Knee Surg Sports Traumatol Arthrosc (2017) 25:1500–1509
DOI 10.1007/s00167-016-4351-3

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Anterior laxity and patient-reported outcomes 7 years after ACL reconstruction with a fresh-frozen tibialis allograft

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Received: 27 April 2016 / Accepted: 28 September 2016 / Published online: 20 October 2016

Abstract

Purpose After reconstructing a torn ACL with a soft tissue allograft, the long-term healing process of graft maturation following the short-term healing process of graft incorporation into the bone tunnels might lead to recurring instability and concomitant decreases in the activity level, function, and patient satisfaction. Relying on roentgen stereophotogrammetric analysis (RSA), the primary purpose was to determine whether anterior laxity increased and whether patient-reported outcomes declined between 1 and 7 years for a particular graft construct, surgical technique, and rehabilitation programme.

Methods Eighteen of 19 patients, who participated in an earlier RSA study which extended to 1 year after the surgical procedure, were contacted 7 years after the surgical procedure. An examiner, different from the treating surgeon, measured anterior laxity under 150 N of anterior force using RSA in 16 patients and obtained outcome scores in 17 patients. One patient moved abroad and could not be contacted. One patient reinjured his reconstructed ACL and was excluded.

Results The average increase in anterior laxity of 1.5 ± 2.1 mm between 1 and 7 years after surgery was not significant ($p = 0.08$), and the average increase in anterior laxity of 2.7 ± 2.3 mm between the day of surgery and 7 years was significant ($p < 0.001$). There were no significant declines in activity (median Tegner score, 6 at 1 year, 6 at 7 years), function (average Lysholm score, 94 at 1 year, 91 at 7 years), and subjective satisfaction (average International Knee Documentation Committee score, 90 at 1 year, 87 at 7 years) between 1 and 7 years after surgery.

Conclusion In demonstrating that the ACL graft construct remains functional in the long term, this study supports the use of a fresh-frozen tibialis allograft in patients with an average age of 37 years at the time of surgery when used in conjunction with a surgical technique which avoids roof and PCL impingement, uses slippage-resistant fixation devices, and allows brace-free, self-paced rehabilitation.

Level of evidence IV.

Keywords Anterior cruciate ligament · Roentgen stereophotogrammetry · Long-term follow-up · Ligamentization · Graft maturation

Introduction

An increase in anterior laxity following anterior cruciate ligament (ACL) reconstruction is worrisome because it can cause recurrent instability, and a reduction in activity level, function, and patient satisfaction [7]. The causes of an increase in anterior laxity are several and can be broadly categorized as short term, which extends over the period of graft incorporation into the bone tunnels and is limited to 3–4 months [29, 39], and long term which extends over the period of graft maturation beyond 3–4 months.

Focusing on soft tissue allografts, depending on the graft construct, surgical technique, and rehabilitation regimen,

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increases in anterior laxity can be limited in the short term and patient-reported outcomes can reach high levels. For example, one study used non-irradiated, non-chemically cleansed fresh-frozen tibialis allografts fixed with slippage-resistant fixations, a surgical technique which avoids impingement of the graft against the intercondylar roof in extension and the posterior cruciate ligament (PCL) in flexion, and a rehabilitation programme which encouraged immediate full weight bearing without a brace, self-administered exercises, and a return to activities after 4 months [39]. Based on roentgen stereophotogrammetric analysis (RSA) in 19 patients, the average increase in anterior laxity due to short-term causes was limited to 1.1 mm and activity level, function, and patient satisfaction were high at 6 months and 1 year.

Although ACL reconstructive surgery with soft tissue allografts can be successful in the short term [39], long-term follow-up is needed. The composition of the collagen fibres and mechanical properties of the ACL graft continue to evolve during the 'ligamentization' or maturation phase of healing, which extends well beyond 1 year after surgery [1, 3, 23, 26, 33, 35, 43]. Therefore, it is of interest to measure the long-term changes in anterior laxity and patient-reported outcomes in relation to short-term changes before concluding that graft maturation does not lead to recurrent instability and a reduction in patient-reported outcomes and that the surgical procedure is successful. For study of changes in anterior laxity, RSA is attractive because of the high accuracy compared to that of a manual arthrometer [10].

