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Article

Outcomes of Patients with Lower Limb Loss after Using a Training Prosthesis: A Retrospective Case Series Study

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Abstract: The aim of this retrospective case series study was to investigate outcomes in patients with lower limb loss, based on whether or not they used a training prosthesis (TP) during their rehabilitation. The medical records of 171 consecutive patients admitted to rehabilitation hospitalization between January 2014 and December 2018 following a major amputation of the lower limb were reviewed. Patients were categorized into two groups: patients who underwent rehabilitation with a TP and patients who did not used a TP. Outcomes (i.e. discharge destination, length of stay, number of sockets required and number of size adaptation of each socket as well as functional level) were compared between groups. Of the 171 patients, 126 underwent rehabilitation with a TP, and 45 patients underwent rehabilitation without any TP. We found that patients who used a TP had a significantly shorter hospital length of stay when compared to those who did not. This length of stay for patients with TP was not influenced by age but was lowered by higher BMI, tibial instead of femoral amputation and male gender. No association was found between use of TP and discharge destination, functional level, number of socket modification and number of sockets required.

Keywords: training prothesis; rehabilitation; amputation; outcomes

1. Introduction

The leading causes of amputation worldwide are vascular diseases, followed by trauma, cancer and finally congenital impairment (1,2). Vascular causes are expected to remain the primary reason for amputation for the foreseeable future considering the prevalence of peripheral vascular disease and diabetes. In fact, between 2000 and 2010, the number of people with peripheral arterial disease increased by almost 25% worldwide, and concerned both high-, middle- and low- income countries (3). The global prevalence of diabetes in 2019 has been estimated at 9.3% and projections for 2030 and 2045 give an estimated prevalence of 10.2% and 10.9% respectively (4).

Limb amputation remains a major cause of public health concern today (5) and amputee rehabilitation holds an important place and represents a major challenge for the rehabilitation physician (6,7). Esquenazi and Meier (6) proposed a nine-phase description of amputee rehabilitation: preoperative, amputation surgery/reconstruction surgery, acute post-surgical, pre-prosthetic, prosthetic prescription, prosthetic training, community integration, vocational rehabilitation, follow-up.

However, there is a lack of consensus regarding postoperative management strategies in amputee rehabilitation (8). The choice of soft, rigid or semi-rigid materials for postoperative dressing is much discussed in literature. A superiority of the rigid system is often mentioned, being more

favorable than soft systems in reducing stump volume, protecting it from external impacts, improving healing or even reducing the time between amputation and acquisition of prosthesis (9,10). However, soft dressing is conventionally chosen, most likely due to the fragility of the skin and because of the risk of stump injury, particularly vascular stumps, and the difficulties in producing the rigid system (11). Finally, a recent Cochrane systematic review (12) concludes that there is no certainty on the superiority of rigid dressing compared to soft dressing in terms of stump healing, pain, skin side effects, the length of stay in hospital, the time between amputation and prosthesis prescription. Interestingly, there seems to be no study on the influence of the type of dressing on comfort, quality of life or financial aspect (12).

Regarding prosthetic rehabilitation, the second half of the 20th century saw the emergence of immediate post-operative prostheses (IPOP) (11). Evidence based data on their efficacy are however still lacking in the literature (13,14). The use of these prostheses seems however to be associated with a decrease in the number of falls and surgical revisions (15) as well as a decrease in the time between amputation and prescription of the personalized prosthesis (16). Immediate prostheses are only prescribed in around 5% of cases, notably due to technical difficulties, skin fragility and more difficult wound monitoring (17).

While IPOPs are used in the post-operative phase, it is possible to use another type of prosthesis, in the pre-prosthetic phase of rehabilitation, for training purposes. This training prothesis (TP) is composed of classic modular prosthetic elements
fixed to a socket made of plaster and manufactured by following the usual stages of molding the stump and working a positive mold. However, although its use is not uncommon, there is a lack of studies on this topic in literature.

The aim of our work was therefore to investigate different health rehabilitation outcomes after rehabilitation of lower limb loss patients, based on whether the patients used a training prosthesis in the rehabilitation program.

2. Methods

2.1. Population

The medical records of 208 consecutive patients admitted to the rehabilitation centers between January 2014 and December 2018 following a major amputation of the lower limb were reviewed. The two hospitals concerned were the University Hospital of Liège – Site "CNRF" (Centre Neurologique de Réadaptation Fonctionnelle of Fraiture – Belgium) and the Regional Hospital Center of the Citadelle – Site "Château Rouge" (Liège – Belgium). The study was conducted in accordance with the Declaration of Helsinki, and the protocol was approved by the respective Ethics Committees of both centers (2018—12-03V1 and JL/bl/TDD2019/11 – B412201940866).

