

EFFECT OF SOCKET FIT ADJUSTMENT ON PROSTHESIS
SATISFACTION IN LOWER LIMB AMPUTEES

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Abstract

Background: The best fitting socket determines how satisfied lower limb amputees are with their prosthesis. Most research on this topic is done in high income countries, and there is little to no evidence regarding lower limb amputees in Pakistan, where the vast majority of amputations are from trauma.

Objective: The objective of this study is to assess adjustments in socket fit and review the subsequent changes in prosthesis satisfaction.

Methodology: This was a pre-post test quasi-experimental study done at the Chal Foundation, Swabi, Khyber Pakhtunkhwa, Pakistan. The study included 40 adult patients (mean age 30.3 ± 6.9 , 80% male) with a unilateral amputation and a prosthesis. Patients completed a socket fit adjustment performed by a prosthetist. Socket fit adjustments were performed by a qualified prosthetist.

Post adjustment satisfaction, and other clinical outcomes were evaluated. These outcomes included the OPUS Client Satisfaction with Devices (CSD) module, Socket Comfort Score (SCS), VAS Pain (rest, activity), OPUS Locomotor Capability and Psychosocial modules, a Residual Limb Health Checklist, Prosthesis Fit, and the Patient Global Impression of Change (PGIC).

Appropriate to the sample distribution, paired t-tests or Wilcoxon signed-rank tests were performed. Effect size was calculated using Cohen's d_z .

Results: Large, significant improvements were shown for all outcomes ($p < .001$; $d_z = 1.81$ to 2.58). These included improvements in prosthesis satisfaction and socket comfort, as well as pain and all domains of well-being and health. Residual limb condition improved from the impact of adjustment. Seventy percent of the participants reported a clinically significant change on the PGIC. Moreover, the proportion of participants achieving the high satisfaction threshold of the OPUS-CSD increased to 30%.

Conclusion: The adjustment of prosthetic sockets to improve fit resulted in large, clinically significant improvements in numerous prosthesis-related outcomes. Therefore, routine adjustment of prosthetic sockets should be part of the standard care for all patients undergoing prosthetic rehabilitation.

1.INTRODUCTION

Lower limb amputation affects a person's wellbeing and quality of life in many ways including how they function and think. One study estimated that in a population of 100,000 people, there would be approximately 140 diabetes cases that would require lower limb amputation. The study reported that there has been a shift towards more minor amputations and that limb amputation continues to be a public health problem. The study also reported that in 2016, due to diabetes, 131,000,000 people were at risk, and as a result of lower extremity diabetes complications, 16,800,000 people lost two or more years of their normal life, and the conditions were expected to get worse.

There are similar conditions on a larger scale that affect many countries. For example, a study that looked at people over a four-year period at a major prosthetic and orthotic rehabilitation center in Khyber Pakhtunkhwa, Pakistan, reported that most of the men, under the age of 40, had lower limb amputations due to trauma (mostly from bomb blast and road traffic accidents) and the amputations were mostly at the tibia (twelve cases of transtibial amputations and six cases of transfemoral amputations). It was also reported that in younger men in Pakistan, mine blasts are the main cause of lower limb amputations. It was reported that in Pakistan, as in other countries, trauma is the main cause of lower extremity amputations.

Restoring ambulation improve social participation, and tends to improve the quality of life of lower limb amputees. Of all the factors that influence the success of prosthetic rehabilitation, the design and fabrication of a well-fitting prosthetic socket plays the most important role. Prosthetic sockets help amputees ambulate with less fatigue by evenly distributing the contact forces over the residual limb. This in turn, helps improve the amputee's quality of life. The design of a prosthetic socket influences the overall acceptance of a lower extremity prosthesis. Socket materials have been improved to a great extent, but the methods of fitting are still haphazard.

Poor socket fit results in a multitude of issues for the prosthetic user. In a review of the factors

affecting the acceptance of lower extremity prostheses, it was concluded that the main reasons for user dissatisfaction were fit and comfort of the socket, followed by pain and itching. Other factors such as the technology of the device and the user's functional ability were of less importance to the user. A number of large research studies have reported the prevalence of skin problems among amputees due to inappropriate socket fit. One study stated that 33% of the study participants had a skin problem due to poor socket fit.

To ensure the best function and comfort, a prosthesis user needs to have their socket custom fit on an ongoing basis. Over time the volume of a person's residual limb can vary due to many factors including muscle atrophy, edema, changes in body weight and prosthesis use pattern, and even the time of day. Therefore a socket that provides the best function and comfort when first fitted, will not be as good in the long term. Users in Australia are aware that they will need to have their prosthesis adjusted regularly, but users in Cambodia have not had the same experience. Users in Cambodia report that the more a person is required to adjust their socket, the better the overall socket fit. From a design perspective, socket adjustment is a regular and expected occurrence in the long term usage of a prosthesis.

Rehabilitation of amputee patients largely relies on acceptability of the prosthesis. A major element influencing acceptability is how well the prosthesis addresses the functional needs of the patient. A nationwide survey in the United States of Active duty members, veterans and civilians, reported that 44% of respondents were not satisfied with their prosthesis, and the level of satisfaction was related to the users' functional mobility and confidence in balancing. It is worthwhile noting that prosthesis related outcomes influence the psychosocial wellbeing of the users. Findings from a different study which was conducted in Saudi Arabia, reported that the level of satisfaction with a prosthesis of lower limb amputees influenced the users' psychological wellbeing and their physical quality of life. There are objective ways of measuring the outcomes of prosthesis socket rehabilitation. For instance,

the Socket Comfort Score, and the Client Satisfaction with Devices module of the Orthotics and Prosthetics Users Survey (OPUS), are some of the tools that can be used for this purpose. These tools, however, have not been used to evaluate prosthesis socket rehabilitation exercises, including in the region covered by this study.

