

*Original article*

## Quality of Life of Patients with Transtibial Amputation and Different Periods of Wearing Prostheses

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### SUMMARY

**Introduction.** Research into patients with lower limb amputation (LLA) puts strong emphasis on quality of life (QoL) and importance of the research in that regard as a measure for the rehabilitation outcomes. The aim of this study was to show which aspects of QoL are related to the duration of wearing a prosthesis in patients with transtibial amputation (TTA).

**Methods.** The study sample comprised 40 patients who used prosthesis for 1 - 3 years (group A), 4 - 7 years (group B) and > 8 years (group C). All patients completed Trinity Amputation and Prosthesis Experience Scale-Revised (TAPES-R).

**Results.** Prosthesis wearing history was significantly different between the groups: group A ( $2.2 \pm 0.7$  years), group B ( $5.5 \pm 1.3$  years) and group C ( $22.9 \pm 13.6$  years),  $p < 0.001$ . Patients in group B were significantly ( $p < 0.05$ ) older compared to patients in group C, displayed a significantly ( $p < 0.05$ ) lower rate of employment and significantly ( $p < 0.05$ ) longer duration of diabetes mellitus. Patients in group C displayed a significantly ( $p = 0.005$ ) lower rate of diabetes mellitus. TAPES-R showed that social adjustment was significantly lower ( $p < 0.05$ ) in patients in group C compared to patients in group A ( $3.14 \pm 0.46$  vs.  $3.55 \pm 0.41$ ).

**Conclusion.** Although patients with TTA showed good QoL, the group with a long history of wearing a prosthesis differed significantly in social adjustment compared to patients with a short period of wearing a prosthesis. The age and etiology of amputation differed significantly between the groups.

**Keywords:** quality of life, transtibial amputation, prosthesis wearing

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## INTRODUCTION

The primary goals for patients with lower limb amputations (LLA) are to ambulate with a prosthesis and perform activities of daily living (1). The adjustment process after an amputation takes a long time, and includes physical and psychological adaptation to the loss of part of the limb and the use of a prosthesis (2). Restoring functional mobility in people with LLA has a positive effect on quality of life (QoL) and satisfaction (2 - 4). Greater use of the prosthesis during the day has an important impact on the level of independence and functionality in patients with LLA (4 - 7). In accordance with the above, patients with below-knee amputations have greater mobility and better quality of life than patients with above-knee amputations (4). Adaptation to the prosthesis, satisfaction with the prosthesis and psychosocial well-being influence the patient's perception of QoL in patients with LLA (2, 3).

Currently, there is a growing need to examine the quality of life in people with LLA as a measure of the outcome of rehabilitation (6). Previous studies have noted an improvement in quality of life if patients live longer with an amputation (5). By analyzing the impact of the prosthesis on the patient's participation in activities, mobility, and psychological functioning, information on the quality of life can be obtained in this population group (7, 8). A relatively limited number of studies (5) focused on the analysis of the period (years) of use of the prosthesis as a factor affecting the QoL in amputees.

The aim of this study was to show which aspects of QoL are related to the duration of wearing a prosthesis in patients with transtibial amputation (TTA).

## MATERIAL AND METHODS

### Study design and sample

This is a cross-sectional study, conducted between March 2023 and July 2023 at the Clinical Centre of Montenegro. We searched the electronic medical records of a local orthopedic company for patients with TTA who had an appointment for making a new prosthesis or correction of an existing one between January 1, 2022 and March 1, 2023. Forty-five patients met our study's inclusion criteria, and forty of them consented to participate in this study. Inclusion criteria were patients having a unilateral

transtibial amputation, use of prosthesis for more than 12 months, ability to walk with the help of prosthesis with or without aids, and age between 18 and 75 years. Patients were excluded if they had inadequate cognitive function, or they were non-ambulatory for reasons related to complications of diabetes, musculoskeletal and neurological disorders.

Before participating in the study, all participants were informed about the purpose of the study and signed informed consent forms approved by institutional Ethics committee.

