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Comparing low-cost monocentric and polycentric prosthetic knees: User satisfaction among persons with unilateral above- and through-knee amputations

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Abstract

Background: The International Committee of the Red Cross (ICRC) developed 2 low-cost prosthetic knees: monocentric (ICRC-MKJ) and polycentric (ICRC-PKJ), both intended solely for above-knee amputees. Independently, Imperial College London designed a low-cost polycentric knee (ICL-PKJ) for both above- and through-knee amputations. Because no affordable through-knee prostheses are currently available, clinics in low-to-middle-income countries often fit the ICRC-MKJ for through-knee amputees, although it is designed exclusively for above-knee amputees.

Objectives: This study assesses user satisfaction with the ICRC-MKJ, ICRC-PKJ, and ICL-PKJ knees across individuals with unilateral transfemoral (UTF) and unilateral through-knee (UTK) amputations.

Study Design: Single arm, repeated-measures design.

Methods: 13 UTF (11 males, 2 females) and 5 UTK (males) consented to participate and trialed the 3 prosthetic knees. Each participant completed the Prosthesis Evaluation Questionnaire (PEQ) and Prosthesis Satisfaction Questionnaire (SAT-PRO) for each prosthesis. Results were compared.

Results: For UTF participants, ICL-PKJ scored 39% lower than ICRC-PKJ ($p = 0.007$) in PEQ Sounds. The Prosthesis Satisfaction Questionnaire perceived risk of harm score was higher with ICRC-MKJ (mean 33.3) than ICRC-PKJ (mean 53.9, $p = 0.014$) and ICL-PKJ (mean 69.2, $p = 0.029$). Aesthetics were rated higher for ICRC-MKJ (mean 87.2) than ICRC-PKJ (mean 66.7, $p = 0.046$) and ICL-PKJ (mean 69.2, $p = 0.047$). For UTK participants, PEQ Well-being increased by 37% with ICL-PKJ compared with their own ICRC-MKJ.

Conclusions: The findings emphasize the need for prosthetic solutions that meet the mobility needs and social considerations of individuals with limb loss. These results underscore the urgent need to develop affordable, dedicated through-knee prostheses to provide effective options for through-knee amputees.

Keywords

prosthetic knee, polycentric knee, monocentric knee, low-cost, above-knee amputee, through-knee amputee

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Background

The 2020 Global Burden of Disease report estimated that there are 28.9 million individuals with unilateral lower limb traumatic amputations, with the highest prevalence found in East and South Asia, followed by Western Europe.[1] The primary causes of these amputations include road traffic accidents, conflict-related injuries, and falls.[1,2]

Appropriate prosthesis design and prescription are crucial for ensuring optimal musculoskeletal system function and health after amputation. In high-income countries (HICs), amputees typically have satisfactory access to prosthetic devices and rehabilitation services. In contrast, low-to-middle-income countries (LMICs)[3] face challenges due to high demand and limited supply of prosthetic devices. It is estimated that 2.9 million people in LMICs

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require P&O services, the need being over 4 times higher than in high-income countries.[3] However, the World Health Organization reports that only 5%–15% of amputees in these regions receive prosthetic devices.[4]

One of the key objectives of the International Committee of the Red Cross (ICRC) Physical Rehabilitation Programme is to develop and distribute appropriate low-cost prostheses. The ICRC has designed affordable monocentric and polycentric prosthetic knees exclusively for transfemoral amputees, distributing 1015 prostheses in Cambodia in 2020, a region where landmines and explosive remnants of war frequently result in amputations.[5] Although these prosthetic knees are intended only for transfemoral amputations, clinics often fit the ICRC monocentric model for through-knee amputees in the absence of any affordable, dedicated through-knee prostheses, thus ensuring people can regain mobility and restore independence.

