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ORIGINAL RESEARCH

Patient's satisfaction with a lower limb prosthesis: a longitudinal study

Satisfação de pacientes com prótese de membro inferior: um estudo longitudinal

Satisfacción de pacientes con protésis de miembro inferior: un estudio longitudinal

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ABSTRACT | This is a descriptive longitudinal study that aimed to verify prosthesis satisfaction of older adults with lower-limb amputation (LLA). In total, This study was composed of 34 older adults with LLA participated of this study. Participant's satisfaction about the lower-limb prosthesis (LLP), the discomforts, and the embarrassment when use it were evaluated through an interview composed of five questions. The occurrence of falls and the independence in prosthesis management were also evaluated. All variables were collected at the last week of ambulatory rehabilitation discharge and after one and three months. A descriptive and inferential statistical analysis was performed. The level of significance was set at 5% ($p < 0.05$). In total, 80% of participants with transtibial amputation and 78.6% of participants with transfemoral amputation were satisfied with the LLP after three months. Tight prosthesis, walking pain, the embarrassment of using LLP, and the occurrence of falls decreased over time. The independence in prosthesis handling did not change significantly after three months. Participants that used manual locking knee ($p=0.040$) and/or Solid-Ankle Cushion Heel foot ($p=0.017$) were more satisfied with LLP. The occurrence of falls reduced ($p=0.039$) after transfemoral participants started to use the prosthesis. Participant's satisfaction with the LLP was high and did not change significantly over time.

Keywords | Aged; Amputation; Artificial Limbs; Physical Therapy Modalities; Patient Satisfaction.

RESUMO | O objetivo do estudo foi verificar a satisfação de indivíduos amputados com a prótese de membro inferior (PMI). Trata-se de um estudo longitudinal descritivo. Participaram 34 idosos com amputação de membro inferior (AMI). A satisfação dos participantes com a PMI, os desconfortos e a vergonha de usá-la foram avaliados por meio de uma entrevista composta por 5 perguntas. A ocorrência de quedas e a independência no manuseio da prótese também foram avaliadas. Todas as variáveis foram coletadas na última semana de alta da reabilitação ambulatorial e após 1 e 3 meses. Foi realizada análise estatística descritiva e inferencial. O nível de significância foi estabelecido em 5% ($p<0,05$). Oitenta por cento dos participantes com amputação transtibial e 78,6% dos participantes com amputação transfemoral estavam satisfeitos com a PMI após três meses de seguimento. A prótese apertada, a dor ao caminhar, a vergonha de usar a PMI e a ocorrência de quedas diminuíram com o tempo. A independência no manuseio da prótese não mudou significativamente após três meses. Os participantes que utilizaram o joelho com trava manual ($p=0,040$) e/ou o pé com calcanhar sólido (SACH) ($p=0,017$) estavam mais satisfeitos com a PMI após alta da reabilitação. A ocorrência de quedas diminuiu ($p=0,039$) nos transfemorais após iniciarem o uso da PMI. A satisfação dos idosos participantes com relação a sua PMI foi alta e não mudou significativamente ao longo do tempo.

Descritores | Idoso; Amputação; Membros Artificiais; Modalidades de Fisioterapia; Satisfação do Paciente.

RESUMEN | El objetivo de este estudio fue verificar si las personas mayores que tienen amputadas un miembro estaban

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satisfechas con la prótesis de miembro inferior (PMI). Se ha realizado un estudio longitudinal descriptivo. Han participado 34 personas mayores con PMI. La satisfacción de los participantes con la PMI, las molestias y la vergüenza de usarla han sido evaluadas a través de una entrevista con 5 preguntas. Las caídas y la independencia en el manejo de la prótesis también han sido evaluadas. Todas las variables fueron recolectadas en la última semana de alta de rehabilitación en el ambulatorio y después de 1 y 3 meses. Se ha realizado análisis estadístico, descriptivo y de inferencia. El nivel de significancia establecido fue del 5% (p<0,05). Un ochenta por ciento de los participantes con amputación transtibial y el 78,6% con amputación transfemoral estaban satisfechos con la PMI después de tres meses de seguimiento. La prótesis apretada, el dolor al caminar, la vergüenza de usarla y las caídas han disminuido con el tiempo. La independencia con el manejo de la prótesis no ha cambiado significativamente después de tres meses. Los participantes que han utilizado la rodilla con traba manual (p=0,040) y/o el pie con tobillo sólido (SACH) (p=0,017) estaban más satisfechos con la PMI tras la rehabilitación. Las caídas han disminuido (p=0,039) en los transfemorales después de empezar a usar la PMI. Los adultos mayores estaban muy satisfechos con la PMI y no han cambiado de opinión a lo largo del tempo.

