A Biomechanical Comparison of Fan-Folded, Single-Looped Fascia Lata With Other Graft Tissues as a Suitable Substitute for Anterior Cruciate Ligament Reconstruction

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Purpose: The purpose of this study was to evaluate the initial biomechanical properties of a fan-folded, single-loop construct of fan-folded fascia lata allograft in comparison to other graft tissues currently being used for anterior cruciate ligament (ACL) reconstruction. **Methods:** Eighteen fascia lata specimens were harvested from 11 donors and fan folded through a proprietary process. Bone–patellar tendon–bone (BPTB), tibialis anterior, tibialis posterior, and peroneus longus tendons were harvested from 4 additional donors. All soft-tissue grafts were tested to failure in an MTS machine (MTS Systems, Eden Prairie, MN) in a single-looped fashion. BPTB grafts were similarly clamped in freeze grips. The ultimate load to failure and stiffness were calculated for each graft type tested. **Results:** The mean ultimate load to failure was 3,266 N and stiffness was 414 N/mm for the single-looped fascia lata grafts (n = 18). There was no significant difference for ultimate load to failure and stiffness between the fascia lata and tibialis anterior (3,012 N and 342 N/mm, respectively), tibialis posterior (3,666 N and 392 N/mm, respectively), and peroneus longus (3,050 N and 346 N/mm, respectively) tendons. The fascia lata grafts performed significantly better ($P < .001$) than BPTB (1,404 N and 224 N/mm, respectively). **Conclusions:** A single-loop construct of fan-folded fascia lata allograft has, on biomechanical testing, initial ultimate tensile strength (3,266 N) and stiffness values equivalent to or better than several other graft tissues currently used in ACL reconstruction, including BPTB (1,403 N), tibialis anterior (3,012 N), tibialis posterior (3,666 N), and peroneus longus (3,050 N). **Clinical Relevance:** In the face of potential allograft tissue shortages and increasing constraints on health care expenditures, the use of fascia lata has the potential to be a readily available graft for ACL reconstruction that performs as well as other grafts and at a comparable or lower cost.

The importance of the anterior cruciate ligament (ACL) to normal knee function is well documented, and injuries to the ACL are common in sporting activities.[1] As a result, over 100,000 ACL reconstructions are performed annually in the United States.[2] For several decades, the gold-standard graft choice has been autologous bone–patellar tendon–bone (BPTB) autograft, with values for tensile load and stiffness (2,977 N and 620 N/mm, respectively) exceeding those of the native ACL (2,160 N and 242 N/mm, respectively).[3] However, persistent concerns remain, including donor-site morbidity, specifically the risk of persistent anterior knee or kneeling pain; postoperative patellar fracture; or patella baja. The use of autologous hamstring tendons has increased partly because of lower donor-site morbidity and comparable clinical performance to autograft BPTB graft with respect to functional outcomes and patient satisfaction, de-

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spite slightly higher objective laxity on KT-1000 testing (MEDmetric, San Diego, CA).[4]

Over the past 10 years, allograft use for ACL reconstruction has increased in popularity.[5] Proponents of allograft use argue that operative time, donor-site morbidity, and postoperative pain are all decreased. In addition, patients aged over 45 years treated with allograft tendons recover more quickly.[6] In the case of revision surgery or multiligamentous knee injury, the use of allograft tissue provides many more reconstructive options. Factors influencing the performance of an allograft include preservation methods, immunogenicity, host remodeling, and technical factors such as tunnel position, graft position, initial graft tension, and postoperative rehabilitation with soft-tissue grafts.[7] With frozen allografts, the risk of rejection from immunogenicity is negligible and the risk of disease transmission is minimal with appropriate donor screening and gamma irradiation.[8,9] However, the use of radiation has been shown to negatively affect the strength of grafts at doses higher than 2.5 megarads.[4]

The use of BPTB allograft has been widespread because of proven clinical performance and likelihood of bone-to-bone healing.[5] However, the inability of tissue banks to keep up with demand for these grafts has fueled interest in alternative allograft types (unpublished data, H.T.T. [chief of University of Miami Tissue Bank, Miami, FL], June 2009). With recent advances in soft-tissue fixation techniques and improved sterilization techniques, there has been a resurgence of interest in alternative allograft sources, such as tibialis anterior, quadriceps, and Achilles tendons.

