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Research Article

Evaluation of Functional Health and Well-Being in 23 Transfemoral Amputees After Distal Weight-Bearing Implant

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Abstract

Purpose: Functional health in patients with transfemoral amputations can be compromised when using standard socket prostheses due to problems associated with the skin-socket interface, lack of distal support and inability to transfer load to the residual limb. Osseoanchored implants that allow distal weight-bearing of the residuum can be an alternative for prosthetic attachment in these individuals. The objective of this study was to evaluate the effect of a distal weight-bearing implant on function, health, and well-being in patients with transfemoral amputations using the SF-36 Health Survey.

Methods: Interrupted time series clinical trial where 29 patients with previous transfemoral amputations were recruited under the same protocol from 5 hospitals and received an osseoanchored distal weight-bearing implant. Patients were followed for a 14-month period and assessed pre-and post-surgically using SF-36. The Wilcoxon test was used to evaluate the differences between variables and the minimally important difference threshold to assess clinical significance.

Results: All the Individual Health Domain scores of the SF-36 improved after intervention. The overall mean change is 3.94 ± 9.22 for the summary Physical Component and 1.14 ± 8.07 for the summary Mental Health Component. For both, improvement is greater in female patients, patients ≤ 50 years old and patients with traumatic amputations.

Conclusions: Significant and clinically meaningful improvements on the Physical Component Score and several individual domains suggest overall improvement in health-related functioning for patients after receiving a distal weight bearing implant.

Keywords: Amputee; Distal Weight Bearing Implant; Prosthesis; SF-36; Transfemoral Amputation

Introduction

Traditionally, patients who have undergone a transfemoral amputation are fit with a socket prosthesis. However, socket-related problems have been reported to reduce the quality of life of amputated patients [1-5]. Problems in the socket-skin interface and volume changes of the stump may lead to poor fit of the socket, lack of control of the prosthesis, and overall reduction of movement [6-10]. Gait changes that reduce hip flexion and extensions and may therefore lead to pelvic tilt have also been reported [11,12]. Previous studies have evaluated the functional capacity of patients with transfemoral amputation following the

placement of an implant in the femoral medullary canal, allowing direct anchoring of the prosthetic knee but not facilitating distal weight-bearing of the residuum [13-16]. These osseoanchored transfemoral implants have been reported to increase quality of life, overall well-being, prosthetic use, body image, hip range of motion, sitting comfort, and walking ability [17-19]. Several studies have examined the effect of osseoanchored prostheses on joint movement and the skin-socket interface relative to standard socket prostheses [11,17,20].

Apart from the aforementioned transfemoral amputations, there also exists another level of femoral amputation known as knee disarticulation. A knee disarticulation preserves femoral condyles, which facilitates the fitting of the socket with distal support for the residuum. This distal support is the most important clinical advantage of a knee disarticulation versus a transfemoral amputation because it permits a direct load transfer to the residual limb, which encourages greater walking independence and less energy consumption [21-24]. The advantages of knee disarticulation versus transfemoral amputation [25,26] have led to the design of an osseoanchored implant with a distal spacer that allows a direct load on the residuum over the distal surface of the socket and performs the same function as femoral condyles for patients with transfemoral amputations with the exception that the implant does not aid in suspension. In a preliminary study, Guirao, et al. 2017 [27] reported the utility of the implant in improving gait distance and velocity in these patients. The hypothesis of this study is that the use of an osseoanchored distal weight-bearing implant should improve the quality of life of patients with traditional transfemoral amputations that do not permit distal weight-bearing. The objective of this study was to evaluate the effect of a distal weight-bearing implant on quality of life in adult patients with transfemoral amputation using the 36-Item Short Form Health Survey before and after implant insertion first in all patients and then stratified by age, sex and etiology of amputations.

