


# Evaluating the use of a thermoplastic socket in Kenya: A pilot study

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## Abstract

**Background:** Many people with amputations who live in low-resourced settings struggle to access the workshops where qualified prosthetists provide appropriate care. Novel technologies such as the thermoplastic Confidence Socket are emerging, which could help facilitate easier access to prosthetic services.

**Objectives:** The objective of this study was to evaluate the satisfaction and the performance of transtibial prosthesis featuring the Confidence Socket.

**Study design:** This is a longitudinal repeated-measures design study.

**Methods:** A convenience sample of 26 participants who underwent transtibial amputation were fitted with the Confidence Socket. The performance of the socket was evaluated after a follow-up period between 1 month and 6 months using the L test of functional mobility and the amputee mobility predictor. Satisfaction with the prosthesis was measured using the Trinity Amputation and Prosthetic Experience Scales and purposefully designed 7-point Likert scales.

**Results:** Ten of the 26 participants returned for follow-up. Perceived activity restriction and L test times improved significantly at follow-up, but the self-reported satisfaction with the Confidence Socket was lower at follow-up compared with that after fitting.

**Conclusions:** The Amparo Confidence Socket represents a potentially viable alternative to improve access to appropriate prosthesis in Kenya, but some aspects of users' self-reported satisfaction should be further investigated.

## Keywords

prosthesis, socket, low-income countries, direct manufacturing

Date received: 21 April 2021; accepted 15 February 2022.

## Background

According to estimates from the World Health Organization, in 2010, there were more than 30 million people in need of prosthetic and orthotic devices across Africa, Asia, and Latin America.<sup>1</sup> This number is likely to have grown significantly in the past decade, in line with trends recorded for the general need of assistive technology.<sup>2</sup> For many people who undergo a lower limb amputation, access to an appropriate prosthesis is essential to restore functional mobility and ensure good quality of life.<sup>3</sup> Ultimately, an appropriate lower-limb prosthesis (LLP) can enable people with amputation to fulfill their desired role in their family, work, and community life.<sup>4</sup>

Unfortunately, most people living in less-resourced settings (LRSs) are unable to receive an appropriate LLPs, with a negative

impact on their independence and their ability to access basic rights.<sup>5</sup> Factors that limit access to LLPs encompass aspects such as high cost of devices, broken supply chains that limit availability of parts, and lack of trained personnel needed for provision.<sup>6</sup> A recent survey highlighted how the lack of trained personnel necessary to assess, manufacture and fit LLPs is particularly relevant to LRS.<sup>7</sup> Although the number of prosthetists being trained worldwide has increased, the manufacturing process necessary to produce LLPs often necessitates use of machinery that is available only in dedicated workshops, which are few and far between, limiting access opportunities for amputees who live in remote locations and are unable to travel.<sup>8</sup>

The socket is arguably the most complex component of an LLP because it represents the interface between the human body and the prosthesis and needs to be tailor made specifically for each person. When using traditional production methods, the socket manufacturing process is time consuming, labor intensive, and requires multiple visits.<sup>9</sup>

New prefabricated transtibial prosthetic sockets using direct manufacturing techniques enable prosthetists to mold the socket directly on the stump of the person within a single visit.<sup>10</sup> Furthermore, they do not require complex and bulky machinery during the fitting process, allowing mobile fittings to be completed away from the traditional workshop. This significantly reduces the time and complexity of the process and facilitates access for people with amputations.<sup>11,12</sup> One of the prefabricated transtibial prosthetic sockets currently available on the market is the Amparo Confidence Socket.<sup>13</sup> The Confidence Socket is an off-the shelf product made of

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**Associate Editor:** Adam Arabian

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DOI: 10.1097/PXR.0000000000000130

low-temperature thermoplastic that can be heated and then molded directly to the patient's residual limb. Compared with other similar products, the Confidence Socket offers the added advantage of allowing prosthetists to remold the same socket, if required, to adjust for changes in volume and shape of the residual limb.

