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The use of allograft tendons in primary ACL reconstruction

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Abstract

Purpose Graft choice in primary anterior cruciate ligament (ACL) reconstruction remains controversial. The use of allograft has risen exponentially in recent years with the attraction of absent donor site morbidity, reduced surgical time and reliable graft size. However, the published evidence examining their clinical effectiveness over autograft tendons has been unclear. The aim of this paper is to provide a current review of the clinical evidence available to help guide surgeons through the decision-making process for the use of allografts in primary ACL reconstruction.

Methods The literature in relation to allograft healing, storage, sterilisation, differences in surgical technique and rehabilitation have been reviewed in addition to recent comparative studies and all clinical systematic reviews and meta-analyses.

Results Early reviews have indicated a higher risk of failure with allografts due to association with irradiation for sterilisation and where rehabilitation programs and post-operative loading may ignore the slower incorporation of allografts. More recent analysis indicates a similar low failure rate for allograft and autograft methods of reconstruction when using non-irradiated allografts that have not undergone chemically processing and where rehabilitation has been slower. However, inferior outcomes with allografts have been reported in young (< 25 years) highly active patients, and also when irradiated or chemically processed grafts are used.

Conclusion When considering use of allografts in primary ACL reconstruction, use of irradiation, chemical processing and rehabilitation programs suited to autograft are important negative factors. Allografts, when used for primary ACL reconstruction, should be fresh frozen and non-irradiated. Quantification of the risk of use of allograft in the young requires further evaluation.

Levels of evidence III.

Keywords Anterior cruciate ligament reconstruction · Allografts · ACL · Graft choice · Decision making · Autografts

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Introduction

Over the past decade, allografts have been used in greater frequency for both primary and revision ACL surgery. In a recent study of over 16,000 ACL reconstructions from a community-based registry, allografts were used in 42.4% of primary and 78.8% of revision cases in the United States [77]. The aim of ACL surgery is to restore stability, enabling return to sport and activity, and to reduce the subsequent risk of arthritis. Graft choice remains controversial, as the desire for the best graft with minimal donor site morbidity, accurate reproduction of the host original ligament and rapid incorporation, has to be balanced against the risk of re-rupture or adverse events related to the graft. Allograft tissue avoids problems related to donor site morbidity both acutely at time of surgery and later during rehabilitation, and may allow 'easier' initial recovery, however, factors including incorporation of the tissue, risk of re-rupture and potential for disease transmission must be considered.

The cosmetic appearance of less scarring in addition to reduced operating time and the ability to reproducibly provide an adequately sized graft are, however, positive and persuasive factors to add to the decision making. Marrale et al. [82] reported the advantages of allograft being lower surgical time, less incisions (cosmetic advantage) and less arthrofibrosis, but that allografts appeared to have an increased failure rate compared to the autografts. Early published results indeed indicated that allograft reconstructions had poorer clinical outcomes than autografts, but in more recent systematic reviews, the non-irradiated and non-chemically treated allografts appear to produce similar results to autografts [80, 130].

The purpose of this paper is to provide a narrative review of the current available evidence for the use of allograft tissue for primary reconstruction of the anterior cruciate ligament.

Allograft types

Structurally, allografts available for primary anterior cruciate ligament (ACL) reconstruction can be broadly divided into soft tissue allografts and bone–tendon–bone allografts. Further description of their sub-types can be found in Fig 1 (Classification of Allografts used for Primary ACL Reconstruction). The BPTB allograft is the only option for bone-to-bone healing on both the femoral and tibial sides. Achilles tendon and quadriceps tendon allografts contain a single bone block providing bone-to-bone healing on one side and tendon-to-bone healing on the other. Soft tissue allografts include the hamstrings, tibialis anterior, tibialis posterior, peroneal tendons, and iliotibial band/fascia lata. There is variation in strength and stiffness among allografts harvested from different sites, although most meet or exceed the ultimate tensile strength of the native ACL. Non-looped tibialis allografts have the lowest, and quadriceps tendon grafts have the highest load to failure [69]. Graft size should be customised to the individual patient's native anatomy [52], however, it should be noted that increasing graft diameter does positively affect mechanical properties for bone and soft tissue allografts [15, 106]. Allografts derived from older donors older are associated with a lower tensile strength and lower load to failure. The use of grafts from donors younger than 40 years old is favoured, specifically when used in younger patients. Gender appears to have a minimal effect on biomechanical graft properties [69].

Allograft healing

Healing and 'ligamentization' of allograft tendons in ACL reconstruction tends to follow a similar natural history when compared with autografts [49, 56, 106]. Early healing is different between graft types. Bone-to-bone healing involving incorporation into the host bone is relatively fast, usually maturing by 6 weeks. In comparison, soft tissue to bone healing occurs slowly, taking 8 to 12 weeks for maturation [51]. The healing process is also influenced by many different factors including graft placement, graft length within the

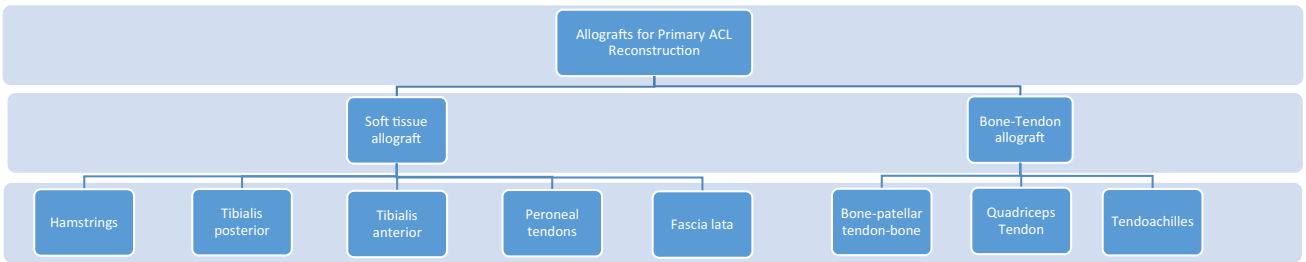

Fig. 1 Classification of allografts used for primary ACL reconstruction

bone tunnel, graft fixation, graft tensioning, and graft–tunnel micromotion. These variables may even vary for different regions of the bone tunnels [13, 37]. The sequential stages of inflammation and graft necrosis, revascularization, cell population and remodelling occur during the graft incorporation [40, 56, 57], however, the process is slower and the stages are delayed in allografts [88, 103].

