Development of a Standardized Multicenter Knee Osteoarthritis Database in Japan: Insights from a New Real-World Database - RWD36

Junichi Oyama, BA,* Akie Seno, BSc, MBA, RN,† Motohiro Yamano, BSc,‡ Kohei Nishitani MD, PhD,∞ Shuichi Matsuda, MD, PhD∞

*Smith+Nephew, Tokyo, Japan; †Smith+Nephew, Singapore, Singapore; ‡PRiME-R, Inc., Kyoto, Japan; ∞Kyoto University, Kyoto, Japan

Introduction

- Knee osteoarthritis (OA) affects an estimated 25 million individuals in Japan, with prevalence expected to rise in parallel with the aging population1.

- Large scale real-world data (RWD) resources are available in Japan such insurance claim-based database (e.g. NDB, JMDC), hospital-based claim database (e.g. MDV), and knee arthroplasty databases exist in a form of national procedure registries- JOANR2-4.

- However, those RWD resources are often limited in available datapoints and often lack standardized, procedure-specific outcome variables and key details are fragmented across individual hospital systems, limiting their utility for comprehensive analysis. To address this gap, four hospitals in Japan have formed an initiative to build a standardized OA database.

- This study describes patient characteristics and outcomes of knee arthroplasty using the newly established database, and evaluates its potential as a reliable RWD source for further research.

Methods

Database description

- The data source for this study was the Japanese retrospective knee arthroplasty database from four hospitals, established with technical support of PRiME-R, Inc.

- Data were collected from Kyoto University Hospital, Kindai University Hospital, Kurashiki Central Hospital, Osaka Red Cross Hospital.

- Eligible cases were recorded by medical facilities using a standardized Excel-based case report, ensuring consistent data entry across institutions.

- The study population included patients who underwent KA between February 2012 and March 2024.

- The use of data for this study was conducted under the approval of the Institutional Review Board of Kyoto University.

Study design

- A retrospective descriptive analysis was conducted using the study database.

- Patient demographics, surgical characteristics, length of stay, postoperative adverse events, and discharge disposition were summarized descriptively.

- Representativeness was assessed by comparing age distribution with NDB Open Data5 (Apr 2014–Mar 2023).

- Kaplan–Meier curves were used to illustrate cumulative revision rates overall and between unicompartmental knee arthroplasty (UKA) with robotic assistance and manual instrumentation.

- All analyses were descriptive; no statistical testing was performed.

Results

- A total of 3,521 patients were identified, with a mean age of 74.6 (SD 7.9) years and 858 (24.3%) were male, 2,664 (75.6%) were female. (Table 1)

- Age distribution comparison of the study database and NDB Open Data is illustrated (Figure 1).

- The surgical details of 4,698 knee arthroplasty cases are summarized (Table 2). Of which, 4,557 (97.0%) were primary surgeries and 141 (3.0%) were revision surgeries. Mean operative time were 101.2 (SD 35.0) minutes, mean blood loss were 27.6 (SD 80.7) ml, and N=4385 (93.3%) cases reported less than 100mL blood loss during operations. Conventional instrumentation was used for N=3,549 (77.9%), N=696 (15.3%) cases were performed with navigation systems and N= 309 (6.8%) cases were performed with robotic assistance systems.

- Length of stay, adverse events, and disposition were summarized (Tables 3–5).

- Kaplan–Meier curves illustrates overall and UKA cumulative revision rates (Figures 2–3).

A New Real-World Database; A Multicenter, Disease-Specific Database for Knee Arthroplasty in Japan: Establishing A Platform For Real-World Evidence and Early Evaluation of Emerging Technologies.

Conclusion

- The feasibility of a newly established multicenter, disease-specific database for knee arthroplasty in Japan, was demonstrated through the age distribution comparisons with NDB Open Data, supported by its representativeness. The database is expected to serve as a valuable platform for generating real-world evidence in knee arthroplasty research.

- Although limited by the small sample size from few participating hospitals and a descriptive design, this pilot study visualized a trend toward reduced revision rates in robotic-assisted UKA.

- This database facilitates early evaluation of emerging technologies, such as robotic-assisted procedures, and supports evidence-based clinical decision-making and adoption.