Materials and Methods

This interrupted time series clinical trial has been approved by Agencia Española de Medicamentos y Productos Sanitarios with the following registration number: 358/10/EC. Participants were recruited and selected using a single standardized protocol from March 1, 2011 through November 1, 2014 in the outpatient Department of Rehabilitation of the 5 participant hospitals (Hospital de Mataro, Hospital Universitario y Politecnico La Fe, Hospital Universitario Virgen del Rocio, Hospital Universitario Virgen Macarena and Hospital Universitario Nuestra Señora de Candelaria). This study was approved by the Ethical Committee of one of the participating hospitals (358/10/EC) and as per national legislation, recognized by the Ethical Committees of the other participating hospitals. The trial meets the standards of the Helsinki Declaration. All participants gave their informed consent. The inclusion criteria for intervention were: unilateral femoral amputation, femur length of the amputated limb of at least 15 cm measured from the greater trochanter, use of the prosthesis for at least 12 months and for more than 6 hours per day prior to enrollment, and ability to walk indoors with or without supervision and with or without ambulation aids. The exclusion criteria were: hip flexion deformity greater than 30°, body weight over 100 kg, active oncological pathologies, active infection, previous residuum infection, psychological disorders, cognitive impairment hindering the ability to follow instructions or perform the tests and/or pregnancy. Patients meeting the inclusion criteria were interviewed individually and the intervention as well as the advantages of distal support and its possible effect on functionality were carefully explained before they were asked to participate in the study.

A total of 29 patients with transfemoral amputations were invited to participate and all agreed and were enrolled and followed in this interrupted time series clinical trial. The reason most patients stated for wanting to participate in the study was that even though their functionality was high, their current sockets were so uncomfortable that they were willing to summit to another surgical procedure if that meant there might be an improvement in the comfortability of the socket. Each patient who received an implant allowing distal weight-bearing of the residuum within the socket acted as its own reference in the experimental before and after intervention study. The follow-up period post-intervention was 14 months. Each patient underwent pre- and post-surgical controls to evaluate the study variable. The pre-surgical controls were performed during the period of preoperative testing and the post-surgical controls at 14 months post-intervention once the patients had been rehabilitation-free for 4 months. All patients maintained the same prosthetic knees and feet used previously and underwent surgery by the same surgical team.

Implant

The distal weight-bearing implant designed for this study is composed of four pieces (Figure 1).

Figure 1: Distal weight-bearing implant components.

The femoral stem consisted of a titanium alloy (Ti-6Al-4 V) to facilitate anchoring within the residual femoral canal and a spacer made of ultra-high-molecular-weight polyethylene, which was distally connected to the stem by a titanium screw and a polyethylene plug. The spacer allowed distal support of the residuum within the socket (Figure 2).

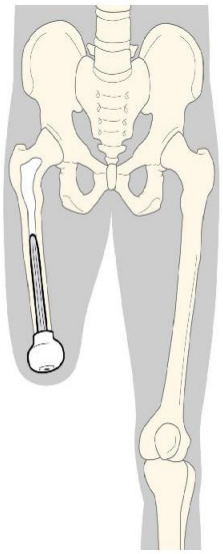

Figure 2: Placement of the implant.

The implant is designed for optimal long-term osseointegration. It is expected that the bone–implant bond will progressively get stronger and therefore reduce the risk of loosening.

Surgery

The distal part of the residual femur was smoothed, and the medullary canal was reamed to the appropriate diameter to create space for the implant stem. Specialized tools were used to determine the appropriate size of the stem, both in length and diameter, while the size of the spacer was determined with trial implants. The length of the stem ranged from 120 to 180 mm and the diameter from 12 to 17 mm. The spacer size used was the largest size available (54, 58 or 62 mm) that permitted closure without soft tissue tension. The definitive implant was assembled and placed into the femur with the press fit method. Soft tissue closure was performed with a myoplasty procedure that completely covered the spacer. The myoplasty consisted of grouping soft tissues by muscle groups, completely enclosing the spacer and suturing distally. This myoplasty procedure must not be confused with the abductor myoplasty that was previously performed on the patients during their amputations.

