

## Original Article

# Perioperative and posttraumatic anti-edematous decongestive device-based negative pressure treatment for anti-edematous swelling treatment of the lower extremity - a prospective quality study

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**Abstract:** Background: The perioperative management of trauma cases and orthopedic procedures is negatively influenced by tissue swelling and edema. They delay surgical treatment, extend stay in hospital and prolong the overall time of convalescence. In case of traumatic or postoperative edema the limited transport capacity (missing muscle pump and destruction of lymphatic channels) is casual. Edema mostly results in pain, limited function of the extremity, change in shape, higher infection rate and wound disorders. Manual lymph drainage (MLD) is a treatment option with respect to the complex physical decongestion (CPD). Objective: To evaluate whether a device-based negative pressure lymph drainage (NPLD) is capable of reducing posttraumatic and perioperative swelling of the lower extremity effectively and sustainably. Methods: Prospective quality study submitted to the Ethics Committee. The patients only received the procedures after signing the informed consent. The negative pressure was applied locally by using LymphaTouch® device (LT) (FDA approved) with a silicone-coated applicator. The lymphatic drainage had been either applied by a local stationary manner or by using the "Lift + Twist" technique. A negative pressure has been adjusted between 50-250 mm Hg depending on the skin and tissue texture. The frequency was chosen between 90-70 Hz. Type of application: pulsed or continuous negative pressure treatment. The procedure always began in the supraclavicular fossa and continued until reaching the area of surgery in the lower extremity. Duration approx. 30 min. The patient was encouraged to drink fluids after the LymphaTouch treatment (LTT). The results were documented by measurement of the girth and movement according to neutral-zero-method (NZM) and photographs. Statistics: Multi-variance, Wilcoxon test non-parametric. Inclusion criteria: Patients with injury to the lower extremity (LE), elective patients, age > 18 years, signed informed consent. Results: 101 patients with injuries/surgical interventions to the lower extremity, age:  $64.9 \pm 13.17$  years. The swelling was more pronounced at the knee. After 4 treatments, there was a measurable decrease in swelling of 11.6% at the lower extremity. In patients with trauma to the hip joint or hip interventions, the swelling at the femur was reduced by 8.6% between LTT 0 vs. 4. In patients with trauma to the knee joint and surgical interventions, significantly more female patients showed a positive effect to LTT. The mobility improved substantially, while the level of pain decreased. The patients reported immediate pain relief. No complications occurred. Conclusion: The perioperative and posttraumatic swelling at the lower extremity can be positively affected by the LT-NPLD within the first days. The preoperative duration until surgical intervention was decreased. The postoperative stage of wound and soft tissue swelling was reduced.

**Keywords:** Edema, manual lymphatic drainage, MLD, device-based negative pressure treatment

## Introduction

Posttraumatic swelling and edema following orthopedic surgery is frequently observed and classified as physiologic tissue reaction: an abnormal excess accumulation of serous fluid in connective tissue is found. Edema formation occurs subsequent to a traumatic event that

initiates the inflammatory process [1]. The release of several mediators is followed by increase of permeability especially in the capillaries with capillary leakage: Most cases of posttraumatic and postoperative conditions lead to dynamic insufficiency of the venous system and subsequently of the lymphatic system. In the presence of exudate and edema the

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workload of the lymphatic system is elevated. If the edema is not treated promptly, it can lead to secondary posttraumatic lymphedema [2, 3]. Their chronic progression can lead to disablement on the basis of posttraumatic lymphedema [3, 4].

Crushing injuries, burns, and other traumas to the body can affect the lymphatic vessels inhibiting flow. The lymphatic system is temporarily overwhelmed, but not permanently damaged, e.g. in ankle sprains. In severely injured patients the soft tissue, including the lymphatic vessels, is destroyed. After burn injuries, the complete regional lymphatic system may also be affected. Posttraumatic edema is classified as secondary lymphedema.

Once edema is formed, the lymphatic system plays a tremendous role in removing excess interstitial fluid and returning the fluid to the circulatory system [1]. Preventing or at least reducing posttraumatic and postoperative edema is key concern in the treatment of orthopedic trauma [1]. Manual lymphatic drainage (MLD) uses manual massage movements to promote lymphatic flow from the periphery to central. Profound evidence for the effectiveness of this treatment is not found in the literature up to the present day. A completely different method in the treatment of swelling, in contrast to MLD, is the substitution of an appliance-based negative pressure application. So far, there has been no study about this technique on the lower extremity in the post-traumatic and post-operative field. In this non-invasive method of swelling treatment, a small mobile device is used to increase lymphatic drainage by applying negative pressure or suction to the edematous tissue. We for the first time present a prospective clinical trial evaluating the effects of an innovative therapy against (postoperative) edema.