- The database is currently expanding prospective data collection include imaging findings, knee-specific functional assessments, and patient-reported outcomes. Concurrently, nationwide recruitment of participating hospitals is underway. These enhancements are expected to strengthen the database's utility in evaluating emerging technologies and clinical outcomes.
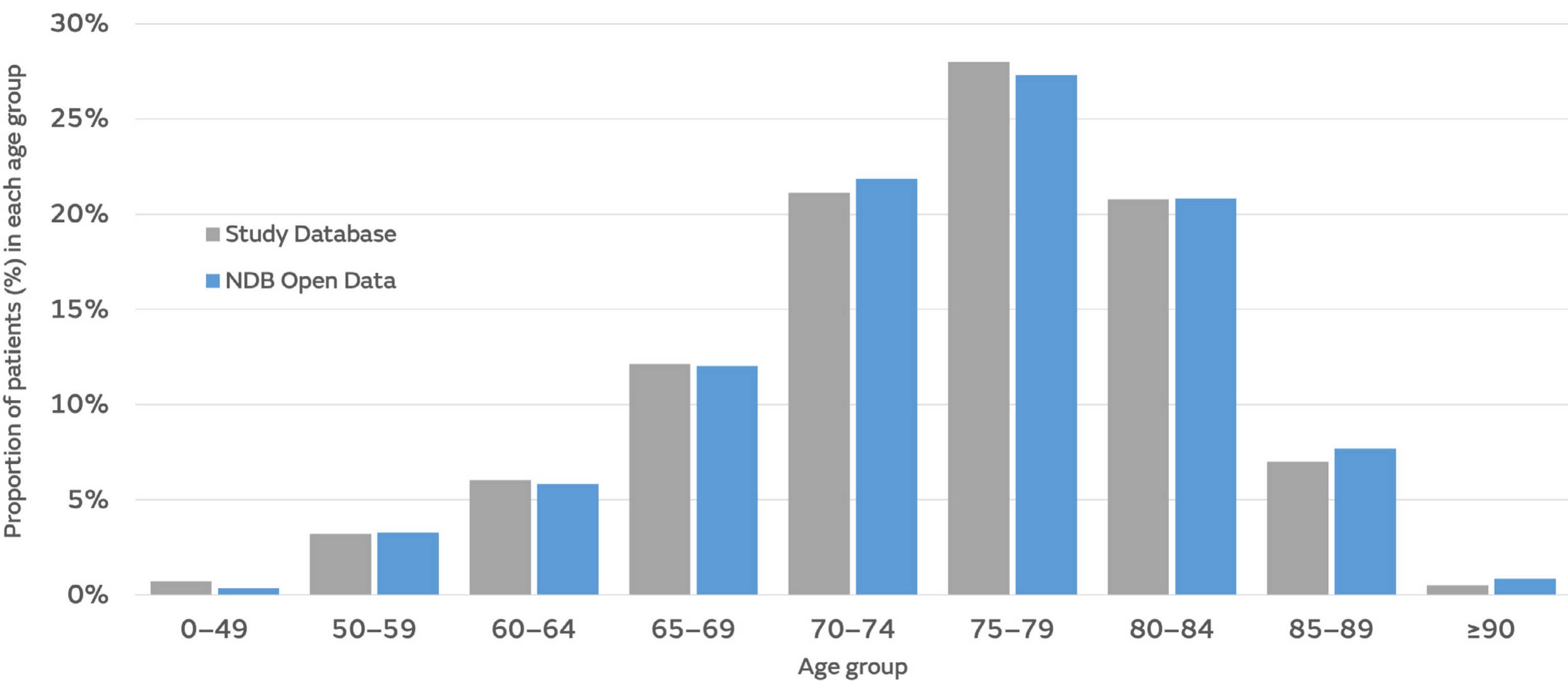
Figure 1. Age distribution of patient

Figure 2. Kaplan-Meier estimates of cumulative revision proportion for any reason, including all surgical techniques for primary knee arthroplasty.