The Confidence Socket is currently provided to people with transtibial amputations in several European countries and has been reviewed positively by both prosthetists and prosthetic limb users, but it has never been trialed in LRSs, where it could provide additional benefits.<sup>14</sup>

Our hypothesis was that direct manufacturing sockets have viability and potential in LRS. As part of this pilot study, we evaluated the impact of the Confidence Socket on a patient's functional mobility, comfort, quality of life, and satisfaction with the LLP.

## Methods

### Study settings

The study was conducted in two different locations in Kenya, Hospital in Kijabe and Association of the Physically Disabled (APDK) rehabilitation clinic in Mombasa. Three local prosthetists, one from the first site and the other two from the second site, performed the fittings in participants and conducted data collection with participants. The prosthetists had between 4 and 10 years of experience, and they routinely performed prosthetic fittings using traditional methods but had no previous exposure to any direct manufacturing techniques. Prosthetists received a 1-week training on the use of the Confidence Socket and data collection methods for the trial. Training was provided by an instructor from Amparo and a researcher from University College London. Ethical approval for the trial was obtained from the Internal Review Board (IRB) of both institutions and the ethics committee of University College London to ensure compliance with national and international guidelines.

### Study participants

Participants who were aged at least 18 years, underwent a transtibial amputation (unilateral or bilateral) at least 6 weeks before, and were able to use a passive valve suspension system with a knee sleeve were recruited for the study. Early postamputation fitting of the prosthesis, in line with the guidelines outlined by O'Keeffe and Rout,<sup>15</sup> was made possible by the features that allow the socket to be remolded as the residual limb changes within the initial period of prosthesis wear without having to manufacture a new socket for the individual. Persons with ongoing skin issues, weighted more than 125 kg, whose residual limb was longer than 25 cm or with a distal circumference greater than 45 cm were excluded from the study because they did not meet the fitting criteria for the Confidence Socket. Participants were recruited by the prosthetists from preexisting pools of patients. Interested participants were invited for an in-person screening and, if suitability was confirmed by the prosthetist, asked to sign an informed consent before being fitted with the Confidence Socket. All participants were informed that their participation was voluntary and that they could keep the LLP and continue to

receive appropriate care from the clinic even if they decided to opt out of the study at any point. Participants who had already had a LLP before the start of the trial or used other assistive technologies for mobility were told they could stop wearing the new LLP at any time and return to their other assistive devices if they wished to do so. All participants were provided with the prosthesis free of charge, and full cost was covered by the project funds.

## Materials

The Amparo Confidence Socket is made of a moldable low-temperature thermoplastic and features a preassembled attachment point at the bottom. When fitting the prosthesis for a patient, the prosthetists first place spacer pads in any required area of the stump to avoid pressure concentration. The patient then slides on the silicone liner and the prosthetist wraps the residual limb using a stretchable foil to achieve the desired level of compression. The Confidence Socket is placed on a stand and inside a cylinder made of heat-insulating textile material and then heated up to the desired temperature with a portable heat gun. Once the plastic of the socket is easily pliable, the prosthetist widens the top part and places it on the residual limb. After the shape of the socket is satisfactorily molded, the prosthetist seals the proximal end and connects the distal end to a portable vacuum pump, which ensures total surface contact for optimal suspension. Once the socket cools down and hardens, the prosthetist removes it from the residual limb, cuts the top rim to the correct shape and smooths the edges. Once the socket is complete, the prosthetist attaches the pylon and foot and aligns them using standard procedures. The patient is provided with a knee sleeve for appropriate suspension.

## Outcome measures

The following outcome measures were measured by prosthetists alongside reports of any problem or concern that arose either during the fitting process or follow-up period.

### Patient's satisfaction

Patient's satisfaction with the new LLP and impact on daily life were measured using the Trinity Amputation and Prosthesis Experience Scales (TAPES).<sup>16</sup> The TAPES is a multidimensional instrument that enables researchers to collect data concerning satisfaction, activity restriction, adjustment to the use of a prosthesis, and overall quality of life using nine different subscales.

### Patient's comfort and use

Participant's level of comfort, overall satisfaction with the socket, and their level of comfort during the fitting process were measured using a purposefully designed 7-point Likert scale.