The aim of this quality insurance study was to analyze posttraumatic and/or postoperative edema reduction by apparatus applied negative pressure in trauma and orthopedic patients.

### Material and methods

#### *Patients*

Patients with trauma and orthopedic surgery between 2016 and 2018 who attended a class

I trauma center were included in the investigation.

#### *Inclusion criteria*

In detail, the following inclusion criteria were established: trauma patient with unilateral injury to the lower extremity (mono trauma), orthopedic and trauma patients with unilateral surgery to the lower limb, age older than 18 years, written informed consent.

#### *Exclusion criteria*

Excluding criteria were: no written informed consent, concomitant injury on other location (e.g., spine), multiple traumas, acute local or systemic infection, open wounds (vac-closure), eczema, chronic lymphedema, acute phlebotrombosis, peripheral vascular disease, suspicion of tumor, acute bronchial asthma and MLD after trauma or surgery.

#### *Method of negative pressure treatment*

From the LymphaTouch device, as soon as the treatment cap is placed airtight on the skin, a suction is applied to the tissue. This negative pressure pulls and expands the underlying tissue in a repetitive manner. This process tightens the anchor filaments and opens pores of the lymphatic capillaries. At the same time, the expansion of the tissues causes fluid to collect in the interstitial space, which can be transported further to the lymph capillaries during the next suction process.

#### *Treatment sequence*

The negative pressure therapy was chosen for all patients from 80-220 mm Hg out of a possible range from 20-250 mm Hg. The pulsation pressure with a pulse length of 2 s and a rest time of 50% was used, work/rest ratio 2/50. Classification medical device: CE-MDD/93/42/EEC, FDA device class 1 exempt.


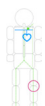
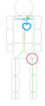
#### *Type of application*

*Stationary technique:* Via vertical tissue pull, the decompression was achieved with pulsation or continuous pulsation. The treatment cup was held for 3-5 pulsations at the same spot and then moved so that the following treatment is performed with one-third of overlap.

*Lift and twist technique:* With rotary motion the tissue was mobilized to loosen up adhesions

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**Table 1.** Treatment sequence and specifications with the negative pressure device

Treatment area	Technique	Negative pressure [mm Hg]		Work to rest ratio	Details	Duration [minutes]
		Preop.	Postop.			
 Supraclavicular fossa region (both sides)	Stationary	50-80	50-80	2.0 s/50%	Bilateral treatment 3 pulsations on 5 spots/side	1
 Inguinal area of injured side	Stationary	50-100	50-100	2.0 s/50%	3-5 pulsation on same spot followed by movement to next spot	1
 Thigh circumferential	Stationary	80-200	50-150	2.0 s/50%	1. step: 3-5 pulsation on same spot followed by movement to next spot	4
	Sliding	80-200	50-150	2.0 s/50%	2. step: Direction distal to proximal towards inguinal lymph nodes	2-3
 Knee anterior + posterior	Stationary	80-200	50-150	2.0 s/50%	3-5 pulsation on same spot followed by movement to next spot	2
 Lower thigh circumferential	Stationary	80-180	50-150	2.0 s/50%	1. step: 3-5 pulsation on same spot followed by movement to next spot	4
	Sliding	80-200	50-150	2.0 s/50%	2. step: Direction distal to proximal	2-3
 Ankle joint	Stationary	80-180	50-150	2.0 s/50%	3-5 pulsation on same spot followed by movement to next spot	2-3
 Foot dorsal and plantar	Stationary	80-200	50-150	2.0 s/50%	3-5 pulsation on same spot followed by movement to next spot	2
 Entire lower limb	Sliding	80-200	50-150	2.0 s/50%	Direction distal to proximal, repeated	5
 Inguinal area of injured side	Stationary	50-150	50-150	2.0 s/50%	3-5 pulsation on same spot followed by movement to next spot	1
 Supraclavicular fossa region	Stationary	50-80	50-80	2.0 s/50%	Treatment 3-5 pulsations	1

and to soften fibrotic tissues. The pulse work and rest length between the pulses was adjustable. During the working period of the negative pressure cycle, the applicator is lifted and twisted. In the intermediate rest period, the cup is placed to the neighboring area, where the lift and twist treatment goes to the opposite rotational direction.

