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ORIGINAL ARTICLE

Functional results of allograft vs. autograft tendons in anterior cruciate ligament (ACL) reconstruction at 10-year follow-up

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Abstract

Purpose The anterior cruciate ligament (ACL) tear is one of the most common sports injuries of the knee, and the arthroscopic reconstruction is the gold standard. Nevertheless, controversies about the surgical techniques and the type of graft still exist. Allografts have been considered by many surgeons as valid alternative to autografts. The aim of this study was to assess the effectiveness of allografts compared to autografts at approximately 10 years of follow-up, investigating the level of physical activity currently performed by patients of each group.

Methods Ninety-four patients, divided into two groups (allografts and autografts), have been retrospectively studied. The two groups did not significantly differ in preoperative sport activity level, age (mean 40.70 years for autografts and 41.23 for allografts) and characteristics. Allograft group received a fresh-frozen graft from the musculoskeletal tissues bank. Evaluations were made using the International Knee Documentation Committee (IKDC) and Lysholm score; every patient was interviewed for complications.

Results The mean follow-up time was approximately 10 years for both groups, with a minimum of 8 years. There were no statistically significant differences between the two groups. Average IKDC scores were 75.21 (SD 15.36) and 80.69 (SD 13.65) for the allograft and autograft groups, respectively. The mean Lysholm score was 87.57 (SD 9.43) for the allografts and 89.10 (SD 8.33) for the autografts. No major complications linked to the allograft tissue arose.

Conclusion Both groups achieved almost the same functional outcomes at an average 10 years of follow-up, indicating fresh-frozen allografts as a reasonable alternative for ACL reconstruction.

Level of evidence IV, Retrospective case–control study

Keywords Acl · Graft · Allograft · Reconstruction

Introduction

Anterior cruciate ligament (ACL) tears are still very common, and according to some studies, they account for almost 50% of all knee injuries [1]. Most importantly, they occur in different subgroups of the population, such as professional athletes but also highly active amateur individuals and lastly occasionally active individuals (usually middle-aged).

As of today, the current standard of care for ACL complete tears is ACL reconstruction. Despite the popularity of the procedure, there is still a considerable amount of controversy over the surgical techniques. They involve several choices among sites of tendon harvesting, type of graft and system of fixation [2–4]. One of the main issues is the choice between autograft and allograft: each technique showed advantages and limitations, while both lead to successful

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outcomes and allow patients to return to a significant level of activity after surgery [5]. Reconstruction with autografts has the major benefits of earlier engraftment and no risk of rejection or disease transmission but can lead to potential donor-site morbidity. Allografts have the main advantage of eliminating the donor-site morbidity, with consequent less postoperative pain and easier rehabilitation [2, 6]. However, allografts have the major disadvantages of higher graft failures, disease transmission, possible immunogenicity, slower incorporation of the new ligament and thus lastly a longer rehabilitation time [7, 8]. Although the potential for disease transmission has been the main concern for surgeons and patients, the improved donor screening and the modern harvesting and sterilization techniques have significantly decreased this risk; lately, the use of gamma irradiation has been reduced in favor of antibiotic solutions [9–11].

The purpose of this study was to assess the effectiveness of allografts compared to autografts focusing on a long follow-up time. The first step was to investigate the long-term clinical and functional status. Then, long-term complication and failure rates have been analyzed with possible causes. The hypothesis was that the reconstruction with allografts is safe and durable and therefore can be suitable in certain types of patients, such as those who prefer to avoid the donor-site morbidity of the autograft reconstruction techniques, middle-age individuals and moreover patients willing to endure a longer and delayed rehabilitation program, without the wish of rushing into sports activities.

Material and methods

Between January 2008 and December 2011, over 650 primary ACL reconstructions were performed at our Institution, 56 of which were performed using allograft tissue. The allograft group was based on the patients operated by the senior author for ACL reconstruction with the allograft technique, with a minimum follow-up of 8 years and a maximum follow-up of 12 years. Since nine had to be excluded according to the disclosed criteria, 47 patients were finally enrolled in the allograft group.

