Analytical Plan for Comparison of baseline characteristics of patients undergoing ACLR under the option of the LET surgical technique

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Analytical Plan for Comparison of baseline characteristics of patients undergoing ACLR under the option of the LET surgical technique

Document version

Version	Alterations
01	Initial version
02	Data: patient ages were computed from dates with calendar accuracy

1 ABBREVIATIONS

- ACL: anterior cruciate ligament
- ACLR: ACL revision
- BMI: body mass index
- LCL: lateral collateral ligament
- LET: lateral extra-articular tenodesis
- MCL: medial collateral ligament
- MTPS: medial tibial posterior slope
- PCL: posterior cruciate ligament

2 CONTEXT

2.1 Objectives

Compare the baseline demographic and clinical characteristics of patients undergoing Anterior Cruciate Ligament Revision surgery whether or not they the Lateral Extra-articular Tenodesis technique was employed.

2.2 Hypotheses

LET and no LET groups are comparable at baseline.

2.3 Study design

Cross-sectional observational study.

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3   DATA

3.1   Raw data

The raw data was provided in an Excel file with two sheets, one for each group (LET and No LET). As a firsts processing step the raw data was copied into a new sheet with both groups, with one observation (patient) per line. The column structure of the resulting "clean" table corresponds to the original per-group tables.

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.

Column names were adjusted to avoid repeated names, using suffixes to identify the section each variable originally came from, as follows:

- section `concomitant injuries primary ACLR` – received the `pri.inj` suffix
- section `Concomitant injuries most recent revision ACLR` – received the `inj` suffix
- section `surgical data primary ACLR` – received the `pri` suffix
- section `surgical data most recent revision ACLR` – names were kept as the original

Some dates in `Date of last clinical visit` column (`Follow-up notes data` section) were typed with different separator symbols, and all values in this column were standardized to allow date format recognition.

Ages were calculated as the number of years between the date of birth and the date of ACLR surgery, with calendar accuracy.

There were two columns named `grade` (`Slope data` section), and they were both renamed `grade1` and `grade2`.

The original raw data provided descriptive information for the encoding of each variable in the first line. A Data Dictionary was created from this information and was saved in a separate table for ease of consultation and processing.

The resulting "clean" raw data sheet was shared with the client for archival purposes.

3.2   Analytical dataset

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 12 variables were included in the analysis with 69 observations. Table 1 shows the structure of the analytical dataset.

Table 1 *Analytical dataset structure after variable selection and cleaning.*

id	age	sex	bmi	let	graft	graft_diameter	medial_meniscus	lateral_meniscus	cartilage	fu_months	mtps
1											
2											
3											
…											
69											

The analytical dataset will be included in the private version of the report, and will be omitted from the public version of the report.

4 STUDY VARIABLES

4.1 Primary and secondary outcomes

Specification of outcome measures (Zarin, 2011):

1. (Domain)
2. (Specific measurement)
3. (Specific metric)
4. (Method of aggregation)

Primary outcome

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

4.2 Covariates

The distribution of the characteristics will be 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

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5   STATISTICAL METHODS

5.1   Statistical analyses

5.1.1 Descriptive analyses

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

5.1.2 Inferential analyses

All comparisons will be performed as univariate analyses. Continuous variables will be compared between groups with the independent t test with Welch correction. Difference in distribution of categorical variables will be assessed with the Fisher exact test.

5.1.3 Statistical modeling

No adjustment for covariates will be performed.

5.1.4 Missing data

No missing data imputation will be performed. All evaluations will be performed as complete case analyses.

5.2   Significance and Confidence Intervals

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

5.3   Study size and Power

Raw data received has 70 observations corresponding to patients assessed at primary ACL surgery and ACL revision. Surgeries that employed the LET technique include 38 patients and 32 patients undergone surgery with LET technique.

With these group sizes a t test can detect an effect size as large as **d = 0.68** with 80% power and 5% significance level (Cohen, 1988).

5.4   Statistical packages

This analysis will be performed using statistical software R version 4.1.1.

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6   OBSERVATIONS AND LIMITATIONS

N/A

7   REFERENCES

- **SAR-2021-004-TV-v01** – Comparison of baseline characteristics of patients undergoing ACLR under the option of the LET surgical technique.
- Cohen, J. (1988). Statistical power analysis for the behavioral sciences (2nd Ed.). New York: Routledge.
- Zarin DA, et al. The ClinicalTrials.gov results database — update and key issues. N Engl J Med 2011;364:852-60 (https://doi.org/10.1056/NEJMsa1012065).
- Gamble C, et al. Guidelines for the Content of Statistical Analysis Plans in Clinical Trials. JAMA. 2017;318(23):2337–2343 (https://doi.org/10.1001/jama.2017.18556).

8   APPENDIX

This document was elaborated following recommendations on the structure for Statistical Analysis Plans (Gamble, 2017) for better transparency and clarity.

8.1   Availability

Both this analytical plan and the corresponding analysis report (**SAR-2021-004-TV-v01**) can be downloaded in the following address:

https://philsf-biostat.github.io/SAR-2021-004-TV/

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