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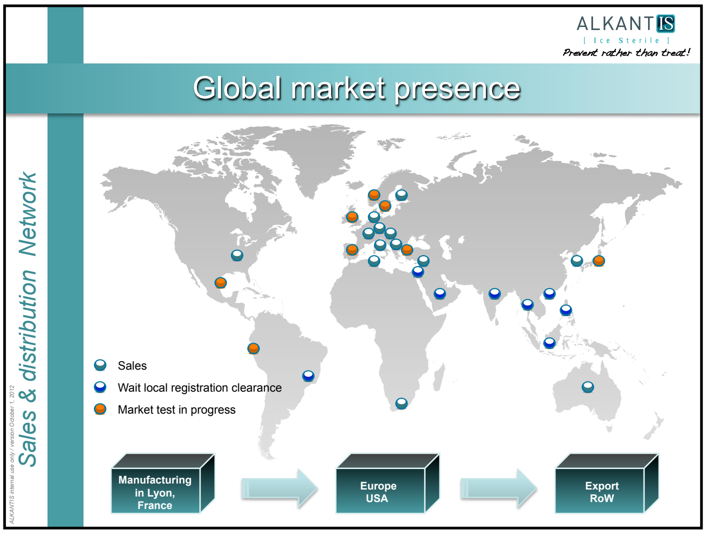
News letter

ALKANTIS, A World's First !

The smart idea is to introduce cold therapy:

1. **At the right time !**
2. **At the right place !**

Sooner the Better !



For the second year ALKANTIS is showcasing at the world's largest healthcare trade show, MEDICA between the 14th -16th November 2012.

MEDICA®
14 – 17 Nov 2012
Düsseldorf · Germany

ALKANTIS has been specially designed for the Operating Theater (orthopedics, general surgery, cardiac...) and also Wound Care.

www.alkantis.com

We are looking to welcome you on the ALKANTIS booth 16A15 located in hall 16 Medica.
(from Wednesday 14 to Friday 16, November

Next pages:

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Specificity, therapeutic advantages and medico-economic perspectives

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Specificity, therapeutic advantages and medico-economic perspectives

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1. Introduction

Cold Therapy is the most common approach in functional re-education and in post-surgery.

To cool the underlying tissue and lower its metabolic activity.

Protect the surrounding tissue from a post-traumatic ischemia and protect it from catabolic enzyme reactions which accompany the induced lesions.

By slowing down the nervous influx, lowering the temperature Induces a local analgesic action.

The sooner the cooling is implemented better is the effect. Rapid cooling is preferred while maintaining a stable low cooling temperature over a prolonged period of time would be useful.

These technical advantages have significant potential financial consequences.

2. The Alkantis cryotherapy medical system

The Alkantis system reduces the risk of nosocomial infections related to the use of reusable, non sterile equipment such as the traditional ice pack.

3. Cryotherapy and musculotendinous traumas

Musculotendinous traumas represent the typical ailments for which the benefits of cryotherapy have been the most studied.

During the severe, inflammatory phase of the trauma, cryotherapy will have an anti-inflammatory effect via vasoconstriction and could reduce the hypoxic consequences by lowering local metabolic needs

. Reducing the skin temperature below 15°C is also followed by a local analgesic effect which is undoubtedly secondary to a slowing down of nerve conduction speeds [7, 8].

3.1. The optimum temperature window

In this context, the data available for the Alkantis system makes it possible to guarantee reaching a skin surface temperature of between 5 and 15°C in less than 5 minutes; this temperature window will be maintained for approximately 3 hours. This is a specific advantage of this system.

