

# Epidemiological profile of patients undergoing ACLR and comparison of baseline characteristics between usage of the LET surgical technique

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## Document version

Version	Alterations
01	Initial version

## 1 ABBREVIATIONS

- ACL: anterior cruciate ligament
- ACLR: ACL revision
- BMI: body mass index
- CI: Confidence Interval
- LCL: lateral collateral ligament
- LET: lateral extra-articular tenodesis
- MCL: medial collateral ligament
- PCL: posterior cruciate ligament
- SD: standard deviation

## 2 INTRODUCTION

### 2.1 Context

### 2.2 Objectives

Compare the baseline characteristics of patients undergoing ACL revision (ACLR) surgery whether or not they the LET technique was employed in the ACLR.

### 2.3 Hypotheses

LET and no LET groups are comparable at baseline.

## 2.4 Data reception and cleaning

In total there were 126 variables in the dataset received. Variables in the raw data sheet were grouped into sections. For this analysis only the baseline **demographic** characteristics and the variables in the **surgical data most recent revision ACLR** section were selected.

All variables in the analytical set were labeled according to the raw data provided and values were labeled according to the data dictionary for the preparation of production-quality results tables and figures.

After the cleaning process 10 variables were included in the analysis with observations. Table A1 shows the structure of the analytical dataset (section 8.3). The data cleaning procedures employed are detailed in the analytical plan (**SAP-2021-004-TV-v01**).

## 3 METHODS

### 3.1 Study Variables

#### 3.1.1 Primary and secondary outcomes

This analysis describes the epidemiological characteristics of surgical patients that undergone ACLR, and no endpoints were assessed.

#### 3.1.2 Covariates

The distribution of the characteristics were compared at baseline between the two study groups. Variables to be considered for baseline comparison are:

- Age
- Sex
- BMI
- Graft diameter
- Medial meniscus
- Lateral meniscus
- Cartilage

### 3.2 Statistical analyses

The epidemiological profile of each study group (LET and no LET) were described at baseline. Demographic and clinical variables were described as mean and standard deviation or as counts and proportions, as appropriate. Distributions were summarized in tables and visualized in exploratory plots.

All comparisons were performed as univariate analyses. Continuous variables were compared between groups with the independent t test with Welch correction. Difference in distribution of categorical variables were assessed with the Fisher exact test. No adjustment for covariates were performed.

All analyses were performed using the significance level of 5%. All significance hypothesis tests and confidence intervals computed were two-tailed.

### 3.2.1 Statistical packages

This analysis was performed using statistical software R version 4.1.1.

## 4 RESULTS

### 4.1 Study population and follow up

A total of 70 patients that undergone ACLR surgery were included in the study, where the LET technique was used in 32 patients and 38 acted as a control. Ages varied between 14 and 55 years, with an average age of 27 years with a SD of 10 years. There were 29 (41%) male patients and 41 (59%) female. Patients had BMI values ranging from 19 to 40 kg/m<sup>2</sup> with average BMI of 26.6 kg/m<sup>2</sup> and SD 4.5 kg/m<sup>2</sup>.

Primary ACL surgeries recorded occurred between 1984-01-01 and 2017-08-30, and ACL revisions occurred between 2010-03-09 and 2020-07-17. Per patient follow up time between the two primary ACL and ACLR ranged from 33 weeks to 27 years, with an average followup time of 6.57 years, and median follow-up time of 4.08 years.

The distributions of these variables can be seen in Figures A1–A4 (Section 8.1).

The typical profile of the patient that required ACLR surgery was a 27 years female with an average BMI of 26.6 kg/m<sup>2</sup>.

### 4.2 Surgical characteristics and baseline comparison

Patients included in the study required grafts with diameters ranging from 19 to 40 mm. Average graft diameter used was 9.6 mm with an SD of 0.7 mm. Most patients did not require procedures in the medial meniscus (47%), the lateral meniscus (57%) or in the cartilage (96%). A total of 14 patients (20%) had partial resection in the medial meniscus, indicating a possibility of arthrosis in the knee joint, and 13 (19%) had partial resection in the lateral meniscus.

None of the characteristics evaluated in this study indicated significant differences when using the LET procedure compared to not using it (Table 1). Demographic characteristics had comparable distributions for sex ( $p = 0.334$ ), age (Cohen's  $D = 0.32$ , 95% CI = -0.16, 0.80,  $p = 0.187$ ) and BMI (Cohen's  $D = 0.20$ , 95% CI = -0.33, 0.73,  $p = 0.462$ ). Surgical

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characteristics also had comparable distributions for graft diameter (Cohen's  $D = 0.04$ , 95% CI = -0.43, 0.51,  $p = 0.877$ ), medial meniscus ( $p = 0.582$ ), lateral meniscus ( $p = 0.521$ ) and cartilage ( $p = 0.496$ ).