Many factors ultimately contribute to the success or failure of an allograft reconstruction, including graft preparation at the time of surgery, tunnel placement, graft fixation, postoperative rehabilitation protocol, and allograft incorporation and remodeling. Despite this, laboratory values for ultimate tensile strength and stiffness provide at least an initial indicator of how an allograft might perform in vivo, and such values have been reported in recent studies testing similar soft-tissue allografts.[8,10,11]

The purpose of this study was to compare the initial biomechanical properties (ultimate tensile strength and stiffness) of a fan-folded, single-looped fascia lata construct with other graft tissues being used today for ACL reconstruction. The working hypothesis was that this novel construct would have equal or better initial biomechanical properties compared with other graft tissues.

METHODS

Eighteen fascia lata specimens were harvested from 11 donors with a mean age of 38 years (range, 21 to 56 years). These grafts were harvested from the distal-lateral thigh and were approximately 22 cm in length and 4 cm in width, depending on the donor. Donors designated for research purposes had entire lower extremity specimens fresh frozen within 24 hours postmortem. The specimens were then thawed to harvest and prepare the fascia lata grafts. These fan-folded grafts were frozen again until testing. By use of a custom template (Fig 1), the fascia specimens were fan folded to achieve a tubular-like graft that was multiple layers thick (Fig 2). This fan-folded construct was then secured with several simple sutures of No. 3-0 Vicryl (Ethicon, Somerville, NJ) along the length of the graft (Fig 3). A single-loop construct of the final fan-folded fascia lata graft was then created for testing purposes. Before testing, each graft was passed through the smallest possible tendon sizer. Of the 18 grafts used in testing, 3 were 7 mm in diameter, 5 were 8 mm, 9 were 9 mm, and 1 was 10 mm.

For comparative purposes, 4 additional donors that had been allocated for research purposes were used to harvest a total of 8 tibialis anterior, 8 tibialis posterior, and 8 peroneus longus specimens, as well as 16 BPTB half-patella specimens. The mean age of the donors was 46 years (range, 25 to 61 years). Each of the soft-tissue grafts were atraumatically stripped of any muscle attachment, and a single loop was created. As with the fascia lata grafts, these specimens came from

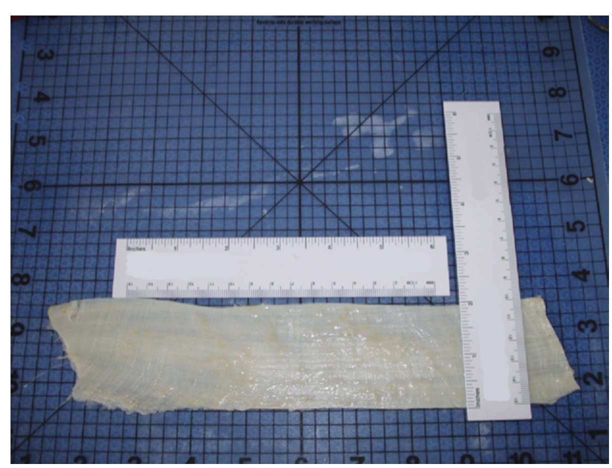

FIGURE 1. Sheets of fresh-frozen fascia lata are harvested from the mid-thigh region, where tissue consistency is even. Sheets measuring at least 20 × 5 cm in size are needed to construct an adequately sized graft.

