

# Results of prosthetic rehabilitation on managing transtibial vascular amputation with silicone liner after wound closure

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## Abstract

**Objective:** To investigate the effect of a standardized silicone liner programme on the duration of prosthetic rehabilitation in patients who underwent transtibial amputation as a result of peripheral arterial disease.

**Methods:** This retrospective study enrolled patients who underwent transtibial amputation followed by one of two stump management programmes at the same rehabilitation centre over a period of 14 years. The study compared the duration of rehabilitation following a standardized silicone liner programme compared with that following a conventional soft dressing programme.

**Results:** This study included 16 patients who underwent the silicone liner programme and 11 patients who underwent the soft dressing programme. There were no significant differences between the two groups in age, sex, interval between amputation and admission to the rehabilitation centre and stump length. The duration required for the completion of the rehabilitation programme was significantly shorter for the silicone liner programme compared with the soft dressing programme (mean  $\pm$  SD: 77.3 days  $\pm$  13.4 versus 125.4 days  $\pm$  66.4 days, respectively).

**Conclusion:** A standardized silicone liner programme reduced the duration of rehabilitation and could be a valuable replacement for soft dressing-based stump management.

## Keywords

Prosthesis, rehabilitation, amputation, transtibial, stump management, peripheral arterial disease, vascular

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## Introduction

Recent progress in endovascular treatment and vascular surgery has reduced the number of cases of peripheral arterial disease (PAD) that lead to major amputations,<sup>1</sup> but according to the analysis of US Medicare data from 2000 to 2008, of approximately 3 million patients hospitalized with PAD, 186 338 underwent major lower limb amputation during that time.<sup>1,2</sup> The importance of preserving the knee joint when selecting the amputation level became widely known, with two thirds of the patients requiring major amputation due to PAD being amputated at the transtibial level.<sup>1,3,4</sup> Therefore, prosthetic rehabilitation for vascular transtibial amputees is very important. However, the rate of successful prosthetic rehabilitation has not improved over 40 years.<sup>5</sup> Effective postamputation stump management and subsequent prosthetic rehabilitation strategies remain to be established for transtibial amputees.<sup>5,6</sup>

Rigid dressing management is generally thought to be the desirable postoperative management in terms of progress in the maturation of the stump,<sup>7-9</sup> and it appears to enable earlier prosthesis fitting, thereby reducing the rehabilitation period as compared with soft dressing management.<sup>3,10-13</sup> But the risk of soft tissue ischaemia makes it difficult to apply rigid dressings for transtibial amputees caused by PAD.<sup>14</sup> Soft dressing management is one of the options for postoperative stump management,<sup>10</sup> but this management method needs much more time for wound healing,<sup>15,16</sup> and uniform global standard protocols for stump management and rehabilitation have not been established.<sup>14</sup> Using removable rigid dressings with silicone liners has been reported to be effective for wound healing,<sup>6,15,16</sup> and it reduces the period of hospitalization for prosthetic rehabilitation.<sup>15,17-20</sup> Our institution introduced a standardized stump

management and prosthetic rehabilitation programme using silicone liners in a time-series framework after wound closure of transtibial amputation in 2006.

This present study investigated the effect of a standardized silicone liner programme on the prosthetic rehabilitation period in patients who had undergone transtibial amputation caused by PAD by retrospectively evaluating the outcomes compared with those following an earlier soft dressing management programme that was used prior to the introduction of the standardized silicone liner programme.

## Patients and methods

### *Study population*

This retrospective study analysed the data from consecutive patients with PAD who had undergone unilateral transtibial amputations at local community hospitals and were then referred to the Department of Physical Medicine and Rehabilitation, Hyogo Rehabilitation Centre, Kobe, Japan for prosthetic walking training between January 2006 and December 2014. All patients underwent a standardized stump management programme using silicone liners (silicone liner programme group). The control group consisted of consecutive patients with PAD who had undergone unilateral transtibial amputation at local community hospitals and were then referred to the Department of Physical Medicine and Rehabilitation for prosthetic rehabilitation between January 2001 and December 2005, which was before the standardized stump management programme using silicone liners was introduced at Hyogo Rehabilitation Centre, Kobe, Japan. Control patients had received soft dressing management and trained on provisional prostheses that were made for them (soft dressing programme group). Data from all patients with vascular transtibial amputation who were admitted to the Department

of Physical Medicine and Rehabilitation during both time periods were analysed in this study.