Palabras clave | Ancianos; Amputación; Miembro Artificiales; Modalidades de Fisioterapia; Satisfacción del paciente.

INTRODUCTION

The aging process contributes to the increase in the incidence of chronic noncommunicable diseases[1]. According to the Brazilian Diabetes Society, diabetes mellitus presents a high prevalence among these chronic diseases[2], and diabetic foot is one of its main complications[3]. Diabetic foot is the cause of many amputations and hospitalizations of patients with diabetes mellitus[3]. This population is 15 to 46 times more vulnerable to suffer lower-limb amputation (LLA)[4].

The individual who suffered an amputation can feel fear, sense of defeat, and incapacity[5]. Thus, psychological problems and corporal scheme deconstruction are common deficits in individuals with LLA[5]. These motor and psychological injuries should hinder the adaptation process of lower limb prosthesis (LLP) use[6].

The dependency on others to work and to perform activities of daily living (ADL) increases with aging. Although LLP improves individual's mobility, self-esteem, body image, and reliability[7], older adultsopulation with LLA present more difficulty to adapt train to the prosthesis[8]. The satisfaction with the prosthesis plays a key role in regaining mobility and it is important for optimizing the use of the prosthesis, preventing rejection, and increasing compliance with the medical regimen[9].

The prosthetic discomfort should be a negative factor to LLP rehabilitation. The aesthetics, prosthesis weight, stiff socket edge, safety, and inguinal pain are common prosthetic discomforts[10]. Multidisciplinary intervention is fundamental to solve these problems and has a significant role in functional re-education and autonomy promotion[11].

Physical therapy improves gait capacity and makes individuals with LLA more independent to perform their ADL[10]. Most studies in this area have addressed psychological and cognitive functions, comorbidities, functional abilities, compliance, and the use of assessment tools. However, these aspects are not enough to guide clinical practice. Results of studies exploring LLP user's satisfaction based on its comfort, aesthetic appearance, and functional independence may assist the scientific evidence on that subject.

Thus, this study aimed to verify the satisfaction of older adults with LLP during ambulatory rehabilitation discharge and after one and three months of follow-up.

METHODOLOGY

This is a descriptive longitudinal study carried out in a public center for the prevention and rehabilitation of people with disabilities. Data collection occurred from June/2016 to February/2018. The study was carried out in accordance with the Declaration of Helsinki. All participants provided voluntary written informed consent.

Participants

The convenience sample consisted of older adults with transtibial or transfemoral amputation. All participants were receiving discharge from the rehabilitation program of a public ambulatory. The inclusion criteria were: individuals aged ≥60 years, transfemoral or transtibial amputation level, prosthetic

ambulation, and telephone contact. The exclusion criteria were: visual, hearing, and cognitive impairment and bilateral amputation.

The sample was divided into two groups: older adults with transtibial amputation (G1) and older adults with transfemoral amputation (G2). All participants performed a pre-prosthetic rehabilitation program that consisted of body strengthening and stump preparation to receive the prosthesis. The participants performed resistance exercises of the trunk, lower and upper limbs, and ambulation with unipodal support. Therapeutic procedures as manual lymphatic drainage, compressive bandage, stump desensitization, massage therapy, stretching, and stump resistance exercises were performed in order to prepare the stump to receive the prosthesis. They also performed a post-prosthetic rehabilitation program, composed of a training with the prosthesis in the parallel bars, gait re-education—using ambulatory assistive devices, stairs, and ramp exercises—, proprioceptive and functional training.

