8 mm group with a higher percentage increase until reaching a 70% higher final value ( $D_{F,400}$ ). The 9 mm + ST group had a 31% and 47% increased initial and final stiffness compared with the 9 mm group.

For each soft tissue graft group, a representative stiffness over peak elongation progression during force control is shown and referenced to native ACL behavior during walking activity (Fig 8). Final dynamic stiffness and peak elongation of both reinforced groups at late rehabilitation loads (400 N) are in the range of the

native ACL behavior indicated by the ACL function zone.<sup>32,33</sup> In addition, the final peak elongation of the isolated ST group at late rehabilitation loads is shown representing the ultimate safety belt function.

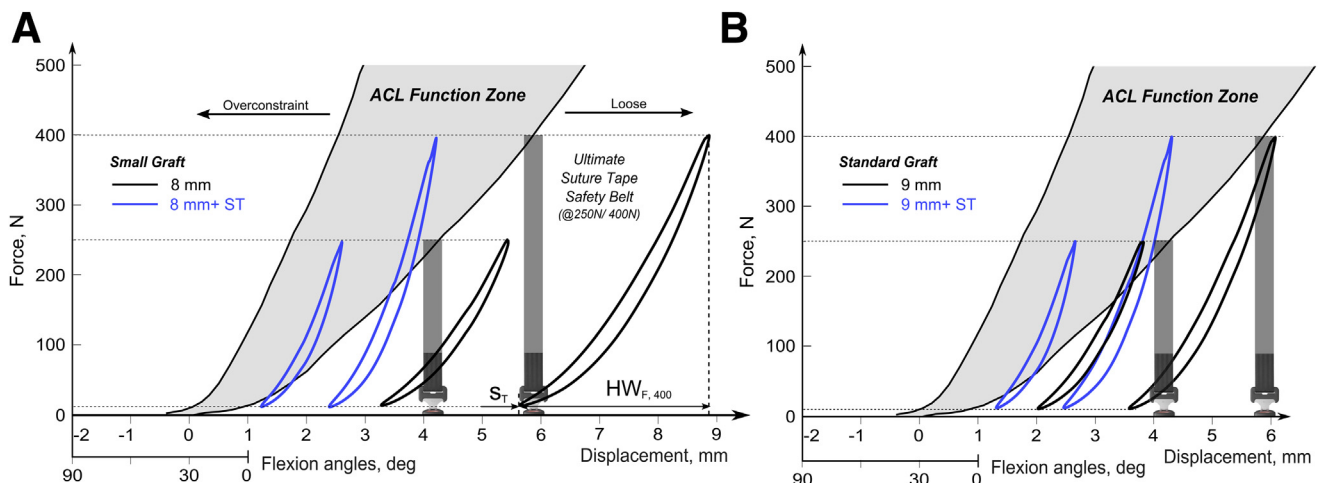
### Ultimate Failure

None of the test specimens failed during cyclic testing; therefore, all constructs were subject to a final load-to-failure test. Independent suture tape reinforcement of the tripled graft improved the ultimate load and stiffness for a 64% and 77% increase. Reinforcement of a quadrupled graft revealed a 40% and 45% increase in ultimate failure load and stiffness. Control and suture tape reinforced groups' common mode of failure was damage of the adjustable loop sutures and fixation site damage of the suture tape and the adjustable loop sutures, respectively.

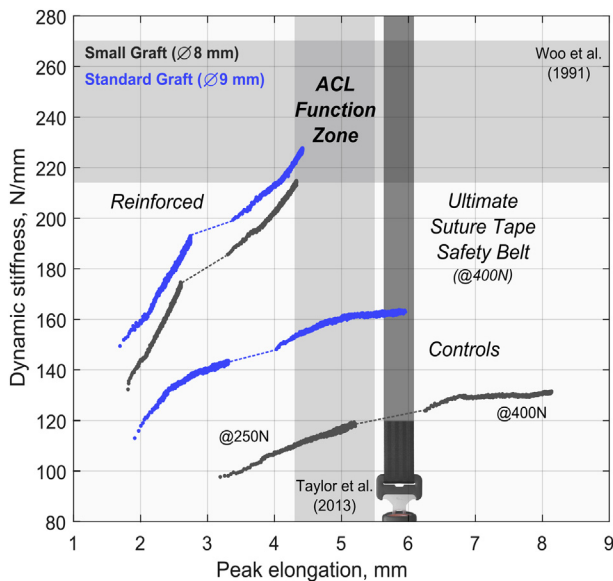
### Discussion

Study results showed that independent suture tape reinforcement provides for an increased stabilization potential for ACL reconstruction graft constructs, but still conforming to native ACL behavior while significantly enhancing ultimate failure strength. There are many variables determining the success of ACL reconstruction with ultimate goals including restoration of normal joint stability and full range of motion, as well as return to sport activity function without graft tears. In the present study, a biomechanical evaluation focusing on the stabilization effect of independent reinforcement of a small and standard diameter soft tissue graft for an entire ACL graft construct with suture tape was performed.