3.2. Expected advantages of the thermodynamic properties of Alkantis

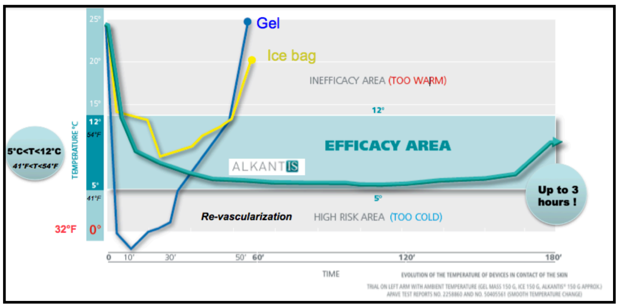
From a thermodynamic point of view, heat transfer is always a single direction process in the direction of the lowest temperature from the highest. Therefore tissue cooling is a loss of heat through transfer, firstly by absorption by the applied system of the heat from the superficial skin layers, then from the deeper layers towards the previously cooled superficial layers. From this point of view, the capacity of the system to firstly favour heat transfer, and secondly to absorb heat, will be the determining factors in its performance.

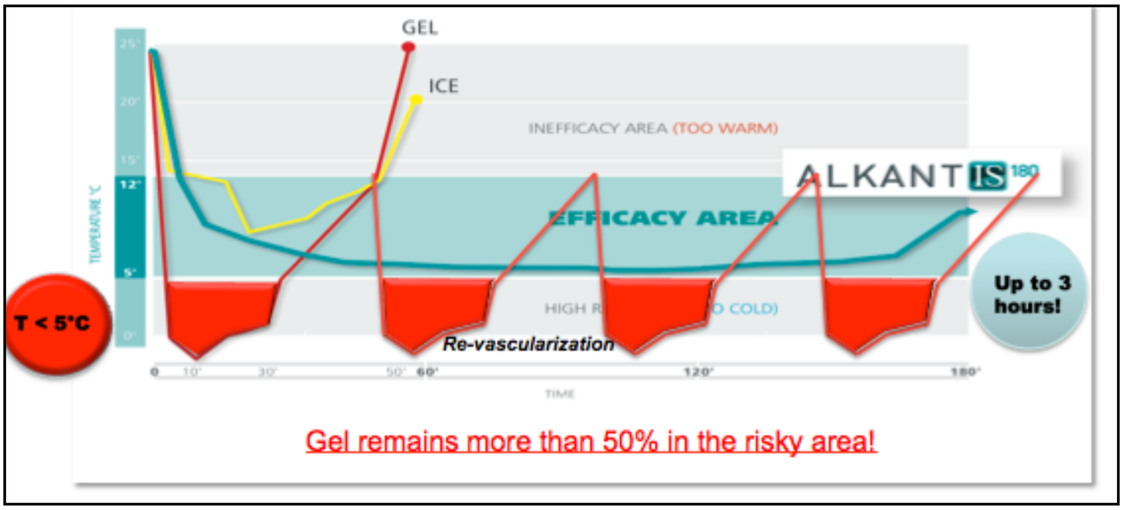
Another element to be taken into account is the capacity of the cooling material used to change phases. because ice will be transformed to liquid (phase change) during the heat transfer process, it will require 80 times more heat to increase the temperature of one Kg of this material by 1°C compared to a cooling gel which will not change phases.

Due to this, the theoretical heat absorption capacity of ice is much higher than that of a gel, even if the initial temperature of the latter is sometimes lower.

Finally, if the heat transfer between the skin tissues and the applied system occurs via a conductive mechanism, the dry cold used by Alkantis will make it possible (up to a certain point) for the water originating from the change of phase of the ice to evaporate. This phenomenon will increase the heat absorption capacities via an additional convection mechanism.

Globally, this theoretical data has been observed on man. The use of ice as a cooling agent shows a more pronounced lowering of the subcutaneous temperatures compared to a gel which is not subject to phase changes [17]. This data has been several times confirmed [18-22]. Thus, on 9 volunteer subjects [21], the cutaneous thermal effect of the application of crushed ice is greater than the effect observed when using a cooling gel (application zone: the elbow; application duration: 30 min; reduction of the skin temperature: 19.6 ± 3.8 °C vs. 13.2 ± 5.1 °C; $p<0.001$) Further, after the withdrawal of an ice pack applied for 20 minutes (measurements taken from 16 volunteers on the quadriceps), the deep tissues (between 2 and 3 cm) lose heat for up to 40 minutes after the withdrawal whereas, at the same time, the skin and superficial tissues (1 cm) warm. [5].





