Outcomes of ACL Reconstruction Using Supercritical CO2-Sterilized Allografts

A/Prof Keran Sundaraj
Dr John Farey, A/Prof Justin Roe,
Dr Lucy Salmon, Vivianne Russell,
Prof Leo A. Pinczewski AM

North Sydney Orthopaedic Research Group
North Sydney Orthopaedic & Sports Medicine Centre
The Mater Hospital

Disclosures

Dr Keran Sundaraj

- Speaker for Corin U.S.A., DePuy, Orthofix, Inc., Stryker
- Paid Consultant for DePuy, Stryker

Professor Leo Pinczewski

- IP royalties from Australian Biotechnologies
- Stock and stock options from Australian Biotechnologies
- Research support from the Friends of the Mater Foundation, Smith+Nephew.
- IP royalties from Signature Orthopaedics

A/Professor Justin Roe

- Stock in 360KS
- Paid Speaker for Smith and Nephew
- Paid Consultant for Enovis
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Introduction

Benefits of allograft for ACL Reconstruction

- absence of donor site morbidity,
- reduced post-operative pain compared to autografts,
- predictable graft size compared to hamstring tendon (HT) autografts

However, the use of allografts for primary ACL reconstruction is contentious.

- Observational studies report a higher time-dependent risk of re-rupture compared to autografts, especially for irradiation-based sterilization [1-4]

BUT historical series may be biased by

- graft processing methods that degrade the biomechanical properties of donor tendons
- heterogenous graft processing methods [5]

Allograft Processing Techniques

- Allograft processing techniques that maintain the structural integrity of collagen without compromising sterility or immunogenicity of donor tissues are desirable.
- Allograft processing ‘disinfection methods’ include chemical and antibiotic treatments that target microorganisms
- Allograft processing ‘terminal sterilization methods’ traditionally include irradiation, ethylene oxide, or heat treatments and eliminate living microorganisms

- **Supercritical carbon dioxide ($SCCO_2$) processing is considered a terminal sterilization method for biomaterials at physiological temperatures without irradiation**
- In vivo use of $SCCO_2$ processed tendon allografts for primary ACL-R has not been reported
- **The aim of this study** was to report ACL graft reinjury rates of patients undergoing primary ACLR using human allografts processed with terminal SCCO2 sterilization, in a prospective cohort at 1 and 2 years postoperatively, as well as to report validated knee scores and clinical assessments.

Operative Technique & Participant Flow

- The tendon allograft was prepared as either a 2-, 3-, 4- or 6 -strand using a No. 1 Vicryl (Ethicon) whipstitch to achieve a suitable size
- Anatomical femoral tunnel drilling via the anteromedial portal for a target tunnel position 5 mm anterior to the posterior wall of the lateral femoral condyle
- The tibial tunnel was drilled 1/3 between the anterior horn insertion of the lateral meniscus and medial tibial spine.
- Femoral and tibial graft fixation was achieved with a PEEK RCI interference screw

ACL RC with SCCO2 Allograft
May 2019 - December 2020
N=213

Inclusion Criteria
- isolated ACL RC
- no contralateral ACL injury
- not receiving compensation
- consent to research
N=144

