

Efficacy of rehabilitation after provision of ICRC lower limb prostheses in low-income and middle-income countries: A quantitative assessment from Myanmar

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Abstract

Background: Low-income and middle-income countries (LMICs) have poorly resourced health services. Lack of access to assistive devices, such as prosthetics, may limit the functional outcomes of persons with amputation and affect quality of life (QoL).

Objective: The objective of this study was to assess the functional level and QoL of prosthetic users in LMICs when prescribed a prosthesis made from International Committee for Red Cross (ICRC) components.

Study design: The study design included a quantitative descriptive methodology assessing functional outcomes and QoL after prosthetic provision.

Methods: Participants were identified from the prosthetic service in Mandalay, Myanmar. Included participants were those with unilateral, traumatic, lower limb amputations, with ICRC devices delivered at least 6 months earlier. Participants attended the prosthetic service and were assessed using the Amputee Mobility Predictor with Prosthesis tool and the World Health Organization Quality of Life Brief and Disability modules.

Results: Thirty-five participants completed the study; of them, 63% were persons with transtibial level amputation and 37% were with transfemoral level amputation. Approximately 83% achieved a score of more than 37 using the Amputee Mobility Predictor with Prosthesis. There is a strong positive correlation between QoL and physical health ($r = 0.55$; $p < 0.001$), social relationships ($r = 0.66$; $p < 0.001$), and inclusion ($r = 0.53$; $p < 0.001$). Participants had a better QoL and overall health when they had better psychological health.

Conclusion: The patient-based results presented within this study could be considered as a contribution to the evidence base and importance of provision of prosthetic services in LMICs. It was observed that participants with an amputation were able to achieve a high level of physical function with the ICRC prostheses while also reporting a high QoL.

Keywords

ICRC components, Amputee Mobility Predictor with Prosthesis (AMPPRO), World Health Organization quality of life Brief (WHOQoL-Bref), outcome measures, low-income rehabilitation

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Background

It has been estimated that more than 29 million people who live in low-resource settings, with limited access to health care, remain in need of prosthetic or orthotic provision.¹ In many low-income and middle-income countries (LMICs) including Sri Lanka, Pakistan, and Vietnam, rehabilitation centers for amputees use low-cost

components manufactured by the International Committee for Red Cross (ICRC). Between 2009 and 2018, there were 5,267 reported amputation surgeries in Myanmar²; this significant number emphasizes the need for these devices. In 2017, the Mandalay Orthopaedic Hospital (MOH) in Myanmar with assistance of foreign funding (The Nippon Foundation, Japan; Exceed worldwide, United Kingdom), established a new Prosthetic and Orthotic facility. This facility provides custom-made assistive devices to service users and rehabilitation through a period of initial gait training before discharge.³ Despite ICRC components being widely used in LMICs, there is an absence of evidence to evaluate their impact on functional outcomes.

Recent global initiatives that have been implemented by the World Health Organization (WHO) have provided insight for the sustainability and development of currently available health services, including prosthetic and orthotic services, in Myanmar. In 2017, the WHO in collaboration with International Society for Prosthetics and Orthotics and the United States Agency for International Development prepared and published the global standards and implementation manual for prosthetics and orthotics with the aim of integrating Prosthetic and Orthotic (PO) services into health systems to increase access.⁴ The authors

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found no evidence available on the quality of life (QoL) of the general population in Myanmar. Zin et al⁵ reported that in the elderly population, in Myanmar, better access to health care, social interaction, and participation in group activities are all documented as improving QoL.

