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Enhancing Quality of Life and Satisfaction through Prosthetic Intervention: A Prospective Study on Lower Limb Amputee Patients

Houda Migaou, Amine Kalai, Ameni Ameur, Soumaya Boudokhane, Anis Jellad, Zohra Ben Salah Frih

Department of Physical Medicine and Rehabilitation, Faculty of Medicine, University of Monastir, Monastir, Tunisia
Email: amine.kalai@rns.tn

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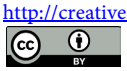

Abstract

Background: Limb amputation is a surgical procedure performed out of necessity, resulting in severe disability, poor quality of life (QOL), and poor socio-professional reintegration. We aimed to assess the QOL of patients with lower limb amputations before and after having their prosthesis and to evaluate their satisfaction at the first consultation and 6 months later. **Methods:** A prospective study was held for 1 year, involving patients with lower limb amputations. We evaluated and followed the QOL using the scale (Sf-36), the functional fate (walking range, SIGAM), the pain scale (VAS), and satisfaction with their equipment (SAT-PRO). **Results:** Thirty-five lower limb amputee patients were included. Twenty patients had diabetes (57.14%) and 4 patients (11.43%) had an arterial disease. Infectious etiology was the most frequent cause of amputation in our series (40%) and trans-tibial amputation was the most represented type of amputation (74.29%). We observed a significant improvement ($p < 0.01$) in the QOL, functional outcomes after amputation, immediately after prosthesis fitting, and 6 months afterward as well as satisfaction with their prosthesis in 2 evaluations. A significant association was noted between QOL and age, level and the indication of the amputation, the time between amputation and prosthesis fitting, pain (VAS), and functional outcomes ($p < 0.01$). We also noted a significant relationship between satisfaction with the prosthesis and certain socio-demographic characteristics (age, socio-economic level, presence of medical history, urban area), clinical characteristics (level and indication of amputation, pain intensity), functional evolution, and QOL ($p < 0.01$). **Conclusion:** The acquisition of prostheses is a determining factor in improving lower limb amputees' QOL and satisfaction.

Subject Areas

Rehabilitation

Keywords

Amputation, Lower Limb, Prosthetic, Quality of Life, Satisfaction

1. Introduction

Limb amputation is a surgical procedure performed out of necessity when other therapeutic options have failed or are impossible [1]. As such, amputation should not be considered a failure of treatment [2], but the ultimate solution to preserve the patient's vital prognosis.

Those of the lower limbs are associated with severe disability, poor quality of life (QoL), and low socio-professional reintegration. They are often attributed to post-operative functional disability in amputees.

Successful amputation requires a good surgical result and careful coordination with rehabilitation services. In addition, the aim is to produce a well-healed, cushioned stump that is not edematous, pain-free, and sufficiently long for fitting [3] [4].

A well-adapted and well-designed prosthesis is essential for restoring a degree of functional autonomy. This leads to improved quality of life, satisfaction with the new body image, and psychological well-being [5].

As prosthetic technology advances, the mode of movement, comfort, and safety of sockets are becoming increasingly important in new prostheses. However, some amputees experience problems with the prosthesis in terms of satisfaction and stump quality, which can lead to rejection or abandonment of the prosthesis [6].

The main objective of our study is to assess the quality of life of patients with lower-limb amputations before and after fitting.

The second objective is to evaluate the satisfaction of fitted patients with their prostheses at the first post-fitting consultation and 6 months later.

2. Methods

2.1. Setting

This was a prospective study at Fattouma Bourguiba University Hospital in Monastir, extending from February 2021 to February 2022.

2.2. Study Population

We included in this study patients who agreed to participate in the study and who had undergone amputation of one or both lower limbs, whatever the etiology and level of amputation.

Patients aged under 18 years old, with an associated upper limb amputation, not having completed the study period, and being followed for a previous psychiatric disease were not included in this study.

2.3. Data Collection

Data were collected based on a questionnaire and clinical examination of the patients. Demographic and clinical data were gathered such as age, gender, profession, marital status, amputation characteristics: date, etiology, level, stump quality, and local complications.