Rehabilitation

Rehabilitation was initiated after wound healing, around 15 days after surgery, with a program of distal loads to the residuum using a progressive schedule, starting with 5 kg until a maximum of 20 kg was achieved in week 4, without causing pain. A provisional socket with distal support was manufactured between 4 and 6 weeks, and the definitive socket was constructed at week 12. To avoid bias and better evaluate the functionality of the implant all patients were fitted with the same socket design, a Contoured Adducted Trochanteric-Controlled Alignment Method socket with distal support such as those for knee disarticulation. This socket design reduced both ischium support and the skin-socket interface surface in relation to the sockets previously worn by the patients. As previously mentioned, patients maintained the same prosthetic knees and feet used before the use of the distal weight-bearing implant. During the rehabilitation period, the patients were monitored at Rehabilitation Departments for prosthesis adjustment and gait reeducation. No additional training was performed after the adaptation period of the prosthesis.

Measures

36-Item Short Form Health Survey is a 36-question patient-rated health survey designed to be a generic measurement of health [28-30]. Within the 36-Item Short Form Health Survey there are 8 individual scales that evaluate domain-specific functioning (4 physical and 4 mental) and 2 summary component scores, the Physical Component Summary and Mental Component Summary which are generated from the individual scales [31]. Raw scores can also be transformed into norm-based scores relative to general population normative scores for a variety of countries and population subgroups [30]. The 36-Item Short Form Health Survey may be used in a wide range of applications across various populations and disease states, including the evaluation of the change in an experimental before-and-after intervention study. 36-Item Short Form Health Survey is commonly used in orthopedic research [32,33] and has been previously used in studies with amputees [7, 34-40]. In this study we have concentrated on the 4 physical Individual Health Domains and the 2 summary component scores.

To further evaluate the change, the results were stratified by age, sex and etiology of amputation and the differences between pre and post-implant summary component scores were calculated to determine if the improvement exceeded the threshold for minimally important differences [30].

Data Analysis

The data analyses were performed with SPSS 12.0 v21. Results with a value of $P<0.05$ were considered significant. Descriptive statistical analyses were performed on the baseline data. Mean and standard deviation were used to describe the quantitative variables, and percentages were used for qualitative variables. The 36-Item Short Form Health Survey scores of the patients pre and post-implant were compared using the Wilcoxon signed-rank test with a Bonferroni correction. If the P values were smaller than 0.0125, the results were considered statistically significant. The effect size was also calculated for each test performed.

Results

The initial sample of the study was 29 patients. One patient was excluded for not completing the established schedule due to required immobilization of the contralateral knee and five patients required the removal of the implant: three of them due to secondary infection after the implantation because of surgical treatment and two of them after aseptic loosening. Other adverse events (one bone fissure during surgery solved with a cerclage, three screw loosening solved by retightening with a dynamometric

screwdriver and one seroma surrounding the spacer that reabsorbed with changes in the socket design) that occurred during the clinical trial were solved satisfactorily.

23 participants with a mean age of 52.65 ± 15.62 years and a range between 18 and 87 years old were eligible for inclusion in the study. Men represented the majority of the participants. The average BMI of the patients was 24.5 ± 2.74. The etiology of amputation was traumatic in 11 patients (47.8%), vascular in 9 patients (39.1%) and oncologic in 3 patients (13.0%). Oncologic and traumatic amputations were considered together for the analysis due to the low number of oncologic amputations and the greater similarities between the two amputations. A summary of the demographic characteristics of the sample is shown (Table 1).

	n	Percentage/Mean (SD)
Sex		
Male	18	79.3
Female	5	21.7
Age	23	52.65 (15.62)
Weight (kg)	23	67.97 (11.96)
Height (cm)	23	166.3 (9.34)
BMI	23	24.51 (2.74)
Etiology		
Trauma	11	47.8
Oncologic	3	13.0
Vascular	9	39.1
SD: standard deviation		

Table 1: Basic demographics of study sample.

All the physical Individual Health Domain scores of the of the 36-Item Short Form Health Survey improved after intervention (Table 2). The improvement in the Physical Functioning domain was statistically significant (Table 2). The effect size for this particular domain is 0.75 meaning that the average person in the post-implant group would score higher than 77.8% of a pre-implant group that was initially equivalent.