**Table 1** Patient characteristics at baseline.

$n$  (%); Mean (SD);  $d$  = Cohen's  $D$ ; CI = Confidence Interval;  $p$ -value = Fisher's exact test; Welch Two Sample  $t$ -test.

Characteristic	Overall, N = 70 <sup>1</sup>	no, N = 38 <sup>1</sup>	yes, N = 32 <sup>1</sup>	$d^2$	95% CI <sup>2,3</sup>	$p$ -value <sup>4</sup>
<b>Sex</b>						0.334
male	29 (41%)	18 (47%)	11 (34%)			
female	41 (59%)	20 (53%)	21 (66%)			
<b>Age (years)</b>	27 (10)	28 (11)	25 (8)	0.32	-0.16, 0.80	0.187
Unknown	3	3	0			
<b>BMI (kg/m2)</b>	26.6 (4.5)	27.0 (4.7)	26.1 (4.2)	0.20	-0.33, 0.73	0.462
Unknown	15	8	7			
<b>Graft diameter (mm)</b>	9.59 (0.73)	9.61 (0.80)	9.58 (0.66)	0.04	-0.43, 0.51	0.877
<b>Medial meniscus</b>						0.582
none	33 (47%)	17 (45%)	16 (50%)			
partial resection	14 (20%)	6 (16%)	8 (25%)			
repair	19 (27%)	12 (32%)	7 (22%)			
MAT	4 (5.7%)	3 (7.9%)	1 (3.1%)			
<b>Lateral meniscus</b>						0.521
none	40 (57%)	24 (63%)	16 (50%)			
partial resection	13 (19%)	6 (16%)	7 (22%)			
repair	16 (23%)	7 (18%)	9 (28%)			
MAT	1 (1.4%)	1 (2.6%)	0 (0%)			
<b>Cartilage</b>						0.496
none	67 (96%)	35 (92%)	32 (100%)			
OATS auto	0 (0%)	0 (0%)	0 (0%)			
OATS allo	0 (0%)	0 (0%)	0 (0%)			
Micro-Fx	2 (2.9%)	2 (5.3%)	0 (0%)			
MACI	0 (0%)	0 (0%)	0 (0%)			
DeNovo	1 (1.4%)	1 (2.6%)	0 (0%)			

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<sup>1</sup>n (%); Mean (SD) <sup>2</sup>Cohen's D <sup>3</sup>CI = Confidence Interval <sup>4</sup>Fisher's exact test; Welch Two Sample t-test

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All of the observed Cohen's D standardized mean differences (Cohen, 1988) range from very small ( $d = 0.04$ ) to small ( $d = 0.32$ ). Note that the minimum effect size detectable by this study would be of a medium effect size ( $d = 0.68$ , see **SAP-2021-004-TV-v01**) or larger.

## 5 EXCEPTIONS AND OBSERVATIONS

N/A.

## 6 CONCLUSIONS

The typical profile patient that required ACLR surgery was a 27 years female with an average BMI of 26.6 kg/m<sup>2</sup>.

None of the characteristics evaluated in this study indicated significant differences when using the LET procedure compared to not using it. Patients had comparable distributions for demographic characteristics such as sex ( $p = 0.334$ ), age ( $p = 0.187$ ,  $d = 0.32$ ) and BMI ( $p = 0.462$ ,  $d = 0.20$ ), as well as surgical characteristics such as graft diameter ( $p = 0.877$ ,  $d = 0.04$ ), medial meniscus ( $p = 0.582$ ), lateral meniscus ( $p = 0.521$ ) and cartilage ( $p = 0.496$ ).

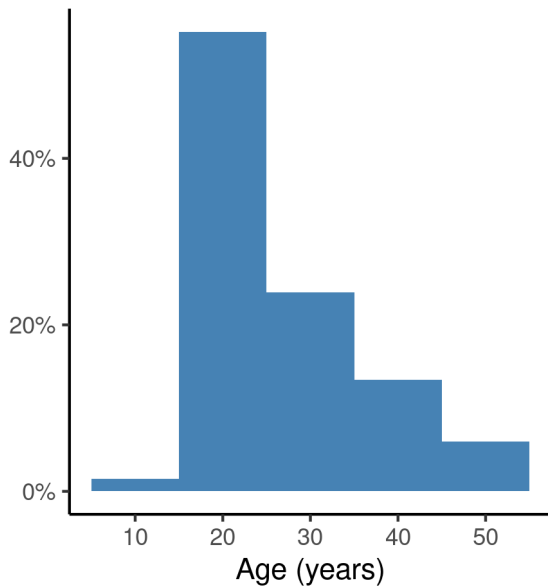
Therefore, LET and no LET groups are comparable at baseline.

