► **Original Article** ◀

A Novel Arm Sleeve for Upper Extremity Lymphedema: A Pilot Study

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Objective: To investigate the safety and efficacy of a novel arm sleeve composed of a conventional arm sleeve extending to a wider area of the body.

Materials and Methods: Five subjects with post-mastectomy upper extremity lymphedema, who had already been using their own arm sleeve, used a brand-new conventional arm sleeve for 2 weeks, followed by a novel arm sleeve for 2 weeks. The adverse events, arm-related symptoms, interface pressures, and subcutaneous fluid distributions observed by magnetic resonance imaging (MRI) were assessed.

Results: The use of the novel arm sleeve resulted in a graduated compression extending to the shoulder (forearm, 21.8 ± 3.7 mmHg; upper arm, 15.2 ± 3.3 mmHg; shoulder, 8.8 ± 3.1 mmHg). By eliminating the wring seen in the conventional arm sleeve, the disturbed proximal diffusion of the subcutaneous fluid and venous occlusion were successfully avoided, as confirmed by MRI. No adverse event or worsening of arm-related symptoms was reported.

Conclusion: The novel arm sleeve seemed to provide graduated compression to a wider area, allowing improved subcutaneous fluid and venous drainage without any adverse events. Therefore, the novel arm sleeve may be recommended as a compression therapy option for upper extremity lymphedema.

Keywords: arm, lymphedema, sleeve, compression

Introduction

It is estimated that 1.38 million women worldwide are diagnosed with breast cancer every year,¹⁾ with approximately 21% of patients developing arm lymphedema.²⁾ For these patients, combined physical therapy (CPT) is recommended as a first-line, non-operative treatment, which involves two phases. The first phase aims to provide aggressive decongestion,

while the second phase aims to maintain and optimize the outcome of the first phase.³⁾ In this maintenance phase, elastic arm sleeves are widely used as a tool for compression therapy. The most popular design of the arm sleeve consists of covering the region extending from the wrist to the axillary level, and holding it in place using rubber bands at each end. However, these rubber bands often wring the arm, which may worsen the edema. On the other hand, loosening the proximal band may cause it to slip down. To overcome these problems, a strap has been used, instead of the proximal rubber band, in another arm sleeve. Although the strap design does not wring the upper arm, many patients do not find it comfortable and stable. In addition to the hand and arm, upper extremity lymphedema also affects the shoulder and adjacent trunk quadrant.⁴⁾ Therefore, compression therapy for patients with upper extremity lymphedema should ideally be applied to all areas at risk,

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Received: January 26, 2014; Accepted: March 19, 2014
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Fig. 1 The novel and conventional arm sleeves. (A) Left: the novel arm sleeve; Right: the conventional arm sleeve. (B) Interface pressures derived from the sleeves.

similarly to the pantyhose-type garment used for lower extremity lymphedema. For this purpose, we have developed a prototype of a novel arm sleeve. This is composed of an arm sleeve extending to a wider area of the body to improve the stability of the arm sleeve, and to provide compression to the shoulder and part of the body trunk (Fig. 1A, left). In this pilot study, we tested the safety and efficacy of this novel arm sleeve.

Patients and Methods

This study was approved by the Institutional Review Board at Yamaguchi University Hospital (Ube, Yamaguchi, Japan). All participants signed an informed consent form before enrollment in this study. The subjects were five patients aged 48–78 years (median,

70 years), with post-mastectomy upper extremity lymphedema. All of these patients were in stage II lymphedema. Three patients had level II, and one had level III lymph node dissection at the time of mastectomy. In one patient, the detailed information about the surgery could not be obtained because it was 30 years ago. These patients were already in the maintenance phase of complex physical therapy, namely, they had used their own sleeves prior to enrolling in the study. The characteristics of the patients and their pre-study arm sleeves are summarized in Table 1. All of them had used arm sleeves from the wrist to the axillary level, whose proposed interface pressures were similar to those of currently tested arm sleeves. They tended to use their own arm sleeves for excessive periods (range, 7–26 months; median, 13 months). In the current study, each patient was provided with a brand-new Medical Support® arm sleeve (Medicks Corporation, Tokushima, Japan) of an appropriate size, which covered the area from the wrist to the axillary level. We ensured that the interface pressure (15–25 mmHg at the wrist) generated by the novel arm sleeve was the same as that generated by the conventional sleeve (Fig. 1A, right).

