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Original Article

Comparison of Personal Independence Between Soft Dressing and Immediate Postoperative Prosthesis Method in Older Diabetic Amputees

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ABSTRACT

Background: Elderly diabetic patients face a lack of independence in daily and social activities such as going to the toilet and bathing, aside from walking and communication, which are affected by the ability to stand and walk bilaterally. This study aims to compare the rehabilitative outcome of post-amputation soft dressing with IPOP

Methods: In this randomized clinical trial study four parameters were measured, including the time between amputation and the first standing, amputation and taking the first steps, amputation and an independent personal activity and amputation and fitting the first permanent prosthesis. Thirty elderly diabetic patients (aged 65-80) were divided into two groups. The Intervention group received IPOP and the control group received soft dressing.

Results: Patients who received immediate post-operative prosthesis took significantly lower time in all four variables.

Conclusion: The results showed that it takes the control group, on average, 148 days longer to receive their first final prosthesis and achieve the same ADL and social status as the intervention group.

Introduction

Physical deficiency and recovery can be examined in different diseases, but investigation of older diabetic amputees has high priority since they face major problems such as peripheral nerve and/or skeletal impairments [1]. The main post-amputation goal in the healing period between the amputation and receiving permanent prosthesis is wound healing and empowerment. For this purpose, various methods have been developed, including soft dressing, semi-rigid dressing, rigid dressing, and Immediate Post-operative Prosthesis (IPOP) [2].

The idea of using temporary prostheses was first introduced after World War I in 1968 by Philip Wilson, a surgeon, and was completed after World War II by Michael Belmont in a study on 21,000 amputated soldiers [3-6]. In 1968, Borges and Romano reported the application of immediate postoperative prostheses (IPOP) in public hospitals [5]. IPOP is a temporary prosthesis that is applied in the operating room for patients with amputation. Its foot and other components make the weight-bearing possible [7].

While soft dressing seems to be a low-risk method, some studies have shown a higher risk for revision surgery and skin breakdown [8-11]. Psychological effects of different care methods have been sufficiently cleared but in rehabilitation and returning to pre-amputation activity level, there is no enough reliable studies to clarify the rehabilitation duration difference between immediate post-operative prostheses and soft dressing

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[9, 11-13]. As diabetic amputees are at a higher risk of both revision surgery and rehabilitation failure, these patients have been considered more than other groups of patients in studies with IPOP intervention [11, 14-16]. However, no study has been conducted on the efficacy of this special thermoplastic IPOP on the acceleration of elderly diabetic patients' rehabilitation. Our aim in this study was to evaluate the extent and time of achieving individual independence of lower limb amputees between the two groups of patients using a special immediate post-operative prosthesis and soft dressing.

Materials and Methods

As this type of IPOP was utilized for the first time in Iran, this randomized clinical trial was conducted. The operation center was chosen randomly among all the hospitals which perform the amputation for diabetic elderly patients. We gathered data on all patients capable of joining the study in a one-year period (2019-2020). Each group consisted of fifteen patients, the first group received an IPOP, and the control group used the traditional soft dressing method. Table 1 shows the demographics of the patients in the current study.

The intervention group used an IPOP, with the following characteristics [17]: Casting was performed immediately after surgery, then the same prosthetists modified the molds and made the prostheses for all the participants. IPOP was fitted on patient's stump on the operation day or a day after. Patients were encouraged to wear their prostheses 23 hours a day for the best outcome.

They were given exercises [11] to strengthen the thigh muscles and apply 10 pounds on the prosthetic limb for the first three days after amputation. To understand the exact amount of pressure, they push their prosthetic leg on a scale. At the end of the three-day period, if the physical ability and health of the suture area were acceptable, each patient was allowed to stand with pressure of 20 pounds on the prosthetic limb [18].

Each patient stood with a walker. To control the applied pressure on the prosthetic leg while standing, the trainer tried to rotate the artificial foot to the left and right. The ease of moving the toe ensured that the applied pressure was not too much. Standing exercises (3 to 5 days) continued over time, increasing pressure on the prosthetic leg. At the end of the standing phase, they were allowed to walk with a walker. To implement the training course protocol [17], each patient was trained with an expert for 5 sessions.