ICRC introduced a monocentric knee joint (ICRC-MKJ) before developing a polycentric knee joint (ICRC-PKJ), which has been distributed worldwide in ICRC operational areas since 2018. The ICRC-PKJ is a mechanical 4-bar polycentric knee joint, designed with its instantaneous center of rotation located more posteriorly and superiorly than the mechanical axes when the knee is fully extended. This design provides greater stability while standing and allows users to control the prosthetic knee more efficiently using their residual muscles, compared with the simple hinge mechanism of monocentric knees.[6,7] Polycentric knees also allow for shank shortening and greater toe clearance during mid-swing compared with monocentric prosthetic knees, reducing the risk of stumbling.[8]

Through-knee amputees have reported better walking ability and quality of life compared with transfemoral amputees.[9] However, through-knee surgeries are less common due to the limited availability of suitable prosthetic components. Given the long-term advantages of through-knee amputations and advancements in surgical techniques, there is a significant demand for affordable polycentric prosthetic knees tailored for individuals with through-knee amputations. The Imperial College polycentric knee joint (ICL-PKJ) has been designed to meet the specific needs of people in LMICs, accommodating for both above- and through-knee amputees. It features a patented 4-bar linkage system and, unlike the ICRC-PKJ, incorporates a spring extension assist mechanism that pushes the knee toward extension throughout its range of motion.[10] Unlike conventional designs, it eliminates the singularity feature—where the spring action pushes the knee toward extension before reaching the singularity angle and toward flexion beyond that angle—potentially improving symmetry and walking speed.[10]

The impact of these prosthetic knee joints on user satisfaction has not yet been evaluated. This study aims to assess user satisfaction with the ICRC-MKJ, ICRC-PKJ, and ICL-PKJ and compare outcomes among these prostheses in individuals with unilateral transfemoral (UTF) and unilateral through-knee amputations (UTK), noting that the ICRC knees are solely designed for above-knee users.

Methods

Ethical approval was obtained from the Cambodian National Ethics Committee for Health Research (No 035, 299 NECHR), the Kilimanjaro Christian Medical University College (Certificate number: 2493), and the Imperial College Research Ethics Committee (Reference number: 20IC6268). Signed informed consent was obtained from 13 UTF (11 males, 2 females) and 5 UTK (all male). All participants had been amputees for at least 24 months, had previously used the ICRC-MKJ prosthetic knee, and had no other disabilities. The median age at the time of the trial was 39 years (interquartile range [IQR]: 20–58) for UTF and 58 years (IQR: 38–68) for UTK. All participants had K3 (ability or potential for ambulation with variable cadence) or K4 levels (ability or potential for prosthetic ambulation that exceeds basic ambulation skills), except for one who was at the K2 level (ability or potential for ambulation with the ability to traverse low level environmental barriers).[11]

The UTF group completed trials using 3 prosthetic knees: their personal ICRC-MKJ, followed by the ICRC-PKJ and ICL-PKJ. For the UTK group, it is important to note that the ICRC does not recommend the use of the ICRC-MKJ or ICRC-PKJ for through-knee amputation, as they are solely designed for above-knee amputations. Because of lack of suitable alternatives, clinics often fit the ICRC-MKJ to through-knee amputees. For this study, the UTK group completed trials with their own current prosthesis (an ICRC-MKJ) and ICL-PKJ only. As per ICRC's guidelines, the ICRC-PKJ was not trialed by the UTK group. All prosthetic knees were paired with a solid-ankle-cushioned-heel (SACH) foot. The participants' existing prosthetic sockets and feet were used with their own ICRC-MKJ. Certified prosthetists fabricated 2 new sockets for each participant to accommodate both the ICRC-PKJ and ICL-PKJ prosthetic knees. The sockets used in the polycentric knees were fabricated to match the same socket type each participant had with the ICRC-MKJ (ischial-containment for transfemoral users and end-bearing for knee disarticulation users). All sockets were made from polypropylene. The fitting process was conducted in a specialized clinic by a certified prosthetist following instructions for use from the manufacturers for both ICL-PKJ and ICRC-PKJ. Participants were provided with the new prostheses and given a minimum of 3 weeks for familiarization at home. Participants were only enrolled in the study if their ICRC-MKJ was suitable for continued use and they were not in need of a replacement prosthesis, as participants were expected to return to their MKJ after the trial. This ensured that comparisons were made against devices in good working order.

