ABSTRACT

Objective: To determine the initial resistance of fixation using the Rigid Fix® system, and compare it with traditional fixation methods using metal interference screws; and to evaluate the resistance of the fixation with the rigid fix system when the rotational position of the bone block is altered in the interior of the femoral tunnel. Methods: forty ovine knee specimens (stifle joints) were submitted to anterior cruciate ligament reconstruction (ACL) using a bone-tendon-bone graft. In twenty specimens, the Rigid Fix method was used; this group was subdivided into two groups: ten knees the pins transfixed only the spongious area of the bone block, and ten for fixation passing through the layer of cortical bone. In the twenty remaining specimens, the graft was fixed with 9mm metal interference screws. Results: comparison of the RIGIDFIX® method with the metal interference screw fixation method did not show any statistically significant differences in terms of maximum load and rigidity; also, there were no statistically significant differences when the rotational position of the bone block was altered inside the femoral tunnel. For these evaluations, a level of significance of p < 0.017 was considered. Conclusion: fixation of the bone-tendon-bone graft with 2 bioabsorbable pines, regardless of the rotational position inside the femoral tunnel, gave a comparable fixation in terms of initial resistance to the metal interference screw, in this experimental model.

Keywords - Anterior Cruciate Ligament; Bone-Patellar Tendon-Bone Graft; Knee; Sheep

INTRODUCTION

In reconstructing the anterior cruciate ligament, graft fixation is an extremely important factor. The fixation method has to be rigid and resistant to traction forces so that postoperative rehabilitation using current principles can be applied(1). Autografts are preferred because of their low complication rate. Among these, the ones most used in anterior cruciate ligament reconstruction surgery are the flexor tendons (semitendinosus and gracilis), bone-tendon-bone removed from the patella, the central third of the patellar tendon and the anterior tuberosity of the tibia. Bone-tendon-bone grafts enable rigid fixation inside the tunnels. The fixation technique using interference screws is the one most used for this graft and is considered to be the gold standard for fixation(2-8).

However, large numbers of complications from using interference screws for graft fixation in ligament

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reconstructions have been described. The commonest of these are lesions to the graft at the bone-tendon transition at the time of femoral fixation, rupture of the posterior cortical bone and screw divergence in relation to the tunnel direction\(^{(9-14)}\).

This has led to development of new fixation methods with different materials, especially using implants made of bioabsorbable material.

Recently, a system using bioabsorbable pins of 2.7 mm in diameter by 42 mm in length for bone-tendon-bone fixation and 3.3 mm for quadruple semitendinosus-gracilis grafts was developed. Among the advantages of the system the following have been reported: greater graft-bone block contact in the tunnel (100%); potentially less risk of rupture of the posterior cortical bone, and the possibility of graft fixation even if such situations occur; possibility of performing magnetic resonance imaging after the operation without signal interference; and, in cases of revision, the femoral tunnel will be closed and there will not be any need to remove the metal implant\(^{(15)}\).

This method using special guides that position two implants parallel to each other and perpendicular to the orientation of the femoral tunnel and consequently to the graft.

Because this is a recent method, there are only a few studies demonstrating the resistance and rigidity of this fixation system.

The aims of the present study were to determine the initial fixation resistance of the system using transverse bioabsorbable pins and to compare this with the traditional fixation method for bone-tendon-bone grafts using 9 mm metal interference screws, and to evaluate the fixation resistance of this system when the rotational positioning of the bone block inside the femoral tunnel is modified.

**MATERIAL AND METHODS**

Forty knee (stifle joint) specimens (18 right and 22 left) from skeletally immature sheep of ages ranging from 12 to 18 months were acquired from a sheep meat trading company. After the animals had been slaughtered for human consumption, the knees were separated during the deboning process, with preservation of the femur and the proximal third of the tibia, together with the knee joint and extensor apparatus. The specimens were wrapped and preserved at \(-20^\circ\)C until the date of the surgery. At the time of the procedure, the specimens were defrosted in groups of 10, at room temperature, before performing the surgery. From all the knees, a patellar tendon graft of 1 cm in width with two bone blocks was harvested. The blocks removed from the patella were 2.8 mm in length by 10 mm in diameter (Figure 1).

