Pretensioning of quadruple flexor tendon grafts in two types of femoral fixation: quasi-randomised controlled pilot study

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Abstract Pretensioning of the flexor tendon graft of the knee is used to improve the stability of anterior cruciate ligament (ACL) reconstructions. The objective was to demonstrate the pretensioning of grafts of the semitendinosus and gracilis in situ with range of flexion and extension of 0–110°, and determine the appropriate number of cycles in two types of femoral fixation. ACL reconstruction was performed in 60 patients, aged 16–48 years, 90% male, with 50% right knees and 50% left knees, divided into two groups of 30 patients: One with the femur fixed using interference screws (direct form) and the other with the transcondylar cross-pin screw (from a distance). Total length of the grafts, their circumference and the measurements on the radiographs of length of the grafts submitted to pretensioning and the measurements with ten, 25 and 50 cycles of flexion and extension were determined. There was no significant difference in relation to the total tendon lengths and their circumferences. The lengths of the portions submitted to pretensioning were significantly different: 7.90 cm for the interference and 10.92 cm for the transcondylar (mean). After tensioning, in the interference and transcondylar groups, respectively, lengthening was 3.57 mm/3.97 mm with ten, 6.30 mm/7.03 mm with 25, and 6.83 mm/7.7 mm with 50 cycles. The greater the length of the graft, the greater the

lengthening on pretensioning throughout the substance; the shorter the length, the earlier the end of the lengthening was achieved, close to 25 cycles; more than ten cycles were necessary, 25 being sufficient.

Introduction

One of the best grafts for reconstruction of the anterior cruciate ligament is the patellar ligament, which has a mean resistance of between 2,376 and 2,900 N [1], higher than that of the anterior cruciate ligament, which in young people is $2,160 \pm 157$ N [2]. However, over the years, complications have been observed in relation to the harvest site, such as residual pain, loss of flexion and extension and the development of early osteoarthritis in comparison to graft reconstruction using the flexor tendons of the knee [3].

In view of these complications, interest in the use of the semitendinosus and gracilis flexor tendon graft is increasing. In quadruple form, a resistance of $4,090 \pm 295$ N [4], also greater than the resistance of the anterior cruciate ligament, can be achieved. However, flexor tendon grafts are not free of problems, and there are doubts as to the best form of fixation, whether pretensioning is necessary, and the strength, form and amount of tension that should be exerted.

Objective

The objective of this prospective, quasi-randomised pilot clinical trial was to establish the validity of graft pretensioning of the flexor tendon graft of the knee, in situ, using two different anchorages in the femoral tunnel (“interfer-

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ence screw” and “transcondylar screw”) to determine the sites of these lengthenings and their response to the fixations. The secondary objective was to establish the number of pretensioning cycles needed, considering each cycle as tensioning with a range of flexion and extension of between 0 and 110°.

Methods

Casuistics and setting

All consecutive patients with a primary lesion of the anterior cruciate ligament treated operatively at the Hospital Nossa Senhora do Rosário, in São Paulo (SP), Brazil between January and June 2008 were studied. The study was submitted to and approved by the Institutional Ethics Committee, and the patients signed terms of free and informed consent.

During the period of the trial, 60 patients were admitted for treatment and included in the study. The patients who underwent surgery were aged between 16 and 48 years, (mean age 29–50 years, standard deviation of ± 8.38 years and median of 30 years). Only six (10.0%) were female. Of the 60 patients, 30 (50%) underwent surgery on the right knee and the remainder on the left knee. None of the patients presented other ligament lesions associated with that of the anterior cruciate ligament, and none had neurological, vascular or tendinous lesions, or associated fractures or angular deformities.

All 60 patients received a quadruple graft and pretensioning with ten, 25 and 50 cycles. Each tensioning cycle had a range of flexion and extension of between 0 and 110°. The patients were divided into two groups as follows: the “interference” group, with 30 patients whose grafts were fixed with metallic interference screws in the femur and tibia, and the “transcondylar” group, with 30 patients whose grafts were fixed with metallic transcondylar screws in the femur.