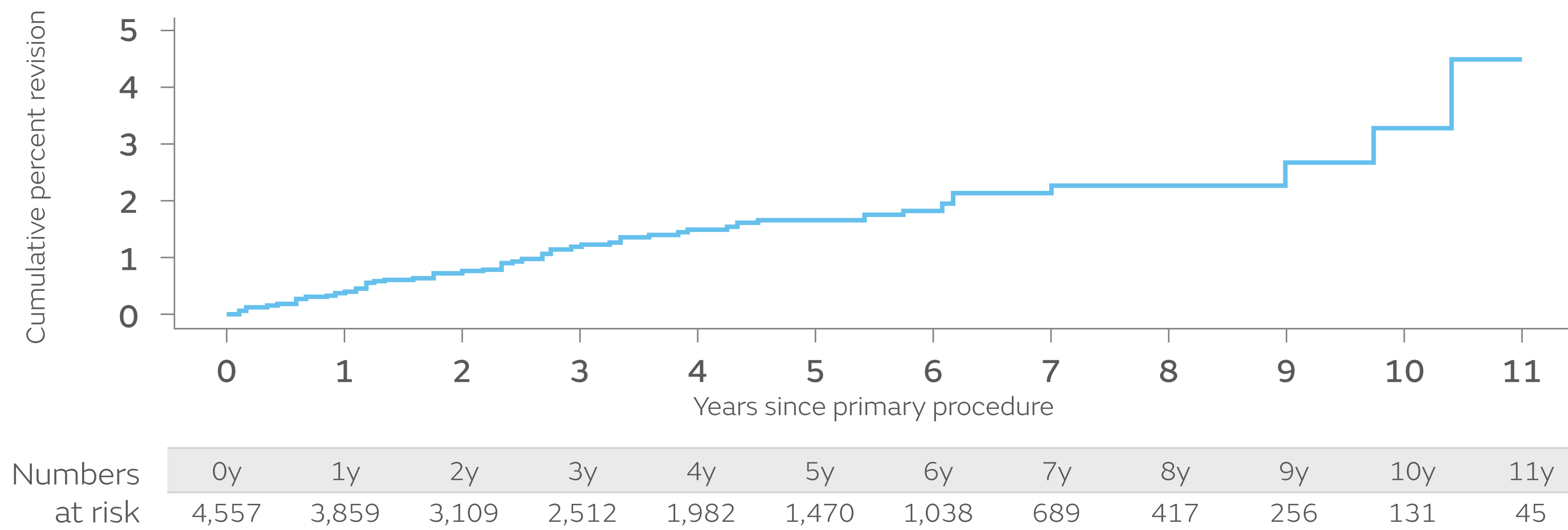| Numbers at risk	0y	1y	2y	3y	4y	5y	6y	7y	8y	9y	10y	11y
	4,557	3,859	3,109	2,512	1,982	1,470	1,038	689	417	256	131	45

Figure 3. Kaplan-Meier estimates of cumulative revision proportion for unicompartmental knee arthroplasty (UKA) performed with robotic assistance (left) and manual instrumentation (right), for revision for any reason. No statistical comparison was conducted; results are descriptive only.
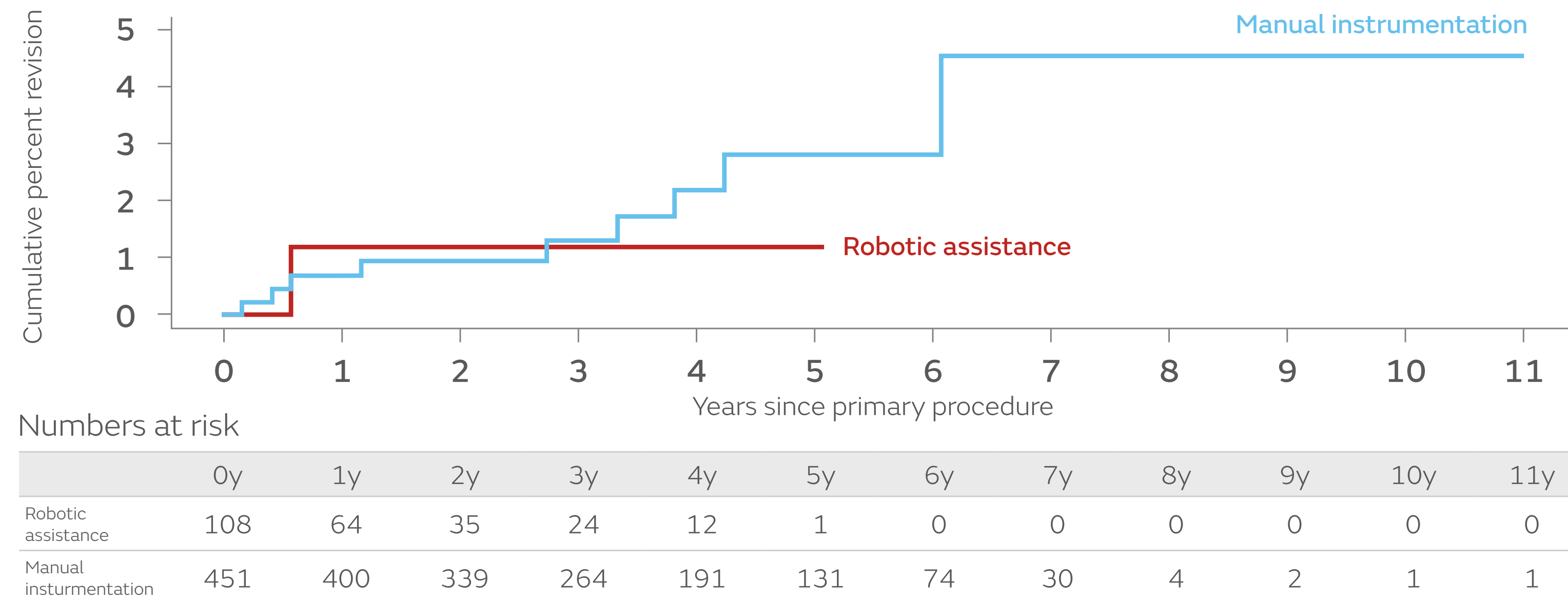