Patients were included in the study if they had undergone a major amputation of the lower limb (above the ankle and below the hip), without restriction of age, comorbidity or etiology.

When several amputations have taken place, either at the same lower limb or on the opposite side, the last amputation that took place during the period concerned was the referenced amputation in our study. If a major amputation of each lower limb occurred during the same hospitalization, the two amputations were selected as the referenced amputations with a bilateral status.

As the study deals with the consequences of using a training prosthesis or not, patients were excluded from the study if there was no initial fitting intention, for medical reasons or because of patient's choice.

2.2. Training prosthesis

The training prosthesis is a rehabilitation tool used during the rehabilitation phase, when the condition of the stump allows for it, mainly meaning that there was sufficient healing and pain was bearable. A metal rod (with or without knee articulated according to the femoral or tibial status of the amputation) was placed in the plaster cast at its upper end and was connected distally to a prosthetic foot.

This prosthesis is not systematically used in the rehabilitation of the amputee patient, because it requires that the patient portrayed certain faculties and technical skills. The TP was made by members of the rehabilitation team who have undergone specialized training. The two rehabilitation centers included in this study were selected as both are in the same geographic area and the patients are usually treated by the same surgical teams and the casting and prosthetics are made by the same teams of prosthetists. In addition, the rehabilitation centers followed the same rehabilitation protocols and objectives are usually similar. However, the CHU-CNRF regularly integrates the training prosthesis technique into the rehabilitation of amputee patients, while the CHR-Château Rouge does not use it.

2.3. Outcomes investigated

The potential impact of the use of TP was assessed on several factors:

Discharge destination: when patients were discharged, if they were allowed to go home or to a nursing facility (NF). This orientation is considered to reflect the autonomy of the patient. The decision was made based on whether the patient required the implementation of adequate aids or not, and if the aids provided sufficient autonomy at home, while living in a NF meant that patients were monitored and that there was constant help from qualified personnel if needed, due to insufficient autonomy.

Length of stay in rehabilitation hospitalization measured the number of days between admission to the rehabilitation center and discharge from the center with either continuing rehabilitation as an outpatient or stopping multidisciplinary rehabilitation with or without physiotherapy at home. The day of discharge from rehabilitative hospitalization represents the day on which no further benefit was expected from hospitalization.

Number of sockets required and number of size adaptations of each socket, which is related to the stability of the evolution of the stump volume, but which also represents a potential financial factor. This point relates to the first prosthesis prescribed, therefore the "evaluation" prosthesis (EP).

Functional group. At least six months after the prescription of the EP, the definitive prosthesis (DP) can be prescribed, based on the category corresponding to the functional level of the patient. There are five categories. Category 1 includes patients for whom no walking prospects are expected. The prosthesis fulfills a purely aesthetic function in this category. Category 2 covers patients with a greatly reduced walking function and prostheses in this category essentially fulfill a transfer function. In category 3, patients have a reduced walking function but can move around without the help of a third person, provided technical aids are available (walking frame, cane, etc.). The following two categories include patients who can move without technical aid. A walk test is performed for these patients based on their level of amputation. If the results of this test reach or exceed the required value, the patient is classified in category 5. Otherwise, they are classified in category 4. For this study, an additional category was also created, "category 0", which includes patients who have not had a DP prescription, most often because of a prosthesis abandonment, or because of a very limited use or a non-wish to change the EP.

2.4. Statistical analysis

The normality of the continuous variables was checked by examining the histogram, the quantile-quantile plot, the Shapiro-Wilk test and the difference between the mean and the median values. Distribution was considered not normal if the data met less than 3 of the 4 conditions. Quantitative variables following a Gaussian distribution were expressed as the mean and standard deviation. Quantitative variables not following a Gaussian distribution were expressed as the median (25th percentile – 75th percentile). Qualitative variables were described by absolute (n) and relative (%) frequencies. First, the samples of the two study groups (with TP versus without TP) were compared with each other, to check if the characteristics of the population were represented in a similar way between both groups. Secondly, rehabilitation outcomes were compared between groups. Finally, we performed subgroup analyses on gender, age (<65 years vs ≥65 years), Body Mass Index (BMI) (<25kg/m² vs ≥25kg/m²) and amputation level (unilateral femoral vs tibial) and measured

possible associations between TP and outcomes within each of these subgroups. Because of the non-Gaussian distribution, the non-parametric Mann-Whitney U test was used to compare continuous outcomes between groups in all analyses. Categorial variables between groups were compared using Chi squared (X²) test. Because of the non-equivalence of the two groups in terms of sample size, we performed an additional analysis in which each patient that did not receive a TP (n=45) were matched to a patient that received a TP (n=45) for gender and age (±5years). The same analyses were performed on this new sample to test the robustness of the results. Data were processed using the SPSS Statistics 24 (IBM Corporation, Armonk, NY, USA) software package. All results were considered statistically significant at the 5% critical level.

