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# Prevalence of knee implant loosening in patients with prior surgery in a German hospital: case-control study

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## Document version

Version	Alterations
01	Initial version

## 1 ABBREVIATIONS

- CI: confidence interval
- OR: odds ratio
- PR: prevalence ratio

## 2 CONTEXT

In **SAR-2021-002-JF-v02** the average survival time of knee implants was estimated. After that retrospective cohort was analyzed, aggregated counts of previous surgery were made available, and this analysis will investigate whether or not this exposure is a significant risk factor for loosening.

### 2.1 Objectives

Calculate the prevalence of knee prosthesis loosening in patients with prior history of knee surgery in Helios Klinikum Berlin-Buch, Germany.

### 2.2 Data reception and cleaning

The original data was already aggregated into counts of exposure and outcome. No individual information was available on these patients (see Observations).

## 3 METHODS

The methods of this analysis are fully described in the annex document **SAP-2022-032-JF-v01**.

This analysis was performed using statistical software R version 4.2.1.

## 4 RESULTS

### 4.1 Prevalence analysis

There were 105 patients included in the analysis, of which 20 experienced a loosening event (Table 1). The prevalence of loosening among patients exposed to prior surgery was 25.7% (9 out of 35), while among unexposed it was 15.7% (11 out of 70).

**Table 1** Frequencies of loosening events and exposures in cases and controls.

	Loosening	No loosening	Total
Prior surgery	9	26	35
No prior surgery	11	59	70
Total	20	85	105

The prevalence ratio was 1.64 (95% CI 0.75 to 3.58). This means that the prevalence of loosening among the exposed was 64% greater than the prevalence among the unexposed. Since the CI includes the PR = 1, then the PR is not significant.

### 4.2 Retrospective analysis

The odds of loosening among patients exposed to prior surgery was 1.86 (95% CI 0.69 to 5.02) times greater than the outcome odds among the unexposed. This means that, starting from the cases and analyzing the retrospective risk factor, the chance of patients that experienced the outcome also having had a prior surgery is 86% higher than the controls. Since the CI includes the OR = 1, then the OR is not significant (chi-square test:  $p = 0.219$ ).

The attributable fraction in the exposed is 45.8%. This means that 45.8% of outcomes in the exposed were attributable to exposure (95% CI -67.3% to 82.1%).

## 5 OBSERVATIONS AND LIMITATIONS

### Aggregated sample data

No individual-level data was available for this analysis. This means that we cannot control for confounding either in regression models or stratified analyses. It is recommended that this be reported as a limitation of the study, since it raises the risk of bias of the study.

### Recommended reporting guideline

The adoption of the EQUATOR network (<http://www.equator-network.org/>) reporting guidelines have seen increasing adoption by scientific journals. All observational studies are recommended to be reported following the STROBE guideline (von Elm et al, 2014).

In particular when a retrospective study is conducted using hospital records, it is recommended that the RECORD extension of the STROBE guideline is considered (Benchimol et al, 2015).

## 6 CONCLUSIONS

The prevalence of loosening was 25.7% among cases and 15.7% among controls. Cases had 86% higher odds of loosening when compared to controls.

## 7 REFERENCES

- **SAP-2022-032-JF-v01** – Analytical Plan for Prevalence of knee implant loosening in patients with prior surgery in a German hospital
- **SAR-2021-002-JF-v02** – Implant failure rates in a knee prosthesis sub-population of the Helios Klinikum Berlin-Buch hospitals
- Benchimol EI, Smeeth L, Guttman A, Harron K, Moher D, Petersen I, Sørensen HT, von Elm E, Langan SM; RECORD Working Committee. The REporting of studies Conducted using Observational Routinely-collected health Data (RECORD) statement. PLoS Med. 2015 Oct 6;12(10):e1001885 (<https://doi.org/10.1371/journal.pmed.1001885>).
- von Elm E, Altman DG, Egger M, Pocock SJ, Gøtzsche PC, Vandenbroucke JP; STROBE Initiative. The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) Statement: guidelines for reporting observational studies. Int J Surg. 2014 Dec;12(12):1495-9 (<https://doi.org/10.1016/j.ijsu.2014.07.013>).

## 8 APPENDIX

### 8.1 Exploratory data analysis

N/A

### 8.2 Associated analyses

This analysis is part of a larger project and is supported by other analyses, linked below.

#### **Implant failure rates in a knee prosthesis sub-population of the Helios Klinikum Berlin-Buch hospitals**

<https://philsf-biostat.github.io/SAR-2021-002-JF/>

### 8.3 Availability

All documents from this consultation were included in the consultant's Portfolio.

The portfolio is available at:

<https://philsf-biostat.github.io/SAR-2022-032-JF/>

### 8.4 Analytical dataset

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