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Effects of Test Socket on Pain, Prosthesis Satisfaction, and Functionality in Patients with Transfemoral and Transtibial Amputations

Authors' Contribution:
Study Design A
Data Collection B
Statistical Analysis C
Data Interpretation D
Manuscript Preparation E
Literature Search F
Funds Collection G

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Background: The aim of this retrospective study was to investigate the frequency of admissions, reason for admissions, and test socket satisfaction in patients who received a lower-limb prosthesis with or without a test socket in our unit.

Material/Methods: A total of 88 patients (54 men, 34 women) were included in the study. Patients were divided into 2 groups: the group with test socket (Group I, 44 patients) and the group without test socket (Group II, 44 patients). Variables related to the functional status, frequency of complaints, and test socket satisfaction were investigated in the 2 groups. The Trinity Amputation and Prosthesis Experience Scales (TAPES) and Beck Depression Inventory (BDI) were used to assess the level of patient satisfaction with their prosthesis. The VAS (Visual Analogue Scale) was used to assess pain at rest and during walking.

Results: We found that the TAPES values were more significant in Group 1 in both transtibial and transfemoral amputations (P<0.05). However, prosthesis delivery time was more significant in Group 2 in both transtibial and transfemoral amputations (P<0.001) whereas the frequency of admissions within 3 months was more significant in Group 1 in both transtibial and transfemoral amputations (P<0.001). There was no statistically significant difference between the 2 groups in terms of other parameters (P>0.05).

Conclusions: Although the use of a test socket increases the cost of prosthesis units, we showed that patients with transtibial and transfemoral amputations have fewer complaints related to prosthesis increases patient functionality, and that it reduces pain and increases patient satisfaction with the prosthesis.

MeSH Keywords: **Amputation Stumps • Chronic Pain • Quality of Life**

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Background

Amputation is one of the oldest surgical procedures. It is performed due to war-related injuries, tumors, and infections, and significantly affects functional status and activities of daily living [1]. Lower-extremity amputations constitute 80–85% of all amputations. Nowadays, peripheral artery disease causes over 90% of amputations. In 2005, there were an estimated 1.6 million individuals living with limb loss in the United States [2]. Of these, 25% had a transfemoral amputation and 65% had a transtibial amputation [3]. There is no clear data on this subject in Turkey. After amputation, patients struggle with physical disabilities and psychosocial problems due to inappropriate prostheses [4]. Regardless of the shape and level of lower-extremity amputation, the patient needs a prosthesis to be mobilized and to continue daily life activities. As the level of lower-extremity amputation shifts to the proximal side, the patient's balance, sense of proprioception, walking time, walking distance, and social activities are restricted. For this reason, functionally designed prostheses are needed for below-knee and above-knee amputations. For a functional prosthesis, there must be a fit between residual limb and socket [5]. For this purpose, the use of conventionally produced below-knee PTB (patellar tendon bearing) and quadrilateral above-knee sockets is most common. These types of sockets have been used since 1950 [6]. The socket is the most important part of the prosthesis. Designing and producing the appropriate socket is a process that requires experience. Wearing an inappropriate prosthesis can cause pain, stress, skin irritation and ulceration, and even repeated amputations [7]. Therefore, the use of test sockets has accelerated in recent years in order to minimize such complications. The test socket is a temporary socket used after the amputation. This socket typically resembles a permanent socket and is manufactured from a transparent, highly heat-resistant, and thermoplastic material (e.g., polyethylene terephthalate or polypropylene) (Figure 1). This material is a softer and more easily processed plastic compared to permanent sockets. The test socket remains attached to the patient for 20–30 days. The patient is admitted to the unit due to complaints from residual limb and socket. The center can make changes on the test socket to address the patient's complaints, and changes are made to the test socket until the patient's complaints are resolved. When the final shape is obtained, the inside of the test socket is filled with gypsum paste and is measured. The new and permanent socket is designed according to the changes made to the test socket [8].