3. Results

3.1. Population

From the 208 medical records of patients admitted to the "Château rouge" or to the "CNRF" during the years 2014 to 2018 for multidisciplinary rehabilitation following a major amputation in the lower limbs, apparatus intent noted for 171 of them. Among these 171 patients, 126 benefited from the TP technique and 45 were rehabilitated without this technique, of which seven were treated in the center which usually works using these prostheses. No differences were observed between groups in terms of age, gender, BMI, prevalence of vascular etiology of amputation, site of amputation and time between amputation and entry to the rehabilitation center (all p>0.05). Population characteristics are available in **Table 1**.

Table 1. Population characteristics.

	Rehabilitation with TP (n=126)	Rehabilitation without TP (n=45)	*p*-Value[a]
Gender (*men*)	93 (73.8)	32 (71.1)	0.73
Age (*years*)	66.5 (57.7-74)	62 (55.5-70.5)	0.47
BMI (*kg/m²*)	23.2 (20.1-27.3)	26.5 (20.9-31.4)	0.18
Vascular etiology (*yes*)	110 (87.3)	40 (88.4)	0.78
Site of amputation			
Unilateral above-knee amputation (*yes*)	54 (42.9)	16 (35.6)	0.67
Unilateral below-knee amputation (*yes*)	68 (54.0)	27 (60.0)	
Bilateral (*yes*)	4 (3.2)	2 (4.4)	
Time between amputation and entrance into the rehabilitation center (*days*)	20 (14 – 28)	16 (12 – 27)	0.10

TP: Training Prothesis; BMI: Body Mass Index Qualitative variables are expressed in absolute (n) and relative (%) frequencies; quantitative variables are expressed in median and interquartile range (P25-P75) [a]p-values obtained from the Mann-Whitney U test for continuous variables and the X² test for categorial variables.

3.2. Outcomes associated with rehabilitation using TP

A summary of the impact of a TP on rehabilitation on discharge destination, length of stay, number of sockets required, and number of size adaptation of first socket and functional level is available in Table 2.

After rehabilitation, 91.1% of the patients re-educated without using a TP returned to home versus 82.5% of patients re-educated with TP. The other patients were oriented to nursing home facilities. No significant difference between groups was observed (p=0.17).

Regarding length of stay in rehabilitation, a significant longer average length of stay of was observed for re-educated patients without a TP (median of 99 (80-154) days) when compared to those who used a TP during their rehabilitation (median of 68.5 (53-88) days) (p<0.001).

The number of sockets used and the number of size adaptation of the first EP sockets was assessed across only 164 patients (43 patients, 44 stumps in the group of patients without a TP and 121 patients, 125 stumps in the group of patients with a TP). The maximum number of sockets per

stump was 2 in both groups and the maximum number of procedures of size adaptation was 3 in the group of patients without TP and 4 in the group of patients with TP. The frequency of number of sockets required for rehabilitated stumps was not significantly different between groups (p=0.913), as well as the frequency of number of interventions for size adaptation of the first EP socket which was not significantly different either (p=0.597).

Functional group outcome was assessed in only 114 patients in the group of patients using TP (eight died before the DP could be prescribed and four were ultimately not fitted despite the initial intention) and 30 patients in the group of patients who did not use a TP (no data available for 15 patients). In the two groups, patients were most often classified in category 3 and least often classified in category 2. Category 1, which corresponds to patients benefiting from a prosthesis for aesthetic purposes only, is not included in this study since it does not correspond to patients for whom there was initially an intention to have a fitting. No significant difference was observed in regards of the distributions in these different categories (p=0.83).