The autograft group was set selecting a group of patients operated at our Institution for ACL reconstruction with the autograft technique. In order to get the most accurate match, according to the inclusion and exclusion criteria, for each patient in the allograft group, the most similar patient in terms of age and with the same gender who underwent autograft reconstruction between the three previous and the three following months was selected and recruited; among the 47 patients primarily selected, 3 were not traceable and were immediately replaced to obtain a paired group of 47 patients. A total of 94 patients were finally included in this study (47 allografts and 47 autografts); none of these was lost to follow-up.

Inclusion criteria: age between 16 and 70 years with or without minor meniscal tears in the white-white zone requiring partial meniscectomy; *Exclusion criteria:* multiligament injury of the knee; severe chondropathy; major meniscal tears requiring meniscal repair; previous reconstruction and/or revision of the same ligament; congenital malformations of the lower limbs; malalignment of the lower limbs; previous meniscectomy; previous local and/or systemic infections; diabetes and rheumatic diseases.

Surgical technique: autograft group

Graf harvesting: The gracilis and semitendinosus tendons were identified and prepared for harvesting through a 3–5 cm oblique incision in the skin projection of pes anserinus. The two tendons were duplicated into a four layers bundle [4].

Graft positioning: The tibial tunnel was positioned with a 55° angle to the coronal plane and 30° angle to the tibial axis. The femoral tunnel was drilled with the trans-tibial technique. In all cases of the autograft group, the femoral fixation was performed with a transverse fixation system, while for the tibial fixation resorbable interference screws have been used.

Surgical technique: allograft group

The tendons used in this group have been collected from the Musculoskeletal Tissue Bank of our Institution. The process of tendon harvesting consists of several phases, all of them performed in sterile conditions in orthopedic-grade operating room. After the harvest, the tendons are sunk in an Amukine 0.05% bath for ten minutes, followed by a test for bacterial detection performed with swabs for Petri dishes. Then the tendons undergo a second bath in antibiotic solution (10 fl of rifampicine 500 mg in 10 L of saline solution), this time followed by a biopsy sample for histological for bacterial analysis. The tendons are then packaged in triple plastic sterile cryo-resistant bag each closed with a sterile lace and covered with forth layer of hydro-repellent material. The tendons are then stored at -80 °C. The allografts are de-frozen 1 h before surgery and sunk for 20 min in an antibiotic solution (gentamicin 160 mg per liter of saline solution) in the operating room before the use.

Graft selection and preparation: The used tendons were 21 tibialis anterior, 18 peroneus and 8 Achilles. The preference was for thick long tendons such as tibialis anterior, but the definitive choice was given by the availability of the graft. When a bone part was present, it was removed (Achilles). The tendon was duplicated into a two-layer bundle.

Graft positioning technique with allografts: The tibial tunnel was positioned with a 55° angle to the coronal plane

and 30° angle to the tibial axis. The femoral tunnel was drilled with the trans-tibial technique. In all cases of the allograft group, the femoral fixation was performed with a cortical button suspension device, while for the tibial fixation resorbable interference screws have been used.

Clinical evaluation

Physical examination was routinely carried out at 1–2–4 months postoperatively and then scheduled for return to sport (RTS) allowance. Return to contact or pivoting sports was set at 7 months for autografts and at 10 months for allografts if common RTS criteria were satisfied.

Further examinations were reserved to patients' complaint of pain, swelling or sensation of instability; MRI was executed when clinical findings were unconvincing.

At the last follow-up, patients of both groups were evaluated with the subjective IKDC Questionnaire (International Knee Documentation Committee) and with the Lysholm score [12, 13]. Patients were asked to report any case of failure related to the type of graft such as rejection, intolerance, infection, mechanical failure and elongation documented as residual or relapsing instability.

Statistical analysis

The collected data were processed for statistical analysis with IBM SPSS® (Data Analysis and Statistical Software); a Kolmogorov–Smirnov test of normality was used to study the values distribution in all data series. Differences were considered significant if p-value was < 0.05.

