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Expert opinion on the topic of
**Use of the intermittent compression system VADOplex®
(foot impulse technology) for treating localized infections.**

Ladies and gentlemen,

Thank you very much for your inquiry.

As agreed, I hereby send you a short expert opinion on the use of the VADOplex® system for the treatment of a localized infection based on an extensive systematic literature review.

Summary
Both at a national and international level, there is consensus on the contraindications of compression in the acute phase of extensive soft-tissue infections such as, for example, erysipelas or phlegmon in the extremities. So far, no scientific data has been published to support this view, which is based on logical pathophysiological factors.

There are no recommendations and there is no scientific evidence suggesting that there are general limitations to compression therapy for localized infections such as wound infections.

A high level of treatment comfort for the patient must be ensured.
Due to the great significance of the clinical assessment for the course of a local infection, systems that hinder visual examination as little as possible have proven to be most practical. In this context, intermittent compression systems can be an advantage, in particular when using foot impulse technology.

1. General application rules

1.1 Indications and application rationale

The VADOplex® system is an intermittent compression system working according to the principle of foot impulse technology.

With this system, a mechanical compression in the area of the foot or hand vessels is created using intermittently filled pneumatic pads. The mode and character of the compression created corresponds to the typical physiological pressure pattern during movement (for the foot, this is walking).

Pressure is only applied in the area of the foot or hand, respectively.

There is no compression of areas such as the ankle, calf or forearm that are not covered by the pad.

This mode of application promotes effective reflux of fluid from the extremity. This reduces existing edema of various genesis (vascular and post-traumatic/ post-operative), improves run-off and, thanks to due to the reduced risk of stasis in the case of immobility, has a prophylactic effect against thrombosis.

Reducing the tissue edema will always lead to an improvement in microcirculation. Therefore, the system can be considered an established application of intermittent pneumatic compression.

1.2 Infections as potential application restrictions

It has been repeatedly advised not to use apparative intermittent compression (or other compression methods) for the treatment of patients with infections. In this context, the guideline „intermittent pneumatic compression“ issued by the German Society of Phlebology [1] is often cited. This guideline, however, only lists erysipelas as an infection-associated contraindication.

Yet, infections of any type are assumed to be potential contraindications, although there is no factual evidence to back up this theory.

By way of justification, it is often noted that drainage-related activation and removal of potentially microbiologically contaminated edema fluid can always cause a bacteremic or „otherwise“ mechanically triggered spreading of the infection.

The guideline neither includes a comparable note nor does it list contraindications apart from erysipelas.

2. Assessment of existing literature on contraindications for the application of apparative intermittent compression (using the VADOplex® system) in the case of infections

2.1 Initial considerations

According to general pathophysiological observations on the drainage of infectious edema, it can be concluded on the one hand that the removal of inflammatory edema might possibly also be associated with the potential risk of removing fluids contaminated by microorganisms due to infections. This would, however, also be the case with any type of edema reduction.

On the other hand, the reduction of a local edema is a prerequisite for improving microcirculation in the inflamed area. This is what makes improved local circulation and increased efficiency of cellular and humoral defense mechanisms possible in the first place. At the same time, one can assume that improved microcirculation is the reason why potentially systemic antimicrobial measures become more efficient due to an improvement in tissue penetration.

In addition, reducing the inflammatory reaction is one of the main objectives when treating an infection and in most cases leads to improved patient comfort.

Independent of this, it needs to be clarified whether the available scientific literature contains any evidence of contraindications or basic restrictions on the application of apparative intermittent compression in the case of localized infections.

2.2 Systematic literature review

A comprehensive database search was undertaken within the framework of a systematic scientific literature review using Medline, Biosis, DÄ, Embase/Embase Alert, gms and SciSearch. The search was undertaken purely from the perspective of relevance to human medicine. There were no restrictions in terms of the publication date. All documents available have been taken into account.

The relevance of the documents registered using the retrieval strategy was subsequently verified by evaluating the title and, where applicable, the abstract. In individual cases, the original publication was read in its entirety at this point.