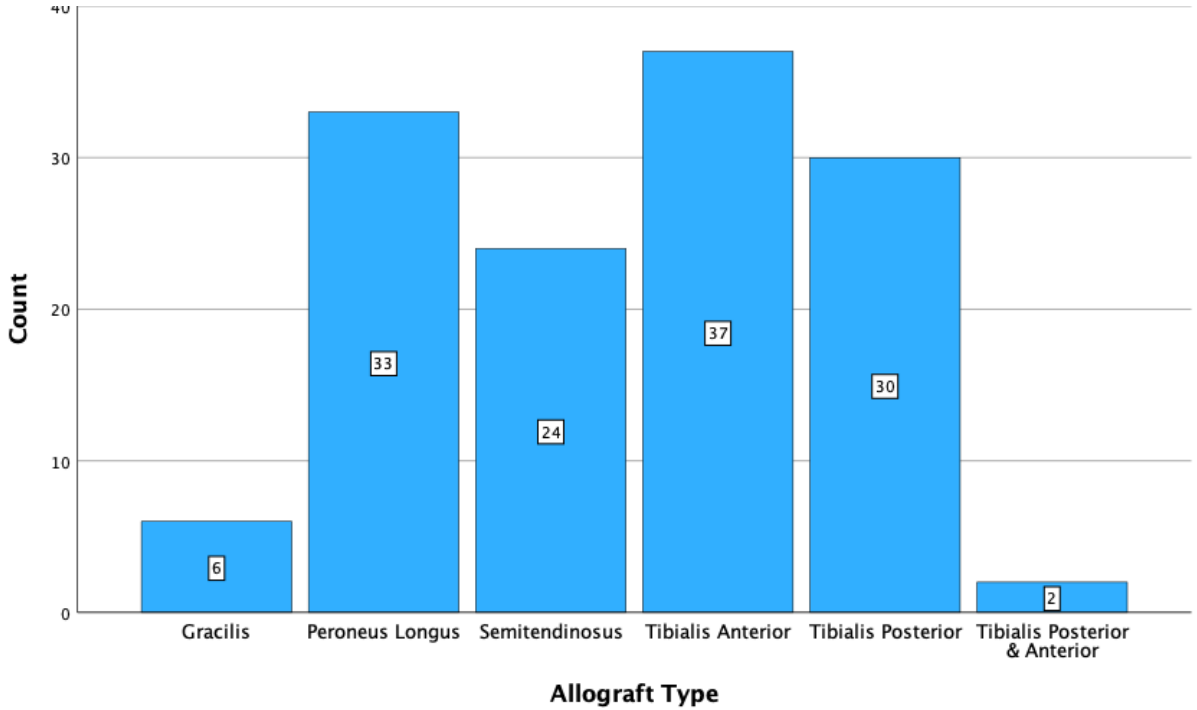
Primary outcome: Re-injury
Secondary outcome: PROMs
132 (92%) reviewed at 2 years

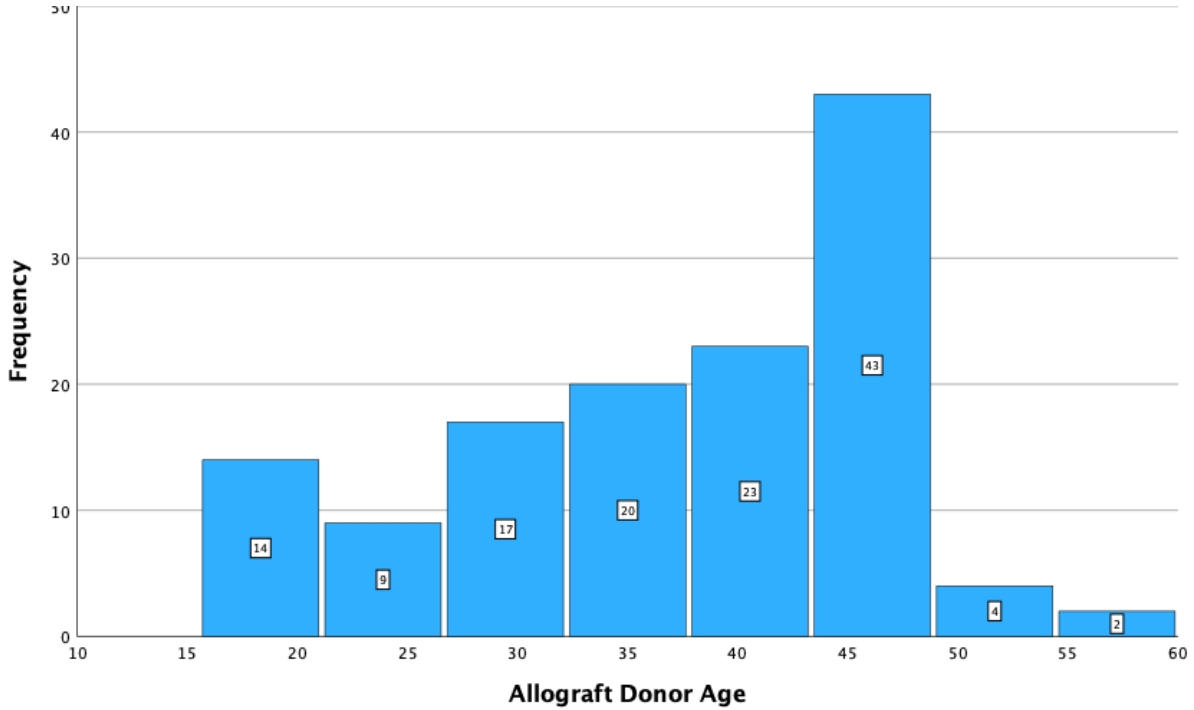
Patient Characteristics

Patient Age median (IRQ)	26 (14)
Male (%)	77 (58%)
Surgery < 12 weeks (%)	113 (86%)
Concurrent Meniscal Surgery (%)	
Medial Meniscus Repair	5 (4.0)
Medial Meniscus Partial Excision (<1/3)	0 (0.0)
Lateral Meniscus Repair	8 (6)
Lateral Meniscus Partial Excision (<1/3)	18 (14)
Tibial Slope (Median + Range)	11° (4-20°)

