1 Title: A Cohort Study Evaluating Device Quality and Satisfaction at Delivery

during an Intensive Prosthesis Fitting Camp, and at 3-Month Follow-Up

3

- 4 Author Information:
- 5 Thearith Heang¹, Sisary Kheng^{1,2}, Maggie Donovan-Hall^{2,3}, Amos Channon^{2,3}, Alex Dickinson^{2,3}, Carson
- 6 Harte^{2,}
- 7 Exceed Cambodia, Phnom Penh, Cambodia
- 8 ² Exceed Research Network, Lisburn, UK
- 9 ³ University of Southampton, Southampton, UK
- 10 ⁴ Exceed Worldwide, Lisburn, UK

- 12 **Disclaimers:** The views expressed in the submitted article are the authors' own and are not an
- official position of the institution or funder.
- 14 Sources of Support: This work was supported by the Exceed Research Network (ERN) and funded by
- the Nippon Foundation. The funders had no role in the study or in the decision to publish it.
- 16 Study Approvals: Ethical approval for data collection was granted by the Cambodian National Ethics
- 17 Committee for Health Research (NECHR, ref160) and for analysis by the University of Southampton
- 18 Ethics and Research Governance Office (ERGO, ref102303).
- 19 Word Count: 3082
- 20 Number of Figures: 3
- 21 Number of Tables: 4
- 22 Disclosure of Relationships and Activities: Authors TH, SK and CH declare employment at Exceed
- 23 Worldwide, another NGO providing domestic physical rehabilitation services in Cambodia, and
- 24 authors MDH, AC and AD have no interests to declare, beyond previous collaboration with Exceed
- 25 Worldwide.

26	Abstract:
20	Abstract:

- 27 Objective: Prosthetic limbs can enable mobility, independence and social participation. Fitting camps
- 28 provide devices to many individuals in intensive sessions. This study addressed concerns regarding
- device design and fabrication at a fitting camp for 525 people in Cambodia.
- 30 Methods: We assessed device quality and satisfaction at prosthetic limb provision, and device usage
- 31 and preference at 3-month follow-up.
- 32 Findings: Many devices failed to meet International Society for Prosthetics and Orthotics standards
- for usage, workmanship, and client satisfaction. Interviews revealed dissatisfaction with function
- 34 (26%), workmanship (34%), and fit (56%). At follow-up, 36% of clients reported discomfort or pain.
- 35 80% with a previous prosthesis preferred it. 81% reported not very often, rarely, or never using their
- 36 new device, whereas 87% of clients with a previous device reported often or always using it. 29%
- 37 were using a previous device observed at the camp as unused, broken, painful, or poorly fitting,
- 38 suggesting many rely on an inadequate or potentially dangerous prosthesis.
- 39 Conclusion: These findings indicate that shortcomings in quality and satisfaction of the studied
- 40 prosthesis system persist, and raise new questions about inclusiveness of patient selection and
- 41 effectiveness of funding use in the intensive delivery format. Inadequate training and aftercare may
- 42 exacerbate these issues, burdening local rehabilitation services or leaving vulnerable clients without
- 43 support. Camps may be more appropriate when need is clearly demonstrated, should integrate fully
- 44 with existing services, and provide adequate materials and components for repairs. Screening
- 45 patients for need is essential, as is engaging the practitioners who will continue with their care.

Introduction:

- 47 Functional prostheses can greatly enhance the lives of individuals with lower limb amputation by
- 48 improving mobility, fostering independence and enabling social participation, benefitting overall
- 49 quality of life [1]-[4]. However, the unmet need for prosthetic and orthotic provision is
- 50 disproportionately high in less-resourced settings (LRS), particularly in regions affected by
- 51 humanitarian disasters, conflicts, or landmine legacies [5], [6].
- 52 To address this need, short-term initiatives such as prosthetic and orthotic 'missions' or 'fitting
- 53 camps' aim to provide devices to large numbers of individuals in intensive sessions, often in LRS, on a
- 54 similar principle to vaccination camps. These camps are distinct from mobile services operated by
- local prosthetic providers [7], as they are typically funded and delivered by Non-Governmental
- Organisations (NGOs) who often operate internationally.
- 57 Although these missions are well-intentioned, the International Society for Prosthetics and Orthotics
- 58 (ISPO) has raised concerns around the standard of device design, quality of fabrication, and
- 59 adequacy of aftercare [8]. These concerns highlight the potential harm caused by raising clients'
- 60 expectations without sustainable care plans, which can negatively affect both individuals and
- 61 existing local services. The broader challenges of sustainable prosthetic provision are underscored
- 62 by ISPO's definition of appropriate technology in P&O. This concept, established in
- recommendations from 1996 to 2001, emphasises prosthetic rehabilitation services that ensure
- 64 proper fit and alignment based on sound biomechanical principles, meet individual needs and
- 65 remain affordable and sustainable with local resources. Notable examples include the Polypropylene
- 66 Technology limbs introduced by the International Committee of the Red Cross (ICRC) [9]–[11] and
- 67 the Jaipur Foot and Jaipur Limb [12].
- 68 Cambodia provides a compelling case study in external support for landmine clearance and physical
- 69 rehabilitation services following the Vietnam War, Cambodian Civil War, and Khmer Rouge regime.
- 70 The Cambodian government has historically struggled to manage a multitude of often incoherent
- 71 external health interventions [13]. However, NGOs operating in the country have successfully
- 72 established sustainable P&O services using a strategy of transitioning management to domestic
- 73 authorities. Jaipur technology featured in Cambodian clinical use in the 1980s and 90s but was
- 74 replaced to a national standard of ICRC/Rehab'Impulse polypropylene devices as ISPO/WHO training
- 75 came on stream in 1995. The polypropylene devices are often used with domestically-produced
- 76 rubber feet, which are well designed and tested. While somewhat heavy, their design features allow
- 77 excellent longevity even in barefoot walking [14]. By 2023, Cambodia's physical rehabilitation
- 78 network comprised 11 centres run by the Royal Cambodian Government and INGOs, all using the
- 79 standardised ICRC/Rehab'Impulse polypropylene devices.
- 80 At the time of writing, the Jaipur Foot Organisation's website reports having held 111 'on-the-spot'
- 81 fitment camps since 1975 across 44 countries in Asia, Africa, and Central and South America [15]. In
- 82 March 2023, the Jaipur Foot Organisation organised an intensive prosthetic limb fitting camp in
- 83 Cambodia, by visiting technicians, from 14-31/03/2023, near Sisophon, Banteay Meanchey Province,
- 84 near the Cambodian-Thai border. Following diplomacy discussions with the Indian Embassy, the
- 85 Cambodian Mine Action and Victim Assistance Authority (CMAA) requested that the authors
- 86 independently assess the prosthetic devices fitted during the camp. In response to this request, we
- 87 evaluated both the quality of the delivered devices and the clients' satisfaction.