There are several limitations associated with lower limb amputation, regardless of setting, which are known to affect the physical, psychological, social, and economic aspects of a person's life.⁶⁻⁸ Physical activity is a significant measure in the rehabilitation of those with lower limb amputation and is a key factor affecting their QoL.⁹⁻¹¹ Crucially, physical rehabilitation aims to improve functional and physical activity levels while also improving QoL.¹² For those capable of ambulating, comprehensive measurable prosthetic rehabilitation remains an important factor to retrain and assist in reintegration back into society.¹³ Quality of life is defined as "an individual's perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals,"⁹ and it has become an important measurable concept in lower limb amputee rehabilitation.^{12,14,15} The use of outcome measures to evaluate prosthetic care has gained importance and can provide an understanding of the factors that can influence rehabilitation, highlighting ways to improve it.¹⁶

Studies based in LMICs tend to focus on the appropriateness of technology and devices, patient satisfaction, or lack of access to services.¹⁷⁻²¹ Uniquely, this study aims to provide evidence of the efficacy of ICRC devices and consider the relationship between functional outcomes and the QoL, specifically of persons with transtibial (TT) and transfemoral (TF) amputation. The research was completed at the PO center at MOH, which is a good example of an LMIC service. Two study hypotheses were formed: (1) when using ICRC prostheses, there will be a greater capability in performing physical activities that would lead to an improved perception of QoL, and (2) a higher functional score, quantified by their Amputee Mobility Predictor with Prosthesis (AMPPRO) score, would lead to a greater QoL score.

Methodology

Two assessment tools were used; the AMPPRO²² to assess mobility through physical activity and the WHO QoL Brief and Disability modules (WHOQoL-Bref-Dis)²³ to assess individuals' QoL in the context of their culture, values, goals, standards, and concerns.²⁴ The AMPPRO is a 21-item objective measure to assess mobility tasks with increasing difficulty. The WHOQoL-Bref-Dis modules are a 39-item, self-report measure, which considers the following factors: physical health, psychological health, social relationships, and environment. Both measures have been shown to have good validity and internal reliability in other studies.²⁵⁻²⁷

The WHO granted permission to translate the WHOQoL-Bref-Dis modules. Two MOH staff members, whose first language is Burmese, were recruited to assist in the forward translation of the participant information sheets, consent forms, WHOQoL-Bref and disabilities, and the AMPPRO tasks. The documents were then checked against the English version, and backward translation was completed by an independent Burmese translator. The translations were finalized by the research assistants using feedback from the independent translator and then cross-checked and approved by the ethics committee at the Mandalay Medical University. This

aimed to minimize the discrepancies and to achieve conceptual equivalence with the original version.²⁸

Participants were identified through patient files. To fulfil the inclusion criteria, patients were required to be older than 18 years of age, have a unilateral TT or TF amputation due to trauma, be using a primary prosthesis made with ICRC components delivered from MOH by a certified prosthetist, and using the device for at least 6 months before the appointment. Six months was deemed an appropriate postprosthetic rehabilitation period, and all patients had been discharged from initial rehabilitation. At TT level, the prosthesis consists of a polypropylene socket, supracondylar suspension, and a solid ankle cushion heel (SACH) foot. At TF level, a polypropylene socket, Silesian belt, uniaxial knee, and SACH foot were provided. Patients were excluded if they did not meet the inclusion criteria or if they were expectant mothers and anyone who had severe injuries to the contralateral limb including bilateral amputations. A total of 170 participants were initially identified as meeting the inclusion criteria. All participants were contacted through telephone to explain the nature of the research. Due to the coronavirus disease (COVID-19) pandemic, the total number of participants had to be limited due to travel restrictions and department capacity of 10 volunteers per session. Only 135 were located within the travel zone, and of them, 49 agreed to participate. Of the 49 whom attended, only 35 results were suitable for inclusion after incomplete responses were excluded. Participants provided written consent when they attended the MOH.

All assessment tools were easily administered²⁹ and were applied by an IPSO category I certified prosthetist with AMPPRO results verified by PO research assistants. The AMPPRO was completed in the gait training area with clear instructions given before task completion. A quiet space was provided to complete the WHOQoL-Bref-Dis questionnaire with a research assistant available for question clarification. Ethical approval for the study was granted by the University of Strathclyde UEC20/07: Murray/ Weerasinghe and the Myanmar health and sports ministry 407(MOHS)/ UMM/ 2020.