Table 1 Patients' demographics and functional scores (mean, SD = standard deviation and range)

Parameters	Allograft ($n = 47$)	Autograft HS ($n = 47$)
Age (years)	41.23 (SD 9.33) [range 16–66]	40.7 (SD 7.59) [range 16–52]
Male/female	27:20	27:20
Right knee/left knee	27:20	32:15
Follow-up (months)	124.1 (SD 12.25)	124.63 (SD 12.32)
Lysholm score	87.57 (SD 9.43)	89.10 (SD 8.33)
IKDC	75.21 (SD 15.36)	80.69 (SD 13.65)

Results

Patients' demographics and characteristics along with the IKDC and Lysholm score results are reported in Table 1. The mean age at intervention was 40.70 (SD 7.59) for autografts and 41.23 (SD 9.33) for allografts, with no significant difference at Student's t test ($p = 0.76$). The male/female ratio was 27:20 in both groups. The mean follow-up time was 124.19 (SD 12.25) months for the autograft group and 124.64 (SD 12.36) months for the allograft group, with no significant difference at Student's t test ($p = 0.86$). The mean individual IKDC score was 75.21 (SD 15.36) in the allograft group and 80.69 (SD 13.65) in the autograft group, with no significant difference at Student's t test ($p = 0.07$). The mean Lysholm score was 87.57 (SD 9.43) in the allograft group and 89.10 (SD 8.33) in the autograft group, with no significant difference at Student's t test ($p = 0.41$). Table 2 reports the status of the physical activity of the patients at the last follow-up, which was thoroughly investigated about eventual reasons for stopping any kind of activity, for both groups.

No major complications directly related to the allograft have been reported. The rate of minor complications (wound complication, deep venous thrombosis, swelling, hematoma) was 5% in the allograft group and 6% in the autograft group; all complications have been treated with medical therapy.

One case of failure was registered in each group: a 45-year-old male in the autograft group at 127 months of follow-up due to a soccer injury and a 49-year-old male carpenter in the allograft group at 129 months of follow-up due to a work accident; since both these patients were still indecisive whether to undergo surgery or not, no surgical revision occurred in the study population

Discussion

Autografts have been more popular in ACL reconstruction than allografts (Fig. 1) [1, 2, 5]. For many years, the first choice has been the patellar tendon (BTB), overtaken lately by the hamstring (HS) tendons [1, 2, 5]. This was due to harvesting site (medial third of patella, tibial tuberosity and patellar tendon) being associated with frequent morbidity, such as patellofemoral osteoarthritis, tendon shortening,

Table 2 Patients' physical activity level at follow-up

	Allograft group ($n = 47$)			Autograft group ($n = 47$)		
Stayed highly active	5 (11%)			7 (15%)		
Light to moderate activity	22 (47%)			20 (43%)		
Stopped due to fear of new injury	9 (19%)			10 (21%)		
Stopped due to other causes	11 (23%)			10 (21%)		
Adherence to rehabilitation program	Low 12%	Mid 50%	High 38%	Low 15%	Mid 57%	High 28%

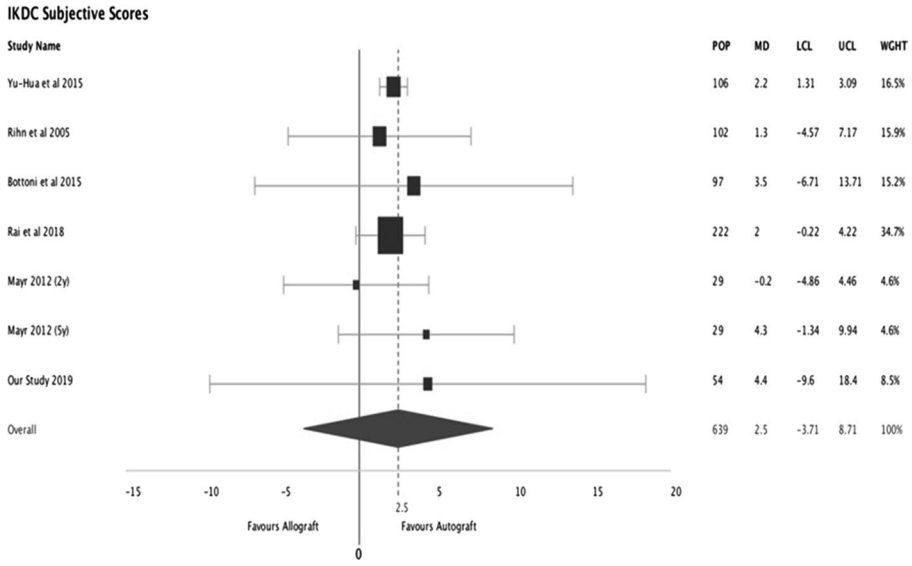

Fig. 1 (Forest Plot):IKDC scores and comparison between autograft and allograft, according to the literature [Yu-Hua 2015[28], Rihn 2005[25], Bottoni 2015[19], Rai 2018[26], Mayr 2012 (2y)[27], Mayr 2012 (5y)[27]]. (POP = population; MD = mean difference; LCL = lower control limit; UCL = upper control limit; WGHT = weight/size of the box)