Cohort consisted of isolated ACL injury to reduce confounding.
Those with >1/3 meniscectomy or chondral injury were excluded n=69, but followed for repeat ACL injury

Allograft Characteristics





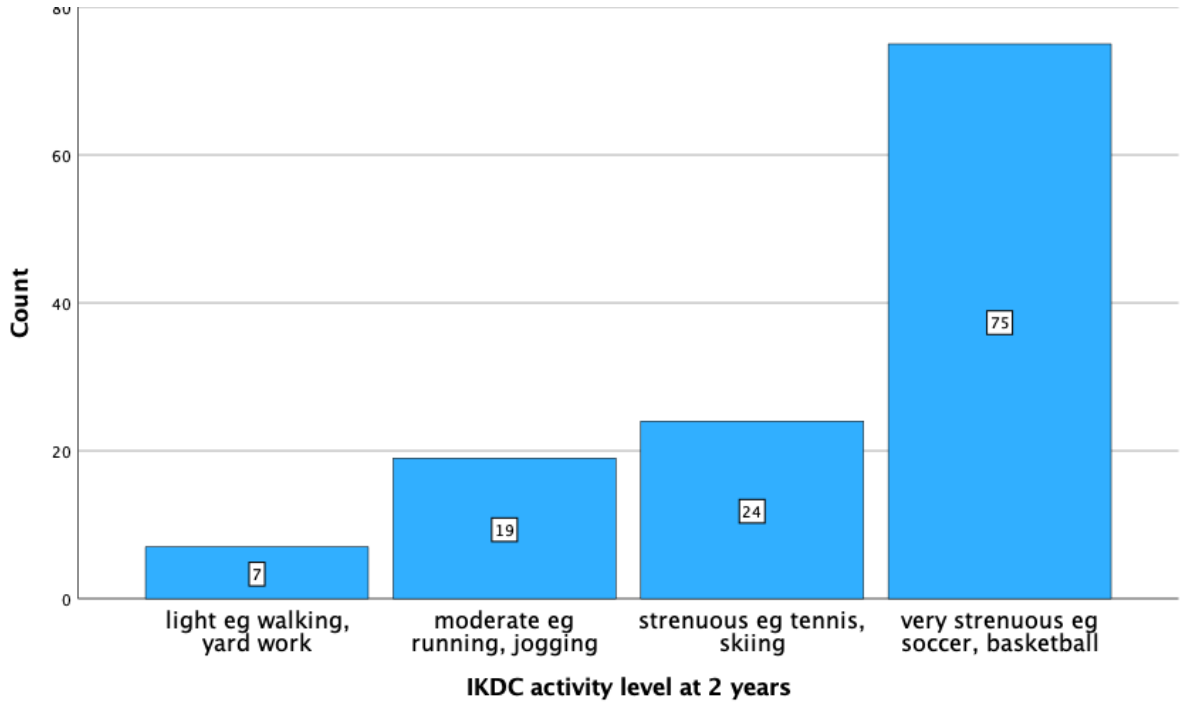
ACL Graft Failure

- ACL graft failure occurred in 7 patients over 2 years (5%)

		N	Graft Rupture, %	p	Odds Ratio (95%CI)
Age	25 or less	66	7 (11%)	0.007	*
	>25 years	66	0		
Gender	Female	55	4 (7%)	0.401	1.9 (0.4-9.0)
	Male	77	3 (4%)		
Donor Age	>40 years	66	4 (6%)	0.699	1.4 (0.3-6.3)
	40 or less	66	3 (5%)		
Donor Gender	Male	110	6 (6%)	0.862	1.2 (0.1-10.6)
	Female	22	1 (5%)		
Family Hx	Yes	31	3 (10%)	0.108	2.6 (0.5-12.3)
	No	101	4 (4%)		
Tibial Slope	≥ 12°	49	5 (10%)	0.108	4.0 (0.7-21.3)
	< 12°	72	2 (3%)		