Methods:

- 89 This study is reported using the STROBE cohort study guidelines [16]. Ethical approval for data
- 90 collection was granted by the Cambodian National Ethics Committee for Health Research (NECHR,
- 91 ref160) and approval for analysis by the University of Southampton Ethics and Research Governance
- 92 Office (ERGO, ref102303).
- 93 Study design:
- 94 We were given approval by the mission organisers to assess the camp's clients after discharge, but
- 95 not to intervene, and thus we conducted an observational, cohort study. To comprehensively
- 96 evaluate both device quality and client satisfaction, a multiple-methods approach was employed.
- 97 This included a standardised assessment of device delivery, completed jointly by a prosthetist and
- 98 the client immediately after fitting and discharge, followed by an invitation to participate in a second
- 99 interview three months later. All clients were invited to participate. For clients who consented to be
- 100 followed up, telephone interviews were conducted to gather insights into their experiences and
- satisfaction with the device in a community setting. The study design was tailored to the Cambodian
- 102 context, specifically to assess the outcomes and user experiences at an intensive fitting camp. At
- 103 both stages, to ensure a standardised and efficient approach to data collection, a bespoke Microsoft
- 104 Form was developed, allowing data to be collated in a Microsoft Excel spreadsheet for analysis.
- 105 Stage 1: Device quality assessment tool
- 106 A device assessment checklist was completed by ISPO-certified clinicians and clinical educators from
- the Cambodian School of Prosthetics & Orthotics (CSPO), who were separate from the technicians
- who provided the devices, and had no prior knowledge of the clients. The check out procedure and
- assessment tool are complementary and reflect the professional standard used by CSPO (Appendix)
- 110 to assess a final-year prosthetist-orthotist student's skills and readiness to graduate and provide
- 111 P&O services with ISPO-certification. It evaluated five factors associated with device quality, and
- seven factors related to client acceptance. Finally, the clinicians provided further comments,
- allowing a summary of their observations and any additional detailed comments made by the
- clients. A team of nine administered the quality assessment, in pairs which included one senior
- prosthetist with >15yrs experience, and a second with minimum 5yrs experience.
- 116 Stage 2: Follow-up structured telephone interviews
- 117 For consenting clients who could be contacted, additional interviews were conducted by telephone
- three months after device delivery. These employed a semi-structured approach, with questions
- associated with status and frequency of use of their new device, the ongoing use of their previous
- device where applicable, and their preferences for a future device. Interviews were carried out by
- 121 five of the same ISPO-Certified Prosthetists who carried out Stage 1.

123 Data Analysis:

- Data was analysed by a team of researchers who were independent from data collection (AC, MDH, AD), to ensure objectivity and minimise researcher bias.
 - Stage 1: Device quality assessment tool
 - Data from the standardised assessment tool was coded into positive and negative responses, and analysed using descriptive statistics. Categories for missing data were included. Open-ended responses were analysed using content analysis [17]. This is an established method for categorising text and summarising the frequency of response categories. Each response was a treated as a separate unit of analysis and assigned a descriptive code based on their content. These codes were then organised into a coding frame, which was used to analyse related responses. New codes were added if existing ones did not adequately capture the content. The final coding frame was used to systematically code the data and determine the frequency of responses. Throughout the analysis, the coding process and tentative categories were discussed between MDH & AD and revised to enhance the credibility of the findings. Consensus was high, with only minor modifications following these discussions.
 - Stage 2: Follow-up structured telephone interviews
 Data from the telephone follow-up interviews was coded into categories representing device status, use level and preference, and analysed using descriptive statistics.