The patients were assigned to one of the groups by order of surgical appointments (quasi-randomised method). Thus, those patients with odd-numbered appointments (protocol of inclusion in the trial) were assigned to the interference group, while those with even-numbered appointments were assigned to the transcondylar group. Thus, the division of the patients into the two groups was not influenced by sex, age, affected leg or sports activity practised.

Surgical technique

Arthroscopy was performed to carry out partial meniscectomies, clean the chondral remains where necessary and reconstruct the ligament. In the transcondylar group, the TransFix [5] technique was used, and in the other group,

the fixation was done with interference screws, both in the femoral tunnel.

The flexor tendons were prepared differently in both techniques, with separation of the muscle mass adhering to the tendons, and in the case of the interference screw, in the femoral tunnel, each tendon was folded into two equal parts and stitched at the four ends with No. 1 absorbable multifilament violet synthetic suture thread to a length of 3 cm in both distal portions of the graft. When the transcondylar cross-pin screw was used in the femoral tunnel, the suture was also performed at the tendon ends, to a length of 3 cm, using the same thread, but without folding them; they were folded only when the tendons were passed through the tibial and femoral tunnels.

After fixation of the graft in the femoral tunnel, the knee was placed in total extension and the first mark was made at the distal end of the graft, next to the cortical end, in the distal part of the tibial tunnel. Pretensioning was carried out by flexing and extending the knee between a range of 0–110°, initially with ten cycles, then a new marking was made on the graft, measuring the lengthening obtained. The same procedure was performed with tensioning of 25 and 50 cycles.

The graft was fixed in the tibial tunnel in both techniques. The graft was fixed in the tibial tunnel with metallic parallel surface interference screws with a length of 30 mm and diameter 1 mm greater than the calibre of the tunnel, with the knee in 30° of flexion.

Post-surgical evaluation protocol

The following variables were measured in the 60 patients: total length of the graft, measurement on the X-rays of length of the graft used, circumference of the graft, and lengthening obtained with flexion and extension cycles (of ten, 25 and 50). Radiographs were performed in anteroposterior and profile views of the knee to determine the positioning of the femoral and tibial tunnels and to measure the length of the portion of graft submitted to pretensioning. In the technique in which the interference screw was used, the fixation was carried out closer to the joint, with the intra-articular portion and the portion of tibial tunnel subjected to tensioning. In the other procedure, anchored by the transcondylar screw, the fixation was performed at a distance, and the intra-articular portions of the femoral and distal tunnels of the graft are subjected to tensioning. All of the patients were evaluated according to the criteria of the International Knee Documentation Committee (IKDC) Group 4 [6].

Statistical analysis

Based on the hypothesis of a 50% of increase in length with the pretensioning cycles, and considering a 5% significance

level and 80% power for the study, admitting a standard deviation of 5 unit, a sample of at least 24 patients would be necessary in each group. Taking into consideration the longitudinal design of the study and a possible loss of information of approximately 20% of cases, the sample calculation indicated a minimum of 30 patients in each group.

Initially, all of the variables were analysed descriptively. The quantitative variables were described as minimum and maximum values, calculation of means, standard deviations and medians. For the qualitative variables, the absolute and relative frequencies were calculated.

Student's *t* test was used to analyse the hypothesis of equality of means between the groups. To test the homogeneity of the groups in relation to the proportions, the chi-square test and Fisher's exact test were used, which is recommended for comparison of proportions when the responses present expected frequencies of below five.

To determine the behaviour of the groups, considering the proportions studied, analysis of variance was carried out with repeated measurements, which consists of adjusting a multivariate linear model, used to test the following hypotheses:

H¹: the mean response profiles corresponding to the groups (interference and transcondylar) are parallel, i.e. there is no interaction between the factor "group" and the factor "evaluation condition" (10, 25 and 50).

H²: the mean response profiles coincide, i.e. there is no effect of the factor "group".