mild to severe pain and in few cases even patellar fracture [2, 15]. As an alternative strategy, the use of tendons such as HS and quadriceps gained popularity [2, 15, 16]. Nonetheless, they may be associated with complications related to the donor site and potentially to a longer recovery time [15, 17]. Therefore, due to these potential complications, surgeons started considering allografts [2, 3, 15] or other strategies [7]. The choice of the graft for ACL reconstruction depends on the individual evaluation, after the assessment of pros and cons. Currently, allografts tend to be utilized in a great number of revisions or in patients that do not require strenuous physical engagement [5, 18, 19].

Risk of bacterial and viral diseases transmission is one of the major concerns associated with the use of allograft tissue [3, 10, 11]. Sterilization is a crucial and mandatory process for reducing the development of infections [3, 10, 11]. Various techniques have been considered for disinfection: gamma rays irradiation, ethylene oxide, beta-propiolactone, antibiotic solutions, peracetic acid and ethanol [3]. In this study, fresh-frozen grafts have been used and they were treated with ATB solutions before surgery. It is well known that gamma irradiation has the best bactericidal and virucidal properties. Thus, apart from donor screening and aseptic harvesting technique, gamma irradiation has been for long time the most popular method for sterilization of allografts [3]. However, studies have shown that gamma irradiation has adverse effects on biomechanical properties of allografts in a dose-dependent manner [14].

A comparative analysis with previous similar studies is reported in Table 3. According to the literature, failure rates of allografts turn out to be higher than those of autografts. Prodromos et al. reported a failure rate of 5% for autografts vs 14% of allografts [21]; Kaeding et al. reported a failure rate of 3.5% for autografts vs. 8.9% for allografts [22]. Also, in recent meta-analysis studies conducted by Prodromos et al., Yao et al. and Zeng et al. [21, 23–28], the same failure rate emerged, but with significant pain reduction when an allograft is used, due to the lesser surgical trauma and to the absence of morbidity at the harvesting site. Furthermore, patients managed to resume training dramatically sooner in the allograft group, compared to the autograft, even though engraftment time is longer (therefore, gradual physiotherapy is strongly suggested prior to starting intense physical activities) [17]. Tibor et al. demonstrated a greater amount of laxity with the allograft reconstruction, but this finding did not appear to change the outcome of the patients [18]. In a retrospective review of 125 consecutive ACL reconstruction using

Table 3 Studies comparison. BTB: bone-patellar tendon-bone. SD: standard deviation, [Yu-Hua 2015[28], Rihn 2005[25], Bottoni 2015[19], Rai 2018[26], Mayr 2012 (2y)[27], Mayr 2012 (5y)[27]]

Study	No. of patients	Autograft type	Allograft type	Mean age auto/allo	Follow-up (mo)
Yu-Hua 2015	106	Hamstring	BPTB	31/28	81
Rihn 2005	102	BPTB	BPTB	25.3/44	50.4
Bottoni 2015	97	Hamstring	Tibialis posterior	28.9/29.2	126
Rai 2018	222	Hamstring	Tibialis anterior	28.7/30.5	49
Mayr 2012 (2y)	29	BPTB	BPTB	36.9/32.5	19.2 (± SD5,8)
Mayr 2012 (5y)	29	BPTB	BPTB	41.1/36.5	68.8 (± SD6,8)

anterior tibialis allograft, Singhal et al. [29] reported a significant increase in failure rate in patient younger than 25 years; they assumed that the high failure rate in their series could be attributed to a combination of graft choice, method of fixation (double interference screw) and accelerated rehabilitation program. With similar patients' age and activity level, Shino et al. previously reported a graft failure rate of 3% and good or excellent subjective results in 94% of ACL reconstruction using soft-tissue fresh-frozen allograft with a delayed return to sports (11–12 compared to 4 months) [30]. Based on these emerging discordant findings, allograft reconstruction was proposed and thoroughly discussed with the patients and was not considered as a first choice for young and active individuals at our Institution; consequently, our study population consisted mainly of older (> 30 years of age) individuals.