*Sliding technique:* The decompression is achievable with pulsation or continuous settings plus frequency alterations. The aim is to redirect fluid from the edematous tissue into to the lymphatic system. The treatment cup is slid softly over the skin. Amelioration of the sliding is achieved with disinfectant. See **Table 1**.

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## *Evaluation measurements*

With the neutral-zero-measurement (NZM) [5], a defined acquisition of the lower limb circumferences at constituent measure points plus movement measurements were collected. The circumferences according to NZM were at 20 cm and 10 cm above the knee at the thigh, at 15 cm below the knee joint, smallest girth of the lower thigh, girth at the ankle joint, at the instep and forefoot.

## *Ethics*

Approval of the local ethics committee (DOK\_185\_2016).

## **Data evaluation**

The raw data was collected with Microsoft® Excel 2014. All data was collected in strictly pseudonymous form. All statistical analyses except SEM were performed with IBM® SPSS Statistics® version 24. SEM was calculated with JASP (JASP Team (2020). JASP (Version 0.12.2) [Computer software]). Graphical assessments were performed with GraphPad Prism (version 5.04, GraphPad Software, La Jolla California USA). After validation of the Gaussian distribution by the Shapiro-Wilk-Test, the t-test for normal distributions and the Wilcoxon-test for non-normal distributions were performed. The level of significance was 5% ( $P < 0.05^*$ ,  $P < 0.01^{**}$ ,  $P < 0.001^{***}$ ). The data are shown as the mean values with the standard error of the mean (SEM). Linear mixed models (LMM) were performed to detect influencing factors of the circumferential differences. Significant univariate effects were further tested in a multivariate test.

## **Results**

### *Patient characteristics and treatment allocation*

A total of 101 patients was included in the study: 53 female (52.5%) and 48 male (47.5%) patients. The age distribution between the gender showed no great overall difference with 64.9 years (SD 13.17), [Range 23.48-88.26] for female patients and 63.9 years (SD 18.49), [Range 21.12-95.64] for male. The analyzed body regions were calculated with: 46.53% knee, 18.81% hip, 12.87% lower thigh, 10.89%

ankle joint, 7.92% thigh and 2.97% foot. 364 treatments were performed and recorded with an average of 3.5 (SD 1.01) treatments per patient. See **Table 2**.

### *Main area of swelling and temporal influence of treatment*

Analyzing the girth at the knee joint the data showed that this area has been affected in all injuries to the lower extremity. See **Figure 1**.

The most evident decreases in swelling were found between the first and second negative pressure treatment, example **Figure 3**. Analyzing the total reduction of swelling measured in relation to day 0 measurements, a reduction rate of 10.36% on day one, 11,35% on day two and 17,34% on day three have been achieved. See **Table 3**. On the final day of measurement, the number of measured points were reduced by 78.22% to only 22 patients. See **Table 3**.

### *Segmental analysis of the lower extremity*

The detailed analysis of the sections of the lower extremity demonstrates the highest decrease of swelling at instep 32,4%, ankle 23,2%, forefoot 22,9% and femur 20 cm above the knee joint 20,5%. See **Table 4**. and **Figure 2**. T-test analytics pointed out significant differences in decrease of swelling of the thigh at 20cm above the knee in comparison to the knee circumferences with  $p$ -value of 0.001. The factor *age* showed no significant influence in the multivariate model, but *gender* did. Calculated (LMM) for all 101 patients the swelling was measured highest after injuries or surgical intervention in the thigh region ( $P=0.019^*$ ), followed by hip injuries/surgeries ( $P=0.034^*$ ) and knee injuries/surgeries, ( $P=0.035^*$ ). Measurements at 20 cm above the knee joint showed significant differences of girth in relation to the number of treatments. Patients with injuries at the lower thigh had the highest swelling reduction followed by those with ankle injuries.