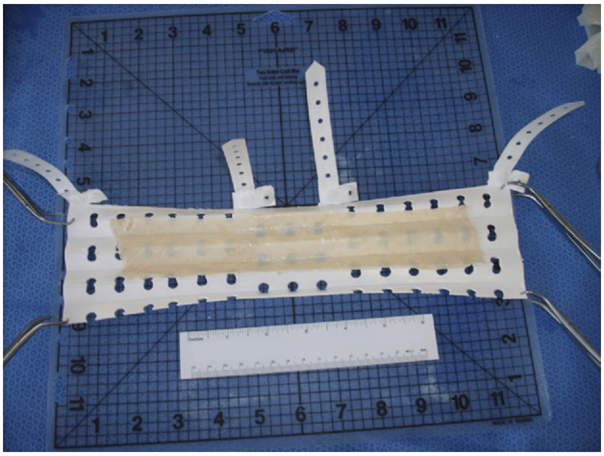

FIGURE 2. The sheet of fascia lata is mounted on a custom cardboard folding template to allow the tissue to be folded easily into multiple pleats of the same width.

donors that had the entire lower extremity fresh frozen within 24 hours postmortem. The lower extremities were thawed to allow harvesting of the grafts, and the grafts themselves were again frozen until testing. On the day of testing, grafts were tested immediately after being thawed without any pretest cycling. For the tibialis anterior, there was one 8-mm specimen, six 9-mm specimens, and one 10-mm specimen. For the tibialis posterior, there were two 9-mm specimens, five 10-mm specimens, and one 11-mm specimen. For the peroneus longus, there were five 8-mm specimens and two 9-mm specimens. Two half-patella specimens

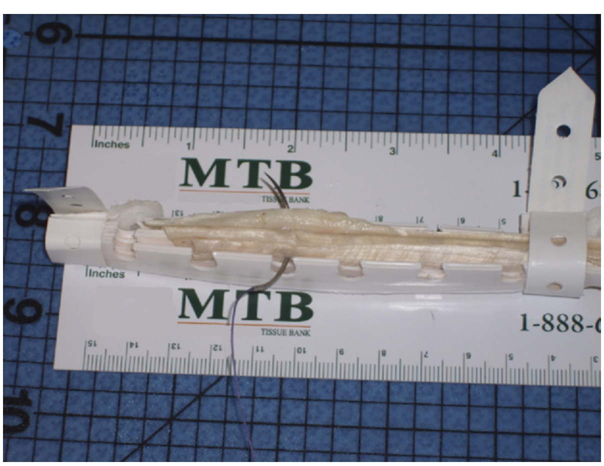

FIGURE 3. Once the sheet of fascia lata has been fan folded and compressed, several simple sutures are used along the length of the graft to secure the folds of tissue. The finished construct has a tendon-like appearance and can then be looped over for testing purposes.

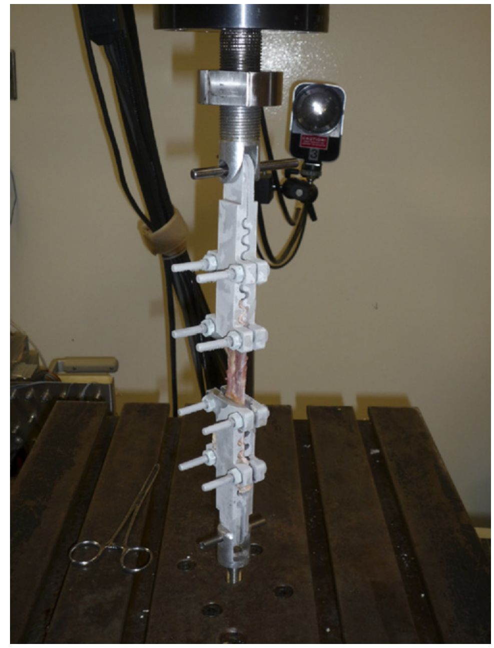

FIGURE 4. All soft-tissue grafts were similarly mounted on serrated freeze clamps with 5 cm of tissue between the clamps. Graft fixation was achieved by freezing the ends in liquid nitrogen for 20 seconds, leaving the intervening tissue between the clamps thawed. All specimens were mounted on an MTS machine and distracted to failure, yielding values for both ultimate tensile strength and stiffness. All failures were intrasubstance tears with no pullout from the freeze clamps.

