

Intraoperative Discovery of Incorrect Femoral Component Packaging during Bilateral Total Knee Arthroplasty: A Near-Miss Case Report

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Learning Point of the Article:

Even with correct external labeling, implant mismatch may remain undetected until intraoperative opening, emphasizing meticulous verification and immediate availability of appropriate backup implants.

Abstract

Introduction: Incorrect implant delivery during total knee arthroplasty (TKA) is rare but represents a potential patient safety risk. Implant discrepancies may remain undetected until intraoperative opening despite correct external labeling.

Case Report: A 76-year-old woman with bilateral varus knee osteoarthritis underwent simultaneous bilateral TKA using a medial pivot system planned with computed tomography-based patient-specific instrumentation. Cementless fixation was intended for both knees. The left knee was implanted uneventfully. During right TKA, a femoral component with correct external labeling was opened; however, the implant inside was a cemented component, one size larger than planned, and intended for the contralateral side. An appropriately sized backup component was available, allowing completion of surgery without interruption. At 1 year, range of motion improved from -5° – 110° to 0° – 120° on the left and from -10° – 114° to 0° – 125° on the right. Pain on the visual analog scale improved from 67 to 0, and the Western Ontario and McMaster Universities Osteoarthritis Index score improved from 56.1 to 90.6.

Conclusion: This intraoperative implant packaging discrepancy represents a near-miss event. Even with correct external labeling and meticulous pre-operative planning, implant mismatch may occur. Intraoperative verification and immediate availability of appropriate backup implants are essential to prevent patient harm.

Keywords: Total knee arthroplasty, implant mismatch, near miss, patient safety, medical device error, medial pivot.

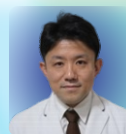
Introduction

Total knee arthroplasty (TKA) is a highly standardized and widely performed procedure with generally predictable outcomes. Its success depends not only on surgical technique and pre-operative planning but also on accurate delivery of appropriate implant components. Errors related to implant selection or delivery, including incorrect size, laterality, fixation type, or incompatible components, are recognized as uncommon but potentially serious patient-safety events in joint

replacement surgery [1, 2].

Implant-related errors may reflect system-level failures in verification and device-management processes rather than isolated surgical mistakes. Implant-selection errors have been documented even in high-volume arthroplasty practice, and wrong-side implantation has been reported during bilateral TKA [2, 3]. When the external package label itself is correct, but the enclosed implant is incorrect, conventional pre-operative verification cannot identify the discrepancy before the package is

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SIZE	TYPE	SURFACE	STYLE	FIT
5 RIGHT	PRIMARY	POROUS	CS/CR	CEMENTLESS

Figure 1: External package labeling showing the intended implant size and side (identifying information removed).

opened.

Near-miss events are incidents that could have resulted in patient harm but are intercepted before injury occurs. Analysis of such events is central to a systems approach to patient safety because it can reveal latent vulnerabilities in safeguards and workflows [4].

We report a near-miss case in which a correctly labeled femoral component package contained an implant that differed in fixation type, size, and laterality and was discovered intraoperatively during bilateral TKA. This case highlights the limitations of label-based verification and the importance of backup implants and system-level approaches to implant safety.

Case Report

A 76-year-old woman with bilateral varus knee osteoarthritis underwent simultaneous bilateral TKA. Pre-operative planning was performed using computed tomography (CT)-based patient-specific instrumentation (PSI), and a medial pivot-type knee system was selected. Cementless fixation was planned for both femoral and tibial components.

Surgery was performed under general anesthesia with pneumatic tourniquet control using a parapatellar approach. The left knee was addressed first. Bone resections were completed according to the PSI guides, and cementless femoral and tibial components were implanted without any intraoperative issues.

The right knee was then prepared using the same PSI protocol. After completion of bone cuts, implantation was initiated. The cementless tibial baseplate was inserted as planned. However, on opening the femoral component package, despite correct labeling indicating the intended side, size, and cementless fixation (Fig. 1), the actual implant inside was inconsistent with the label. The femoral component was a cemented type rather than cementless, one size larger than planned, and intended for the contralateral (left) knee (Fig. 2).

Fortunately, a backup femoral component of the appropriate size designed for cemented fixation was available. Given the intraoperative situation, the surgical plan was modified, and a cemented femoral component was implanted on the right side. The procedure was completed without further complications. Total operative time for bilateral TKA was 2 h and 9 min. Pre-

operative range of motion was -5° – 110° in the left knee and -10° – 114° in the right knee. Pre-operative pain severity assessed using a visual analog scale (VAS) was 67, and the pre-operative Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) score was 56.1.

At the 1-year follow-up, post-operative range of motion improved to 0° – 120° in the left knee and 0° – 125° in the right knee. The patient reported complete pain relief with a VAS score of 0. The WOMAC score improved to 90.6. No implant loosening, infection, or revision surgery was observed during follow-up. Written informed consent was obtained from the patient for publication.

Discussion

This case represents an implant-related near-miss event identified intraoperatively during bilateral TKA. Despite correct external labeling, the femoral component inside the package was inconsistent with the intended implant in fixation method, size, and laterality. Such discrepancies pose a patient-safety threat and illustrate vulnerabilities that may exist beyond the control of the operating surgeon. To the best of our knowledge, intraoperative discovery of a correctly labeled but internally mismatched femoral component during bilateral TKA has rarely been reported.