Materials and procedure

Data collection included age, sex, education level, body mass index, amputation level, and prosthetic components (socket, knee, and foot). Information about whether participants cleaned the LLP and used it to perform exercises and recreation activities were also collected. The occurrence of falls and the independence in prosthesis management were also collected.

Prosthetic satisfaction after concluding the prosthesis rehabilitation program was evaluated by an interview prepared by the author (Table 1). This interview is a mixture of three scales/questionnaires such as the Satisfaction with Prosthesis Questionnaire (SAT-PRO)[12], the Prosthesis Evaluation Questionnaire[13], and the Trinity amputation and prosthesis experience scales[14]. The interview was composed of the five most frequent questions among the three scales/questionnaires[12,13,14] chosen regarding participant's satisfaction, adaptation, and expectation with the LLP.

Data collection occurred in three moments: at the last week of ambulatory rehabilitation discharge, after one and three months of follow-up. The occurrence of falls three months before the participants started using the LLP at home was also collection. The follow-up data were collected by telephone calls. Two trained researchers performed the participant evaluation.

Table 1. Interview mixture of three scales/questionnaires.

Question	Answer
1. Satisfaction	
Are you satisfied with your LLP?	0. No; 1. Yes
2. Adaptation	
Is your LLP comfortable?	0. No; 1. Yes
If your answer to the previous question was "no", explain the reasons for your discomfort.	Open answer
Do you feel embarrassed when you use the prosthesis?	0. No; 1. Yes
3. Expectation Did the prosthesis meet your expectation?	0. No, it did not. 1. Yes, it met a little. 2. Yes, it did. 3. Yes, it met a lot. 4. Yes, it exceeded my expectations.

Fonte: Gallagher et al.[14], Baars et al.[15]e Pezzin et al.[16].
LLP: lower limb prosthesis.

Statistical analysis

A descriptive statistical analysis was performed. The quantitative variables were summarized in mean and standard deviation and qualitative variables in absolute and relative frequencies. Although this is a descriptive study, we chose to make the statistical inference to better understand the studied sample, that is, it was not intended to make probabilistic statements. The Student's t-test and Pearson's chi-squared test were used to compare epidemiological variables of participants with transtibial and transfemoral amputation and other independents variables. The McNemar test was used to compare qualitative variables in three different moments (last week of ambulatory rehabilitation discharge, after one and three months of follow-up). Significance level was set at 5% ($p<0.05$). The Statistical Package for the Social Sciences (SPSS – version 22) software was used.

RESULTS

During the recruitment process, 35 older adults were invited, one candidate declined to participate and 34 volunteers were evaluated. Five participants were lost because of phone calls contact inconsistencies and 29 older adults participated in the study (Figure 1).

The two groups presented similar epidemiological measurements, education level, and number of fallers. Group 1 presented a worse body mass index compared to G2 (Table 2).

According to prosthesis components, the most used were *Kondyen Bettung Münster* (KBM) quadrilateral socket, weight-activated stance knee, and Solid-Ankle Cushion Heel (SACH) foot (Table 2).

