

Outcome of ACL Reconstruction Utilizing Supercritical CO₂ Sterilized Allografts

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Introduction:

The ipsilateral hamstring tendon and bone-patella-tendon-bone are considered to be the gold standard graft in anterior cruciate ligament (ACL) reconstruction surgery. However, graft site morbidity, the necessity for revision surgeries and a more difficult rehabilitation has led to investigation into allograft tissue. The advantages of the use of allograft in ACL reconstruction include no donor site morbidity, no associated weakness of the knee flexor or extensor mechanisms, shorter operating time, less post-operative pain, no loss of donor tendon function and availability of larger graft sizes.

There has been a reluctance to adopt allografts given their poor results in the literature. Traditionally, allografts are harvested in non-sterile environments and are then sterilised with gamma radiation. This is recognised to induce structural damage to the tissue and influences the success rate of ACL reconstruction surgery. The majority of the literature available on allograft tissue reports on irradiated allografts. A systematic review by Mascarenhas et al found no significant difference in ACL graft re-injury rate, postoperative laxity or patient reported outcomes in ACL reconstruction between autograft and non-irradiated allografts.

In Australia, allograft tissue that has been available for use in ACL reconstruction has undergone processing that includes antibiotic and antiseptic washing. With the increasing availability of human tissue banks and new methods of preparing allografts, supercritical carbon dioxide (SCCO₂) processing is another alternative in graft preparation for ACL reconstruction. This technology is used to terminally sterilise tendon allografts, by washing them with SCCO₂ removing the need for irradiation. This process of sterilisation has been shown to exhibit strong sterilisation properties and is non-toxic, inert and does not leave any residue in the tissue.

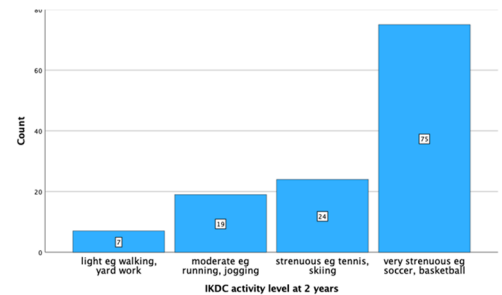
The purpose of this study is to report the 2 year re-injury rates, knee scores and clinical outcomes of SCCO₂ processed human allografts in a prospective cohort of patients undergoing primary ACL-R.

Methods:

Patients underwent primary ACL reconstruction with SCCO₂ processed human gracilis, peroneus longus, semitendinosus, tibialis anterior and tibialis posterior tendon allografts. Patient demographics were collected, as well as tendon donor age and sex. At 1 year, subjective International Knee Documentation Committee (IKDC), and ACL RSI scores were collected, as well as clinical evaluation. At 2 years, the IKDC and ACL RSI scores were repeated, and return to sport and further knee injuries were recorded.

Results:

144 participants with a mean age of 27 ± 10 years formed the study group. The majority (58%) were male, and 24% had a family history of ACL rupture. The lost to follow-up rate was 9% ($n = 13$). The mean allograft diameter was 8.9 ± 1.0 mm. At 2 years, 79% of subjects reported regular participation in strenuous or very strenuous sports.



ACL graft rupture occurred in 5% ($n = 7$), and contralateral ACL occurred in 2%. All graft ruptures were in patients aged ≤ 25 years ($p < 0.006$). Donor age (≤ 40 years, > 40 years) and gender was not associated graft rupture risk ($p > 0.05$). The mean IKDC subjective score was 91 ± 11 , the mean ACL RSI score was 69 ± 23 .

Conclusions:

This study investigated the clinical outcomes of supercritical CO₂ sterilized tendon allografts at 2 years post-operatively in patients undergoing primary ACL reconstruction. We observed an ACL graft re-rupture rate of 5% at 24 months and a contralateral ACL rupture rate of 2%. This is a group at high-risk of both ipsilateral and contralateral ACL injury, and the rate we observed is concordant with the published estimates of re-rupture rates of autograft in this population^(Wiggins et al). In addition a high rate of return to sport and successful clinical outcomes was observed, suggesting that SCCO₂ sterilization results in a suitable graft choice for primary ACL-R.