After the familiarization period for each prosthetic knee, participants completed 2 validated questionnaires: the Prosthesis Evaluation Questionnaire (PEQ)[12] and the Prosthesis Satisfaction Questionnaire (SAT-PRO).[13] Both questionnaires were translated into Khmer and Swahili. The PEQ consists of 79 questions assessing user satisfaction with their prosthetic leg and quality of life, divided into the following categories: Ambulation, Appearance, Frustration, Perceived Response, Residual Limb Health, Social Burden, Sounds, Utility, Well-being. The SAT-PRO contains 15 questions focused on satisfaction with the prosthesis. For both the PEQ and SAT-PRO scores, the analysis below focuses on scales and questions most likely influenced by the prosthetic knees rather than the sockets—thus excluding the PEQ Residual Limb Health score and the SAT-PRO item on ease of use without a cane, as no participants used a walking aid.

Statistical analysis of UTF data was conducted using IBM SPSS version 28. A one-way, repeated measures ANOVA compared

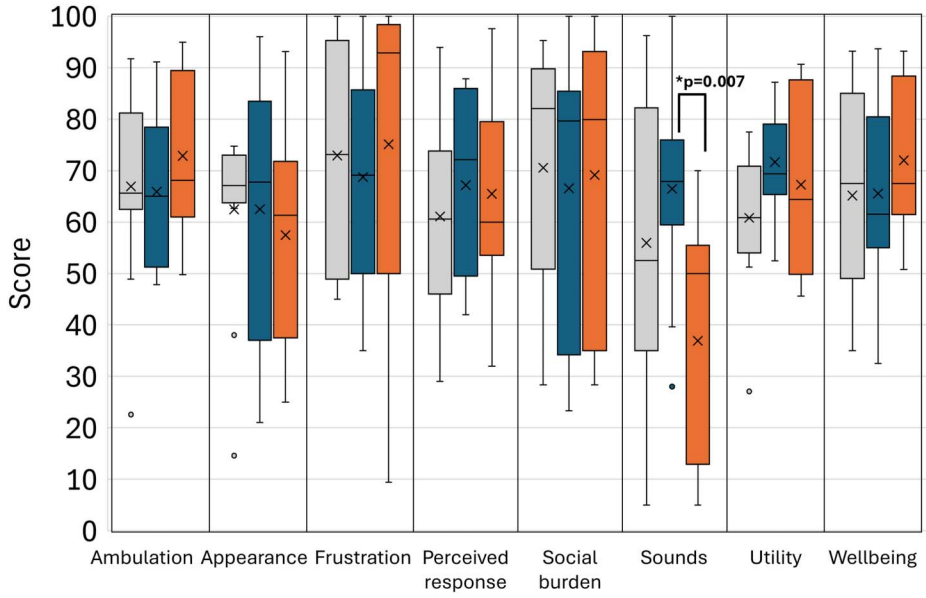

Figure 1. PEQ scale results for persons with unilateral transfemoral amputations, with 100 representing the best possible outcome. Gray: ICRC-MKJ (n = 13), blue: ICRC-PKJ (n = 13), orange: ICL-PKJ (n = 13). *Statistically significant difference between prostheses ($p < 0.05$).

scores across the 3 prostheses, with Bonferroni-corrected pairwise comparisons. Nonparametric data were analyzed using the Friedman test. The UTK data were analyzed descriptively only due to the limited sample size. Participants acted as their own controls.

Results

Persons with unilateral transfemoral amputations

Figure 1 presents the PEQ scale results for the 3 prostheses tested for the UTF patients (n = 13). The ICL-PKJ scored an average of 39% lower on the PEQ Sounds scale than the ICRC-PKJ (p = 0.007). No significant differences were found between the prostheses on the other scales.