Scheffler et al. [103] investigated the biological incorporation of ACL autografts versus allograft in 48 sheep. They discovered that recellularization and revascularization was significantly delayed at 6 and 12 weeks of healing in the allograft group and remodelling at 52 weeks significantly delayed and urged caution with early rehabilitation in allograft ACL reconstructions. This was further supported by an imaging study performed by Muramatsu et al. [88] that investigated the MRI appearances of ACL autograft and allografts at an average follow-up time of 2 years. They concluded that despite having a negative lachman test, the allograft group had a slower onset and rate or revascularisation compared with autograft [88].

Allograft storage and sterilisation: structural issues

Storage of allografts can be performed as fresh-frozen, freeze-dried or cryopreserved. Fresh-frozen allografts are stored through a deep-freezing procedure. After harvesting, the graft is frozen for 2–4 weeks, while waiting for the results of serologic studies. When the results become available, the graft is thawed, soaked for 1 h in antibiotic solution and then frozen to − 80 °C to be stored for 3–5 years. It is the simplest and most frequent method for allograft storage [19]. In freeze-drying, the allografts are lyophilized [12]. After sterile harvest, the tissue is frozen while serologic tests are performed and is then soaked in antibiotic solution. The tissue is refrozen and lyophilized to reduce the moisture content to less than 5%. The graft can then be stored at room temperature for 3–5 years. Both fresh-frozen and freeze-dried allografts have no viable donor cells.

In cryopreservation, controlled freezing of the allograft tissue is achieved through the extraction of cellular water with the help of cryoprotectant media, e.g. dimethylsulfoxide, and the graft is stored ultimately in liquid nitrogen at − 196 °C [55]. It has more than a 10-year shelf life. Interestingly, the cryoprotectants have been found to promote angiogenesis and reduce the host's intravascular immune response [55].

Sterilisation of allografts can be performed using low dose irradiation, high dose irradiation and alternate methods (e.g. supercritical CO) [12, 85]. All these methods affect the structural integrity of the grafts to various extent [68, 114, 119]. Gamma irradiation has been found to adversely affect the biomechanical properties of allograft tissue, delay healing [29, 42] and increase risk of failure [45]. This has been found to occur in a dose-dependent fashion. Dosage has been minimised (< 2.5 mRad) to reduce the effect on the mechanical properties but the subsequent dose is not adequate to deactivate the HIV virus and in a recent systematic review of 21 studies, the rate of graft failure was still higher than autografts [95]. This was confirmed more recently in a meta-analysis by Grassi et al. [46] evaluating 1192 patients in 32 studies undergoing autograft or allograft reconstruction. Minimum follow-up was over 2 year and if irradiated grafts were excluded then similar outcomes between autografts and allografts were seen. Ethylene oxide sterilisation, another form of preparation, has limited ability to penetrate the tissue and may cause postoperative synovitis.

Low-temperature chemical methods (e.g. BioCleanse) which are able to kill spores while aiming to preserve the mechanical properties of the tissue may be the answer [28, 60, 76]. However, this treatment has been reported to have deleterious effects on the tissue and a higher failure rate. Maletis et al. [75] reported on factors leading to revision in 14,015 ACL reconstructions, showing that any radiation with or without chemical processing resulted in a higher failure rate at both 1 (4.39%) and 2-year (7.35%) time points, when compared with BPTB autografts (1.9%). The study also showed that nonirradiated allografts subjected to the BioCleanse (8.87%), Allowash, and AlloTrue (9.56%) processes also did significantly worse at 1-year timepoints than the BPTB autografts. In a subsequent analysis of over 10,000 reconstructions using allografts, the same group reported that there was no difference in the likelihood for 90-day deep infection for processed versus non-processed allografts with a very low overall incidence of deep infection after allograft ACLR (0.15%), concluding that there is unlikely to be a need for chemical processing, which may affect the graft, when the infection rate is so low [129].

Roberson et al. [101] also studied the effect of such processing analysing the results from 13 clinical, and 11 biomechanical studies in 2017. At time zero, there were no biomechanical differences and clinical failure rates were similar (BioCleanse: 5.4%; AlloTrue: 5.7%; MTF: 6.7%). The authors noted that the sole BioCleanse clinical study demonstrated excellent clinical outcomes, but the study received scrutiny for being industry sponsored and the fact that 42% of patients were lost to follow-up. Two other important points were made in this paper: first that reporting of graft processing is not clearly described in many papers making analysis difficult and that the use of 'low dose' or 'terminal radiation' for what are thought to be non-irradiated grafts is unclear and variable, also making analysis difficult [101].

Another possible solution for decontamination could be a method proposed by Paolin et al. [94] where a two-step decontamination protocol was used. The method included using a solution of Ceftazidime, Lincomycin, Polymixin B

and Vancomycin twice, each time for 24–48 h. The samples for culturing were collected three times: upon retrieval, after first decontamination, and after second decontamination. This resulted in reduction of positive culturing from musculoskeletal allografts (from non-heart-beating donors) from 55% at the first culturing, to 0.5% at the third one.

Allograft Infection risk

Since 1993, careful donor screening for HIV, HBV and HCV have made transmission of these viral diseases rarely reported, although still possible. Recent advances in laboratory testing (e.g. nucleic acid cadaver serum testing) are hoped to further reduce this risk [12, 47, 78]. In our knowledge, no publication has reported contamination by HIV through musculoskeletal allograft used in ACL reconstruction. Safety remains the main aim, noting that the allografts are being used for life enhancing procedures rather than life saving, and very strict procedures are applied in tissue banks [116] to avoid any transmission.

