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ORIGINAL ARTICLE

A prospective randomised study of alginate-drenched low stretch bandages as an alternative to conventional lymphologic compression bandaging

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Abstract
Background Breast-cancer-related lymphoedema, either caused by the tumour itself or its therapy, can be found in approximately 24% of all patients. It results in disabilities, psychological distress and reduced quality of life. Therefore, proper therapy for this entity is very important. Guidelines recommend a therapy in two phases, an intensive phase I for 3 weeks for volume reduction and, between the cycles of phase I, a reduced phase II to maintain the result. During phase I therapy, manual lymphatic drainage often cannot be administered on weekends or holidays; only a reduced therapy, mainly by application of a more or less passive compression by bandaging, is administered. For this, conventional low-stretch bandages are hitherto being used. Several attempts have been made to overcome this disadvantage by either impregnating or covering the bandage with sticky or adhesive substances such as india rubber, elastomeres, polyacrylates, etc. Recently, new bandages are available, which are drenched with alginate that becomes semi-rigid after drying for approximately 6 h. It was the aim of this study to compare alginate bandaging to a conventional lymphologic-multilayered low-stretch bandaging with individual supportive lining as to their effect concerning their congestive capacity in exactly delimited time periods of reduced decongestive therapy as well as the patients' tolerance.
Materials and methods From December 2007 until May 2008, 61 female patients with a one-sided lymphoedema of the axillary tributary region after axillar dissection who underwent a phase I complex decongestive therapy were prospectively selected for our investigation. On weekends, group A got the conventional low-stretch compressive bandaging, whereas group B got an alginate semi-rigid bandage. Arm volumes were measured before and after these bandages were applied. Additionally, the subjective sensations of the skin caused by the compression were measured by means of a five-level Likert scale.
Results and conclusions The initial volumes (V_0) of the two groups (A, 2,939.0 ml±569.182; B, 3,062.6 ml±539.161) varied within the same magnitude, with somewhat smaller values in group A. The same was true for the final volumes (V_6), measured at day 22 (A, 2,674.5 ml±480.427; B, 2,740.1 ml±503.593). During the weekends, the arm volumes re-increased (first weekend: A, 16.4 ml vs. B, 4.7 ml; second weekend: A, 14.2 ml vs. B, 2.7 ml; third weekend: A, 7.5 ml vs. B, 1.1 ml). A significantly smaller

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volume increase appeared in the alginate group during the weekends. There were no serious side effects in both groups. Concerning the patients' comfort, the values of the alginate group were clearly better than those of the conventionally bandaged group. Additionally, the volume changes in the alginate group revealed fewer fluctuations. As a summary, one can state that a good alternative to the conventional bandaging is available with the alginate bandages, bringing distinct advantages for the patients when administered properly.

Keywords Breast-cancer-related lymphoedema · Post-mastectory lymphoedema · Chronic lymphoedema · Bandages/alginate-drenched · Bandages/conventional · Prospective randomised controlled trial (pRCT)

Introduction

Breast-cancer-related lymphoedema is a well-known and widespread entity [1, 2]. In 2006, Neuhüttler et al. [3] calculated in their review that approximately 24% of patients (2,459 out of 10,259 patients) with breast cancer will suffer from a lymphoedema, either caused by the tumour itself or its therapy. Based on the given incidences of the tumour, they calculated a worldwide incidence of breast-cancer-related lymphoedema with 275,966 patients a year. Such a lymphoedema results in disabilities, psychological distress, and reduced quality of life [4]. Additionally, on such a lymphoedema, also a Stewart–Treves syndrome might develop as a lethal complication [5, 6]. Therefore, proper therapy for this entity may well be of even vital importance [7-11].

The guidelines [12-14] recommend a therapy in two phases, an intensive phase I consisting of manual lymphatic drainage (MLD), multilayered inelastic compression bandaging, remedial exercises, meticulous skin care and other supportive measures for 3 weeks for volume reduction and, between the cylces of phase I, a reduced phase II to maintain the results by means of using a daytime elastic compression sleeve or stocking, nocturnal wrapping as well as continued exercises [15-17].