3.3 *Methods of application of the cooling system*

A vast systematic review [23] suggests that an intermittent application of the cooling agent every 10 minutes, compared to a continuous application, would seem more efficient in reducing the superficial and deep tissue temperatures. This conclusion is based both on the results of studies carried out on animal subjects and on healthy volunteers. This type of application makes it possible to obtain a skin temperature of 5°C immediately after starting the procedure accompanied by a rapid analgesic effect [24]. For example, in a random double blind test [25], in the immediate treatment of a benign ankle sprain, intermittent application (ice pack at 0°C: total of 89 patients) was followed, compared to continuous application, by a significantly higher reduction of pain when mobilising the ankle.

The properties of the Alkantis system allow an optimum adaptation to this type of treatment protocol. In fact, the preservation over a long period (approximately 3 hours) of the required temperature constraints of the system in standard room temperatures (atmosphere at 21°C) makes it possible to use intermittent application without having to change the equipment, this advantage is not shared by other currently available methods (ice pack or cooling gel).

3.4 *Conclusions and the place of cryotherapy*

In the immediate treatment of cumulative trauma disorders, cryotherapy represents an initial care therapy. For example, in an ankle sprain its use is recommended by many knowledgeable bodies such as the American Academy of Family Physicians or by the American Academy of Orthopedic Surgeons [26-28].

The direct application in the region of the trauma makes it possible to reduce the inflammatory reaction, the pain and may encourage a faster functional recovery [29]. However, because of the variations in the type of systems used and in the application operating methods (duration of the application, intermittent or continuous application, association or not to mobilisation), there are differences of opinion as to the grade of the current clinical proof for this treatment (especially as to the medium or long term functional results), treatment which is, nevertheless, supported by several good quality random studies [9, 30-32].

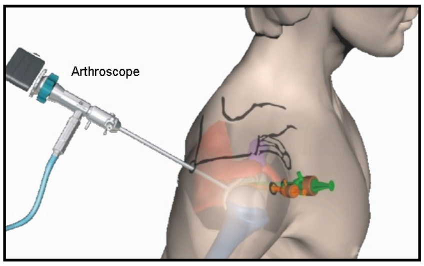
In this context, the Alkantis system brings an optimised response to the technical issues of cryotherapy for this treatment. Besides its sterile characteristics, its design allows a perfect adaptation to anatomical constraints, a very good contact between the system and the application zone, great ease of use (use without special training, by all types of health professional and by the patient) and, more especially, the guarantee that an appropriate temperature will be maintained efficiently, without the risk of too much cooling, applicable to all types of protocol (intermittent or continuous application). Further, this system is usable immediately, without any delay or handling as opposed to the most common system of the ice pack (there is no need for an ice-making machine, no handling to fill the ice pack).

The specific advantages of the Alkantis system make possible its use very simply in cryotherapy as well as in other treatments.

4. Other indications for cryotherapy by local application of a system

There are many other medical applications for cryotherapy from which the benefits mainly come from the anti-inflammatory action or from the analgesic action of the treatment. As examples, some of these cryotherapy applications will be very briefly described in this chapter.

4.1 Cryotherapy following arthroscopy



The use of cryotherapy following an arthroscopy is used to reduce the intra-articular temperature, even following a surgical operation such as the repair of the anterior cruciate ligament [33-36]. A meta-analysis has shown that this treatment was followed by a significant analgesic effect immediately following such an operation [37].

For this application, two types of procedure are used: either standard cryotherapy using an ice pack, or continuous cryotherapy using pneumatic water cooling systems. If the latter favour a nocturnal analgesic effect, the differences between the two approaches seem irrelevant from a clinical point of view [38].

However, here also a control of the lowering of the temperature is required, especially in the case of continuous cryotherapy, in order to avoid local cold related skin complications [39].