### Sociodemographic and amputee-related characteristics

The study included 40 patients who used the prosthesis for at least twelve months. Prostheses used for transtibial amputation were PTB (patellar tendon bearing) with dynamic feet. According to the prosthesis wearing history, patients were divided into three groups: a) group A including 13 patients with short prosthesis wearing history from 1 to 3 years, b) group B involving 11 patients with medium prosthesis wearing history from 4 to 7 years, and c) group C including 16 patients with long prosthesis wearing history for more than 8 years.

In group A, the cause of amputation was more commonly related to diabetes mellitus (8 patients) than trauma (3 patients). Peripheral arterial disease (PAD) was the cause of amputation in two patients. In group B, diabetes mellitus (DM) was the cause of amputation in most cases (9 patients), whereas trauma was the cause of amputation in two patients. In group C, amputation was caused by trauma in the majority of patients (12 patients) and by DM in six patients.

### Measurement instrument

Trinity Amputation and Prosthesis Experience Scale-Revised (TAPES-R)

We measured prosthetic function and satisfaction using the TAPES-R (8, 9). It includes 3 scales: a) psychosocial adjustment (general, social, and limitation adjustment) with a four-point rating scale (strongly agree, agree, disagree, and strongly disagree), b) activity restriction based on ten items with a three-point rating scale (limited a lot, limited a little, and not at all limited), c) satisfaction with the prosthesis (aesthetically and functionally) using a 3-

point rating scale (dissatisfied, satisfied, and very satisfied). A single overall index of satisfaction with the prosthesis was calculated using the Numerical Rating Scale (NRS) ranging from 0 to 10 (“not at all satisfied” and “very satisfied”). The TAPES-R contains a second section (Part II) that assesses the experience of phantom limb pain and residual limb pain.

### Statistical analysis

Data analyses were performed using IBM SPSS (version 25; IBM Corp.). Shapiro–Wilk tests indicated that diabetes mellitus duration (years) data and most items from TAPES-R (except social adjustment, adjustment to limitation, and activity restriction) were not normally distributed and therefore required non-parametric analyses. Chi-square tests were used to analyse differences in distribution of categorical variables [sex (male/female), employment status (yes/no), marital status (married/unmarried), residential location (urban/rural), diabetes mellitus diagnosis (yes/no), stump ulcer (yes/no), peripheral artery disease (yes/no), dominant side amputation (yes/no) and phantom limb pain (yes/no)] between the groups. Post hoc procedures were

conducted for Chi-square tests where appropriate, while adjusting for type I error ( $p < 0.017$ ). While a preliminary correlation analyses revealed a possible confounding influence ( $p < 0.05$ ) of BMI on some items of TAPES-R (general adjustment, social adjustment, adjustment to limitation, activity restriction and overall satisfaction with prosthesis), this confounding influence was not controlled as a covariate since there was no significant difference in BMI between groups. On the other hand, no confounding influence of patients’ characteristics was observed on the remaining TAPES-R parameters. In this regard, differences between the groups in TAPES-R were compared using the Kruskal-Wallis test for non-normally distributed data or one-way analyses of variance for normally distributed data.

## RESULTS

### General characteristics

General characteristics for patients with short, medium, and long prosthesis wearing history are presented in Table 1. Prosthesis wearing history was significant differently between groups: group A ( $2.2 \pm 0.7$  years), group B ( $5.5 \pm 1.3$  years) and group C

**Table 1.** General characteristics (mean  $\pm$  standard deviation) in patients with short (Group A), medium (Group B) and long (Group C) prosthesis wearing history