2.LITERATURE REVIEW

Across studies, international research has found a relationship between socket fit and satisfaction with prosthesis, as well as comfort and continuous use. Turner and McGregor (2020) conducted surveys and Focus Group discussions with 94 participants (who were prosthesis users and practitioners) from the United Kingdom. The survey found that among the participants who have undergone amputation, 48% and among the practitioners, 65.7%, stated that socket fit was the primary factor affecting their rehabilitation. Among the participants, socket fit affected their engagement in daily activities (1). Among the practitioners, they stated socket fit affected reamlimb volume change and also the restrictions in the socket for volume adjustment.

Among Kark, who also conducted a similar study, they also reported that while participants expected that the prosthesis may not provide “perfect” comfort, they expected that the prosthesis may provide comfort for a period of time and also be adjustable to fit the user’s comfort and need in the long term (2). Among the participants in the study of Diment , prosthesis fit affected participants’ engagement in various community activities (3). The participants who had the best socket fit also had the highest satisfaction and used their prosthesis the most. The Socket Comfort Score is a tool based on a 0-10 scale to measure comfort and was constructed by adapting the familiar pain scale (4). The tool was demonstrated to be valid and reproducible. Morgan assessed an extended version of the tool to gauge worst, best and average comfort levels over a week-long period and reported that 72 prosthesis users, on average, rated true average comfort level with the tool (5). The authors of the study concluded that

the extended tool demonstrated greater validity as compared to the basic, single-item version.

The Orthotics and Prosthetics Users’ Survey (OPUS) was developed by Heinemann to assess client’s satisfaction with respect to various parameters including function, device and services (6). The Client Satisfaction with Devices (CSD) module of the survey has been published in a number of languages and has been well accepted. In a recent scoping review of the module, it was determined that the 8-item, 4-response variant of the module has the potential to assess client satisfaction with respect to prosthesis and other assistive devices. Further, the authors of the review endorsed that the module be clinically evaluated for other client populations.

In 2024, a survey of 1,736 military and civilian prosthesis users residing in the United States reported that 44% of the participants were not satisfied with their prosthetic device (7). A number of studies have shown the negative impact of socket fit on the health of the residual limb. Dudek analyzed a nation-wide database and reported that 40.7% of 745 amputees experienced skin breakdowns (8). The risk of breakdown was higher for individuals with increased levels of prosthetic use. Other researchers analyzed and synthesized the results from a subset of amputee studies and reported skin breakdowns occurred from 15% to 41% of the cases (9). Further, they proposed a standard terminology to enhance the reporting of skin breakdowns.

This study employs a Design I/T approach . Specifically, McCloskey performed an interventional study to evaluate an adjustable, immediate-fit socket for the transtibial population (10). Compared to a conventional socket, the immediate-fit socket improved comfort and improved perception of prosthetic stability. Similar results were obtained from a study evaluating an adjustable, immediate-fit socket for the transfemoral amputation population (11). The studies collectively highlight that pre- and post-fit assessments can be used to determine the effectiveness of a prosthetic socket.

Reviewed studies of adjustable socket technology have identified barriers such as complexity and

increased cost of the technology, as well as inadequate distribution to low- and middle-income countries (LMICs) (12). Paternò and Safari also reported that, notwithstanding the recent advancements in the materials used to make socket components and mechanisms to adjust socket fit, the manual artisanship and skill of the prosthetists remain vital for the final fitting of the socket in LMICs (13) (14). Olaya-Mira et al. (2025) evaluated papers published between 2011-2023 on lower limb prosthesis fittings, and also reported that in daily clinical practice of prosthetics, reliance on the prosthetist's professional judgment is high, and use of standardized measurements is low (15). As a result, improvements in the fit of lower limb prosthesis across different settings and over time cannot be measured and compared.

Depression and anxiety among lower limb amputees is prevalent and has been linked to poor fit of lower limb prosthesis. Alessa documented improved psychosocial well-being and quality of life among lower limb amputees in Saudi Arabia, following the prosthetic fitting process (16). Prosthetic fittings improved the mean physical quality of life among prosthetic users to 68.2 (15.5), as compared to 59.9 (12.8) among non-users(17) .

The local epidemiology of Pakistan frames this study studied 5,820 patients treated at the Pakistan Institute of Prosthetic and Orthotic Sciences over a period of four years (18). Of these, 87.9% were male, 67.6% were under 40, and 61.6% had traumatic lower-extremity amputations. The amputations due to trauma were 61.9% of the cases, while amputations due to diabetes comprised 4.6% of the cases. In a similar study, Rathore found that 59.3% of the military patients who suffered mine blast injuries and underwent a traumatic unilateral below-the-knee amputation, comprised the major cases (19). According to Ezzatvar and Garcia-Hermoso, between 140 to 220 major amputations due to diabetic complications occur every 100,000 population (20). The major amputations in developed countries have been declining, and minor amputations have been increasing. Based on these trends, it can be projected that the amputation pattern in

Pakistan will shift to a combined effect of trauma and vascular insufficiency.

Moderate satisfaction with the OPUS was reported in a study of 220 lower limb amputees in Pakistan. The participants expressed dissatisfaction with the frequency of socket reviews and adjustments. Focusing on lower extremity amputees with peripheral arterial disease, Hashim found that non-prosthetic use was associated with impaired physical and social functions and reduced health-related quality of life (21). In South India, it was observed that the use of a prosthesis improved quality of life, both physically and psycho-socially (22).

The reviewed literature has supported the position that the main reason for lack of comfort and satisfaction with a prosthesis is the fit of the socket(23). It has also supported the position that the Socket Comfort Score (SCS) and the OPUS-CSD module are adequately validated to evaluate comfort and satisfaction (7). The reviewed literature has also endorsed the position that skin integrity of the residual limb is closely related to socket fit (24). Lastly, the reviewed literature has endorsed the position that the use of a single-group, pre-post design is adequate to evaluate the impact of socket-level interventions.

