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Effects of the use of conventional versus computer-aided design/computer-aided manufacturing sockets on clinical characteristics and quality of life of transfemoral amputees

Cad/cam socket applications on positive effects on quality of life in transfemoral amputees

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Abstract

Aim: Amputee mobilisation requires prosthetic device use regardless of the amputation level and type. The socket is the most important part of the prosthesis and is manufactured by conventional methods worldwide. Recently, computer-aided design/computer-aided manufacturing systems have been frequently used in Europe and the United States for socket design. Use of the computer-aided design/computer-aided manufacturing method for socket production is increasing day by day. Are the sockets produced by this method advantageous or disadvantageous for amputees compared to the sockets produced by the conventional method? These results will provide guidance for units and centres that produce both above-knee and below-knee prostheses. For this purpose, we investigated whether there are differences between amputees fitted with conventional sockets and those fitted with computer-aided design/computer-aided manufacturing sockets in terms of their clinical characteristics and quality of life. Material and Method: In total, 56 patients, 28 fitted with a conventional socket (CS group) and 28 fitted with a computer-aided design/computer-aided manufacturing socket (CAD/CAM group), were included in the study. The duration of daily prosthetic use, walking time with the prosthesis, walking distance with the prosthesis, walking time with the prosthesis without pain, time of adaptation to the prosthesis, causes of amputation, and manufacturing and fitting time of the prosthesis were investigated. Quality of life was evaluated using the 36-item Short-Form Health Survey (SF-36) and Turkish version of the Trinity Amputation and Prosthesis Experience Scales (TAPES). Pain was evaluated using the visual analogue scale (VAS). Results: General and mental health statuses were somewhat better in the CAD/CAM group. Results were more favourable in the CAD/CAM group for the other items of the Short-Form 36 (SF-36) questionnaire ($p > 0.05$). The CAD/CAM group performed better in restriction of activity subscale ($p = 0.012$). There were no statistically significant differences between the groups regarding other parameters of TAPES ($p > 0.05$). The daily walking time with the prosthesis was higher in the CAD/CAM group than in the CS group (statistically significant; $p = 0.020$). The manufacturing and fitting time of the prosthesis was significantly different between the CAD/CAM and CS groups ($p = 0.017$). The VAS pain score was significantly lower in the CAD/CAM group ($p < 0001$). Discussion: Prosthetic sockets manufactured for above-knee amputees using the CAD/CAM method yielded some better outcomes than those manufactured with conventional methods in terms of quality of life.

Keywords

CAD/CAM Socket; Conventional Socket; Transfemoral Amputation; Quality of Life; TAPES; SF-36

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Introduction

Amputation is the removal of the whole or a portion of an extremity. Lower-extremity amputation represents a trauma that impairs the individual's quality of life and restricts social activities. Regardless of the amputation type and level, patients require prostheses to mobilise and perform activities of daily living. Balance, proprioceptive sensation, walking time, walking distance, and social activities become restricted as the level of amputation gets higher. Thus, both above- and below-knee amputees need functionally designed prostheses. The residual limb socket fit needs to be good for a functional prosthesis [1]. The socket is the most important part of the prosthesis. Various methods are used in socket manufacturing. Conventional sockets (CSs) are widely-used type and they are manually produced by prosthesis technicians worldwide. CSs are often referred to as quadrilateral socket in above-knee prostheses. Quadrilateral sockets were used and named for the first time at the University of California, Berkeley, US in 1950. The patients are prescribed this socket with the assurance that it would last for 30 years as it allows more comfortable and efficient gait pattern in the amputees [2]. Computer-aided design/computer-aided manufacturing (CAD/CAM) systems are used to capture residual limb shape in a digital environment and this method relies on processing all measurements and modifying the model using computer software. The CAD/CAM method was introduced into practise in 1985 in many international centres to design and manufacture prostheses and orthoses [3-8]. This method provides significant advantages to the central production units. However, despite these advantages, sockets manufactured using the CAD/CAM method have not been reported to be superior to those manufactured using conventional methods [9]. There are also studies suggesting no superiority of one method to the other [10,11]. In addition, there are few studies evaluating quality of life, and they have used a limited number of parameters [12,15]. We aimed to investigate whether patients fitted with CSs and CAD/CAM sockets show differences in their clinical characteristics and quality of life.