Search key word/ search term	Number of hits	Number of results relevant to the subject after survey	Number of results actually relevant after survey	Comment
apparative compression therapy [and] contraindication	8	7	0	Hits only on the subject of bandages/ stockings (irrelevant)
intermittent compression therapy [and] contraindication	112	42	3	Multiple entries; high number of duplicate results
intermittent compression therapy [and] infection	163	29	3	Both of the relevant results already included in search 3
infection [and] compression therapy of the leg	105	7	2	Actually relevant documents
Actually relevant documents	**n.a.**	**55**	**4**	**Literature references 2 to 5**

Tab. 1: Database search (Medline, Biosis, DÄ, Embase/Embase Alert, gms and SciSearch) - overview of the search strategies, hits found and assessment of relevance

The relevant documents found are listed as sources 2 to 5 in the bibliography.

2.3 Additional results and book contributions (Google Scholar search and free search)

Apart from the documents found in the systematic database search, the Google Scholar search and free search yielded further documents, which are listed in the bibliography as sources 6 and 7.

3. Evaluation of the results

To conclude, there is no demonstrable evidence to consider an infection as a contraindication for apparative intermittent compression in view of the systematic search using the most common established medical databases.

In the case of referred infections, explicitly with an existing erysipelas and certainly in the same way with phlegmonous infections of the soft tissue, there is an evident but not evidenced requirement to wait with compression until the systemic infection seems to be healing (this is also part of the guideline „intermittent pneumatic compression“ [1]). This is confirmed by standard publications on general compression management both nationally [5] and internationally [2-4] for typical indications of vascular compression [3,5] as well as other indications [1,2].

This requirement is now included in common textbooks on compression. As an example, we cite a relatively new publication by Reich-Schupke and Stücker [6], although practically all current textbooks on this topic agree with this proposed requirement.

Based on this agreed approach, compression only needs to be considered contraindicated as standard in the case of an infection that has manifestly spread.

A contraindication of applying compression in general and apparative intermittent compression, in particular, to an existing localized infection in the run-off area (e.g. in the case of a localized wound infection on an extremity), cannot be substantiated at this point in time.

Neither the guideline [1] or the reports of international consensus statements [2,3] provide evidence of this, nor has it been proven by an extensive literature review. Any cases where justifiable concerns were raised or application restrictions given were based on questions of practicality and the treatment comfort of the patient [3,4,7]. In addition to the unpleasant heat accumulation forming under conventional compression material (bandages and stockings) [3,4,7], the limited options for clinical evaluation of applied compression systems were cited [3,7]. Sibbald suggests using removable and reusable systems as a possible solution [7].

This implies a further logical advantage of intermittent compression systems, as they are always only applied temporarily and can in general be removed easily and quickly. A system such as VADOplex®, which works according to the principle of foot impulse technology and with the pad only applied to the foot, offers even more benefits.

Mechanical compression limited to the area of the vascular network of the foot (or of the hand) creates pressure only in the corresponding area. All other parts of the body, for example the rest of the foot as well as the entire ankle and calf region, are neither affected mechanically nor covered by an application or compression system. This makes easy and efficient visual examination possible at any time. Heat accumulation can be avoided.

4. Conclusions

Both on a national and international scale, there is consensus on the contraindications of compression in the acute phase of extensive soft-tissue infections such as erysipelas.

So far, no scientific data substantiating this requirement based on general pathophysiological factors could be found in the literature.

There are no recommendations and there is no scientific evidence suggesting that there are limitations to compression therapy in connection with localized infections, for example wound infections.

The treatment comfort of the patient must be guaranteed. Due to the particular importance of the clinical assessment of progress in making a prognosis about a localized infection, application methods that hinder visual examination as little as possible have proven to be of most benefit. In this context, intermittent compression systems have promising application, in particular when using foot impulse technology.

Sincerely,

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References:

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[5] Földi E, Baumeister RGH, Bräutigam P, Tiedjen KU. “Zur Diagnostik und Therapie“ (on diagnostics and therapy). “Deutsches Ärzteblatt“ (German medical journal) 1998; 95(13): A-740 / B-605 / C-565“

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