Results:

144 Stage 1: Device quality assessment

Device delivery assessments were completed for 542 devices received by 532 individual clients, of whom 330 completed a follow-up telephone interview between 25/05 and 12/06/2023 (Table 1). Data were collected for all except six participants who left the camp before they could be spoken to. Nine devices were orthoses which were left out of the subsequent analysis, leaving 525 individual clients at delivery, who were prescribed with 533 prosthetic limbs. The median age was 59 years (inter-quartile range IQR 54-64). Clients were predominantly male, with transtibial amputations due to mine or other weapon/ordnance injury. The median time since last device delivery was 5 years (IQR 3-11). All except seven consented to be followed up. At three months, 324 clients were contacted, with the remainder not answering the telephone after multiple attempts, or their numbers were found to be incorrect.

		Count	%
Gender *	Female	24	4.6
	Male	243	46.3
	Missing	255	48.6
User Type	Experienced	475	90.5
osci Type	Primary	46	8.8
	Missing	4	0.8
		_	
Age (yrs) *	0-29	3	0.6
	30-39	8	1.5
	40-49	8	1.5
	50-59	68	13.0
	60-69	70	13.3
	70+	351	2.7 66.9
	Missing	221	66.9
Year of	2020-2023	14	2.6
Amputation	2010-2019	27	5.1
	2000-2009	34	6.4
	1990-1999	212	39.9
	1980-1989	212	39.9
	1970-1979	6	1.1
	1960-1969	0	0.0
	Missing	20	3.8
Device Type	Partial Foot	1	0.2
(n=533)	Ankle Disarticulation	3	0.6
	Transtibial	374	70.2
	Knee Disarticulation	12	2.3
	Transfemoral	106	19.9
	Wrist Disarticulation	2	0.4
	Transradia	34	6.4
	Transhumeral	1	0.2
Side	Right	252	47.3
	Left	236	44.3
	Bilateral	10	1.9
	Missing	35	6.6
Cause of	Mine/Weapon	465	88.6
Amputation	Electric Shock	7	1.3
	Traffic Accident	19	3.6
	Illness	5	1.0
	Other	1	0.2
	Trauma/Machine	12	2.3
	Congenital	8	1.5
	Missing	8	1.5
Number of	1	54	10.29
Previous	2-3	145	27.62
Devices	4-6	154	29.33
	7-10	67	12.76
	11-20	22	4.19
	Missing or N/A	83	15.81
Condition of	Good	125	23.81
Previous	Condition Unclear	138	26.29
Device	Broken/Damaged/Worn	127	24.19
	Old	30	5.71
	Poorly Fitting / Painful	46	8.76

	Stopped Using	8	1.52
	None (First Device, lost, etc.)	47	8.95
	Missing	4	0.76
Time since	0-1 years	72	13.5
prescription	2-3 years	72	13.5
of Previous	4-5 years	82	15.4
Device	6-9 years	78	14.7
	10-19 years	109	20.5
	20 or more years	32	6.0
	Primary	46	8.7
	Missing	41	7.7

^{*} High numbers of records were missing for gender and age because these were not collected in the digital study record, but a partial record was replicated from paper notes, respectively for 270 and 174 of the clients.

Device delivery assessments (Figure 1, Table 2) identified several areas in which the devices did not meet safety, workmanship and client satisfaction criteria. Examples of poor workmanship and cosmetic appearance are shown in Figure 2. Overall the clients' opinion was more positive than the prosthetists', though nearly 2/3 of clients were not sufficiently satisfied with the new device to give up their previous device.

Table 2: Prosthetist assessments of quality, and client feedback on satisfaction, at the point of camp discharge.

Prosthetist Assessments:	Yes	No	% Yes	% No
P1. Is the general workmanship appropriate?	15	507	3	97
P2. Is the socket fit of device correct? (Weight bearing, total contact, shape, socket fitting, comfortable?)	45	474	9	91
P3. While standing, is the height of the device correct?	315	203	61	39
P4. While walking, is the dynamic gait & alignment correct? (pole vertical, foot full contact, stable, any major gait deviations?)	44	462	9	91
P5. After doffing the device, is the residual limb in good condition?*	407	107	79	21
Client Feedback:	Yes	No	% Yes	% No
Client Feedback: C1. While standing, walking and sitting is the device comfortable and stable?	Yes 333	No 188	% Yes 64	% No 36
C1. While standing, walking and sitting is the device comfortable and stable?	333	188	64	36
C1. While standing, walking and sitting is the device comfortable and stable? C2. While walking and sitting, is the suspension or straps adequate?	333 272	188 248	64 52	36 48
C1. While standing, walking and sitting is the device comfortable and stable? C2. While walking and sitting, is the suspension or straps adequate? C3. Can the patient use the device independently? (donning, doffing, walking,)	333 272 495	188 248 27	64 52 95	36 48 5
C1. While standing, walking and sitting is the device comfortable and stable? C2. While walking and sitting, is the suspension or straps adequate? C3. Can the patient use the device independently? (donning, doffing, walking,) C4. Does the device's function meet the patient needs? Correct prescription?	333 272 495 285	188 248 27 229	64 52 95 55	36 48 5 45

^{*} This was assessed after approximately ten minutes owing to constraints of the number of clients to see within the study period, which may be insufficient to detect a risk of residual limb tissue injury. This would usually be assessed after approximately one hour of device use (i.e. gait training) in a conventional clinic.