A prototype of the novel, tailor-made arm sleeve was provided by the Medicks Corporation (Japan). The characteristics of the arm part of this sleeve are the same as those of the arm part of the conventional sleeve. The large elastic body piece to cover the shoulder and the body trunk was attached to the novel sleeve, which was made of nylon (97%) and polyurethane (3%) with the front part fastened using Velcro (Fig. 1A, left).

Study protocol

At the beginning of the study, the initial assessment (Assessment 1) consisted of the measurement of arm circumferences, administration of a questionnaire on arm-related symptoms, and measurement of interface pressures when the brand-new conventional arm sleeve was worn.

Arm circumferences were measured immediately after the patients' own arm sleeves were removed. Starting at the cubital fossa, circumferences were measured at 5 cm intervals, upward to the axillary level and downward to the wrist. In the questionnaire for arm-related symptoms, five symptoms (heaviness, dullness, tension, shoulder stiffness, and arm pain) were evaluated, in which each symptom

Table 1 Characteristics of the patients and their arm sleeves

Subject	Age	Duration of lymphedema (years)	Pre-study arm sleeve	Proposed interface pressure (mmHg)	Period of use (months)
1	48	4	Maxis® arm sleeve, class II (MAXIS a.s., Krásno nad Bečvou, Czech Republic)	23–32	7
2	66	2	Medical Support® arm sleeve (Medicks Corporation, Tokushima, Japan)	15–25	12
3	78	26	Maxis® arm sleeve, class II (MAXIS a.s., Krásno nad Bečvou, Czech Republic)	23–32	14
4	78	1	Medical Support® arm sleeve (Medicks Corporation, Tokushima, Japan)	15–25	13
5	70	7	Mediven® 95 arm sleeve, class I (Medi GmbH & Co.KG, Bayreuth, Germany)	18–21	26

was graded as: none, 0; mild, 1; moderate, 2; and severe, 3. The interface pressures for the conventional arm sleeve were measured using an air pack-type analyzer (Model AMI-3037-SB; AMI Co., Tokyo, Japan). The measurements were performed with the subjects sitting with their arms in the dependent position. The upper arm sensors were placed in the front aspect of the biceps brachii muscle, 10 cm proximal from the cubital fossa, while the forearm sensors were placed in the front aspect of the flexor carpi radialis muscle, 10 cm proximal to the wrist. The interface pressure at the body trunk was not assessed, because the body piece was adjustable and the interface pressure could not be kept constant there.

Following the first assessment, patients were asked to apply the conventional arm sleeve during daytime, for 2 weeks. The second assessment consisted of an MRI of the arm with the conventional arm sleeve, measurement of arm circumference, administration of a questionnaire for arm-related symptoms, and measurement of interface pressures with a novel arm sleeve.

This assessment also included measurement of the interface pressure at the shoulder (at the middle of the deltoid muscle). The 3.0 T superconductive MRI system (MAGNETOM Skyra; SIEMENS, Munich, Germany) was used to measure the subcutaneous fluid distribution. In addition, short TI inversion recovery (STIR) 3D (TR 2000 ms, TE 77 ms, TI 220 ms, slice thickness 0.9 mm, Acq. matrix: 320 × 320), and STIR 2D (TR 4800 ms, TE 78 ms, TI 220 ms, slice thickness 4 mm, Acq. matrix: 224 × 320) sequences were

obtained in the area extending from the shoulder to the proximal forearm. Following the second assessment, patients were asked to apply the novel arm sleeve during daytime, for 2 weeks. The third and final assessment consisted of an MRI of the arm with the novel arm sleeve, measurement of arm circumferences, administration of a questionnaire for arm-related symptoms, and administration of a questionnaire to compare the conventional and novel arm sleeves.

In this last questionnaire, the novel arm sleeve was compared to the conventional arm sleeve in terms of stability of the arm sleeve, arm mobility, comfort, and chest compression. The grading system was as follows: very unfavorable, –2; unfavorable, –1; the same, 0; favorable, 1; very favorable, 2.

During the study, the patients were allowed to use their own mittens or gloves. Since the duration of compression to the hand is uneven due to their activity conditions (housework, business, etc.) assessment of the hand was not performed in this study.