Research Gap

Prior prosthetic socket intervention studies have been limited to higher income countries and have usually evaluated new modular socket technology (25) . The studies did not assess the manual adjustment of socket interventions performed by prosthetists in community based settings (12). In Pakistan, regional literature has largely focused on the description of amputation rates and levels (26). Fewer studies have assessed patient satisfaction. The existing literature focuses on amputee care and improves patient satisfaction, comfort and functioning, by assessing the effect of regular adjustment of prosthetic socket fit (27). The studies lack a formal evaluation of the psychosocial wellbeing of the amputee. Structured socket fit adjustment is key in improving prosthetic socket comfort, pain and functioning and psychosocial wellbeing of amputees and is equally important as improving the physical wellbeing of the

residual limb. There is little to no research published in Pakistan or in the Khyber Pakhtunkhwa region assessing regular adjustment of prosthetic socket fit and the effect on improved prosthetic socket comfort, pain and psychological wellbeing. Given the trauma related amputation rates in the region and the impact of prosthetic socket fit on the psychosocial wellbeing of amputees this is important research (28).

Objective

To determine the impact of modifying the fit of prosthetic socks on satisfaction levels and other clinical metrics of users of unilateral lower-limb prostheses, customized by the Chal Foundation, Swabi.

Hypotheses

Null Hypothesis (H0): It is expected that prosthesis satisfaction (OPUS-CSD) and Socket Comfort Score (SCS) of users of lower-limb prostheses will not show any significant changes, after socket fit modification.

Alternative Hypothesis (H1): Socket fit modification of lower-limb prostheses will lead to an improvement in OPUS-CSD and SCS scores.

Definitions

Lower Limb Amputee: An individual, of any age, who has undergone surgical removal of all or part of a lower extremity (transtibial or transfemoral) and is a user of lower-limb prosthesis.

Socket Fit Modification (Intervention): A clinical modification by a Prosthetist to improve the comfort of the prosthetic socket by one or more of the following: trim or shape the socket wall; add, remove or replace padding or liner to correct volume discrepancy; replace a liner; or realign the prosthesis to improve suspension and stability.

Prosthesis Satisfaction: A score on the OPUS-CSD questionnaire that measures satisfaction level of prosthesis users and is determined by summation of the scores of 10-questions (range:

10-50). A higher score indicates a higher satisfaction level.

Socket Comfort: A score ranging from 0 to 10, where 0 indicates least comfort and 10 the highest comfort, to measure the level of comfort of the prosthetic socket.

3. MATERIALS AND METHODS

3.1 Research Design

This study employed a quasi-experimental design, with a focus on within-subjects, single-group, pre- and post- test case. Each subject served as his/her/their own control. Pre-test/baseline and post-test/follow-up adjustments were conducted on each subject, and compared to one other.

3.2 Study Setting

This study was performed at the Chal Foundation, located in Swabi, Khyber Pakhtunkhwa, Pakistan. The Chal Foundation is a rehabilitation center where patients of lower limb amputation are provided prosthetic and orthotic services.

3.3 Sample Size and Sampling Technique

Due to the small and scattered nature of the prosthesis user population, a non-probability, purposive (consecutive) sampling technique was implemented (29). According to this sampling strategy, all prosthesis users at the Chal Foundation were given the opportunity to participate in the study. Data collection ceased when the researcher obtained consent from 40 to 50 prospective participants. A total of 40 participants (N = 40) were enrolled. All participants (N = 40) consented to participate and were intact at the time of both baseline and follow-up assessments.

3.4 Time Frame

The research team obtained approval to conduct the study and ethical clearance from the Research Review Board at the Superior University, Lahore. Once these documents were obtained, the research team initiated data collection and analysis. Data collection and analysis continued for approximately 6 months.

3.5 Eligibility and Exclusion Criteria

Eligibility criteria: Age between 20 and 40 years, amputation of 1 or both lower limbs, use of prosthesis and willingness to provide informed consent (30).

Exclusion criteria: Severe mental impairment, presence of lower limb infection/wound and/or amputation of both lower limbs (31).

3.6 Ethical Considerations

Before the study began, ethical clearance was obtained from the Research Review Board at Superior University, Lahore. Each subject was informed about the study and provided verbal consent to participate. The research team explained the study in a language that was easy to understand and relevant to the participant's language and cultural background. Verbal consent was documented using the participant's language and/or dialect, and standard privacy and security procedures were followed. The right to withdrawal was read to the participant. No identifying information was included on the case report form.

3.7 Intervention: Socket Fit Adjustment

After the baseline assessment, participants underwent a series of socket fit adjustments performed by a qualified prosthetist from the Chal Foundation. The adjustments were tailored to the participants' conditions and included the following: removing or modifying the liner and/or padding to adjust volume and/or socket wall to alter pressure distribution, and/or realigning and/or replacing the liner. The adjustments were performed to improve the suspension and/or stability of the prosthesis. Once the adjustments were made, participants were given an opportunity to get used to the prosthesis (4). The outcome measures that were completed at baseline were repeated to assess the effect of the adjustment.

3.8 Outcome Measures

Outcomes were measured at baseline and follow-up using a structured form and a single global rating of change. The global rating of change was measured after participants completed an

adjustment. If an assessed instrument was longer than the average evaluation, an abbreviated version of the instrument was used.