## **Discussion**

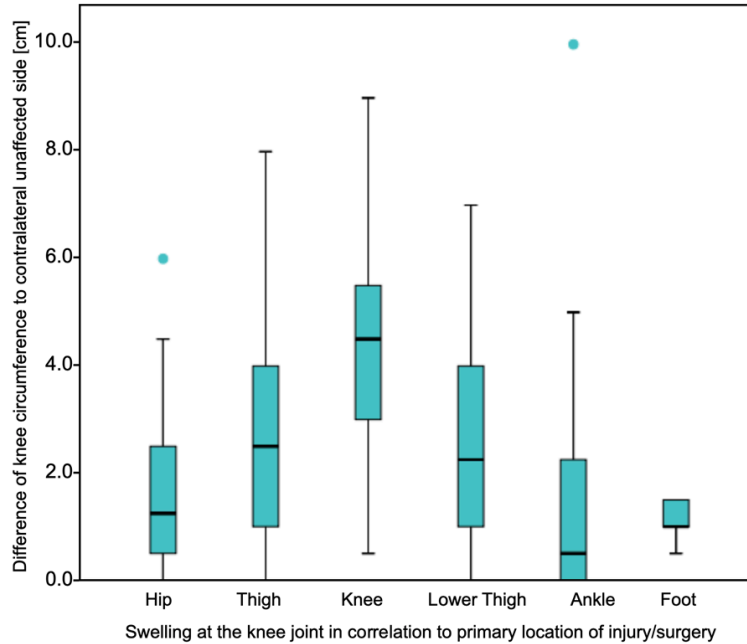
Posttraumatic and postoperative edema (PT-POE) following surgical intervention with local swelling or swelling of the whole extremity resulting from fluid accumulation in the interstitium are a physiological process. This manu-

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**Table 2.** Patient characteristics

Localization	All patients				Male patients					Female patients					Treatments		Treatment start	
	No.	%	Age	SD	Male	(%)	Age	SD	Range	Female	(%)	Age	±SD	Range	No. (MV)	±SD	at day	±SD
Hip	19	18.81%	70.9	17.6	8	42.11%	78.47	12.4	58-96	11	57.89%	65.37	19.26	50-88	3.63	0.9	6	3
Thigh (femur)	8	7.92%	71.2	9.57	5	62.50%	72.78	10.3	55-81	3	37.50%	73.55	15.39	50-88	3.25	1.04	13	5
Knee	47	46.53%	66.6	11	17	36.17%	66.86	14.8	22-85	30	63.83%	66.46	8.46	51-81	3.64	1.07	5	4
Lower leg	13	12.87%	59.5	16.1	8	61.54%	56.88	17.7	35-81	5	38.46%	63.83	13.78	43-79	3.69	0.85	4	3
Ankle joint	11	10.89%	53.1	18.4	8	72.73%	55.08	15.8	28-82	3	27.27%	47.77	25.08	23-74	3.64	1.12	5	6
Foot	3	2.97%	33.9	21.7	2	66.67%	21.35	0.33	21-22	1	33.33%	59			3.33	1.53	9	2
Total	101				48					53								

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**Figure 1.** Boxplot: alterations of swelling circumferences of the knee joint in relation to primary region of trauma or surgery.

script focusses on secondary PTPOE and apparatus-based edema therapy.

Traumatic and postoperative swelling and edema of lower limbs is often characterized by long-lasting swelling of the limb, erythema, and increased skin temperature at the site of injury [6]. It is caused by a slowdown of venous drainage and no muscle pump function by immobilization (e.g., long-lasting cast immobilization), or hyperactivity of growth factors and cytokines at the trauma site, lymphatic destruction or obstruction. The open surgical procedures further destroy lymphatic vessels [6, 7]. The trauma itself systematically influences the soft tissue reaction and formation of interstitial fluid. Crush injuries, burns, and other severe injuries result in direct regional disruption of the lymphatic system by trauma and surgery. Edema is present at the site of injury and distally. In traumatized lower extremities enlarged lymphatic vessels can be detected [8]. Underlying reason is the increase of the capillary permeability and protein filtration into the interstitial space. Edema is a common postoperative issue after osteosynthesis and joint arthroplasty that usually cannot be averted [9].

Edematous soft tissue is less resistant against opportunistic infection with pathogens and leads to higher postoperative complication

rates [10]. Postoperative edema negatively impacts patient's pain and functional ability, lead to a reduction of mobility and well-being and can reduce quality of life and rehabilitative progress, subsequently extending length of stay [1, 10-17].

It is known that lymphatic transport is facilitated by extrinsic factors like muscle contractions, negative pressure in central veins, deep inspiration and external compression. Many of the advances in the management of edema after trauma are based on the research completed on lymphedema [18].

Several treatment options are currently used to support the edema and lymphatic drainage.