General characteristics	Group A (n = 11)	Group B (n = 13)	Group C (n = 16)	P
Age (yr)	62.7 $\pm$ 7.5	66.8 $\pm$ 5.9	58.0 $\pm$ 9.3	<b>0.024</b>
Body mass (kg)	96.6 $\pm$ 13.7	83.3 $\pm$ 10.5	80.5 $\pm$ 12.5	<b>0.004</b>
Height (cm)	180.3 $\pm$ 10.6	175.2 $\pm$ 7.1	176.42 $\pm$ 7.3	0.286
Body mass index	27.7 $\pm$ 3.8	28.2 $\pm$ 5.0	26.9 $\pm$ 3.1	0.672
Sex (Male/Female)	10/3	8/3	12/4	0.972
Employment status (Yes/No)	5/8	0/11	7/9	<b>0.037</b>
Marital status (married, unmarried)	9/4	8/3	11/5	0.973
Residential location (urban/rural)	10/3	10/1	11/5	0.399
Diabetes mellitus diagnosis (Yes/No)	8/5	9/2	4/12	<b>0.011</b>
Diabetes mellitus duration (yr)*	6.5 $\pm$ 6.6	13.1 $\pm$ 10.4	3.8 $\pm$ 7.5	<b>0.025</b>
Glycosylated hemoglobin	6.3 $\pm$ 0.5	6.4 $\pm$ 0.8	7.4 $\pm$ 0.4	0.104
Stump ulcer (Yes/No)	1/12	2/9	0/16	0.211
Peripheral arterial disease (Yes/No)	2/11	0/11	2/14	0.416
Dominant side (Yes/No)	9/4	4/7	7/9	0.224
Prosthesis wearing history (yr)	2.2 $\pm$ 0.7	5.5 $\pm$ 1.3	22.9 $\pm$ 13.6	<b>&lt; 0.001</b>

Note: bolded p value indicates statistically significant differences at  $p < 0.05$ ,

\*data analyzed using Kruskal-Wallis test

( $22.9 \pm 13.6$  years),  $p < 0.001$ . Patients in group B were significantly ( $p = 0.022$ ) older compared to patients in group C,  $66.8 \pm 5.9$  vs.  $58.0 \pm 9.3$  years, respectively. Body mass was significantly higher in patients in group A compared to patients in group B ( $96.6 \pm 13.7$  vs.  $83.3 \pm 10.5$ ,  $p < 0.05$ ) and group C ( $96.6 \pm 13.7$  vs.  $80.5 \pm 12.5$ ,  $p < 0.05$ ). Patients in group B displayed significantly ( $p < 0.05$ ) lower rate of employment compared to patients in group A and group C. Patients in group C displayed significantly ( $p = 0.005$ ) lower rate of diabetes mellitus diagnosis compared to patients in group A and group B. Diabetes mellitus duration (years) was significantly ( $p < 0.05$ )

longer in patients in group B compared to patients in group C ( $13.1 \pm 10.4$  vs.  $3.8 \pm 7.5$  years).

#### Trinity Amputation and Prosthesis Scales-Revised

The mean  $\pm$  SD for each item of the Trinity Amputation and Prosthesis Scales-Revised (TAPES-R) are presented in Table 2. Social adjustment was significantly lower ( $p < 0.05$ ) in patients in group C compared to patients in group A,  $3.14 \pm 0.46$  vs.  $3.55 \pm 0.41$ . Non-significant differences were observed between the groups in other items of the TAPES-R.

**Table 2.** Differences between the groups in Trinity Amputation and Prosthesis Scales-Revised (TAPES-R)

TAPES-R	Group A (n = 13)	Group B (n = 11)	Group C (n = 16)	P
<b>PART I</b>				
<i>Psychological adjustment</i>				
General adjustment*	$3.55 \pm 0.45$	$3.53 \pm 0.40$	$3.36 \pm 0.48$	0.482
Social adjustment	$3.55 \pm 0.41$	$3.42 \pm 0.45$	$3.14 \pm 0.46$	<b>0.045</b>
Adjustment to limitation	$3.15 \pm 0.47$	$2.96 \pm 0.48$	$3.09 \pm 0.46$	0.599
<i>Activity restriction</i>				
Activity restriction	$0.87 \pm 0.47$	$0.96 \pm 0.48$	$0.89 \pm 0.37$	0.856
<i>Satisfaction with prosthesis</i>				
Aesthetic satisfaction*	$8.54 \pm 0.66$	$8.09 \pm 0.83$	$8.13 \pm 0.81$	0.210
Functional satisfaction*	$10.69 \pm 2.21$	$12.45 \pm 2.11$	$11.19 \pm 2.37$	0.075
Overall satisfaction with prosthesis*	$7.77 \pm 1.64$	$8.72 \pm 1.55$	$8.25 \pm 1.34$	0.227
<b>PART II</b>				
General health*	$3.85 \pm 0.80$	$3.45 \pm 0.93$	$3.38 \pm 0.87$	0.340
Prosthesis wearing time per day (h)*	$21.23 \pm 6.81$	$16.36 \pm 8.80$	$15.31 \pm 8.04$	0.172
<i>Phantom pain</i>				
Phantom limb pain (Yes/No)	7/6	7/4	11/5	0.709
Phantom pain per week (n)*	$4.00 \pm 2.31$	$4.14 \pm 3.13$	$3.81 \pm 0.87$	0.676
Average length of episode pain*	$3.29 \pm 1.38$	$2.28 \pm 0.76$	$2.63 \pm 0.50$	0.153
Average level of phantom pain*	$2.29 \pm 1.38$	$2.43 \pm 0.79$	$2.45 \pm 0.52$	0.595
Lifestyle interference*	$2.29 \pm 1.28$	$2.43 \pm 0.79$	$2.36 \pm 0.50$	0.635