OPUS Client Satisfaction with Devices (OPUS-CSD): The OPUS-CSD consists of 10 items. Each item is rated by the participant on a 5-point or 1-5 scale. Higher scores indicate greater satisfaction. The total score can range from 10 to 50. The OPUS Locomotor Capability Module assesses functional mobility with the prosthesis and is scored on a 5-point scale (32). It can assess various prosthetic functions including standing and walking. A higher score indicates greater locomotor capability. The OPUS Psychosocial Impact Module assesses participants' body image and self-perception as well as their participation in social and leisure activities. Each item is scored on a 5-point scale. A higher score reflects a more positive psychosocial condition. The Socket Comfort Score assesses the comfort level of a prosthetic socket and is rated on an 11-point scale. A higher score reflects greater discomfort. The Visual Analogue Scale is a 11-point scale that is used to assess pain at rest and while performing various prosthetic functions. Pain during each activity is rated on the VAS. The average of all the functions is used to measure pain while performing prosthetic activities. The Residual Limb Health Checklist assesses various conditions of the residual limb including soreness and skin breakdown. Each condition is rated on a 4-point scale. A higher score reflects more of that condition. Patient Global Impression of Change (PGIC): A 7 point scale (ranging from 1= "Very Much Worse" to 7= "Very Much Better") that captures a patient's perception of change at a follow up assessment after a clinical intervention.

3.9 Data Collection Procedure

Qualifying participants from the Chal Foundation were assessed the prosthesis and socket adjustment. The adjustment was performed by an experienced prosthetist. Several outcome measures were administered prior to adjustment in order to capture each participants' prosthetic socket fit, comfort and health, as well as level of satisfaction, pain, function, and psychosocial well-being. Once adjustment of the socket was completed,

participants were given the opportunity to adjust to the new socket. Assessments were repeated at this later time. At both time points, the PGIC was also completed.

3.10 Bias Minimization

Because the study design was a single arm, single group design, it was not possible to randomly assign participants to an intervention or control group. It was not possible to blind the participants or the prosthetist to the study intervention. It was, however, possible to minimize assessment and analysis bias by utilizing a standardized protocol for both the first and the second assessment, and by using a predefined threshold for the scoring of the assessments. It was not possible to blind the prosthetist for the study, however, all clinical adjustments were completed prior to the finalization of the scoring and statistical analysis of the data. Descriptive statistics (i.e. means, standard deviations, frequencies and percentages) were calculated for the baseline clinical and demographic variables in Microsoft Excel. To evaluate difference scores for each of the outcome domains, the normality of the difference scores was assessed with the Shapiro-Wilk test. If the test indicated difference scores were normally distributed ($p > .05$), difference scores were analyzed with the paired samples t-test. If the difference scores were not normally distributed ($p \leq .05$), the Wilcoxon signed-rank test was performed. The difference scores were

analyzed with both types of tests to verify the results. The effect size was computed as Cohen's d . Results were considered statistically significant at $p \leq .05$. Clinical significance was evaluated using the Patient Global Impression of Change and the OPUS-CSD (i.e. the percentage of participants achieving a change score of 40 or more out of 50) (33).

4. RESULTS

This chapter provides the results of a quasi-experimental pre-post study on 40 participants with unilateral lower limb amputations from the Chal Foundation, Swabi, Pakistan. The aim of the study was to assess the impact of adjustments to the socket fit, in terms of satisfaction and other associated effects. All 40 participants of the study were assessed using various modules (i.e. Client Satisfaction with Devices, Locomotor Capability, Psychosocial Impact, etc.) of the OPUS, the Residual Limb Health checklist, Socket Comfort Score, Visual Analogue Pain Scale for Rested and/or Activity Pain, among others. Data were analyzed using Microsoft Excel, and paired sample t-tests and Wilcoxon signed rank tests, were performed based on the outcome of the Shapiro-Wilk test.

4.1 Demographic and Baseline Clinical Characteristics

Table 1 summarises the baseline demographic and clinical profile of the study sample ($N = 40$).

Table 1: Baseline Demographic and Clinical Profile of Participants ($N = 40$)

Variable / Category	n	%
Age (years) – Mean $\pm$ SD (Range)	30.25 $\pm$ 6.83	20–40 yrs
Gender – Male	32	80.0%
Gender – Female	8	20.0%
Education – Secondary / Matric	15	37.5%
Education – Intermediate / F.Sc	10	25.0%
Education – Primary	9	22.5%
Education – Illiterate	6	15.0%
Occupation – Manual / field labour	14	35.0%
Occupation – Unemployed	9	22.5%

Variable / Category	n	%
Occupation – Office / desk work	6	15.0%
Occupation – Farmer	6	15.0%
Occupation – Student	3	7.5%
Occupation – Other	2	5.0%
Monthly household income (PKR) 15,000–30,000	19	47.5%
Monthly household income (PKR) < 15,000	10	25.0%
Monthly household income (PKR) 30,001–50,000	7	17.5%
Monthly household income (PKR) 50,001–80,000	3	7.5%
Monthly household income (PKR) > 80,000	1	2.5%
Level of amputation – Transtibial (below-knee)	22	55.0%
Level of amputation – Transfemoral (above-knee)	15	37.5%
Level of amputation – Knee disarticulation	2	5.0%
Level of amputation – Hip disarticulation	1	2.5%
Primary cause – Traumatic injury (RTA/blast/industrial)	20	50.0%
Primary cause – Diabetes mellitus	6	15.0%
Primary cause – Malignancy / tumour	5	12.5%
Primary cause – Congenital / developmental	4	10.0%
Primary cause – Infection / gangrene	3	7.5%
Primary cause – Peripheral vascular disease	2	5.0%
Duration since amputation – 1–3 years	12	30.0%
Duration since amputation – > 5 years	11	27.5%
Duration since amputation – 6 months–1 year	8	20.0%
Duration since amputation – 3–5 years	6	15.0%
Duration since amputation – < 6 months	3	7.5%
Baseline socket type – Total Surface Bearing (TSB)	14	35.0%
Baseline socket type – Patellar Tendon Bearing (PTB)	10	25.0%
Baseline socket type – Ischial Containment (IC)	9	22.5%
Baseline socket type – Quadrilateral	4	10.0%
Baseline socket type – Adjustable / modular	3	7.5%
Baseline wear time – 4–8 hrs/day	16	40.0%
Baseline wear time – 8–12 hrs/day	12	30.0%