4.2 Post-surgical cryotherapy

In a prospective randomised study, 97 patients who had undergone a craniotomy, were, or were not, treated using cryotherapy (ice pack applied to the surgical wounds and cooling gel at the level of the periorbital for 20 minutes every hour starting 3 hours after surgery for 3 days) [40]. In the treated group, the periorbital oedema was significantly reduced, the pain was also lessened as well as the bruising.

Similar effects were reported after maxillary surgery [41].

More generally, the use of cryotherapy in post-surgical applications could make it possible to better control pain [42] and significantly reduce needs in level III analgesics [43].

4.3 Cryotherapy and localised acts

Many localised procedures, which are more or less invasive, could benefit from the effects of cryotherapy if its implementation were easier than ice packs.

Thus, a controlled study on young, school aged children, has shown that 3 minutes cooling using an ice pack before taking a blood sample, would very significantly improve the behavioural response to the procedure [44].

Another controlled study has highlighted the fact that pre-treatment using an ice pack very significantly improved the comfort and reduced the pain during skin test procedures to identify allergens [45].

Another example of use is the application of an ice pack during the 5 minutes that precede a botulinum toxin injection for aesthetic purposes. The post-injection pain is very significantly reduced [46].

The preparation of an ice pack imposes the use of various equipment and a large proportion of manual handling. this "hand made" preparation is a source of contamination of the equipment by hospital germs at each step. An additional problem can be mentioned since the use of the ice pack involves several categories of staff. The placing of the ice pack is an act that is medically prescribed and is initially carried out by the nurse, however clinical support workers will participate in the treatment through monitoring and the renewal of the system.

This multiplicity of participants increases the risks of contamination each time a new person intervenes. In this context, the risk of contamination of the system by transmission from the hands is very high, this is a first hand risk of the spread of virulent germs and/or multi-resistant germs within hospital structures [48-50].

Thus, the preparation and practical use of the ice pack does not comply with the minimum quality rules that apply to semi-critical systems (and even to non critical systems). This issue is a preoccupation of many Coordination Centres for the Prevention of Nosocomial Infections. The Alkantis system is currently the only available alternative that makes it possible to meet elementary hospital hygiene requirements [51, 52].

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5. The Alkantis system: medical and economic perspectives

Schematically compared to an ice pack, or even other cooling gel based systems, the Alkantis system has five main advantages which have potentially major medical and economic consequences:

- *i.* **Sterile single use.**
- *ii.* **Immediately available without any special preparation.**
- *iii.* **Prolonged effect of a dry and compressive cold.**
- *iv.* **The guarantee of the preservation of an optimal temperature range.**
- *v.* **The system is adaptable to most of the anatomical zones to which it might be applied.**

5.1 The advantages of a single use sterile system

The common ice pack or ice bag system is not sterile equipment and at least two sources of contamination can be identified: the water used to make the ice and the equipment used to apply the cooling system to the zone to be treated. Only a single use sterile system can guarantee the elimination of the risk of microbe contamination and its sometimes dramatic consequences.

5.1.1 Water related risks

In the same way as for general water distribution systems [53-55], several publications have underlined the implication of ice making machines in the development of nosocomial infections in the hospital environment [56-60]. These machines were the origin of legionellosis and infections linked to certain mycobacteria. Their use required precise maintenance (frequent changes of filters and very frequent decontamination). It is true that the ice used in a pack or bag is not in direct contact with the application zone. Nevertheless, leaks when the pack is being filled or via a damaged pack or an incorrectly closed pack cannot be excluded (all the more so because these packs are normally subjected to decontamination treatments that are aggressive to the material they are made of).

Table 1. Types of micro-organisms involved in nosocomial infections related to water [61]

Pseudomonas aeruginosa
Stenotrophomonas maltophilia
Chryseobacterium
Non tuberculosis mycobacteria
Various legionelloses
Mycobacterium avium complex
Fungi: *Fusarium*
Parasites: *Cryptosporidium*
Various viruses

5.1.2. Risks related to the equipment used

The preparation of an ice pack or bag requires multiple handling steps, all of which are potential sources of contamination.