Note: \* data analyzed using Kruskal-Wallis test

## DISCUSSION

The main findings of this study are that there are no significant differences in the quality of life among users of TT prostheses, which were assessed with the TAPES-R instrument, across the three categories of years reflecting the time since amputation, with the exception of social adjustment. Also,

the mean scores of TAPES-R suggest that the patients have reached their almost the best possible outcome in first three year since amputation.

In our study, patients in these three groups were significantly different in prosthesis wearing history. In Asano et al. study, the period since amputation was categorized as: 0 - 3, 4 - 13 and 14+ years. The previous study (5) suggested that there is a dif-

ference in reported QoL across the three categories of years reflecting the time since amputation. Fortington et al. concluded (6) that domain scores of QoL differed little from the population norm values after 6 – 18 months, with the exception of physical function.

Our patients with short prosthesis wearing history (group A) successfully used prosthesis for  $2.2 \pm 0.7$  years, mean age  $62.7 \pm 7.5$  years, with mixed etiology of amputation. The majority of patients were married, lived in an urban location and most of them were employed. Prosthesis wearing history in our study correlated with time points in other studies (6, 10). By evaluating the values of TAPES-R, the average score for the general adjustment was  $3.55 \pm 0.45$  and  $3.55 \pm 0.41$  for social adjustment, with the maximum allowed being 4.0. The lower positive adjustment was on the adjustment to limitation subscale ( $3.15 \pm 0.47$ ). No statistically significant differences were observed when comparing the adjustment scores to group B and group C, except for the social adjustment in group C ( $3.55 \pm 0.41$  vs.  $3.14 \pm 0.46$ ). In a multi-variable regression analysis of predictors of QoL, Asano et al. (5) categorized a long period of using prosthesis as +14 years, and found that social support and social activity participation are important predictors of subjects' perceived QoL. Patients in group C, in our study, used prosthesis for  $22.9 \pm 13.6$  years, with a lower score for the social adjustment than patients in group A. Thus, Asano et al. (5) suggested to test "the response shift hypothesis" in patients who had their amputation for a longer period of time.

Patients with medium prosthesis wearing history (group B) wore the prosthesis for  $5.5 \pm 1.3$  years. They were significantly older than group C ( $66.8 \pm 5.9$  vs.  $58.0 \pm 9.3$  years). In this group, amputation were related to vascular etiology with DM, in accordance with previous literature (1, 11). All patients in group B were unemployed. This suggests that amputation has an impact on employment status. Sinha et al. (12) found similar results, compared to our respondents; the difference was in age ( $66.8 \pm 5.9$  vs.  $43.7 \pm 15.0$  years). In our study, TAPES-R showed positive general adjustment and social adjustment, and lower score for adjustment to limitation ( $2.96 \pm 0.48$ ). The results of our study were in agreement with previous findings (4, 12, 13) which indicate worse men's ability to deal with the limitation. Another possible explanation is duration

of DM ( $13.1 \pm 10.4$  years), which is in keeping with other studies (14, 15).

Patients with long prosthesis wearing history (group C) used prosthesis for  $22.9 \pm 13.6$  years. As mentioned above, social adjustment was significantly lower in group C compared to group A. Kizilkurt et al. (16) reported that perceived social support was related to QoL. Patients in this group were younger than patients in group A where trauma was the cause of amputation.