The Immediate post-operative prosthesis was made custom molded. All prostheses were made by the same prosthetist and approved by two other experts. The Immediate post-operative prosthesis has two strapping systems (Figure 1): one (blackstrap) is used to increase the pressure inside the socket and reduce edema, and the other (red strap) is utilized to adjust the prosthesis suspension system and limit cylindrical movements. The socket is made of polypropylene thermoplastic at 180 degrees of centigrade on patient's stump mold using suction, while the upper trim line extended 15 cm over the knee to limit knee joint movement in order to prevent knee flexion contracture [17]. Also, the socket at the suture line was modified to relieve pressure on that area. Other parts, including artificial foot and other components, were selected according to the expert's advice and the patient's final decision.

In order to eliminate confounding variables in the selection of prosthetic individuals, the same design and manufacturing system was used for all the IPOPs.

The control group participants were patients admitted by the same physicians and hospital (Bahman hospital) but did not accept IPOP intervention. Information of patients in the control group was collected by phone calls and on the initial prosthesis fitting admission date. Applying for initial prosthesis fitting was allowed by physicians considering scar healing and stump edema control. To avoid any bias in the procedure, the research team and the IPOP practitioners did not comment on the fitting timings and the rehabilitation process. Patients were not forced to speed up the process as the hospital staff and physicians did not intervene in their routine process.

Table 1: Demographics data of patients in the two groups of control (soft dressing after amputation) and intervention (Immediate postoperative prosthesis (IPOP))

		Mean	ST	Age	Height	Sex	Unit of scales
Variable 1	Intervention	9,93	5.90	71	171	5 men 10 women	Days
	Control	20.73	3.23	65	174	15 men	Days
Variable 2	Intervention	18,53	6.17	71	171	5 men 10 women	Days
	Control	179,93	60.50	65	174	15 men	Days
Variable 3	Intervention	19,53	11.89	71	171	5 men 10 women	Days
	Control	50,13	14.71	65	174	15 men	Days
Variable 4	Intervention	40.13	9.72	71	171	5 men 10 women	Days
	Control	177,33	60.50	65	174	15 men	Days
Variable 5	Intervention	25.57	6.06	71	171	5 men 10 women	Days
	Control	105.27	36.56	65	174	15 men	days

Variable 1: the required time after amputation to standing
Variable 2: the required time after amputation to Walking
Variable 3: the required time after amputation to gaining personal independence
Variable 4: the required time after amputation to fitting final prosthesis
Variable 5: rehabilitation success (average of all parameters)

Figure 1: Immediate post-operative prosthesis: the blackstrap increases pressure inside the socket and the red strap adjusts the prosthetic suspension.

After the patients were ready to visit a prosthetist, they were free to choose the time and date. For more edema control, the figure-eight bandage was prescribed for patients in the first visit. They were encouraged to do the figure-eight bandage and send the stump circumference every night. Patients were asked to go back to the clinic for casting when their night stump measuring remained the same for at least three nights.

Inclusion criteria for this study are lower limb amputation, no stump skin graft, no open stump wound, age over 50 years, clinical diagnosis of diabetes, unilateral amputation, below-knee amputation, full consciousness, and k-level of at least 1 [19-23].

The study proposal was approved by the ethics committee in the research committee of Iran University of Medical Science with the ethics code of IR.IUMS.REC.1399.685 and also by Iranian randomized clinical trial committee with IRCT code: IRCT2014012816395N1. The individuals were informed about the study and the probable side effects of taking IPOP, and they were asked to sign an informed written consent prior to collecting the information and starting the study. In this study, to evaluate the speed of a person returning to daily living activity, time factors including the first date of standing, the first date of walking, the first date when the person can perform personal activities independently, and the date of receiving the first final prosthesis were collected. In this study, the criterion for a person's ability to do their own personal task is the ability to go to the bathroom without the help of others. Also, the criterion for the first date of standing and walking was when they could stand and walk without the need for devices or other people (Figure 2).