Figure 2 shows the overall results of the SAT-PRO questionnaire with no significant differences observed between prostheses, and the detailed scores for individual SAT-PRO questions. The ICRC-MKJ scored significantly lower in ease of cleaning compared with both the ICRC-PKJ (p = 0.026) and ICL-PKJ (p = 0.047). Users also reported a significantly higher perceived risk of harm when using the ICRC-MKJ relative to the ICRC-PKJ (p = 0.014) and ICL-PKJ (p = 0.029). ICRC-MKJ received significantly higher

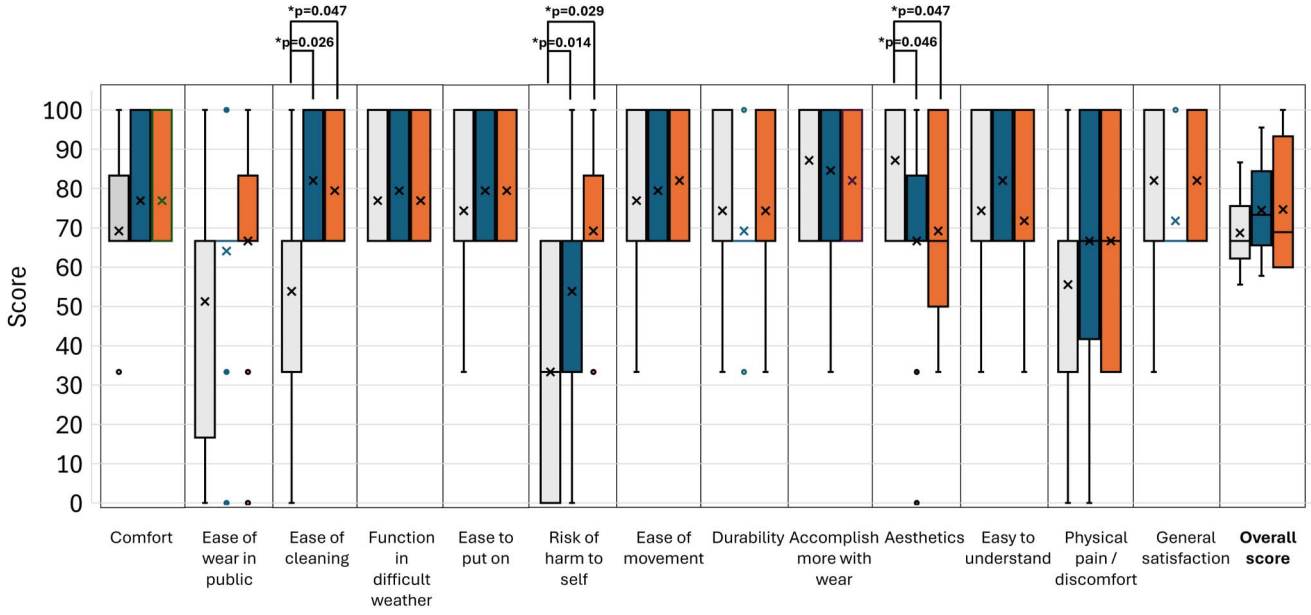

Figure 2. SAT-PRO individual question and overall results for persons with unilateral transfemoral amputations, with 100 representing the best possible outcome. Gray: ICRC-MKJ (n = 13), blue: ICRC-PKJ (n = 13), orange: ICL-PKJ (n = 13). *Statistically significant difference between prostheses ($p < 0.05$).

scores for aesthetics than both the ICRC-PKJ ($p = 0.046$) and ICL-PKJ ($p = 0.047$).

Persons with unilateral through-knee amputations

Figure 3 presents the PEQ scale results and overall SAT-PRO scores for the 2 tested prostheses, with scores spanning from 0 (poorest possible outcome) to 100 (best possible outcome). Complete follow-up PEQ data are available for 4 of the 5 participants. Participants showed a 14.7% increase in the well-being score with the ICL-PKJ compared with the ICRC-MKJ.

Discussion

This study compares user satisfaction among UTF between 3 low-cost prosthetic knees: 1 monocentric (ICRC-MKJ) and 2 differently designed polycentric knees (ICRC-PKJ, ICL-PKJ). For UTK, satisfaction was assessed between ICRC-MKJ (used in clinics for through-knee amputees despite being designed solely for above-knee amputation) and ICL-PKJ. All users had previously only used the ICRC-MKJ.