Statistical analyses

To test the hypotheses, data from WHOQoL-Bref-Dis modules were assessed by each of their subcategories (ie, overall QoL, overall health, physical, psychological, social, and environmental, and overall disability, discrimination, autonomy, and inclusion, respectively). To explore relationships between each of these subcategories, linear regressions and correlations ($\alpha = 0.05$) were used across the sampled population with further subanalysis by gender, age (by decade), and level of amputation (TT and TF). Moreover, regressions and correlations ($\alpha = 0.05$) were used to explore the strength of the relationship (if any) between the AMPPRO and overall WHOQoL-Bref-Dis modules. These latter regressions and correlations were also explored by sampled population and with further subanalysis (by gender, age, and level of amputation) as previously described. Finally, group mean comparisons ($\alpha = 0.05$) between TT and TF were performed to explore whether there were any significant differences on the AMPPRO and WHOQoL-Bref-Dis scores. Of note, the AMPPRO was used to define the functional classification of each prosthetic user.^{30,31} All statistical analyses of data were completed using Minitab 21.1 Statistical software (2021), LLC.

Results

A total of 35 participants were included in the trial (3 F; 32 M). All participants were older than 30 years. Of them, 22 (63%) were persons with TT amputation and 13 (37%) were persons with TF amputation. Participant demographics are shown in Figure 1. Data relevant to the WHOQoL-Bref-Dis modules were normally distributed ($p > 0.05$; Ryan-Joner). The AMPPRO was analyzed using nonparametric tests.

When the mobility was assessed, AMPPRO results showed an average score (mean \pm SD) for the sampled population (40.77 ± 5.05). When analyzed by amputation level, TT and TF were as follows: (43.32 ± 2.46) and (36.46 ± 5.44), respectively. A Mann-Whitney test indicated this difference was statistically significant, $U(N_{TT} = 22, N_{TF} = 13) = 506, p < 0.001$. The AMPPRO results were analyzed by medicare functional classification level and by amputation level (Table 1).

When assessed, the WHOQoL-Bref-Dis modules showed a strong positive correlation between overall QoL and the following factors: (1) physiological health ($r = 0.550, p < 0.001$); (2) social relationships ($r = 0.659, p < 0.001$); and (3) autonomy and inclusion ($r = 0.525, p < 0.001$). Further moderate positive correlations were found between overall QoL and the following factors: (1) psychological health ($r = 0.492, p = 0.005$); (2) environment ($r = 0.352, p = 0.052$); and overall disability ($r = 0.449, p = 0.008$).

When overall health was assessed (WHOQoL-Bref), moderate positive correlations were observed with the following factors: (1) physiological health ($r = 0.338, p = 0.051$); (2) psychological health ($r = 0.480, p = 0.006$); (3) environment ($r = 0.431, p = 0.016$); (4) autonomy ($r = 0.392, p = 0.022$); (5) inclusion ($r = 0.493, p = 0.003$); and (6) overall disability ($r = 0.449, p = 0.008$).

(Table 2). When the WHOQoL-DIS was assessed, there was a strong negative correlation between overall disability and discrimination ($r = -0.515, p < 0.05$). Table 2 summarizes all test statistics.

It was observed that participants demonstrated a better overall QoL when they had a positive perception about their psychological health (Figure 2) ($F [1, 29] = 9.25, p = 0.005; r = 0.492, CI = [0.166-0.721]$). Moreover, participants were shown to have an improved QoL when they perceived to engage more in social activities ($F [1, 31] = 23.80, p < 0.001; r = 0.659, CI = [0.408-0.817]$).

When participants felt included (WHOQoL-DIS Inclusion), they also had an improved perception of their overall QoL ($F [1, 32] = 12.86, p = 0.001; r = 0.535, CI = [0.241-0.740]$). This can be seen in Figure 3.

Participants were observed to enjoy better overall health when their psychological health was higher ($F [1, 29] = 8.70, p = 0.006; r = 0.480, CI = [0.152-0.713]$, Figure 4).