Bacterial infection following allograft ACL reconstruction is significantly reduced by sterilisation. According to Crawford et al. [27], the use of sterile allograft results in a significant decrease risk of postoperative infection. In his group of 331 patients, infection occurred only in patients in which non-sterile allograft was used compared with autograft or sterile allograft group. Logical concerns about risk of transmission of infection with non-processed allografts exist, but the actual incidence of overall infection has been found to be low [8, 80]. One recent study [18] based on the MOON cohort (2198 patients) suggests that there is a lower risk of infection when using a BPTB autograft comparing with hamstring autograft and all types of allografts. According to this and other authors [9, 30, 64, 78], allograft is not a risk factor for infection.

Bacterial contamination of the graft versus clinical infection is an important consideration. According to Ibrahim et al. [53], 27% of allografts cultured positive at the time of harvesting. After death, microorganisms may pass through intestinal wall and seed into other tissues of the donor. These organisms can be dangerous, even life threatening for the patient as they include bowel flora (e.g. *Clostridium* spp. or Enterobacteriacae). During the refrigeration process clostridia sporulate and may survive for years. After the implantation of spore-containing, non-sterilized allografts into the knee, the acute surgically traumatised tissue, and in cases of ACL reconstruction, foreign body fixation devices make an ideal setting for Clostridium infection to develop [96].

In 2002, after the death of a 23-year-old male who received a femoral osteochondral allograft infected with *Clostridium* spp., the CDC (National Center for Infectious Diseases) conducted an investigation and published a guidance report [1, 23]. In this report, allograft-associated infection was carefully defined (see Table 1) to exclude postoperative infections that were not associated with allograft implantation. In a consecutive series of 25 cases of bacterial infections associated with allograft implantation, performed during the course of the investigation, 50% were found to be infected with *Clostridium* spp. Analysing all reports of allograft contamination, the majority of cases included tissue that was part bone, and solely soft tissue ACL allograft contamination cases are less frequently reported [60].

Management of a positive culture from an allograft

Centeno et al. [22] addressed the question if positive culture from allograft actually correlates with clinical infection. He prospectively analysed 210 cases of primary ACL allograft reconstruction with fresh-frozen tibialis anterior or posterior grafts. All allografts were cultured and then washed 3 times (last wash was bacitracin solution) before implantation. All patients received preoperative i.v. Cephasolin infusion (in allergic patients Clindamycin was administered). All patients were followed for a minimum of 90 days. Among those 210 cases, 10 allografts cultured positive (4.8%): 6 with *Staphylococci*, 1 *Streptococcus*, 1 *Clostridium*, 1 Enterobacteriacae and 1 polymicrobial. In three patients (with highly virulent cultures: *Clostridium*, Enterobacteriacae and polymicrobial), prophylaxis antibiotic therapy was prescribed, whilst the remaining 7 patients were observed. None of the patients who obtained polluted allograft developed any symptoms of infection.

Centeno et al. [22] described four possible case scenarios:

(a) True negative would be the most frequent situation in 87–95% of cases [22, 34].

Table 1 Classification and description of infection associated with infection

Allograft-associated infection
Any surgical site infection (SSI) at the site of allograft implantation occurring within 12 months of allograft implantation in otherwise healthy patient, without known risk factors for SSI (e.g. diabetes)
Cases could be culture-negative if diagnosed by infectious disease physician/surgeon and diagnostic/operative findings are supporting SSI diagnosis
If only *Staphylococcus* spp. was isolated, patients were excluded unless other microbiologic evidence suggested allograft contamination

(b) In the Centeno study, there were no true positive cases, however, in a study by Barbour et al. [8] four cases of true positive culture (all with *Clostridium septicum* after ACL reconstruction) were reported. Culturing allografts before implantation has a potential benefit for the patients, as it allows for early, organism-specific antibiotic therapy and possibly greater chances of graft preservation [22].
(c) False-negative cultures were found in 0.5% of cases in the study by Centeno et al., (one case of clinical infection over 200 negative cultures). His team stated that theoretically in this case the allograft was not likely to be the source of infection. In a case of clinical infection after allograft implantation but with negative culturing then the clinician should take into consideration possibility of allograft-transmitted infection (especially with clostridium, Gram-negative bacillary, enterococcal or polymicrobial infections) and empirical, antimicrobial treatment that covers those organism should be administered [96].
(d) False-positive cultures may occur in 5–13% of cases [22, 34]. Without a prospective randomized trial, however, we cannot be sure if clinical infection would ever occur in no-treatment group. In the Centeno study, allografts that were cultured were then washed three times (and the last time with bacitracin solution), potentially disinfecting the graft and explaining a very low rate of infection. In addition, it should be noted that swab cultures have several limitations in both sensitivity and reproducibility and therefore many scientists do not recommend swab culturing as an appropriate method by which to assess allograft tissue. Instead, alternative, validated microbial detection methods should be developed.

Putting all this information together then, although rare, there is a risk of contamination of the allograft and likely pathogens are often highly virulent, such as *Clostridium* or other bowel microorganisms. In cases of clinical infection after allograft implantation, with negative cultures, the clinician should take into consideration the possibility of allograft-transmitted infection (especially with clostridial, Gram-negative bacillary, enterococcal or polymicrobial infections) and empirical, antimicrobial treatment that covers the known organism should be administered.

Surgical technique: allograft compared with autograft

Regardless of graft choice, ACL reconstruction should be performed anatomically, maintaining principles of stump preservation, secure fixation and avoidance of graft impingement. One advantage of allograft tendons is that surgery does not require a graft harvest. The pre-packaged allograft is defrosted and thawed on the back table at room temperature in sterile normal saline solution, whilst the lead surgeon can begin the arthroscopic preparations. Soft tissue allografts are usually larger than autografts thereby negating the requirement to triple or augment an allograft, again shortening operative time. Once the graft is prepared and sized, it is covered in moist vancomycin-soaked gauze [120].

Notch anatomy needs to be evaluated and if impingement is likely due to either a small notch or a large allograft then both sidewall and roof notchplasty need to be performed. Impingement should be checked before insertion of the graft by visualisation of the guidewire position or insertion of the arthroscope up the tibial tunnel with the knee in extension.

In the absence of an incision for graft harvest, a separate incision is required for the tibial tunnel. This will usually be smaller than an incision for harvest of hamstring tendons and can be positioned in the transverse direction to reduce risk to the cutaneous nerves. Care should be taken to position the tunnel proximal to the hamstring tendon insertion.