- Age was the only significant predictor of ACL graft failure.
  - All graft failures were in those <25 years

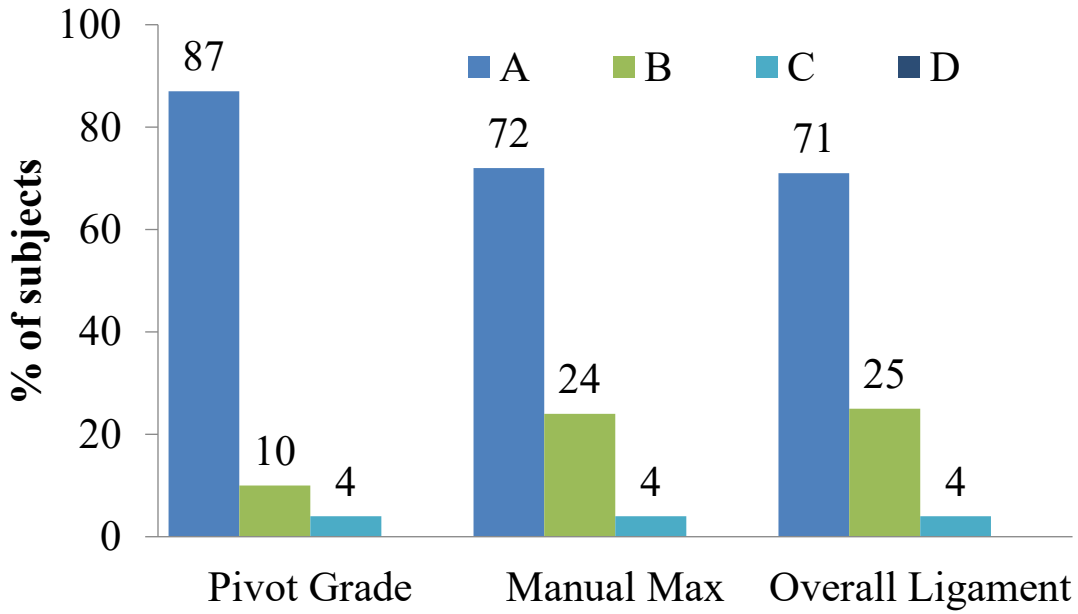
Activity Level at 2 years



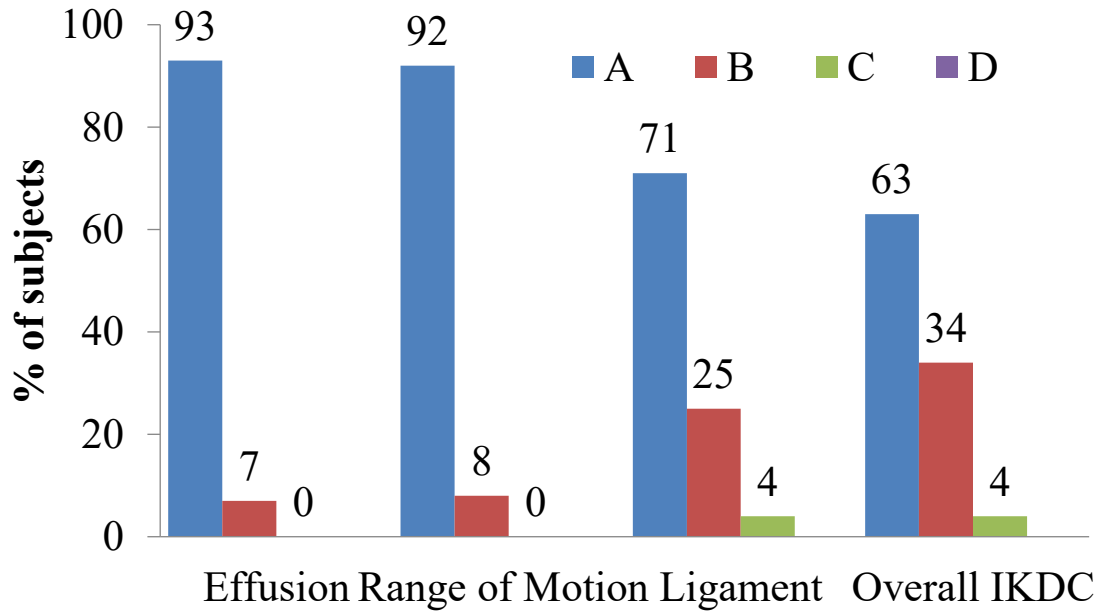
85 subjects (68%) reported that they had returned to their preinjury level of activity.
86 (69%) reported that their knee did not restrict their activity level.