Subanalyses of the results highlighted those participants with TF and TT amputations had a better QoL when they engaged in social activities ($r = 0.573, p = 0.041; r = 0.700, p < 0.001$, respectively), Figure 5. Transfemoral participants had a greater perception of their disability when they felt being discriminated ($r = -0.927, p < 0.001$). Transtibial participants demonstrated to have a better overall QoL when they had a high perception of their physical and psychological health ($r = 0.668, p < 0.001; r = 0.639, p = 0.004$, respectively). Both inclusion and disability domains had a moderate positive correlation with QoL ($r = 0.539, p = 0.012; r = 0.425, p = 0.055$, respectively).

Considering the overall health score, TF participants demonstrated a greater perception of health when their psychological health was greater ($r = 0.479, p = 0.044$), when their environment

Participants split by gender, age category, and level of amputation

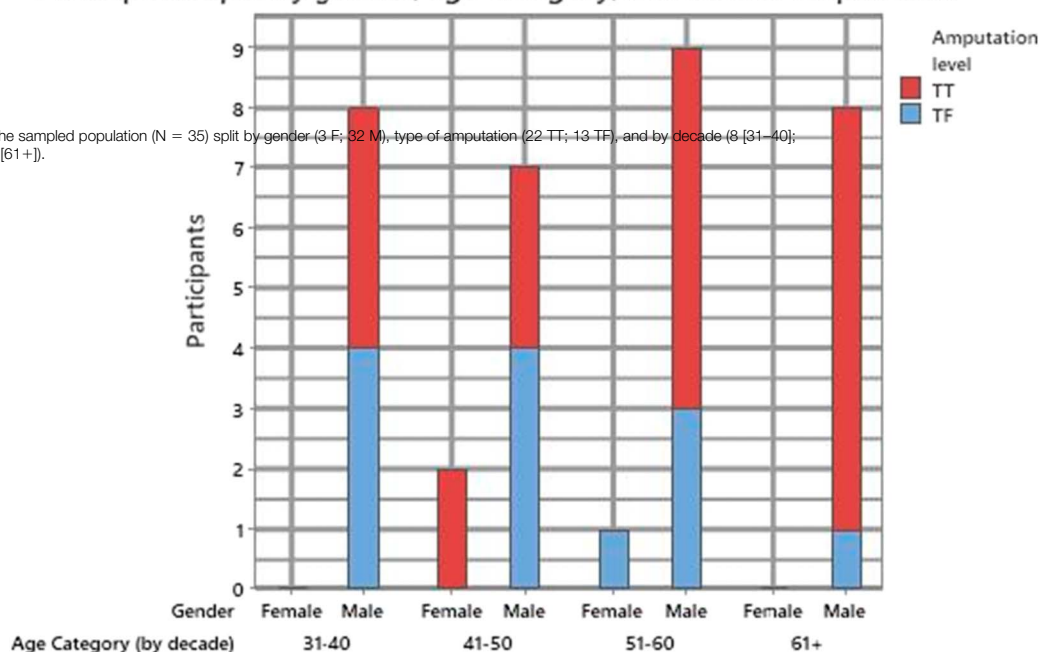


Figure 1. Demographics of the sampled population (N = 35) split by gender (3 F; 32 M), type of amputation (22 TT; 13 TF), and by decade (8 [31-40]; 9 [41-50]; 10 [51-60]; and 8 [61+]).

Table 1. MFCL for participants from AMPPRO results.

MCFL	Participant N (%)	Age (mean ± SD)	TT N (%)	TF N (%)	AMPPRO score (mean ± SD)
K2	6 (17.14)	(52.17 ± 9.68)	0	6 (17.14)	(31.50 ± 3.15)
K3	11 (31.43)	(51.82 ± 13.82)	4 (11.43)	7 (20)	(39.82 ± 1.54)
K4	18 (51.43)	(49.50 ± 12.62)	18 (51.43)	0	(44.44 ± 1.20)

Abbreviations: MFCL, medicare functional classification level

was perceived as adequate ($r = 0.632, p = 0.005$), had a feeling of independence ($r = 0.438, p = 0.047$), feeling of inclusion ($r = 0.533, p = 0.013$), and an acceptance of their disability ($r = 0.520, p = 0.016$). No TT participant had any association with the WHOQoL-Dis score in any subcategory.