Nevertheless, there is a problem during phase I therapy. In many cases, MLD can be administered on normal working days but not on weekends or holidays. During these days, only a reduced therapy can be administered, mainly by application of a more or less passive compression by bandaging. For bandaging, hitherto conventional low-stretch bandages are being used [18]. These bandages have the disadvantage of loosening quite soon and therefore cannot be applied for a day and night without redressing. Several attempts have been made to overcome this disadvantage by either impregnating or covering the bandage with sticky or adhesive substances such as India rubber, elastomeres, polyacrylates, etc. Unfortunately, several of these substances may result in contact eczema or allergies [19, 20].

Recently, new bandages drenched with alginate have been made available. Alginates, a product obtained from brown sea algae, have been used for chronic wounds for many years and are a solid component of a modern humid wound treatment [21, 22]. Alginates have not only an absorbing and consequently cleaning effect but also a granulation-promoting effect. The alginate-drenched compression bandage becomes semi-rigid after drying for approximately 6 h, thus sustaining the skin's own supports and counteracting the refilling of the lymphoedema optimally, without restricting the mobility of the extremity. With respect to rigidity, this bandage may be compared to a zinc bandage. Its advantage lies in the water-solubility of the alginate component. Therefore, the bandage can be removed by wettening without any problems, even by the patients themselves. Additionally, a welcome chilling effect occurs with corresponding moderate re-moistening. Furthermore, this bandage needs a two-layer wrapping only.

Our primary goal was to determine whether a difference exists between conventional and alginate bandaging in the sense of a lower volume increase or re-filling of the lymphoedema, when the bandages are applied in periods with reduced decongestive therapy. A secondary goal was to find out the tolerance on the part of the patients.

Materials and methods

Ethical issues

The current study was approved by the Ethical Committee for Salzburg (Austria), no. 888. All patients gave their informed consent before study commencement.

Study concept

From December 2007 until May 2008, 61 female patients with a one-sided lymphoedema of the axillary tributary region (i.e. the region drained by the axillar lymphatics) after axillar dissection (level I or II) due to the treatment of breast cancer by modified mastectomy (five patients) or lumpectomy (56 patients), who were assigned to a 3-week inpatient lymphologic rehabilitation, were prospectively selected for the investigation. None of these patients showed additional alterations of the skin, such as infections, hyperkeratosis, papillomatosis, fistulae, cysts, or ulcerations. Thirty-five patients had radiation, three of them adiuvant chemotherapy. Forty-one patients underwent a non-standardised treatment with MLD and compression

garment 6 month prior to this admission. Randomisation took place before admission to the treatment by assigning the patients randomly to one of the two alphanumeric groups, with group A receiving conventional bandaging and group B alginate bandaging. The average age of the patients was 57.4 years ±8.926, with a maximum of 81 and a minimum of 28 years. During their stay, all patients were subjected to a phase I complex decongestive therapy (CDT).

All patients suffered form a unilateral lymphoedema of stage 2 or 3 according to ISL-staging [13] for a mimimum of 6 months up to 5 years before admission, and all were classified L>2, V>2, F>2 according to the localization–volume-fold index (LVF) classification [23] (see also Table 1).

Exclusion criteria were acute additional diseases, such as erysipelas, a possible malignant lymphoedema, pregnancy, current radiation or chemotherapy, thrombembolic processes, hyperthyreosis, decompensated heart insufficiency as well as coagulopathies. Additionally, intolerance of the bandaging made obvious by skin reactions was declared a stop criterion.

A detailed therapy plan is given in Table 2. All patients received a MLD from Monday until Friday twice a day with a total duration of 90–120 min. In connection with this treatment, compressive bandaging including the fingers was applied. Textile-elastic low-stretch bandages from one single manufacturer were used. The supportive lining was done with cotton wool bandages and foam pads that were positioned individually [17]. For skin care, a polidocanole-containing balm was uniformly applied. As additional movement therapy (MT), a uniform water gymnastics programme in the morning and dry gymnastics in the afternoon were carried out. An accompanying intermittent pneumatic compression (IPC) was administered daily starting on the third day of treatment and also on Saturdays and Sundays, 30 min in each case with an incipient pressure of 5,333.2 Pa (40 mmHg; Lymphapress, Villa Sana, Weiboldshausen) [9, 24].

