Acutely repaired proximal anterior cruciate ligament ruptures in sheep – by augmentation improved stability and reduction of cartilage damage

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The aim of this study was to evaluate the healing capacity of proximal anterior cruciate ligament (ACL) ruptures following primary repair with and without a bioresorbable augmentation. The ACL was transected at the femoral origin in the right knee joint of 24 sheep. The ACL was repaired in eight sheep (group B) without, and in eight sheep (group C) with a bioresorbable augmentation. Eight sheep without repair served as a control (group A). No immobilization was performed in any group. The sheep were sacrificed 13 weeks post-operatively. Macroscopically, all repaired ACLs were healed. The augmentation device was broken in all cases, but not completely degraded. In group A, none of the transected ACLs had healed. The anterior drawer under a load of 50 N was significantly lower in group C than in group A ($p < 0.01$). No significant difference was seen between groups B and A. The distribution and extent of chondromalacia (CM) in the operated knees depended on the type of operative treatment ($p < 0.01$). Groups A and B showed significantly more CM in the operated knee than in the non-operated knee (each $p < 0.05$). Proximal ACL ruptures can heal in sheep after both non-augmented and augmented ACL repair with free-functional rehabilitation. However, augmented repair leads to significantly better stability of the knee joint compared to transected controls and better limits the development of degenerative changes.

1. Introduction

It is well established that anterior cruciate ligament (ACL) insufficiency leads to symptomatic instability, decreasing activity, secondary meniscal pathologies, and degenerative changes [1–12]. Owing to the natural history of the ACL deficient knee, the indication for operative treatment, especially in the younger, active patient, is well accepted [13–17]. Several opinions exist, however, regarding the best type of operative treatment in a given case.

During the last few years, reconstruction of the ruptured ACL using a free bone–patellar tendon–bone autograft has become the golden standard [17–20]. While this technique has been shown to be highly effective in cases of chronic anterior instabilities [18, 21], its use in the treatment of acute ACL injuries remains controversial, despite wide recommendation.

A second option is ACL repair. Success rates observed in long-term follow-up studies after primary ACL repair, however, have been varied [22–27] thus prompting in recent years the consideration of augmentation as a means to stabilize adequately the healing tissue. Owing to the protection of the suture repair with an augmentation device [28, 29], early free functional rehabilitation is possible and elongation of the repaired ligament during the healing process is minimized. In the last few years, good clinical results have been reported after primary repair of ACL ruptures in combination with different augmentation devices [26, 30–32]. Augmented repair of proximal ACL ruptures, in particular, has shown superior results to other rupture locations [32, 33].

Several materials have been used. Permanent augmentation devices, either biological [20, 30, 34, 35] or synthetic [32, 33, 35], are well established. The use of biological materials, i.e. patellar or semitendinosus tendon, is associated with donor-site morbidity and weakening of secondary knee stabilizers. Synthetic

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materials, such as Kennedy LAD or Trevira, do not produce donor-site morbidity but have problems with long-term stability and biocompatibility. A disadvantage of all permanent materials is that they may produce long-term stress-shielding. Therefore, resorbable synthetic augmentation devices, like Polydioxanone (PDS II cord), have been developed, and are in clinical use [36–39]. However, until now, no *in vivo* study comparing the natural history of ACL ruptures, primary ACL repair, and augmented primary ACL repair, combined with free-functional rehabilitation, has been published.

Therefore, this study was designed to test the following hypotheses:

1. Healing of proximal ACL ruptures is possible following acute repair.

2. Joint stability, measured by anterior drawer, is better with augmented than with non-augmented repair.

2. Materials and methods

Twenty-four adult female sheep, weighing 72.5 ± 6.7 kg (range 57–93 kg), were operated on. They were divided into three groups using a randomization plan, with eight sheep in each group, and operated on in a randomized order. The principles of laboratory animal care (NIH publication 86-23, revised 1985) were followed, as well as the pertinent German laws. Permission was given by the Regierungspräsidium Tübingen, Tierversuchsgenehmigung 504, AZ 37-9185.81-3.

2.1. Operative methods

Group A: arthroscopic transection of the ACL at the proximal insertion site, as a model for a ruptured ligament without operative treatment (control group) (Fig. 1).