When the sampled population was subanalyzed by gender, there were not enough female participants to conduct any statistical test; as for the male participants, it was observed that they had a better perception of their overall health when they had improved psychological health ($F [1, 26] = 8.14; p = 0.008, r = 0.488, CI = [0.141-0.729]$).

Subanalysis by decades showed different relationships for the different decades. For 31–40 age group ($N = 8$), there seemed to be improved overall QoL when they perceived to be more active ($r = 0.841, p = 0.018$); however, these participants had a greater feeling of their disability when they felt discriminated, not included, and disabled ($r = -0.898, p = 0.002; r = -0.755, p = 0.030; r = -0.809, p = 0.015$, respectively). They (41–50) ($N = 9$), had a greater perception of their overall QoL when they engaged in social activities ($r = 0.716, p = 0.030$) while also perceiving greater disability when their environment was not perceived as appropriate ($r = -0.953, p = 0.001$). The 51–60 ($N = 10$) age group was observed to enjoy a better QoL when their physical activity was higher ($r = 0.755, p < 0.001$), when they were socially engaged ($r = 0.710, p = 0.032$), with sense of independence ($0.652, p = 0.041$), and with inclusion ($0.878, p = 0.001$); however, they showed to have a reduction in their overall QoL when they perceived discrimination ($r = -0.681, p = 0.043$). This decade category also enjoyed better health when they felt included ($r = 0.6751, p = 0.041$). By contrast, they felt greater

disability when they perceived discrimination ($r = -0.898, p = 0.002$), were not included ($r = -0.755, p = 0.030$), were disabled ($r = -0.809, p = 0.015$), and were discriminated ($r = -0.856, p = 0.003$). The 61+ age group ($N = 8$) had a better overall QoL when socially active ($r = 0.716, p = 0.030$), independent ($r = 0.704, p = 0.051$), and had a better perception of their disability ($r = 0.708, p = 0.050$). All the subcategories for both Bref and Dis (except discrimination) were found to have a positive impact on their overall health, with no significant relationship between overall disability and any subcategory.

Discussion

Although the participants in this study were provided with components that would be deemed basic in terms of form and function, our results highlight that the use of ICRC devices have demonstrated achieving high-level functional mobility and QoL. It was also observed that there was a variation when the amputation level was assessed and compared. In general, all the results highlighted a positive perception in QoL, Health, and (little) Discrimination directly related to a perceived high level of function and satisfaction in all participants and by all subanalyses (except by gender because there were not enough female participants to make this conclusion).

The AMPPRO questionnaire was designed as a tool to help assess prosthetic user rehabilitation progress and detect changes in function.²² It can be used to gauge their ambulatory level against the medicare functional classification level.¹⁶ This is part of the United States Health Care Financing and Administration used to describe the activity level of a person with amputation. The results

Table 2. Statistical results from Pearson correlations ($\alpha = 0.05$) when associations between each overall score for WHOQoL-Bref (overall QoL and health) and for WHOQoL-DIS (overall disability) by each subcategory were explored on the sampled population ($N = 35$).

Overall score Subcategory	QoL r, p	Health r, p	Disability r, p
Physiological	0.550, 0.001 ^a	0.338, 0.051 ^a	-0.137, 0.447
Psychological	0.492, 0.005 ^a	0.480, 0.006 ^a	-0.033, 0.862
Social	0.659, <0.001 ^b	0.225, 0.209	0.115, 0.530
Environmental	0.352, 0.052 ^a	0.431, 0.016 ^a	-0.145, 0.446
Discrimination	0.080, 0.657	0.195, 0.277	-0.515, 0.002 ^a
Autonomy	0.298, 0.087	0.392, 0.022 ^a	0.004, 0.984
Inclusion	0.525, 0.001 ^a	0.493, 0.003 ^a	-0.004, 0.984
Disability	0.449, 0.008 ^a	0.495, 0.003 ^a	-0.190, 0.290

^a $p < 0.05$.^b $p < 0.001$.