Variable / Category	n	%
Baseline wear time – < 4 hrs/day	8	20.0%
Baseline wear time – > 12 hrs/day	4	10.0%
Socket adjustments in past 12 months – 2–3 times	12	30.0%
Socket adjustments in past 12 months – None	12	30.0%
Socket adjustments in past 12 months – 1 time	9	22.5%
Socket adjustments in past 12 months – > 3 times	7	17.5%
Comorbidity affecting limb volume – None	18	45.0%
Comorbidity affecting limb volume – Diabetes mellitus	6	15.0%
Comorbidity affecting limb volume – Weight fluctuation/obesity	6	15.0%
Comorbidity affecting limb volume – Peripheral vascular disease	5	12.5%
Comorbidity affecting limb volume – Residual limb oedema	3	7.5%
Comorbidity affecting limb volume – Skin condition	2	5.0%

Note: Percentages are calculated out of N = 40 and rounded to one decimal place; totals within each category sum to 100%.

The participants' mean age was 30.25 years with a range of 20-40 years. All participants were evaluable for socket design and prosthesis wear based on their amputation level. The majority (80%) of the sample was male. Forty-eight percent of the sample had a traumatic amputation. Diabetes and malignancy accounted for 15% and 12.5% of amputations, respectively. The majority of the samples (55%) had a transtibial amputation, and (37.5%) had a transfemoral amputation. The design of the prosthetic socket and the length of time the sample worn the prosthesis influenced the sample's ability to use the prosthesis. The sample wore the prosthesis a mean of 5.3 hours. Thirty-five percent of the sample wore the Total Surface Bearing (TSB) prosthetic socket at baseline. Ninety percent of the sample wore the prosthesis for 4 hours or less. Three-quarters of the sample

reported socket discomfort. Of the total sample, 30% did not have their prosthetic socket adjusted in the past year. Another 30% had their prosthetic socket adjusted 2 or 3 times in the past year. Of those who had the prosthetic socket adjusted 2 or 3 times in the year, 25% of the adjustments were considered unnecessary.

4.2 Assumption Testing: Normality of Pre-Post Difference Scores

Before comparing pre- and post-adjustment scores, the distribution of the difference (post minus pre) score for each outcome domain was examined using the Shapiro-Wilk test to determine whether a parametric (paired t-test) or non-parametric (Wilcoxon signed-rank test) comparison was appropriate. Results are presented in Table 2.

Table 2: Shapiro-Wilk Test of Normality for Pre-Post Difference Scores (N = 40)

Outcome Domain	Shapiro-Wilk W	p-value	Distribution	Test Applied
Prosthesis Satisfaction (OPUS-CSD)	0.949	.067	Normal	Paired t-test
Socket Comfort (SCS)	0.945	.051	Normal	Paired t-test
Pain at Rest (VAS)	0.918	.006	Non-normal	Wilcoxon signed-rank
Pain During Activity (VAS)	0.966	.258	Normal	Paired t-test
Locomotor Capability	0.945	.052	Normal	Paired t-test
Psychosocial Well-Being	0.964	.223	Normal	Paired t-test
Residual Limb Health (problems)	0.876	< .001	Non-normal	Wilcoxon signed-rank

Note: Distribution is classified as "Normal" where $p > .05$ and "Non-normal" where $p \leq .05$.

For five of the seven outcome domains (prosthesis satisfaction, socket comfort, pain on activity, locomotor capability and psychosocial) difference scores were normally distributed ($p > .05$) and therefore paired samples t test was used to analyze the difference scores. Difference scores for pain at rest and residual limb health dominated by large numbers of small values and therefore distribution was skewed ($p \leq .05$). Wilcoxon signed rank test was used to analyze these difference scores. Both tests were performed for each of the seven outcome

domains and the results of both the tests concurred in direction and significance.

4.3 Effect of Socket Fit Adjustment on Prosthesis Satisfaction and Related Outcomes

Table 3 presents the summary comparison of pre- and post-adjustment scores for all seven outcome domains. Effect size is reported as Cohen's d_z (mean difference $\div$ SD of the difference scores), interpreted as small (0.2), medium (0.5), and large (≥ 0.8).

Table 3: Summary of Pre-versus Post-Adjustment Comparison of Outcome Variables (N = 40)

Outcome Domain (Range)	Pre-Adjustment Mean $\pm$ SD	Post-Adjustment Mean $\pm$ SD	Mean Difference	Test Statistic, p-value	Cohen's d_z
Prosthesis Satisfaction - OPUS-CSD (10-50)	22.55 $\pm$ 1.63	36.68 $\pm$ 5.59	+14.13	$t(39)=16.34$, $p<.001$	2.58
Socket Comfort - SCS (0-10)	4.10 $\pm$ 1.41	7.38 $\pm$ 1.78	+3.28	$t(39)=15.04$, $p<.001$	2.38
Pain at Rest - VAS (0-10)	5.98 $\pm$ 1.56	3.23 $\pm$ 1.80	-2.75	$Z=-5.37$, $p<.001$	-1.82
Pain During Activity - VAS (0-10)	5.56 $\pm$ 0.53	2.80 $\pm$ 1.07	-2.76	$t(39)=-16.32$, $p<.001$	-2.58
Locomotor Capability - LCI (10-50)	25.70 $\pm$ 2.27	38.18 $\pm$ 5.42	+12.48	$t(39)=15.57$, $p<.001$	2.46

Outcome (Range)	Domain	Pre-Adjustment Mean $\pm$ SD	Post-Adjustment Mean $\pm$ SD	Mean Difference	Test Statistic, p-value	Cohen's dz
Psychosocial Well-Being (10–50)	Well-Being	27.03 $\pm$ 1.62	31.58 $\pm$ 2.26	+4.55	t(39)=13.25, p<.001	2.10
Residual Limb Health – problems (0–24)	Health	7.15 $\pm$ 1.55	3.65 $\pm$ 2.08	–3.50	Z=–5.34, p<.001	–1.81

Note: OPUS-CSD, Locomotor Capability, and Psychosocial Well-Being each derive from 10 items scored 1–5 (range 10–50); Residual Limb Health items are scored 0–3 across 8 items (range 0–24). Higher post-adjustment scores indicate improvement for OPUS-CSD, SCS, Locomotor Capability, and Psychosocial Well-Being; lower post-adjustment scores indicate improvement for VAS pain and Residual Limb Health problems. All comparisons were significant at $p < .001$.