Pain assessment was evaluated by the Visual Analog Scale (VAS).

We also evaluated functional activities: dressing, grooming, wearing prostheses, driving, and walking perimeter (WP).

2.4. Frequency of Patient Assessment

During the first six months after the first consultation in our department, all patients had their definitive prostheses. They thus benefited from three consultations during the period of this study:

- The first consultation after amputation.
- The second consultation is immediately after fitting, *i.e.* 6 months after the first consultation.
- The third consultation is at six months post-fitting, with a maximum of 1 year after the first consultation.

All patients benefited from regular rehabilitation at a rate of 3 sessions per week from the first consultation until 1 month after fitting.

2.5. Questionnaire

The "Short form 36" (SF-36)

It is a general multidimensional scale, independent of etiology, gender, age, and treatment. It can be administered as a self- or hetero-questionnaire.

It includes 36 questions divided into eight dimensions, each corresponding to a different aspect of health: physical function (PF), role physical (RP), bodily pain (BP), general health (GH), vitality (VT), social function (SF), role emotional (RE), mental health (MH) and health thinking (HT). The score for each dimension of the SF-36 is calculated on a scale from 0 to 100, and the higher the total score, the better the QOL.

In addition, two scores are calculated from these domains: the Physical Composite Score (PCS) and the Mental Composite Score (MCS) [7] [8].

The "Special interest group of the amputee medicine" (SIGAM)

The score has an excellent reliability and validity. It is easy to use, with six clinical grades (A to F) for mobility in fitted amputees.

According to a pre-established algorithm, SIGAM reflects the patient's functional ability to walk. In addition, it provides the clinician with information on walking aids, nursing care, or patient rehabilitation, as well as prosthesis use according to walking surface and weather conditions. It is therefore also useful for patient follow-up [9].

The "questionnaire on the satisfaction of persons with lower-limb amputations towards their prosthesis" (SAT-PRO)

It is a questionnaire used to assess satisfaction with the use of prostheses. It comprises 15 items and everyone is rated on 4 levels (0 = completely disagree, 3 = completely agree). Items 6 and 14 are deliberately scored in reverse. The total score of the questionnaire ranges from 0 to 45 points and is then expressed as a percentage. The final result ranges from 0 to 100, with 0 indicating maximum dissatisfaction and 100 maximum satisfaction [10].

2.6. Statistical Analysis

Statistical analysis was performed using The Statistical Package for Social Sciences (SPSS) software version 22.0.

Quantitative variables not following a normal distribution were expressed as median and standard deviation. Qualitative variables were presented as frequencies and percentages.

For the analysis of the association between a qualitative and a quantitative variable, we used the Mann-Whitney test for the comparison of 2 means and the Kruskal-Wallis test for the comparison of several means. The Spearman test was used to study the presence of a correlation between 2 quantitative variables, given the non-Gaussian distribution. The Wilcoxon test was used to compare two medians belonging to two matched groups.

A p-value < 0.05 was considered significant.

3. Results

3.1. Descriptive Statistics

In the current study, thirty-five patients were enrolled including 30 men (85.71%) and 5 women (14.29%). Infectious etiology was the most frequent cause of amputation (40%), and trans-tibial amputation was the most common type of amputation (74.29%). The median time between fitting and surgery was 4 months, with extremes between 2 and 6 months. Socio-demographic data are detailed in the following table.

The various socio-demographic and clinical characteristics of patients are shown in **Table 1**.

3.2. Clinical Characteristics of the Stump

The majority (55.88%) of our patients had a moderate-quality stump (mainly a short stump for 7 patients (20.50%)). Fifteen patients (44.12%) had a good-quality stump (**Figure 1**).

Muscular atrophy was the most common complication in our study (33.33%), followed by necrosis and stump neuromas for 10 patients (30.3%). Twenty-one patients (60%) had phantom limb sensation.

