

INTRODUCTION

This study highlights the potential of clinical databases in advancing orthopedic research and improving patient care. By focusing on rotator cuff tear, a frequent cause of chronic shoulder pain and reduced function, the research uses the Ortho+ specialized clinical database to analyze outcomes following surgical repair. With this comprehensive data management system, the study aims to identify key factors influencing surgical success or failure. The integration of clinical databases like Ortho+ ensures enhanced data accuracy, supports long-term patient tracking, and incorporates specialized clinical indicators. This allows researchers to derive actionable insights for refining treatment protocols and improving patient outcomes. As a use case, this study demonstrates the crucial role of clinical databases in supporting evidence-based healthcare and advancing medical research, particularly in complex orthopedic procedures.

OBJECTIVE
This study uses the Ortho+ clinical database to assess rotator cuff surgery outcomes, with a focus on identifying factors contributing to surgical failures. By leveraging the detailed data within Ortho+, the study aims to demonstrate how specialized clinical databases can be used to improve surgical protocols and enhance patient care.

METHOD

Ortho+ ensured **high-quality data** by capturing structured and standardized information throughout the patient's clinical journey, from preoperative consultations to long-term follow-up. This robust dataset minimized common Real-World Data (RWD) challenges such as missing or incomplete records across various orthopedic procedures, with significant patient numbers (Figure 1). The following data categories were collected:

- Demographic Data:** Age, gender, and other relevant personal information.
- Preoperative Clinical Information:** Detailed pathology scores, risk factors.
- Surgical Data:** Information about the surgical procedure, including the type of surgery (e.g., single versus double-row repair), the **medical devices** used (anchors), and the surgical technique used.
- Postoperative Outcomes:** Recovery metrics, including postoperative shoulder mobility, pain (EVA), Constant Score, and postoperative adverse events. Reoperation events were tracked within two years post-surgery.
- Follow-up Data:** Long-term follow-up was conducted to assess outcomes such as quality of life and satisfaction scores.

Statistical Analysis:
The primary outcome was the failure rate of rotator cuff repair, assessed by Kaplan-Meier survival analysis to estimate the time to reintervention. Cox proportional-hazards regression models were used to evaluate risk factors for surgical failure. Secondary analyses focused on identifying preoperative clinical factors that contributed to a higher likelihood of failure and comparing outcomes between different surgical techniques (e.g., single versus double-row repair).