Differences in post-operative management and rehabilitation

A recent systematic review and consensus suggested the use of only a criterion-based approach following ACL reconstruction rather than a time-based plan [118], but this is not appropriate following allograft ACLR where the time element plays an important role due to prolonged biologic incorporation, well after a patient may have reached and fulfilled the required criteria [88, 103]. Overall, rehabilitation should follow a systematic approach that would allow for progressive strengthening while protecting the reconstructed ligament [118].

A comparison of BTB autografts to allografts 6 months following ACLR in goats showed the autograft-reconstructed knees had less anterior/posterior displacement, twice the force to failure, a greater cross-sectional area, and a greater number of small-diameter collagen fibrils [57]. Donor site morbidity from graft harvest such as anterior knee pain in bone–patellar tendon–bone grafts (BTB) and hamstring spasm/weakness with hamstrings autografts [63, 66], is eliminated when using allograft and patients are tempted to push the boundaries of their rehabilitation. It is therefore important that patients following allograft ACLR should follow a delayed rehabilitation protocol to allow for appropriate graft incorporation and healing [75].

Despite the fact that non-irradiated allograft tissue strength has been shown comparable to that of autograft tissue, graft incorporation and biologic remodelling (ligamentization) are slower, and so these grafts may be weaker and less prepared to withhold higher loads early in the rehabilitation process [8, 118]. Therefore, progression through

the rehabilitation process, especially in allograft patients, should be individualised, based on objective measures assessed during each phase of rehabilitation, while respecting the prolonged period necessary for the graft's biologic incorporation.

Bracing after allograft ACL reconstruction

The use of a brace following an allograft ACLR may offer several benefits such as graft protection, controlled ROM, decreased swelling, improved proprioception, and improved kinematics leading to regaining a normal gait pattern [14]. Bracing in the early postoperative period has been demonstrated to reduce swelling and improve ROM, mainly as it seems to aid in achieving full knee extension [87]. The role of bracing in more advanced phases in post-op management and rehabilitation has limited evidence [86, 126]. It has been suggested, however, that functional bracing may aid in preventing re-injury in skiers [109].

Return to sport after allograft ACL reconstruction

Return to sport (RTS) is an important outcome measure after ACL reconstruction. It has been reported that 82% of patients are able to RTS, however, only 63% have been reported to be able to return to pre-injury level [3], and among children and adolescents, the proportion of patients that return to sport is higher with a recent meta-analysis reporting a 92% rate [65]. High-quality studies that specifically investigate RTS after primary allograft ACL reconstruction are hard to find. In addition, there is a lack of stringent definition for RTS in terms of type of sport, level and frequency of activity which should be established [41]. Without randomized controlled trials, data are influenced by selection bias as the indication for allograft may be affected by patient age, physical requirements, comorbidities and concomitant injuries, and these same factors influence a patient's decision to return to sport.

Precise measures of a patient's level of function and rehabilitation prior to return to sport are lacking in the literature [7], with many objective measures suggested [7, 118]. The importance of testing the injured leg in isolation (i.e. with single-leg hop tests) should be highlighted as two-leg tasks may not fully reveal unilateral deficits [26, 89]. With recent data suggesting the benefit of delayed return to sport following autograft ACLR [48], sport-specific rehabilitation for allograft ACLR should be further delayed accordingly [121]. Delaying return to sports (RTS) for at least 9 months following autograft ACLR is associated with reduced second knee injury risk [48]. This study prompts caution when it comes to allograft ACLR. Carter and Rabago [21] provide further evidence when analysing outcome in young patients age less than 25, following using tibialis anterior and achilles allografts that were not irradiated or chemically processed. Patients were managed in a brace for 4 weeks followed by a slow rehabilitation program. At 6 months most had not reached return to sport goals and were held back from sport for subsequent months. There was only one case of re-rupture in this high-risk population.

Several studies have reported that patients who undergo allograft bone–patellar tendon–bone (BPTB) ACL reconstruction, score significantly lower in postoperative Tegner activity scale [113] compared with patients undergoing autograft BPTB ACL reconstruction [11, 66, 67, 122]. One study compared patients with non-irradiated allograft BPTB to patients with an autologous BPTB graft at a minimum of 24-month follow-up, with allograft patients reporting significantly lower mean Tegner compared with autograft (5.36 for autograft and 4.97 for allograft) [11]. Patients who received the autologous BPTB graft also reported significantly lower pain in the visual analogue scale in 14 of 15 items relating to sport-specific tasks [11]. The risk of allograft failure was highest for patients with a high pre-injury activity level compared with patients with a low pre-injury activity level, and this questions the validity of the use of allograft in the highly active population that more commonly return to sport after a relatively short period of rehabilitation [11].

A meta-analysis including 17 studies that compared return to pre-injury level among patients with BPTB allograft and BPTB autograft concluded that the odds ratio (OR) for achieving pre-injury activity level was significantly in favour of the allograft, since 68.3% of patients with allograft and 57.1% with autograft were able to return to pre-injury activity level (OR = 0.62 [95% confidence interval, 0.45–0.85]) [66]. Tegner score, recorded in only 11 studies, was significantly higher in the autograft group [66]. Nevertheless, the odds for subsequent graft rupture were 3.24 times higher in the allograft group. The authors also highlighted the fact that the pre-injury level of patients selected to receive allograft might be lower compared with that of the autograft population, which could explain why the patients who received allograft were more likely to return to pre-injury activity level.

Another meta-analysis [127] reported no difference in the postoperative Tegner score between BPTB allograft and autograft in general. However, in a subgroup analysis between fresh-frozen allografts and autografts, the patients who received fresh-frozen BPTB allograft group had significantly lower Tegner scores [127]. For hamstring tendon autograft compared with allograft, a meta-analysis of randomized controlled trials found no difference in postoperative Tegner score [30]. Barrett et al. [11] found that allograft BPTB advantages include quicker return to sporting activities and disadvantages included increased laxity and higher incidence of failure. The authors found that allograft was not a superior graft source in this patient population, leading them to offer both options.