NORM-BASED INDIVIDUAL HEALTH DOMAINS				
Physical health domains		**Mean (SD) (n=23)**	**P value[a]**	**Effect Size[b]**
Physical Functioning	Pre score	39.00 (10.11)	**0.005**	0.75
	Post score	45.84 (8.07)		
Role Physical	Pre score	51.94(8.98)	0.410	0.15
	Post score	54.09 (3.95)		
Bodily Pain	Pre score	51.08 (11.77)	0.331	0.22
	Post score	53.29 (8.13)		
General Health	Pre score	51.30 (10.12)	0.362	0.11
	Post score	52.42 (9.82)		
[a] P values calculated using Wilcoxon test				
[b] Effect size calculated as: [(mean post)- (mean pre)/pooled SD]				
SD: Standard Deviation SF-36: 36-Item Short Form Health Survey				

Table 2: Descriptive pre- and post-operative values for SF-36 individual health domains.

When stratified by age (Table 3) there appears a clear difference in the trend for 36-Item Short Form Health Survey scores between the two groups. While in the group ≤50 years old (n=12) all scores improved post-implant compared to pre-implant, in the group >50 years old (n=11) the scores were worse post-implant in 3/4 physical domains, being Physical Functioning the exception. Statistically significant improvements appear only in the ≤50 years old group for the Physical Functioning domain. The effect size here is 1.26 meaning that the average person would score higher post-implant than 89% of those pre-implants.

		≤50 years			>50 years		
		Mean (SD) (n=12)	**P Value[a]**	**Effect size[b]**	**Mean (SD) (n=11)**	**P Value[a]**	**Effect size[b]**
NORM-BASED INDIVIDUAL HEALTH DOMAINS							
Physical health domains							
Physical Functioning	Pre score	36.87 (10,67)	**0.008**	1.26	41.32 (9.40)	0.474	0.18
	Post score	48.58 (7.61)			42.84 (7.78)		
Role Physical	Pre score	49.17 (11.68)	0.104	0.69	54.95 (2.86)	0.317	-0.48
	Post score	55.06 (2.75)			53.03 (4.86)		
Bodily Pain	Pre score	46.80 (12.23)	0.059	0.72	55.74 (9.73)	0.507	-0.38
	Post score	54.22 (8.07)			52.28 (8.47)		
General Health	Pre score	51.71 (10.12)	0.090	0.35	50.85 (10.60)	0.438	-0.11
	Post score	54.95 (8.60)			49.66 (10.71)		
[a] P values calculated using Wilcoxon test							
[b] Effect size calculated as: [(mean post)- (mean pre)/pooled SD]							
SD: Standard Deviation SF-36: 36-Item Short Form Health Survey							

Table 3: Descriptive pre- and post-operative values for SF-36 individual health domains stratified by age.

If the patients are divided by sex (Table 4), all the physical Individual Health Domain scores improve after intervention. However, improvements are not significant for both men and women. Even though, the *P*-values show no statistically significant results, the effect size for women in the Physical Functioning domain must be mentioned. Its value of 1.69 would mean that the average women post-implant would score higher than 95.5% of those pre-implant group.

		Men			Women		
		Mean (SD) (n=18)	**P Value[a]**	**Effect size[b]**	**Mean (SD) (n=5)**	**P Value[a]**	**Effect size[b]**
NORM-BASED INDIVIDUAL HEALTH DOMAINS							
Physical health domains							

Physical Functioning	Pre score	40.83 (9.40)	0.061	0.51	32.39 (10.84)	0.043	1.69
	Post score	45.49 (8.70)			47.08 (5.82)		
Role Physical	Pre score	53.49 (6.92)	0.942	0.14	46.34 (13.79)	0.285	0.7
	Post score	54.28 (4.06)			53.41 (3.87)		
Bodily Pain	Pre score	53.19 (10.63)	0.836	0.01	43.48 (13.78)	0.144	0.91
	Post score	53.26 (8.59)			53.42 (7.10)		
General Health	Pre score	52.68 (9.09)	0.825	0.05	46.30 (13.12)	0.223	0.3
	Post score	53.15 (9.94)			49.77 (9.97)		
[a] P values calculated using Wilcoxon test							
[b] Effect size calculated as: [(mean post)- (mean pre)/pooled SD]							
SD: Standard Deviation SF-36: 36-Item Short Form Health Survey							

Table 4: Descriptive pre- and post-operative values for SF-36 individual health domains stratified by sex.