Statistical tests appropriate to the information were used to examine the differences in the effect of the utilized methods in the two independent groups of patients between the years 2019-2020. The confidence interval was set at 95%. (α=0.05)

Figure 2: wearing BK IPOP after surgery, ICU, Bahman hospital

Results

Among the participants in the present study, the mean age of the control group was 72±8 years (those who used soft bandaging) and the intervention group was 71±6 years (those who used IPOP after surgery). The anthropometric data of the participants is shown in Table 1.

Table 2 shows the independence related variables of both groups during post-amputation rehabilitation. There were significant differences in all four variables between IPOP group and soft dressing group ($P<0.05$). In the IPOP group, the time required for first standing, first walking, first independent daily activity, and final prosthetic fitting were lower than that of soft dressing group by 10.8 (days), 161.4 (days), 34.6 (days) and 137.2 (days), respectively.

The results of the Shapiro-walk test were not normal, so the Mann-Whitney U test was conducted to compare the means of the two independent groups. At the confidence level of 95% in the test, there was a significant difference between the rehabilitation results, so the outcomes were not equal ($P<0.01$). Regarding the variables of the required time after amputation to standing, walking, gaining personal independence, and receiving the final prosthesis, the IPOP shows a significant difference in comparison with the conventional method.

In the Functional Independence Measure Questionnaire [24], issues such as eating, grooming, bathing, upper and Lower body dressing, going to toilet, bladder management, bowel management, bed to chair transfer, locomotion (ambulatory or wheelchair level), climbing stairs, cognitive comprehension, expression of willing, social interaction, problem-solving, memory, shower and toilet transfer were measured. Among these domains, patients with lower-limb amputation may typically experience difficulty in activities such as grooming, bathing, going to toilet, locomotion (ambulatory or wheelchair level) and social activities. Despite the complexity amputees might face, in the present study, all parameters were analyzed and results showed significant differences in each variables (Table 3).

Table 2: Patient's data

Time between amputation surgery and permanent prosthesis (Days)		Time between amputation surgery and personal daily life activity (Days)		Time between amputation surgery and first standing (Days)		Time between amputation surgery and first walking activity (Days)	
IPOP group	**Soft dressing**	**IPOP group**	**Soft dressing**	**IPOP group**	**Soft dressing**	**IPOP group**	**Soft dressing**
60	56	9	46	5	17	15	56
50	263	9	69	10	18	25	263
25	179	28	50	23	20	12	209
36	160	38	57	6	21	14	160
35	212	14	25	8	25	23	212
32	98	10	54	6	18	27	99
36	267	8	73	8	20	20	267
41	170	25	48	15	19	10	171
52	154	40	63	5	25	21	156
36	200	12	30	9	25	25	202
41	102	11	54	7	19	10	102
41	250	7	60	11	15	27	250
53	180	30	53	6	25	11	180
29	170	35	47	23	21	19	172
35	199	17	23	7	23	19	200
Mean: 40.13	Mean: 177,33	Mean: 19,53	Mean: 50,13	Mean: 9,93	Mean: 20.73	Mean: 18,53	Mean: 179,93

Immediate postoperative prosthesis (IPOP)

Table 3: Test results for differences between the two groups

Variable	Sig. (2-tailed)) (Days)	Std. error difference (Days)	95% confidence interval of the difference (Days)	
			Lower	Upper
Time between amputation surgery and first standing	0.000	20.40	7.00	73.00
Time between amputation surgery and personal daily life activity	0.000	91.53	7.00	267.00
Time between amputation surgery and permanent prosthesis	0.000	7.22	5.00	25.00
Time between amputation surgery and first walking activity	0.000	96.22	10.00	267.00
Rehabilitation success	0.000	51.50	10.75	156.75

Among all the options, the largest difference belongs to the variable of receiving the final prosthesis, and the data showed that the IPOP method was more effective than other methods (IPOP: 40 days, control group: 177.33 days) (Table 2).

Discussion

In the present study, the measured values do not indicate the ability of individuals, but it has measured just how the rehabilitation process is being conducted in each of the two groups in Iran. Admittedly, in the control group, participants may have been able to complete the rehabilitation process in less time, but the research team did not interfere in the regular rehabilitation process of Iranian elderly amputees.