In a large prospective analysis from the MOON cohort, Keading et al. reported a significant higher rate **of** failure in allograft ACL reconstruction compared to BTB autograft within 2 years of follow-up; this difference was most clinically relevant in the younger age group and was progressively attenuated with increasing age, in so far by the mid-30s the difference between the grafts appears not clinically significant [31]. A recent systematic review [32] confirmed a clear difference in failure prevalence favoring primary ACL reconstruction performed with autograft over allograft tissue in young (≤ 25 years of age) or highly active patients.

This study has several limitations: it is a retrospective study; it has a low number of patients and its nature does not allow the comparison between preoperative and postoperative data. The study does not consider the fixation efficacy and the behavior of the tunnels in the long period. The level of the return to sport could have been evaluated with specific tests [20]. Despite the attempt to have two homogeneous groups matched on age, gender and follow-up time, there could still be differences between the two groups, possibly leading to a selection bias. Furthermore, the allograft group has been operated by the senior author; meanwhile, the autograft group has been operated by more than one surgeon; the femoral fixation was different; the autograft was a hamstring graft in each case, while several types of allografts were used according to their availability. Moreover, given the lack of clinical examination paired with sensible imaging, it is possible that failure rates were underestimated.

With the above-mentioned limitations, our study helps demonstrating that patients treated with allografts have functional results comparable to the autograft group; in fact IKDC score and Lysholm score, which are considered reliable outcome reporting tools for ACL reconstruction [12, 13], did not show a significant difference. Nonetheless, one of the major findings of this study is that the use of allograft does not correlate with complications directly connected with the nature of the tissue itself.

One of the main concerns of the authors was to evaluate the level of physical activity currently performed by the allograft patients: it was found that the majority of them maintained intense sports (such as ski, soccer, running, tennis, etc.) without major differences with the autograft group. Regarding the return to sport activities, the status of the physical activity of the patients was assessed and particular attention was dedicated to investigating if anyone gave up physical activity and why. The two groups showed similar results, with a general return to the previous sport but with a reduced level of activity. A certain percentage of patients was stopped by a further injury, thus suggesting the problem of rehabilitation and full recovery. Recent studies underlined the importance of rehabilitation, as immediate knee mobilization and strength/neuromuscular training [17]; in this series, patients who dropped out of rehabilitation programs referred a greater amount of fear of new injury; meanwhile, patients that continued rehabilitation for up to 2–4 months after the standard protocol noticed a better outcome and felt safer while performing various activities (Table 2). Finally, patients who stayed active were satisfied with the outcome of the reconstruction: they were able to resume their favorite sport and none of them showed signs of instability or invalidating pain.

Therefore, allografts may be considered to be a valid alternative strategy, especially for patients refusing to undergo donor-site morbidity caused by tendon harvesting, for middle aged patients, for patients who avoid strenuous physical activity while remaining considerably active. Given that we focused only on functional results and subjective findings, based on the current literature [19], we still would not recommend allografts as a first choice for younger patients and professional athletes.

Conclusion

Satisfactory and similar subjective functional results can be achieved with the use of fresh-frozen allograft tendons compared with autografts for primary ACL reconstruction in middle-aged active patients. In this study, the return to sport activities was thoroughly investigated, suggesting that with a good adherence to physical therapy programs the use of allografts can be helpful in achieving great functional results and personal satisfaction**.** Therefore, allografts can be considered as an alternative strategy in selected patients.

Author contributions All authors contributed to the study.

Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest and received no funds for this study.

Ethical approval The study was authorized by the local Institutional Revision Board (IRB) in accordance with the ethical standards.

Informed consent Patients gave their informed consent for the treatment of the data before surgery. The study was authorized by the local institutional revision board (IRB) and was performed in accordance with the ethical standards. Data are available upon request. The work has not been published before in any language, is not being considered for publication elsewhere and has been read and approved by all authors. Each author contributed significantly to one or more aspects of the study. No benefits in any form have been received or will be received from a commercial party related directly or indirectly to the subject of this article.

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