When split according to etiology (Table 5), scores improved for all physical domains for patients with traumatic amputations and in 3/4 physical domains for vascular amputees. Significant improvements were observed in the Physical Functioning domain for traumatic amputees. The effect size for this group and domain is 0.94, meaning that the average post-implant patient scored higher than 83% of pre-implant patients.

		Trauma			**Vascular**		
		Mean (SD) (n=14)	**P Value[a]**	**Effect size**	**Mean (SD) (n=9)**	**P Value[a]**	**Effect size**
NORM-BASED INDIVIDUAL HEALTH DOMAINS							
Physical health domains							
Physical Functioning	Pre score	38.87 (11.32)	**0.008**	0.94	39.20 (8.53)	0.312	0.38
	Post score	48.00 (7.87)			42.46 (7.56)		
Role Physical	Pre score	51.69 (10.23)	0.518	0.33	52.31 (7.17)	0.68	0.24
	Post score	54.22 (3.31)			53.88 (5.00)		
Bodily Pain	Pre score	50.39 (12.31)	0.432	0.26	52.14 (11.54)	0.575	0.13
	Post score	53.15 (8.14)			53.52 (8.61)		

General Health	Pre score	52.36 (9.97)	0.149	0.23	49.64 (10.73)	0.751	0.04
	Post score	54.53 (8.45)			49.12 (11.36)		
[a] P values calculated using Wilcoxon test							
[b] Effect size calculated as: [(mean post)- (mean pre)/pooled SD]							
SD: Standard Deviation SF-36: 36-Item Short Form Health Survey							

Table 5: Descriptive pre- and post-operative values for SF-36 individual health domains stratified by etiology of amputation.

The differences in pre- and post-intervention scores for the summary Physical Component Summary and Mental Component Summary were calculated (Table 6).

			n	Mean (SD)	P-value[a]	Effect size[b]
Pre-Post PCS			23	3.94 (9.22)		
	Age					
		≤ 50 years old	12	8.51 (9.62)	0.014	1.19
		> 50 years old	11	-1.04 (5.72)		
	Sex					
		Men	18	1.77 (7.95)	0.037	1.19
		Women	5	11.75 (10.04)		
	Etiology					
		Trauma	14	4.73 (8.48)	0.378	0.21
		Vascular	9	2.72 (10.67)		
Pre-Post MCS			23	1.14 (8.07)		
	Age					
		≤ 50 years old	12	3.07 (9.08)	0.389	0.50
		> 50 years old	11	-0.96 (6.58)		
	Sex					
		Men	18	0.92 (8.22)	0.655	0.12
		Women	5	1.92 (8.36)		
	Etiology					
		Trauma	14	2.86 (8.44)	0.231	0.55
		Vascular	9	-1.53 (7.06)		
[a] P values calculated using Wilcoxon test						
[b] Effect size calculated as: [(mean post)- (mean pre)/pooled SD]						
MCS: Mental Health Component Score; PCS: Physical Component Score; SD: Standard Deviation						

Table 6: Differences in pre- and post-operative PCS and MCS.

For both components, the improvement is greater in the groups of patients ≤50 years old, female and with traumatic amputation. However, the difference in improvement is not significant for either Physical Component Summary or Mental Component Summary. The effect size for the Physical Component Summary in relation to age and sex must be noted. It is 1.19 for both cases which would mean that the average woman and patient ≤50 years old would score higher than 88% of men and patients >50 years old respectively.

The frequency with which the threshold for minimally important differences were exceeded was calculated (Table 7).