### Prosthesis performance

The performance of the LLP and its impact on participants' mobility were measured using the L test and the amputee mobility predictor (AMP). The L test is a variation of the Time Up and Go test, specifically designed for lower limb amputees, featuring a walking distance of 20 m, two transfers, and four turns, and conducted at self-selected walking speed.<sup>17</sup> The AMP is a test to assess ambulatory potential featuring 20 items including balancing

**Table 1.** Overview of participants' characteristics.

Variable	Mean $\pm$ SD	Range	Frequency
Age	49 $\pm$ 15 (y)	20–71 (y)	
Time since amputation	9.6 $\pm$ 10.7 (y)	3–45 (y)	
Sex			20 M, 6 F
Amputation side			14 Left, 9 right, 3 bilateral
Amputation cause			14 Trauma, 9 diabetes, 3 snake bite
Previous prosthesis use			18 Yes, 8 no
Time since first prosthesis <sup>a</sup>	12 $\pm$ 11 (y)	7–42 (y)	
Completed follow-up			10 Yes (6 previous LLP users), 16 no
Follow-up window <sup>b</sup>	3.5 (m)	1–6 (m)	

Abbreviation: LLP, lower-limb prosthesis.

<sup>a</sup>Only computed for participants who had previous prosthesis use.

<sup>b</sup>Only computed for participants who completed the follow-up.

and ambulation tasks.<sup>18</sup> In contrast to other ambulatory scales, the AMP allows the comparative evaluation of amputees with (AMPPRO) or without (AMPnoPRO) an LLP, enabling the monitoring of functional changes overtime for participants who did not have an LLP before entering the trial.<sup>19</sup>

## Procedure

The study was conducted in two phases: fitting and follow up. In the first phase, standardized questionnaires and functional test were conducted before the participant was fitted with the Confidence Socket. Likert scales measuring socket comfort and satisfaction were administered after fitting. All tests were repeated at follow-up. Initially, follow-up was scheduled for each participant between 1 month and 3 months from the date of fitting. However, due to the difficulties encountered by participants with returning to the clinic for their appointment, the follow-up window was extended to 6 months from the date of fitting. These difficulties are well documented in research and prosthetic care and are linked to a variety of factors, including cost of travel, low awareness concerning the importance of follow-up visits, time, and opportunity cost. Moreover, the restriction imposed on the provision of nonessential healthcare services in response to the COVID-19 pandemic created additional barriers to participants' ability and willingness to attend follow-up visits. As a result, only 10 of the 26 amputees who had been fitted with the Confidence Socket were able to return for follow-up within a period of 6 months. Unfortunately, due to the deadline imposed by the end of the project, it was not possible to extend the follow-up period beyond 6 months.

## Data analysis

Overall descriptive statistics of the measures collected during the fitting appointment are presented for all participants. Data were summarized as mean values and SDs or frequencies and percentages, as appropriate. Results of the L test conducted at fitting and follow-up were tested for normality using the Shapiro–Wilk test. As assumptions of normality were respected, paired *t* tests were conducted to evaluate the impact of the LLP featuring the Confidence Socket on participants' functional mobility. The TAPES scores were grouped according to three subscales (psychosocial adjustment, activity restriction, and satisfaction with the prosthesis), and a comparison of scores between

fitting and follow-up appointments was conducted using Wilcoxon signed rank test. AMP differences in K level between fitting and follow-up and satisfaction with the Confidence Socket after fitting and at follow-up were compared for significance using the Wilcoxon signed rank test. All statistical analysis conducted to measure differences pre–postintervention was calculated only among the subgroup of participants who completed follow-up. Owing to the low number of participants, which would affect the reliability of statistical tests performed on the sample, no further disaggregation between participants with different characteristics was conducted during the analysis. Level of significance was set at  $P < 0.05$  for all tests.

## Results

### Participants

In total, 27 participants took part in the study, 10 were recruited by the AIC Cure Hospital in Kijabe and 17 by the APDK rehabilitation clinic in Mombasa. Unfortunately, one of the participants did not meet the fitting requirements of the Confidence Socket and was instead provided with a standard PTB prosthesis and excluded from the study, resulting in 26 total participants. A summary of participants' characteristics is summarized in Table 1. Among the 26 participants who were fitted with the Confidence Socket, 18 reported previous prosthesis use. Among the 10 participants who completed the follow-up, seven reported previous prosthesis use.