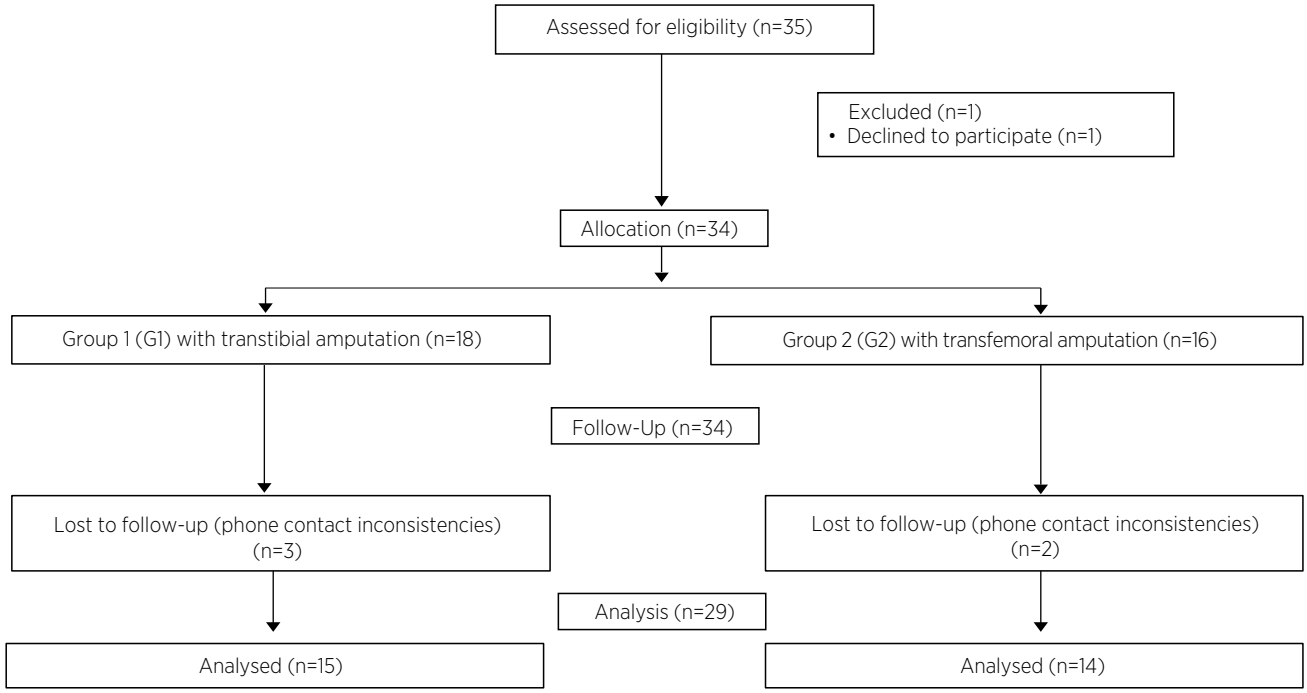

Figure 1. Flow diagram

Table 2. Epidemiological data of participants with transtibial and transfemoral amputation

Characteristic	G1 (n=15) Mean (±SD) n (%)	G2 (n=14) Mean (±SD) n (%)	p
Age (years)	69 (±7)	70 (±7)	0.645
BMI (Kg/cm²)	27 (±5)	23 (±4)	0.024
Sex			
Male	6 (40)	9 (64.3)	0.191
Female	9 (60)	5 (35.7)	
Schooling			
Illiterate	3 (20)	1 (7.1)	
<8 years	2 (13.3)	4 (28.6)	
8 years	6 (40)	4 (28.6)	0.613
8> and <11years	2 (13.3)	1 (7.1)	
≥11 years	2 (13.3)	4 (28.6)	
Fallers*	6 (40)	9 (64.3)	0.191
Foot			
SACH	14 (93.3)	9 (64.3)	0.054
Single Axis	1 (6.7)	5 (35.7)	
Knee			
Manual locking knee		6 (42.9)	
Weight activated		8 (57.1)	
Socket			
KBM	12 (80.0)		
PTB	3 (20.0)		
Quadrilateral		14 (100.0)	

BMI: body mass index; SD: standard deviation; SACH: Solid Ankle Cushion Heel; KBM: Kondylen Bettung Münster; PTB: Patellar Tendon Bearing.
*Prevalence of falls three months before starting to use the prosthesis at home.

A significant difference was also found in satisfaction (p=0.017) according to the type of foot used by the participants. A total of 21 (91.3%) participants who were using SACH foot reported being satisfied with the prosthesis after three months. However, three (50%) participants who were using single-axis foot reported being satisfied with the LLP.

Table 3 shows the data of both groups in three different periods regarding participant's satisfaction with the prosthesis and family support, the occurrence of falls, the independence in prosthesis handling, the use of LLP during exercises and recreation activities, comfort and embarrassment to use the prosthesis.

