

Peri-Operative Complications, Safety, and Early Outcomes of a Novel ACL & ALL Reconstruction Technique Using IT Band vs. Patellar Tendon ACLR:

A Retrospective Pilot Study of the SATURN (Skeletally-Mature ACLR Technique Using Reinforcement) Study Group

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Disclosures

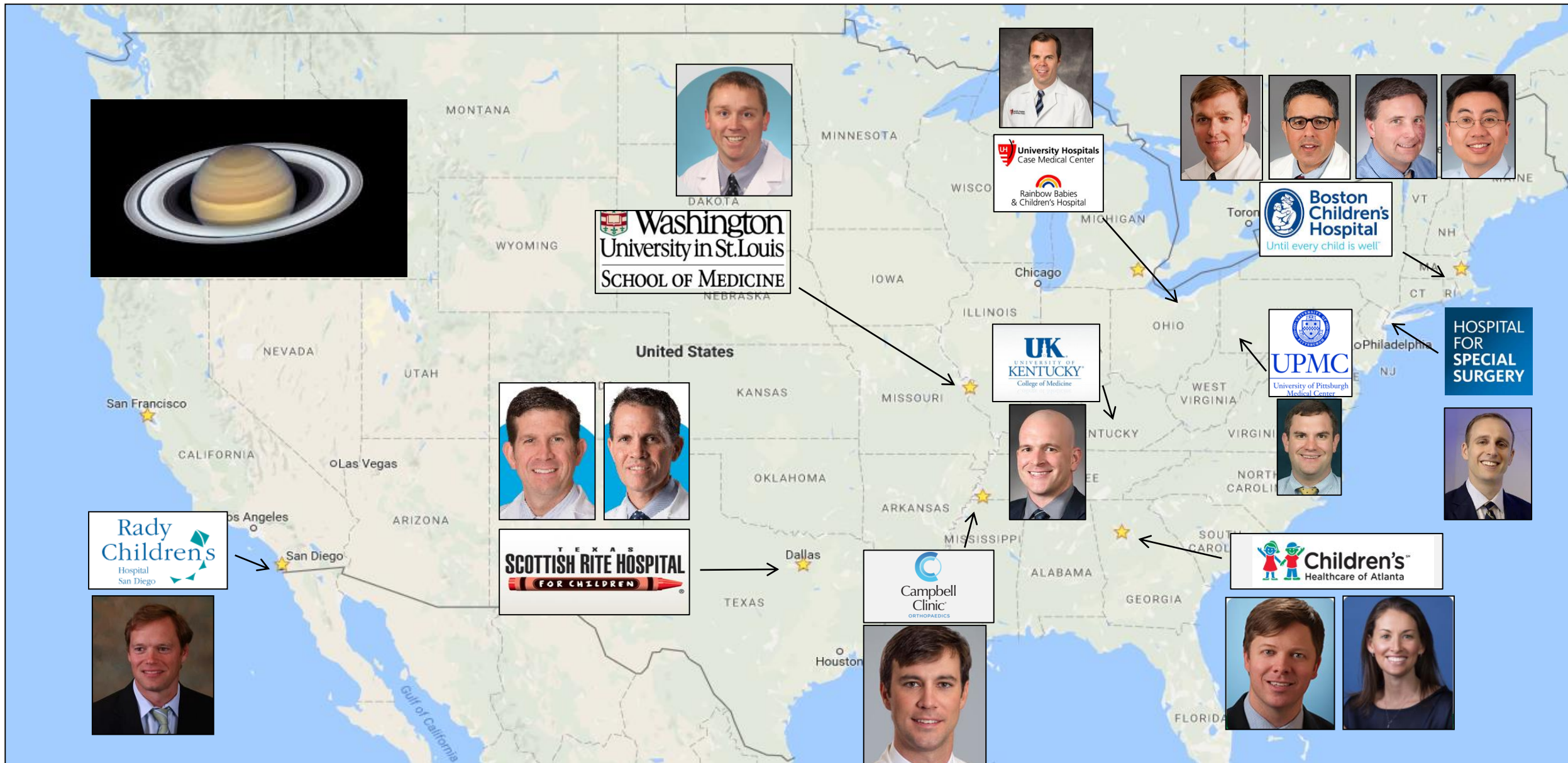
Dr. Heyworth is a paid consultant for Arthrex, Inc. and Kairos Surgical.