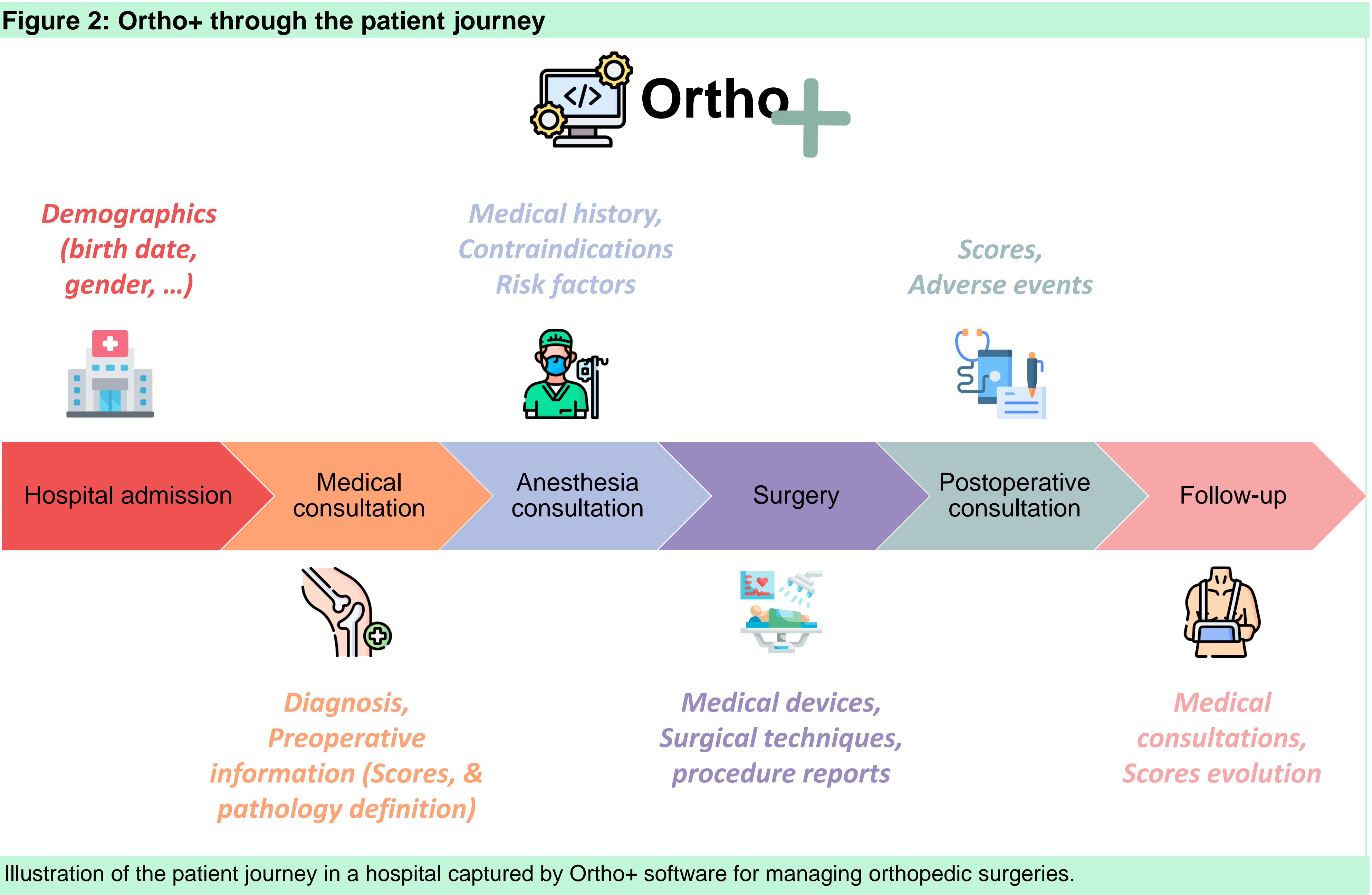
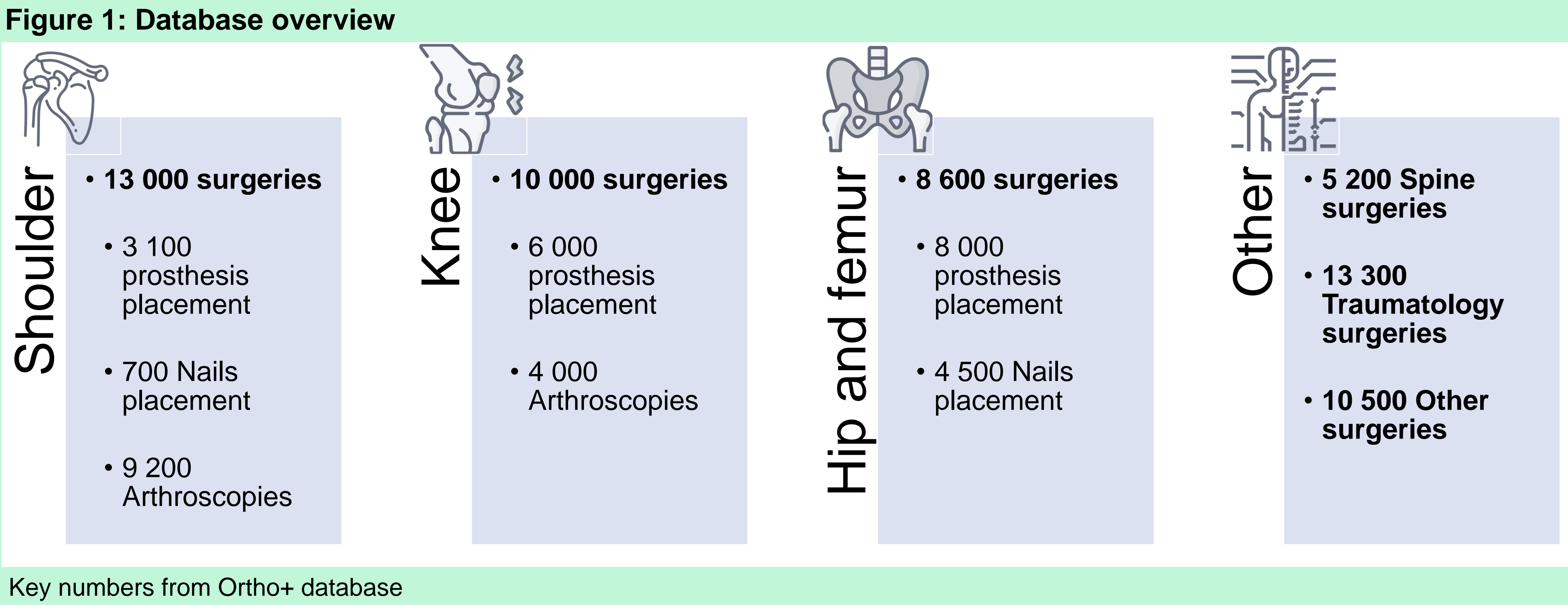