In the analysis of satisfaction with prosthesis, we found no significant differences in aesthetic, functional and overall satisfaction with prosthesis between the three groups. According to our results, the overall satisfaction was lower in group A ( $7.77 \pm 1.64$ ). The evaluation of satisfaction with the prosthesis requires the analysis of several different factors (17). In the Baars et al. study (17), higher scores of satisfaction were associated with employment, sex, non-vascular reason for amputation and a longer period of time since amputation. Also, Baars et al. suggested that there is room for improvement in the overall satisfaction with the prostheses (17).

We found that some patients suffered from phantom limb pain for years (group C), and the average level of phantom pain was  $2.45 \pm 0.52$ . Greater time since amputation is associated with less phantom pain (18, 19). Other factors such as satisfaction with prostheses, optimism, and lower level of amputation were also mentioned in the studies (18, 19).

In our study, the subjects reported relatively high quality of life. Some authors (5, 6) discussed changes in the importance of the QoL domain in different periods of time since the amputation. In the period of wearing a prosthesis for up to 12 months, physical function is more important than in the later period when social adaptation takes precedence. Also, Fortington et al. suggested examining the social aspect in age-specific groups (6).

The limitations of this study include a small number of patients, which limited the division into multiple time categories according to etiology, a mixed cause of amputation and lack of elderly persons with traumatic amputation. Longitudinal studies are suggested for this population, as this will allow a better description of the variation in quality of life over time.

The practical implications are that our findings supported the claim that TAPES can be used to evaluate quality of life in rehabilitation practice.

Healthcare professionals should understand the importance of long-term support to this population group.

## CONCLUSION

This study showed that patients experienced a good quality of life after different periods of wearing a transtibial prosthesis. Patients with long prosthesis

wearing differed significantly in social adjustment from the group with short prosthesis wearing history. Different age and etiology of amputation were found in patients with long prosthesis wearing. This finding suggests the importance of comparing age-specific groups when evaluating specific domains of QoL for patients who wear a prosthesis for different years.

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# Kvalitet života bolesnika nakon transtibijalne amputacije i različiti periodi nošenja proteze

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## SAŽETAK

**Uvod.** Proučavanje pacijenata kojima je izvršena amputacija donjih ekstremiteta (engl. *lower limb amputation* – LLA) odražava se na sve veće isticanje kvaliteta života i njegovu sve češću upotrebu kao mere ishoda rehabilitacije. Cilj ovog istraživanja bio je da pokaže koji su aspekti kvaliteta života povezani sa trajanjem nošenja proteze kod bolesnika kojima je izvršena transtibijalna amputacija (TTA).

**Metode.** Studija je obuhvatila 40 bolesnika koji su koristili protezu od jedne do tri godine (grupa A), od četiri godine do sedam godina (grupa B) i duže od osam godina (grupa C). Svi bolesnici popunili su upitnik *Trinity Amputation and Prosthesis Experience Scale-Revised* (TAPES-R).

**Rezultati.** Period nošenja proteza značajno se razlikovao među grupama – u grupi A iznosio je  $2,2 \pm 0,7$  godina, u grupi B  $5,5 \pm 1,3$  godine, a u grupi C  $22,9 \pm 13,6$  godina;  $p < 0,001$ . Bolesnici u grupi B bili su značajno ( $p < 0,05$ ) stariji od onih u grupi C, imali su značajno ( $p < 0,05$ ) nižu stopu zaposlenosti i značajno ( $p < 0,05$ ) duže trajanje dijabetesa melitusa. Bolesnici u grupi C imali su značajno ( $p = 0,005$ ) nižu stopu dijabetesa melitusa. TAPES-R je pokazao da je socijalno prilagođavanje značajno niže ( $p < 0,05$ ) kod bolesnika u grupi C nego kod onih u grupi A ( $3,14 \pm 0,46$  prema  $3,55 \pm 0,41$ ).

**Zaključak.** Iako se pokazalo da je kvalitet života kod bolesnika nakon TTA dobar, treba istaći da se grupa sa dugom istorijom nošenja proteze u socijalnom prilagođavanju značajno razlikovala od grupe koja je protezu nosila kraće. Starost bolesnika i etiologija amputacije značajno su se razlikovali među grupama.

**Ključne reči:** kvalitet života, transtibijalna amputacija, nošenje proteza