The ability to stand up independently is one of the essential features of independence as it helps the patients decide when to walk without asking others. For some patients, standing is even more difficult than walking. Three patients in the IPOP group were able to stand independently several days after being capable of walking. Patients in the intervention group started standing significantly earlier than the control group. Participants who received IPOP were informed, encouraged and ensured safety to stand in the first week after amputation by the therapist. These were not provided for the soft dressing group. It took almost an average of 10 days for IPOP group patients to stand while taking the soft dressing group about 21 days. All the patients in both groups finally stood successfully. Only four patients (26%) in the IPOP group took more than 10 days to stand without any other persons' help.

Complete independent walking ability is defined as walking without any aid devices. Participants needed an artificial leg to have such performance. None of the patients in the soft dressing group could walk independently before fitting with a permanent prosthesis, so these two variables are entirely dependent in the soft dressing group. The IPOP Group walked independently 154 days (5 months) earlier than the soft dressing group. With more follow-up and better advisements such as in-home muscle strengthening, body balance practices, and edema control, patients in the soft dressing group might have an earlier rehabilitation process. However, our rule in this study was to have no interference in their rehabilitation process to compare the standard rehabilitation process using soft dressing.

Results of a study conducted by Rost in 1991 indicated that increasing the activity of hospitalized diabetic patients has a substantial effect on improving their subsequent physical activity [25]. Our results show that it takes the control group 148 days, on average, longer to receive the first final prosthesis and achieve the same level in social and home activities than the intervention group.

Finally, regaining the sufficient ability to carry out personal tasks is of paramount importance in the elderly

diabetic amputees. According to previous studies and our findings, there is enough information to claim that for patients who receive IPOP, it takes less time to rehabilitate and walk efficiently again. Patients with IPOP in the study of Moore could be fitted with final prosthesis after 32 days, but the control group with soft dressing received final prosthesis after 125 days [11]. In an experimental work by Walsh, patients started walking between 17 to 28 days after amputation [13]. Even though this study did not have a control group to compare, no study has shown a close rate for soft dressing patients. Ali et al. also reported a 51-day interval between amputation and fitting with a final prosthesis for IPOP patients, but this study did not report the same data for their control group either.

As most physicians were not familiar with the IPOP, only one accepted to refer patients. Also, with the covid-19 lockdown, more patients decided not to get in touch.

Conclusion

This study was undertaken to investigate if this kind of IPOP, which was developed in Iran, can facilitates the rehabilitation process of older diabetic amputees. Older diabetic amputees are at a higher risk of missing rehabilitation due to increased weakness resulted from a long inactivity after amputation. The findings show that IPOP was associated with faster standing, walking, receiving permanent prosthesis, and general independence in home and social activities compared with traditional dressing (10,154,135 days earlier respectively). It can be concluded that the use of IPOP can significantly facilitate the rehabilitation process in comparison with the common traditional method.

Conflict of Interest

All of the authors participated in this study certify that they have NO affiliations with or involvement in any organization or entity with any financial interest (such as honoraria; educational grants; participation in speakers' bureaus; membership, employment, consultancies, stock ownership, or other equity interest; and expert testimony or patent-licensing arrangements), or non-financial interest (such as personal or professional relationships, affiliations, knowledge or beliefs) in the subject matter or materials discussed in this manuscript.