We examined the files of patients who were previously prosthetized in our Orthotics prosthesis unit. 35 transfemoral amputees receiving the traditional socket and 35 receiving a socket made using CAD/CAM were invited to participate in the study. Four amputees who were treated with conventional methods and three amputees who were treated with CAD/CAM were excluded from the study because they did not meet the inclusion criteria. In addition, four amputees with conventional sockets and three amputees with CAD/CAM sockets did not agree to participate in the study. A total of 56 above-knee amputees (28 conventional, 28 CAD/CAM sockets) were included. Their ages ranged from 18-85 years and the prostheses were manufactured by the Dicle University Prosthetics and Orthotics Unit between July 2012 and February 2015. The inclusion criteria were prosthesis ≥3 months before enrolment and age ≥18 years. Patients aged <18 years and those with diabetes, infections, circulatory disorder, sensory disorder, malignancy, progressive neurological disease, severe osteoporosis, severe obesity, pregnant women, patients with pacemakers, and those with a chronic disease (e.g., hypertension and chronic kidney disease) were excluded. All patients provided oral and written consent to participate in the study. The study was approved on 18 July, 2012 by the Ethics Committee of Dicle University, Faculty of Medicine. The same unit and operator produced prostheses for patients for whom sockets were produced with the CS or CAD/CAM methods. The TracerCAD programme was used to produce sockets. A silicone liner, monocentric knee joint and solid ankle cushion heel were used for above-knee suspension in all patients. All patients attended a 3-week walking, balance, and strengthening rehabilitation programme after receiving their prosthesis. Age, gender, body mass index, dominant hand, income level, occupation, and educational status of the patients were recorded. Furthermore, the duration of daily prosthetic use, amputation side, presence of neurological deficits, visual analogue scale (VAS) pain score, the method used in socket fabrication, duration of daily prosthetic use, walking distance with the prosthesis, production time of the prosthesis and compliance to rehabilitation programme with the prosthesis were evaluated. Duration of prosthetic use (months): calculated from the time of prosthesis delivery until enrolment in the study as determined by reviewing patient files. Daily prosthesis use (hours): estimated hours per day that the prosthesis was worn as reported by patients. Daily walking distance with the prosthesis (m): estimated distance walked in a day as reported by patients Walking time without pain (min): estimated duration of walking without pain as reported by patients. Assistance in ambulation (Y/N): assessment of whether an ambulation aid (walker, crutch, walking stick, etc.) was used as reported by the patients. Duration of adaptation to prosthesis (days): after the prosthesis was made, the length of the rehabilitation process was evaluated as determined by reviewing patient files. Prosthesis production time (days): the elapsed time for the prosthesis to be made and inserted into the patient after taking the residual limb size of the patient as determined by reviewing patient files. Test socket use (Y/N): assessment of whether a test socket was used during production of the prosthesis as determined by reviewing patient files.

The SF-36 questionnaire was used to evaluate the patient quality of life. Kocyigit et al. evaluated the validity and reliability of the Turkish version of this questionnaire [16]. The SF-36 Health Survey contains eight domains, including physical function, physical role functioning, bodily pain, general health, vitality, social role functioning, emotional role functioning, and mental health, with a total of 36 items. Each domain is scored on a scale of 0–100 points. Higher scores indicate better quality of life [16,17]. We evaluated adaptation to the prosthesis and the quality of life using the Turkish version of the Trinity Amputation and Prosthesis Experience Scales (TAPES) [18]. This questionnaire is composed of psychosocial adjustment, activity restriction, and prosthetic satisfaction subscales. Higher scores in the psychosocial adjustment subscale indicate better psychosocial adjustment, higher scores in the activity restriction subscale indicate higher activity restriction, and higher scores in the prosthetic satisfaction subscale indicate higher satisfaction with the prosthesis [19]. Pain was evaluated using VAS. The patients were instructed to mark the number that best corresponded to their pain level between 0 (no pain) and 10 (intolerable pain). A face-to-face interview was conducted with the patients to complete the study forms and questionnaires. Data were analysed using the Statistical Package for the Social Sciences, version 17 (SPSS Inc, Chicago, IL). The normality of the variable distributions was tested by the Kolmogorov–Smirnov test. In addition to descriptive statistics, comparison between the groups was performed using the independent samples t-test, and the Mann–Whitney U test was used as a nonparametric test. The x2 test with the Yates correction or Fisher's exact test was used for the comparison of nonparametric variables. Quantitative variables were expressed as median (minimum–maximum), and categorical variables were expressed as numbers and percentages. P < 0.05 was considered significant. The sample size was calculated via the GPower statistical software package. Physical function scores of SF-36 were evaluated by comparing the change in primary outcome measures between the groups. For the given effect size (0.9264) and alpha (0.05), the power was 0.80 at a sample size of 32.