Pain assessment using the visual analog scale (VAS)

After amputation, the VAS for pain had a median of 1 at rest and during mobilization, with extremes of 1 to 5 at rest and 1 to 6 during mobilization.

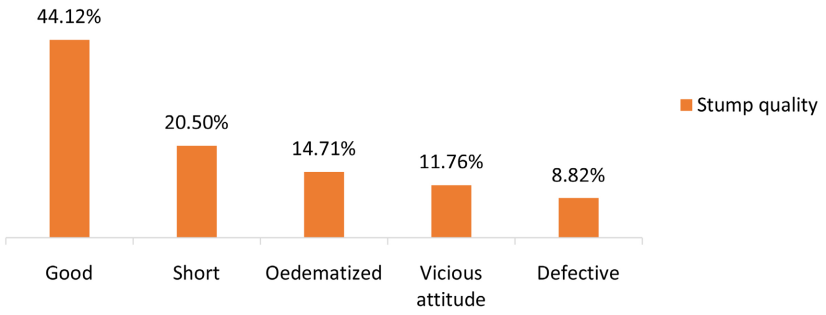

Figure 1. Distribution of patients according to stump quality.

Table 1. Sociodemographic and clinical characteristics of patients.

Variable		Value
		Median (min; max)
Age (years)		62 ± 15 [19 - 95]
		N (%)
Gender	Male	30 (85.71)
	Female	5 (14.29)
Living place	Rural	19 (54.29)
	Urban	16 (45.71)
Profession	Manual worker	22 (62.86)
	Office worker	7 (20)
	Unemployed	5 (14.28)
	Other	1 (2.86)
Presence of stairs at home	Yes	13 (37.14)
	No	22 (62.86)
Marital status	Married	30 (85.71)
	Divorced	4 (11.43)
	Widowed	1 (2.86)
Social security	Yes	30 (85.71)
	No	5 (14.28)
Medical History	Diabetes	20 (57.14)
	Arteriopathy	4 (11.43)
	High Blood Pressure	1 (2.86)
	Without medical history	4 (11.43)
	Other	6 (17.14)
Indication of Apmutation	Infectious	14 (40)
	Traumatic	11 (31.43)
	Vascular	10 (28.57)
Level of amputation	Below the Knee	26 (74.29)
	Above the Knee	8 (22.86)
	Gritti	1 (2.86)

N: Frequency.

Functional assessment

At first, most patients (77.14%) were able to dress themselves and twenty-one patients (60%) could groom themselves without assistance. Concerning the WP, the initial median was 25 meters, with extremes ranging from 0 to 140.

Quality of life assessment using the Short Form 36 (Sf-36) score

In our study, we assessed the QoL score before the acquisition prosthesis, afterward, and at 6 months post-fitting. After amputation, the physical component (PCS) was more affected than the mental component (MCS), with a median PCS score of 31 and extreme scores ranging from 22 to 56. The median MCS score was initially 32, with extremes ranging from 21 to 74.

In terms of general dimensions, FP was initially the most affected.

3.3. Evolution of the Study Population after Fitting in 2 Times (at the Beginning after Fitting and 6 Months Later)

Socio-professional reintegration

After amputation, 13 patients (37.14%) quit their jobs, 10 of our patients remained in the same post (28.57%) and 8 patients (22.87%) took early retirement.

Functional evolution

The number of patients initially able to groom themselves increased from 21 to 25 after fitting, then to 28 after 6 months. Then the number of those who were able to dress unaided rose from 27 to 29, then to 31 after 6 months. Two patients retained the ability to drive after fitting.

For the WP, it increased significantly ($p < 0.001$) both at the beginning and after 6 months ($p = 0.002$). Moreover, the median increased from 25 to 150 meters with extremes from 2 to 500 meters immediately after fitting, then to 350 meters with extremes from 3 to 850 meters 6 months later.

SIGAM score

The majority of patients (28.57%) were at grade D (ability to walk outdoors > 50 meters with or without aids) at the time of fitting and 6 months later. Seven patients had an initial SIGAM grade B score. Three patients showed functional improvement at 6 months post-fitting, moving to grade E (Table 2).