The influence of irradiation is important. Mariscalco et al. [81] conducted a systematic review which reported that no difference existed between the graft choices in terms of post-operative Tegner score. For irradiated allografts, on the other hand, another meta-analysis found the Tegner activity score to be significantly lower among the irradiated allografts compared with autografts [127].

Complications following allograft ACL reconstruction surgery

Complications following ACL reconstructions using allografts are important, and for this review, data from recent papers have been assessed and summarized (Table 2). For hardware problems, any surgery for hardware removal due to pain or discomfort was included, and for knee pain, any remnant of pain at the time of review was included. Graft failure was defined as a need for revision surgery with rupture of the graft proven by MRI imaging or by clinical instability, graft laxity defined as laxity > 5 mm in anterior translation compared with the contralateral side or a Lachman ≥ grade 2. Infections are reported in the table, including all mentions of any infectious event, deep or superficial. Finally, knee stiffness was defined as any knee requiring manipulation under anaesthesia or surgical arthrolysis. Review articles were not included in the analysis to produce the table.

Table 2 illustrates that the failure rate of allograft ACLR is extremely variable ranging from 0 to 35%. One of the confounding factors that could explain these differences is now shown to be the irradiation dose for the irradiated allografts. Rihn et al. were one of the first to support this type of sterilisation but in this study doses of 2.5 Mrad were used. Later, many authors reported an increased laxity and failure rate with irradiated allografts [100]. In fact, Dashe et al. [32] showed in his review, and DiBartola et al. [35] proved mechanically that irradiation greater than 2.5 Mrad was harmful to the mechanical properties of the transplant. Dashe et al. concluded that this type of sterilisation should be performed with low dose gamma irradiation (< 2.1 Mrad). According to this principle, no differences were found in clinical outcomes between autograft, non-irradiated allograft and low-dose irradiated allograft. Another factor that has been proven to increase the failure rate of allografts is smoking [30, 66].

Concerning the infection rate, no proof of greater risks has been reported in the latest studies concerning allografts [47, 75]. The principal problem that can be related with septic complication is the transmission by the allograft. To our knowledge, no publication reported contamination by HIV through musculoskeletal allograft, but safety remains the main aim and very strict procedures are applied in tissue banks to avoid any transmission. One recent study based on the MOON cohort (2198 patients) suggests that there is a lower risk of infection when using a BPTB autograft comparing with hamstring autograft and all types of allografts [17]. According to this and other papers, allograft does not seem to be a risk factor for infection [9, 30, 116].

Table 2 also shows that allografts are rarely mentioned to cause stiffness with rates of manipulation or arthrolysis between 0 and 6, 7%, but this is reported in only 4 of 41 studies. In a recent meta-analysis, Yao et al. did not find any difference between autograft and allograft for last follow-up range of motion and for anterior knee pain [127].

In conclusion, allografts with good sterilisation procedure and/or low dose irradiation do not seem to be associated with higher complication rate than autografts.

Clinical outcomes

For this review, we have assessed the literature from 2000 onwards related to single bundle ACL reconstruction. There has been an evolution in the results over time, with the main parameters being irradiation of the graft, processing of the graft and the age of the patient. In this section, we outline the progression, initially by summarising recent clinical studies and then by detailing the clinical reviews and meta-analyses.

11 comparative clinical studies were found, and the main results are summarized in Table 3. Four studies were randomized [16, 73, 97, 102] and seven non-randomized [11, 24, 36, 45, 98, 111, 115]. Similar clinical outcomes between allograft and autografts were found by four authors [24, 38, 98, 117]. Chang et al. [24] compared BTB autograft with BTB allograft for primary ACL reconstruction when augmented with iliotibial tenodesis and found no significant difference in clinical outcome scores or KT-1000. It is important to note that this was a retrospective review and mean follow-up assessed at 3 years. Another study by Edgar et al. [36] prospectively analysed the clinical outcomes of autograft 4-strand hamstring with allograft 4-strand non-irradiated hamstring and found no difference in Lysholm, IKDC, Tegner and KT-1000. In contrast to this, four recent studies [73, 102, 110, 115] have concluded that patients had similar subjective clinical results, but the difference in instrumented KT-1000 laxity between the two groups was significant in favour of the autograft group in 3. Rose et al. [102] compared hamstring graft versus folded over tibialis anterior allograft treated with low-dose irradiation and Allowash preparation showing no difference in graft failure.

Gorchewsky et al. [45] found a 45% failure rate in the allograft group in their study. Based on their data, they concluded that the regular use of BPTB allografts, particularly for physically active patients, is inappropriate. However, it must be noted that the allografts used in this study were irradiated and treated with acetone as part of the sterilisation process. Bottoni et al. [16] found that over 80% of all grafts were intact and had maintained stability. However, those

Table 2 Literature review of complications following ACL reconstruction with allografts