were discarded because of tissue quality, and the remaining 14 specimens were trimmed to a tendon width of 10 mm. The patellar and tibial bone blocks were similarly trimmed to allow fixation by the freeze grips. Achilles tendon grafts were not included in this study because of specimen availability and because the aim was primarily to compare the single-looped fascia lata with other grafts commonly used in a single-loop fashion (tibialis and peroneal tendons). BPTB graft was included because this is the most common graft choice clinically.

All the soft-tissue grafts were prepared in a single-loop configuration and held by serrated metal clamps (Fig 4) on either end with a distance of 50 mm between the clamps. Both clamps were then frozen in liquid nitrogen for 20 seconds to allow freezing and bonding of the clamped tissue ends to the metal. The intervening 50 mm of tissue between the clamps was left unfrozen. The clamped ends were mounted on an MTS Mini Bionix 858 testing apparatus (MTS Systems, Eden Prairie, MN) and brought slowly apart until the grafts were taut before the actual testing. The MTS TestStar Station Manager was used to collect information about ultimate tensile strength and stiffness of the grafts (Table 1). At this point, the grafts were loaded to failure at 100% nominal strain rate per second. With the active length of each graft fixed at 50 mm, the distraction rate of the grafts was thus carried out at 50 mm/s. Values for ultimate tensile strength and stiffness and mode of failure were recorded. The BPTB grafts were similarly tested with both bone blocks secured by the freeze grips. Statistical analysis consisted of a Student *t* test to compare values between fascia lata and the other tested graft types.

RESULTS

The mean load to failure for the tested fan-folded, single-looped fascia lata grafts was 3,266 ± 987 N (Table 2). This was comparable to the mean values observed for tibialis anterior (3,012 ± 794 N, P = .52), tibialis posterior (3,666 ± 782 N, P = .32), and peroneus longus (3,050 ± 684 N, P = .58) allografts in this study. The fascia lata construct performed significantly better than the 10-mm BPTB allograft (1,404 ± 511 N, $P < .001$) in this setting. A similar trend was observed for graft stiffness values, with fascia lata having the higher mean stiffness (414.10 ± 151 N/mm). However, this was not statistically significant compared with values for the tibialis anterior (343 ± 97 N/mm, P = .24), tibialis posterior (392 ± 27 N/mm, P = .69), and peroneus longus (347 ± 91 N/mm, P = .26). Compared with BPTB (224 ± 71 N/mm), the fascia lata was significantly stiffer ($P <$ .001).

We performed a separate analysis excluding the 3 grafts from the fascia lata group that were 7 mm in diameter. This was done because a 7-mm graft would be unlikely to be used in a clinical setting (in a single-bundle reconstruction) and because there were no 7-mm grafts in any of the comparison groups. The ultimate tensile loads (1,919 N, 1,979 N, and 2,023 N, respectively) and stiffness values (303 N/mm, 242 N/mm, and 231 N/mm, respectively) for these 7-mm outliers were markedly lower than those for the rest of the fascia lata specimens. With these grafts excluded, the mean ultimate tensile strength of the fascia lata specimens increased to 3,524 ± 867 N, and the mean stiffness increased to 445 ± 146 N/mm. However, these values were still not significantly different than the values obtained for the soft-tissue grafts (tibialis and peroneal tendons) tested in this study.