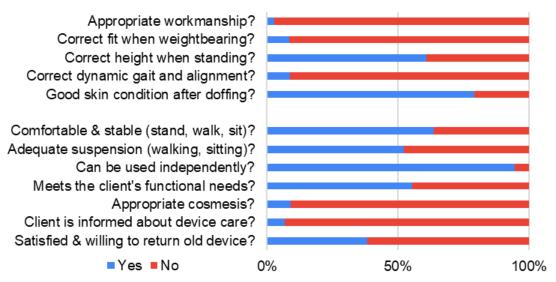


Figure 1: Prosthetist assessments of quality, and client feedback on satisfaction, at the point of camp discharge.



Figure 2: photographs of representative example transtibial prosthetic devices showing poor device design quality and fabrication workmanship. (Top row, L-R): devices and liners were observed to have thick walls, with roughly finished brims. Some had exposed screws at the ankle, and poor cosmesis including pen marks, excess adhesive, and visible transition between cosmesis and foot. (Bottom row, L-R): others had poor alignment of componentry such as knee axis height, or the socket positioned in flexion, or poorly sized liners and sockets.

184 Content analysis of clinicians' responses to the open 'Further Comments' question at device delivery 185 (Table 3) revealed a widespread range of reasons for dissatisfaction and inadequacies associated 186 with use and mobility, cosmesis and finish, device fit and client experience, consistent with the 187 quality assessment and photographic evidence (Figure 2). Clinicians reported gait deviations (n=139, 188 26%), wrong height (n=110, 21%) and poor alignment (n=66, 12%). The majority also reported 189 observing, or the client reporting, a socket fit that was either too loose (n=230, 43%) or too tight 190 (n=67, 13%), and poor finishing (n=175, 34%) including pen marks, exposed rivets, sharp trim lines 191 and unadhered cosmeses, though some commented positively on the device's light weight (n=51,

183

Content Analysis of Open-Ended Comments

Table 3: Content analysis of structured interview responses at device delivery.

Category		Code	Count
Use / mobility	Positive	Client can walk, do activities of daily living	4
	Negative	Gait deviation	139
	Negative	Prosthesis wrong height	110
	Negative	Poor alignment	66
	Negative	Difficulty donning and doffing	14
	Negative	Difficult / unstable walking	12
	Negative	Knee functions poorly, or hard to control	12
	Negative	Noise when walking	6
	Negative	Difficulty wearing device	5
	Negative	Requires training/practice	5
	Negative	Cannot walk unaided	3
	Negative	Walks with knee locked	2
	Negative	Cannot walk at all	1
Cosmesis / Finish	Positive	Client likes appearance	2
	Negative	Poor cosmesis / finish in general	175
	Negative	Trim line sharp or uneven	74
	Negative	Cuff suspension visible through long pants	5
	Negative	Rivet/cuff not secure	2
	Negative	Socket attachment	2
	Negative	Visible when sitting	2
	Negative	Rivet showing	1
	Negative	Rubber not stuck	1
	Negative	Prosthesis not strong enough	1
Socket Fit	Positive	Good socket fit in general	19
	Negative	Too loose	230
	Negative	Poor socket fit in general	143
	Negative	Too tight/pressure	67
	Negative	Incorrect trim line height	29
	Negative	Inadequate suspension	10
Experience	Positive	Light weight	51
	Negative	Socket causes pain	19
	Negative	Socket not smooth	10
	Negative	Prosthesis uncomfortable	6
	Negative	Prosthesis too heavy or bulky	2
	Negative	Straps too tight	1

Stage 2: Follow-Up Interviews

Analysis of Stage 2 interview questions at 3-months follow-up showed that 138 (45%) clients considered their new device comfortable or somewhat comfortable, compared to 112 (36%) not comfortable or painful (Table 4, Appendix Figure 4 top). Five reported the new device was broken.

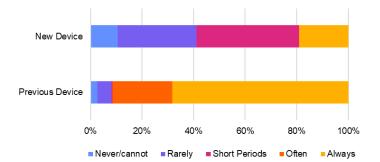
Of the clients who could compare between their new and previous devices (i.e. excluding primary patients) 39 said they could walk further and faster with the new device compared to 233 who selected their previous device, and 21 reported both were the same (Table 4, Appendix Figure 4 bottom). 233 (80%) preferred their previous device.

Table 4: Categoric responses to questions at three month follow-up, regarding device condition, use level and preference

		Count	%			
Condition of new	Comfortable	108	33.3			
device	Somewhat comfortable	34	10.5			
	Not comfortable	115	35.5			
	Broken	6	1.9			
	Does not fit / function					
	Has poor cosmesis					
	Painfu	2	0.6			
	Easy to use	1	0.3			
	Do not use	54	16.7			
Which device can you	New device	39	13.0			
walk further and	Previous device	241	80.1			
faster on?*	Neither	21	7.0			
Which device do you	New device	41	13.9			
prefer?*	Previous device	237	80.3			
	Neither	17	5.8			
Use level of the new	61	18.8				
device	Often	0	0			
	Short Periods / Some Days	127	39.2			
	Rarely	97	29.9			
	Never / Cannot use / Broken	34	10.5			
	Does not have	0	0			
	Time not stated / Other	5	1.5			
Use level of the	Always	185	57.1			
previous device	Often	63	19.4			
	Short Periods / Some Days	1	0.3			
	Rarely	15	4.6			
	Never / Cannot use / Broken	20	6.2			
	Does not have	35	10.8			
	Time not stated / Other	4	1.2			
	Missing	1	0.3			

^{*} only includes those who could compare; excludes those who did not have a previous device, e.g. primary patients.

