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Case Study

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Outcomes in Lower Limb Amputation Rehabilitation

André Tadeu Sugawara[1], Eliana Lima de Souza[1], Lucas Ramos De Pretto[2], Marcio Vinicius Cegatto da Silva[1], Rodrigo Collado Moreno[1], Milton Oshiro[1], Marta Imamura[1,3] and Linamara Rizzo Battistella[1,3]*

[1]Instituto de Medicina Física e Reabilitação, Hospital das Clínicas HCFMUSP, Faculdade de Medicina, Universidade de São Paulo, Brazil

[2]Instituto de Pesquisas Energéticas e Nucleares, IPEN-CNEN/SP, Brazil

[3]Departamento de Medicina Legal, Ética Médica e Medicina Social e do Trabalho, Faculdade de Medicina FMUSP, Universidade de São Paulo, Brazil

Abstract

Introduction: Lower leg amputations affect mobility and can be solved with prosthesis. Despite being included in the Package of Rehabilitation Interventions created by the World Health Organisation, there are lacks in rehabilitation outcome research.

Objectives: Reveal the rehabilitation outcomes and, secondarily, determine predictors of prosthesis use for at least two years.

Methods: Retrospective cohort study of patients with major lower limb amputations aged between 18 and 70 years with no other disabilities. Rehabilitation outcomes and the predictors of prosthesis use at discharge (time II) compared to the two-year follow-up (time III) were evaluated.

Results: 703 patients were included. At time II, 95.73% (673) completed the treatment, with a prosthetic gait rate of 73.12%. Age was a predictor for prosthetic gait, as each one-year increase in age corresponded to a 3.29% decrease in prosthesis use. At time III, 54.21% of the patients had higher prosthetic gait performance, for 2 years at least, requiring a new device.

Conclusion: The rehabilitation ensures mobility though high-performance prosthetic gait regardless of age, sex, or aetiology, for at least 2 years from rehabilitation discharge. Though with a lower prosthesis use rate with increasing age.

Keyword

Amputee, Rehabilitation, Limb prosthesis

Abbreviations

ICD-10: International Code of Diseases Tenth Revision; PGG: Prosthetic Gait Group; WMG: Wheelchair Mobility Group; HPGP: Higher Prosthetic Gait Performance group; LPGP: Lower Prosthetic Gait Performance

Introduction

Amputation is recommended in life-threatening situations when other treatments have failed to manage, usually consented by the patient. Results in a permanent physical disability that abruptly restricts mobility and functionality. Although it is a common disability, with a prevalence of 35.3 million cases in 2017, and is included as one of the 20 health conditions in the Package of Rehabilitation Interventions created by the World Health Organisation, there are gaps in rehabilitation outcomes understanding [1-3].

The diagnosis is based on the visual inspection, and generally, a non-trained eye could recognise an amputation. At the same time, this fact simplifies the health professional's assessment, and brings stigmatisation, prejudice, and other attitudinal and invisible barriers, amplifying physical barriers

***Corresponding author:** André Tadeu Sugawara, Instituto de Medicina Física e Reabilitação, Hospital das Clínicas HCFMUSP, Faculdade de Medicina, Universidade de São Paulo, Rua Domingos de Soto, 100, São Paulo, SP, 04116-040, Brazil, Tel: +55-11-99496-1917

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(urbanistic and geographic issues), enhancing inferiority feelings and lack of worth [4,5]. However, the prostheses allow a new improved appearance in the modified body, enhancing self-concept and steem, allowing a new meaning in the functionality and independence [5,6].

Assistive devices restore mobility, such as wheelchairs and different types of crutches and walkers. However, there are higher patient´s expectations associated with rehabilitation for receiving a prosthesis [7]. Walking with a prosthesis allows for increased mobility, re-establishment of functionality, and reduction in the emotional and social impact of amputation, leading to increased well-being and quality of life [8,9].