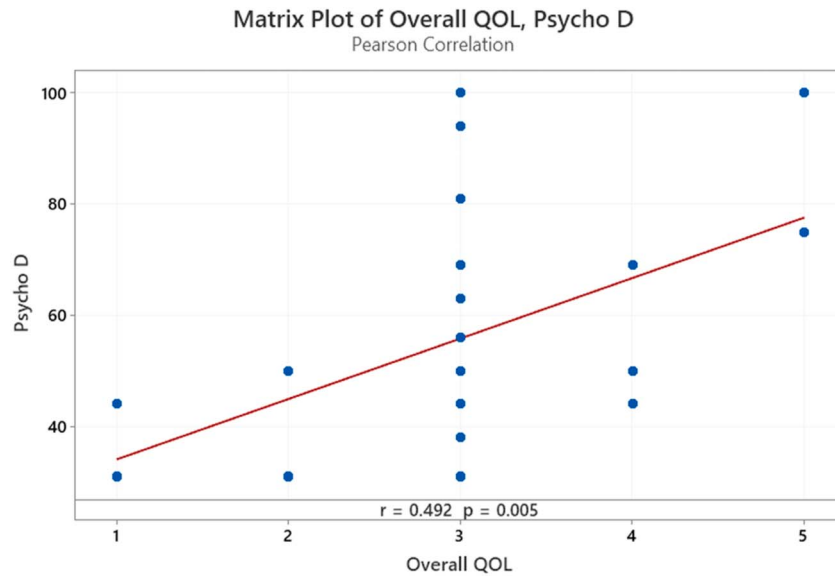


Figure 2. Matrix plot from Pearson correlations between QoL and the psychological domain across the entire population (N = 35). One indicates low QoL, 5 indicates best QoL. In the psychological domain, 0 indicates the least perception and 100 indicates the highest perception of QoL in psychological domain.

showed that all TT users achieved at least a K3 (n = 4) but most a K4 (n = 18) activity level. This would indicate a high level of functionality and independence. For the TF participants, there were 7 (54%) who achieved K3 and 6 (46%) who achieved K2 levels. This is still indicative of a population that can achieve some community ambulation with the use of ICRC components.

Our study indicates that when participants were more mobile (as measured by the AMPPRO) when they had a positive perception of their physical and mental health, they were socially active, were included, and were independent. In turn, when participants had a perception of being less mobile, they also had a

greater awareness of their disability, which is in line with previous findings of Harness and Pinzur,³² in a population of people with dysvascular TT amputations.

When analyzing the individual facets of Disability module, autonomy, discrimination, and inclusion, they all had a mean score of more than 50 points for each facet. However, the weaker correlation between the disability module facets and WHOQOL-Bref domains revealed the participants' perception of QoL was not affected by their perception of their disability status. These results also could suggest the amputee subjects' standpoint on their own disability status was weaker and did not affect the