Finally we assessed the clients' usage of both the new and previous devices at 3-months follow-up (Stage 2, Figure 3 top). 258 respondents (81%) reported not very often, rarely, almost never or never using their new device, and 61 (19%) reported always using their new device. Asked about their previous device, of 280 clients who still had one, 244 (87%) reported often or always using it. A high proportion (80-92%) who had a previous device at the camp visit (Stage 1) had reverted to using it most or all of the time across all previous device condition categories (Figure 3 bottom). Of clients whose previous device was damaged or worn out, only 28% were using their new device all the time.





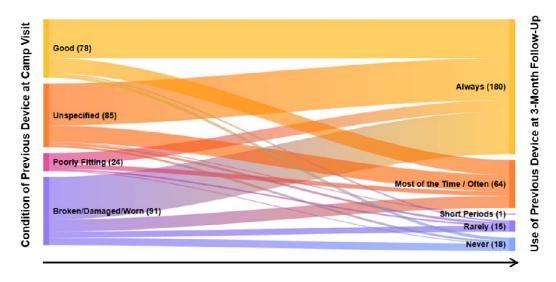


Figure 3: Client report of previous and new device usage at 3 months follow-up (top); and mapping from the clients' reported previous device condition to their level of use of their previous device at 3 months follow-up (bottom). Bracketed numbers are counts.

Discussion:

Key findings and comparison to prior studies

The present study was conducted on the request of the Royal Government of Cambodia's Mine Action and Victim Assistance Authority (CMAA) following the organisation of a camp providing Jaipur limbs. The outcomes did not meet International Society for Prosthetics and Orthotics (ISPO) benchmarks, which include 95% compliance, 90% satisfaction, 60% good socket fit (including maximum 10% needing socket change), 90% acceptable alignment and 90% good craftsmanship [18], [19]. In conventional Cambodian PRCs, devices failing any of the twelve quality or satisfaction checks at delivery would be re-worked, especially considering those criteria which might lead to poor function and potential injury. Additionally, the outcomes were lower than those reported in multiple low-resource settings (Cambodia, Vietnam, El Salvador and Tanzania) in ISPO/USAID-supported initiatives [14].

While the Jaipur Foot meets many mechanical, social, and cultural-specific needs, it has faced criticism for its weight, lack of manufacturing standardisation and limited durability particularly for individuals with higher body weights [20], [21]. The present study's findings suggest quality and satisfaction remain key concerns for these devices, aligning with reports from more than 20 years ago. In 2004, ISPO-affiliated authors conducted a three-country, ~3-year follow-up of Jaipur devices

at transtibial [22] and transfemoral [23] levels. They identified poor craftsmanship in 56% of transtibial and 86% of transfemoral devices, primarily due to fit, alignment, socket wall adequacy, and leg length discrepancy. Although satisfaction and compliance were reported to be good for transtibial device users (85% and 94%, respectively) and moderate in transfemoral device users (58% and 65%, respectively) fewer than half the participants could walk more than 1km and many reported discomfort and pain. These 2004 papers report a considerably longer follow-up than the present study, however the device fit, length and alignment shortcomings at three months cannot be expected to improve without further intervention. Indeed, where those shortcomings might be managed, measures such as accommodating socket looseness by wearing socks may be undesirable

in the warm, humid climate experienced for most of the year in Cambodia [22].

Furthermore, many clients opted to retain their old devices, and a large proportion had reverted to using their previous device within three months of receiving the new prosthesis. This suggests that, despite their initially more positive assessment, the clients' experience aligned over time with the prosthetists' assessments at fitting. Culturally, Cambodia's political history instilled norms of "hierarchy and ranking, deference and command" [24], which may be more prominent in rural communities [25]. Individuals may be unaccustomed or reluctant to voice concerns about their physical rehabilitation care and prosthetic devices, especially when these are provided free of charge. This is reflected in the present study, where clients reported some level of satisfaction with their new devices while also noting discomfort, imperfect fit, and concerns about cosmesis and workmanship.

More broadly, these findings raise questions about patient selection for the camp, and specifically whether all attendees had a genuine need for a new device or if their previous prosthesis remained adequate. An important characteristic of the present study's population is that those with a previous device reported having used it for a median of 5 years (Table 1). Our previous analysis of clients of a regular NGO-run physical rehabilitation service in Cambodia showed a median time to device repair of two years [11], and this may indicate that a notable proportion of the clients had poorer than normal access to physical rehabilitation services. However, at least 125 clients were identified to have a previous device described as in good condition at the point of new device delivery, representing 23.8% of the full cohort. 72 clients were using devices that had been delivered in the last year, of whom 17 received their devices prior to the camp during 2023, making them less than three months old. The camp organisers recruited patients with assistance of local authorities, largely from the veterans' community, but without insights into their clinical need.

In contrast, 211 clients (40.2% of the cohort) were reported to have a previous device that was unused, broken, painful and/or too loose or tight. However, 94 of these clients, representing 29.0% of those completing Stage 2 reverted to using their previous device after 3 months, suggesting a significant number of people could be living with an inadequate or dangerous prosthesis. Of the 138 clients who had a previous device whose condition could not be ascertained, 90 completed Stage 2 and of them the majority (78 clients, 87%) had returned to using the previous device. As such, both the percentages of clients who had a well-functioning alternative device prior to the camp (indicating poor client selection), and those who had returned to using an inadequate device three months after it (indicating poor device quality), are likely to be under-estimates.