Table 2. Outcomes associated with rehabilitation with TP.

	n	Rehabilitation with TP	Rehabilitation without TP	*p*-Value[a]
Discharge destination				0.17
Back to home	171	104 (82.5)	41 (91.1)	
To nursing facilities		22 (17.5)	4 (8.9)	
Length of stay in rehabilitation center *(days)*	169	68.5 (53-88)	99 (80-154)	**<0.001**
Number of sockets required *(nbr)*				
1 socket		107 (88.4)	37 (86.0)	
2 sockets	164	14 (11.6)	6 (13.3)	0.68
Interventions for first EP socket *(nbr)*				
None		58 (47.9)	24 (55.8)	
1 size adaptation	164	32 (26.4)	9 (20.9)	0.83
2 size adaptations		20 (16.5)	7 (16.3)	
≥3 size adaptations		11 (9.1)	3 (7.0)	
Functional group				
Group 0		25 (19.8)	4 (13.3)	
Group 2		2 (1.6)	1 (0.33)	
Group 3	144	52 (41.3)	16 (53.3)	0.83
Group 4		19 (15.1)	5 (16.7)	
Group 5		16 (12.7)	4 (13.3)	

TP: Training Prothesis; EP: Exercise prothesis Qualitative variables are expressed in absolute (n) and relative (%) frequencies; quantitative variables are expressed in median and interquartile range (P25-P75) [a]p-values obtained from the Mann-Whitney U test for continuous variables and the X² test for categorial variables.

3.3. Subgroup influences on outcomes

Length of stay was significantly shorter for patients with TP. Influence of gender, age groups, BMI categories and level of amputation on this outcome was studied through subgroup analyses (**Table 3**). A significant lower length of stay in rehabilitation for patients with TP compared with patients without TP is only observed in men (p<0.001) but not in women (p=0.19). A similar observation is made for BMI categories where a significant lower length of stay in rehabilitation for patients with TP compared with patients without TP is only observed in overweight/obese patients (p=0.001) and not in normal/low BMI patients (p=0.89). Moreover, a significantly lower length of stay in rehabilitation for patients with TP compared with patients without TP is only observed in patients with a tibial amputation (p<0.001) and not in patients with femoral amputation (p=0.22). No influence of age (<65 or ≥65 years) on the length of stay of patients with TP could be demonstrated.

We did not find additional associations between rehabilitation using TP and the other outcomes (discharge destination, number of sockets required, number of size adaptations of each socket and functional level) in any of the subgroup analyses *(data not shown)*.

Table 3. Median length of stay (days) in rehabilitation center for group with TP and group without TP according to subgroups.

	n	Rehabilitation with TP Median (P25-P75)	Rehabilitation without TP Median (P25-P75)	*p*-Value[a]
Gender				
Men	124	66 (52-85)	101 (80-164)	**<0.001**
Women	45	77 (64-92.5)	93 (67-138.2)	0.76
Age				
<65 years	83	60 (46.5-85.5)	99 (63-153.2)	**0.005**
≥65 years	86	76 (61.5-92)	94 (84-159)	**0.005**
BMI				
<25kg/m²	91	70 (57-86.2)	67 (48.5-89.5)	0.89
≥25kg/m²	67	66 (51-94.5)	99 (87-148)	**0.001**
Level of amputation				
Femoral	69	68 (57-95)	92 (46-101)	0.22
Tibial	94	71 (51.2-84.7)	105 (83.7-156.5)	**<0.001**

TP: Training Prothesis; BMI: Body Mass Index Quantitative variables are expressed in median and interquartile range (P25-P75) [a]p-values obtained from the Mann-Whitney U test.

3.4. Additional analyses

Additional analyses were performed on a sample of 90 participants, the 45 without a TP matched on age and gender on 45 patients with a TP (characteristics of the population available in Supplementary Materials **Table S.1**). The post-hoc paired analyses confirmed the findings, with a significantly lower length of stay for patients that used a TP compared to patients that did not (p<0.001). Moreover, using these matched analyses, we also observed a higher number of patients that required 2 sockets for rehabilitation stumps in the group of patients that did not receive a TP compared to those that received it (p=0.049) (Data available in Supplementary Materials **Table S.2**).

4. Discussion

The objective of this study was to study the impact of integrating a training prosthesis in the rehabilitation of patients with lower limb amputation. This impact has been assessed through various outcomes (discharge destination, number of sockets and size adaptations of the first socket, length of stay, functional group). This is an original article, the first of its kind, and therefore the absence of prior studies prevents comparisons with literature.

One of the outcomes studied was the discharge destination. No difference was highlighted between the two groups for this point. Regarding patients with lower limb amputation, factors influencing the discharge destination have been mentioned in the literature, such as age, amputation level and comorbidities (18–20). However, clinical features did not appear to be associated with a particular destination (20).