Table 2. Evolution of "Special Interest Group of the Amputee Medicine" (SIGAM) score.

SIGAM score Category	Initial assessment (1 to 6 months after amputation and acquisition of prosthesis) N (%)	Assessment at 6 months post-fitting N (%)
A	0	0
B	7 (20%)	4 (11.43%)
C	9 (25.71%)	9 (25.71%)
D	10 (28.57%)	10 (28.57%)
E	3 (8.57%)	6 (17.14%)
F	6 (17.14%)	6 (17.14%)
Total	35 (100%)	35 (100%)

N: Frequency.

Pain evolution

For our patients, we observed a statistically significant increase between the initial VAS values at rest and during mobilization, and the values assessed at the second consultation after fitting. At the third visit, we noted a significant regression in pain compared with the second visit.

We also noted a significant reduction in pain VAS on mobilization compared with the first visit ($p = 0.009$), but not significant for pain at rest ($p > 0.05$). (Table 3)

- The gain has been calculated in comparison with the initial value.

Improvement in quality of life

After fitting, we noted a significant improvement in the PCS and MCS scores ($p < 0.001$), as well as in all domains of the sf-36 score. The only exception was SF, where the improvement was not significant ($p = 0.084$).

What's more, this improvement continued to remain significant for all elements of this score in the 6 months post-fitting, even when comparing the gain with the initial evaluation (Table 4).

Changes in satisfaction with the fitting

A statistically significant improvement ($p < 0.001$) was observed in patient satisfaction with their fitting. The median SAT-PRO score rose from 66.66% ± 11.02% to 75.55% ± 10%.

3.4. Analytical Study

Quality of life

We noted a significant association between all domains of the SF-36 score and the age of patients, before, immediately, and 6 months after fitting ($p < 0.001$). Indeed, older amputees had a more impaired QoL than younger patients for the different domains of the Sf-36.

We also identified a significant but negative association between the time between fitting and surgery and the evolution of the PCS and MCS of the Sf-36 score ($p < 0.001$).

We found that the more proximal the level of amputation, the lower the QoL. In addition, we found that traumatic amputations were associated with significantly higher QoL scores than those of infectious or vascular origin ($p < 0.001$). This association remained significant after 6 months of fitting ($p < 0.05$).

Table 3. Evolution of pain after fitting.

	Immediately post-fitting		6 months after fitting	
	VAS at rest	VAS on mobilization	VAS at rest	VAS on mobilization
Median gain ± SD	−1 ± 1	−2 ± 1	1 ± 1	2 ± 2.031
Minimal gain	−5	−5	−2	−5
Maximal gain	3	4	4	3
p	0.014*	<0.001**	0.001**	0.002**

*: p: < 0.05, **p: < 0.01, VAS: visual analog scale, SD: Standard deviation.

Table 4. Evolution of different median scores Short form-36 (Sf-36) elementary scores.

	Initial median	Median immediately following fitting	Median after 6 months of fitting	p (immediately following fitting)	p (after 6 months of fitting)
PF (med ± SD)	17 ± 11	28 ± 11	38.42 ± 11	<0.001**	<0.001**
RP (med ± SD)	28.3 ± 16	49 ± 12	56 ± 6	<0.001**	<0.001**
BP (med ± SD)	46 ± 17	51 ± 11	53.6 ± 10	<0.001**	0.003**
SF (med ± SD)	35 ± 18	40.5 ± 11	46 ± 9	0.084*	<0.001**
MH (med ± SD)	30.6 ± 12	41 ± 12	48 ± 9	0.001	<0.001**
RE (med ± SD)	24 ± 18	55 ± 11	55 ± 8	<0.001**	0.001
VT (med ± SD)	41 ± 13	46 ± 11	51.7 ± 9	0.001	<0.001**
GH (med ± SD)	39 ± 20	45 ± 11	50 ± 12	<0.001**	<0.001**
PCS (med ± SD)	31.3 ± 8	35 ± 10.01	46 ± 8	<0.001**	<0.001**
MCS (med ± SD)	32 ± 11	47 ± 12	52 ± 8	<0.001**	<0.001**

med: median; SD: Standard deviation; physical function (PF), role physical (RP), bodily pain (BP), general health (GH), vitality (vitality: GH), vitality (VT), social function (SF), role emotional (RE), mental health (MH) and health thinking (HT); *: $p < 0.05$, **: $p < 0.01$.