Dr. Heyworth owns stock or stock options in Imagen Technologies, Inc.

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Dr. Heyworth receives textbook royalties from Springer Science and Business Media.

SATURN Study Group: 15 Surgeons, 10 Centers



Background

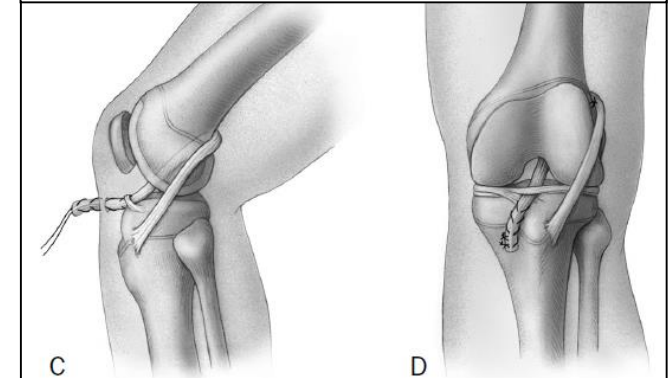
- Outcomes of ACL Reconstruction (ACLR) in skeletally immature patients are being studied by the PLUTO group.
- The Modified Macintosh ACLR with IT Band autograft, developed by Dr. Lyle Micheli, has shown favorable results in prepubescent children
- Older adolescents with closing or closed physes are the *most* affected age group with the highest retear rates.
- Therefore, longstanding interest in application of the Micheli technique for older adolescents has led to modifications of the technique for this age group.



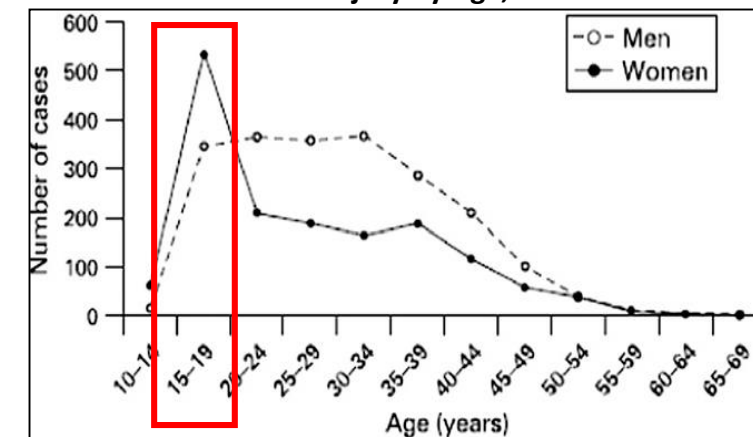
Outcomes of Physal-Sparing ACL Reconstruction with Iliotibial Band Autograft in Skeletally Immature Prepubescent Children

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Investigation performed at Boston Children's Hospital, Boston, Massachusetts



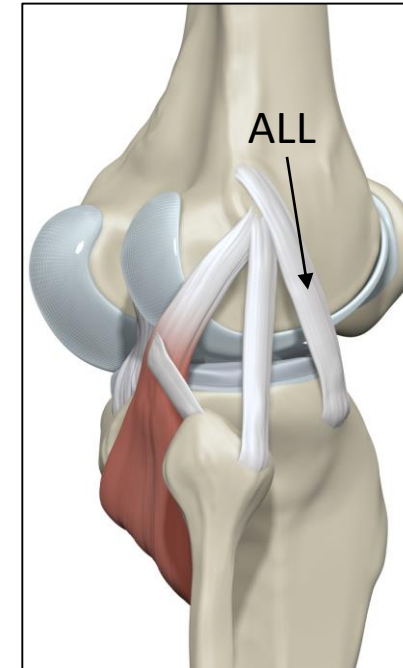
ACL Injury by Age, Sex



Renstrom P, Ljungqvist A, Arendt E, et al. Non-contact ACL injuries in female athletes: an International Olympic Committee current concepts statement. Br J Sports Med. 2008;42(6):394-412.