Limitations:

The study used an assessment tool which considered quality and satisfaction against criteria previously defined by ISPO. The assessment tool was not standardised or previously validated but reflects the device delivery assessment procedure used as part of the ISO9001 quality management

286 system at established Cambodian PRCs for over 20 years (Appendix). Its use in the field led to some 287 heterogeneity in completion of the questions, and some potentially valuable client criteria were not 288 captured, notably gender. Furthermore, potential biases arise due to the circumstances of the 289 assessment and the need to collect large amounts of data in a timely manner, and to assess all 290 clients. The data was collected by a relatively large number of certified prosthetist assessors 291 potentially leading to some subjectivity, and the study did not include a process of recording or 292 checking. A significant proportion of the study participants (38%) could not be contacted for the 293 Round 2 telephone interviews and so were considered lost to follow-up. However, no substantial 294 difference was observed between the Stage 1 data for these clients and the full group (Appendix 295 Table 5), indicating no systematic link between satisfaction or quality and loss to follow-up.

Summary and outlook:

296

297

298

299

300

301

302

303

304

305

306

307

308

309

310

311

312

313

314

315

316

317

318

319

320

321

322

323

324

325 326 Central to Dr Sethi's vision for the Jaipur Limb was the demystification of prosthetic knowledge and the simplification of technology, enabling the establishment of camps that not only provide devices but also train local artisans to fabricate, adjust, and repair them [12]. Beside the large number of camps and delivered devices reported by the Organisation [15], it has been stated that "Somewhere down the line, the number of amputees fitted at these camps overtook the concept of imparting training to the local artisans, and it all boiled down to a game of numbers" [26]. This has been attributed in part to replacement of the initially successful beaten aluminium socket fabrication technique with use of thermoplastic from HDPE pipes, which was quicker and cheaper but heavier and more difficult to achieve the desired alignment and fit. Further, the ISPO-affiliated 2004 followup studies of these devices reported that the "material and components are of high technical standard and could provide a low-cost possibility, but improvement is needed. The utilisation of manpower is unacceptable. The untrained, so-called technicians are unable to adapt a prosthesis to an amputation stump with a functional result even with more sophisticated materials and components. A recognised prosthetics training is required to ensure proper use of materials and correct alignment of the prosthesis." [23]. In initial discussions the authors offered to provide training needs analysis and training for technicians working in this camp, but this was not accepted.

Though the generalisability cannot be confirmed, the present study identifies that concerns reported previously in a three-country study regarding the quality and satisfaction with the studied prosthesis system may persist. The study also presents new evidence which calls into question whether their delivery at intensive limb fitment camps represents an inclusive model of care or an effective use of funding, despite the best intentions to provide care to those who may not be able to access it. Previous research has identified that device durability and access to repairs and servicing are reported as issues of top priority to people in LRS who use prostheses and orthoses [4], [27], [28] Inadequacies in training and follow-up care may have widespread consequences of burdening local physical rehabilitation services if they exist, or leave vulnerable clients without support, especially in this scenario where the camp was delivered in a format and with devices that do not integrate with the currently available services. Camps may be more appropriate for patients whose need is clearly demonstrated, should be fully integrated with the existing services, and should leave behind adequate materials and components for repairs and replacement. Screening of patients for need is essential, as is engagement of the practitioners who will be expected to continue with their care.