Statistical analysis

The results are expressed as mean ± standard deviation or count, unless otherwise indicated. The extremity volume was calculated using the following formula for a truncated cone⁵⁾: $V = h(C^2 + Cc + c^2)/12\pi$, where V is the volume (mL) of an extremity segment, C and c are circumferences (cm) at each end, and h is the distance between the ends (cm). Thus, the extremity volume is the sum of all segment volumes, except the hand. We also calculated the percentage excess

volume⁶⁾ using the following formula: *percentage excess volume* = $[(V_a - V_u)/V_u] \times 100$, where V_a represents the volume (mL) of the affected arm and V_u represents the volume of the unaffected arm (mL).

The Kruskal-Wallis test was used to test the differences in interface pressures, extremity volumes, percentage excess volumes, and scores obtained from questionnaires in each assessment. The Wilcoxon signed-rank test was used for multiple comparisons. Statistical analyses were performed using JMP 11.0 (SAS Institute, Cary, North Carolina, USA). A p -value <0.05 was considered significant.

Results

No adverse event was observed during the use of either the conventional or the novel arm sleeve, during the study period.

Interface pressures achieved by the sleeves are shown in **Fig. 1B**. In the forearm and upper arm, the conventional and novel arm sleeves showed similar interface pressures (forearm, 22.4 ± 2.5 vs. 21.8 ± 3.7 mmHg, respectively; upper arm, 15.8 ± 2.7 vs. 15.2 ± 3.3 mmHg, respectively). With the novel arm sleeve, the shoulder was subjected to a pressure of 8.8 ± 3.1 mmHg, confirming that a successful graduated compression was achieved up to this level.

When the subject's own arm sleeves were changed to a brand-new conventional arm sleeve, a significant reduction of the total arm volume (2087 ± 574 vs. 2015 ± 55 mL, $p < 0.05$, respectively) as well as percentage excess volume ($17.8\% \pm 14.9\%$ vs. $13.8\% \pm 14.7\%$, $p < 0.05$, respectively) were observed. Following the application of the novel arm sleeve, an insignificant but additional reduction of arm volume (1982 ± 543 mL, $p = 0.09$ vs. the conventional arm sleeve) and percentage excess volume ($11.9\% \pm 14.0\%$, $p = 0.09$) were observed (**Fig. 2**).

With the conventional arm sleeve, the MRI examination of the upper extremity revealed an accumulation of marked subcutaneous fluid distal to the wringing by the proximal rubber band in four out of five subjects. (**Fig. 3A** and **3B**) In one subject (subject 1), subcutaneous fluid accumulation was not observed in the upper arm. In the shoulder, subcutaneous fluid accumulation was not observed in four out of five subjects. Only one subject (subject 4) had a mild accumulation of fluid along the muscular fascia (**Fig. 3E**). At the level of the proximal wring of the conventional

Fig. 2 Changes in the extremity volume and percentage excess volume. (A) Whole arm. (B) Upper arm and forearm. The black line indicates the changes in mean values. †: $p < 0.05$ vs. assessment 1.

arm sleeve, various degrees of occlusion of the superficial and deep veins were observed in all subjects (**Fig. 3C** and **3D**).

With the novel arm sleeve, the proximal wring was successfully eliminated, allowing the subcutaneous fluid that had accumulated to extend more proximally beyond this level (**Fig. 3F** and **3G**). The occlusions of the veins were successfully freed as well (**Fig. 3H** and **3I**). In subject 4, the fluid accumulation along the muscular fascia was reduced when the novel arm sleeve was used (**Fig. 3J**).

In terms of arm symptoms related to lymphedema, the use of the novel arm sleeve did not result in any improvement or worsening (**Fig. 4A**). When the novel arm sleeve was directly compared to the conventional

Fig. 3 Magnetic resonance imaging (MRI) in the affected upper extremity. (A) The affected arm of Subject 2, who is wearing a conventional arm sleeve. The proximal rubber band wrung the upper arm (thick white arrow). (B) Subcutaneous fluid accumulation (thin white arrow) is observed below the level of the wring (thick white arrow). Note that no subcutaneous fluid accumulation is observed above this level. (C) At the level of the proximal wring (thick white arrow), venous flow is disturbed (thin white arrow). (D) At the level of the proximal wring, the arm shape became round due to excessive pressure. The visualization of both superficial and deep veins is reduced (thin white arrows). (E) The thin subcutaneous fluid accumulation along with the muscular fascia (thin white arrow) is only observed in subject 4. (F) The affected arm of subject 2, who is wearing a novel arm sleeve. (G) The proximal wring disappeared, and the subcutaneous fluid accumulation extended more proximally (thin white arrow). (H) Venous flow is not disturbed (thin white arrow) with the novel arm sleeve. (I) Without the proximal wring, the arm shape seemed closer to its original shape. The visualization of both superficial and deep veins is improved when compared with Fig. D (thin white arrows). (J) The subcutaneous fluid accumulation along with the muscular fascia in subject 4 is reduced.