PTB and permanent quadrilateral sockets are usually made by lamination or hard plastic pulling methods [9]. It is not possible to make a change after the permanent socket is made (Figure 2). The test socket has been used as the standard in most prosthesis manufacturing centers since 1990 [10]. However, it is not commonly used in the private sectors in Turkey because it increases the cost and takes a long time. Its usage rate in prosthesis manufacturing and application centers in public institutions and organizations is approximately 50%.

Figure 1. Transtibial (TT), Transfemoral, (TF) Test socket.

Figure 2. Transtibial (TT), Transfemoral (TF), Permanent laminated socket.

In the present study, we assessed the effects of the use of test sockets on prosthesis satisfaction, pain, and functionality.

Material and Methods

This was a retrospective study. The files of patients who received a lower-limb prosthesis in our unit were examined. This study included a total of 120 patients with transtibial (TT) and transfemoral (TF) amputations aged 18 years and over (60 patients with test socket and 60 patients without test socket). Patients who did not meet the criteria or did not agree

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to participate were excluded from the study. A total of 88 patients (44 patients with test socket and 44 patients without test socket) were included in the study. The study was carried out between January 2016 and May 2017. Patients who had used their prostheses for at least 6 months, who underwent lower-limb amputation for acquired reasons, and who had sufficient intellectual capacity to answer questions were included in the study. We excluded patients who were younger than 18 years or older than 70 years, who had bilateral lower-limb amputation, who underwent lower-limb amputation due to reasons such as tumors, congenital anomalies, infections, burns, and poliomyelitis, and who had silicone linear, active, and passive vacuum suspension systems. Patients who used SACH foot (Solid Ankle, Cushion Heel) were selected in the study both in the test socket group and in the non-test socket group. TF amputees using monocentric knee joints for both groups were used in transfemoral amputees. This joint makes flexion-extension movements possible in the knee joint. When the transfemoral and transtibial test socket manufacturing method is CAD/CAM and permanent socket, patients undergoing the conventional lamination method were selected. When the transfemoral and transtibial test socket manufacturing method is CAD/CAM and permanent socket, patients undergoing conventional lamination method were selected.

The patients were informed about the study. Written and verbal approvals were obtained from the patients. The study was approved by the Local Ethics Committee (local ethics board number: DUTF-2014-324).

For 88 amputee patients, we recorded demographic data (age, gender, height (cm), weight (kg), body mass index (BMI), education, and occupation), amputated side (right/left), amputation level (transtibial, transfemoral), prosthesis delivery time (days), frequency of admissions within 3 months, duration of daily prosthesis use (h), daily walking distance with prosthesis (m), 10-meter walking on a flat surface (s), 10-step climbing up (s), 10-step climbing down (s), 10-meter walking up an 8% slope (s), and 10-meter walking down an 8% slope (s). Patients were divided into 2 groups: the group with test socket (Group I, 44 patients) and the group without test socket (Group II, 44 patients). Patients were asked to mark on the Visual Pain Scale (VAS (0-10 cm); 0=no pain and 10=very severe pain) in order to assess pain severity (at rest and during walking). The Beck Depression Inventory (BDI) was used to assess anxiety and depression [11]. The Beck Depression Inventory consists of 21 questions. Each question has 4 options. Each item is scored 0 to 3 points for a total score range of 0 to 63. The total score is directly proportional to depression level [12]. Prosthesis satisfaction was assessed with the Turkish version of the Trinity Amputation and Prosthetic Experience Scales (TAPES) [13]. This scale contains 3 subscales, including psychosocial adjustment, activity restriction, and prosthesis satisfaction. Psychosocial adjustment is scored on a 5-point Likert scale. Total scores range from 5 to 75, and higher scores indicate higher level of psychosocial adjustment. Activity restriction is scored on a 3-point Likert scale. Total scores range from 12 to 36, and higher scores indicate high level of activity restriction. Prosthesis satisfaction is scored on a 5-point Likert scale. Total scores range from 10 to 50, and higher scores indicate higher level of prosthesis satisfaction [14].