Previous long-term longitudinal studies which isolate the effects of maturation of soft tissue allografts on anterior laxity and patient-reported outcomes are lacking. Only one other longitudinal RSA-based study known to the authors used a soft tissue autograft and that study evaluated patients only for 1 year [19]. Other longitudinal studies that were long term followed patients up to 7 years but used hamstrings autografts [12, 30]. Another study evaluated patients with tibialis allografts at 10.5 years [2], but only one time point was used so that long-term effects of graft maturation on increases in anterior laxity and changes in patient-reported outcomes could not be independently evaluated from short-term effects. Furthermore, all long-term studies cited above used a different graft construct, surgical procedure, and rehabilitation programme than that used in the earlier short-term RSA study [39] so that results may not translate.

The purposes of the present study were twofold. Using RSA, the primary purpose was to re-examine the same cohort of patients at 7 years that was examined up to 1 year [39] and determine whether the average anterior laxity increased and whether average activity level, function, and patient satisfaction declined between 1 and 7 years. A secondary purpose was to determine whether the average anterior laxity increased between the day of surgery and 7 years. For the graft construct, surgical procedure, and rehabilitation programme used in the short-term study mentioned above [39], the hypotheses were that anterior laxity and patient-reported outcomes would not be affected by graft maturation between 1 and 7 years.

Materials and methods

All 19 patients or their relatives that were enrolled in the previous study and had been treated with an ACL reconstruction with a tibialis allograft between June 2007 and September 2008 [39] were contacted. Of these 19 patients, 16 had their anterior laxity measured with RSA, and 17 patients reported their activity (Tegner score), function (Lysholm score), subjective satisfaction (International Knee Documentation Committee score), and KOOS (knee injury and osteoarthritis outcome score) at 7 years after the index surgery. One patient known to have moved abroad could not be contacted. One patient reinjured his reconstructed ACL and was excluded. The average follow-up time was 7 years, 4 ± 4 months, with a minimum follow-up time of 6 years, 8 months and a maximum follow-up time of 8 years.

The following is a brief description of the surgical technique of the ACL reconstruction, implantation of tantalum beads to perform the RSA measurement of anterior laxity, and rehabilitation programme [39]. Each patient was treated with a transtibial single-tunnel, arthroscopically assisted ACL reconstruction surgery [22, 39] (Fig. 1). The tissue source for the ACL graft was an aseptically harvested, fresh-frozen, non-irradiated, non-chemically treated tibialis allograft from a tissue bank accredited by the American Association of Tissue Banks (Musculoskeletal Transplant Foundation, Edison, New Jersey). Irradiated or chemically treated allografts were not used because they have a higher failure rate [20, 28]. The surgical procedure avoided roof and PCL impingement and strived to match the tension pattern of the graft to that of the intact ACL during passive motion to prevent lengthening of the graft from these mechanical causes [13–15, 36, 39]. Tantalum markers 0.8 mm in diameter (model 20401, Tilly Medical Products AB, Lund, Sweden) were implanted into the femur ($n = 6$) and tibia ($n = 6$) with a bead injector (model 20202, Tilly Medical Products) to measure the anterior laxity with the technique of RSA [39]. The measurement of anterior laxity using RSA is repeatable and has no detection bias because it is quantitatively computed [17–19, 31, 32, 38]. Rehabilitation was self-administered without a brace with the goal of walking without crutches by 1–2 weeks, jogging by 8 weeks,