References

1. Geurts, A.C. and T.W. Mulder, *Reorganisation of postural control following lower limb amputation: theoretical considerations and implications for rehabilitation.* Physiother Theory Pract, 1992. **8**(3): p. 145-157.
2. Eneroth, M., *Factors affecting wound healing after major amputation for vascular disease: a review.* Prosthet Orthot Int, 1999. **23**(3): p. 195-208.
3. Smith, D.G., et al., *Postoperative dressing and management strategies for transtibial amputations: a critical review.* J Rehabil Res Dev, 2003. **40**(3): p. 213-224.
4. Golbranson, F., C. Asbelle, and D. Strand, *Immediate Postsurgical Fitting and Early Ambulation: A New Concept in Amputee Rehabilitation.* Clin Orthop Relat Res (1976-2007), 1968. **56**: p. 119-132.
5. BURGEss, E.M. and R.L. ROMANO, *12 The Management of Lower Extremity Amputees Using Immediate Postsurgical Prostheses.* Clin Orthop Relat Res®, 1968. **57**: p. 137-146.
6. Bonner Jr, F. and R. Green, *Pneumatic Airleg prosthesis: report of 200 cases.* J Phys Med Rehabil, 1982. **63**(8): p. 383-385.
7. Decker, T.D., et al., *Bent Knee Temporary Prosthesis to Support Early Ambulation after Transtibial Amputation: A Case Report.* Pm&r, 2019. **11**(9): p. 1027-1030.
8. Ali, M.M., et al., *A contemporary comparative analysis of immediate postoperative prosthesis placement following below-knee amputation.* Annals of Vascular Surgery, 2013. **27**(8): p. 1146-1153.
9. Kihn, R.B., et al., *The immediate postoperative prosthesis in lower extremity amputations.* Arch Surg, 1970. **101**(1): p. 40-44.
10. MOORE, T.J., et al., *Prosthetic usage following major lower extremity amputation.* Clin Orthop Relat Res®, 1989. **238**: p. 219-224.
11. Schon, L.C., et al., *Benefits of early prosthetic management of transtibial amputees: a prospective clinical study of a prefabricated prosthesis.* Foot Ankle Int, 2002. **23**(6): p. 509-514.
12. Samuelsen, B.T., et al., *The impact of the immediate postoperative prosthesis on patient mobility and quality of life after transtibial amputation.* Am J Phys Med Rehabil, 2017. **96**(2): p. 116-119.
13. Walsh, T.L., *Custom removable immediate postoperative prosthesis.* J Prosthet Orthot, 2003. **15**(4): p. 158-161.
14. Folsom, D., T. King, and J.R. Rubin, *Lower-extremity amputation with immediate postoperative prosthetic placement.* Am J Surg, 1992. **164**(4): p. 320-322.
15. Horne, C.E. and J.A. Neil, *Quality of life in patients with prosthetic legs: a comparison study.* J Prosthet Orthot, 2009. **21**(3): p. 154-159.
16. Pinzur, M.S., et al., *A safe, pre-fabricated, immediate postoperative prosthetic limb system for rehabilitation of below-knee amputations.* Orthopedics, 1989. **12**(10): p. 1343-1345.
17. Burgess, E.M., J.E. Traub, and A.B. Wilson, *Immediate postsurgical prosthetics in the management of lower extremity amputees.* 1967: Prosthetic and Sensory Aids Service, Veterans Administration.
18. Hayes, J., et al., *Immediate FIT Prosthesis*, in *Control Aspects of Prosthetics and Orthotics*. 1983, Elsevier. p. 145-148.
19. Pinzur, M.S., G. Graham, and H. Osterman, *Psychologic testing in amputation rehabilitation.* Clin Orthop Relat Res, 1988(229): p. 236-240.
20. PINZUR, M.S., et al., *Functional outcome of below-knee amputation in peripheral vascular insufficiency: a multicenter review.* Clin Orthop Relat Res®, 1993. **286**: p. 247-249.
21. Sage, R.A., et al., *Amputation and rehabilitation of the diabetic foot*, in *The diabetic foot*. 2006, Springer. p. 363-389.
22. Pinzur, M., *New concepts in lower-limb amputation and prosthetic management.* Instr Course Lect, 1990. **39**: p. 361.
23. Pinzur, M., *Current concepts: amputation surgery in peripheral vascular disease.* Instr Course Lect, 1997. **46**: p. 501.
24. Ottenbacher, K.J., et al., *The reliability of the functional independence measure: a quantitative review.* J Phys Med Rehabil, 1996. **77**(12): p. 1226-1232.
25. Rost, K.M., et al., *Change in metabolic control and functional status after hospitalization: impact of patient activation intervention in diabetic patients.* Diabetes Care, 1991. **14**(10): p. 881-889.