		Frequency	Percentage	CI 95%
Pre-Post PCS Difference	>3[a]	11	47,8	27,42-68,91
	<3[a]	12	52,2	31,58-73,18
	Total	23	100	

Pre-Post MCS Difference	>3[a]	7	30,4	14,05-53,00
	<3[a]	16	69,6	46,99-85,94
	Total	23	100	
[a] Anchor-based MID based on baseline values as indicated by Ware et al. 2007.				
CI: Confidence Interval; MCS: Mental Health Component Score; MID: Minimally Important Difference; PCS: Physical Component Score				

Table 7: Frequency with which the pre- and postoperative difference in PCS and MCS exceeds the threshold for MID for group level data.

For the Physical Component Summary, the improvements exceeded minimally important differences in 47,8% of the cases and for the Mental Component Summary in 30,4% of the cases.

Discussion

To our knowledge, this study is the first to report on the clinical trial experience of using a distal weight-bearing implant for transfemoral amputees using the 36-Item Short Form Health Survey to assess quality of life. This implant was designed to maximize the advantages of osseoanchored implants by adding a distal weight-bearing component. The results of this study indicated overall improvements in the 36-Item Short Form Health Survey scores of amputees 14 months after receiving a distal weight-bearing implant for amputations of vascular, traumatic, or oncologic origin. The distal weight-bearing implant can potentially provide an improvement in quality of life and function. More significant improvements can be expected at longer follow-up intervals. This study demonstrates the short-term benefits of using a distal weight-bearing implant implant for transfemoral amputations in a clinical trial of patients.

The overall mean Physical Component Summary change (3.94 ± 9.22 points) exceeds the threshold for minimally important differences [30] established at 3 points. Given this, the use of the distal weight-bearing implant can be said to improve the physical function of its users. The patients included in this study already had an acceptable functional capacity before the implant and therefore, the results after intervention could have been even more relevant if the patients included had been less mobile.

While no other studies on the effect of a distal weight-bearing implant on 36-Item Short Form Health Survey scores were found, there are studies that show an improvement in physical abilities in transfemoral amputees with this type of implant [27]. Guirao, et al. 2017 [27] evaluated physical functionality using a 2-minute walk test and the physiological cost index with satisfactory results. The 2-minute walk test is a good measure of functional health and an improvement in timed walk tests is associated with an improvement in 36-Item Short Form Health Survey scores [41]. Given that timed walk test scores correlate with 36-Item Short Form Health Survey scores, it would be expected that the results of this study be comparable to those of studies on osseoanchored implants where the outcome was assessed using timed walk tests. However, it must be noted that using the 36-Item Short Form Health Survey presents a more complete picture of functional health given that it covers 8 individual physical and health domains. Therefore, and given also the higher number of patients included in this study, the strength of this study is greater than that of the preliminary study.

While as the results show, the distal weight-bearing implant is an improvement in relation to other socket prosthesis, there also exist prosthesis that do not need a socket. To date, there are 3 osseointegrated implants that permit direct anchoring of lower limb prostheses and therefore eliminate the need for a socket: Integral Leg Prosthesis (Orthodynamics GmbH; Lübeck, Germany), Osseointegrated Prosthetic Limb (Permedica s.p.a; Lecco, Italy) and the Osseointegrated Prosthesis for the Rehabilitation of Amputees (Integrum AB; Mölndal, Sweden) [42,43]. Van de Meent, et al. 2013[19] found Integral Leg Prosthesis to improve the global score of the Questionnaire for Persons with a Transfemoral Amputation, prosthesis use, 6-minute walk test, Timed Up & Go test, and oxygen consumption during treadmill walking. Al Muderis et al. 2017 [44] have shown that Osseointegrated Prosthetic Limb implants significantly improve Questionnaire for Persons with a Transfemoral Amputation, 36-Item Short Form Health Survey, 6-minute walk test and Timed Up & Go test scores. Osseointegrated Prosthesis for the Rehabilitation of Amputees implants improved Questionnaire for Persons with a Transfemoral Amputation, Physical Functioning, Physical Component Summary and Short-Form Six-Dimension health index scores, increased prosthesis use and decreased physiological cost index [18].