### Satisfaction, life impact, intensity of use, and comfort of the prosthesis

Psychosocial adjustment, as measured by the TAPES, was subdivided across the three components of general adjustment, social adjustment, and adjustment to limitation. Each subscale had a maximum mean score of 4, with higher scores indicating higher levels of adjustment. The perceived degree of restriction on activities caused by the prosthesis measured by the following section of the TAPES had a maximum mean score of 2, with higher scores corresponding to greater perceived limitations. Satisfaction with the prosthesis was measured on three subscales: aesthetic (maximum score = 9), functional (maximum score = 15), and overall satisfaction (maximum score = 10). For all three subscales, greater scores

**Table 2.** Comparison of scores from the TAPES and the Likert scales for Comfort and Satisfaction with the socket between visit 1 and follow-up visit.

Variable	All participants—visit 1	Participants who completed follow-up—visit 1	Follow-up visit
TAPES general adjustment	3.54 ± 0.45	3.7 ± 0.41	3.54 ± 0.66
TAPES social adjustment	3.42 ± 0.61	3.9 ± 0.17	3.94 ± 0.13
TAPES adjustment to limitations	2.59 ± 0.66	2.43 ± 0.92	2.86 ± 0.61
TAPES perceived activity restriction	0.92 ± .44	0.75 ± 0.30	<b>0.67 ± 0.54<sup>a</sup></b>
TAPES prosthesis aesthetic satisfaction	6.26 ± 1.76	7.50 ± 1.52	6.7 ± 1.42
TAPES prosthesis functional satisfaction	10.00 ± 2.88	10.73 ± 4.43	11.10 ± 2.98
TAPES prosthesis overall satisfaction	7.17 ± 1.95	8.17 ± 2.23	7.10 ± 2.47
TAPES N of hours wearing a prosthesis	12.33 ± 3.25	14.33 ± 1.86	13.17 ± 1.6
Perceived socket comfort	6.04 ± 1.01	6.3 ± 0.82	6.28 ± 0.92
Satisfaction with the socket	6.19 ± 1.08	6.44 ± 0.53	<b>5.4 ± 1.17<sup>a</sup></b>

Abbreviation: TAPES, Trinity Amputation and Prosthesis Experience Scale.

<sup>a</sup>Among participants who completed follow-up, difference between visit 1 and follow-up visit was significant ( $P < 0.05$ ).

indicate greater satisfaction. Results of the analysis are summarized in Table 2.

### Performance of the prosthesis

Overall, participants' level of functional mobility improved after fitting with the Confidence Socket. Table 3 summarizes the comparison of L test times at the initial and follow-up visits, whereas Figure 1 displays K-levels recorded by the AMP before fitting and at follow-up. Although a functional improvement at follow-up was recorded with the AMP, the Wilcoxon signed rank test indicates that this was not significant ( $Z = -1.41$ ,  $P = 0.16$ ).

### Discussion

The aim of this article was to evaluate the impact of the use of the Confidence Socket on different patient outcomes among LLPs prosthetic users in Kenya. Data support our overarching hypothesis that direct manufacture sockets have viability and potential in LRS. Results from both subjective and objective measures showed that, overall, participants exhibited improved outcomes after being fitted with the Confidence Socket. This is in line with existing literature showing that access to an appropriate LLP positively influences functionality and quality of life among users living in similar settings.<sup>20</sup>

Although not all the changes reported were significant, it is interesting to notice that measurements collected at follow-up seem to indicate that participants witnessed improvements in most functional outcomes both objectively, as shown by the increased AMP score and decrease L test times, and subjectively, as indicated by greater adjustment to limitations, functional satisfaction, and reduced perception of activity restriction on the TAPES. However,

general levels of adjustment to the LLP, aesthetic and overall satisfaction, and number of hours wearing an LLP per day all decreased, albeit not always significantly, at follow-up. Furthermore, the reported level of comfort with the socket decreased between fitting and follow-up.