Author year	Journal	Number of patients	Age at surgery (years)	Follow-up (months)	Hematoma (*n*/%)	Hardware problem (*n*/%)	Knee pain (*n*/%)	Graft laxity (*n*/%)	Graft failure (*n*/%)	Infection (*n*/%)	Stiffness (*n*/%)
Bach 2005 [4]	AJSM	59	Mean: 41 18–61	At least 24	0	3/5.1	1/1.7	X	5/8.5	0	0
Barrett 2005 [10]	AJSM	38	40 to 58	3.4	X	X	X	3/7.9	1/2.6	0	0
Rappé 2007 [99]	AJSM	Ir: 33 Non-Ir: 42	Ir: 26 Non-Ir: 27	At least 6	X	X	X	X	Ir: 11/33 Non-Ir: 1/2.4	X	X
Edgar 2008 [36]	CORR	46	Mean: 31	48	0	0	0	0	3/8	0	0
Katz 2008 [64]	Arthroscopy	628	Mean: 32 15–61	X	X	X	X	X	X	4/0.63	X
Nakata 2008 [90]	Arthroscopy	61	Mean: 20.9	138	X	X	8/13	2/3	X	0	0
Almqvist 2009 [2]	KSSTA	55	Mean: 25 17–50	126	X	X	X	0	4/7.3	3/5.5	0
Sun 2009 [110]	KSSTA	Non-Ir: 34 Ir: 32	Non-Ir: 31.8 Ir: 30.1	Non-Ir: 27.3 Ir: 25.6	0	0	0	Non-Ir: 3/8.8 Ir: 11/34.4	X	Non-Ir: 1/2.9 Ir: 0	0
Barber 2010 [5]	Arthroscopy	32	Mean: 35 18–55	35	X	X	X	1/3.1	11/34.4	0	0
Barrett 2010 [11]	Arthroscopy	78	12–40	62.7	X	X	X	19/24.4	12/15.4	X	X
Greenberg 2010[47]	JBJS	640	Mean: 31.2	11.7	X	X	X	X	X	17/2.66	X
Lee 2010 [71]	Arthroscopy	BPTB: 60 TA: 153	BPTB: 27.9 TA: 28.6	BPTB: 39 TA: 34	X	X	X	BPTB: 2/3.3 TA: 3/2.0	BPTB: 5/8.3 TA: 5/3.3	0	BPTB: 4/6.7 TA: 3/2.0
Mascarenhas 2010 [84]	Arthroscopy	19	Mean: 28.11	124	X	X	X	1/5.3	0	0	0
Shah 2010 [105]	Arthroscopy	144	Mean: 29.5	40	X	X	X	1/0.7	8/5.7	0	X
Snow 2010 [108]	KSSTA	64	Mean: 27 16–55	At least 24	X	1/1.6	X	0	5/8	0	0
Chehab 2011 [25]	HSS J	43	30–68	33	X	X	X	0	0	1/2.3	0
Sun 2011 [111]	Arthroscopy	31	20–51 Mean: 30.3	43	X	1/3.2	0	10/32.3	X	0	0
Sun 2011 [112]	AJSM	95	18–59 Mean: 31.2	95	0	0	0	8/8.4	X	2/2.1	0
Ellis 2012 [38]	Arthroscopy	20	14–18	15.4	X	X	X	X	7/35	X	X
Guo 2012 [50]	Arthroscopy	101	16–40	X	X	X	X	13/12.9	6/5.9	0	0

Table 2 (continued)

Author year	Journal	Number of patients	Age at surgery (years)	Follow-up (months)	Hematoma (*n*/%)	Hardware problem (*n*/%)	Knee pain (*n*/%)	Graft laxity (*n*/%)	Graft failure (*n*/%)	Infection (*n*/%)	Stiffness (*n*/%)
Lawhorn 2012 [70]	Arthroscopy	48	Mean: 33.3	At least 24	0	2/4	X	0	0	0	1/2
Crawford 2013 [28]	The Knee	271	12–60	6	2/0.5	6/2.2	X	X	1/0.2	11/4.1	1/0.2
Goddard 2013 [44]	AJSM	32	8–16	At least 24	1/3.1	X	X	1/3.1	2/6.2	0	0
Indelicato 2013 [54]	KSSTA	67	Mean: 34	24	X	0	0	0	0	0	0
Maletis 2013 [76]	BJJ	4014	Mean: 33.9	0 to 60	X	X	X	X	70/17.4	X	X
Maletis 2013 [78]	AJSM	4404	Mean: 33.9	X	X	X	X	X	X	17/0.39	X
Noh 2013 [93]	Arthroscopy	77	19–45	24 to 39	0	0	0	2/2.6	0	1/1.3	0
Shybut 2013 [107]	Bull hosp Jt Dis	19	19 to 60	24 to 38.4	X	X	X	4/21.0	2/10.5	X	0
Wasserstein 2013 [123]	AJSM	676	15–60	X	X	X	X	X	25/3.7	X	X
Barber 2014 [6]	Arthroscopy	28	14–25	37	X	X	X	0	2/7.1	X	0
Engelman 2014 [39]	AJSM	38	11–19	32.5	X	X	X	0	11/28.9	0	0
Bottoni 2015 [16]	AJSM	49	Mean: 29	126	X	X	X	X	13/26.5	X	X
Kang 2015 [62]	KSSTA	84	Mean: 29	32	X	X	X	5/5.9	X	0	0
Yoo 2015 [128]	KSSTA	64	13–52	34.5	X	X	X	4/6.25	1/1.6	2/3.1	0
Niu 2015 [91]	KSSTA	88	Mean: 25	At least 48	0	0	0	5/5.7	7/7.9	0	0
Dai 2016 [31]	KSSTA	113	20–48	52	0	0	0	5/4.4	10/8.8	0	0
Rose 2016 [102]	The Knee	57	31–41	24	X	1/1.7	X	X	3/5.3	2/3.5	1/1.7
Niu 2016 [92]	The Knee	96	21–31	40	X	X	X	11/11.5	5/5.2	0	0
Kane 2016 [61]	KSSTA	123	Under 25 skeletally mature	At least 24	X	X	X	X	12/9.8	X	X
Tian 2016 [115]	AJSM	43	18–50	81.6	0	0	X	X	13/30.2	2/4.6	0

Table 2 (continued)

Author year	Journal	Number of patients	Age at surgery (years)	Follow-up (months)	Hematoma (*n*/%)	Hardware problem (*n*/%)	Knee pain (*n*/%)	Graft laxity (*n*/%)	Graft failure (*n*/%)	Infection (*n*/%)	Stiffness (*n*/%)
Mardani-Kivi 2016 [79]	Int Orthop	104	20–51	56	0	0	0	17/16.3	2/1.9	0	0

BPTB bone–patellar tendon–bone, *TA* tibialis anterior, *Ir* irradiated, *Non-Ir* non-irradiated, *X* not specified

patients who had an allograft failed at a rate over 3 times higher than those with an autograft.

Recent studies, however, show similar failure rates between allograft and autograft. In a 5-year follow-up of patients who had ACL reconstruction with either Achilles allograft or BTB autograft, Poehling and colleagues demonstrated over all similar long-term outcomes between groups [98]. Of note, the allograft patients reported less pain 6 weeks after surgery and better function 3 months and 1 year after surgery; and fewer activity limitations throughout the follow-up period.