Group B: open transection of the ACL at the proximal insertion site, and immediate repair of the ACL using eight resorbable 2.0 sutures at varying depth, passed through two parallel femoral drill holes, and knotted over the bone bridge (Fig. 1).

Group C: the same as group B, but with additional parallel augmentation using a resorbable (polydioxanone) 2 mm PDS II cord (Ethicon, Norderstedt, Germany) placed through two tibial drill holes, parallel to the ACL, and through the femoral drill holes. After pretensioning with 100 N the augmentation device was fixed by two staples in the bucket-handle technique at the lateral distal femur (Fig. 1).

All operations were performed on the right knee and the non-operated left knee served as intra-individual control. After premedication with 0.1 mg kg^{-1} Xylazin (Rompun®; Bayer, Leverkusen, Germany) and 0.05 mg kg^{-1} Atropin (Atropin®; Bayer, Leverkusen, Germany), the sheep were anesthesized with 10 mg kg^{-1} Thiobarbital (Trapanal®; Bayer, Leverkusen, Germany). After intubation, 2–4 vol % Halothane was administered.

For the arthroscopic ACL transection (group A), we used an anterolateral portal for the arthroscope and an anteromedial portal for instrumentation. The ACL was transected at the fermoral insertion site using a meniscus cutter under prevention of any cartilage damage.

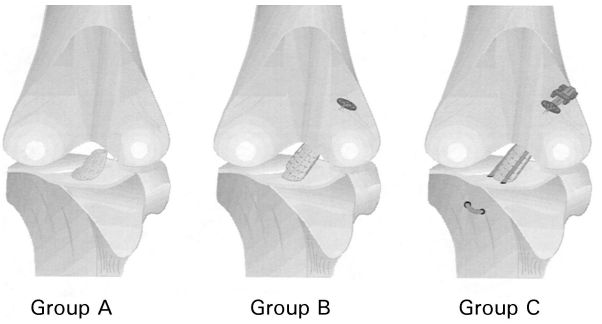

Figure 1 Operative techniques of groups A, B, and C.

In groups B and C, the knee joint was approached through a lateral parapatellar incision. The patella was luxated medially, so that the ACL could be accessed easily. Then the ACL was transected at its femoral insertion using a meniscus cutter in the same manner as in group A. The transected ACL was sutured immediately with eight resorbable PDS II 2-0 sutures at varying depth from the anteromedial to the posterolateral bundle. Two parallel 2.5 mm drillholes, anterior and posterior to the femoral insertion site on the transition line and 3 mm apart, were made from intra-articular to the lateral distal femur using a custom-made parallel drill guide. In group B the sutures were guided through the femoral drill holes so that the ACL bundles were orientated as before transection, and were then knotted over the femoral bone bridge (between the two drill holes) using a resorbable washer to prevent suture loosening due to bone resorption at the bone bridge.

In group C, following the femoral drill holes, two additional tibial 2.5 mm drill holes were made, using a drill guide, anterior and anteriomedial of the tibial ACL insertion site. Then the 2 mm augmentation device was pulled through the tibial drill holes forming a figure U. Then the dorsal ACL sutures were pulled through the dorsal femoral drill hole followed by the bundle of the augmentation device which was located anteromedially to the tibial insertion site so that this part of the augmentation device was parallel to the posteromedial ACL bundle. Afterwards, the anterior part of the sutures was pulled through the anterior-located femoral drill hole followed by the second part of the augmentation device, which was then parallel to the anterolateral ACL bundle. Then the ACL sutures were knotted in the same way as in group B. After pretensioning of the augmentation device with 100 N, it was fixed in the bucket-handle technique using two staples (10 mm × 16 mm, Smith & Nephews Richards, Schenefeld, Germany). Then the knee joints were washed with saline solution and the patella was reduced. The capsule was sutured with 4–0 resorbable sutures, and the fascia and cutis were closed with 2–0 sutures.

2.2. Augmentation device

For an augmentation device we used a doubled 2 mm PDS-cord II made of polydioxanone. The initial

rupture force of the doubled cord is about 1900 N, and the initial stiffness 120 N mm^{-1}, using a length of 30 mm for measurement. Eight weeks after implantation the remaining rupture force is about 950 N. At both ends of the cord is a steel wire to facilitate transosseus application.