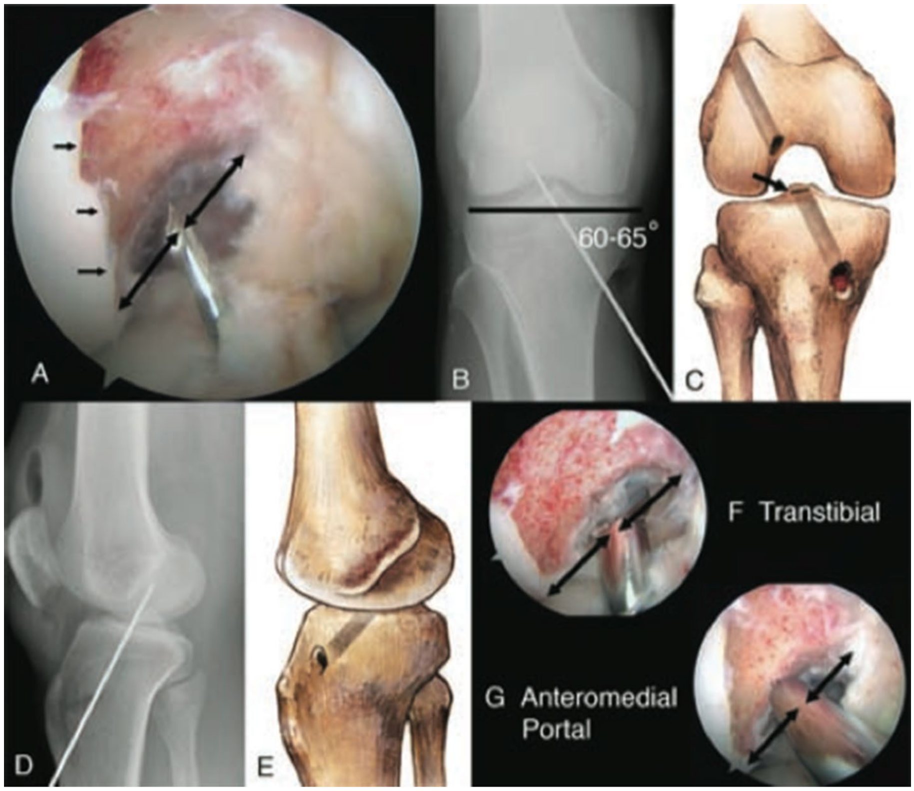

Fig. 1 Composite of a right knee showing the key arthroscopic steps for placing the tibial tunnel and drilling the femoral tunnel through the tibial tunnel (transtibial technique) so that impingement of the ACL graft against the PCL in flexion and against the roof in extension are avoided, and the tension pattern of the ACL graft matches that of the intact ACL throughout the flexion–extension arc. Widen the notch until the space between the PCL and lateral femoral condyle exceeds the width of the graft by 1 mm (*three small arrows*) (**a**). In the coronal plane, place the tibial guidewire so that the angle between the wire and the medial joint line is 60°–65° (**b**), and place the lateral edge of the tibial tunnel so that it passes through the tip of the lateral tibial spine (*arrow*) (**c**). In the sagittal plane, place the tibial guide wire 4–5 mm posterior and parallel to the intercondylar roof with the knee in extension (**d**), which places the anterior edge of the tibial tunnel 1–2 mm posterior and parallel to the intercondylar roof (**e**). Check arthroscopically that the tip of the tibial guidewire lies midway between the apex and base of the notch (wire bisects *three double-headed arrows*) (**a**). If the tip lies closer to the apex of the notch (vertical placement), then the ACL graft has PCL impingement, which will limit flexion or stretch the graft, causing instability. If the tip lies closer to the bottom of the notch (posterolateral tunnel placement), then the tension in the graft will be greater than that of the intact ACL in extension, which will limit extension or stretch the graft, causing instability. Once the tibial tunnel is drilled following these steps, the femoral tunnel can be drilled by passing the femoral aimer through the tibial tunnel (**f**). Alternatively, the femoral tunnel can be drilled in the same location through the anteromedial portal (**g**) [39]

and returning to sport by 4 months without treatment by a physical therapist [39].

The following is a brief description of the methods for loading the knee, and technical issues for imaging the knee with digital biplanar radiographs, and the precision of the anterior laxity measurement, which were used to compute anterior laxity of the knee. Each subject's knee was placed in a custom-designed load application apparatus as shown in Fig. 2. The knee was positioned in a calibration cage (Model 10, Tilly Medical Products) required for subsequent RSA analysis, and the ankle and thigh were secured to their respective supports with straps. Flexion of the knee was set at 25° and verified by a goniometer. A pneumatic actuator was used to apply posterior and anterior forces to the tibia while these forces were measured with load cells at the ankle support and at the pneumatic actuator. The two loads registered by load cells were regulated to transmit an 90-N posterior and 150-N anterior force at the knee. The amount of force to be applied to the tibia to transmit these loads at the knee was calculated based on the weight and length of the patient's shank using a previously described technique [38]. Surface electrodes placed over the vastus lateralis, long head of the biceps femoris, and medial head of the gastrocnemius (Bagnoli-8, DelSys, Boston, MA) monitored muscle excitation to avoid exposing the radiographs while there was muscle contraction. The contraction of these muscles affects anterior laxity [8, 11, 41]. A custom program (LabVIEW version 7.1, National Instruments Corporation, Austin, TX) that monitored the output of the surface electrodes indicated muscle contraction