327 References:

- 328 [1] D. Wyss, S. Lindsay, W. L. Cleghorn, and J. Andrysek, "Priorities in lower limb prosthetic
- service delivery based on an international survey of prosthetists in low- and high-income
- 330 countries," *Prosthet. Orthot. Int.*, vol. 39, no. 2, pp. 102–111, 2015, doi:
- 331 10.1177/0309364613513824.
- 332 [2] B. F. Mundell, H. M. Kremers, S. Visscher, K. M. Hoppe, and K. R. Kaufman, "Predictors of
- Receiving a Prosthesis for Adults With Above-Knee Amputations in a Well-Defined
- 334 Population," *PM&R*, vol. 8, no. 8, pp. 730–737, 2016, doi:
- 335 https://doi.org/10.1016/j.pmrj.2015.11.012.
- 336 [3] R. Stuckey, P. Draganovic, M. M. Ullah, E. Fossey, and M. P. Dillon, "Barriers and facilitators to
- work participation for persons with lower limb amputations in Bangladesh following
- prosthetic rehabilitation," Prosthet. Orthot. Int., vol. 44, no. 5, pp. 279–289, 2020, doi:
- 339 10.1177/0309364620934322.
- 340 [4] N. Ramstrand, A. Maddock, M. Johansson, and L. Felixon, "The lived experience of people
- 341 who require prostheses or orthoses in the Kingdom of Cambodia: A qualitative study,"
- 342 Disabil. Health J., vol. 14, no. 3, p. 101071, 2021, doi: 10.1016/j.dhjo.2021.101071.
- 343 [5] J. Borg, A. Lindström, and S. Larsson, "Assistive technology in developing countries: A review
- from the perspective of the Convention on the Rights of Persons with Disabilities," *Prosthet.*
- 345 Orthot. Int., vol. 35, no. 1, pp. 20–29, 2011, doi: 10.1177/0309364610389351.
- 346 [6] A. J. Ikeda, A. M. Grabowski, A. Lindsley, E. Sadeghi-Demneh, and K. D. Reisinger, "A scoping
- 347 literature review of the provision of orthoses and prostheses in resourcelimited
- environments 2000-2010. Part one: Considerations for success," *Prosthet. Orthot. Int.*, vol.
- 349 38, no. 4, pp. 269–286, 2014, doi: 10.1177/0309364613500690.
- 350 [7] M. Farrar, Y. R. Niraula, and W. Pryor, "Improving access to prosthetic services in Western
- Nepal: a local stakeholder perspective," Disabil. Rehabil., vol. 45, no. 7, pp. 1229–1238, 2023,
- 352 doi: 10.1080/09638288.2022.2057599.
- 353 [8] C. Harte, "Prosthetic orthotic missions: Ethics and efficacy," Prosthet. Orthot. Int., vol. 46, no.
- 354 5, p. 407, 2022, doi: http://doi.org/10.1097/PXR.000000000000186.
- 355 [9] J. S. Jensen and S. Heim, "Evaluation of polypropylene prostheses designed by the
- 356 International Committee of the Red Cross for trans-tibial amputees," *Prosthet. Orthot. Int.*,
- 357 vol. 24, no. 1, pp. 47–54, 2000, doi: 10.1080/03093640008726521.
- 358 [10] S. Weerasinghe, A. Aranceta-Garza, and L. Murray, "Efficacy of rehabilitation after provision
- of ICRC lower limb prostheses in low-income and middle-income countries: A quantitative
- assessment from Myanmar," Prosthetics Orthot. Int., no. November, 2023, doi:
- 361 10.1097/pxr.000000000000300.
- 362 [11] A. S. Dickinson et al., "Understanding repair and replacement of prosthetic limbs using
- 363 routinely-collected data: a retrospective study over three decades in Cambodia," medRxiv,
- 364 pp. 1–27, 2024, doi: https://doi.org/10.1101/2024.10.15.24315396.
- 365 [12] P. K. Sethi, "Technological choices in prosthetics and orthotics for developing countries,"
- 366 Prosthet. Orthot. Int., vol. 13, no. 3, pp. 117–124, 1989, doi: 10.3109/03093648909079418.
- 367 [13] F. Bourdier, "Health inequalities, public sector involvement and malaria control in Cambodia,"
- 368 Sojourn J. Soc. Issues Southeast Asia, vol. 31, no. 1, pp. 81–115, 2016, doi: 10.1355/sj31-1c.
- 369 [14] J. Steen Jensen and S. Sexton, "Appropriate Prosthetic and Orthotic Technologies in Low

- 370 Income Countries (2000-2010)," USAID/ISPO, Brussels, 2010.
- 371 [15] "BMVSS Jaipur Foot." [Online]. Available: www.jaipurfoot.org. [Accessed: 16-Dec-2024].
- 372 [16] E. von Elm, D. G. Altman, M. Egger, S. J. Pocock, P. C. Gotzsche, and J. P. Vandenbroucke, "The
- 373 Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) Statement:
- 374 guidelines for reporting observational studies," Bull. World Health Organ., vol. 85, pp. 867-
- 375 872, 2007, doi: 10.2471/BLT.07.045120.
- 376 [17] P. Mayring, Qualitative Content Analysis: A Step-by-Step Guide. London: SAGE Publications, 377 2021.
- 378 [18] J. S. Jensen, R. Nilsen, and J. Zeffer, "Quality benchmark for trans-tibial prostheses in low-379 income countries," Prosthet. Orthot. Int., vol. 29, no. 1, pp. 53-58, 2005, doi:
- 380 10.1080/17461550500085147.
- 381 [19] J. S. Jensen, W. Raab, J. Fisk, C. Hartz, A. Saldana, and C. Harte, "Quality of polypropylene 382 sockets for trans-tibial prostheses in low-income countries," Prosthet. Orthot. Int., vol. 30, no.
- 383 1, pp. 45–59, 2006, doi: 10.1080/03093640600568336.
- 384 A. P. Arya and L. Klenerman, "The Jaipur foot," J. Bone Jt. Surg. - Ser. B, vol. 90, no. 11, pp. [20] 385 1414-1416, 2008, doi: 10.1302/0301-620X.90B11.21131.
- 386 I. Huber et al., "Epidemiological study of failures of the Jaipur Foot," Disabil. Rehabil. Assist. 387 Technol., vol. 13, no. 8, pp. 740-744, 2018, doi: 10.1080/17483107.2017.1369593.
- J. S. Jensen, J. G. Craig, L. B. Mtalo, and C. M. Zelaya, "Clinical field follow-up of high density 388 [22] 389 polyethylene (HDPE)-Jaipur prosthetic technology for trans-tibial amputees," Prosthet. 390 Orthot. Int., vol. 28, no. 3, pp. 230–244, 2004, doi: 10.3109/03093640409167755.
- 391 J. S. Jensen, J. G. Craig, L. B. Mtalo, and C. M. Zelaya, "Clinical field follow-up of high density [23] 392 polyethylene (HDPE)-Jaipur prosthetic technology for trans-femoral amputees," Prosthet. Orthot. Int., vol. 28, no. 2, pp. 152-166, 2004, doi: 10.1080/03093640408726700. 393
- 394 [24] D. Chandler, Facing the Cambodian Past: Selected Essays 1971-1994. Chiang Mai: Silkworm 395 Books, 1998.
- [25] 396 K. Un, "State, society and democratic consolidation: The case of Cambodia," Pac. Aff., vol. 79, 397 no. 2, pp. 225–245, 2006, doi: 10.5509/2006792225.
- 398 R. Bhargava, "The Jaipur foot and the 'Jaipur Prosthesis," Indian J. Orthop., vol. 53, no. 1, pp. [26] 399 5-7, 2019, doi: 10.4103/ortho.lJOrtho_162_18.
- 400 L. Magnusson and G. Ahlström, "Patients' Satisfaction with Lower-limb Prosthetic and 401 Orthotic Devices and Service delivery in Sierra Leone and Malawi," BMC Health Serv. Res., vol. 402 17, no. 1, pp. 1–13, 2017, doi: 10.1186/s12913-017-2044-3.
- 403 E. Kombe, Y. Prior, H. L. Ackers, S. Day, and M. Donovan-Hall, "A qualitative synthesis to [28] 404 explore clinician and user experiences of accessing prosthetic and orthotic services in low-405 and middle-income countries using the three-delays model as a framework," Disabil. Rehabil., 406 pp. 1–15, 2025, doi: 10.1080/09638288.2025.2516170.