The pouch itself is used many times (between 20 and 30 uses, sometimes more). Between two uses it must be disinfected using specific baths. This is a decontamination and not a sterilisation. If fact it is not stored in a sterile environment, and its handling by hospital staff is not sterile either. To limit this problem, some hospitals use freezer bags which are disposed of after use. However this system is fragile (frequent leaks), can only be used on small areas and, especially, has the risk of a very poor control of the cooling temperature. It is not sterile either.

Further, the bag containing the ice is, very often, wrapped in a cloth for application (frequently a bath towel). Here too, much published data shows the frequent and rapid inter-patient transmission of multi-resistant germs with the use of equipment that is not single-use, such as bedding, hospital clothing worn by the subjects, bath or toilet towels or even the curtains of a hospital room [62-66]. In the same vein, surfaces which are not directly in contact with the patient have been implied as a potential reservoir at the origin of a risk of spreading multi-resistant hospital germs [67-71]. It is therefore highly improbable that the bag or pack is exempt from this problem. An alternative is the use of a sterile field, this alternative is however not frequently used.

5.1.3. Risks related to the treated zone

The ice of an ice pack is far from being reserved for applications on healthy skin. In fact, in its post-surgical applications there is a possible entry point, the sutured area or the input zone for an arthroscope and the post-surgical part of the operation must use a rigorous aseptic procedure [72]. Finally, for the treatment of musculotendinous traumas, it is not exceptional that the trauma has resulted in associated skin abrasions (or even the loss of skin). These facts clearly impose the use of sterile equipment.

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5.2 Immediate use of the Alkantis system

The use of ice packs requires the availability of an ice producing machine. Generally this unit is located in a specific technical room within the hospital structure. Therefore, the ice must be fetched, the adequate ice pouch must be on hand, the ice may eventually have to be prepared for various reasons (crushed ice), and the pouch must be filled for application. Besides the fact that all these steps carry a risk of bacterial contamination, the entire process will take at best from 15 to 60 minutes for the final preparation of the material. This constraint is clearly a major limitation to the use of a simple and efficient treatment in many situations.

As opposed to this, the Alkantis system is stored in a freezer. This makes its use immediate when needed and needs no handling. This alternative therefore makes it possible to eliminate the use of the ice making machine and all the standard material acquisition and preparation phases. Above all, this immediate availability will be an aid to time management in some services such as the emergency room. The arrival, for example, of a patient with a sprained ankle can be dealt with very quickly. As a secondary benefit, once the cryotherapy effect is obtained (after 10 to 30 minutes of application) a medical functional examination can be carried out in optimum conditions. This situation may even possibly avoid the need for precautionary hospitalisation or superfluous additional examinations.

5.3 Consequences and other advantages of the Alkantis system

As discussed above, the intrinsic properties of this system make it an optimal cryotherapy tool. The guarantee of the preservation of an adequate temperature range will favour the attainment of therapeutic objectives while minimising all local risks related to excessive cold. This property is not shared by ice packs. In the absence of a heat sensor (never used outside experimental studies), the level of thermal reduction cannot be known. Further, the obtained thermal effect is transitory, and does not exceed about twenty minutes maximum. The main issue in this case is the most often that it is not very efficient, the threshold of tolerance to cold can even be exceeded. The Alkantis system clearly makes it possible to mitigate these limitations while extending the use of some protocols such as intermittent application without the need to change the equipment.

5.4 Conclusions

Globally, this optimisation of cryotherapy through the introduction of the ALKANTIS system into hospital structures will result in the simplification of locally applied treatments, a better management of human resources within a service, and even by a reduction in the use of analgesics while extending the use of this treatment.

Above all, this sterile, single-use system totally meets the quality and safety requirements expected from all treatment systems.

Its development is part of a quality approach designed to avoid the risk of infection for the patient and the staff.

Calendar

14 to 16 November 2012
MEDICA

March 2013
AHS / Orlando / USA

May 2013
Hernia congress / Poland / Gentz

June 14, 2013
Meish / Paris

October 2013
ACS / San Francisco / USA

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