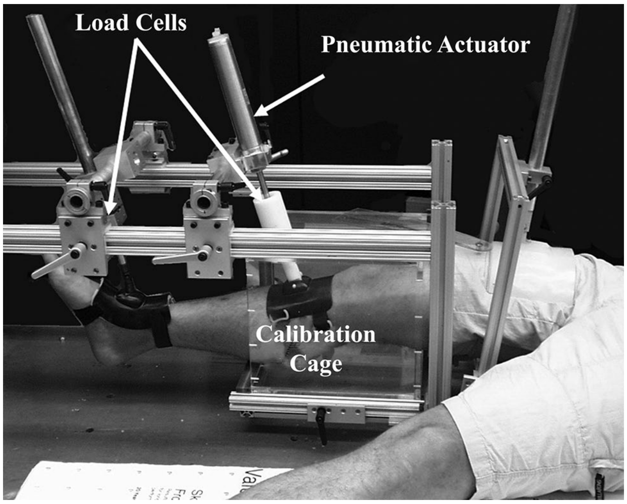

Fig. 2 Photograph showing the limb in the loading apparatus. The knee was centred in the calibration cage and was flexed 25°. The ankle and thigh were secured in supports. The pneumatic actuator was oriented perpendicular to the shank and parallel to the knee joint at a distance of 12.5 cm distal to the joint line. The pneumatic actuator applied anterior and posterior forces to the tibia. Load cells measured the applied force and the reaction force at the ankle joint [39]

by illuminating a light bulb. When muscle excitation was absent, simultaneous biplanar radiographs were taken with portable X-ray machines (model HF80+, MinXray Inc., Northbrook, IL) [39]. A lead shield was placed over the patient's gonads and trunk to confine the radiation to the knee, and the portable X-ray machines were positioned to expose biplanar (coronal and lateral) views of the knee 87 cm from their respective film planes [39]. The precision is 0.5 mm when performing serial measurements of anterior laxity with the RSA loading apparatus used in the present study and accounts for the sum total of all errors caused by inconsistent positioning of the limb in the loading apparatus, variability in the applied anterior load at the knee, undetected excitation of leg muscles, exposure of the radiographs, and intraobserver error associated with image and data processing [40].

RSA was used to compute the three-dimensional coordinates of each marker from the biplanar radiographs in the same manner as the previous study with the exception that the radiographs were digital rather than film, which meant the images were directly imported into the computer rather than scanned for analyses [31]. The two-dimensional coordinates of each marker on each radiograph were input into the previously used custom software written with a commercial software package (MATLAB version 8.3, The MathWorks Inc., Natick, MA), and the three-dimensional coordinates of each marker were computed [39].

The axes for computing laxity were determined [39] using an anatomical coordinate system constructed at the centre of rotation of the knee [32, 38]. Details of the coordinate system and the choice of coordinate system used were described by Smith et al. [39] and Roos et al. [32], respectively.

In the previous study, anterior laxity was assessed on the day of surgery within 2 h of awakening the patient. Preconditioning of the knee was not performed before obtaining radiographs because loading the knee could have caused slippage of the ACL graft at the sites of fixation, which would have underestimated the increase in anterior laxity computed at subsequent intervals of evaluation [39]. Three sets of biplanar radiographs were taken, one set with no load, one set with a 90-N posterior force, and one set with a 150-N anterior force applied at the knee. The set with no load was used to define both a neutral position for the knee and the anatomical coordinate system [32]. The set taken with 90 N of posterior force was used to determine the 90-N posterior limit of translation, which was a negative quantity. The set taken with 150 N of anterior force was used to determine the 150-N anterior limit of translation, which was a positive quantity. The anterior laxity on the day of surgery was computed as the difference between the 150-N anterior limit of translation and the 90-N posterior limit of translation along the anterior–posterior axis of the anatomical coordinate system.

Anterior laxity was also computed at 1, 2, 3, 4, 6, and 12 months after surgery in the previous study [39]. In contrast to the day of surgery, the knees evaluated at these follow-up visits were preconditioned by applying ten cycles of a 90-N posterior force followed by a 150-N anterior force transmitted at the knee. One set of biplanar radiographs was taken with a 150-N force transmitted at the knee, which was used to compute a 150-N anterior limit at the specified time of follow-up. Anterior laxity at a specified time of follow-up was the difference between the posterior limit of translation recorded on the day of surgery and the anterior limit specified time of follow-up. The change in anterior laxity was computed as the difference between anterior laxity at a specified time of follow-up and the day of surgery. This same preconditioning, loading, and imaging protocol was used to assess each patient at 7 years after the surgery. Because the knee was not preconditioned on the day of surgery, and because the knee was preconditioned at the 1 and 7 years after surgery, any increase in anterior laxity could be a slight overestimation.