The tibial block was of conical shape, with a width of 2 cm and a depth of 2 cm in the proximal portion, by 3 cm in length. An opening was made in the most proximal portion of the patellar bone block, with the purpose of positioning a no. 5 suturing thread for graft traction. The femur of each specimen was isolated to make a tunnel of 10 mm in diameter, positioned in the intercondylar space and oriented at one o’clock in the left knees and at 11 o’clock in the right knees, and preserving posterior cortical bone of 1 to 2 mm in thickness.

For the tunnels in 20 specimens, the RigidFix\(^{\text{®}}\) guide was adapted. This consists of two nails joined together in a U shape. One of the guide nails was positioned inside the femoral tunnel and the other was external, with a device to adapt to two jackets, through which two openings were made such that they intercepted the tunnel perpendicularly, halfway along its diameter in the coronal plane (Figures 2A and 2B).

The jackets were left at the entrances to the openings in the lateral cortical bone of the femur, to serve as guides for drilling and inserting two bioabsorbable pins of diameter 2.7 mm, through the bone blocks of the proximal end of the grafts.

To position the graft inside the femoral tunnel of the specimens, a traction thread was used at the proximal end of the bone blocks in order to enable control during insertion. Because this was a variable of interest, two forms of bone-block guidance were used for positioning the bioabsorbable pins. The first method took the orientation of the cortical part of the bone block, to

![Figure 1 – Photograph of graft with bone block of 10 mm in diameter.](image-url)
allow the fixation pins to transfix the bone plate, and this was used in ten specimens. The other method allowed the pins to transfix only the spongy part of the bone block, which was used in another 10 specimens (Figure 3).

The next step was to drill the graft inside the tunnel, aided by the guide jackets and using special drills of diameter 2.7 mm, and to insert the pins using an impacting device and hammer. The specimens were duly identified by means of adhesive tape applied to the proximal portion of the femur, and then were wrapped and refrozen at -20ºC.

Another 20 knees were operated, taking the same care regarding defrosting, graft harvesting and construction of the femoral tunnel, as described above. The graft was placed under traction inside the tunnel in the same manner, but the graft fixation was done by using interference screws made of cannulated steel, with dimensions of 9 mm in diameter by 20 mm in length, inserted by means of Kirschner guidewires. The screws were positioned on the spongy bone, parallel to the orientation of the bone block inside the tunnel (Figure 4).

The specimens were identified regarding the fixation method using adhesive tape on the proximal portion of the femur and then were wrapped for refreezing at -20ºC until 24 hours before performing the tests, when they were defrosted at room temperature.

The tests were performed at the Federal Technological University of Paraná (UTFPr), on a MTS 810 universal hydraulic machine. The specimens were adapted to the machine such that traction was performed longitudinally at a velocity of 50 mm/min (Figures 5A and 5B).
Figures 5A and 5B – Photographs showing the composition of the MTS 810 hydraulic machine.

STATISTICAL ANALYSIS

To assess the hypothesis that the variables presented normal distribution, the Shapiro-Wilks test was used. For situations in which the maximum force did not meet the condition of normal distribution, the groups were compared in pairs by means of the non-parametric Mann-Whitney test.

For the rigidity variable, which met the condition of normal distribution, the groups were compared in pairs by means of Student’s t test for independent samples, taking into consideration the homogeneity of the variance. The significance level used was $p < 0.05$, and this was corrected using the Bonferroni multiple comparison test (values of $p < 0.017$ indicated statistical significance).

RESULTS

The mean traction resistance obtained in a single cycle in the groups of transverse bioabsorbable pins did not present statistically significant differences between each other or in relation to the control group with interference screws. Table 1 and Figure 6 show the mean values of the different groups and their variations, and Table 2 shows the $p$ values of the comparisons made using the nonparametric Mann-Whitney method, taking $p < 0.017$.

The mean rigidity results also did not show any statistically significant differences between the different fixation methods, taking $p < 0.017$. The mean rigidity is presented in Table 3 and the $p$ values for comparisons between the different groups are in Table 4.

The types of failure and the place of occurrence in the specimens fixed with interference screws are shown in Table 5 and Figures 7A and 7B.