The failure mode for all tested specimens was also recorded. Of the 18 tested fascia lata specimens, 16 had purely intrasubstance ruptures whereas only 2

Table 1. *Graft Data*

Graft Type	Diameter (mm)	Ultimate Tensile Strength (N)	Stiffness (N/mm)
Fascia lata	7	1,918.56	302.83
Fascia lata	7	1,978.82	241.69
Fascia lata	7	2,022.95	231.02
Fascia lata	8	2,379.57	367.60
Fascia lata	8	3,160.01	398.11
Fascia lata	8	2,281.51	324.86
Fascia lata	8	3,272.23	406.62
Fascia lata	8	3,658.18	412.19
Fascia lata	9	4,110.24	464.32
Fascia lata	9	4,323.83	536.46
Fascia lata	9	4,402.78	590.64
Fascia lata	9	2,020.68	214.54
Fascia lata	9	4,727.42	509.70
Fascia lata	9	4,064.68	500.52
Fascia lata	9	3,709.99	324.14
Fascia lata	9	2,834.70	265.20
Fascia lata	9	3,327.07	791.27
Fascia lata	10	4,596.53	572.16
Peroneus longus	8	3,266	292.8
Peroneus longus	8	3,166	308.8
Peroneus longus	8	3,715	493.3
Peroneus longus	8	3,295	259.1
Peroneus longus	8	3,186	225.1
Peroneus longus	9	1,584	383.1
Peroneus longus	9	3,615	378.6
Peroneus longus	9	2,576	432.2
BPTB	10	1,015	153.4
BPTB	10	1,454	223.1
BPTB	10	1,740	240.3
BPTB	10	1,221	290.3
BPTB	10	1,116	333.7
BPTB	10	870	164.5
BPTB	10	1,452	276.7
BPTB	10	2,837	336.2
BPTB	10	1,581	248.8
BPTB	10	1,205	180.9
BPTB	10	1,089	256.9
BPTB	10	1,585	156.8
BPTB	10	1,697	164.3
BPTB	10	789	108.5
Tibialis anterior	8	2,155	237.5
Tibialis anterior	9	3,965	375.0
Tibialis anterior	9	1,909	276.4
Tibialis anterior	9	3,704	498.3
Tibialis anterior	9	2,268	201.1
Tibialis anterior	9	3,582	399.9
Tibialis anterior	9	3,439	378.5
Tibialis anterior	10	3,075	376.3
Tibialis posterior	9	2,304	367.0
Tibialis posterior	9	3,352	392.8
Tibialis posterior	10	3,740	422.0
Tibialis posterior	10	3,158	375.8
Tibialis posterior	10	4,205	406.0
Tibialis posterior	10	4,471	410.2
Tibialis posterior	10	4,691	419.2
Tibialis posterior	11	3,403	347.2

TABLE 2. *Summary of Results*

Graft	Mean Diameter	Ultimate Tensile Strength	Stiffness
Fascia lata	8.44 mm	3,266 ± 987 N	414 ± 151 N/mm
Tibialis posterior	9.88 mm	3,666 ± 782 N, $P = .32$	392 ± 27 N/mm, $P = .70$
Peroneus longus	8.38 mm	3,050 ± 684 N, $P = .58$	347 ± 91 N/mm, $P = .26$
Tibialis anterior	9 mm	3,012 ± 794 N, $P = .53$	343 ± 97 N/mm, $P = .24$
BPTB	10 mm	1,403 ± 511 N, $P < .001$	224 ± 71 N/mm, $P < .001$

NOTE. *P* values compare fascia lata data with each of the other test graft types.

failed toward the clamped end. A majority of the failures in the other soft-tissue grafts were also intrasubstance ruptures, with occasional failures toward the clamps. Of the tibialis anterior/posterior grafts, 2 of 8 failed toward the grips from each group, whereas 3 of 8 peroneus longus grafts had similar failures. A remaining majority of failures were purely midsubstance ruptures. There were no instances of soft-tissue slippage from the freeze clamps. This is in contrast to the BPTB group, where a slight majority of the failures (8 of 14) were at the bone-tendon interface, with the remainder (6 of 14) being intraligamentous ruptures. Again, there were no instances of bone pullout from the clamps.