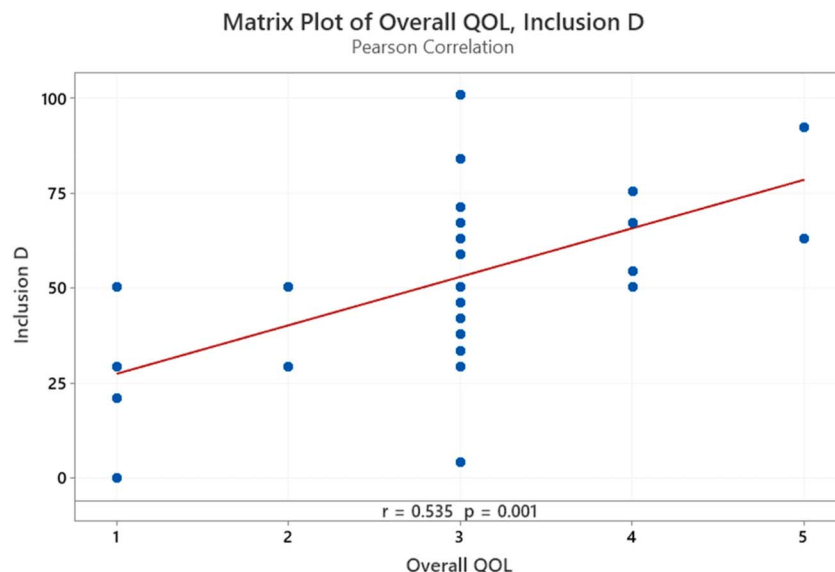


Figure 3. Matrix plot from Pearson correlations between the overall QoL and inclusion domain for entire population (N = 35). One indicates low QoL, 5 indicates best QoL. In the inclusion domain, 0 indicates least inclusion and 100 indicates highest perception in feeling included.

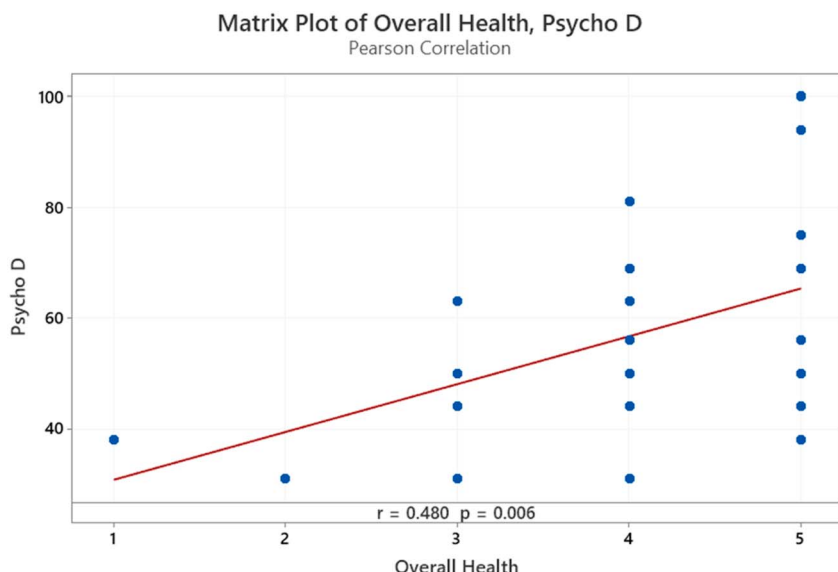


Figure 4. Matrix plot from Pearson correlations between overall health and psychological domain for entire population (N = 35). 1 indicates low health, 5 indicates best health. In the psychological domain, 0 indicates least perception and 100 indicates the highest perception on QoL in psychological health.

functional independence. Future research is important to find greater clarification on this correlation and to support this argument.

Of importance, the results demonstrate a strong positive link between perceived mobility (AMPPRO) and perceived QoL (WHOQoL-Bref). These results suggest that the participants' capabilities in performing simple tasks have a strong positive effect in their perception on their physical and psychological health, in their social activities, and their environment. Participants had received their device at least 6 months before testing, so they will have achieved their rehabilitation potential, and scores are likely to be the highest they will achieve³³ without further intervention.