Analysis of the UTF cohort data showed that the ICL-PKJ received significantly lower sound scores compared with the other prosthetic knees. This scoring was found to be mainly related to the clicking sound when the ICL-PKJ reached full extension. Although some participants felt these sounds negatively affected stigma, others found them helpful for indicating when the knee was fully extended and ready for heel strike. The sounds were caused by the collision of hard bumpers between the knee's top and bottom components at full extension. This feedback was used to refine the ICL-PKJ design, which was still under development during the clinical trial. Softer bumpers have since been implemented to reduce the noise generated by the prosthesis. This highlights the importance of user feedback in prosthetic design, as it allows for continuous improvements that address real-world challenges and enhance user experience.

Although there were no notable differences in the overall SAT-PRO scores between the 3 prostheses, a closer examination of specific SAT-PRO questions provided valuable insights about user experiences with each device, highlighting both strengths and potential areas of improvement. As each participant used the same type of SACH foot and the same type of socket across ICRC-MKJ and both polycentric knees, matched to their original end-bearing or ischial-containment design, the observed differences between fitting conditions were due to the prosthetic knee specifications alone.

The perceived risk of harm during walking was lower with the ICL-PKJ and ICRC-PKJ compared with the ICRC-MKJ, suggesting greater stability with polycentric knees. In the UTF population, falls are often caused by low toe clearance during the swing phase of the gait cycle.[14,15] Previous studies have aimed to improve toe clearance in polycentric knee prostheses for use in LMICs, where stability on uneven terrain is particularly important.[16] Both ICL-PKJ and ICRC-PKJ feature polycentric designs that allow for shank shortening and increased toe clearance compared with monocentric knees,[8,15] thus explaining this study's results. ICL-PKJ's specific linkage mechanism and spring assist mechanism have been optimized for a more natural start of swing and a continuous extension assist moment,[10] providing better control during ambulation.

In aesthetics, participants preferred the ICRC-MKJ, as reflected in its higher aesthetics score on the SAT-PRO compared with both the ICRC-PKJ and ICL-PKJ. All participants wore a custom-made EVA foam cover, which, due to the rounded design of the ICRC-MKJ, effectively concealed most of the prosthesis, providing a more natural appearance. In contrast, the external links of the polycentric knees did not allow for complete coverage. Participants anecdotally reported that the appearance of the prosthesis was