Statistical evaluation

Statistical analysis was performed with the IBM SPSS Version 21.0 statistical software package. Numerical variables are expressed as means ± standard deviation (SD). Categorical variables are expressed as number and percentage (%). We assessed the normality of data distribution. The normality of the variable distributions was tested by the Kolmogorov-Smirnov test. If the data showed a normal distribution, one-way analysis of variance was used to compare the mean of multiple groups. The homogeneity of variance test was used in multiple comparisons. The Tukey's test was applied for variables with $P>0.05$. The Tamhane T2 test was applied for variables with $P<0.05$. The chi-square (χ^2) test was used to compare qualitative variables between groups. The hypotheses were bidirectional. A p-value of ≤0.05 was considered statistically significant.

Results

The mean age was 40.31±12.08 years (16 women, 28 men) in Group I and 38.89±11.53 years (18 women, 26 men) in Group II. There was no significant difference between the 2 groups in terms of the other demographic data such as weight, height, BMI, and amputated side. In Group I, 32 patients had TT and 12 patients had TF. In Group II, 31 patients had TT and 13 patients had TF. Most of the patients in both groups were primary and high school graduates. The percentage of primary and high school graduates was the same for both groups (Groups I and II=79.54%). Most of the patients in both groups were employed (Group I=61.36%, Group II=59.97%). There was no significant difference between the 2 groups in terms of the demographic data (P>0.05) Table 1.

The frequency of admissions within 3 months was more significant in patients who underwent a TT test socket compared with patients who did not undergo a TT test socket. However, prosthesis delivery time was more significant in patients who did not undergo a TT test socket compared with patients who underwent a TT test socket (P<0.001). Daily walking distance with prosthesis, 10-step climbing up, 10-meter walking up an 8% slope, walking VAS, and all TAPES subscales (including psychosocial adjustment, activity restriction, and prosthesis satisfaction) were more significant in patients who underwent a

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Table 1. Clinical and demographic data.

n= 88	Group with test socket Group I (n=44)		Group without test socket Group II (n=44)		P
Age (years)	40.31±12.08	(18/70)	38.89±11.53	(18/68)	0.714
Gender (Male/Female)	28/16	(63.63%/36.36%)	26/18	(59.09%/40.90%)	
Weight (kg)	77.12±8.52	(56/97)	75.76±8.73	(55/94)	0.809
Height (cm)	172.18±5.58	(159/186)	170.21±6.07	(161/188)	0.844
BMI (kg/cm^2)	26.05±2.69	(20.4/32. 3)	25.97±2.65	(20.1/31.1)	0.911
Amputated side (right/left)	30/14	(68.18%/31.81%)	27/17	(54.54%/38.63%)	
Amputation level					
Transtibial	32	(72.72%)	31	(70.45%)	0.962
Transfemoral	12	(27.27%)	13	(29.54%)	0.921
Education level					
Illiterate	5	(11.36%)	6	(13.63%)	0.887
Primary education	11	(25.00%)	12	(27.27%)	0.918
High school	24	(54.54%)	23	(52.27%)	0.963
University	4	(9.09%)	3	(6.81%)	0.752
Occupation					
Unemployed	9	(20.45%)	11	(25.00%)	0.687
Employed	27	(61.36%)	26	(59.09%)	0.967
Housewife	8	(18.18%)	7	(15.90%)	0.872

BMI – body mass index; Transtibial – below-knee amputation; Transfemoral – above-knee amputation.

TT test socket compared with patients who did not undergo a TT test socket (P<0.05). However, duration of daily prosthesis use, 10-meter walking on a flat surface, 10-step climbing down, 10-meter walking down an 8% slope, rest VAS, and Beck Depression Inventory parameters did not show a statistically significant difference between the 2 groups (P>0.05) Table 2.

TF amputees had similar results to TT amputees. The frequency of admissions within 3 months was more significant in patients who underwent a TF test socket compared with patients who did not undergo a TF test socket. However, prosthesis delivery time was more significant in patients who did not undergo a TF test socket compared with patients who underwent a TF test socket (P<0.001). Daily walking distance with prosthesis, 10-step climbing up, 10-meter walking up an 8% slope, walking VAS, and all TAPES subscales (including psychosocial adjustment, activity restriction, and prosthesis satisfaction) were more significant in patients who underwent a TF test socket compared with patients who did not undergo a TF test socket (P<0.05). However, duration of daily prosthesis use, 10-meter walking on a flat surface, 10-step climbing down, 10-meter walking down an 8% slope, rest VAS, and Beck Depression Inventory parameters did not show a statistically significant difference between the 2 groups (P>0.05) Table 3.