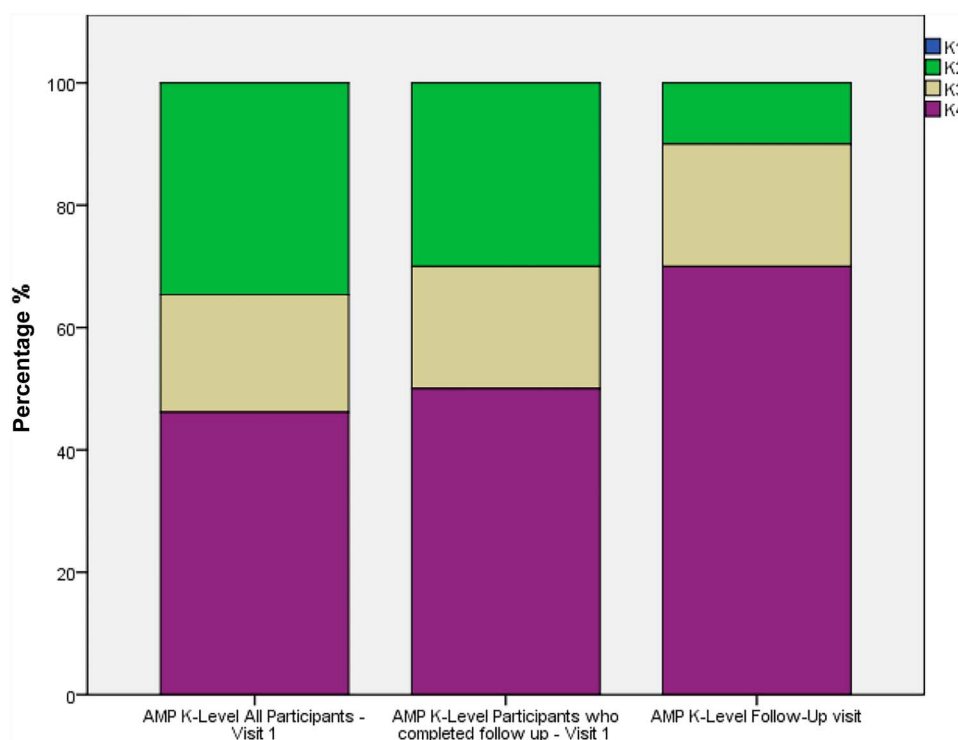
A reduction in the number of hours per day of LLP wearing is in line with the results reported by Giesberts et al.<sup>11</sup> However, as hypothesized by the authors, these results need to be carefully interpreted because estimations of prosthesis use from both amputees and clinicians might not necessarily be accurate.<sup>21,22</sup> Besides potential inaccuracies, a reduction in the number of hours of prosthesis wear could be explained by the thermal discomfort associated with the protracted use of silicon liners.<sup>23,24</sup> Heat-related and sweat-related issues might be particularly relevant in the hot conditions, which are typical of many parts of Kenya in the summer months, when the study took place.<sup>25</sup> At the same time, it is important to remember that discomfort associated with heat and excessive perspiration is not a sole prerogative of amputees who use silicone liners.<sup>26</sup>

The mismatch between improved objective functional outcomes and decreased satisfaction are interesting and might be considered somewhat contradictory. However, similar results were reported by Kark and Simmons,<sup>27</sup> where no significant correlation was found between satisfaction and performance-based measures assessing functional ability. More unexpected was the discrepancy between lower satisfaction with the prosthesis despite increased functional satisfaction and reduced self-reported activity limitation. One possible explanation is that, as highlighted by Deans et al,<sup>28</sup> some of the more athletic activities listed on the TAPES, such as performing vigorous activities or running for a bus, might have very limited importance in the everyday lives of some participants,

**Table 3.** Comparison of recorded times to complete L test at visit 1 and follow-up.

Variable	All participants—visit 1	Participants who completed follow-up—visit 1	Follow-up visit
L test time to complete	33.71 ± 14.81 (s)	30.51 ± 14.73 (s)	<b>24.59 ± 9.1 (s)<sup>a</sup></b>

<sup>a</sup>Among participants who completed follow-up, difference between visit 1 and follow-up visit was significant ( $P < 0.05$ ).