A statistically significant and negative association was also found between pain and QoL ($p < 0.01$). On the other hand, we don't find an association with other clinical data.

For functional evolution and immediately after fitting, we noted a statistically significant association between WP, QoL scores ($p < 0.001$; $r = 0.412$ for PCS and $p < 0.001$; $r = 0.339$ for MCS) and SIGAM score ($p < 0.001$) as well as 6 months later ($p = 0.012$).

Satisfaction with prosthesis

We found that the youngest patients ($p = 0.016$; $r = -0.345$), from urban areas ($p < 0.001$) and with the highest salaries ($p = 0.01$; $r = 0.254$), had the best prosthesis satisfaction scores (SAT-PRO). These results were maintained after 6 months of fitting ($p < 0.05$).

In addition, patients who had been accidentally amputated ($p = 0.025$), who had a lower level of amputation ($p = 0.029$), who had no previous medical history ($p < 0.001$), and who had the lowest pain intensity ($p < 0.001$), were the most satisfied with their prosthesis even when assessed at the third consultation.

We noted also that there was a significant relationship between the WP, the SIGAM score, the Sf-36 score, and the SAT-PRO (Table 5).

4. Discussion

Our study aimed to assess QoL before and after fitting and to evaluate satisfaction immediately post-fitting and 6 months later.

Table 5. Functional evolution and immediately after fitting.

	Immediately post fitting				The time between fitting and 6 months later			
	WP	SIGAM	PCS	MCS	WP	SIGAM	PCS	MCS
SAT-PRO	p = 0.001** r = 0.383	p < 0.001**	p < 0.001** r = 0.343	p < 0.001** r = 0.263	p < 0.001** r = 0.423	p = 0.012*	p < 0.001** r = 0.210	p = 0.003** r = 0.237

WP: walking perimeter, SIGAM: Special interest group of the amputee medicine, PCS: physical composite score, MCS: mental composite score, SAT-PRO: questionnaire on the satisfaction of persons with lower limb amputation. *:p < 0.05, **:p < 0.001.

Sociodemographic and clinic characteristics:

The median age in our study was 62 years, with extremes [19 to 95] and a sex ratio of 0.16. These data are in line with the literature [11] [12] [13] [14].

Similarly, 62.86% of our patients were manual workers; post-amputation evaluation showed that 28.57% of patients who had undergone traumatic tibial amputation were back at the same work. This is in accordance with the literature [15].

Darter *et al.* [16] reviewed the literature on factors influencing functional outcome and return to work after amputation, and found that most authors found that age, distal level of amputation, traumatic origin, recovery time after amputation, presence of comorbidities, level of education and psychological adjustment had an impact on return to work. They also concluded that professional support may be necessary to facilitate the return to work after amputation and should include a biopsychosocial assessment of the patient's situation.

The majority of our patients were diabetic (57.14%), which is consistent with several studies [17] [18]. This is explained by the high prevalence of foot ulcers in diabetic people. This, in turn, is the result of a complicated association of different risk factors such as peripheral neuropathy, foot deformities, arterial insufficiency, trauma, and impaired resistance to infection [19].

On the other hand, a study based in England by Ahmad *et al.* [20] showed that 55% of amputated patients were non-diabetic and that the rate of major amputations had decreased in the diabetic population. They found that non-diabetic amputees had ulcerations of various origins, and were in more critical condition than those of diabetic origin. This was explained by the greater accessibility to care and regular check-ups for diabetic people in England.