409 Appendices:

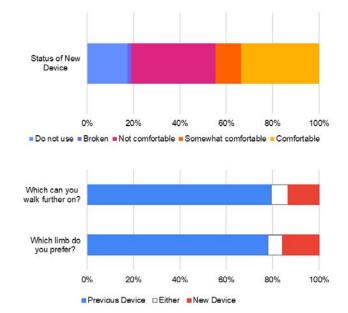


Figure 4: Client report of device status (top), and device preference (bottom) at 3 months follow-up. For latter two categories, percentages calculated using clients who reported having both devices, unbroken.

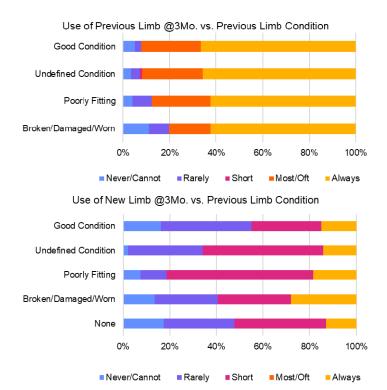


Figure 5: Client report of previous (top) and new (bottom) device usage at 3 months follow-up, broken down by groups according to previous limb condition.

Table 5: Prosthetist assessments and client feedback at the point of device delivery.

	Full G	roup	Follow	ed Up	Lost to Follow Up	
Prosthetist Assessments:		% No	% Yes	% No	% Yes	% No
P1. workmanship	3	97	2	98	5	95
P2. socket fit	9	91	8	92	10	90
P3. height	61	39	63	37	56	44
P4. dynamic gait & alignment correct	9	91	8	92	10	90
P5. residual limb in good condition	79	21	78	22	81	19
Client Feedback:		% No	% Yes	% No	% Yes	% No
C1. device comfortable and stable	64	36	64	36	64	36
C2. suspension or straps adequate	52	48	54	46	50	50
C3. use the device independently	95	5	97	3	92	8
C4. function meet the patient needs	55	45	54	46	58	42
C5. cosmetic appearance appropriate	9	91	8	92	11	89
C6. informed about device care	7	93	7	93	7	93
C7. satisfied and willing to give up current device	38	62	34	66	44	56

424 Device Checkout Form

so 9001:2015 exceed equip matte, empower			Quality Check out for Prosthesis and Orthosis			Code: FR-PO-714 Reference: QP 7 Version: 10 Issued/Reviewed Date: 23-Sep -21				
	Fitting date: Name of PO conducting Device fitting:									
No. Questions to ask			Before Finishing Comment for improvement			Delivery		Comment		
	`	Yes	No	N/A		Yes	No	N/A		
1	Is the general workmanship satisfactory?									
2	Before donning the device, is problem site in good condition?									
3	While Standing, is the length of the device acceptable?									
4	While standing, walking & sitting is the device comfortable?									
5	While walking and sitting, is the suspension or straps adequate	?								
6	While walking, is the dynamics gait & alignment is acceptable	?								
7	After doffing the device, is problem site in good condition?									
8	Can patient use the device independently?									
9	Does device's function meet patient's needs?									
10	Is device's cosmetic is acceptable?									
11	Is the client informed about problem site/device care?									
12	Does the client satisfy with device provided?									
13	Is the client informed about future appointment?									
		Befo	Before finishing Checked by:			Deli	Delivery checked by:			
1	Note: The above Questions are asked based on Work	Date:				Date	Date:			
	Instruction code: WI-PO-06. N/A= Not Applicable	PO 🗆	PO 🗆 /PT 🗀. Name:			PO	PO 🗆 /PT 🗀. Name:			
			Can be finished ☐ Yes ☐ No, need to re-do			Can	Can be delivered ☐ Yes ☐ No, need to re-do			
Stamp here for manufacturing progress.			Device recipient							
			Rece	Received date:						
				Signature/Thumbprint:			t:			