The published studies use different techniques to quantify swelling and reduction of swelling which make it impossible to compare the results. The clinical consequence of a certain amount of edema reduction is unknown [19]. Two treatment methods are established with the distinction of pressure application used: positive or negative pressure.

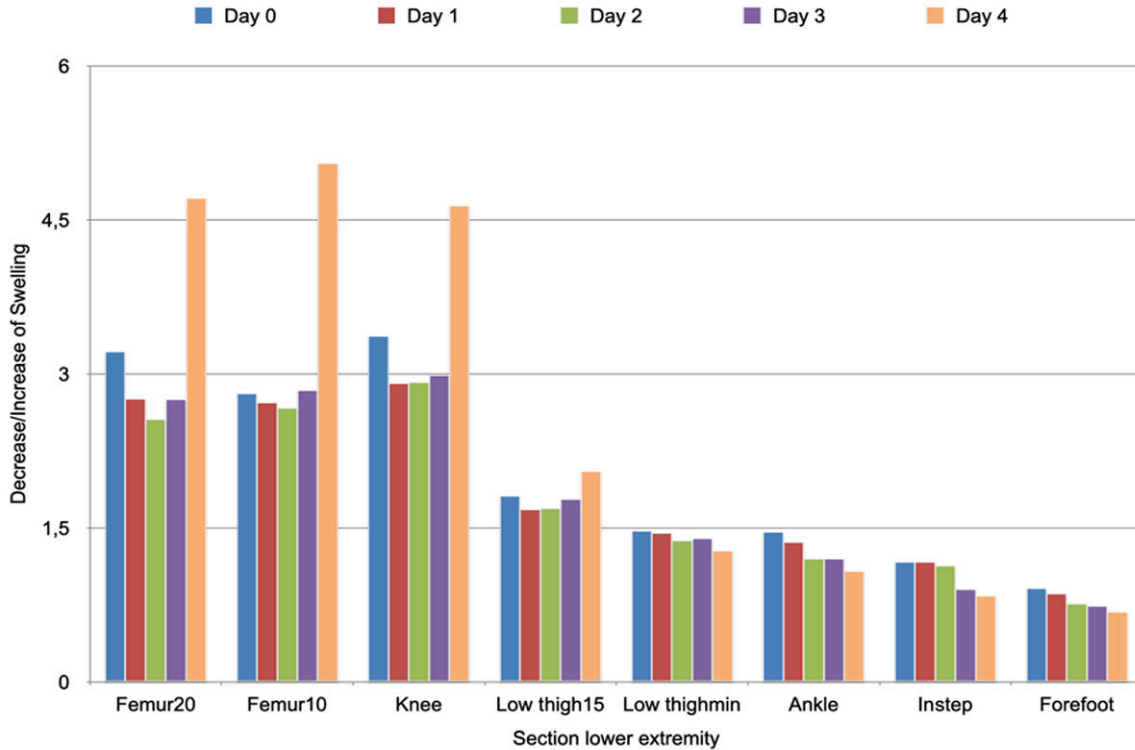
Most of the anti-swelling therapies use positive pressure techniques and/or devices [20], this may include, for example, manual lymphatic drainage (MLD) [1, 20-23], compression bandages [19, 24-26] or pneumatic compression devices [9, 14, 27-29]. The current evidence is only limited [1, 18, 25, 26, 30, 31].

Only one existing treatment option follows a negative pressure concept. Kinesiotaping partly generates negative pressure while elevation of skin and soft tissues with adhesive tapes lifting the skin during movement of the limbs and opening the valves in the lymphatic vessels [32-34]. After open surgery, the kinesiotaping does not seem adequate to be applied on or besides surgical incisions. In summary there is low evidence for the efficacy of kinesiotaping for the treatment of postoperative swelling [32, 34].

Our investigation at the lower extremity shows that apparatus applied negative pressure



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**Figure 2.** Progress monitoring of swelling at the lower extremity at different section treated with negative pressure treatment, for day 4 a low number of patients was recorded. Influences with mean value are depicted.



**Figure 3.** A-D: Exemplary application of LymphaTouch device at lower extremity. Patient, 57 y, male, tibia plateau fracture, metaphyseal comminution, fracture fibula head, compartment syndrome, primary fasciotomy (compartment release) and external fixator. Complex reconstruction of articular surface, angle-stable plate osteosynthesis, closure of compartment approach 16 days after injury. A: Significant swelling 3 days after ORIF, comparison with contralateral uninjured side. B: Lateral aspect of lower thigh after osteosynthesis and closure of fasciotomy on day 3 after surgery. C: Soft tissue reaction during first application of the negative-pressure device. D: Lower thigh before second negative-pressure application. E: Detail of skin (arrow in 3D) shows decrease of swelling.