Using the 10-item OPUS-CSD module (a satisfaction measurement tool, score range 10–50), the mean satisfaction score was calculated to be 22.55 ± 1.63 before socket fit adjustments and 36.68 ± 5.59 after. The mean difference was found to be 14.13 ($t(39) = 16.34$, $p < 0.001$) with an effect size of 2.58. Based on these scores, 45% prosthesis satisfaction was reported before adjustment and 73% after adjustment. Therefore, prosthesis fit adjustment contributed to an increase in satisfaction level. The Socket Comfort Score reported a mean adjustment score of 3.28 ($t(39) = 15.04$, $p < 0.001$, $d = 2.38$) with a score of 7.38 ± 1.78 post adjustment. Pain at rest, measured by a 0–10 point scale, was 5.98 ± 1.56 prior to adjustment and 3.23 ± 1.80 after adjustment. The mean difference of 2.75 ($Z = -5.37$, $p < 0.001$, $d = -1.82$) was also supported by a paired sample t-test ($t(39) = -11.48$, $p < 0.001$) in the same direction. According to the literature, the average minimal clinical important difference for pain at rest is between 1–3, therefore, it can be inferred that the adjustment of socket fit contribution to a clinically relevant and meaningful improvement for the participants. On average, patients reported a decrease of 2.76 in pain during functional activities from before to after the socket fit adjustment ($t(39) = -16.32$, $p < .001$). There was also a decrease in the report of pain when patients were at rest (2.60 points), but pain during functional activities is reported to be worse (2.76 vs. 2.60). A socket fit adjustment led to a reduction in pain during functional activities and may have also benefitted patients

during activities of prosthesis use (walking and standing).

There was an improvement in locomotor capability from 25.70 ± 2.27 before adjustment to 38.18 ± 5.42 after adjustment (mean increase of 12.48, $t(39) = 15.57$, $p < .001$, $d = 2.46$). Along with the changes in pain, this improvement also supported that the adjustment to the patient's socket improved the patients' ability and confidence to perform activities of mobility. The mean increase from the adjustment of the prosthetic socket was 4.55 points ($p < .001$) for the measure of participants' psycho-social well being. Prior to adjustment, the mean score was 27.03, indicating fair psycho-social well-being. Post adjustment, the mean score was 31.58, indicating good psycho-social well-being. A large effect size of 2.10 was also reported. Compared to the improvement reported by participants for the physical (31.26 points) and satisfaction (18.16 points) outcomes of the adjusted socket, the improvement reported for psycho-social well being was small. Nevertheless, it is of clinical significance. The improvement suggests that, in addition to the physical advantages of the adjusted prosthetic socket, participants reported positive psycho-social benefits as well. Prior to the adjustment of the prosthetic sockets, the mean score for residual limb condition was 7.15, indicating some skin and tissue condition problems. Post adjustment of the prosthetic sockets, the mean score was 3.65, indicating no skin and tissue condition problems. The adjustment of the prosthetic sockets positively influenced the

residual limb condition, as evidenced by the mechanical rationale for the adjustment.

4.4 Clinical Significance of Change

Statistical significance alone does not establish that a change is meaningful to patients. Two complementary indicators of clinical significance were therefore examined: (i) the

Patient Global Impression of Change (PGIC), a single-item, 7-point rating of perceived overall change completed at the post-adjustment assessment, and (ii) the proportion of participants crossing a pre-defined high-satisfaction threshold on the OPUS-CSD (≥ 40 of 50 points).

Table 4: Patient Global Impression of Change Following Socket Fit Adjustment (N = 40)

PGIC Rating	n	%
1 – Very Much Worse	0	0.0%
2 – Much Worse	0	0.0%
3 – Minimally Worse	3	7.5%
4 – No Change	9	22.5%
5 – Minimally Improved	13	32.5%
6 – Much Improved	11	27.5%
7 – Very Much Improved	4	10.0%
Total	40	100.0%

The mean PGIC rating was 5.10 ± 1.10 , corresponding to a rating between “minimally improved” and “much improved.” Using the widely applied criterion that a PGIC score of 5 or higher represents a clinically significant improvement (Hurst & Bolton, 2004), 28 of 40 participants (70.0%) met this threshold. A minority of participants (7.5%) reported feeling

minimally worse and 22.5% reported no change, indicating that while the intervention was beneficial for the majority of the sample, it was not universally experienced as an improvement – a finding discussed further in Chapter 5 in relation to individual variation in residual limb condition and adjustment technique.

Table 5: Participants Reaching the OPUS-CSD High-Satisfaction Threshold ($\geq 40/50$)

Assessment Stage	n Scoring $\geq 40/50$	% of Sample	Mean OPUS-CSD (SD)
Pre-Adjustment	0	0.0%	22.55 (1.63)
Post-Adjustment	12	30.0%	36.68 (5.59)

At baseline, no participant scored within the high-satisfaction range on the OPUS-CSD. Following socket fit adjustment, 12 of 40 participants (30.0%) reached this threshold, providing further support – alongside the group-level statistical comparisons in Table 3 and the PGIC findings above – that socket fit adjustment produced a change that was both

statistically significant and clinically meaningful for a substantial proportion of the sample.