Functional outcomes

Most of our patients were initially able to dress unaided (77.14%), and 60% were also able to groom themselves. This is following the data of Van Schaik [21] and Zidarov [22], who have shown in their work that amputees have few limitations in their daily living activities.

The median WP initially after amputation was 25 meters, with extremes ranging from 0 to 140 meters. Compared with normal values, these results are very disturbing. However, they appear logical given the motor handicap caused by lower-limb amputation [23] [24]. In addition, the SIGAM scores of our patients showed that the majority (28.57%) were at Grade D at the time of fitting

and 6 months later.

Qol Assessment and Predictive Factors

Our study's results, relating to the analysis of QoL using the SF-36 questionnaire, highlight that amputees had an alteration in PCS and MCS, with a more marked alteration in PCS. This is consistent with several studies in the literature [25] [26].

After fitting, we noted a statistically significant improvement in all domains of the Sf-36 score immediately and 6 months later. It would therefore seem that the fitting is a decisive factor in improving this score in lower-limb amputees [27].

Wurdeman *et al.* [28] found that vascular and diabetic lower-limb amputees had improved long-term HRQOL and mobility after being fitted. These scores remained significantly elevated until 61 to 84 months after amputation.

Given those results, we can conclude that most authors agree that limb fitting is the most important factor in improving the QoL of people with lower limb amputations.

In our study, we found that the post-fitting QoL was significantly and linearly associated with several factors. Thus, the patients with the highest Sf-36 scores were the youngest with a traumatic amputation and a more distal level. They had a shorter time between amputation and fitting, better functional outcome scores (WP and SIGAM), and lower pain intensity.

The first two factors on which almost all authors agree are age and functional status [27] [28] [29] [30] [31]. Other factors are also predictive of QoL, but not collectively accepted by all authors: the level and indication of amputation, the time between surgery and fitting, the frequency of use and satisfaction with their prosthesis, and the presence of comorbidities [32] [33] [34] [35] [36].

Evaluation of satisfaction with Prosthesis and factors associated.

We found that our patient's satisfaction with their prostheses improved after 6 months of fitting. The median SAT-PRO score rose from 66.66% to 75.55%. These findings may be explained by the time it takes patients to adapt to the prosthesis.

The patients most satisfied with their prosthesis were the youngest, had a good socio-economic level, had no comorbidities, and were from an urban environment. They had a distal level with a traumatic indication for amputation, lower pain intensity, and good functional evolution and QoL.

Baars [6] and Haboubi [37] reported that the level of satisfaction of patients with lower-limb amputations was negatively associated with the level of amputation. However, Pezzin *et al.* [38] found that satisfaction was associated with gender, race, and level of education, but not with the level or indication of amputation. Several studies [6] [33] [38] [39] have focused on certain characteristics of the prosthesis itself (fitting, quality of prosthesis components, weight, ease of use, etc.), as well as the psychological profile [5] [40], for a good level of satisfaction.

Consequently, satisfaction with prostheses is a multifactorial issue that depends on the patient himself and the characteristics of the fitting.

5. Study Limitations

Some limitations should be acknowledged. First, we opted for a monocentric study because of the difficulty of following patients from many centers prospectively.

Secondly because of the small size of our population. We could not follow up with more patients, as many were waiting to be fitted, or could not complete their follow-up during the study period.

6. Conclusion

QOL among lower limb amputees seems to be significantly associated with various factors, including age, amputation level, indication for amputation, time elapsed between amputation and prosthesis fitting, pain levels and functional outcomes. Additionally, a significant connection was identified between satisfaction with the prosthesis and specific socio-demographic characteristics (such as age, socio-economic status, presence of medical history, and urban residence), clinical factors (amputation level, indication, and pain intensity), functional progress, and QOL.

Our study has shown that the acquisition of prostheses is a determining factor in improving lower limb amputees' quality of life and satisfaction. It is important to carry out other studies, particularly multicenter studies on larger samples, to better identify the associated factors and to improve the quality of care for this type of patient.

Conflicts of Interest

The authors declare no conflicts of interest.

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