Being able to participate in activities and social interactions are vital for high QoL scores.⁵

Transfemoral participants scored lower in physical domain and in AMPPRO scores. This may be suggesting the existence of limitations in their physical activities when performing daily activities. These findings are in line with other studies where TF amputation results in a greater degree of physical impairment.³⁴ Some of these limitations could be arising from the ICRC knee component and SACH foot, which were used to manufacture the device. The knee joint has a manual locking system, with a constant friction swing phase control resulting in a constant shank speed. In addition, some of the TF amputee participants favored walking

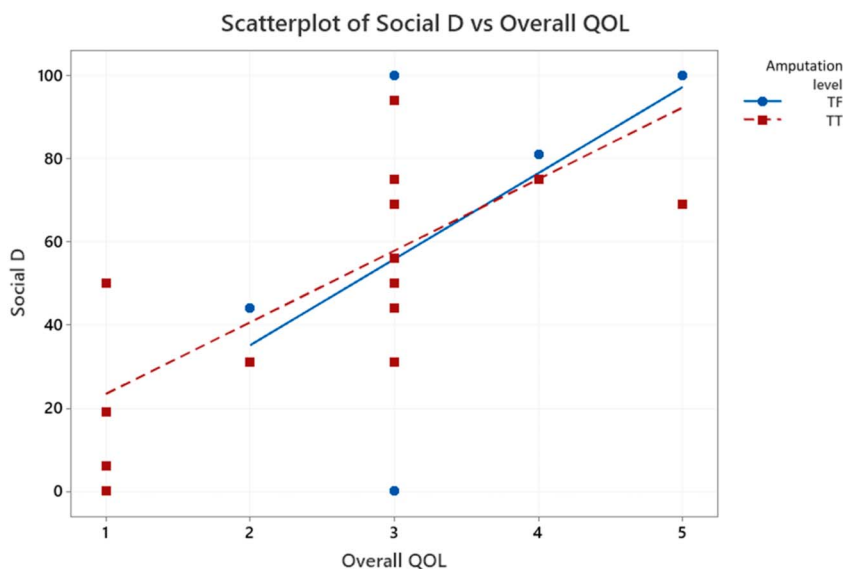


Figure 5. Pearson correlations of social domain vs. overall QoL.

with a locked knee position to increase stability. The SACH foot components provide limited functionality. Because of these reasons, many participants had difficulties completing the tasks in AMPPRO tool, such as changing the speed while walking and stepping over an obstacle. The influence that factors such as age and gender may have on these results was not explored and deserves further study. There could be other factors such as age and gender influencing this result too.

Some limitations of this study are found. The selected study sample was small, due to COVID-19, and nonrandomized; therefore, there was a significant sampling error. Most of the participants able to attend were TT prosthetic users and were able to exceed basic ambulatory potential, which could be reasons for obtaining higher values of correlation between all WHOQoL-Bref and DIS domains and AMPPRO. The participants were selected only from Mandalay city due to travel restrictions imposed for COVID-19. This could have influenced the lower numbers of female and TF participants. The political unrest that started in February 2021 in Myanmar led the MOH premises to close. Therefore, data collection had to be stopped and the resultant number of participants further reduced.

There was a lack of baseline data for comparison because all included participants were provided with a prosthesis, and data on the QoL in the general population in Myanmar were not available. However, this population can be considered as a good representation of LMIC PO clinics, and therefore, it can help as evidence to demonstrate that ICRC devices contribute to improvements in user mobility and QoL.

Conclusion


The evidence base for the efficacy of provision of prostheses in LMICs is limited. The patient-based results presented with this study should be considered as a contribution to the evidence base and the importance of provision of prosthetic and orthotic services in LMICs regarding functional outcomes, QoL, and perception of disability. Participants with an amputation demonstrated being able to achieve a high level of physical function with the prostheses supplied, using ICRC components, while also reporting a high QoL.


Albeit limited in the sampling size, this work highlights that the work of the WHO to introduce standards of practice and improve access to services must continue. Future studies should be conducted to find the causes for having weaker correlations between the AMPPRO and WHOQoL-DIS module facets. In addition, more comprehensive study designs could be developed to find factors affecting physical independence by using low-cost components in physical rehabilitation after amputation. These study results will be important to the government and non-government organizations, funding agencies, and other stakeholders who are responsible for implementation and maintenance of these services.

Declaration of conflicting interest

Stephney Weerasinghe is an employee of Exceed Worldwide. The other authors state no conflict of interest.

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