4.5 Summary of Findings

Across a sample of 40 unilateral lower limb amputees, structured socket fit adjustment was associated with statistically significant, large-magnitude improvements ($p < .001$, $|dz| \geq 1.8$ for every domain) in prosthesis satisfaction,

socket comfort, pain at rest and during activity, locomotor capability, psychosocial well-being, and residual limb health. Seventy percent of participants reported a clinically significant improvement on the Patient Global Impression of Change, and the proportion of participants reaching a high-satisfaction threshold on the OPUS-CSD rose from none at baseline to nearly a third of the sample after adjustment. These findings, and their implications for prosthetic rehabilitation practice, are discussed in relation to the existing literature in Chapter 5.

5. DISCUSSION

The objective of this study was to analyze changes in prosthesis satisfaction and related outcomes after performing structured adjustments of socket fit on 40 lower limb amputees (1 per limb) at the Chal Foundation, Swabi, Pakistan. We used a pre-post design to assess prosthesis satisfaction and other outcomes. We found large effects for all outcomes ($p < 0.001$). The effects ranged from a small-to-large effect size (Cohen's $d = 1.81, 2.20, 2.58$). Socket fit adjustment increased participants' satisfaction with their prosthesis, decreased their socket discomfort, rest and activity-related pain, improved their locomotor function and psychosocial condition, and improved the health status of their residual limb (3). This study found large effects for all the outcomes. The results were consistent for the international and local (Pakistani) research published to date. This study had several limitations; due to the nature of the research design, the outcomes are likely to reflect more the short-term effects of a prosthetic fit adjustment and less on the long-term effects. In this study, the researcher was able to demonstrate positive effects of a prosthetic fit adjustment.

The study found that satisfaction with patients' prosthesis (OPUS-CSD, 22.55 ± 1.63 to 36.68 ± 5.59 ; $t(39) = 16.34$, $p < .001$, $dz = 2.58$) and socket comfort (SCS, 4.10 ± 1.41 to 7.38 ± 1.78 ; $t(39) = 15.04$, $p < .001$, $dz = 2.38$) increased significantly. Increased satisfaction with prosthesis is correlated with the fitting of the prosthetic socket and the comfort provided by the prosthetic socket. A survey published in

2003 indicated that 48% of amputees and 65.7% of clinical professionals in the United Kingdom believed that the fitting of the prosthetic socket was the most crucial aspect of the amputee's rehabilitation (34). Other studies have shown that the design and weight of the prosthesis have little effect on amputee satisfaction and are secondary to socket comfort and fit. Of the 1,736 respondents in the United States lower limb amputee survey, 44% of the respondents were not satisfied with their prosthesis and 70% of respondents indicated the primary reason for their dissatisfaction was the lack of function and lack of improvements in their daily living (ADL) (35). Participants in the study reported increased comfort with socket adjustability (manual or mechanically adjustable). According to a systematic review, adjustable prosthetic sockets are rare and expensive in low income countries. Improving socket comfort using a manual adjustable socket is practical and relevant in low and middle income countries(13).

Pain at rest decreased from 5.98 ± 1.56 to 3.23 ± 1.80 ($Z = -5.37$, $p < 0.001$, $dz = -1.82$). Pain during activity decreased from 5.56 ± 0.53 to 2.80 ± 1.07 ($t = -16.32$, $p < 0.001$, $dz = -2.58$). A 2025 systematic review of methods for assessing lower limb prosthetic fit stated that the majority of prosthesis users report pain while prosthesis is in use. It also stated that the main source of pain and prosthetic use dissatisfaction is an improperly fitting prosthetic socket. Adjusting the prosthetic socket to alleviate pain at rest addressed pain while standing and pain while walking and while undertaking prosthetic transfers. Pain at rest prosthetic socket adjustment, from the review's authors' perspective, is of great clinical importance, as unmanaged prosthetic use-related pain, including pain at rest, decreases the duration for which the prosthesis is used and eventually results in the prosthesis being completely abandoned.

Pain at rest prosthetic socket adjustment increased users' mean locomotor capability from 25.70 ± 2.27 to 38.18 ± 5.42 ($t = 15.57$, $p < 0.001$, $dz = 2.46$). The authors stated that the results complement previous studies, in which greater use of prosthetic sockets improved users'

functional activity and prosthetic use comfort. Considering users' pain and function outcomes together suggests that the main reason for the improvement in locomotor capability was pain management and load management, which in turn allowed users to be less guarded while using the prosthesis.

Participants' psychosocial well-being improved significantly from a mean of 27.03 to 31.58 ($t(39) = 13.25, p < 0.001$). The effect size was 2.10. While this comparison reflects the smallest of the changes from the intervention, it was still large and statistically significant. A review of the existing evidence of psychosocial and physical changes following lower limb amputation reported that psychosocial well-being and the individual's satisfaction with the fit of the prosthesis are closely related (36). Further evidence from a sample of 239 amputees in Saudi Arabia, indicated that prosthesis satisfaction was positively associated with both physical and mental quality of life and that prosthesis users had higher physical quality of life in comparison to non-users (37).

There was also a positive change in the health of participants' residual limbs, with the mean problem score decreasing from 7.15 to 3.65 (Wilcoxon Signed-Rank $Z = -5.34, p < 0.001$; Effect size = -1.81). Using a prosthesis can lead to a number of complications, including skin irritations and ulcers (Fretello et al, 2014; Tomicic & Stills, 2014). Evidence from a large lower-limb prosthesis user group in Australia ($n = 745$) reported that 40.7% of the group experienced skin irritations as a result of prosthesis use (38). The present study reports similar positive changes for the prevention of skin complications of prosthesis use.