There was no statistically significant difference between the 2 groups in terms of other parameters between TT and TF amputees who underwent a test socket and TT and TF amputees who did not undergo a test socket (P>0.05).

Discussion

In this study, we found that the use of test socket test had significant effects on functionality, pain, and prosthesis satisfaction in patients with transtibial and transfemoral amputations. The use of test socket has become more important with the widespread use of silicon linear, active-passive vacuum suspension systems in recent years. These suspension systems require compliance with a permanent socket because

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Table 2. Comparison of functionality, anxiety-depression, and prosthesis satisfaction in TT amputees.

n=63	Those with TT test socket (n=32)		Those without TT test socket (n=31)		P
Prosthesis delivery time (days)	19.32±2.2	(17/23)	5.13±1.1	(4/7)	**0.000**
Frequency of admissions within 3 months	0.84±0.21	(0/2)	4.33±2.03	(2/7)	**0.000**
Duration of daily prosthesis use (h)	12.24±1.67	(5/14)	9.81±1.39	(4/13)	0.245
Painless daily walking distance with prosthesis (meters)	1332.14±254.66	(750/1800)	1047.62±228.71	(500/1450)	**0.032**
10-meter walking on a flat surface (s)	18.13±4.01	(13/28)	21.24±4.13	(14/31)	0.104
10-step climbing up (s)	20.07±4.71	(16/30)	25.76±5.03	(17/33)	**0.043**
10-step climbing down (s)	19.77±4.53	(15/28)	23.62±4.77	(17/31)	0.065
10-meter walking up at an 8% slope (s)	28.13±5.81	(22/38)	35.19±5.86	(25/42)	**0.022**
10-meter walking down at an 8% slope (s)	26.27±5.21	(19/31)	29.43±5.01	(21/36)	0.145
Rest VAS (0–10)	2.1±1.2	(1-3)	2.7±1.4	(1-4)	0.072
Walking (0–10)	3.2±1.7	(2-5)	4.3±2.1	(3-6)	**0.018**
Beck Depression Inventory (0–42)	20.37±4.89	(14/28)	24.71±4.67	(16/29)	0.122
Tapes					
Psychosocial adjustment (5–75)	62.48±5.45	(47/72)	52.26±4.67	(44/60)	**0.023**
Activity restriction (12–36)	13.50±4.05	(7/21)	19.02±5.19	(8/27)	**0.048**
Prosthesis satisfaction (10–50)	45.57±2.93	(37/49)	36.05±2.74	(33/42)	**0.029**

VAS – visual analogue scale; TAPES – trinity amputation and prosthesis experience scales.

they are very costly. The placement of a permanent prosthesis socket after modifying the test socket with weekly visits according to compliance between socket and prosthesis and patient complaints increases patient comfort and positively affects prosthesis satisfaction. The use of test socket increases manufacturing costs by 10%. The placement of a permanent prosthesis socket without using a test socket prevents the improvement of patients' complaints related to the prosthesis and makes the prosthesis unusable. We found that TT and TF patients who did not use test sockets in our study visited our clinic 4–5 times more on average (Tables 2, 3). These patients cannot work during this visit and the prosthesis cost is increased by paying a fee for each extra application to the prosthesis. In addition, the inability of patients to use the prosthesis efficiently leads to a decrease in the quality of life and increased maintenance costs to the patient. Emotional stress caused by pain is accompanied by additional diseases which require visits to psychiatry, rehabilitation and orthopedics clinics as well as prosthetic clinics, and indirect costs are increased. Moreover, we examined the database (PubMed). When we entered the keywords such as "test socket" or "transtibial test socket, transfemoral test socket" on the website (*http://www.ncbi.nlm.nih.gov/pubmed/*), we could not find any specific study. For this reason, we think that the advantages of the use of test sockets will guide many clinicians and researchers in their treatment practices and studies as well as manufacturing options in public and private enterprises engaged in manufacturing. The fact that there was no statistically significant difference between the 2 groups in terms of the demographic and clinical characteristics is important in terms of the homogeneity of evaluations to be made.