At the entrance examination, besides the lymphoedema-specific examination, a volume measurement according to Kuhnke [25] was administered. Therefore, starting at the ulnar styloid process to proximal, the circumference (c) of the respective arm was measured at every fourth centimetre. Since circumference is $c=2r\pi$ and volume is $v=r^2h\pi=(c^2/4\pi)h$, the volume of a 4-cm cylinder can be calculated by $v=c^2/\pi$. The whole volume of an arm can therefore be calculated by dividing the sum of all squares of the circumferences by π (PI; approximately 3.1415): $V=(\Sigma(c^2))/\pi$. The results are given in Table 4. Additionally, a sonographical examination of the skin thickness at standardised points, the middle ventral upper arm, the middle ventral forearm, and the middle back of the hand, was done. Echoless segments in the swollen subcutaneous tissue (lymphatic scissures) with a minimum diameter of 0.5 mm, several times described by Marshall and his co-workers, could be proven in all cases [26-28].

Intervention

All patients were in treatment for a period of 22 days and therefore in hospital for three weekends. On these weekends with restricted treatment without MLD and MT, the two types of bandages were compared. The bandages were applied in each group by the same therapist each time.

Group A got the conventional low-stretch compressive bandaging (Rosidal® K, Lohmann and Rauscher, Vienna, Austria) on Friday after the second MLD as on the other days, with the instruction not to remove the bandages before going to sleep (approximately 9 P.M.). On Saturday and Sunday mornings, after administering IPC, the patients were bandaged the same way, again with the instruction not to remove the bandages before going to sleep.

Group B got their bandaging on Friday after the second MLD with an alginate semi-rigid bandage (Alegro Alginate, Alegro Medical, Homburg, BRD), a low-stretch bandage with an average elasticity of 55% impregnated with a calcium-alginate paste. The bandage with a high working pressure, but a low pressure at rest, was applied directly to the skin. Additionally, a dermato-protective effect was achieved by the alginate impregnation.

The fingers were bandaged conventionally with a gauze bandage. The alginate bandage was applied in two crossed layers from the back of the hand to just below the axilla.

Table 1 LVF classification at the upper extremity [23]

Score	L Location	V Volume difference	F Skinfold index
1	Trunk	+<5%	1.25–2.00
2	Lower arm	+5–10%	2.00–3.50
3	Lower arm and hand	+10–25%	>3.50
4	Lower and upper arm	+25–50%	+Colour changes
5	Whole arm	+>50%	+Secondary diseases of the skin
6	Hand		

Table 2 Therapy plan for both study-groups (day 22 omitted)

	Mon	Tue	Wed	Thu	Fri	Sat	Sun
Week 1							
Day	01	02	03	04	05	06	07
Complex decongestive therapy	A+B	A+B	A+B	A+B	A+B		
Apparative intermittent compression			A+B	A+B	A+B	A+B	A+B
Movement therapy	A+B	A+B	A+B	A+B	A+B		
Conventional bandaging	A+B	A+B	A+B	A+B	A	A	A
Alginate bandaging					B	B	B
Week 2							
Day	08	09	10	11	12	13	14
Complex decongestive therapy	A+B	A+B	A+B	A+B	A+B		
Apparative intermittent compression	A+B	A+B	A+B	A+B	A+B	A+B	A+B
Movement therapy	A+B	A+B	A+B	A+B	A+B		
Conventional bandaging	A+B	A+B	A+B	A+B	A	A	A
Alginate bandaging					B	B	B
Week 3							
Day	15	16	17	18	19	20	21
Complex decongestive therapy	A+B	A+B	A+B	A+B	A+B		
Apparative intermittent compression	A+B	A+B	A+B	A+B	A+B	A+B	A+B
Movement therapy	A+B	A+B	A+B	A+B	A+B		
Conventional bandaging	A+B	A+B	A+B	A+B	A	A	A
Alginate bandaging					B	B	B

A group A with conventional bandaging, *B* group B with alginate bandaging

The patients had the possibility to moisten the alginate bandage by absolute freedom of choice during the whole day. This bandaging was not removed until Monday morning.

During IPC, the alginate bandage stayed in place, and compression was applied over the bandage. IPC was started generally with an incipient pressure of 5,333.2 Pa (40 mmHg), which was increased in consequence by 666.6 Pa (5 mmHg) until a final pressure of 7,999.8 Pa (60 mmHg).

Both groups' volumes were measured on Friday before bandaging and on Monday before the first MLD.

In addition, the patients were instructed to observe and describe exactly the skin of the bandaged arm in respect to changes, especially reddening and furrows. The patients' subjective sensations, such as pressure or heat caused by the compression, were recorded by means of a fifth-level Likert scale (with 1=very unpleasant, 2=somewhat unpleasant, 3=neutral, 4=somewhat pleasant; 5=very pleasant).