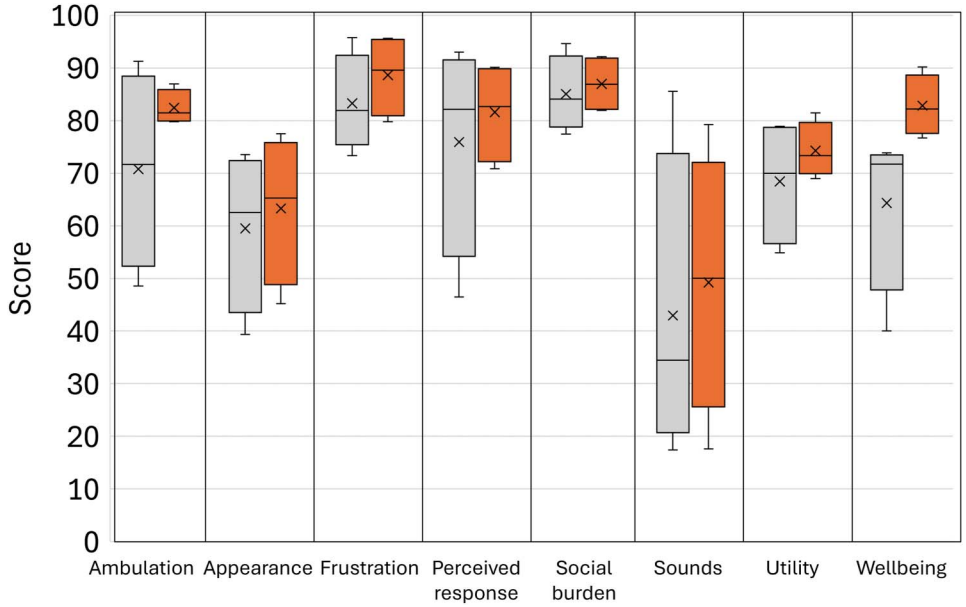

Figure 3. PEQ scale results for persons with unilateral through-knee amputations, with 100 representing the best possible outcome. Gray: ICRC-MKJ (n = 4), orange: ICL-PKJ (n = 4).

a significant factor for them, given the social stigma associated with amputation and prosthetic use in LMICs. The questionnaires used in this study were translated but not revalidated. Although this is a limitation, it was mitigated by involving bilingual prosthetists to help ensure the accuracy of responses.

This study also recruited UTK, who completed the trial using their own prosthesis (ICRC-MKJ) and the ICL-PKJ but not the ICRC-PKJ. Although clinics often fit the ICRC-MKJ to through-knee amputees due to a lack of dedicated options, current ICRC knees are not designed for this level of amputation and, therefore, not optimized for through-knee prosthesis requirements. Their bulky thigh-integrated component leads to knee-level asymmetry, resulting in a longer thigh segment and shorter shank segment compared with the unamputated limb. This means that the prosthetic foot hovers off the ground when seated, which can be a cosmetic concern, potentially leading to negative social perceptions. In addition, the length discrepancies in limb segments can introduce gait deviations such as hip hiking[17] and increased loading of the intact limb,[18] which may negatively affect long-term musculoskeletal health.[19,20] Therefore, it is preferable to use prosthetic knee designs with a shorter proximal section to minimize asymmetry between limbs for through-knee amputees or transfemoral amputees with long residual limbs.

In contrast, the ICL-PKJ is suitable for both through- and above-knee amputees, regardless of residuum length. Its design features a thin proximal section that moves with the thigh and a larger shank component, reducing thigh and shank-length asymmetry for through-knee amputees or transfemoral amputees with long residual limbs. Although not captured by the questionnaires presented here, this improved symmetry, coupled with the increased range of motion provided by the ICL-PKJ's specific 4-bar arrangement enabling kneeling—an essential function for lower-limb amputees in LMICs due to cultural requirements—which the ICRC knee mechanism could not fully support at the time of the clinical trial. The higher PEQ well-being scores for the ICL-PKJ compared with ICRC-MKJ for each participant highlight its functional and comfort benefits, contributing to an improved quality of life. The limited sample size limits the generalizability to a wider amputee population.

The ICRC has released new guidelines for manufacturing cosmetic covers for the ICRC-PKJ, offering a better fit and concealing most of the knee joint.[21] The ICL-PKJ design has also been refined to reduce the bulky shape, and a dedicated cosmetic cover is in development to match its shape, enhance appearance, and allow for customization.

Conclusion

This study evaluated user satisfaction with 3 low-cost prosthetic knees (ICRC-MKJ, ICRC-PKJ, ICL-PKJ) among UTF and UTK participants. Although overall satisfaction was similar across devices, differences were present in specific questionnaire items, including aesthetics and the sound produced by the prosthesis. The findings highlight the importance of user feedback in prosthetic development and the need for functional, comfortable, and culturally appropriate solutions, particularly in LMICs, where accessibility and durability are key. It is important to note that the ICRC advises against using either the ICRC-MKJ or ICRC-PKJ for through-knee amputations, as both are designed exclusively for above-knee applications. This highlights the urgent need for affordable, dedicated prosthetic knees developed specifically for the through-knee amputee population.

Ethical Review and Approval

Ethical approval was obtained from the Cambodian National Ethics Committee for Health Research (No 035, 299 NECHR), the Kilimanjaro Christian Medical University College (Certificate number: 2493), and the Imperial College Research Ethics Committee (Reference number: 20IC6268).

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Declaration of conflicting interest

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