Case series and Registry data have also provided further information on the outcome of using allograft tissue. Maletis et al. [77] examined the results of 9817 primary ACL reconstructions recorded in an ACL-R registry showing that reconstruction with allografts has an aseptic revision rate of 3.02 times higher than BPTB autograft. Failure rate was reported four times higher in the Multicenter Orthopaedic Outcomes Network (MOON) group study [59] and 15 times higher according to Ellis et al. [38].

On the other hand, clinical results with non-irradiated and/or unprocessed allograft have been reported to be comparable to those with autograft [33, 85]. In a series of BTB allografts and autografts in 81 patients under age 25, a failure rate of 7.1% (2 of 28) for the allografts and 9.4% (5 of 53) for the autografts was reported [7]. Reports of case series showing higher rupture rate of allografts over autografts have been criticised in a recent review article [21] citing that when confounding variables are reduced there is no difference in outcome, even in the young under 25 years old, provided grafts are not irradiated and have not had chemical processing, and the patient complies with a slower rehabilitation program.

Systematic reviews of outcome by graft choice

Several recent systematic reviews and meta-analyses have also been written on this topic and over the years the conclusions have evolved. In the 2009 review by Carey et al. [20], short-term clinical outcomes of anterior cruciate ligament reconstruction with allograft were not significantly different from those with autograft, and in the 2010 systematic review by Foster et al. [43], it was concluded that overall the graft source seems to have a minimal effect on the outcome of patients undergoing anterior cruciate ligament reconstruction. In addition, Lamblin et al. [68] also found no difference between nonirradiated allograft and autograft tissue in ACL reconstruction in a 2013 meta-analysis of ACL studies published over a 32-year period.

Against the trend at that time, Kraeutler et al. [66], performed an important meta-analysis of 5182 patients undergoing ACL reconstruction using BTB. When an autologous graft was used, lower rates of ACL re-rupture, lower levels

Table 3 Analysis summary of 11 recent comparative clinical studies involving allograft ACL reconstruction

Author Year	Journal	Country	Number in study (number analysed)	Study design	Mean follow-up in months	Graft	Sterilisation	Procedure duration		Lysholm		IKDC subjective		Failures		Instrumented laxity			
																Autograft		Allograft	
								Autograft	Allograft	Autograft	Allograft	Autograft	Allograft	Autograft	Allograft	<5 mm	>5 mm	<5 mm	>5 mm
Peterson 2001 [97]	Arthr	USA	119 (60)	Randomized	63	BPTB	Non-irradiated	–	–	88.6	90	–	–	3%	3%	93	7	100	0
Chang 2003 [24]	Arthr	USA	89 (79)	Non-randomized	37	BPTB	30 non-irradiated, 10 irradiated	–	–	95.5	93.8	–	–	0%	7%	91	9	91	9
Barrett 2005 [10]	ASJM	USA	63 (63)	Non-randomized	41	BPTB	Non-irradiated	–	–	92	91	–	–	0%	3%	100	0	92	8
Gorschewsky 2005 [45]	AJSM	EUR	268 (186)	Non-randomized	71	BPTB	Acetone solvent drying; irradiation 1.5 Mrad	–	–	93.6	78.3	87.5	36	6%	45%	–	–	–	–
Poehling 2005 [98]	Arthr	USA	219 (159)	Non-randomized	50	BPTB/ Achilles	Freeze-dried	–	–	–	–	90	96	–	–	–	–	–	–
Edgar 2008 [36]	CORR	USA	104 (83)	Non-randomized	50	Hamstrings	Non-irradiated	–	–	91	92.7	87.6	87	8%	4%	92	8	98	2
Sun 2011 [112]	Arthr	China	76 (67)	Non-randomized	42	Hamstrings	Irradiation 2.5 Mrad	76	59	89	87	87	83	–	–	92	8	68	32
Bottoni 2015 [16]	AJSM	USA	99 (79)	Randomized	126	Hamstrings/ Tib post	non-irradiated	71	65	–	–	77	74	8%	26%	–	–	–	–
Li 2015 [73]	Arthr	China	102 (95)	Randomized	71	Hamstrings/ Tib ant	Irradiation 2.5 Mrad	75	59	91.3	88.7	88	84	–	–	96	4	90	10
Tian 2016 [115]	AJSM	China	107 (83)	Non-randomized	83	Hamstrings	Irradiation 2.5 Mrad	115	106	90	86	89	85	8%	30%	97	3	87	13
Rose 2016 [102]	The Knee	USA	98 (57)	Randomized	24	Hamstrings/ Tib ant	Low-level < 20 kGy irradiated + Allowash	42.0	42.0	75.9	83.7	83.6	77.2	6%	4%	Mean 0.88		Mean 0.40	

of knee laxity, and improved single-legged hop test results were observed postoperatively, compared with patients that underwent reconstruction with allograft. The authors recommended autograft BTB over allograft BTB, especially in the younger and more active patients.

Three reviews were published in 2014. Yao et al. [127] reported on a meta-analysis of patella tendon grafts finding a significant difference in clinical failure, with autografts failing less often than allografts, though clinical scores were not statistically different. Lenehan et al. [72] conducted a systematic review of patients younger than age 25 and concluded that allografts had a higher re-rupture rate, and Mariscalco et al. [81], also in 2014, addressed the issue of irradiation, critically reviewing the outcomes of ACL reconstruction with autograft versus exclusively nonirradiated allograft tissue. The authors concluded that there was no statistically significant difference with regard to failure risk, physical examination findings, or patient-reported outcome scores.

In 2015, four analyses were published. Wei et al. reported on a meta-analysis of autografts and non-irradiated allografts. 12 studies up to 2013 were included with only 5 being randomized controlled trials [125]. Patients with autograft exhibited little clinical advantage over non-irradiated allograft with respect to knee stability, function and side effects. Zeng et al. [130] analysed 9 RCTs and 10 systematic reviews in a 'meta-analysis of RCTs and a systematic review of overlapping systematic reviews'. For the meta-analysis part of the paper, noting that only RCTs were included, there were no significant differences between autograft and nonirradiated allograft for all indices and graft failure assessed, but when comparing autograft with irradiated allografts then the autografts had lower clinical failure rate, better Lachman test result, and better Tegner scores. The systematic review of overlapping systematic reviews agreed with the findings, concluding that autografts had greater advantages than irradiated allograft with respect to function and stability, whereas there were no significant differences between autograft and nonirradiated allograft.