Results

The present study included 56 patients, 28 of whom were fitted with CS (CS group) and 28 with a CAD/CAM socket (CAD/CAM group). The mean patient age in the CAD/CAM and CS groups was 40.50 ± 8.64 and 35.50 ± 9.17 years, respectively. Number of males and females was equal in the two groups (11/17). The rate of unemployment was considerably high both in the CAD/CAM and CS groups. Fourteen patients (50%) in the CAD/CAM group and 10 (35.71%) in the CS group were unemployed. With respect to the educational level, patients in the two groups were primary school graduates. The cause of amputation in the two groups was generally trauma. However, there was no significant difference between the two groups with respect to age, gender, body weight, income, educational level, cause of amputation, body mass index, or amputation side (p > 0.05 for each, Table 1).

The daily walking time was higher in the CAD/CAM group than in the CS group and the difference was statistically significant (p = 0.020). Furthermore, there was a significant difference in the time of production and application of the prosthesis to the patient, favouring the CAD/CAM group (p = 0.017). VAS scores were significantly different, favouring the CAD/CAM group (p < 001). However, there was no significant difference between the groups with respect to the duration of daily prosthetic use, walking distance with the prosthesis, duration of walking without pain, time of adaptation to the prosthesis and test socket use (for each p > 0.05, Table 2).

The CAD/CAM patients performed significantly better in mental and general health domains than the CS patients (p = 0.017 and p = 0.045, respectively). However, there was no significant difference between the groups with respect to physical functioning, physical role functioning, bodily pain, vitality, social functioning, or emotional role functioning (for each, p > 0.05, Table 3). The CAD/CAM patients performed better in the activity restriction domain than the CS patients (p = 0.012). However, there was no significant difference between the groups with respect to other parameters of TAPES (p > 0.05, Table 3).

Discussion

In the present study, the CAD/CAM method yielded some better results than the conventional method in improving patient quality of life. Among other parameters of quality of life, CAD/CAM patients achieved better results in general health, mental health, and activity restriction scales. VAS scores were significantly better in the CAD/CAM group. Significantly results in favor of CAD / CAM during daily walking. This finding suggests that patients using CAD/CAM sockets walk longer distances while consuming less energy and oxygen. Users of CAD/CAM sockets reported wearing their prosthesis longer than users of conventional sockets. In addition, the CAD/CAM group achieved significantly better results for manufacturing and fitting time.

An appropriate socket is required for amputee mobilisation [20]. The socket is the interface between the prosthesis and the residual limb. Therefore, it is the fundamental element for successful prosthetic fitting and plays a key role in load transfer

Table 1. Comparison of demographic characteristics between the CAD/CAM and CS groups

	CAD/CAM group mean,standard deviation, range	CS group mean, standard deviation, range	P
Age, year	40.50 ± 8,64 (19-82)	35.50 ± 9,17 (18-85)	0.603 [a]
Gender, male/female	17/11 (61%–39%)	17/11 (61%–39%)	0.608[b]
Weight, kg	70.04 ± 8.11 (53-110)	73.00±9.75 (55-108)	0.222[a]
Height, cm	170.71 ± 6.81 (156-198)	169.07± 6.84 (154-193)	0.372[a]
Body mass ındex	25.02 ± 2.33 (21.97-34.08)	25.56 ± 2.52 (22.21-33.17)	0.096[a]
Dominant hand right/left	24/4 (86%–14%)	24/4 (86%–14%)	0.648[b]
Amputation side, right/left	17/11 (61%–39%)	20/8 (71%–29%)	0.287[b]
Educational status			
Illiterate	3 (11%)	2 (7%)	
Primary school	18 (64%)	15 (54%)	0.607[b]
High-school	5 (18%)	9 (32%)	
Higher education	2 (7%)	2 (7%)	
Income level			
0–500	20 (71%)	19 (68%)	
501–1000	5 (18%)	4 (14%)	0.727[b]
1001–2000	3 (11%)	5 (18%)	
Occupation			
Unemployed	14 (50%)	10 (36%)	
Worker	1 (4%)	2 (7%)	
Officer	2 (7%)	1 (4%)	
Student	2 (7%)	3 (11%)	
Housewife	7 (25%)	6 (21%)	
Other	2 (7%)	6 (21%)	
Cause of amputation			
Trauma	14 (50%)	12 (42%)	
Diabetes	1 (4%)	1 (4%)	
Peripheral vessel disease	2 (7%)	2 (7%)	
Gunshot injury	3 (0%)	2 (7%)	
Infection	0 (11%)	1 (4%)	
Tumour	5 (17%)	5 (18%)	
Congenital	3 (11%)	5 (18%)	