Table 3 Initial data at day 1

N=		Group A (conventional)	Group B (alginate)	χ^2 value	*P* value
L	2	2	4	3.800	0.284
	3	15	9		
	4	7	7		
	5	7	7		
V	2	17	16	0.257	0.879
	3	11	12		
	4	3	2		
F	2	16	14	2.509	0.285
	3	13	10		
	4	2	6		
ISL-stage	2	22	21	0.007	0.934
	3	9	9		
Mean volume (ml)	V_0	2,939.0	3,062.6		0.388

For L, V, and F, see Table 1

Table 4 Measured volumes

In millilitre		Group A (conventional)				Group B (alginate)				*P* value
		Mean	SD	Min	Max	Mean	SD	Min	Max	
V_0	Day 1	2,939.0	569.182	2,012	4,222	3,062.6	539.161	1,985	4,111	0.705
V_1	Day 5	2,821.1	230.613	1,990	4,080	2,868.8	529.570	1,902	4,010	0.885
V_2	Day 8	2,840.5	533.835	1,999	4,110	2,873.5	532.124	1,900	4,020	0.900
V_3	Day 12	2,720.8	488.241	2,001	3,844	2,791.8	525.228	1,810	3,970	0.764
V_4	Day 15	2,734.9	490.862	2,001	3,860	2,794.2	523.291	1,810	3,950	0.801
V_5	Day 19	2,667.0	480.131	1,930	3,822	2,739.0	504.372	1,822	3,802	0.866
V_6	Day 22	2,674.5	480.427	1,935	3,830	2,740.1	503.563	1,825	3,830	0.884

Statistics

Data were tested for plausibility (validity and reliablity) and subjected to a statistical analysis, including a univariate analysis of variance relating the two groups (SPSS 15.0, SPSS Inc.). The level of significance was set to $p=0.05$. Data in the text are presented as mean±standard deviation.

Results

No premature termination of the rehabilitation occurred.

Both groups were similar in respect to ISL stage, LVF classification, and initial volume (Table 3). Nevertheless, the initial volume of the lymphoedematous arm differed significantly with the parameter 'location', with L2 (lower arm) having the smallest mean volume and L5 (whole arm) having the highest mean volume, whereas L3 (lower arm and hand) and L4 (upper and lower arm) showed quite similar volumes. Concerning the skin-fold indices, the initial volumes increased from F2 (1.12–2.5) up to F4 (with additional changes in skin colour). Finally, patients with an ISL stage 3 showed significantly higher initial volumes than patients with an ISL stage 2.

An overview of the measured volumes on the seven different days (V_0–V_6) is given in Table 4 and Fig. 1. The initial volumes (V_0) of the two groups (A, 2,939.0 ml± 569.182; B, 3,062.6 ml±539.161) vary within the same magnitude, with somewhat smaller values in group A (conventional bandaging). The same is true for the final volumes (V_6), measured on day 22 (A, 2,674.5 ml± 480.427; B, 2,740.1 ml±503.593). The whole lymphologic rehabilitation resulted in an average reduction of the volume of 264.5 ml±174.482 [8.63%±4.960; calculated as $(1-V_1/V_0)\times 100$] in group A and 322.5 ml±139.480 (10.50%±4.433) in group B. Differences between the two groups were not significant.

A detailed analysis of the distinctive treatment periods showed the following results (see also Fig. 2).

Days 1–5 (V_0–V_1), therapy phase I

Group A The first week of intensive treatment brought a decrease of lymphatic fluid between day 1 (V_0) and day 5 (V_1) of 117.9 ml±91.118 (3.8%±2.847) in average. There was a great inter-individual variability with a maximum of 343 ml and a minimum of just 22 ml.

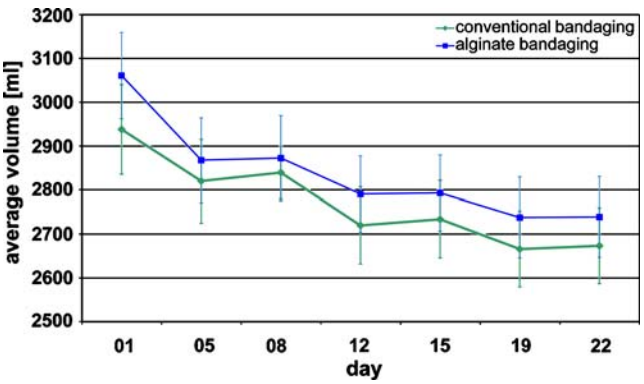

Fig. 1 Average arm volumes during phase I complex decongestive therapy. Volumes were measured by the technique provided by Kuhnke [25]. *Bars* indicate the standard error of mean. Manual lymphatic drainage (MLD) was applied only between days 1–5, 8–12 and 15–19. Between days 5–8, 12–15 and 19–22, patients wore either a conventional bandaging or an alginate bandaging (compare Table 2)