In both the previous and present studies, patients quantified their level of function (Lysholm score), activity (Tegner score), and subjective satisfaction (IKDC score) at each specified time of follow-up. Patients also filled out the knee injury and osteoarthritis outcome score (KOOS) at the 7-year follow-up to assess the subjects' opinions about their knee and associated problems and allow comparison between other studies that use this metric.

The present study was performed following approval from the Institutional Review Boards of the University of California at Davis (IRB No. 284653-4) and Methodist Hospital in Sacramento (IRB No. SAC).

Statistical analysis

Software (JMP, version 11.2.0, 64-bit; SAS Inc., Cary, NC, www.jmp.com) computed the average, standard deviation, and the following statistical tests. A Shapiro–Wilk goodness-of-fit test assessed the normality of the differences in anterior laxity, activity level (Tegner), function (Lysholm), and subjective satisfaction (IKDC) scores between 1 and 7 years, and between day of surgery and 7 years. The differences in anterior laxity were normally distributed, and the differences in the knee scores were not. Accordingly, a repeated measures analysis of variance determined whether the anterior laxity changed over these three time intervals. A Tukey–Kramer test determined whether anterior laxity changed between 1 and 7 years and between the day of surgery and 7 years. A two-sided nonparametric Wilcoxon test determined whether activity level, function, and patient satisfaction changed between 1 and 7 years. In all tests, the level of significance was set at 0.05.

Because the sample size of 16 was somewhat smaller than the 19 patients used in the earlier study [39], a power analysis was performed to determine the probability of wrongly concluding there was no significant change in anterior laxity in the ANOVA (Type II error). For 16 subjects, an effect size of 0.75 (i.e. difference to detect of 1.5 mm/standard deviation of 2.0 mm taken from the earlier study), and a level of significance of 0.05, the power was high at 0.97. Because the probability of a Type II error is limited to 0.03, there is a very low probability of wrongly concluding that there was no significant change in anterior laxity.

Results

The follow-up study consisted of 17 of the original 19 patients, 13 men and 4 women, with a mean age of 44 ± 10 years at the time of follow-up (range 25–55 years). Anterior laxity was measured in 16 patients, and activity level, function, and subjective satisfaction were recorded in 17 patients (Table 1). Of the 16 patients for which anterior laxity was measured, 13 had partial meniscectomy at the time of the ACL reconstructive surgery and 1 had partial meniscectomy following the ACL reconstructive surgery. No patient had partial meniscectomy prior to the ACL reconstructive surgery.

The average increase in anterior laxity of 1.5 ± 2.1 mm between 1 and 7 years after surgery was not significant (n.s.) (Fig. 3). The average laxity 7 years after the surgery increased by 2.7 ± 2.3 mm from the average laxity of 12.4 ± 2.0 mm on the day of surgery ($p < 0.001$).

Between 1 and 7 years after surgery, there was no significant decline in any patient-reported outcome scores. On average, there were no significant declines in activity (median Tegner score, 6 at 1 year, 6 at 7 years), function (average Lysholm score, 94 at 1 year, 91 at 7 years), and subjective satisfaction (average International Knee Documentation Committee score, 90 at 1 year, 87 at 7 years) (Table 2). The average KOOS (100 best) at 7 years was 90 ± 16 and was 90 or higher in 76 % (13 out of 17) of subjects, which indicates 'good' knee injury and osteoarthritis outcomes.

Discussion

The most important findings of the present study were that anterior laxity did not increase between 1 and 7 years after surgery and self-reported knee scores did not decline between 1 and 7 years after surgery but anterior laxity increased between the day of surgery and 7 years. The activity level, function, and patient satisfaction scores suggest that the average increases in anterior laxity of 1.5 mm between 1 and 7 years after surgery and 2.7 mm between the day of surgery and 7 years after surgery were clinically unimportant. This result indicates that maturation of a soft tissue allograft does not cause recurrent instability and concomitant declines in activity level, function, and patient satisfaction. Although 6 of 16 patients had an increase in anterior laxity of 3 mm or greater (range 3–6.7 mm) between day of surgery and 7 years after surgery, 5 of those 6 patients had Lysholm, IKDC, and KOOS scores greater than or equal to 84 out of 100 (range 84–100), and 4 of those 6 patients had Tegner scores that either increased by 1 or remained the same as 1 year after surgery. The other 2 of the 6 patients had Tegner scores that decreased by 2 from 1 year after surgery, indicating that their level of activity had gone down somewhat since 1 year after surgery. Because most of these patients still experience good to excellent function and satisfaction with their reconstructed ACL, it appears that the increase in anterior laxity from day of surgery to 7 years after surgery did not greatly affect their ability to enjoy an active lifestyle.