aIndependent sample t-test, bx2 test.
TL, Turkish Lira.

Table 2. Comparison of parameters of prosthesis use and clinical characteristics between transfemoral CAD/CAM and CS groups

	CAD/CAM group mean, standard deviation, range	CS group mean, standard deviation, range	P
Duration of daily prosthetic use (month)	10.2 ±1.96 (4.8–49.2)	12.0±1.66 (3.6–27.6)	0.222[a]
Using time with the prosthesis (h/day)	12.68 ± 1.91 (6-16)	11.50 ± 1.84 (5-15)	0.020[a]
Walking distance with the prosthesis (meters m/day)	1300±186 (900–2000)	1150±164 (100-1700)	0.170[a]
Walking time without pain (min)	42.50± 3.91 (20–120)	37.50±3.47 (20–90)	0.427[a]
Assisted walking with prosthesis	1/27 (4%–96)	2/26 (7%–93%)	0.500[b]
Duration of adaptation to prosthesis (day)	9± 0.97 (5–14)	13± 1.18 (7–21)	0.156[a]
Prosthesis production time (day)	3 ± 0.32 (2–5)	14 ±1.23 (7–30)	0.017[a]
VAS	1± 0.13 (0–3)	3± 0.27 (0–5)	0.001[a]
Neurological deficits	5/23 (18%–82%)	6/22 (21%–79%)	0.500[b]
Compression wounds	1/27 (4%–96%)	2/26 (7%–93%)	0.500[b]
Ecchymosis	13/15 (46%–54%)	12/16 (43%–57%)	0.500[b]
Test socket use	17/11 (61%–39%)	15/13 (54%–46%)	0.394[b]

[a]Mann–Whitney U test, [b]x2 test.

Table 3. Comparison of the transfemoral CAD/CAM and CS groups using SF-36 and TAPES

		CAD/CAM group mean, standard deviation, range median	CS group mean, standard deviation, range median	P
	Physical Function	70 ± 13.45 (45–90) (71.75)	67.50 ± 14.23 (5–100) (68,50)	0.679[a]
	Physical role functioning	25 ± 7.49 (0–100) (26.20)	25 ± 5.27 (0–100) (25.80)	0.730[a]
	Bodily pain	74 ± 9.11 (41–90) (75.50)	74 ± 14.08 (22–90) (73.45)	0.353[a]
	General health	75.46 ± 15.39 (42-95) (72.50)	64.46 ± 23.84 (32-82) (61.00)	0.045[a]
	Vitality	60 ±10.27 (45–80) (62.25)	55 ±11.05 (5–80) (58.65)	0.716[a]
	Social functioning	75 ± 7.51 (50–87.50) (75.50)	68.75± 14.03 (25–100) (71.25)	0.722[a]
	Emotional role functioning	33.30 ± 8.17 (0–100) (33.50)	33.30 ± 8.89 (0–100) (33.50)	0.064[a]
	Mental health	61.14 ± 9.54 (52-78) (62.65)	54.14 ± 11.55 (44-72) (55.45)	0.017[a]
TAPES	Psychosocial adjustment	55.82 ± 4.26 (44-72) (55.50)	55.43 ± 5.95 (40-68) (54.80)	0.777[a]
	Activity restriction	5 ± 1.02 (1–9) (5)	8 ± 1.67 (3–13) (8)	0.012[a]
	Prosthetic satisfaction	39.14 ± 4.17 (33-47) (39.05)	39.18 ± 2.80 (35-46) (39.20)	0.970[a]