H³: the mean response profiles are parallel to the axis of abscissas, i.e. there is no effect of the factor "condition" on the evaluation.

Hypotheses H² and H³ were only tested when H¹ was not rejected.

The Wilks statistic, with approximation for the *F* statistic, was used in the test of the above hypotheses. The level of significance used for the tests was 5%.

Results

Casuistics

There was no significant difference between the groups in relation to sex, age or leg operated on. The interference group, consisting of 30 patients, had ages ranging from 17 to 46 years, with a mean age of 29.5 ± 7.35 years. In the transcondylar group, the age ranged from 16 to 48 years, with a mean age of 29.5 ± 9.42 . Men were predominant in both groups. The total sample consisted of 30 right knees and 30 left knees. The interference group had 17 right

knees (56.7%) and the transcondylar group had 13 right knees (43.3%) (Table 1).

Graft measurements

The graft measurements in the total sample are shown in Table 2. It can be observed in Table 3 that the groups present significant differences in relation to the measurement on the X-ray of the graft used: the transcondylar group presents significantly higher values than those of the interference group.

In the analysis of variance with repeated measurements, we observed that the groups present no difference in behaviour during the evaluations carried out ($p=0.328$). The groups did not present any statistically significant difference in relation to the three measurements obtained ($p=0.188$). There was an alteration in the measurements over the evaluations in the two groups ($p<0.001$). There was a significant increase, from 10 cycles to 25 ($p<0.001$) and for 50 cycles ($p<0.001$), in both groups. There was also a significant increase from 25 cycles to 50 in both groups ($p<0.001$; Fig. 1).

Through the analysis of variance with repeated measurements of lengthening on X-rays (Fig. 2), we observed that the groups do not present any difference in behaviour over the evaluations carried out ($p=0.286$). The groups presented statistically significant differences in relation to the three measurements obtained ($p=0.027$), with the interference group presenting significantly higher lengthening values than the transcondylar group. There was a change in the means over the evaluations in the two groups ($p<0.001$). There was a significant increase in cycle, from 10 to 25 ($p<0.001$) and to 50 ($p<0.001$), for both groups. There was an increase from 25 to 50 in both groups ($p<0.001$). Calculating the difference between the percentage values of 25 and 50 cycles, we see that in 41.7% of the sample there was no change in this measurement.

When we analysed the percentage values for the measurements from 25 to 50 cycles in the groups

Table 1 Characteristics of the patients, by fixation method

Groups				
Variable	Category	Interference	Transcondylar	<i>p</i>
Age		29.50 ± 7.35	29.50 ± 9.42	1.000 ^a
Sex	Male	28 (93.3%)	26 (86.7%)	0.671 ^b
	Female	2 (6.7%)	4 (13.3%)	
Side	Right	17 (56.7%)	13 (43.3%)	0.302 ^c
	Left	13 (43.3%)	17 (56.7%)	

^a Descriptive level of probability of Student's *t* test

^b Descriptive probability by Fisher's exact test

^c Descriptive level of probability of the chi-square test

Table 2 Mean, standard deviation (SD), median, minimum and maximum values, and medians for graft lengths in the 60 patients

	Mean	SD	Median	Minimum	Maximum
Total length of the graft (cm)	11.62	1.01	12.00	9.00	14.00
Measurement on the X-ray of the graft used (cm)	9.41	1.74	9.00	5.00	12.00
Circumference of the graft (mm)	8.30	0.53	8.00	7.00	9.00
Lengthening obtained with the 10 cycles of flexion and extension (mm)	3.77	1.77	3.00	1.00	9.00
Lengthening obtained with the 25 cycles of flexion and extension (mm)	6.67	2.22	6.00	2.00	12.00
Lengthening obtained with the 50 cycles of flexion and extension (mm)	7.30	2.39	7.00	2.00	13.00

separately, we saw that in the interference group 50% of the patients did not show any changes, and in the transcondylar group 33.3%, but in the transcondylar group the lengthening was more uniform, with 46.7% (Fig. 3).