Background

- Similar to a technique described by the SANTI group, the SATURN technique utilizes a complete femoral tunnel from the ACL footprint (inside the notch) to the ALL footprint (just proximal/posterior to the lateral epicondyle).
- An RCT study investigating a similar technique in adults found no differences in re-rupture rates between ITB and BTB at 15-year follow-up.



Iliotibial band autograft versus bone-patella-tendon-bone autograft, a possible alternative for ACL reconstruction: a 15-year prospective randomized controlled trial

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Lars Konradsen · Uffe Jørgensen · Per Hölmich

Knee Surg Sports Traumatol Arthrosc (2014) 22:2094–2101
DOI 10.1007/s00167-013-2630-9

Conclusion

Using a randomized clinical trial design, we found no differences in re-rupture rates between ITB and BPTB reconstructed patients at 15-year follow-up. Thus, it seems that the ITB reconstruction can be recommended as an attractive and realistic alternative to the conventional methods, and could also be considered in relation to revision ligament surgery and multi-ligament reconstruction where additional graft material is needed.

Purpose

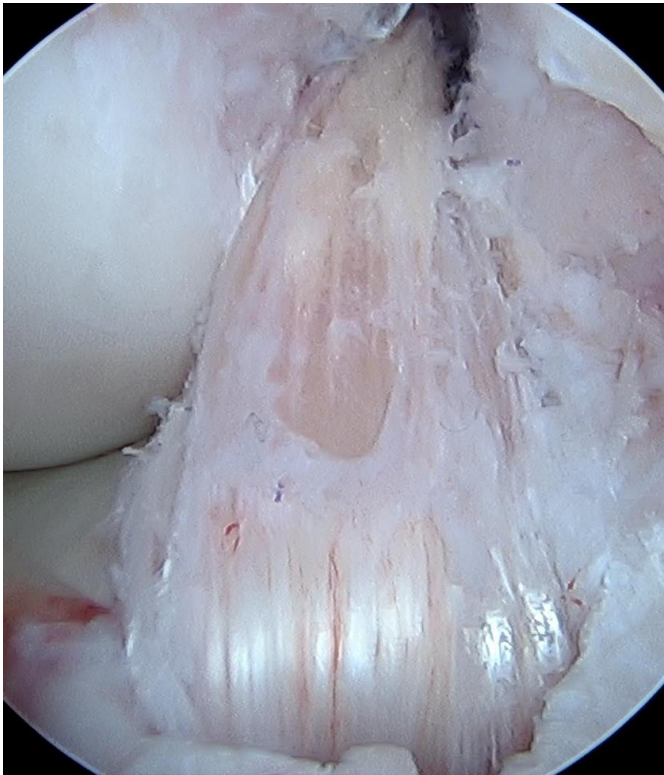
**To investigate, in comparative fashion,
the peri-operative safety, post-operative complications, and
2-Yr Functional/Patient-Reported Outcomes (PROs) of
ITB-ACLR+ALLR vs. BTB-ACLR
in a large demographically and geographically diverse
adolescent population.**