[a]Mann–Whitney U test

between the prosthesis and the residual limb [21]. It is also the most important component for successful rehabilitation following lower-extremity amputation [1,22]. There are various factors affecting energy consumption during walking in patients with above-knee amputations. These factors include the quality of rehabilitation programme, physical eligibility of the amputee, prosthesis adjustments, prosthetic foot, prosthetic device weight, and socket type [23,24]. Early and immediate prosthetic fitting decreases oedema and positively contributes to wound healing, residual limb shaping, development of proprioception, and patients' psychological condition [14]. It is considerably difficult to produce prostheses, perform adjustments, and record information using conventional methods [25]. Furthermore, casting involves additional difficulties for the leg [15]. Capturing the shape and volume of the residual limb using conventional methods is difficult. Furthermore, the conventional methods, which are time-consuming, are insufficient for the increasing number of patients requiring prostheses. The use of CAD/CAM methods in the design and production of lower-extremity prosthetic devices has considerable advantages. Prosthetic devices can be automatically and accurately designed by the technician by entering simple data into the system. This gives the technician more time to handle problems arising in the prosthetic clinic. The use of computerised systems and software while designing the sockets using the CAD/CAM method provides savings on the material costs. Socket designs are accurate and thus rely less on the technician's skills. Furthermore, storage of patient data in the digital CAD/CAM environment represents an important data source for monitoring the progress and general rehabilitation of the patients, many of whom will require a number of prosthetic devices and sockets in the future [26]. This will, therefore, contribute to the improvement in rehabilitation [6,11,22,27].

It has been suggested that the CAD/CAM socket design addresses all the problems that above-knee amputees experience. Flandry et al. used prostheses with quadrilateral sockets in five patients and then switched to prostheses manufactured with the CAD/CAM method; they reported lower oxygen consumption during walking with prostheses manufactured with the CAD/CAM method [14]. Gailey et al. reported no difference between patients fitted with quadrilateral and CAD/CAM sockets and the control groups with respect to oxygen consumption (VO2) and heart rate (HR). In the slow walking phase, they observed higher VO2 (pt0.05) and HR (pt0.01) in the quadrilateral and CAD/CAM groups than in the control group. However, there was no significant difference between quadrilateral and CAD/CAM sockets groups with respect to VO2 or HR [25]. The present study evaluated the walking time with the prosthesis. The walking time with the prosthesis was longer in the CAD/CAM socket group. This finding suggests that patients using CAD/CAM sockets walk longer distances while consuming less energy and oxygen. Bayar et al. studied patients who used the two socket types. In the comparison of the effects on ambulation, they found that patients in the CAD/CAM socket group performed significantly better with respect to the step length in the intact extremity, support surface, cadence of walking, walking speed, ascending and descending stairs, standing up from a chair and stepping over obstacles. Furthermore, they also reported that CAD/CAM sockets were superior in approximating ambulation activities of patients to normal values than the use of quadrilateral sockets [15]. The present study evaluated several parameters, such as the duration of daily prosthetic use, walking distance with the prosthesis, prosthetic gait pattern,, and time of adaptation to the prosthesis. The duration of daily prosthetic use was significantly better in the CAD/CAM group. In the study by Flandry et al., the mean walking speed was 44.5 m/min in the CAD/CAM socket group and 40.4 m/min in the quadrilateral socket group [14]. The present study found significantly better results in the CAD/CAM group with respect to the duration of daily prosthetic use (day/h). However, the walking distance with the prosthesis was not different.

The present study has several limitations. First, prosthetic use was collected using patient self-report. Second, the study did not compare patients with the same occupation. Third, it did not evaluate the psychological and emotional status of the patients.

Conclusions

The present study yielded some better results in the quality of life parameters of patients with transfemoral amputation using CAD/CAM sockets. Furthermore, the study determined improvements in daily walking distance with the prosthesis, production time of the prosthesis, and pain scores in favour of the CAD/CAM socket group. Randomised and controlled studies on larger numbers of patients evaluating more comprehensive parameters are required.

Scientific Responsibility Statement

The authors declare that they are responsible for the article's scientific content including study design, data collection, analysis and interpretation, writing, some of the main line, or all of the preparation and scientific review of the contents and approval of the final version of the article.

Animal and human rights statement

All procedures performed in this study 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. No animal or human studies were carried out by the authors for this article.

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Conflict of interest

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