Discussion

Patellar fractures, partial loss of flexion and extension, pain at the graft removal site, and evolution to osteoarthritis and other problems in reconstructions of the anterior cruciate ligament [3, 7, 8] have led to the decision to change the earlier graft harvest site. Various authors have reported good results with the use of posterior flexor tendons of the knee, the semitendinosus and gracilis in quadruple form [3, 5, 9–12]. Follow-up of the initial reconstructions of these tendons shows a small residual laxity in the ligament tests [6, 13–15], which is slightly different when the patellar ligament graft is used.

Studies by Hamner et al. [4], who tested resistance to linear traction of the flexor tendons in isolation, in double form, and the two tendons in quadruple form, found that, in quadruple form, it was $4,090 \pm 295$ N. The authors also reported lower morbidity at the graft removal site in relation to the patellar ligament.

Biological [16, 17] and biomechanical [8] studies demonstrated that the tendinous graft is totally viable, since its osseointegration and fixation to the wall of the tunnels are not as slow as was believed. This further reinforces our decision to use the semitendinosus and gracilis in quadruple

form in reconstructions of the anterior cruciate ligament injuries.

Even so, despite the good indications in relation to reconstructions with the flexor tendons, some solution is needed to improve this slight residual laxity. Various authors have carried out research in an attempt to improve this aspect through pretensioning [18–21].

Brand et al. [22] analysed the behaviour of the quadriceps tendon graft in reconstructions of the anterior cruciate ligament with two femoral fixation methods—the interference screw and Endobutton® plate—the first being considered a direct fixation method and the second a method carried out from a distance. The results show that when the anchorage was performed using the Endobutton®, it presented three times more laxity or loose tension than with the interference screw; however, pretensioning of the graft in situ, with cycles ranging from 0 to 110°, at 20 cycles of flexion and extension, the results were practically the same.

Zelle et al. [23] performed a similar protocol, reconstructing the anterior cruciate ligament in double femoral tunnel, with autologous graft of the semitendinosus and gracilis and homologous graft of the anterior tibia, fixing them with an Endobutton®, pretensioned from 0 to 120° of flexion and extension, with 20 to 30 cycles, showing an improvement in the residual laxity. These conclusions are important, as they helped us adopt a similar protocol.

We consider pretensioning in situ with flexion and extension movements ranging from 0 to 110° to be superior to linear traction, because the former modifies the position

Table 3 Mean, standard deviation (SD), median, minimum and maximum values of the measurements performed, by type of fixation

Variable	Group	n	Mean	SD	Median	Minimum	Maximum	p ^a
Total length of the graft (cm)	Interference	30	11.73	1.20	12.00	9.00	14.00	0.375
	Transcondylar	30	11.50	0.78	12.00	9.00	13.00	
Measurement on the X-ray of the graft (cm)	Interference	30	7.90	0.88	8.00	5.00	9.50	< 0.001
	Transcondylar	30	10.92	0.81	11.00	9.00	12.00	
Circumference of the graft (mm)	Interference	30	8.33	0.61	8.00	7.00	9.00	0.631
	Transcondylar	30	8.27	0.45	8.00	8.00	9.00	

^a Descriptive level of Student's *t* test

Fig. 1 Mean and standard deviation of lengthening (in mm, y-axis) of the various cycles (x-axis) analysed, by group

of the graft in the bone tunnel, in the fixation material and in the intra-articular space and ensures the appropriate tension for each knee.

To determine the validity of the protocol described here, we used the tendons of the semitendinosus and gracilis in quadruple form, in two femoral fixation methods, with metallic parallel surface interference screws, which we considered to be a direct, more anatomical form of anchorage, as it is closer to the intra-articular space [24] or transcondylar cannulated cross-pins [5], considered a fixation performed at a distance.

Authors [22, 25] who use the method of fixation performed from a distance with the Endobutton® plate affirm that looseness occurs in the interior of the femoral tunnel, in the “graft-tape-plate” portion; Fu et al. [25] call this the elastic cord effect.