Inclusion criteria for all study participants included: (i) ability to stand on their nonamputated leg either unsupported or supported by one hand on a desk at the time of admission to the Department of Physical Medicine and Rehabilitation; (ii) no severe dysfunction of the nonamputated leg or their upper extremities such as joint contracture and paralysis. Patients were excluded if they had any Steinberg factors that might impede their prosthetic walking ability.<sup>21</sup> Exclusion criteria were as follows: (i) history of silicone liner use; (ii) severe mental deterioration; (iii) advanced neurological disorders; (iv) congestive heart failure; (v) advanced obstructive pulmonary disease; (vi) advanced hip or knee flexion contracture ( $\leq 30^\circ$ ). Postoperative stump management and rehabilitation before admission to the Department of Physical Medicine and Rehabilitation was not standardized across the local hospitals in either study group. Stump wounds had already healed fully when patients were referred to the Department of Physical Medicine and Rehabilitation.

Each patient was informed of the purpose of this study, and verbal and written consent was obtained. Patient anonymity was preserved. This study was approved by the Institutional Review Board of Hyogo Rehabilitation Centre (no. 1523) and it was conducted in accordance with the protocol and it followed the ethical and humane principles of human research.

### ***Stump management programme using silicone liners (silicone liner programme)***

The duration of the programme naturally varied according to the unique circumstances of individual amputees, but the standard programme was as described as follows. After wound closure was confirmed,

compression treatment of the stump with a silicone liner was initiated and continued for 2 weeks (Figure 1). The choice of silicone liner that was used, either an ICEROSS DERMO (Össur, Reykjavik, Iceland; January 2006 to December 2010) or a 6Y75 Skeo Skinguard (Ottobock, Duderstadt, Germany; January 2011 to December 2014), was based entirely on the time period in which the patients were admitted to the hospital. The silicone liner fitting period began at 1 h/day and was gradually increased by 2 h/day to eventually reach 8 h/day. From the third week, a provisional prosthesis was made, using cast sockets and silicone liners, with training in standing up between parallel bars beginning on the same day (Figure 2). Training in standing up and walking between parallel bars for 2 weeks was followed by 2 weeks of walking training using walking aids. During that period, suitable silicone liner sizes were selected and changed according to the condition of the stump, when necessary. The cast socket was also remade when necessary. From the seventh week, a provisional prosthesis was made using thermoplastic sockets with silicone liners fitted (Figure 3). The programme was completed after another 2 weeks of intensive walking training, which included applied action training such as going up and down slopes and stairs, and walking outside near to the rehabilitation centre. Ideally, the total duration of the programme was 8 weeks, but it was appropriately extended according to a patient's ability to walk with their prosthesis. A schematic representation of the silicone liner programme is shown in Figure 4.

When determining the silicone liner size, the circumference at a location 4 cm from the stump end was measured according to the manufacturer's instructions, and then a liner that was one-size smaller than the measured value was, in principle, chosen. Before starting a pressure treatment, a liner of the selected size was tried on by the



**Figure 1.** Stump management using a standardized silicone liner programme following unilateral transtibial amputation in patients with peripheral arterial disease. The first stage after wound closure has been confirmed is to fit a silicone liner so that compression treatment of the stump can be initiated. The colour version of this figure is available at: <http://imr.sagepub.com>.

patient under the supervision of a physician for 15 min to check the sense of constriction at the stump and the state of the skin. If no problems were found during the first check, another trial fitting was done for 15 min to confirm the same points. If no problems were found after these two trials, a pressure treatment was started from the following day. The treatment was stopped immediately if something undesirable or abnormal was found on the skin due to wearing the liner. If the subject complained about a strong sense of constriction at the stump, successive liners each being one size larger than the preceding one were tried until one of the appropriate size that caused no sense of constriction was found. Then, a liner of the suitable size was adopted so as to avoid constriction.