## 7 REFERENCES

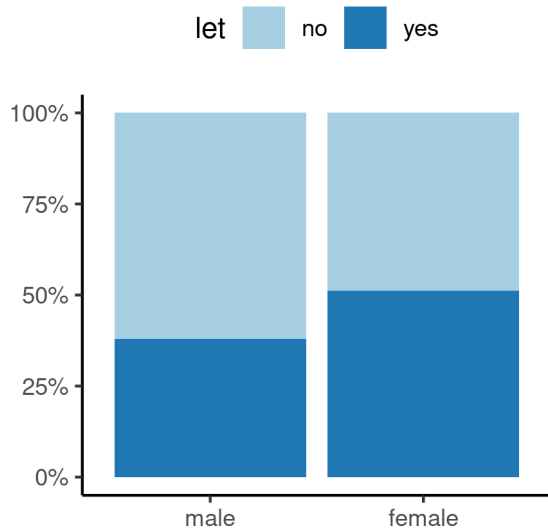
- **SAP-2021-004-TV-v01** – Statistical Analysis Plan for Epidemiological profile of patients undergoing ACLR and comparison of baseline characteristics between usage of the LET surgical technique
- Cohen, J. (1988). Statistical power analysis for the behavioral sciences (2nd Ed.). New York: Routledge.

## 8 APPENDIX

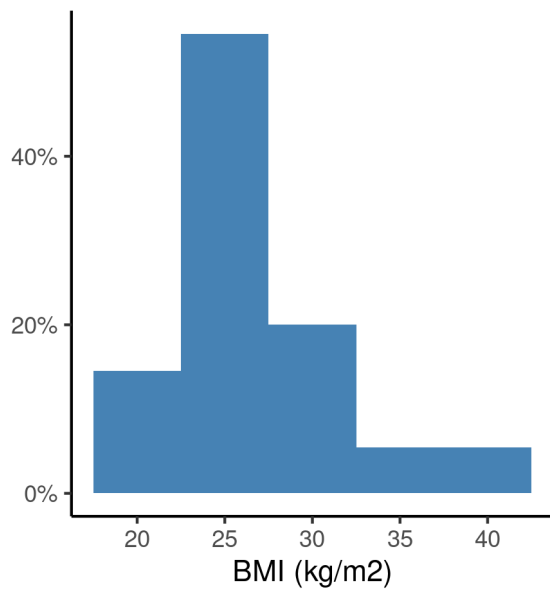
### 8.1 Exploratory data analysis



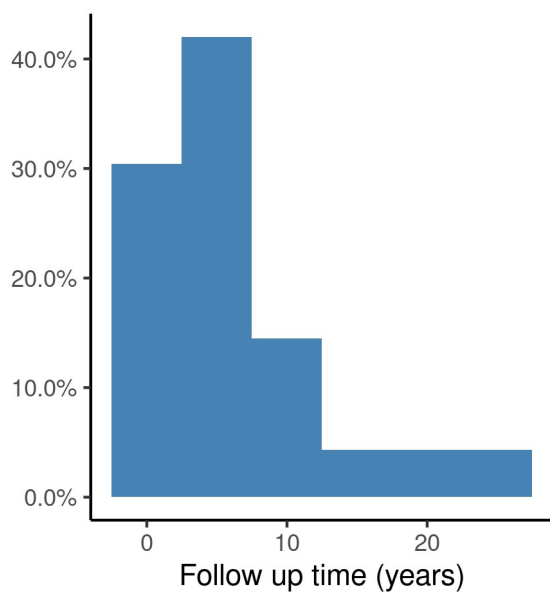
**Figure A1** Distribution of age in the study population.



**Figure A2** Distribution of sex in the study population, according to the study group.



**Figure A3** Distribution of BMI in the study population.



**Figure A4** Distribution of follow up time in the study population.

## 8.2 Availability

This document can be downloaded in the following address:

<https://github.com/philsf-biostat/SAR-2021-004-TV/>



### 8.3 Analytical dataset

Due to confidentiality the data-set used in this analysis cannot be shared online in the public version of this report.

**Table A1** Analytical dataset

id	age	sex	bmi	let	graft	graft_diameter	medial_meniscus	lateral_meniscus	cartilage
1									
2									
3									
...									
70									

DRAFT