Methods

BTB

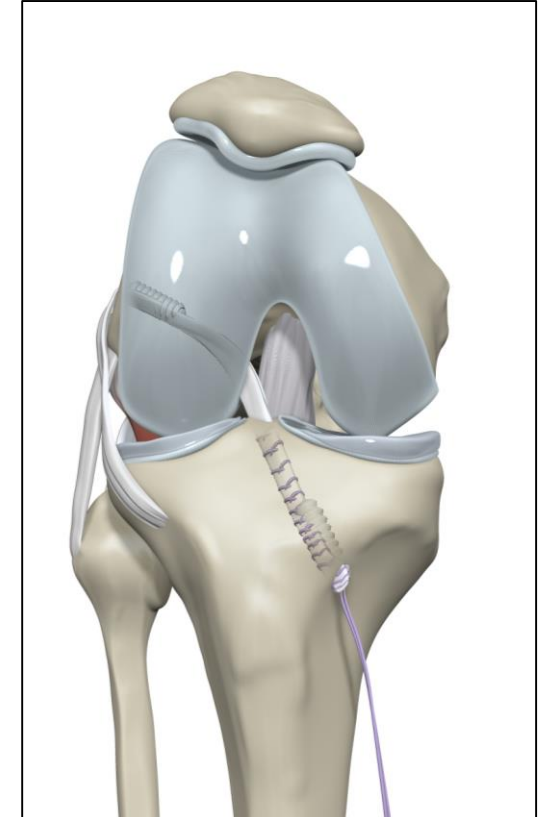
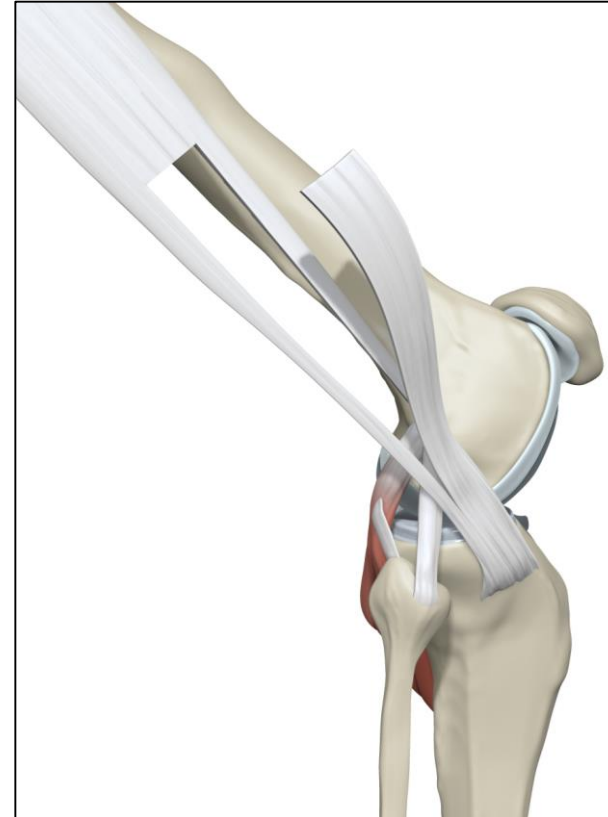
Either

- Suspensory fixation on femur
- Aperture fixation on femur



SATURN ITB (Modified-Micheli)

Femoral tunnel-based (outside in) graft passage



Methods – Data Collection, Forms

Demographic Data

- Athletic status, activity

Injury Data

- Injury activity (Sports vs. recreational play vs. other)
- MOI (contact vs. non-contact)

Radiographic Measurements (AP, lateral XR; MRI)

- Posterior slope
- Notch width

Primary Outcome Measures (Validated PROs)

- Pedi-IKDC, KOOS, HSS Pedi-FABS

Secondary Outcome Measures

- Pain, QOL (EQ5D)
- Satisfaction
- Complications
 - Arthrofibrosis
 - Re-tear
 - Meniscus tear

Pedi-IKDC Subjective Knee Form

Section A: GENERAL INFORMATION

1. Patient's Age: ____ years

2. Patient's Gender: ☐ Male

3. Date distributed: ____ / ____ / ____

MM / DD

Date you injured your knee: ____ / ____ / ____

MM / DD

We would like to learn more about your injured knee. Please answer each question.

SYMPTOMS

1. If you were asked to do the activities listed below, how often would you be able to do them?

☐ Very hard activities
☐ Hard activities like running, jumping, cutting
☐ Sort of hard activities like climbing stairs, walking on uneven ground
☐ Light activities like walking on flat ground, walking in the house
☐ I can't do any of the activities

2. During the past 4 weeks, or since your injury, how often have you been hurt?

Never ☐ 0 ☐ 1 ☐ 2

3. How badly does your injured knee hurt at all?

Does not hurt at all ☐ 0 ☐ 1 ☐ 2

4. During the past 4 weeks, or since your injury, how hard has it been to do your usual activities?

☐ Not at all hard
☐ A little hard
☐ Somewhat hard
☐ Very hard
☐ Extremely hard

KOOS KNEE SURVEY

Today's date: ____ / ____ / ____ Date of birth: ____ / ____ / ____

Name: _____

INSTRUCTIONS

The information will help us know how well you are able to do things you want to do. Answer every question. If you are not sure, give your best answer you can.