In this programme, no stump treatment except the adoption of a compression

treatment using a silicone liner was used during the rest of the day and night. After starting the training with a provisional prosthesis, the time span for wearing a silicone liner was set at 8 h/day. The silicone liner was fitted by the patient alone without help from others.

#### *Stump management programme using soft dressings (soft dressing programme)*

The soft dressing programme was used for stump management prior to the introduction of silicone liner use in 2006 and it did not include protocols for specific stump management and rehabilitation based on a time-series framework.<sup>14,16</sup> Therefore, programme content was established, such as the timing of provisional prosthesis application and gait training, as needed according to the degree of stump maturity and the physical



**Figure 2.** Stump management using a standardized silicone liner programme following unilateral transtibial amputation in patients with peripheral arterial disease. From the third week, a provisional prosthesis (cast socket and silicone liner) was made, and the patient stood in parallel bars on the same day. The colour version of this figure is available at: <http://imr.sagepub.com>.

conditions of amputees, by making good use of the experience of physicians and therapists. Specifically, stump treatment using elastic bandages was introduced so that the programme could be performed for the largest possible number of hours per day. The compression treatment using elastic bandages was conducted by a physician or clinical nurses. A provisional prosthesis using a thermoplastic socket with an inner socket using a suspension cuff was made when stump maturity was achieved (judged by physicians and prosthetists), and training in standing up between parallel bars began. Training in standing up and walking between parallel bars was followed by

walking training using walking aids. The soft dressing programme was completed after applied action training such as going up and down slopes and stairs, and walking outside near to the rehabilitation centre. The training procedure and the goal of the prosthetic walking were the same as for the silicone liner programme, but the duration of each type of training was not fixed in the same way as it was for the silicone liner programme.

#### *Investigation of clinical information*

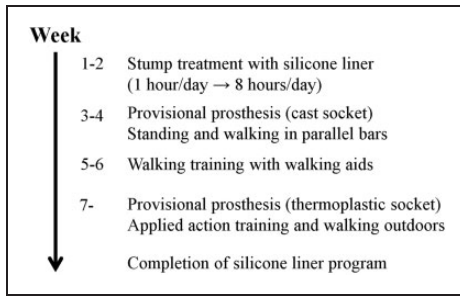
The interval between amputation and admission to the Department of Physical



**Figure 3.** Stump management using a standardized silicone liner programme following unilateral transtibial amputation in patients with peripheral arterial disease. From the seventh week, a thermoplastic socket was fitted and applied action walking training was undertaken. The colour version of this figure is available at: <http://imr.sagepub.com>.

Medicine and Rehabilitation, the stump length (length from knee joint to stump end), and the durations required for the silicone liner programme and the soft dressing programme were retrieved from the

medical records. The duration required for the silicone liner programme was defined as beginning on the first day of silicone liner compression treatment and ending with the completion of provisional prosthesis



**Figure 4.** Schematic presentation of the protocol used for stump management using a standardized silicone liner programme following unilateral transtibial amputation in patients with peripheral arterial disease. This programme consisted of an 8-week time-series framework that could be extended according to a patient's ability to walk with a prosthesis following training.

training. The duration required for the soft dressing programme was defined as beginning on the first day of soft dressing management and ending with the completion of provisional prosthesis training. A retrospective comparison was conducted to evaluate the effects of the silicone liner programme on reducing the rehabilitation period compared with the soft dressing programme.