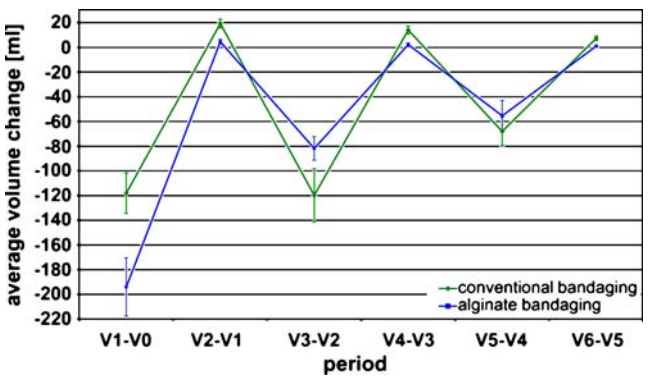

Fig. 2 Changes in arm volume in between the measurements. *Bars* indicate the standard error of mean

Table 5 Tolerance of bandaging on weekends

N	Bandaging	Likert score						χ^2 value	*P* value
		1	2	3	4	5	Mean		
Days 5–8	Conventional	5	8	13	5	0	2.58	8.886	0.064
	Alginate	0	7	11	10	2	3.23		
Days 12–15	Conventional	1	6	20	3	1	2.90	15.359	0.004
	Alginate	1	3	8	16	2	3.50		
Days 19–22	Conventional	2	9	12	8	0	2.84	11.272	0.024
	Alginate	1	3	7	14	5	3.63		

Likert scale: *1* very unpleasant, *2* somewhat unpleasant, *3* neutral, *4* somewhat pleasant, *5* very pleasant

Group B As was to be expected, in group B, the lymphatic volume also decreased in average 193.8 ml±128.933 (6.3%±4.244). Similar to group A, there was a great inter-individual variability (min, 33 ml; max, 592 ml).

It is very interesting that the differences between the two treatment groups were statistically significant (p=0.010).

Days 5–8 (V_1–V_2), therapy-reduced phase

Group A The increase in volume between the measurements V_1 and V_2 was, on average, 19.4 ml±19.662 or 0.7%±0.653, ranging from no increase (±0 ml) up to an increase of 100 ml.

Group B The change of volume between the measurements V_1 and V_2 ranged from a decrease of 24 ml to an increase of 40 ml, on average, an increase of 4.7 ml±10.752 or 0.2%±0.367.

The comparison of the two groups showed a significantly smaller increase in favour of group B (p=0.001).

Days 8–12 (V_2–V_3), therapy phase I

Group A The intensive treatment during week 2 did not result in a further decrease of volume with all patients; one patient even suffered from an increase of 2 ml. Nevertheless, there was an average decrease of 119.7 ml±12.213 (4.0%±3.477).

Group B In this group, too, one patient suffered from an increase in volume, in this case, 13 ml. On average, a decrease (81.7 ml±52.190; 2.9%±1.765) was found.

Overall, group A showed a higher loss of volume than group B, but it remained insignificant.

Days 12–15 (V_3–V_4), therapy-reduced phase

Group A In contrast to the first weekend, on this second weekend, several patients did show an additional loss of volume. Volume changes ranged from −15 ml to + 87 ml (mean, 14.2 ml±17.518; 0.5%±0.585).

Group B In this group also, there were both an increase and a decrease in volume (min, −20 ml; max, +20 ml). On average, there was a slight increase of 2.7 ml±7.337 (0.1%±0.256).

The differences between both groups were significant (p=0.001) in favour of group B.

Days 15–19 (V_4–V_5), therapy phase I

Group A Similar to week 2, the third week of intensive treatment did not suffice to reduce the volume in all patients; four patients suffered from an increase of 4–22 ml. Overall, the CDT of week 3 reduced the volume by 67.9 ml±63.941 (2.5%±2.210) in average.