DISCUSSION

The aim of this study was to test the biomechanical properties of a novel preparation of fascia lata allograft as a substitute graft for ACL reconstruction. The original hypothesis was shown to be valid in that the values for the ultimate tensile strength and stiffness for the fan-folded, single-looped fascia lata graft (3,266 ± 986 N and 414 ± 151 N/mm, respectively) were equivalent to or exceeded those of the comparison grafts (BPTB, 1,403 ± 511 N and 224 ± 71 N/mm, respectively; tibialis anterior, 3,012 ± 794 N and 343 ± 97 N/mm, respectively; tibialis posterior, 3,666 ± 782 N and 392 ± 27 N/mm, respectively; and peroneus longus, 3,050 ± 684 N and 347 ± 91 N/mm, respectively).

Fascia lata has been historically used as an autograft in either substituting for[12-15] or augmenting[16,17] an ACL reconstruction, but these constructs were met with uniformly poor results.[18] Fascia lata allograft has also been used in the past but only in a non-looped, single-strand fashion. Noyes et al.[19] compared their results of ACL reconstruction using allograft BPTB and allograft fascia lata in a rolled, single-strand construct measuring 10 to 11 mm in diameter. Patients with fascia lata allograft had significantly higher anterior-posterior translation as measured with KT-1000 testing, and the only patient with instability was one in whom the fascia lata graft had failed. However, to date, there have been no published studies using fascia lata allograft in a single-loop configuration.

The fan-folding process using a custom folding template was designed to ensure reproducible folding of a sheet of fascia lata. With a typical harvested sheet, a graft of fascia lata approximately 6 layers thick could be fashioned, making the single-loop construct approximately 12 layers thick. With harvested sheet lengths of at least 20 cm, a 10-cm single-loop/double-strand graft can easily be created. This was an adequate length for most clinical scenarios even if cortical fixation devices were to be used. To secure the layers of the folded fascia together, suture windows were created in the folding template at regular intervals. This allowed easy placement of regularly spaced interrupted No. 3-0 Vicryl sutures along the length of the graft to tubularize and secure it. The folding and suturing of the graft, if used clinically, would need to be done at the time of surgery because allograft tissue cannot be distributed with pre-placed sutures. There was no difference between how the fascia lata graft was prepared for testing and how it would be used in a clinical setting except that, for this study, the grafts were prepared well in advance of their use for testing. During harvesting of the fascia lata, it was noted that the thickness of the iliotibial band increased distally in the thigh toward the Gerdy tubercle. However, the tissue at this location was consistently variable and not easily fan folded into the double-strand construct. As such, the tested specimens were harvested from a more central location in the thigh.

The values for ultimate tensile strength (3,266 ± 987 N) and stiffness (414 ± 151 N/mm) for this fascia lata construct were comparable to the other soft-tissue allografts in this study. These numbers improved to 3,525 ± 867 N and 445 ± 146 N/mm, respectively, when the smaller 7-mm grafts were excluded from the analysis, although this did not change the statistical significance of any of the comparisons. The values for the soft-tissue grafts in this study (fascia lata, tibialis anterior, tibialis posterior, and peroneus longus) are also comparable to similar studies in the literature. Haut Donahue et al.[8] evaluated a single-loop construct of tibialis anterior (4,122 N and 460 N/mm, respectively) and tibialis posterior (3,594 N and 379 N/mm, respectively), along with a double-looped semitendinosus/gracilis graft (2,913 N and 418 N/mm, respectively). The ultimate load of the tibialis anterior looped graft in that study was significantly higher than that of the hamstrings, but all other values were comparable. The looped end of the graft was secured with a pulley to allow for equal tensioning of both strands during loading.