IKDC Clinical Examination at 1 year

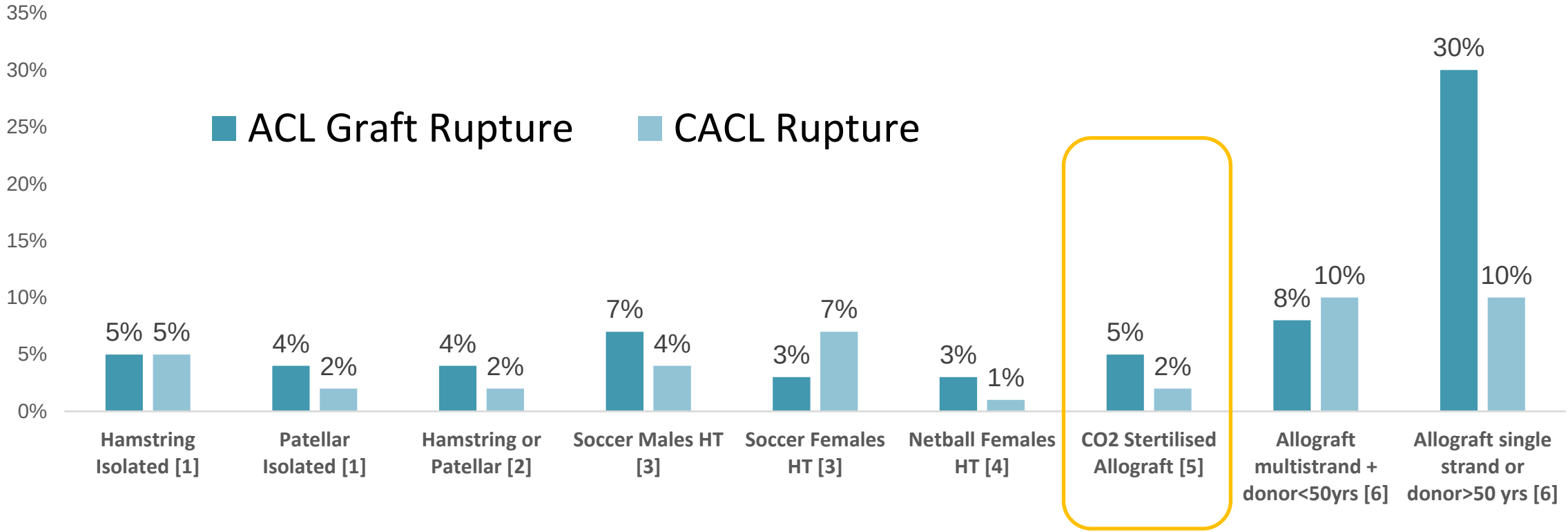
Ligament Evaluation



IKDC Grading



Graft Type and 2 year ACL injury. Comparison to our other published series



[1] Corry et al AJSM 1999
[2] Salmon et al Arthros 2005
[3] Manara et al AJSM 2022
[4] Honeywill OJSM 2023
[5] Farey et al OJSM 2023
[6] Shumborski et al AJSM 2020

Conclusion

- Supercritical CO_2 processing of allograft tendons demonstrated satisfactory clinical and patient-reported outcomes at 2 years in primary ACL-R patients, with similar re-rupture rates and subjective knee scores compared to published series of autografts and fresh frozen non-irradiated allograft.

- Terminal SCCO2 sterilization results in a suitable graft choice for primary ACLR.

- Published OJSM Aug 2024 [6]

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John E. Farey,* MBBS (Hons), MMed (Clin Epi), Lucy J. Salmon,*† PhD,
Justin P. Roe,*‡ MBBS, Vivianne Russell,* BSci (Biomed),
Keran Sundaraj,* MBBS, MSc (Trauma), and Leo A. Pinczewski,*†§ AM, MBBS
Investigation performed at North Sydney Orthopaedic and Sports Medicine Centre, Mater Clinic, Wollstonecraft, Australia

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