This study supports the similar findings reported by Mascarenhas et al. [83], also in 2015, when analysing 8 meta-analyses containing a total of 15,819 patients. Multiple studies were noted to show a lower re-rupture rate with autografts compared with allografts, but overall there did not appear to be a significant difference in clinical outcomes. Four reported similar outcomes and four of the meta-analysis reporting autografts to be superior in one aspect. Age was felt to be the factor explaining the diversity of results along with a variable level of detail reported in trials of allograft sterilisation techniques.

The influence of age on results was assessed by Wasserstein et al. [124] who reported on 7 studies addressing patients age less than age 25 and showed overall a relative risk of failure for autografts was 0.36. For autografts, the pooled failure prevalence was 9.6% (76/788) and for allografts the prevalence was 25.0% (57/228). The number needed to benefit to prevent 1 failure using autograft was 7 patients (95% CI 5–10). Only two studies assessed autograft versus non-irradiated allograft and in this analysis no statistically significant difference in graft failure was seen.

In 2016, Joyce et al. [58] reported on the analysis of 17 studies on non-irradiated patella tendon and soft-tissue allografts. There was only one comparative study found and this showed no difference in clinical and failure results. Including the additional case series in the analysis showed that the outcome with the two non-irradiated graft types was qualitatively similar for failure, laxity and PROMS.

Subsequently, Lording et al. [74], undertook a systematic review of 28 studies covering autografts, non-chemically treated or irradiated allografts, and chemically treated or irradiated allografts. By including more recent papers they showed that both groups of allografts had higher failure rate than autograft, though non-irradiated and non-cleansed grafts were better than irradiated and treated grafts. Clinical scores were similar for autograft and non-irradiated, non-chemically treated allograft reconstructions, but worse for treated grafts. The authors recommended caution in using allografts in the young.

The papers swinging the balance in this work from Lording included work by Bottoni et al. [16] who assessed military personnel and reported revision rate to be increased three-fold in non-irradiated, non-chemically treated allograft reconstructions at 10 years, and Kane [61] who assessed patients under 25 at minimum 2-year follow-up, reporting significantly increased failure rate for non-irradiated, non-chemically treated allograft compared with autograft.

In the most recent assessment Wang et al. [122], reported on a meta-analysis of randomized controlled trials comparing Hamstring tendon autograft versus soft tissue allograft and showed that hamstring tendon autografts had some clinical advantages over soft-tissue allografts with respect to subjective patient evaluation and knee stability reconstruction. Significant differences were found in subjective IKDC and Tegner scores between the groups but difference in the failure rate was not significant (4 of 396 failed in the hamstring tendon autograft group and 13 of 389 in the soft-tissue allograft group).

Discussion and graft selection: allografts versus autografts

The aim of this clinical review is to present the current evidence on the use of allografts in primary ACL reconstruction. The discussion is not a consensus statement but a state of the art review of publications in the literature.

An overview of advantages and disadvantages of the different graft choices is shown in Table 2. Compared to autografts, allografts offer several potential advantages to both the patient and the surgeon, including the absence of donor site morbidity, shortened operating time, greater availability, more predictable graft sizes, and comparable strength and stiffness to autograft tissue at the time of reconstruction [16, 121]. We have shown that there are, however, some disadvantages that need to be considered, such as increased time to incorporation, variability in mechanical strength due to sterilisation techniques and use of irradiation, risk of disease transmission, immunogenic reaction, reports of higher failure rates in the young, and higher cost [16, 69, 104, 115, 117, 121]. Earlier cost effectiveness analysis work has shown that allograft reconstruction is the least effective and most costly method [8]. This has not been the remit of this study but it is reported elsewhere in this journal.

The growing amount of data has helped with decision making in relation to using allograft tissue for ACL reconstruction. There has been an evolution in the results over time, with new parameters found to be affecting results including irradiation, chemical processing of the graft and the age of the patient. The use of chemical processing for preparation of grafts has been identified as a high-risk factor for graft failure and in analysis of registry data where infection has been shown to be low, there does not seem to be any advantage gained using such techniques for graft preparation. For an older patient, outcomes are comparable between allograft and autograft provided the tissue is non-irradiated and that the rehabilitation timeline appreciates the slower biological incorporation of the graft. The lack of morbidity that is associated with graft harvesting is considered to be an advantage in this age group. In highly active younger patients (< 25 years old), where failure rates are higher in general, allografts have been shown to have a higher risk of failure than autografts. In this cohort, autografts should remain the gold standard. Non-irradiated allografts are a safe back up option in this younger age group in the absence of adequate autograft tissue or the presence of multi-ligament knee injury.

Use of allograft tissue for ACL reconstruction is supported by the American Academy of Orthopedic Surgeons in their Clinical Practice Guidelines for the Management of ACL Ligament Injuries [20], stating that strong evidence supports use of autograft or allograft, noting that measured outcomes are similar but that results may not be generalizable to young and highly active patients.

Taken together, graft selection should be individualised according to multiple patient factors such as gender, age, activity level and type of activity, complications and other patient needs and demands [52]. We believe it is important for a surgeon to be familiar with a variety of allografts, along with the specific associated surgical procedures and the advantages and disadvantages of each, with the aim of offering the best graft selection for each individual patient. Patient preference will remain a large influence on graft selection in ACL reconstruction but from this robust narrative review of the available literature, a surgeon will be able to provide current evidence from which a patient can make their choice.

Conclusions

Several authors have reported that equivalent clinical outcomes can be achieved when comparing autograft and allograft ACL reconstructions. However, it is important to note that inferior outcomes with allografts have been reported in young (< 25 years) highly active patients. Data on post-operative rehabilitation indicate a delayed return to sport of at least 12 months over previous time periods of 9 months following allograft ACLR. Inferior outcomes are also reported when irradiated or chemically processed grafts are used. All allografts when used for primary ACL reconstruction should be fresh frozen and non-irradiated.

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Compliance with ethical standards

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