<table>
<thead>
<tr>
<th>Group</th>
<th>N</th>
<th>Mean</th>
<th>Median</th>
<th>Minimum</th>
<th>Maximum</th>
<th>Standard deviation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Interference</td>
<td>20</td>
<td>653.7</td>
<td>677</td>
<td>112</td>
<td>963</td>
<td>180.79</td>
</tr>
<tr>
<td>Pins/cortical bone</td>
<td>10</td>
<td>607.5</td>
<td>598.5</td>
<td>278</td>
<td>940</td>
<td>198.7</td>
</tr>
<tr>
<td>Pins/spongy bone</td>
<td>10</td>
<td>710.1</td>
<td>743</td>
<td>102</td>
<td>921</td>
<td>236.09</td>
</tr>
</tbody>
</table>

Table 1 – Comparison of mean maximum loads between the methods of fixation using a metal interference screw and fixation using the RigidFix® technique to transfix the cortical and spongy bone.
Tables 6 and 7 show the places of occurrence of failures in the groups fixed with transverse pins.

Figures 8A and 8B show the types of failure found in the groups in which bioabsorbable transverse pins were used.

**Table 2** - P values of comparisons made in the different groups.

<table>
<thead>
<tr>
<th>Groups under comparison</th>
<th>p* value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Interference vs. fixed in the rigid part</td>
<td>0.35</td>
</tr>
<tr>
<td>Interference vs. fixed in the spongy part</td>
<td>0.267</td>
</tr>
<tr>
<td>Fixed in the rigid part vs. fixed in the spongy part</td>
<td>0.123</td>
</tr>
</tbody>
</table>

**Table 3** – Comparison of mean rigidity between the fixation method using a metal interference screw and the fixation method using pins transfixing to the cortical and spongy bone.

<table>
<thead>
<tr>
<th>Group</th>
<th>n</th>
<th>Mean</th>
<th>Median</th>
<th>Minimum</th>
<th>Maximum</th>
<th>Standard deviation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Interference screw</td>
<td>20</td>
<td>76.6</td>
<td>72.5</td>
<td>53</td>
<td>106</td>
<td>15.13</td>
</tr>
<tr>
<td>Pin to cortical bone</td>
<td>10</td>
<td>65.8</td>
<td>64.5</td>
<td>38</td>
<td>103</td>
<td>22.19</td>
</tr>
<tr>
<td>Pin to spongy bone</td>
<td>10</td>
<td>74.4</td>
<td>78</td>
<td>44</td>
<td>104</td>
<td>18.61</td>
</tr>
</tbody>
</table>

**Table 4** – Comparison of p values for assessing rigidity between the fixation method using a metal interference screw and the fixation method using transverse pins to the cortical bone in one group and spongy bone in the other group.

<table>
<thead>
<tr>
<th>Groups under comparison</th>
<th>p* value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Interference vs fixed in rigid part</td>
<td>0.127</td>
</tr>
<tr>
<td>Interference vs fixed in spongy part</td>
<td>0.73</td>
</tr>
<tr>
<td>Fixed in rigid part vs fixed in spongy part</td>
<td>0.36</td>
</tr>
</tbody>
</table>

**Table 5** – Types and locations of failure in the fixation method using interference screws.

<table>
<thead>
<tr>
<th>Types</th>
<th>Number of occurrences</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proximal detachment</td>
<td>10</td>
<td>50%</td>
</tr>
<tr>
<td>Distal detachment</td>
<td>2</td>
<td>10%</td>
</tr>
<tr>
<td>Loosening of screw and/or slippage of bone block in femoral tunnel</td>
<td>8</td>
<td>40%</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>20</strong></td>
<td><strong>100%</strong></td>
</tr>
</tbody>
</table>

**Table 6** – Types and locations of failure in the fixation method using bioabsorbable pins fixed to the cortical bone.

<table>
<thead>
<tr>
<th>Types</th>
<th>Number of occurrences</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proximal detachment</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Distal detachment</td>
<td>2</td>
<td>20%</td>
</tr>
<tr>
<td>Fracture of bone block</td>
<td>6</td>
<td>60%</td>
</tr>
<tr>
<td>Failure of implant in femoral tunnel</td>
<td>2</td>
<td>20%</td>
</tr>
<tr>
<td><strong>total</strong></td>
<td><strong>10</strong></td>
<td><strong>100%</strong></td>
</tr>
</tbody>
</table>