2.3. Post-operative protocol

The sheep were not immobilized post-operatively. Immediately after extubation they were brought to the stable. In the first week post-operatively, the operated legs were examined every day and after that, twice a week. Thirteen weeks post-operatively, the sheep were sacrificed and both knees were removed.

2.4. Macroscopic assessment

Both knee joints were examined. The macroscopic aspect of capsule, synovia, ligaments, menisci, and cartilage was carefully recorded. Chondromalacia (CM) of all knees was graded from I°–IV° (Table I) and the area of each grade of CM was planimetrically measured. The intra-individual differences between the right and left knees were used for statistical comparison of the various groups.

2.5. Biomechanical testing

For biomechanical testing, we used a materials testing machine (Zwick 1445, Ulm, Germany). Following two pre-cycles, the anterior–posterior (A–P) translation of the knees was measured in a 90° flexed position under a cyclic anterior–posterior load of ± 50 N at a rate of 10 mm min^{-1}. Applied force and displacement of the tibia relative to the femur were simultaneously measured and plotted by the testing machine. The anterior drawer was measured from the neutral position, characterized by the change of the gradient of the posterior–anterior drawer curve [40].

Stiffness and rupture force of the ACLs were measured in a subsequent tensile test at the same crosshead speed. The tibia and femur were fixed in the testing machine such that the ACL was aligned parallel to the test direction. Load and deformation were recorded by computer. Rupture force was defined as the peak load and stiffness, and was calculated from the linear part of the curve [40].

2.6. Statistical analysis

We used non-parametric statistics because our data were not distributed normally. The significance level was set at $\alpha = 0.05$. To determine significant differences between the groups A, B, and C, the Mann–Whitney U test (two groups) and the Kruskal–Wallis test (more than two groups) were used. The Wilcoxon signed-rank test was used to determine significant differences between the operated and non-operated knees. Relationships between nominal variables were determined by contingency table analysis using Fisher's exact test.

TABLE I Grading of chondromalacia (CM) I°–IV°

CM I°	Softening and swelling of the articular cartilage, superficial surface fissuring
CM II°	Fragmentation and fissuring of the articular cartilage, not reaching the subchondral bone
CM III°	Fragmentation and fissuring of the articular cartilage, extending to the subchondral bone
CM IV°	Erosion of the articular cartilage down to the subchondral bone

3. Results

3.1. Post-operative period

Two to three hours after operation, the sheep were active again. In the early post-operative period the sheep showed varying lameness of the operated leg with a duration of 2–6 days. After 1 week, all sheep used the operated leg regularly. None of the sheep developed a haematoma or an infection.

3.2. Macroscopic assessment

Macroscopically, all repaired ACLs in groups B and C were healed. The augmentation device was broken in all cases, but not completely degraded. In group A none of the transected ACLs had healed, rather only small distal ACL stumps were observed. On the operated side in group A, all sheep had at least one meniscal rupture, whereas in groups B and C only one sheep each had a miniscal rupture ($p < 0.001$). On the non-operated side, none of the knees showed a meniscal rupture.

Distribution and area size of CM in the operated knees depended on the type of operative treatment ($p < 0.01$) (Table II). Groups A and B showed statistically significant more CM of the operated knee in comparison to the non-operated knee (each $p < 0.05$), whereas in group C no difference was seen. Chondromalacia was most marked in group A and least in group C. None of the knees showed chondromalacia IV°.

None of the operated knees showed signs of infection or synovitis. All knees had intact posterior cruciate ligaments (PCL), medial collateral ligaments (MCL) and lateral collateral ligaments (LCL).

3.3. Biomechanical testing

The anterior drawer under a load of 50 N was significantly lower in group C (2.8 ± 0.6 mm) than in group A (4.3 ± 1.3 mm; $p < 0.05$). No significant difference was seen between group B (3.7 ± 1.5 mm) and group A. The difference in anterior drawer between group C and group B was not significant, but tended to be lower in group C ($p = 0.09$).

Concerning stiffness and rupture force, no significant differences were seen between the operated knees of groups B and C (Table III). After 13 week, the operated ACL achieved only about one-third of the stiffness and only about 11% of the rupture strength of the contralateral control ACL.