Symptoms

These questions are about how you feel the last week.

S1. Do you have swelling?
Never ☐

S2. Do you feel grating or catching when you move?
Never ☐

S3. Does your knee feel stiff?
Never ☐

S4. Can you straighten your knee?
Always ☐

S5. Can you bend your knee?
Always ☐

Stiffness

The following questions are about how often you experience stiffness or slow down when you move.

S6. How severe is your stiffness in the morning?
None ☐

S7. How severe is your stiffness after sitting or lying down?
None ☐

Hospital for Special Surgery Pediatric Functional Activity Brief Scale (HSS Pedi-FABS)

Instructions: Choose one answer for each activity or question. In the grid, please indicate how often you performed each activity in your healthiest and most active condition. IN THE PAST MONTH:

	Less than one time per month	One time per month	One time per week	2-3 times per week	More than 4 times per week
Running: running while playing a sport or jogging.					
Cutting: quickly changing directions while running.					
Decelerating: coming to a quick stop while running.					
Pivoting: turning your body with your foot planted (for example: skiing, skating, kicking, throwing, hitting a ball)					
Duration: perform athletic activity for as long as you would like to without stopping.					
Endurance: perform athletic activity for one whole hour without stopping.					

Competition: Do you participate in organized competitive sports or physical activities?

☐ No (or gym class only)
☐ Yes, but WITHOUT an official or judge (such as club or pickup games)
☐ Yes, WITH an official or judge
☐ Yes, at a national or professional level

Supervision: Do you participate in supervised (coach, trainer, instructor) sports practice or activities (other than gym class)?

☐ No
☐ Yes, 1-2 times per week
☐ Yes, 3-4 times per week
☐ Yes, 5 or more times per week

The Hospital for Special Surgery Pediatric Functional Activity Brief Scale (HSS Pedi-FABS) is completed by marking one box in each row based on physical activity within the last month, then selecting one choice for the last two questions [9]. Only the first four questions were used in this study.

Results – Demographic, Surgical Variables

Table 1: Pre-Operative/Baseline Demographic & Peri-Operative/Early* Post-Operative Complications

	ITB-ACLR+ALLR (n = 37)	BTB-ACLR (n = 42)	p-value
Age (<i>years; mean</i>)	16.6 (+/- 3.0)	17.4 (+/- 2.0)	0.19
Sex			0.85
Male	15 (41%)	19 (45%)	
Female	22 (59%)	23 (55%)	
BMI	24.3 (+/- 6.2)	24.5 (+/- 5.5)	0.89
Tunnel diameter			
Femoral (<i>mm; mean</i>)	7.0 (+/- 0.2)	9.7 (+/- 0.7)	<0.001
Tibial (<i>mm; mean</i>)	7.0 (+/- 0.2)	9.8 (+/- 0.6)	<0.001
Operative time (<i>minutes; mean</i>)	135.5 (+/- 27.9)	147.9 (+/- 33.3)	0.14
Tourniquet time (<i>minutes; mean</i>)	113.6 (+/- 16.4)	119.1 (+/- 12.4)	0.19
RTS (<i>months; mean</i>)	9.2 (+/- 1.6)	9.4 (+/- 1.4)	0.45

No significant differences in age, sex, BMI, PROs, operative time, tourniquet time, or RTS time between the two treatment groups.

The tunnel diameter in the ITB-ACLR group is significantly smaller compared to the BTB-ACLR group.