**Table 7** – Types and locations of failure in the fixation method with interference screws.

<table>
<thead>
<tr>
<th>Tipos</th>
<th>Número de ocorrências</th>
<th>Porcentagem</th>
</tr>
</thead>
<tbody>
<tr>
<td>Destacamento na tot Proximal</td>
<td>1</td>
<td>10%</td>
</tr>
<tr>
<td>Destacamento na tot Distal</td>
<td>2</td>
<td>20%</td>
</tr>
<tr>
<td>Fratura do bloco ósseo I</td>
<td>5</td>
<td>50%</td>
</tr>
<tr>
<td>Falha do implante no túnel femoral</td>
<td>1</td>
<td>10%</td>
</tr>
<tr>
<td>Rompimento do tendão no 1/3 médio</td>
<td>1</td>
<td>10%</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>10</strong></td>
<td><strong>100%</strong></td>
</tr>
</tbody>
</table>
Figures 8A and 8B – Photograph showing types of failure in the method with bioabsorbable pins.

DISCUSSION

In the literature, there are few studies evaluating this method experimentally\(^\text{16-18}\) and none that present or discard the possibility of fixation of a bone-tendon-bone graft by means of the spongy portion of the bone block. Based on this point, we decided to evaluate the method that uses 2.7 mm bioabsorbable pins, with two different types of fixation relating to graft rotation inside the tunnel, and to compare these two types with the method that uses 9 mm metal interference screws.

The initial hypothesis in subdividing the group in which the bioabsorbable pins were used was that fixation of implants by means of the cortical face of the bone block of the graft inside the femoral tunnel would be more resistant to traction forces than would passage of the pins solely into the spongy bone. In doing the tests, no statistically significant difference was found, taking \(p < 0.017\) between the two subgroups.

Passage of the 2.7 mm pin through the cortical bone caused fragility in this more resistant portion of the graft, and therefore the resistance depended almost exclusively on the resistance of the two columns parallel to the more distal hole of the graft. This is the commonest site for fractures in this type of fixation (60% in this experiment).

In the group fixed with pins in the spongy bone, the tendon structure continued to be in line with the bone plate and therefore the traction forces were transmitted through the cortical bone. The more resistant bone plate remained intact, without holes for the pins to pass through, thus allowing transmission of the traction forces to the proximal pin. The resistance of the fixation depended on the density of the spongy bone and its adherence to the cortical bone, and the resistance to traction may have come from the sum of the two pins, thereby partially compensating for the lower resistance of this portion of the graft.

In the present study, blocks of 10 mm in diameter were used, taking into consideration the work performed by Zantop et al\(^\text{17}\), who used the same experimental model and observed that the diameter of the bone block was an important factor in the resistance of the fixation when using transfixing pins. These authors recommended against using blocks smaller than 9 mm in diameter.

The absence of soft tissues in the experimental model made it easier to check the positioning of the transverse holes created for passing the bioabsorbable pins into the femoral tunnel. This did not add any technical difference in carrying out the experimental surgery, given that in humans, this observation method is frequently used with the aid of a camera placed by means of the tibial tunnel\(^\text{19}\).

Placement of the specimen at an angle in order to align the direction of traction produced by the machine with the orientation of the tunnel leads to the belief that, both in the case of the screw and in the case of the bioabsorbable implant, the resistance could be greater given that the axis of the forces acting on the knee under normal conditions of movement act tangentially to the joint line\(^\text{8}\).

Sheep were used as the experimental model because of the similarity of the anatomical properties and because they have been accepted as an experimental model in evaluating reconstructions of the anterior cruciate ligament\(^\text{20-27}\).

It is not expected that the present study will lead
to any modification of the technique for inserting bioabsorbable implants for fixation of bone-tendon-bone grafts. There will certainly be a need to conduct further tests on cyclical traction, in order to demonstrate whether this technical variant would be sufficiently secure in cases of necessity.

**CONCLUSION**

Comparison of the method using 2.7 mm bioabsorbable pins for fixation of a bone-tendon-bone graft transversely inside the femoral tunnel with the fixation method using an interference screw did not shown any statistically significant difference with regard to maximum load and rigidity for the initial fixation in a single traction cycle.

With this experimental model, similar resistance was obtained for bone block fixations in the femoral tunnel using bioabsorbable pins transfixed solely in spongy bone and using pins transfixing the cortical bone plate.

**Acknowledgement**

The authors express their gratitude to Dr Carlos Henrique Ramos, who drew the illustration for Figure 3, demonstrating the two types of bone block fixation using transverse pins.

**REFERENCES**