**Figure 1.** K-levels attributed to participants with the Amputee Mobility Predictor at visit 1 and follow-up.

especially when taking into account age or the presence of other medical conditions. Finally, follow-up participants also reported a slight decrease in the level of aesthetic satisfaction with the prosthesis. Although the change was not significant, even minor changes should be taken into account. Previous studies in LRS have shown how satisfaction with the aesthetic aspect of the prosthesis is an important but often overlooked aspect.<sup>12,29</sup> Furthermore, the qualitative study conducted by Hawari et al<sup>30</sup> with lower limb amputees in Malaysia indicates that materials, design concept, and finishing of the socket are the most important aesthetic elements in the eyes of the users—all of which could have played a part in this study.

Studies conducted in LRS have shown how repeated attendance to centralized hospitals, rehabilitation clinics, and orthopedic workshops is often problematic.<sup>31,32</sup> Our study showed a similar pattern. Of the 26 participants who were successfully fitted with the Confidence Socket, only 10 returned for their follow-up appointment (dropout rate 61.5%). In itself, this is a testimony of the difficulties that most patients encountered when attempting to access prosthetics services. Although partly this might have been exacerbated by the barriers to access Technology (AT)-related services during the COVID-19 pandemic, previous research has shown that having to attend prosthetic clinics on multiple occasions is problematic for patients in LRS even in standard circumstances.<sup>4,33</sup> Traditional socket manufacturing for LLP requires the patient to attend the clinic in at least two separate occasions, once for assessment and once for fitting. Considering the observed difficulties, the Confidence Socket and other similar tools and techniques that enable the production and fitting of LLP sockets within a single visit could help reduce access burden to prosthetic services. To better document the impact of direct manufacturing techniques on increasing access to prosthetics in LRS,

future research should seek to perform complete cost–benefit analysis considering both patients and clinicians point of view.

### Limitations

Despite the validity of its results, this study is not free of limitations. First of all, the low number of participants, although not unusual among similar studies, limits the statistical power of the analysis and suggests caution in the generalization of results. Furthermore, a large number of participants were male individuals and had undergone amputation due to a traumatic accident. This might have introduced bias that affected participant's performance and prosthetic use in comparison with studies that primarily involved people with vascular-related amputations.<sup>34</sup>

The length of the follow-up window varied between 1 and 6 months. Participants who returned for their follow-up appointment after an increased window of time would have had more time to adjust to the new prosthesis and improve their functional outcomes. Although this does not seem to be the case when data were visually inspected, the small sample size does not allow to either confirm or reject this potential confounder. Finally, the TAPES were translated from English to Kiswahili to be more accessible to participants. However, it is worth noticing that the translation of standardized questionnaires could lead to different interpretations that might have affected the responses of participants.

### Conclusions

The Confidence Socket could provide an effective solution to improve access to appropriate LLP among transtibial amputees



living in LRS. It is worth noting that, although participants displayed overall improved functional outcomes after being fitted with the Confidence Socket, the self-reported use and general and aesthetic level of satisfaction with the prosthesis were lower compared with that of the LLP they used to wear before the start of the trial. All socket manufacturing and prosthetic fitting procedures could be completed with participants in a few hours and using portable tools. Our study provides evidence that a direct manufacture of prosthetic sockets is effective outside clinics, reducing fitting time and increasing convenience.

## Funding

The authors disclosed receipt of the following financial support for the research, authorship, and/or publication of this article: The research in this paper was made possible by funding from the UK Foreign, Commonwealth & Development Office through the AT2030 Programme ([www.AT2030.org](http://www.AT2030.org)) which is led by the Global Disability Innovation Hub ([www.DisabilityInnovation.com](http://www.DisabilityInnovation.com)).

## Declaration of conflicting interest

The authors disclosed the following potential conflicts of interest with respect to the research, authorship, and/or publication of this article: W.T. reports grants from UK Foreign, Commonwealth & Development Office through the programme AT 2030 to Amparo GmbH during the conduct of the study; and he is the developer of the Amparo Socket technology that was used in this study and a partial owner of the company Amparo GmbH, which sponsored the research. C.H. is the academic director of the Global Disability Innovation Hub that leads the AT2030 programme, funded by the UK FCDO, which sponsored the research. The remaining authors report no conflict of interest.

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## Supplemental material

No supplemental digital content is available in this article.

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