Group B Similar to group A, not all patients succeded in gaining a further decrease of volume; four patients showed an increase, one of 5 ml, two of 20 ml, and another one of no less than 120 ml, and one patient showed no change of volume. Nevertheless, there was a decrease of 55.2 ml±67.980 (1.9%±2.071) in average.

The difference in the volume changes of both groups was statistically not significant.

Days 19–22 (V_5–V_6), therapy-reduced phase

Group A During the final weekend of rehabilitation, volume changes ranged between a decrease of 19 ml to an increase of 31 ml, resulting in an average increase of 7.5 ml±10.311 (0.3%±0.377).

Group B In this group, too, volume changes ranged from a further decrease (−7 ml) to an increase (+16 ml). On average, there was a slight increase by 1.1 ml±4.894 (0.0%±0.184).

The comparison of the two groups showed a significantly higher increase in group A (p=0.003).

Overall volume reduction (days 1–22; V_0–V_6)

Group A The completed lymphologic rehabilitation resulted in a reduction of volume in all patients. Nevertheless, results ranged from a minimum of just 37 ml (1.5%) to a maximum of 730 ml (19.8%). On average, we could find a decrease of volume by 264.5 ml±174.482 (8.6%±4.960).

Group B All patients in group B also showed a total reduction of volume [min, 109 ml (4.9%); max, 743 ml (26.0%)]. The average reduction was 322.5 ml±139.480 (10.5%±4.433).

Surprisingly, the differences between both groups were statistically not significant.

The physical differences concerning the reaction upon the treatments were equally distributed in both groups. Slight reddening was noted by two patients and itching by one patient in group B. Bruises and heat were each noted by one patient in group A.

The subjective sensations (tolerance) of the patients concerning the comfort of the respective bandaging are summarised in Table 5. The results reveal that the alginate bandaging was felt to be more pleasant throughout all weekends; at least, on weekends 2 and 3, the difference is statistically significant.

All patients were informed about the possibility of an increase in the local temperature and thus of an increased perspiration. All patients in group B were informed about the option of additionally moistening their bandage. This was refused by one patient because of a feeling of coldness; all other patients in the group used this option and assessed it positively.

Discussion

The patients recruited for this study had quite similar medical histories, LVF classifications, and ISL stagings. The randomisation worked properly in assigning the patients to the two groups, thus preventing a selection bias with one group showing significantly lower values.

According to the randomisation, the patients within one group also showed a wide range of initial arm volumes; therefore, the standard deviations are relatively high. This was true throughout the whole treatment period. Therefore, significant differences between the two groups were statistically quite robust. Nevertheless, by adding further patients momentarily insignificant differences might become significant, too.

During the therapy-reduced phases (days 5–8, V_1–V_2; days 12–15, V_3–V_4; days 19–22, V_5–V_6), we always found a small average increase in the volumes, with some patients, however, even loosing volume in these phases. This could be interpreted that mainly the MLD is capable to remove lymphoedematous fluid. When MLD is missing in the therapeutic regimen, it depends mainly on the compliance of the patient to do additional exercises (using the muscle pump against the rigid bandage) in order to remove lymphoedematous fluid. Another possibilty for this increase of volume might be based on a lack of compliance concerning the time of application for the compressive bandages; this would explain the higher increases in group A.

The calculated values show clearly that group B (alginate bandaging) had more advantages, both concerning the refilling of lymphoedema during the weekends (twice even significantly) and the total reduction of the lymphoedema. Moreover, the subjective parameter of patients' comfort and tolerance was clearly pronounced to be more advantageous by the the group given alginate bandaging; above all the opportunity of moistening, the bandage was judged positively.

Some patients of the group, too, expressed a high tolerance concerning the compression, and it could be shown that the refilling of the lymphoedema was delayed due to the increasing compliance of the patients.

Our study makes it obvious that the alginate bandage is an alternative with low side effects to the conventional compressive bandaging. Since it contains moisture, an additional cooling or chilling effect is achieved, which is an additional subjective quality criterion for many lymphoedema patients. That this bandage, based on its adherence, especially when dry, can be applied over a longer period without loss of effectiveness is an additional advantage. The high work pressure remains active throughout the whole time. In this study, we see a distinct disadvantage of the conventional compressive bandaging: The time during which this bandage is effective without being renewed is much shorter. Thus, the longer time of application makes for a compensation of the relatively high expenses of the alginate bandage.

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