Ageing is associated with the onset and accumulation of comorbidities (especially diabetes and cardiovascular consequences). Therefore, regardless of the aetiology of the amputation, the risks for other disabilities increases with age [10,11]. Different medical societies consider walking as an important activity for health promotion and disease prevention. Thus, restores ambulation though a prosthesis is important to reach this public health goal and reduces costs [12,13].

Prosthetic gait overloads the cardiovascular system, forbidding the safety use for many patients. For these cases, the rehabilitation goals are centred on mobility though manual or motorised wheelchairs, according to the clinical conditions [14,15].

Disability is a worldwide public health challenge, resulting in worse health outcomes, lower educational achievements, higher poverty rates, and lower economic participation, and is more prevalent in low- and middle-income countries [16]. Thus, restoring mobility is the first step for amputees to access health and other Rights. In this way, the goal to restore mobility through prosthesis or other assistive products is important for the guarantee of rights and social inclusion [17,18].

There are several predictors for prosthetic gait; however, effective prosthesis use rate after rehabilitation has not been adequately studied. In other words, it is not clear how many lower limb amputees walk enough to reduce disease risk and promote health, for at least for 2 years [3,19,20].

The aim was to assess the rehabilitation outcomes and, secondarily, the prosthesis use rate for at least two years after rehabilitation discharge from the rehabilitation to the community.

Methods

This was a retrospective cohort using a digital database from the recruitment phase for the UMASP study (use, maintenance, abandonment, and sustainability of prosthesis use by people with limb absence), a cross-sectional digitally based study approved by the Research Ethics Committee (CAAE No. 06103019.0.0000.0068).

The recruitment included an active search on digital databases from five rehabilitation centres between January 2013 and December 2018, through International Code of Diseases tenth revision (ICD-10) codes associated with amputation, limb absence or malformation (group codes Q, S, T, and Z).

Patients with major lower limb amputations aged between 18 and 70 years were included. Those with foot partial amputations (Chopart, Lisfranc, metatarsals or toes), other concurrent disabilities (hemiplegia, paraplegia, tetraplegia), and more than 50% of incomplete data were excluded.

Data from three different observation points were analysed:

I. Initial assessment.

II. Discharge from the rehabilitation (immediate outcome).

III. 2 years after discharge from rehabilitation to the community (late outcome).

For time I, sex, age (completed years), education (completed years), and amputation aetiology (vascular/diabetes, traumatic, neoplastic, congenital, or infectious) were collected. For II, rehabilitation results (completion or non-completion of the programme) were collected. The reason for not completing the programme was categorised as either abandonment or death. The patients who concluded the programme were divided into Prosthetic Gait Group (PGG) and Wheelchair Mobility Group (WMG), according to the rehabilitation outcome. Subsequently, the variables associated with each outcome were analysed.

For III, the number of patients who walked with the prosthesis enoughtly to wear out it to the point of needing a new device, in 2 years.

Prosthesis condition assessment is an indirect measure for the gait performed by the patient. Patients who walked little or used the device rarely did not wear out its parts and components. However, frequent use in the community environment wears out and a brand-new device becomes necessary [21,22].

For this study, prosthetic socket substitution due to a residual limb size modification, was not considered for a replacement since the other elements of the prosthesis (joints, extensions, and foot) were preserved. Mechanical failures, misuse, or defects parts were treated as maintenance and repair and were not considered for a new prosthesis substitution. Only patients who wore out all prosthetic elements, that is, who routinely used it for walking, were considered to receive a new device.

At time III, based on the need for a replacement prosthesis two years after rehabilitation discharge, the PGG was sub-divided into Higher Prosthetic Gait Performance group (HPGP), including those who used the equipment enough to need a new prosthesis, and Lower Prosthetic Gait Performance (LPGP), with those who did not walk enough to require a new device.