Concerning the results which relate to the number of sockets or size adaptations of sockets, it is tempting to imagine that the results described in the literature on IPOP can be extrapolated to those of TP. IPOP showed an impact on the scarring, shape and edema of the stumps with assessment over a short term (13). Even if this has not been directly studied, one could therefore imagine a decrease in the number of sockets or socket adaptation in patients who have benefited from an IPOP compared to other amputee patients. However, the IPOP and the TP are not used in the same phase. They come into play respectively in the acute post-surgical phase and in the pre-prosthetic phase of lower limb amputation. We therefore chose to assess the stability of the stumps by focusing on the sockets of the EP. Thus, the appearance of the stump is evaluated later after the amputation than what is generally proposed in the literature. However, the volume of the stump takes several months to stabilize (21), although there are significant variations between individuals, which do not allow for clinicians to determine a precise time when the volume is stable (22). It has been suggested that the use of a temporary prosthesis results in the fastest reduction in stump volume when compared to elastic

bandages or pneumatic prosthetics (23). We could thus have expected a lower number of size adaptation of sockets in the group of patients re-educated with TP. This outcome is, however, an imprecise tool to study the volume of the stump. Several more precise methods of stump measurement have been proposed (24). Unfortunately, we did not use these methods in our study and were therefore unable to assess them.

Regarding the length of stay in rehabilitation center, a very clear difference is observed, with a significantly shorter stay for patients whose rehabilitation included the use of TP (68,5 versus 99 mean days). This could be explained by the faster acquisition of autonomy, by earlier healing of the stump or perhaps even by a faster reintegration in socio-family life. This question deserves to be studied more specifically by evaluating the stump's healing time, quality of life questionnaires and an evaluation of the patient's autonomy, for example by measuring functional independence. One can imagine the impact of such a reduction in the length of stay at the economic level by multiplying the cost of a day of hospitalization by the difference between the two average lengths of stay. Similarly put, this reduction in the length of stay has a direct impact on the reduction in morbidity linked to prolonged hospitalizations as well as on the socio-family sphere. Shortening the length of hospital stay also improves patient flow in a context of increasing demand for hospital services (25).

The impact of the use of TP on the reduction of length of stay seems particularly important in men, patients with a BMI ≥25kg/m² and in patients with tibial amputation. Regarding the BMI, we can imagine that a larger volume and a fattier composition of the stump would require more time and more work to attain a sufficiently stable situation. Therefore, the TP plays a more important role in this process in patients with greater BMI. We do not have a specific hypothesis to explain the larger results in men and in patients with tibial amputation and we believe that these observations should be verified thought other studies before confirming them.

Finally, the functional group reached by the patient when the final prosthesis was prescribed was analyzed and compared between the two groups. It would have been imaginable to observe better functionality in patients rehabilitated with TP. However, no difference was observed between re-educated patients with TP and re-educated patients without TP. This could be explained by the fact that the functionality in this study is understood by the functional group reached by the patient only at the time of prescribing DP, therefore after at least six months of using EP. After such a delay, it is understandable that the functionality of the two groups is comparable. A significant difference in the functional capacities of amputee patients could perhaps have been found at an earlier phase of rehabilitation.

The pre-prosthetic phase of rehabilitation is very little studied in the literature. This study, which covers 171 patients, made it possible to evaluate the technique of training prostheses and to demonstrate a completely favorable impact on the length of hospital stay in rehabilitation. The main limitations of this study are inherent in its retrospective nature. The ideal would be to be able to carry out the same work but in a prospective manner, which would give the possibility on the one hand to integrate other observation tools, for example quality of life questionnaires or functional scales carried out in the different centers at the same time of rehabilitation, and on the other hand to decrease the number of unknown data. This would also allow patients to be randomized into re-educated groups with or without TP. Unfortunately, few centers have the technical infrastructure and personal resources to carry out the TP. It would therefore be necessary to conduct the study only in a center which offers this technique, which would reduce the sample or increase the duration of the study, or else to develop the TP technique in an additional center. In view of the results of this study, it would be very interesting to encourage the use of TP in other centers, and to conduct new research on the pre-prosthetic phase of rehabilitation.

5. Conclusions

The use of a training prosthesis seems interesting to improve rehabilitation of patients with lower limb loss, by shortening the length of stay. This innovative technique has been poorly studied in literature so far and additional studies, using preferentially prospective designs, are required before confirming these results.

Institutional Review Board Statement: The study was conducted according to the guidelines of the Declaration of Helsinki, and approved by the Ethics Committees of the University Hospital of Liège and of the Citadelle Hospital (2018—12-03V1 and JL/bl/TDD2019/11 – B412201940866).

Data Availability Statement: Data are available under request to the corresponding author.

Conflicts of Interest: The authors declare no conflict of interest.

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