Results – Complications

Table 1: Pre-Operative/Baseline Demographic & Peri-Operative/Early* Post-Operative Complications			
	ITB-ACLR+ALLR (n = 37)	BTB-ACLR (n = 42)	p-value
Graft Rupture/ACL Re-Tear	2 (5.4%)	--	--
Meniscus Tear	2 (5.4%)	1 (2.4%)	--
Arthrofibrosis	1 (2.7%)	6 (14.3%)	--
Patellar Tendonitis	--	1 (2.4%)	
Superficial Infection	1 (2.7%)	--	--
Quad Neuropraxia a/w Patellar Tendonitis	--	2 (4.8%)	
Tibial Biocomposite Screw, Foreign Body Reaction	1 (2.7%)	--	--
Contralateral ACL Tear	1 (2.7%)	1 (2.4%)	--
Additional (Ipsilateral) Surgeries	5 (13.5%)	7 (16.7%)	--

2 graft ruptures in the ITB-ACLR group (one grossly noncompliant patient), none in BTB-ACLR group.

6 cases of Arthrofibrosis warranting intervention in the BTB group.

2 cases of clinically significant Quad Neuropraxia a/w Patellar Tendonitis affecting early rehab in BTB-ACLR group.

Overall, complications are similar between the two groups.

Results – Patient Reported Outcomes (PROs)

Table 2: Patient Reported Outcome Questionnaires (PROs)							
ITB-ACLR+ALLR (n = 37)				BTB-ACLR (n = 42)			p-value
6 month PRO follow-up time (months; mean)				6.7 (+/- 1.0)			0.18
PRO	n	Median	(IQR)	n	Median	(IQR)	p-value
Pedi-IKDC							
Baseline	33	60.9	(45 – 73)	30	53.8	(43 – 67)	0.29
6 Months	23	87.0	(81 – 94)	28	80.4	(74 – 87)	0.02
HSS Pedi-FABS							
Baseline	33	11.0	(5 – 27)	28	6.5	(5 – 27)	0.98
6 Months	22	14.5	(9 – 18)	25	12.0	(8 – 19)	0.59
KOOS-Pain							
Baseline	33	83.3	(72 – 89)	29	80.6	(69 – 89)	0.45
6 Months	22	97.2	(92 – 100)	26	94.44	(86 – 97)	0.06
KOOS-Symptoms							
Baseline	33	75.0	(61 – 82)	30	70.7	(54 – 82)	0.53
6 Months	22	92.9	(87 – 93)	25	85.7	(79 – 95)	0.09
KOOS-Function, daily living							
Baseline	33	92.7	(82 – 99)	29	86.8	(81 – 96)	0.50
6 Months	22	100	(99 – 100)	27	100	(98 – 100)	0.39
KOOS-Sport/Rec							
Baseline	33	50.0	(30 – 85)	24	35.0	(25 – 53)	0.17
6 Months	22	87.5	(76 – 95)	26	81.7	(65 – 90)	0.06
KOOS-Quality of Life							
Baseline	33	43.8	(25 – 50)	28	31.3	(17 – 44)	0.12
6 Months	22	68.8	(56 – 80)	27	62.5	(44 – 68)	0.10
EQ5D-5L							
Baseline	30	0.86	(0.75 – 0.94)	25	0.72	(0.62 – 0.94)	0.20
6 Months	21	0.94	(0.94 – 1.00)	24	1.00	(0.88 – 1.00)	0.91
EQVAS							
Baseline	30	90.0	(76 – 95)	24	85.0	(70 – 91)	0.33
6 Months	21	92.0	(85 – 95)	24	85.0	(80 – 90)	0.39

6 month PROs showed statistically significant superior Pedi-IKDC results in ITB group compared to BTB.

There were similar activity levels in both groups.

Not statistically significant superior KOOS Pain, Symptoms, and Sports scores in the ITB-ACLR group, although approached it.

All other baseline and 6 month scores were similar.

Conclusions

Preliminary safety and early outcomes data suggests that a novel ACLR+ALLR technique may be:

- Safe, effective in restoring stability, allowing for return to sport
- Comparable, or possibly superior, to BTB-ACLR, in early PROs
- Comparable, in terms of overall complications

Given the potential advantages of the technique (preservation of flexor/extensor muscle groups, technically simple, small tunnels = revision-friendly), continued monitoring, comparative analysis is warranted

- ACL re-tear/graft ruptures – particular attention/monitoring
 - Early cases reported (between 9-15 months)
 - Monitoring over a longer post-operative period, in a larger cohort, performed by a larger number of surgeons.

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