

Project title and REK Number: Bilaterale kne- og hofteproteser i Nasjonalt Register for Leddproteser 1987–2022 #869218

Introduction: The demand for knee and hip replacements is increasing, with 16–22% of osteoarthritis (OA) patients requiring surgery in the contralateral joint. International registry data show a rising lifetime risk for total knee arthroplasty (TKA), and patients with contralateral pain often experience poorer functional outcomes. Simultaneous bilateral TKA has been less common in Norway and Sweden but is gaining popularity. While earlier European studies recommended simultaneous surgery for ASA1–2 patients, ASA 3 patients and those with high BMI had increased risks of complications and longer hospital stays. A 2008 Swedish registry report raised concerns over higher mortality in simultaneous procedures, but recent studies indicate comparable or improved outcomes. In Norway, simultaneous procedures were mainly performed in recent years with fast-track protocols and modern implants.

Primary aim: To evaluate the safety and effectiveness of simultaneous bilateral TKAs and THAs compared to staged and unilateral procedures using 10-year follow-up data from the Norwegian Arthroplasty Register (NAR), assessing patient demographics, implant survival, revision risk, and mortality.

Material and method: From 1987–2022, NAR registered 120,000 TKAs and 270,000 THAs, with patients followed until revision, death, emigration, or study end (31.12.2022). This study includes TKAs and THAs from 2010–2022, focusing on newer surgical techniques. The study groups are:

- **Group 1:** Simultaneous bilateral TKA/THA (same-day surgery)
- **Group A:** Staged bilateral TKA/THA within one year (A1, A2)
- **Group B:** Bilateral TKA/THA with more than one year between surgeries (B1, B2)
- **Unilateral group:** Patients with no staged or simultaneous counterpart at study end

NAR provides detailed data on surgical techniques, patient demographics, and outcomes. Revision is defined as any implant component exchange and linked to primary surgery using national ID numbers. Mortality and emigration data are sourced from Statistics Norway.

Statistical analyses include Kaplan–Meier survival curves with 95% confidence intervals (CI) and Cox proportional hazards models for adjusted hazard ratios (HRs) of revision and infection within 1 and 10 years. HRs are adjusted for sex, age, diagnosis, ASA classification, and fixation method. The proportional hazards assumption is verified using log-minus-log plots. Analyses are conducted using SPSS (v26.0.0.1, IBM) and R (v4.2.1). The study follows STROBE and RECORD guidelines.

Result/Status: A third PROM study will assess patient function and satisfaction across the same groups. Data registration in NAR complies with Norwegian Data Protection laws (Ref: 03/00058-20/CGN) and EU regulations.

Time horizon: Start: 01.01.1987 | End: 31.12.2030

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