Comparing the long-term results of the present study to those of previous studies which used RSA to track changes in anterior laxity following ACL reconstruction with soft tissue grafts is difficult because only one other longitudinal RSA-based study known to the authors used a soft tissue graft and that study followed patients only for 1 year. Khan et al. [19] prospectively studied 14 patients after ACL reconstruction using hamstrings grafts at monthly intervals

Table 1 Patient-specific results for each of the 17 patients followed up at 7 years

Subject	Age[c] (years)	Laxity day of surgery (mm)	Laxity 1 year (mm)	Laxity 7 years (mm)	Tegner 1 year	Tegner 7 years	Lysholm 1 year	Lysholm 7 years	IKDC 1 year	IKDC 7 years	KOOS 7 years
1	40	12.5	16.3	15.5	6	7	90	100	90	98	94
2	51	11.1	13.8	16.6	2	2	65	64	60	53	–
3	35	12.7	12.4	18.2	9	9	95	100	92	98	100
4	53	12.2	13.7	14.4	9	6	100	100	95	94	94
5	51	11.0	13.0	13.3	6	4	96	88	86	78	93
6	25	14.6	18.4	20.3	9	9	99	84	94	89	95
7[a]	46	11.3	12.0	11.6	6	4	95	94	99	85	93
8	49	11.9	15.3	18.6	6	6	100	100	95	100	99
9[a]	48	13.2	13.4	12.2	7	4	100	89	100	86	71
10	52	12.7	12.9	12.6	7	10	99	99	97	91	98
11	26	9.3	14.3	14.3	9	7	100	90	99	90	94
12[a]	48	16.3	15.4	18.1	5	5	99	100	93	99	98
13	55	8.5	4.2	9.9	3	3	78	42	64	33	36
14[b]	52	14.6	15.3	15.8	6	5	95	100	95	100	95
15[a]	51	13.9	13.6	14.5	6	5	88	90	84	90	87
16[b]	33	10.2	10.7	12.9	7	8	96	100	98	100	95
17	40	NA	NA	NA	7	9	100	100	95	100	95
Mean	44.4	12.4	13.4	14.9	6[d]	6[d]	94	89	90	85	89
SD	9.5	2.0	3.1	2.9			10	17	12	19	18

[a] Female patients

[b] Patients which had intact menisci

[c] Age is at time of follow-up at 7 years

[d] Median

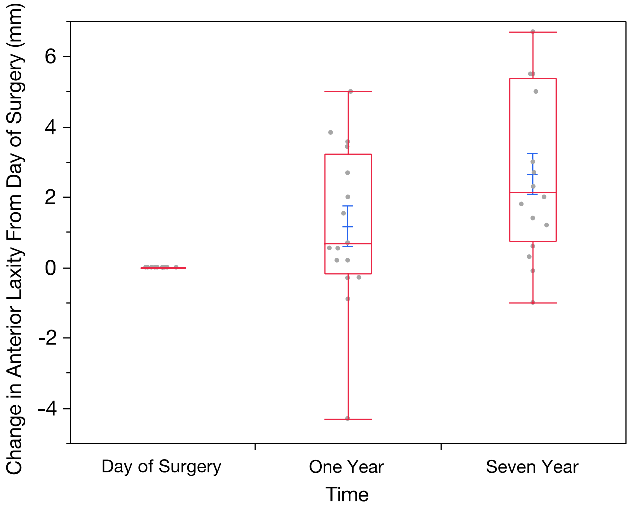

Fig. 3 Distribution of the change in anterior laxity from day of surgery at day of surgery, 1 and 7 years after surgery. The *red line* crossing the middle of the *red box* identifies the median value. The ends of the box identify the 25th and 75th quartiles. The two lines that extend from the end of each box identify the minimum and maximum values. The middle *blue line* identifies the mean value, and the *blue lines* above and below identify the standard deviation. Only the average difference between the day of surgery and 7 years was statistically significant ($p < 0.001$)