one, all subjects were satisfied with the stability of the arm sleeve, although three out of five subjects complained of discomfort due to chest compression (Fig. 4B).

Discussion

There were several major findings in this study. First, the use of the novel arm sleeve did not result in any adverse event or worsening of arm symptoms. Second, a successful graduated compression from the wrist up to the shoulder was achieved using the novel arm sleeve. Finally, the use of the novel arm sleeve

eliminated the wring in the upper arm, allowing the disturbed proximal diffusion of the subcutaneous fluid and the venous occlusion to be freed.

The basic concept behind the currently tested novel arm sleeve was based on the elimination of the proximal wring from the rubber band. This new design aims to increase stability of the arm sleeve, and to achieve a graduated compression extended to a broader area. Our study seems to have accomplished this purpose.

Prior to the current study, the subjects had been using their own arm sleeves, which intended to provide similar interface pressures to that derived from

Fig. 4 (A) Changes in arm symptoms, (B) Evaluation of the novel arm sleeve compared to the conventional arm sleeve.

currently tested sleeves, but they tended to use them for excessive periods (median, 13 months). A previous study reported that the interface pressure achieved by elastic stockings decreased with repeated use.⁷⁾ Therefore, it might be natural that the extremity volume significantly reduced after changing to a brand-new conventional arm sleeve. An interesting finding was that the use of the novel arm sleeve resulted in an additional reduction of the extremity volume, although this increase was insignificant.

One possible explanation for this additional reduction may be related to the improved subcutaneous fluid drainage. In the MRI findings, a marked accumulation of subcutaneous fluid was observed distal to the wring in the upper arm, when a conventional arm

sleeve was used. When a novel arm sleeve was used, the subcutaneous fluid was released and extended more proximally. Regardless of the type of arm sleeve used, no fluid accumulation, other than epi-fascial fluid, was observed in the shoulder area. This observation suggests that the subcutaneous fluid is sufficiently drained in the shoulder area. Thus, fluid transport from the upper arm to the shoulder area may contribute to the reduction in extremity volume. Another explanation may be that the venous drainage is improved. In the MRI findings, occlusion of both superficial and deep veins was observed at the level of the wring in the upper arm. Therefore, the reduced extremity volume observed after releasing the wring may be due to venous occlusion, resulting

in venous congestion and increased interstitial fluid.⁸⁾ A third explanation may be that the “brand-new” effect may have affected the interface pressure. The use of a brand-new conventional arm for only 2 weeks should not cause a significant reduction in interface pressure. However, the use of the “brand-new” novel arm sleeve may have resulted in an added “brand-new” effect. Although the reduction in extremity volume may be considered negligible (approximately 30 mL), the possible explanations discussed above need to be explored in future studies.

In our study, the use of the novel arm sleeve did not result in any improvement or worsening of the subjective arm-related symptoms. In one subject, a reduction in subcutaneous fluid accumulation was noted in the shoulder area, indicating the possible benefit for patients with edema in this area. In addition, all subjects seemed to be satisfied with the stability of the novel arm sleeve, although three out of five subjects complained of discomfort due to chest compression. Such complaints can be expected given the current design of the novel arm sleeve; however, future refinements will aim to improve comfort and arm mobility.

Conclusion

We introduced a prototype of a novel arm sleeve that eliminates the wring in the upper arm and provides graduated compression to a wider area, without any adverse events. Various types of compression stockings are available for lower extremity lymphedema, such as long stockings, long stockings with a belt, pantyhose, etc. These are chosen according to the extremity volume, as well as the extent of the symptoms, patients'

preferences, and expected adherence. Similarly, the novel arm sleeve may widen the choice in compression therapy for upper extremity lymphedema.

Acknowledgement

This study was financially supported by Medicks Corporation (Tokushima, Japan).

Disclosure Statement

All authors declare no conflict of interest.

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