TABLE II ΔA chondromalacia (CM) = A (CM) op $-$ A (CM) non-op (mm^2) ($\pm$ S.D.), where A (CM) op = Area of CM in the operated knee, and A (CM) non-op = area of CM in the non-operated knee

	Group A	Group B	Group C
n	8	8	8
ΔA CM I° (mm^2)	90 ± 115	79 ± 110	$7 \pm 90^{a,b}$
ΔA CM II° (mm^2)	135 ± 88^{c}	60 ± 77^{d}	$3 \pm 30^{b,e}$
ΔA CM III° (mm^2)	225 ± 203^{d}	10 ± 35^{a}	$-8 \pm 20^{b,e}$
ΔA CM IV° (mm^2)	0	0	0
ΔA total (mm^2)	296 ± 240^{c}	150 ± 151^{d}	$3 \pm 99^{e,f}$

[a] $p < 0.05$. [b] $p < 0.005$ (versus group A). [c] $p < 0.05$. [d] $p < 0.01$ (versus group B). [e] $p < 0.05$, [f] $p < 0.0$: (operated versus non-operated knee). Negative values mean larger area of CM in the non-operated knee compared to the operated knee.

TABLE III Anterior drawer under a load of 50 N, stiffness and rupture force ($\pm$ S.D.)

	Operated			Control groups A, B, C
	Group A	Group B	Group C	
n	8	8	8	24
Anterior drawer (mm)	4.3 ± 1.3^{a}	3.7 ± 1.5^{a}	$2.8 \pm 0.6^{a-c}$	0.5 ± 0.2
Rupture force (N)	0	252.6 ± 58.7^{e}	236.8 ± 90.4^{a}	2280.4 ± 271.7
Stiffness (N mm^{-1})	0	69.4 ± 19.2^{a}	77.5 ± 27.1^{a}	204.4 ± 27.4

[a] $p < 0.05$ (operated versus non-operated knee).
[b] $p < 0.05$ (versus group A).
[c] $p = 0.09$ (versus group B).

4. Discussion

Primary ACL repair remains under discussion. In general, the results after primary ACL repair have been varying in their success rate [22–27]. The use of augmentation devices in some studies clearly improved the outcome [26, 30–32], probably due to the protection of the healing zone of the repaired ligament and the possibility of a free-functional rehabilitation. However, experimental *in vivo* data dealing with the primary ACL repair without post-operative immobilization are still lacking.

Only one recent study without post-operative immobilization [41] compared primary repair with and without augmentation. For augmentation, either an autogeneous patellar tendon or a resorbable doubled 2 mm PDS cord was used. The results after augmented repair were significantly better compared to non-augmented repair. Nevertheless, non-augmented repair with PDS or polyester sutures led macroscopically to a healing rate of 100%, despite the fact that the biomechanical properties were clearly worse. These results indicate, in contrast to the consensus of most authors, that freshly repaired proximal ACL ruptures can heal, even without immobilization. Nevertheless, augmentation improves the results due to the protection during the healing period. Our results indicate a significantly improved knee-joint stability after augmented repair compared to the control group (ACL transection without repair), whereas in primary repair without augmentation, no significant differences compared to the control group were seen. As there were no differences concerning stiffness and rupture force, the augmentation seems to prevent stretching of the healing zone during healing without changing the biomechanical properties. The resorbable augmentation device seemed to provide enough primary stability. However, we still do not know exactly the rate at which the biomechanical properties of the augmentation device deteriorate *in vivo*. It remains unclear whether an augmentation device with a longer biomechanical half-life could further improve joint stability. Further investigations are needed to answer this question. Although the anterior drawer after augmented repair was higher compared to the controls, the stability achieved was still enough to prevent the knee joint from developing cartilage damage.

Owing to the short follow-up time, the rupture force and stiffness of the repaired ligaments were clearly lower compared to the controls. Nevertheless, the biomechanical properties were good enough to maintain the integrity of the repaired ligament without rupture in the post-operative period, even without immobilization. Although the biomechanical properties improve by increasing follow-up time [42], further investigations are required to verify the long-term course after primary augmented repair.

5. Conclusion

Proximal ACL ruptures can heal in sheep without post-operative immobilization after non-augmented and augmented ACL repair. Augmented repair leads to significantly better stability of the knee joints and prevents the development of degenerative changes. Therefore, augmented repair seems to be superior to non-augmented repair, especially in combination with free-functional rehabilitation.

The biomechanical properties of the bioresorbable augmentation device used in this study are suitable for

augmented primary repair, and allow a free functional rehabilitation protocol.

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