One of the important stages in the elaboration of this study was the formation of the groups and the criteria for analysis. We sought to be as impartial as possible in the selection of patients to ensure that the sample was not biased.

The mean values for the measurements on the X-rays demonstrate a significant statistic of length of the graft

Fig. 2 Mean and standard deviation of relative lengthening (in mm, y-axis) of the various cycles (x-axis) analysed, by group

Fig. 3 Differences in percentages from cycles 25 to 50

submitted to pretensioning, according to the two femoral fixation techniques used. Through analysis of variance with repeated measurements, we observed, in relation to the mean lengthenings obtained, that when the fixation was carried out with the transcondylar screw the results were slightly higher in the three cycles (10, 25 and 50) than for the interference group, leading to the conclusion that the greater the graft substance submitted to pretensioning, the greater will be its lengthening along the flexor tendons.

Another important observation is that when we analysed the values by means of the percentage in relation to the measurements for graft length on the X-rays, we observed higher levels when the grafts were fixed with the interference screw than with the transcondylar screws, a factor which contradicted our initial conclusion, that the longer the graft, the greater its lengthening will be.

Ahmad et al. [26] tested the anchorage of the flexor tendons in the femoral tunnels with four types of fixation, including the transcondylar screw (Bio-TransFix®) and the absorbable interference screw. Using the transcondylar screw, they obtained a mean adaptation on the screw of 1.14 ± 0.53 mm of slippage of the graft, and in the case of the interference screw, of 5.44 ± 3.25 mm, due to the accommodation and slippage of the graft fixation in the tunnel wall, demonstrating that the transcondylar screw gives a more secure fixation than the interference screw. This conclusion was also observed in our work: Despite the greater lengthening observed in the measurements in millimetres, as a percentage, the numbers were higher when the interference screw was used.

The differences between the values as a percentage of the lengthenings obtained from cycles 25 to 50 were significant, with 41.7% of the sample showing no modification in the measurements from 25 to 50 cycles, and with the remainder of the grafts showing an evolution in lengthening. When this difference was analysed in the two groups, it was observed that in the cases of anchorage with interference screws, 50% of the grafts did not show any progression in lengthening from 25 to 50 cycles. In the

knees with the transcondylar screw, this figure was 33.3%, but with more uniform evolution in the lengthening, leading to the conclusion that the greater the length of the graft, the faster the lengthening becomes stabilised, close to 25 cycles, and the longer the tendon, the less cycles are required for stabilisation. However, we observed that the greater evolutions in the lengthening measurements, from 1 to $\geq 2\%$, occurred in the fixation with the interference screw, probably due to the non-rigidity of the fixation as, we presume, it had already reached its total lengthening before the 25 cycles, proving to be a firmer anchorage with the transcondylar screws.

Observing the evolution of the lengthenings in millimetres from 25 to 50 cycles, despite being statistically significant ($p < 0.001$), as there is a progression of the values, in the measurements the difference is minimal, with an alteration from 25 to 50 cycles of 0.53 mm for the interference screw and 0.64 mm for the transcondylar screw. In the clinical evaluation of the stability of the knee by IKDC Group 4, an advance of up to 2 mm is considered normal [6]. Thus, this difference would be within the acceptable limits for the mechanical ligament evaluations, making it without significance; therefore, we conclude that pretensioning with 25 cycles of flexion and extension is sufficient.

Conclusions

- The greater the length of graft submitted to pretensioning, the greater the lengthening was, occurring throughout its substance.
- The greater the length of the flexor tendons, the sooner the end of the lengthening was reached, occurring close to 25 cycles.
- More than ten pretensioning cycles are necessary, but 25 cycles were sufficient to obtain good results.
- The fixation with the transcondylar cross-pin is more rigid, as it does not allow for looseness of the anchorage, but with the interference screw, this looseness was observed in relation to the tunnel wall.
- Since this is a pilot study, it does not fully support surgical technique modifications yet: the results do, however, indicate a promising future, to be tested in randomised controlled trials.

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

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