According to the occurrence of falls, all participants of G2, which were using manual locking knee, did not fall after three months of follow-up. However, two (2.5%) participants who were using weight-activated stance knee felt during the same period.

Only G2 presented a significant difference (p=0.039) in the number of falls three months before starting use the prosthesis at home and the last week of ambulatory rehabilitation discharge.

The two groups increased their expectative about the prosthesis (Table 4) and reported similar reasons for discomfort in the three periods of time. The stiff socket edge was the discomfort most frequent in both groups. Table 4 shows the discomforts reasons.

Table 3. The occurrence of falls, LLP use to perform gait, ADL, exercise and leisure activities, and participant's satisfaction with the prosthesis

Characteristic	G1 (n=15)					G2 (n=14)				
	After LLP rehabilitation n (%)	After 1 month n (%)	p*	After 3 months n (%)	p**	After LLP rehabilitation n (%)	After 1 month n (%)	p*	After 3 months n (%)	p**
Occurrence of falls	2 (13.3)	2 (13.3)	1.000	1 (6.7)	1.000	2 (14.3)	0 (0.0)	.[b]	0 (0.0)	.[b]
Prosthetic handling independence	12 (80.0)	12 (80.0)	1.000	11 (73.3)	1.000	7 (50.0)	7 (50.0)	1.000	9 (64.3)	0.687
Cleaning the prosthesis	10 (66.7)	13 (86.7)	0.250	12 (80.0)	0.125	9 (64.3)	14 (100)	.[b]	10 (71.4)	1.000
Exercise with LLP	4 (26.7)	3 (20.0)	1.000	5 (33.3)	0.625	0 (0.0)	3 (21.4)	.[b]	0 (0.0)	.[b]
Recreation with LLP	6 (40.0)	8 (53.3)	0.238	8 (53.3)	.[b]	6 (42.9)	6 (42.9)	.[b]	6 (42.9)	0.287
Prosthetic satisfaction	14 (93.3)	13 (86.7)	1.000	12 (80.0)	.[b]	10 (71.4)	10 (71.4)	.[b]	11 (78.6)	1.000
Satisfaction with family support										
Dissatisfied	0 (0.0)	0 (0.0)	0.500	0 (0.0)	.[b]	1 (7.1)	0 (0.0)	.[b]	1 (7.1)	0.287
Not very satisfied	0 (0.0)	0 (0.0)		0 (0.0)		1 (7.1)	2 (14.3)		1 (7.1)	
Satisfied	5 (33.3)	3 (20.0)		0 (0.0)		1 (7.1)	4 (28.6)		2 (14.3)	
Very satisfied	10 (66.7)	12 (80.0)		15 (100.0)		11 (78.6)	8 (57.1)		10 (71.4)	
Comfortable	9 (60.0)	9 (60.0)	1.000	11 (73.3)	0.625	7 (50.0)	10 (71.4)	0.375	9 (64.3)	0.625
Embarrassment	4 (26.7)	3 (20.0)	1.000	0.0 (0.0)	.[b]	4 (28.6)	6 (42.9)	0.625	2 (14.3)	0.500

LLP: lower limb prosthesis; ADL: activities of daily living.
p*: comparison of dependents variables (after LLP rehabilitation x after one month of follow-up).
p**: comparison of dependents variables (after one month of follow-up x after three months of follow-up)
[b]: Computed only for a PxP table, where P must be greater than 1.