Table 1: Data sources comparison				
	SPECIALIZED CLINICAL DATABASE Ortho+	REGISTRIES	ELECTRONIC HEALTH RECORDS (EHR)	RANDOMIZED CONTROLLED TRIALS (RCTs)
Population size	+	++	+++	+
Follow-up	+++	+++	+++	+
Specificity	+++	+++	-	+++
Quality	++	+/-	+/-	+++
Cost efficiency	+++	++	+	-
Time to access	+++	++	+++	+

RESULTS AND DISCUSSION

The Ortho+ system provided consistent and comprehensive data entry, tracking the entire patient journey from hospital admission to follow-up (Figure 2). This longitudinal tracking allowed for precise monitoring of patient progress and surgical outcomes, making it particularly valuable for studies on procedures like rotator cuff repair. This use case highlights that patients with rotator cuff tears resulting from work accidents are more likely to require reintervention, suggesting a need for more specialized treatment to enhance their patient journey. Ortho+ ability to standardize coding (CCAM for procedures, CIM-10 for diagnoses) and automatically generate detailed operative reports significantly enhanced data quality and specificity, ensuring consistency across multiple clinicians and surgical practices.

This high level of detail in the dataset allows for more accurate outcome analysis and better decision-making in clinical practice. In comparison to registries, EHRs, and RCTs (Table 1), Ortho+ demonstrated clear advantages in follow-up consistency, cost efficiency, and speed of data access. The specialized nature of Ortho+'s database for orthopedic surgeries further differentiates it, offering specificity that broader data sources like EHRs often lack. Ortho+ well-structured dataset, enriched with clinical and operative details, provided an excellent foundation for assessing surgical outcomes and exploring potential improvement in clinical decision-making in rotator cuff repair.

CONCLUSION
Specialized clinical databases provide high-quality, comprehensive data that reflect the realities of surgeons' work in practice. Their structured format allows in-depth analysis and valuable insights. These databases have great potential to advance research and improve patient outcomes.

REFERENCES

Hak, David J. MD, MBAa; Mackowiak, John I. PhDb; Irwin, Debra E. PhD, MSPHc; Aldridge, Molly L. MPHd; Mack, Christina D. PhD, MSPHe. Real-World Evidence: A Review of Real-World Data Sources Used in Orthopaedic Research. Journal of Orthopaedic Trauma 35(1):p 56-512, March 2021.

Sherman RE, Anderson SA, Dal Pan GI, Gray GW, Gross T, Hunter NL, LaVange L, Marinac-Dabic D, Marks PW, Robb MA, Shuren J, Temple R, Woodcock J, Yue LQ, Califf RM. Real-World Evidence - What Is It and What Can It Tell Us? N Engl J Med. 2016 Dec 8;375(23):2293-2297

Joeris A, Zhu TY, Lambert S, Wood A, Jayakumar P. Real-world patient data: Can they support decision making and patient engagement? Injury. 2023 May;54 Suppl 3:S51-S56

Gagnier JJ. Patient reported outcomes in orthopaedics. J Orthop Res. 2017 Oct;35(10):2098-2108

Malavolta EA, Assunção JH, Andrade-Silva FB, Gracitelli MEC, Kiyomoto HD, Ferreira Neto AA. Prognostic Factors for Clinical Outcomes After Arthroscopic Rotator Cuff Repair. Orthop J Sports Med. 2023 Apr 12;11(4):23259671231160738.

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The authors declare no conflict of interest