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**Table 3.** Results of swelling influence in relation to treatment days

	Day 0	Day 1	Day 2	Day 3	Day 4
Sum of all mean values of circumference differences of all measuring points	16.49	15.16	14.68	14.79	15.21
Reduction total from day 0		-1.33	-0.48	0.11	0.41
Percentage change of swelling in relation to the previous day		-8.1%	-3.2%	0.8%	2.8%
Percentage change in swelling compared to day 0		10.36%	11.35%	17.34%	3.25%
N of measurements (% diff. from day 0)	101 (100%)	100 (-0.99%)	86 (-14.85%)	55 (-45.54%)	22 (-78.22%)

**Table 4.** Reduction of swelling of the lower extremities for all patients after trauma or who received lower extremity operations

	Fem20			Fem10			Knee			Lowhigh15		
	Mean	SEM	P	Mean	SEM	P	Mean	SEM	P	Mean	SEM	P
Days												
Day 0	3.237	0.280	97	2.825	0.280	97	3.4000	0.220	100	1.810	0.169	93
Day 1	2.740	0.256	96	2.719	0.256	96	2.9541	0.221	98	1.680	0.159	91
Day 2	2.548	0.229	83	2.651	0.229	83	3.0000	0.233	85	1.690	0.165	79
Day 3	2.798	0.351	52	2.837	0.351	52	3.0741	0.283	54	1.780	0.206	51
Day 4	2.575	0.461	20	3.125	0.461	20	3.4318	0.479	22	2.050	0.340	21
Reduction. percentage												
Day 0 to day 1	-15.4%			-3.8%			-13.00%			-6.4%		
Day 1 to day 3	-13.6%			0.4%			-9.6%			-3.8%		
Day 1 to day 4	-20.5%			10.6%			0.9%			11.0%		
	Lowhighsmall			Ankle			Instep			Forefoot		
	Mean	SEM	P	Mean	SEM	P	Mean	SEM	P	Mean	SEM	P
Days												
Day 0	1.470	0.220	93	1.450	0.17	89	1.17	0.137	87	0.91	1.593	87
Day 1	1.450	0.199	91	1.376	0.18	88	1.17	0.128	87	0.86	1.600	86
Day 2	1.380	0.196	79	1.184	0.15	75	1.13	0.137	75	0.76	1.558	73
Day 3	1.400	0.216	51	1.204	0.17	48	0.9	0.134	47	0.74	1.627	46
Day 4	1.280	0.233	21	1.114	0.27	21	0.84	0.225	20	0.68	1.638	20
Reduction. percentage												
Day 0 to day 1	0%			-5.10%			-5.10%			-2.5%		
Day 1 to day 3	-4.9%			-17.00%			-28.2%			-21.4%		
Day 1 to day 4	-13.1%			-23.2%			-32.4%			-22.9%		

Notes: Circumferences according to [5]; Abbreviations: Fem20: 20 cm above knee, Fem10: 10 cm above knee joint, Lowhigh15: 15 cm distal knee joint, Lowhighmin: smallest circumference at lower thigh, P: number of patients.