Statistical analysis

The Shapiro-Wilk test revealed a non-Gaussian distribution of the data. Therefore, numerical data are presented as the median and interquartile range (IQR) and categorical data as the number of observations and percentage of the total population tested. The correlation between quantitative variables was verified through the Spearman's rank correlation coefficient, and the chi-square test was used for categorical variables. A two-tailed Fisher's exact test was used to evaluate the difference in proportions between the groups. Differences between medians were analysed using the Mood's test. Multivariate logistic regression was used to estimate the odds ratio (OR), using vascular aetiology as the reference. Finally, the Holm-Bonferroni method was used for multiplicity correction. In all cases, p < 0.05 was considered statistically significant. All statistical analyses were performed in the Python environment using the SciPy, Statsmodels, Numpy, and Pandas libraries.

Results

The study gathered 1,003 volunteers from the databases. After applying the criteria, the sample size resulted in 703 patients. Predominantly young male adults with a medium education level (high school), most of them married, and with vascular-related amputations, as shown in Table 1.

Table 1: Sample characteristics at time I (n = 703).

Age (years), median (IQR)	54.48 (41.72-63.24)
Education (years), median (IQR)	11 (4-11)
Men, % (n)	74.11% (521)
Women, % (n)	25.89% (182)
Married, % (n)	52.64% (349)
Single, % (n)	34.84% (231)
Divorced, % (n)	9.95% (66)
Widowed, % (n)	2.56% (17)
Vascular E., % (n)	60.60% (426)
Traumatic E., % (n)	33.71% (237)
Neoplastic N., % (n)	2.70% (19)
Congenital E., % (n)	1.85% (13)
Infectious E., % (n)	1.14% (8)

E: Aetiology; n: Number of people; IQR: Interquartile Range

At II, 4.27% did not complete the rehabilitation, 2.28% (16) by abandonment and 1.99% (14) died. The causes for these could not be determined. Completed the rehabilitation 95.73% (673), of which 22.62% (159) failed to reach the prosthetic gait outcome, and 514 amputees acquired prosthetic gait. Prosthetization rate, or the chances of an amputee reaching prosthesis gait, was 73.12% after rehabilitation.

The logistic regression test does not reveal predictors for rehabilitation completion, in a statistically significant way (p > 0.05), as shown in Table 2.

The patients who concluded the rehabilitation programme (673) were divided into the PGG and WMG, according to rehabilitation outcome at time II. After a comparative analysis of the age, sex, and aetiology between the groups, a predominance of vascular amputations were found in the WMG and traumatic aetiology in PGG, which also had a lower median age. All these findings were statistically significant (p < 0.05), as shown in Table 3.

Logistic regressions were used to determine variables associated with PGG or WMG outcomes, as shown in Table 4. Age, vascular and congenital aetiologies were predictors for WMG (p < 0.05). Despite the low frequency of congenital in the sample (due worldwide rarity), this aetiology had 78% less chance to reach the prosthetic gait than other causes. Additionally, the analysis demonstrated that for each one-year increase in a patient's age, there was a 3.29% decrease in the rate of prosthesis use, as shown in Table 4.

Table 2: Rehabilitation completion predictors analysis.

	OR	CI 95%		p-value
Age	1	0.96	1.04	0.969
Sex	1.3	0.42	3.98	0.645
Traumatic E.	1.09	0.38	3.11	0.867
Neoplastic E.	0.63	0.08	5.25	0.669
Infectious E.	4.73	0	44.925	0.997
Congenital E.	3.21	0.26	3.9	0.986

E: Aetiology; OR: Odds ratio; CI 95%: Confidence interval; p-value: Significance level according to the logistic regression test

Table 3: PGG and WMG groups characterisation at time II.