Implant mismatch events, including wrong size, wrong side, and incompatible components, have been documented in total joint arthroplasty [2]. Ast et al. identified implant-selection errors

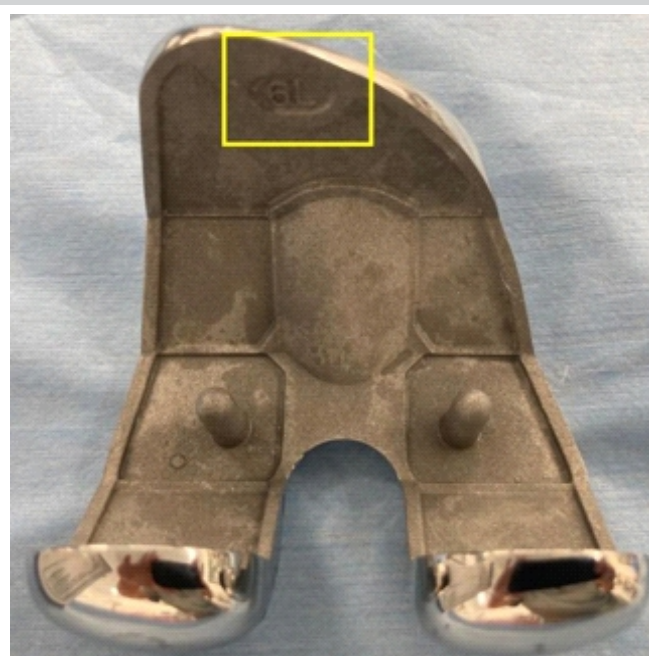


Figure 2: Marking on the actual implant indicating a different size, fixation type, and laterality from the external label (identifying information removed).

before implantation in 169 of 22,847 total hip and knee arthroplasties despite existing safeguards, demonstrating that verification systems remain important even in high-volume practice [2]. Alanazi et al. also reported wrong-side femoral component implantation during bilateral TKA [3]. In contrast, the present event differed because the external label indicated the intended implant, while the enclosed component was simultaneously incorrect in fixation type, size, and laterality.

Standardized surgical safety protocols and verification systems reduce preventable surgical errors, yet rare device-related discrepancies may still bypass routine safeguards [5]. In the present case, CT-based PSI planning and routine verification were performed, but the discrepancy could not be detected before intraoperative opening because the external label itself was correct. Our group has previously reported the use of PSI in technically complex TKA and has also investigated computer-assisted techniques for optimizing intraoperative execution [6,7]. We have further reported clinical outcomes of medial-pivot TKA [8] and associations between intraoperative findings and post-operative knee range of motion [9]. These studies emphasize the value of meticulous planning and intraoperative assessment; however, the present case demonstrates that such measures cannot eliminate errors originating from an incorrectly packaged implant. Despite the unexpected mismatch, prompt recognition and contingency management allowed the patient to achieve excellent 1-year pain, functional, and range-of-motion outcomes.

Importantly, the event was recognized before implantation and therefore constituted a near miss rather than an adverse event. A systems approach to human error emphasizes identifying latent weaknesses in defenses rather than attributing every event solely to individual performance [4]. In this case, the availability of an appropriate backup femoral component enabled immediate intraoperative adaptation and prevented cancellation, prolonged interruption, or implantation of the incorrect component. This highlights the importance of contingency planning, particularly in bilateral TKA, where an unexpected implant problem arises after substantial operative preparation has already been completed.

Beyond intraoperative management, implant-related near-miss

events underscore the need for effective reporting, feedback, and system-level prevention. Comprehensive surgical safety systems have been associated with reductions in surgical complications and mortality, supporting the principle that safety depends on multiple coordinated safeguards rather than a single verification step [10]. For implant-related discrepancies, these safeguards should include accurate packaging and traceability, pre-operative verification, intraoperative confirmation after package opening, ready access to appropriate backup components, and timely reporting of discrepancies so that recurrent hazards can be identified.

Although the clinical outcome in this case was favorable, the event demonstrates that implant packaging errors can occur even in a well-controlled surgical environment and may be impossible for the surgical team to detect while the package remains sealed. Surgeons should therefore remain vigilant when the implant is opened and should verify visible implant characteristics whenever feasible. At the same time, quality assurance throughout manufacturing, packaging, distribution, and hospital inventory processes is critical to minimizing similar events. Reporting near misses of this type may provide useful information for improving implant verification and patient-safety systems.

Conclusion

This case highlights a rare but clinically meaningful implant-related near-miss event in TKA. Despite correct external labeling, discrepancies in fixation type, size, and laterality remained undetected until the package was opened intraoperatively. Prompt recognition and the availability of an appropriate backup implant prevented patient harm. Systematic verification, reporting, and analysis of such events are important for improving implant safety in joint arthroplasty.

Clinical Message

Surgeons should not rely solely on external package labeling during TKA. Implant characteristics should be verified immediately after opening, and appropriate backup components should be readily available to allow safe management of unexpected implant discrepancies.

Declaration of patient consent: The authors certify that they have obtained all appropriate patient consent forms. In the form, the patient has given the consent for his/ her images and other clinical information to be reported in the journal. The patient understands that his/ her names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

Conflict of interest: Tsuneari Takahashi has served as a consultant for MicroPort Orthopedics. Takumi Matsumoto declares no conflict of interest.

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