The socket is the most important part of the prosthesis. Various methods are used in socket manufacturing (e.g., conventional, cad/cam, laser, 3D). However, whichever method is used, the harmony between the residual limb and the socket is very important because an appropriate socket is required for amputee mobilization [15]. Balance, proprioceptive sensation, walking time, walking distance, and social activities become restricted with increasing amputation level from the ground. The socket is the fundamental element for successful prosthetic fitting and it plays a key role in the transfer of load between the prosthesis and residual limb [16]. Furthermore, the socket is the most important component for successful rehabilitation following lower-extremity amputation [5,17]. Thus, patients with below- and above-knee amputations require functionally

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Table 3. Comparison of functionality, anxiety-depression, and prosthesis satisfaction in TF amputees.

n=25	Those with TT test socket (n=12)		Those without TT test socket (n=13)		P
Prosthesis delivery time (days)	20.76±2.3	(17/25)	5.57±1.2	(4/8)	**0.000**
Frequency of admissions within 3 months	0.91±0.24	(0/2)	5.02±2.03	(3/8)	**0.000**
Duration of daily prosthesis use (h)	11.43±1.56	(6/15)	8.69±1.33	(5/13)	0.192
Painless daily walking distance with prosthesis (meters)	1144.14±223.31	(650/1650)	941.62±208.34	(500/1400)	**0.048**
10-meter walking on a flat surface (s)	19.83±4.12	(15/29)	22.21±4.37	(16/31)	0.176
10-step climbing up (s)	21.87±4.82	(17/34)	26.63±5.19	(18/36)	**0.039**
10-step climbing down (s)	20.17±4.61	(16/27)	24.72±4.81	(17/31)	0.052
10-meter walking up at an 8% slope (s)	29.33±5.84	(23/38)	36.11±5.92	(27/42)	**0.019**
10-meter walking down at an 8% slope (s)	26.83±5.29	(20/32)	30.03±5.17	(23/38)	0.127
Rest VAS (0–10)	2.4±1.3	(1-3)	2.8±1.4	(1-4)	0.096
Walking (0–10)	3.4±1.7	(2-5)	4.4±2.0	(3-6)	**0.021**
Beck Depression Inventory (0–42)	22.37±4.77	(15/28)	25.47±4.86	(17/30)	0.138
Tapes					
Psychosocial adjustment (5–75)	60.81±5.45	(47/72)	50.65±4.67	(44/60)	**0.017**
Activity restriction (12–36)	14.78±4.05	(8/21)	21.25±5.19	(9/28)	**0.033**
Prosthesis satisfaction (10–50)	42.33±2.61	(35/47)	34.93±2.14	(30/40)	**0.042**

VAS – visual analogue scale; TAPES – trinity amputation and prosthesis experience scales.

designed prostheses. The residual limb-socket fit needs to be good for a functional prosthesis [1]. A proper and functional socket is better accepted by the patient. For this reason, biomechanical deficiencies of the socket should be eliminated. These deficiencies occur in both transtibial and transfemoral amputees with changes and adjustments made on the test socket. Although permanent sockets with different methods and materials are compared in terms of strength, functionality, and rehabilitation [18–21], unfortunately, the same evaluations were not made for the test socket. Similarly, although many studies have compared suspension systems in prostheses, types of joints, and different types of sockets [10,22,23], there is no any study investigating the effectiveness of socket types. However, most of these studies reported that a test socket was used before the placement of a permanent socket [24,25].

Conclusions

Incompatibility between the residual limb and the socket can cause material and time loss for patients and manufacturers, whether the prosthesis type is conventional, modular, or microprocessor. The process of switching from a test socket to a permanent socket requires time and patience. However, after the socket is properly designed, the patient is not exposed to technical faults and pain caused by the socket for 5–10 years.

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Conflict of interest

None.

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