	PGG N = 534		WMG N = 169		p-value
Age (years), median (IQR)	52,82 (38,48 -6 2,19)		60,00 (49,00 - 65,58)		**< 0.001***
Men, n (%)	400	74.91%	121	74.11%	0.420
Women, n (%)	134	25.09%	48	25.89%	0.420
Vascular E., n (%)	308	57.68%	118	69.83%	**0.025**
Traumatic E., n (%)	195	36.52%	42	24.85%	**0.025**
Neoplastic E., n (%)	17	3.18%	2	1.18%	0.546
Infectious E., n (%)	7	1.31%	1	0.59%	0.688
Congenital E., n (%)	7	1.31%	6	3.55%	0.199

PGG: Prosthetic Gait Group; WMG: Wheelchair Mobility; E: Aetiology; n: number of people; IQR: Interquartile range; p-value: Significance level according to the Fisher's exact test; *p-value according to the Mood's test

Different logistic regression models considering sex and aetiology as independent variables showed that traumatic amputations were associated with a higher prosthetic gait rate. However, when age was included, there is no statistical relationship, demonstrating that traumatic aetiology was a confounding factor for age.

Young people were concentrated in traumatic aetiology, in a statistically significant way ($p < 0.05$, see Table 4). Therefore, trauma was a confounder for age variable, because traumatic events were more prevalent in young people. Thereby, young people with traumatic amputations had a higher likelihood for prosthetic gait outcome, as shown in Table 4.

At time III, of the 514 amputees belonging to the PGG, 277 (54.21%) belonged to HPGP. The Fisher's exact test showed that younger amputees were statistically significantly associated with this subgroup ($p < 0.05$), as shown in Table 5, and logistic regression analysis showed no statistically significant predictors for this higher performance ($p > 0.05$), as shown in Table 6.

Consequently, the prosthetic gait outcome at time II was 73.12% regardless of age, sex, or aetiology. The rate decreases in 3.29%/year at each additional year of age. The performance to walk was higher enough to wear out the equipment for 54.21% of the amputees with prosthetic gait, at point to need a change for a new device. Additionally, for the lower age groups, this percentage was even higher. In 99.28% (275) of the cases, replacements were provided by the public health system, free of charge. Only 0.72% (2) of the patients acquired one using their own financial resources.

Discussion

The results corroborate findings from countries with an ageing population, with pre-existing humanitarian health care and educational crisis, low levels of chronic disease control (especially hypertension and diabetes), and urban violence (especially traffic accidents) which lead to amputations at an early age [23,24].

This retrospective cohort shows that, regardless of age, sex, or amputation aetiology, most patients completed the rehabilitation programme, guaranteeing their right to mobility with a wheelchair or prosthesis.

The prosthetic gait is more advantageous for restoring mobility than a wheelchair, especially for younger people, as it minimises the architectural and geographical barriers. Communities or cities with reduced accessibility, especially not designed for universal use, reduce the already restricted mobility of wheelchair users. Additionally, wheelchair mobility in irregular and clandestine rural and urban settlements, popularly known as "favelas", is tremendously difficult, causing isolation and social exclusion [17,24-28].

The study revealed that rehabilitation access and the efforts to promote early prostheses use are feasible due to high programme completion and prosthesis use rate. Additionally, prosthetic gait promotes health, control diseases, especially diabetes, and prevent further health

Table 4: Rehabilitation outcomes predictors at time II.

	OR	CI 95%		p-value
Age	0.97	0.95	0.98	< 0.001
Sex	0.86	0.58	1.29	0.478
Traumatic E.	1.23	0.8	1.89	0.355
Neoplastic E.	2.47	0.56	10.88	0.23
Infectious E.	2.76	0.33	23.2	0.351
Congenital E.	0.22	0.07	0.74	0.014

OR: Odds Ratio; CI 95%: Confidence Interval; p-value: Significance level according to the logistic regression test

Table 6: Predictors for high prosthetic gait performance two years after rehabilitation discharge (time III).

	OR	CI 95%		p-value
Age	0.98	0.97	1.00	0.103
Sex	0.92	0.61	1.39	0.69
Traumatic E.	0.97	0.64	1.45	0.867
Neoplastic E.	0.63	0.22	1.74	0.37
Infectious E.	0.33	0.06	1.79	0.201
Congenital E.	0.76	0.16	3.72	0.735

E: Aetiology; OR: Odds ratio; CI 95%: Confidence interval; p-value: Significance level according to the logistic regression test

Table 5: Comparison between HPGP and LPGP groups at the 2-year follow-up (time III).