Table 4. Participants' adaptation and expectation with the prosthesis over time

Characteristic	G1 (n=15)					G2 (n=14)				
	After LLP rehabilitation n (%)	After 1 month n (%)	p*	After 3 months n (%)	p**	After LLP rehabilitation n (%)	After 1 month n (%)	p*	After 3 months n (%)	p**
Did the prosthesis meet your expectation?										
0. No, it did not.	1 (6.7)	-	.[b]	2 (13.3)	0.501	1 (7.1)	1 (7.1)	.[b]	3 (21.4)	.[b]
1. Yes, it met a little.	3 (20.0)	4 (26.7)		2 (13.3)		8 (57.1)	5 (35.7)		2 (14.3)	
2. Yes, it did.	4 (26.7)	1 (6.7)		1 (6.7)		2 (0.0)	3 (21.4)		3 (21.4)	
3. Yes, it met a lot.	6 (40.0)	7 (46.7)		6 (40.0)		6 (14.3)	2 (14.3)		1 (7.1)	
4. Yes, it exceeded my expectations.	1 (6.7)	2 (13.3)		4 (26.7)		3 (21.4)	3 (21.4)		5 (35.7)	
Discomfort										
Stiff socket edge	9 (60.0)	9 (60.0)	0.736	11 (73.3)	.[b]	6 (42.9)	9 (64.3)	.[b]	10 (71.4)	.[b]
Walking pain	2 (13.3)	2 (13.3)		-		5 (35.7)	1 (7.1)		-	
Tight prosthesis	2 (13.3)	2 (13.3)		-		3 (21.4)	1 (7.1)		1 (7.1)	
Heavy protesis	2 (13.3)	2 (13.3)		4 (26.7)		-	3 (21.4)		3 (21.4)	

LLP: lower limb prosthesis.
p*: comparison of dependents variables (after LLP rehabilitation x after 1 month of follow-up).
p**: comparison of dependents variables (after 1 month of follow-up x after 3 months of follow-up).
[b]: Computed only for a PxP table, where P must be greater than 1.

Participants of G2 – who were using manual locking knee – decreased their satisfaction with their prosthesis over time. However, participants who were using weight-activated stance knee increased the satisfaction with their LLP after three months of follow-up (Table 5).

Table 5. Accidental falls and satisfaction of G2 participants according to the type of knee

Characteristic	Manual Locking Knee (n=6) n (%)	Weight-Activated Stance Knee (n=8) n (%)	p
Accidental falls			
After LLP rehabilitation	0 (0)	2 (25)	0.186
After 1 month	0 (0)	0 (0)	.
After 3 months	0 (0)	1 (12,5)	.
Satisfaction			
After LLP rehabilitation	6 (100)	4 (50)	0.040
After 1 month	5 (83.3)	5 (62.5)	0.393
After 3 months	4 (66.7)	7 (87.5)	0.347

LLP: Lower Limb Prosthesis.

DISCUSSION

Most theolder adults with transtibial and transfemoral amputation were satisfied with their LLP. This result was maintained until the end of the third month of follow-up.

Patient satisfaction is a key indicator of the quality of care[15]. Although the older adult population with LLA are usually a more fragile population, our results showed that they present similar satisfaction about LLP adaptation comparing with younger adults. The study conducted by Pezzin et al.[16] reinforces our findings. In Pezzin's et al. study, a total of 75.7% of the participants with LLA were satisfied with the prosthesis and its functional utility during their ADL. Berke et al.[17] also observed a high prosthesis satisfaction among the participants with transtibial (91%) and transfemoral (78%) amputation. These authors found that 94% of the participants reported good adaptive skills and more than 96% reported that they were able to live well using their LLP[17].

According to McFarland et al.[18], the most common cause of dissatisfaction with the LLP were the prosthesis properties. Similar to our results, this study reported 18% of prothesis rejection rates[18]. These findings are usually related to the aesthetics of the prosthesis[19]. A possible consequence of this dissatisfaction is the embarrassment of using it. According to our results, the embarrassment of using the LLP was observed during ambulatory rehabilitation discharge. The study of Raddatz et al.[19] also showed a high number of participants that reported embarrassment of using the LLP at ambulatory rehabilitation discharge, confirming our results. However, in our study, the participant's embarrassment of using the LLP decreased over time, confirming the prosthesis adaptation process.

The participant's sensation of security, promoted by prosthesis properties, also should be related to the LLP satisfaction. We found a significant difference between prosthesis satisfaction of the participants who were using manual locking knee and others who were using weight-activated stance knee. Manual locking knee provides more stability during ambulation because it does not allow knee flexion during the stance and swing gait phases[20].