Numbers at risk

	0y	1y	2y	3y	4y	5y	6y	7y	8y	9y	10y	11y
Robotic assistance	108	64	35	24	12	1	0	0	0	0	0	0
Manual instrumentation	451	400	339	264	191	131	74	30	4	2	1	1

Table 1. Patient demographics

Characteristics	Value
Patients, n	3,521
Age, years, mean (SD)	74.6 (7.9)
Sex, n (%)	
Female	2,663 (75.6)
Male	858 (24.4)

Table 2. Surgical details per knee procedure

Characteristics	Value
Knee procedures, n	4,698
Primary diagnosis	
OA	4,086 (89.8)
RA	321 (7.1)
ON	137 (3.0)
Other	8 (0.2)
Procedures	
Primary	
TKA	3,975 (87.2)
Medial UKA	572 (12.6)
Lateral UKA	6 (0.1)
PFA	4 (0.1)
Revision	
TKA	134 (95.0)
Medial UKA	3 (2.1)
Other	4 (2.8)
Operation time, min, mean (SD)	101.2 (35.0)
≤60	452 (9.6)
61–90	1,470 (31.3)
91–120	1,664 (35.4)
121–180	949 (20.4)
>180	150 (3.2)
Blood loss, mL, mean (SD)	27.6 (80.7)
Below detection limit	1,674 (35.9)
1–100	2,711 (58.1)
101–200	165 (3.5)
201–300	56 (1.2)
>300	63 (1.3)
Surgical technique	
Manual instrumentation	3,549 (77.9)
Robotic assistance	309 (6.8)
Navigation assistance	696 (15.3)

Values are n (%) unless stated otherwise. Percentages are calculated per total number of knee procedures. OA, osteoarthritis; RA, rheumatoid arthritis; ON, osteonecrosis; UKA, unicompartmental knee arthroplasty; PFA, patellofemoral arthroplasty; TKA, total knee arthroplasty.

Table 3. Length of hospital stay

Length of hospital stay, days	n (%)
≤7	138 (3.0)
8–14	980 (21.0)
15–21	1,965 (42.1)
22–28	1,117 (23.9)
>28	470 (10.1)
Mean (SD)	20.3 (9.8)

Table 4. Postoperative adverse events

Adverse events	n (%)
Infection	34 (0.7)
Revision for any reason	81 (1.7)

Table 5. Patient disposition

Disposition	n (%)
Follow-up ongoing	2,384 (67.6)
Transfer	137 (3.9)
Deaths	155 (4.4)
Lost to follow-up	848 (24.0)
Other	5 (0.1)

References

1. Yoshimura N, Shigeyuki M, Oka H, et al. Prevalence of knee osteoarthritis, lumbar spondylosis, and osteoporosis in Japanese men and women: the research on osteoarthritis/osteoporosis against disability study. J Bone Miner Metab. 2009;27:620-628

2. Kumamaru H, Togo K, Kimura T, et al. Inventory of real-world data sources in Japan: Annual survey conducted by the Japanese Society for Pharmacoepidemiology Task Force. Pharmacoepidemiol Drug Saf. 202322:e5680

3. Medical and healthcare database utilization committee, Japanese Society for Pharmacoepidemiology. Survey of Japanese databases in Japan available for clinical/pharmacoepidemiology. https://www.jspe.jp/committee/kenkou-iryou/. Accessed August 22, 2025.

4. Taneichi H, Kanemura T, Inoue G, et al. Current status and future prospects of the Japanese orthopaedic association national registry (JOANR), Japan's first national registry of orthopaedic surgery. J Orthop Sci. 2023;28:683-692

5. Ministry of Health, Labour and Welfare. NDB Open Data [in Japanese]. https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/0000177182.html. Accessed August 22, 2025.