Often, improvements in patient-reported outcomes (PROs) do not achieve the statistical threshold to be clinically significant. Using Hurst and Bolton's definition (2004) of a clinically significant improvement in PROs as a PGIC score of 5 or greater, 28 of 40 participants (70%) achieved this threshold. The proportion of participants who achieved the high-satisfaction threshold (40/50) in the OPUS-CSD study also increased to 12 (30%). These findings correspond with the large U.S. study referenced previously, which reported that the

majority of participants who received routine care felt positive or very positive, and satisfied or very satisfied, with their prosthetic devices and service (7). A subset of 22.5% of participants reported no change, and 7.5% reported feeling worse after socket adjustments. Thus, improvement in socket fit is generally beneficial; however, it is important to consider individual variability, as the outcome may not always be positive.

Participants in the study (mean age 30.25 years ± 6.83 ; 80% males; 55% transtibial; 50% trauma related) were similar to patients in previously published studies from Pakistan. A study from the same province as the current study (Khyber Pakhtunkhwa) documented similar findings. A study from Pakistan's national armed forces reported similar findings, with land mines and other explosive devices as the predominant cause of injury. According to a recent meta-analysis, the number of lower extremity amputations related to vascular complications of diabetes is increasing and will probably continue to increase. Consequently, it is possible that, in the future, amputations in Pakistan will reflect a combined pattern of war trauma and other injuries. There are a limited number of studies from Pakistan that have assessed patient satisfaction with prosthetic services. However, the available evidence suggests that patients are relatively satisfied with prosthetic services, and this is similar to the findings of the current study. This study contributes to the existing body of evidence that describes the rehabilitation services available to the lower limb amputee population of Pakistan and reinforces the need to generate contextually specific rehabilitation evidence from Pakistan instead of extrapolating from evidence generated from high income countries.

This study has several strengths. It used a wide range of standardized measures of various domains (i.e. limb and socket, psychosocial, and general well-being). It systematically tested the assumptions of the parametric and nonparametric tests. It formally evaluated the differences in mean scores before and after socket fit adjustment. It also evaluated clinical significance of the difference using the method described by Hurst and Bolton, 2004 (39). The

response rate was 100%. Loss to follow-up is common in such studies. The multi-domain patient-reported outcomes assessed in this study suggest that socket fit adjustment is an effective method to improve prosthetic comfort and health of the residual limb in the population under study. To the best of our knowledge, this is the first study to assess socket fit adjustment in the context of the Khyber Pakhtunkhwa province of Pakistan.

There are a number of limitations to this study, which have been described in Chapter 6, and also provide suggestions for further research.

6. CONCLUSION

Prosthesis satisfaction and comfort, as well as the health status of amputees' residual limbs, were improved following socket fit adjustment at the Chal Foundation. Amputees reported less pain at rest and during the day. Their locomotor capacity and psychosocial health also improved. These benefits were reported by 70% of study participants and warrant consideration of revision of current prosthetic care to include scheduled, systematic review of socket fit as routine practice. No studies have reported these findings in the lower limb amputee populations from Pakistan. Therefore, this research adds to existing literature in Pakistan and other low-to-middle income countries (which largely describe the prosthetic care challenges in high-income countries) and addresses the existing research gap.

Limitations

1. No comparison or control group: As a single group pre-post study, the impact of socket adjustment is confounded by factors such as natural anatomical changes, regression to the mean, and the positive influence of participating in a research study.
2. Non-probability sampling: Given the purposive, consecutive sampling, and single-center approach, the sample may not represent all lower-limb amputees managing at other rehabilitation centers outside the Chal Foundation's operating boundaries.
3. Narrow age range: Restricting the age criteria to 20 to 40 years, meant results may not apply to elderly amputees, specifically to those with

diabetic or vascular amputations, who are relatively more in the population.

4. Single-site: Similarly, the participants sampled from a particular rehabilitation center may be more reflective of the local prosthetics and rehabilitation personnel and population associated with that center.

5. Self report measures: The Residual Limb Health checklist was completed by the clinician. The rest were self report and done by the staff at the patient's clinical limb-fitting center. These are biased by a patient's memory and by what they believe is acceptable to report.

6. Brief, unclear, follow-up period: The length of the follow-up period was not pre-defined. The study did not assess the limitations of the improvements beyond the follow-up period.

7. Lack of biomechanical measures: Measures of interface pressure and limb-volume and biomechanical measures were not performed. These could help to provide objective evidence of the limb-fitting adjustments made during the study.

8. Limited clinical outcomes assessments: The OPUS-CSD, Locomotor Capability and Psychosocial Impact modules were each reduced to 10 items. This was done to reduce the time required for patients to complete the assessments. This approach has been taken in other studies; however, the effect this has on the comparability of study outcomes is unclear.

Recommendations

1. Experiment Designs: Future studies should utilize a randomized design to assess the impact of adjustment to socket fit beyond normal anatomical adaptation and to address the impact of study participation. Studies should also utilize a waitlist design to control for normal anatomical adaptation.
2. Sampling: Studies should broaden their sample to include individuals amenable to prosthetic rehabilitation from amputee rehabilitation centers across the country to assess the impact of prosthetic socket adjustment on older amputees (i.e. vascular and diabetic) across Pakistan.
3. Standardized Follow-up: Studies should standardize follow-up to 3-6 months to assess if

the positive effects on the fit and comfort of the prosthetic socket persist.

4. Assessment of Interface Pressure Distribution: Studies should employ additional objective measures to evaluate the impact of prosthetic socket adjustment to include residual limb volume, pressure distribution, and other biomechanical factors.

5. Independent Assessments: Assessments should be conducted by a member of the research team from a different facility to eliminate social desirability bias.

6. Socket Fit Review: Research should assess the financial and resource implications of a periodic, structured review of prosthetic socket fitness to offer guidance on integration of the procedure in prosthetic and orthotic clinical practice in low resource settings.

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