Pearsall et al.[10] evaluated doubled tibialis anterior, tibialis posterior, and peroneus longus tendons in a manner similar to this study with freeze clamps on both graft ends. The mean failure loads for the tibialis anterior, tibialis posterior, and peroneus longus tendons were 3,412 N, 3,391 N, and 2,483 N, respectively. The mean stiffness values were 344 N/mm, 302 N/mm, and 244 N/mm, respectively. The failure loads and stiffness values for the tibialis anterior and tibialis posterior were significantly higher than those for the peroneus longus in this study. This trend mirrors data from our study with tibialis anterior and posterior grafts being equivalent but stronger than peroneus longus grafts. The experimental setup used in this study was similar to that of Pearsall et al. in terms of the use of freeze grips for both tendon ends, although freezing was performed with liquid nitrogen in this study, which allowed a more rapid freezing/adherence of tendon ends. Testing to failure was done at a 100% nominal strain rate per second (50 mm/s), according to Grood and Noyes.[9] This is in contrast to the study of Pearsall et al., where grafts were elongated only at 1 mm/s, although values for ultimate tensile strength and stiffness for the tibialis anterior, tibialis posterior, and peroneus longus were similar between the 2 studies.

When we compared the fascia lata graft with the 10-mm BPTB grafts, a significant difference for both ultimate tensile load and stiffness was observed ($P <$ .001). Noyes et al.[20] previously reported the strength of a central-third BPTB graft to be 2,900 N, which is twice the value noted in this study. However, it should be noted that the specimens in their study were 14 mm in diameter and from donors with a mean age of 26 years. The stiffness of this wider BPTB graft was reported as 208 N/mm, which was comparable to our value of 224 N/mm. Interestingly, a 16-mm single-strand fascia lata graft from that study had only a mean maximum load of 628 N. Another study found the strength of a 10-mm BPTB graft to be 1,784 N and that of a double-looped semitendinosus-gracilis graft to be 2,421 N.[21] This is in contrast to the strength of the native ACL in the young adult, which has been reported to be 2,160 N.

Values for graft stiffness have been reported to range from 210 N/mm for a 10-mm BPTB graft to 274 N/mm for a 14-mm BPTB graft.[20,21] The stiffness of the fascia lata graft of 414 N/mm in this study greatly exceeds these historical figures and is higher than values for the other soft-tissue grafts in this and other studies,[10] with ranges from 242 to 392 N/mm. On the basis of these data, the single-looped, double-stranded fascia lata graft performs at least as well as any other allograft tissue in laboratory studies with respect to initial ultimate tensile strength and stiffness. A theoretical advantage of this fascia lata construct in vivo is a potentially decreased time to biological incorporation. Because ligament graft tissues incorporate from the periphery,[22] it is conceivable that a graft construct with numerous pleats and a large exposed surface area (i.e., fascia lata) would incorporate faster than a solid tubular graft (i.e., tibialis tendon), although this needs to be investigated formally.

Another consideration is cost and availability of allograft tissue. Many factors including numerous market forces separate from the actual cost of tissue procurement and processing affect the final cost of an allograft. The harvesting and processing of a fascia lata graft do not pose any additional difficulties compared with those of other ACL allograft tissues, and depending on donor size, up to 4 sheets of fascia lata can be harvested versus 2 of any other graft type from a single donor. Although there is no way to put an exact cost on the fascia lata graft, there is no reason to expect it to be any more costly than alternative allograft tissues.

This study does have several limitations with respect to the performance of the fascia lata graft. Because this was an in vitro biomechanical study, no conclusions can be made regarding performance with regard to pullout strength after fixation, potential elongation over time, biological incorporation, or clinical function. In addition, all the grafts used in this study were tested immediately after thawing without any preloading or cycling. Finally, all grafts (both fascia lata and comparison grafts) were fresh-frozen specimens without any further processing such as gamma irradiation[23] or the use of secondary sterilization agents such as ethylene oxide,[24] both of which may have an effect on tissue quality.

CONCLUSIONS

A single-loop construct of fan-folded fascia lata allograft has, on biomechanical testing, initial ultimate tensile strength (3,266 N) and stiffness values equivalent to or better than several other graft tissues currently used in ACL reconstruction, including BPTB (1,403 N), tibialis anterior (3,012 N), tibialis posterior (3,666 N), and peroneus longus (3,050 N).

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