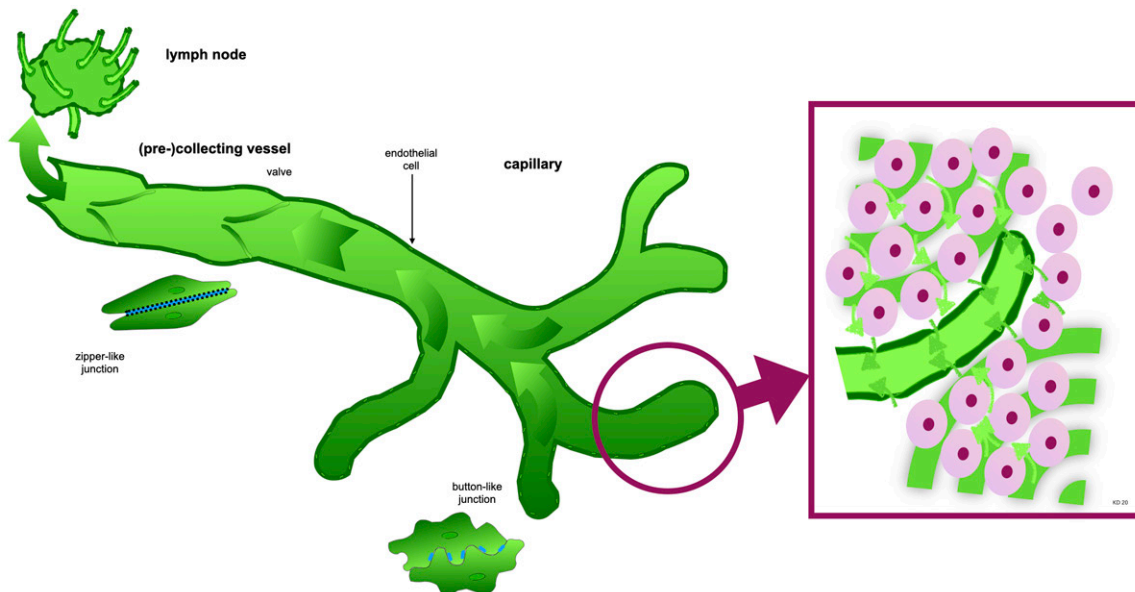
(LymphaTouch) is effective in reducing swelling and edema after trauma and perioperatively at the lower extremity. Livarinen et al. demonstrated that negative pressure induces the interstitial fluid movement in soft tissue and is relevant to treat tissue swelling [35, 36]. Applying negative pressure with the LymphaTouch device stretches the soft tissue and the inlying lymphatic vessels. The lymphatic capillary pores open so that interstitial fluid can enter the lymphatic capillaries. See **Figure 4**. With the same physical effect, the valves in the pre- and collecting vessels are opened and the lymphatic flow is activated. The visible movement of the tissues as seen when a negative pressure ther-

apy (NPT) device is placed onto the tissue is called macrostrain [37]. Negative pressure could be used to facilitate normal lymphatic system physiology by using variations in interstitial pressures to encourage flow through lymphatic vessels [20]. Saul et al. recently demonstrated an effective posttraumatic and postoperative deswelling with LymphaTouch at the upper extremity [38]. This group demonstrated that the mean reduction of postoperative swelling from day zero to day four was 17.34%.

Our patients with trauma or orthopedic surgery on the lower extremity showed swelling not only at the site of injury or surgery. In many cases



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**Figure 4.** Anatomical overview of lymphatic system modified using [39, 40].

the complete extremity was affected by swelling. Analyzing the swelling in the knee joint area for all patients, it was seen that even when the injury was not located at the knee, e.g., in the hip region, the knee swells concomitantly. The knee region was highest affected by measurable circumferential increase of swelling.

The same sequence of treatment as in MLD was used. The possible high-frequency vibration out of a possible range from 20-90 Hz was not used in this investigation. The effect of decreased swelling was obvious. After four treatments, there was a measurable decrease in swelling of 11.2% at the lower extremity. As we have shown respecting aseptic conditions, the device can be applied near fresh surgical incisions without complications. We have seen no adverse effect using the LymphaTouch device, especially no skin reaction like erythema and no infection near the surgical approach. The decrease of swelling until day three of treatment was verified. The German DRG-system obliged the hospital to dismiss patients as soon as possible without any respect to ongoing studies. Outpatients could not be included in this study.

The greatest percentage reduction of the lower extremity after negative pressure treatment was documented for the distally located body regions: ankle joint, instep and forefoot. This is in accordance with results recently pub-

lished for the upper extremity where the distal regions had shown higher reduction of swelling after negative pressure treatment [38].

### Conclusion

This study of negative pressure device treatment of the lower extremity in orthopedic and trauma patients proved a significant decrease in posttraumatic and perioperative swelling. No complications occurred during application of the device on patients who recently had surgery.

In the future it may be used in out- and inpatient settings. Future randomized controlled trials of the same interest (ROI) (injuries/surgeries) are necessary.

### Disclosure of conflict of interest

DS, A-CF, WL, CS declare that no conflicts of interest exist that could affect this paper. Additionally, no funding was obtained to support this manuscript. KD declares that at the end of this study he became a medical adviser for one year (2019) for LymphaTouch® to initiate RCTs. DS was funded by the Deutsche Forschungsgemeinschaft (DFG, German Research Foundation) - 413501650.

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