	HPGP (n = 277)		LPGP (n = 237)		p-value
Age (years), median (IQR)	50.10 (36.93-62.10)		55.74 (44.00-62.91)		0.005*
Men, n (%)	210	75.81%	174	73.42%	0.99
Women, n (%)	67	24.19%	63	26.58%	0.99
Vascular E., n (%)	156	56.32%	140	27.24%	0.99
Traumatic E., n (%)	108	21.01%	80	15.56%	0.79
Neoplastic E., n (%)	7	1.36%	9	1.75%	0.985
Infectious E., n (%)	2	0.39%	5	0.97%	0.931
Congenital E., n (%)	4	0.78%	3	0.58%	1

HPGP: Higher Prosthetic Gait Performance group; LPGP: Lower Prosthetic Gait Performance; E: Aetiology; n: Number of persons; IQR: Interquartile range; p-value: Significance level according to the Fisher's exact test; *p-value according to the Mood's test impairments, increasing access to other mobility-related Rights such as access to health, education, employment, and income in a young economically active population.

The best predictor for prosthetic gait was age, with a lower age associated with higher gait performance. This can be explained by the accumulation of comorbidities, lower levels of control, the additive effect of dysfunctions of several organs, and the lack of effort or energy to use or maintain the use of a prosthetics with advancing age [23,29].

Young people with traumatic amputations without comorbidities associated with ageing have a greater chance for high gait performance compared to older patients with vascular amputations. However, the biological predictor for prosthetic gait was age and that traumatic aetiology was a confounder. Young people have greater exposure to urban violence, while older people are more exposed to the consequences of comorbidities, amplified by low access to health care and disease control [16,30].

There was a lower prosthetic gait rate for congenital amputations. The Right to access rehabilitation is a relatively recent policy, in our country. So, these patients were referred to rehabilitation late, generally after having adopted mobility strategies with crutches or strollers, which require low energy expenditure. Unfortunately, this hinders the development of a prosthetic gait, which thus requires effort and may cause cardiovascular overload [31,32].

More than half of prosthesis users require a new device after two years due to wear out by routine use, especially for youngsters. Some factors can influence older patients' reduced prostheses use, including sedentary lifestyle, routines with low activity diversification, attitudinal barriers related to the self-concept of becoming deficient, and the effort required to prosthetic gait [21,31,32].

These findings can be applied to health policy planning. Amputation is a permanent disability; thus, access to a prosthesis is necessary for the rest of their lives [24]. As demonstrated in this study, most people depend on the public health system for access to prosthetic equipment free of charge.

People with disabilities, especially those with low level education, have low employment opportunities 25, and, without work or income, have no financial resources available to buy a prosthesis [25,29]. Therefore, most people with amputations depend on public services to acquire subsequent prostheses to ensure their ability to walk.

A complicated situation is expected due to forecasted increased amputations prevalence for all aetiologies, in a economic resource contingency situation, aggravated by low employability and income of people with disabilities, especially after the COVID-19 pandemia [7,24,29]. This study demonstrates the needs for rehabilitation policies and strategies connected with prosthesis distribution and delivery until the last day of amputee life to materialise the mobility Right guarantee.

Conclusions

The rehabilitation ensures mobility though high-performance prosthetic gait regardless of age, sex, or aetiology, for at least 2 years from rehabilitation discharge. Though with a lower prosthesis use rate with increasing age.

Disclosures

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Authors' Contributions

Sugawara ATS contributed to the study concept and design, data collection, analysis, data interpretation, and the drafting and submission of the manuscript; De Pretto LR contributed to the analysis and interpretation of the data; Eliana Lima de Souza EL contributed to data collection and analysis; Silva VC contributed to data collection; Moreno RC contributed to data collection; Oshiro M contributed to data collection and the organisation of the study; Battistella LR contributed to the final approval; Imamura M contributed to the study concept and design, data analysis and interpretation, drafting of the manuscript, and final approval. All author(s) read and approved the final manuscript.

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