The tripled small diameter ACL reconstruction model (8 mm) revealed significantly worse performance than



**Fig 7.** Representative hysteresis curves of small (A) and standard diameter grafts (B) at the end of each dynamic force control test block with total elongation ( $s_T$ ) as well as hysteresis width ( $HW_{F,400}$ ) as an indicator for the final loading situation in reference to final isolated suture tape peak elongation representing the ultimate safety belt function and native ACL behavior. (ACL, anterior cruciate ligament; HW, hysteresis width; ST, suture tape.)



**Fig 8.** Exemplary stiffness over peak elongation progression during force control loading (250 N, 400 N) for each test group with final isolated suture tape peak elongation representing the ultimate safety belt function at late rehabilitation loads with native ACL references.<sup>32,33</sup> (ACL, anterior cruciate ligament.)

standard quadrupled grafts (9 mm) with increased elongation and decreased stiffness values. Avoidance of graft elongation is critical for a successful ACL reconstruction because knee laxity also depends on the graft length over time.<sup>43</sup> This theory is consistent with the current literature reporting that the risk of graft rupture increases with decreasing graft diameter and subsequently worse mechanical properties.<sup>11,21</sup> Increased graft lengthening during dynamic loading may also be contributed to differences in the preparation technique of the tripled tendon model (8 mm) compared with the quadrupled model (9 mm) with a different number of tendon loops and securing circumferential stitching at the graft end for ALD suspension.

The isolated ST group starts load bearing at a higher elongation relative to all other groups and restricts greater dynamic elongations during cyclic loading because of increased stiffness. The final isolated suture tape loading situations at early- and late-rehabilitation loads revealed slightly loose states next to native ACL behavior with peak elongation indicating ultimate safety belt functions.

Adding an independent suture tape to small and standard diameter grafts led to statistically significant improvement in mechanical behavior, but *no* inter-group statistically significant differences regarding elongations or dynamic stiffness were found. In synergistic load-sharing configuration with soft tissue, the function of the suture tape appears like a *dynamic* safety belt: as soft tissue graft elongation progresses, the more

dominant the suture tape as secondary stabilizer will become. In particular, small diameter grafts are not able to resist higher loadings and thus elongate, but they can be protected against overstretching by the increasing supportive stabilization potential of the suture tape reinforcement. Therefore, lower loads are completely transferred over the soft tissue itself until reaching an elongation range, where the suture tape starts taking over load and reduce absolute peak loads on the soft tissue side. Also, following the principle of a parallel spring configuration, the resistance against elongation increases because of individual stiffness summation of the tendon graft and suture tape during load-sharing situation. The final hysteresis width ( $HW_{F,400}$ ) as a representative parameter for the construct load-bearing capability and dynamic stiffness provides for information about this underlying load-sharing concept. Both suture tape supplemented tendon groups have increased loading capabilities ( $HW_{F,400}$ ) and decreased stiffness compared with the isolated ST group, which indicates initial full weight bearing of the soft tissue graft with succeeding supportive suture tape function during load sharing. Consequently, although the reinforcement primarily allows for improving the performance of weak tendons, it simultaneously protects full-strength tendons against overconstraining due to an adequate soft tissue graft support according to its mechanical properties. The used synergistic load-sharing configuration successfully bypasses any stress-shielding effects and allows for absorbing continuous loads on the soft tissue during weight-bearing situations, and therefore should represent an optimized technique compared with others.<sup>43</sup>

Reconstruction of the ACL aims to reproduce the mechanical properties of the native ligament ensuring appropriate knee laxity as well as stability over normal range of motion. Overconstraint of the knee can lead to kinematic limitations and cause graft or fixation failure.<sup>44,45</sup> Native ACL peak strain and stiffness values during walking activity were used in this study specifically to evaluate whether the biomechanical behavior of the ACL reconstruction restores native ACL function at late rehabilitation loadings (400 N).<sup>32,33</sup> Both reinforced groups reached the native ACL function zone without overconstraining the knee.

Notably, ACL graft reinforcement allows creation of higher failure loads. Ultimate failure strength for ACL reconstruction is not that important for daily living activities as tensile loading of the normal ACL has been estimated not to be more than 20% of the native ACL ultimate load to failure. However, the suture tape reinforcement might aid in managing peak forces, as they can occur during accelerated rehabilitation or an accidental fall and reduce the risk of a rupture with subsequent revision.



## Limitations

We acknowledge limitations to the current study. Porcine bone, bovine extensor tendons and an acrylic bloc were used as substitute material for human tissue. The use of animal tissue enables a better comparability within the testing groups because of more consistent mechanical properties. Porcine bone and bovine tendon has been previously reported to approximate the biomechanical properties of human tissue.<sup>25,46</sup> The triple-stranded graft model was chosen as “small” diameter because sometimes human HS graft harvest results in short tendons and quadrupling the graft is then not possible.<sup>23</sup> In addition, loads were applied longitudinally to the graft, which represents a worse-case scenario for ACL reconstruction tests but is not correspondent to the common in vivo loading situation. Finally, this is an in vitro, time-zero biomechanical study, simulating the effect of independent suture tape reinforcement on the mechanical behavior of ACL reconstruction, and further short- and long-term clinical follow-up studies are needed to confirm the technique as a possible clinical solution for the aforementioned problems with graft ruptures.

## Conclusions

Independent suture tape reinforcement of soft tissue grafts for ACL reconstruction leads to significantly reduced elongation and higher ultimate failure load according to in vivo native ACL function data without stress-shielding the soft tissue graft.

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