### Statistical analyses

All statistical analyses were performed using the SPSS<sup>®</sup> statistical package, version 20.0 (SPSS Inc., Chicago, IL, USA) for Windows<sup>®</sup>. Continuous variables (age, interval between amputation and admission, stump length and duration of training) were compared with Student's *t*-test and categorical variables (sex) with  $\chi^2$ -test. A *P*-value < 0.05 was considered statistically significant.

### Results

A total of 16 patients (13 males and three females) underwent unilateral transtibial amputations due to PAD and then

underwent the standardized silicone liner programme. Their mean  $\pm$  SD age was  $62.1 \pm 11.8$  years. Eight patients were fitted with an ICEROSS DERMO silicone liner and eight patients were fitted with a 6Y75 Skeo Skinguard silicone liner. The control group consisted of 11 patients (nine males and two females) who had undergone unilateral transtibial amputation due to PAD that was followed by a soft dressing programme for stump management. Their mean  $\pm$  SD age was  $56.3 \pm 12.6$  years.

There were no statistically significant differences in age, sex, interval between amputation and admission to the rehabilitation centre and stump length (Table 1). The mean  $\pm$  SD duration required for the completion of the prosthetic training programme was significantly shorter for the silicone liner programme compared with the soft dressing programme ( $77.3$  days  $\pm$  13.4 versus  $125.4$  days  $\pm$  66.4 days, respectively;  $P < 0.05$ ). The type of silicone liner (ICEROSS DERMO or 6Y75 Skeo Skinguard) had no influence on the duration taken to complete the training for the silicone liner programme (mean  $\pm$  SD  $76.3 \pm 12.3$  days versus  $78.3 \pm 15.2$  days, respectively). All patients in this study completed their prosthetic training programme without: (i) any interruptions from major complications, such as the need for wound debridement; and (ii) any internal complications that needed to be treated at another hospital during the rehabilitation period.

### Discussion

The results in this present study showed that a standardized prosthetic rehabilitation programme using silicone liners for vascular transtibial amputees significantly reduced the rehabilitation period compared with a conventional soft dressing programme. These results suggest that a silicone liner programme may be a favourable method for

**Table 1.** Demographic characteristics and results for patients who underwent stump management using a standardized silicone liner programme or a soft dressing programme following unilateral transtibial amputation resulting from peripheral arterial disease.

Characteristic	Silicone liner programme group, n = 16	Soft dressing programme group, n = 11
Age, years	62.1 ± 11.8	56.3 ± 12.6
Sex, male/female	13/3	9/2
Interval between amputation and admission, days	68.6 ± 38.3	80.3 ± 41.8
Stump length, cm	14.5 ± 2.7	13.2 ± 1.9
Duration of prosthetic training, days	77.3 ± 13.4*	125.4 ± 66.4

Data presented as mean ± SD or n of patients.

\* $P < 0.05$  compared with the soft dressing programme group; continuous variables were compared with Student's *t*-test and categorical variables (i.e. sex) with  $\chi^2$ -test.

postoperative stump management and prosthetic rehabilitation for transtibial amputation caused by PAD.

Although using a rigid dressing is a recommended method for both postoperative stump management and the subsequent prosthetic rehabilitation,<sup>6,15,17-20</sup> this method greatly relies on the experience and expertise of the physicians and skilled prosthetic team responsible for the patient.<sup>14</sup> Therefore, its application in clinical practice can be difficult, particularly in a community hospital setting. Soft dressing management is easier and safer to apply for vascular transtibial amputees, but it needs a longer time to achieve wound healing, resulting in delayed prosthetic fitting, and it might increase the time taken for prosthetic rehabilitation.<sup>6,14</sup> Various reports demonstrated the efficacy of a removable rigid dressing using silicone liners for achieving earlier stump healing and a reduction of stump volume,<sup>6,16-20</sup> and for reducing the rehabilitation period,<sup>17-20</sup> compared with soft dressing management. In the present study, the mean duration of prosthetic training required for the silicone liner programme was 77.3 days, a significant reduction of 48.1 days compared with the soft dressing programme. The silicone liner programme investigated in the present study was applied to patients referred from other

institutions for a certain period after amputation, so there was no continuous process from amputation through rehabilitation, a point which differs from other reports.<sup>17-20</sup> However, provided that the silicone liner programme is implemented promptly after wound closure, it appears that the required period for rehabilitation can be shortened compared with conventional soft dressing stump management. The reliable effect of the silicone liner on the facilitation of stump maturation might be the factor that contributed to a shorter rehabilitation duration in the silicone liner programme.<sup>17,18</sup>