during the 1 year after surgery. Their results showed that an autogenous double-looped semitendinosus and gracilis hamstrings graft had a relatively large increase in anterior laxity of 8.6 mm at 1 year. Presumably this increase in anterior laxity occurred in part because of large slippage at the sites of fixation of 7.1 mm which can be traced to the use of interference screws for soft tissue graft fixation [21]. This large difference in anterior laxity increase between Khan's study of 8.5 mm at 1 year and the present study of 1.0 mm at 1 year highlights the earlier discussion that the variables of the treatment regimen used in ACL reconstruction (i.e. surgical technique, graft construct, and rehabilitation programme) can profoundly influence the results of the follow-up.

Comparing results of the present study to those of previous studies which used non-invasive means such as the KT-1000 or KT-2000 to measure increases in anterior laxity for soft tissue grafts in long-term follow-ups is likewise difficult because of the differences in the treatment regimens and patient cohorts between studies. Moreover, any comparisons can be made only for patient-reported outcomes because of the difficulties in comparing anterior laxities between the KT-1000 and RSA mentioned earlier. Recognizing these difficulties, arguably the most relevant study for comparison is that by Almqvist et al. [2] because this study used tibialis allografts in 50 patients which were followed up at 10.5 years. Although different statistics were computed between our study (mean and standard deviation for Lysholm and IKDC) and that by Almqvist et al. (median for Lysholm and IKDC), the median is probably comparable to the mean owing to the relatively large sample size thus allowing comparison (Table 3). Other comparisons are necessarily limited to those studies which used hamstrings autografts. Four studies which evaluated patients at least at 7 years are those by Asik et al. [4] which included 271 patients, Roe et al. [30] which included 90 patients, Gifstad et al. [12] which included 56 patients, and Zaffagnini et al. [42] which included 40 patients. For all available metrics, patient-reported scores herein compare favourably with those for both tibialis allografts and hamstrings autografts (Table 3). Based on their patient-reported outcome scores and KT measurements of anterior laxity, the comparison studies concluded that their treatment regimen provided reasonably good subjective outcomes and objective stability at least at 7 years which is consistent with the findings of the present study.

Some limitations should be considered when interpreting the results. Because the present study examined a treatment regimen consisting of a specific graft construct, surgical technique, rehabilitation programme, and patient cohort, generalization of the findings to other treatment regimens should be made cautiously. In particular, an aseptically harvested, fresh-frozen, non-irradiated, non-chemically treated tibialis allograft was used. Irradiated and chemically treated allografts are known to have a higher rate of traumatic rupture [20, 28]. Also used was a transtibial technique designed to minimize impingement of the ACL graft against the roof during knee extension, minimize impingement of the ACL graft against the PCL during knee flexion, and restore tension in the graft similar to

Table 2 Statistics of knee scores on the day of surgery, 1 year after surgery, and 7 years after surgery

Knee score	Day of surgery	1 year	7 years
Tegner score (best is 10)	4 (range 1–7)[a]	7 (range 2–9)[b]	6 (range 2–10)[b]
Lysholm score (best is 100)	58 (range 28–85; SD 16)[a]	94 (range 65–100; SD 9)[b]	91 (range 42–100; SD 16)[b]
IKDC score (best is 100)	49 (range 23–78; SD 15)[a]	90 (range 60–100; SD 12)[b]	87 (range 33–100; SD 18)[b]
KOOS	–	–	90 (range 36–100; SD 16)

Time points with dissimilar letters indicate that the difference in the median Tegner score and the average Lysholm and IKDC scores between time points was significantly different at a minimum value of $p < 0.05$

Table 3 Comparison of statistics of patient-reported scores for soft tissue grafts between the present study and previous studies

Knee score	Present study 7 years tibialis allograft	Almqvist et al. [2] 10.5 years tibialis allograft	Asik et al. [4] 7 years hamstrings autograft	Gifstad et al. [12] 7 years hamstrings autograft	Roe et al. [30] 7 years hamstrings autograft	Zaffaragnini et al. [42] 8 years hamstrings autograft
Tegner	6[b] (2–10)	6[b] (4–9)	7.5	NA	NA	6[b]
Lysholm	91 (42–100)	95[b] (76–100)	90	92	93	NA
IKDC	87 (37–100)	97[b] (74–100)	NA	NA	NA	NA
KOOS[a]	90	NA	NA	90	NA	NA

