

Outcomes of Endoscopic ACL Reconstruction utilising Supercritical CO₂ Sterilised Allografts: Progress Report

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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 primary and revision 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 recent 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 allografts¹. In Australia, allograft tissue that has been available for use in ACL reconstruction has been harvested under sterile conditions and undergone processing that includes antibiotic and antiseptic washing. Our research paper reported that these fresh frozen sterile harvest allografts are non-inferior to autograft tissue in ACL reconstruction².

With the increasing availability of human tissue banks and new methods of preparing allografts, supercritical carbon dioxide (CO₂) processing is another alternative in graft preparation for ACL reconstruction. This technology is used to terminally sterilise tendon allografts, by washing them with supercritical CO₂ 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.

AIM:

This study aims to prospectively report on patients who receive supercritical CO₂ sterilised allografts for ACL reconstruction. The primary outcome is to observe re-injury rates within the first 2 years post-surgery and assess if supercritical CO₂ sterilised allografts are a comparable graft option for ACL reconstruction to ipsilateral hamstring autograft and fresh frozen allograft.

HYPOTHESIS:

We hypothesise that supercritical CO₂ sterilised allografts will be a non-inferior graft option for ACL reconstruction.

METHODS:

Subjects who meet the inclusion criteria are recruited to the study.

Inclusion Criteria:

- Undergoing primary ACL reconstruction with Prof Pinczewski or A/Prof Roe between May 2019 and December 2020 and receive a supercritical CO₂ sterilised allograft
- Be willing and capable of providing written informed consent

Exclusion Criteria:

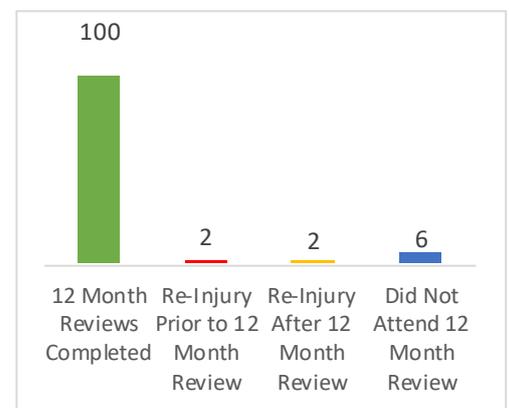
- Subjects who do not wish to participate in a research program
- Subjects undergoing revision surgery or have had a previous contralateral ACL injury or reconstruction
- Subjects who are seeking compensation for their injury

Patients will be reviewed at the 1 and 2 year post-operative mark with full clinical examination, International Knee Documentation Committee (IKDC) evaluation, Lysholm Knee Score, ACL Return to Sport Index and an EOS scan for posterior tibial slope. Subjects will be matched for age, gender and IKDC activity level and compared to historic control groups who received ipsilateral hamstring tendon autografts and fresh frozen allografts.

PROGRESS RESULTS:

Patients Recruited (15.5.2019-17.12.2020)	N = 214
Age 25 or less at time of surgery	N = 103

12 MONTH REVIEWS:



To date, in terms of 1 year re-injury rates and clinical and patient reported outcomes, supercritical CO₂ allografts are superior to ipsilateral hamstring autograft and fresh frozen allograft in ACL reconstruction. Follow-up will continue to determine the 2 year outcomes.

REFERENCES:

1. Mascarenhas R, Erickson BJ, Sayegh ET, et al. Is there a higher failure rate of allografts compared with autografts in anterior cruciate ligament reconstruction: a systematic review of overlapping meta-analyses. *Arthroscopy*. 2015;31(2):364-372.
2. Shumborski S, Salmon LJ, et al. Allograft Donor Characteristics Significantly Influence Graft Rupture After Anterior Cruciate Ligament Reconstruction in a Young Active Population. *Am J Sports Med*. 2020;48(10):2401-2407.