Another problem associated with rigid dressing management is it makes accessing the wound much more difficult and thus makes it harder for the medical staff to detect any complications resulting from the amputation, especially those caused by PAD.<sup>14</sup> Removable rigid dressings with silicone liners makes wound inspection much easier than rigid dressings with plaster casts, and solves the problem of wound complications related to rigid dressings. In this present study, none of the patients experienced stump wound complications in either study group. These present findings suggest that the standardized silicone liner programme can be safely used in patients with transtibial amputations.



Conventional soft dressing stump management using elastic bandages has disadvantages, such as variations observed in the progress of stump maturation, which depends on the skill level of the medical staff in charge.<sup>17,18</sup> Furthermore, soft dressing management lacks the protocols for consistent stump management and rehabilitation based on a time-series framework.<sup>14,16</sup> A standardized silicone liner programme presents clearly defined protocols in this respect (Figure 4), which might be regarded as one of the factors that reduced the rehabilitation period. Even if adequate dressing management is not available immediately after amputation surgery in institutions that lack well-established stump management and rehabilitation programmes, the standardized silicone liner programme could sufficiently achieve the facilitation of stump maturation as well as effectively reduce the time needed for rehabilitation, provided that this programme is applied properly after wound closure. This standardized silicone liner programme may be feasible in a community hospital setting that lacks a skilled prosthetic team. The numbers of elderly transtibial amputees due to PAD is expected to increase considerably in the future.<sup>22</sup> Therefore, the establishment of an effective stump management protocol is important for both improving patient outcomes and managing the economics of healthcare. Using the standardized silicone liner programme might contribute towards helping both of these issues by reducing the time taken for patient prosthetic rehabilitation.

This present study had several limitations. First, the sample size was relatively small, so verification by multicentre studies recruiting larger sample sizes is required. Secondly, it was not clear whether the silicone liner programme could replace rigid dressing management because there were no past data available for a comparison

study. Thirdly, the study evaluated the rehabilitation duration as a primary outcome measure to show the efficiency of the standardized silicone liner programme compared with the soft dressing programme. However, the patients in the soft dressing programme group were admitted up to 14 years earlier than those in the silicone liner programme group, which brings into question the suitability of the soft dressing programme group as a reliable comparator group. However, the demographic and clinical characteristics of the patients in both groups were similar in terms of age, sex, interval between amputation and admission to the rehabilitation centre and stump length. In addition, the stump wound in every patient had already healed at the time of starting either programme. Physical conditions were also similar in terms of their ability to stand on their nonamputated leg, the presence of upper extremity function, and the absence of comorbidities relating to Steinberg factors. The goal of prosthetic rehabilitation was also the same in both groups. Furthermore, the funding models for supply of prosthesis and prosthetic rehabilitation have not changed (except for the introduction of silicone liners) in Japan over the period of this study. Taking all of these factors into consideration, the patients in the soft dressing programme group were considered to be reliable comparators for the silicone liner programme group.

In conclusion, the findings of the present study showed that the application of a standardized silicone liner programme reduced the duration of rehabilitation in patients who had undergone unilateral transtibial amputation as a result of PAD. This standardized silicone liner programme could be applied after wound closure regardless of the stump management method employed immediately after amputation and it might also be feasible in a community hospital setting that lacks a skilled prosthetic team.

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## Declaration of conflicting interests

The authors declare that there are no conflicts of interest.

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