Unless noted otherwise, values are mean scores. The range is given in parentheses

[a] KOOS is the average over the five categories

[b] Value is the median

that of the native ACL [13, 14, 24, 27]. Knees with roof and PCL impingement and abnormal tension patterns during passive motion have more instability and motion loss [13, 14, 24, 27]. Fixation devices were used that grip cortical bone, making them more slippage-resistant than interference screw fixation [6, 19, 21, 25, 37]. Finally, the present study consisted of patients who were older (mean age of 37 years at the time of ACL reconstruction), predominantly male, and whose activity level was recreational rather than competitive. The rate of reinjury of an ACL reconstruction in these subjects might be lower than younger, female, and competitive or professional athletes [34].

The number of patients included in an invasive study which uses RSA is necessarily limited by a number of factors. These factors include the number of patients willing to volunteer, the cost associated with conducting the experiments, and the technical complexity of RSA involved in processing the images for each patient to compute the anterior laxity. Moreover, the earlier study from which the patients were derived measured a host of dependent variables other than anterior laxity which greatly increased the experiment cost and complexity [39, 40]. Nevertheless, the number of patients in the present study is comparable to that of other longitudinal studies of ACL reconstruction which have used RSA [5, 16, 18, 19]. Notwithstanding the number of patients, the probabilities of committing Type I and Type II errors in the statistical analyses of anterior laxity were very low at 0.05 and 0.03, respectively.

Several issues complicate the determination of the clinical importance of the average increases in anterior laxity of 1.5 mm between 1 and 7 years after surgery and 2.7 mm between the day of surgery and 7 years. One issue is that the clinically important difference of 3 mm used to indicate a torn ACL as measured with a KT-1000 arthrometer at applied loads of either 89 N or a maximum manual load (estimated to be 133–178 N) is computed as the difference in anterior laxity between the injured and contralateral normal knee [7]. In the present study, the increase in anterior laxity was computed as the difference between the day of surgery and specified times of follow-up in the ACL-reconstructed knee and not between the ACL-reconstructed knee and the contralateral knee because the ethics committee did not approve insertion of tantalum beads in the contralateral knee. The second issue is that stiffening of the knee from the post-operative swelling on the day of surgery would have diminished at each specified time of follow-up, which might have caused an overestimation of the change in anterior laxity over time. The third issue is that preconditioning was not applied before determining the anterior laxity of the reconstructed knee on the day of surgery and preconditioning was applied before determining anterior laxity at each specified time of follow-up, which might have caused an overestimation of the change in anterior laxity over time. The fourth issue is that it is unknown though possible that the anterior laxity of the reconstructed knee measured on the day of surgery without preconditioning might have been less than that of the contralateral knee. In this case, the increases in anterior laxity at 1 and 7 years might have overestimated the change in anterior laxity relative to that of the contralateral knee. Finally RSA measurement of anterior laxity is an underestimation of the KT-1000 measurement of anterior laxity [9]. Hence, while a 3-mm difference in anterior laxity has been validated as an indicator of clinical instability when measured with the KT-1000 and compared to the laxity of the contralateral healthy knee, it remains unknown whether a 3-mm increase in anterior laxity is a valid indicator of clinical instability when measured with RSA over time in the ACL-reconstructed knee.

Conclusion

Although an ACL reconstruction with a soft tissue allograft trended towards an average increase in anterior laxity of 1.5 mm between 1 and 7 years, this increase was not statistically significant and there was no change in patient-reported activity level, function, and patient satisfaction. These results indicate that maturation of a soft tissue allograft does not cause recurrent instability and concomitant declines in activity level, function, and patient satisfaction. In demonstrating that the ACL graft construct used herein remains functional in the long term, the present study supports the use of a fresh-frozen tibialis allograft in patients with an average age of 37 years at the time of reconstruction when used in conjunction with a surgical technique which avoids roof and PCL impingement, uses slippage-resistant fixation devices, and allows brace-free, self-paced rehabilitation. Using allografts for ACL reconstruction avoids the morbidity associated with harvesting autografts.

Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

Funding No funding was received for this study.

Ethical approval All of the 19 patients who participated in our earlier study with 1-year follow up or their relatives were contacted for participation in the present study with 7-year follow up

Informed consent Informed consent was obtained from all 17 study patients and the study was approved by the Institutional Review Board

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