The advantage of these implants is not necessitating a socket and therefore patients' quality of life in terms of mobility and general satisfaction is higher than for those wearing a socket. However, most patients who receive osseointegrated prosthesis were unable to walk a long distance with a socket, their residual stump is often very short, and amputations caused by vascular disease are often an exclusion criterion for osseointegrated prosthesis fixation [44,45]. For these reasons, this trial has compared the 36-Item Short Form Health Survey scores between transfemoral amputation socket prosthesis users, being the only difference the use of the distal weight-bearing implant. The improved functionality reflected in the results of this study due to the use of the distal weight-bearing implant show that even with the need to use a socket, albeit with reduced ischium support and less skin-socket interface surface which therefore reduce any socket-related problems, the inclusion of an osseoanchored distal weight-bearing component results in an improvement in the quality of life of patients with transfemoral amputation.

An advanced extension that would allow for both direct anchoring of lower limb prostheses and distal weight-bearing of

the residuum is under development for the distal weight-bearing implant studied. In theory, the use of such implant should mean an even greater improvement in functionality since it would completely eliminate any socket related issues along with those that arise from the lack of distal weight-bearing and load transfer such as osteoporosis of the femur or problems in the ischium.

While the main objective of utilizing a distal weight-bearing implant is to improve physical function, the mental health component cannot be ignored. The overall mean Mental Component Summary is also positive (1.14 ± 8.07) but does not exceed the minimally important differences threshold of 3 points [30]. The improvement is therefore not significant however it must be noted that the observed trend shows a slight improvement in the mental health of the patient's post-intervention compared to pre-intervention. This is especially important when considering that the patients were already amputated and participation in this study meant a new surgery and extensive rehabilitation which can have a negative effect on mental well-being.

When classifying the results based on age, gender, and etiology of amputation, an improvement in 36-Item Short Form Health Survey scores was found in functional health specially in the group of patients ≤ 50 years old and with amputations of traumatic origin. These results may be due to several factors. First, lack of difference observed between the sexes may be due to the small number of women in the study (5) and therefore this finding must be taken with precaution. Future studies where more women are included may show a difference in the improvement after the distal weight-bearing implant between the sexes. The improvement might be more pronounced in younger patients with traumatic amputations due to the intrinsic nature of these patients given that this group is normally healthier and has less associated comorbidities than older vascular amputees. As stated, older patients with amputations of vascular etiology are patients with associated comorbidities and when analyzing their quality of life at 14 months, diseases may have appeared, or existing ones worsened which would explain why they do not improve as much as younger patients with traumatic amputations.

Limitations and Strengths

This study has several important limitations. First is the total number of patients this study included a sample size of 23 patients. However, given the design of the clinical trial where each patient acted as his/her own reference, the internal validity of the trial is very high. The complication rate of 17% is not small and further reduced our already small starting sample size. Complications were due to uncontrollable circumstances and could continue to present a problem. The second limitation is the heterogeneity of the sample, given mainly by the causes of amputation. The different etiologies of amputation are linked with different comorbidities and patient characteristics. Stratifying the results by etiology in addition to age and sex allows for a clearer picture of the clinical relevance of the use of a distal weight-bearing implant within each patient group.

Conclusion

The results of this study show an improvement in 36-Item Short Form Health Survey scores in transfemoral amputees 14 months after having received a distal weight-bearing implant, especially in patients younger than 50 years of age and with amputations of traumatic origin. Further studies in larger clinical trials of patients, over longer follow-up periods and using a wider range of relevant outcome measures, such as bone mineral density of the implant region given that implants affect remodeling and stress shielding in the surrounding bone, are needed to confirm the improvements observed.

Compliance with Ethical Standards

Conflict of Interests

The authors report no declarations of interest.

Research Involving Human Participants

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

Informed Consent

Informed consent was obtained from all individual participants included in the study.

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