Another result that confirms these findings is the significant difference we found between the prosthesis satisfaction of participants who were using SACH foot and others who were using the single-axis foot. The participants who were using SACH foot reported a high satisfaction comparing to the others who were using the single-axis foot. The SACH foot provides more stability because it did not allow ankle movements during the gait[21]. Thus, older adult should be more satisfied with LLP composed of components that promote more corporal stability. These prosthesis components provided a better postural balance, sense of security, and less fear of falling because they did not allow prosthesis arms movements. In our study, the number of falls decreased significantly after the prothesis adaptation process, and all participants with transfemoral amputation that used manual locking knee did not present falls.

Amputees with higher LLA levels consume more energy and usually present more difficulty in adapting to the prosthesis. People with transtibial LLA can more easily perform advanced ADL (exercises and recreation activities) compared to individuals with transfemoral amputation. According to D'Elboux[22], older adults with LLA may present more difficulty to perform leisure activities. This difficulty occurs due tobecause of the amputation and the problems related to the environment in which they are inserted, such as irregularities in the ground and difficulty in locomotion[22].

In our study, the transtibial group presented the best results on the independence to handle the prosthesis, use of LLP to practice exercise and leisure activities. The study of Webster et al.[23] confirms these findings. They showed that, while 92% of all amputee participants were fit with prosthesis, those with transfemoral amputation had a significantly reduced rate compared with adults

with transtibial or transmetatarsal amputation[23]. A prior study also supported this reduced rate of prosthesis fitting following transfemoral amputation[24]. At that time, worse physical capacity in transfemoral amputees and the environmental architectural barriers may justify these findings.

Another significant aspect of disability adaptation is the time[25]. Our results confirm this statement, once both groups decreased, although not significantly, the occurrence of falls, as well as improved – also not significantly – the independence to handle the prosthesis, and their expectation on it after three months of follow-up. The comfort sensation when using the prosthesis may also be related to the satisfaction rate with the LLP and the functional independence. According to our research, participants' comfort and their embarrassment to use the LLP also improved over time. This aspect plays a significant role in functional recovery after a LLA. It is possible that a comfortable prosthesis should facilitate the adaptation process, favor gait performance, and promote patients' mobility. In our study, tight prosthesis, pain when walking, stiff socket edge, and heavy prosthesis were the main causes of discomfort and complaints by the older adults in the period of outpatient training. The frequency of pain when walking and tight prosthesis in the transtibial and transfemoral group decreased in the follow-up periods of one and three months. However, the frequency of stiff socket edge and heavy prosthesis increased in both groups in the same period. The study of Raddatz et al.[19], composed of nine participants with transfemoral amputation submitted to a post-prosthetic rehabilitation program, confirms our findings. These results may guide professionals who work in the rehabilitation process of individuals with LLA in therapeutic conducts that could improve the LLP adaptation.

The support of the multidisciplinary health team and family members are important for the rehabilitation process and LLP adaptation of older adults with LLA. According to the results obtained in our study, family support may have contributed positively to the process of prosthesis adaptation, once most participants in both groups reported being very satisfied with the family support from the outpatient training until the third month of follow-up. Santos et al.[26] evidenced the significance of family support and the network of social relations for the amputee. Ramos et al.[27] also emphasized the significance of family support, and this rapprochement between people in providing health benefits, sense of well-being, and security for these individualss.

The study presented some limitations, such as the small sample size and the reduced follow-up time. The number of scientific papers that address the satisfaction with the use of the prosthesis of older adults amputees after a post-prosthetic rehabilitation program is still scarce. We suggest that future cohort studies should be carried out on the subject to investigate the index of aged amputees satisfied with the prosthesis over time and the causes of possible dissatisfaction.

CONCLUSIONS

Older adult with LLA presented a high satisfaction and expectation with their LLP in the short- and long-term. The participants with transtibial amputation presented a better adaptation with the prosthesis comparing to transfemoral amputees of the same age. Prosthesis components as manual locking knee and SACH foot were related to a better satisfaction with the prosthesis. The reasons for discomfort with the stiff socket edge and the heavy prosthesis have increased after three months of follow-up. However, the number of falls has decreased after the participants started using the LLP.

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