

Combination of Gentle Local Hypothermia and Technical Lymphatic Drainage to Decrease Fracture Swellings

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Abstract: The project presented below deals with tissue swellings caused by external mechanical effects associated with injuries of living tissue (trauma), especially in the field of fractures. Based on a mnemonic trick from the emergency medicine, therapeutic interventions are discussed, the state of the art in these fields is briefly described and technical improved systems, like the gentle local hypothermia and the technical lymphatic drainage, are presented.

Keywords: fracture, extremities, gentle local hypothermia, technical lymphatic drainage, cooling and compression bandage, trauma, RICE – Rest Ice Compression Elevation

1. Introduction

Bone fractures belong to the most common injuries in the field of the trauma and reconstructive surgery. Shortly after the injury process, there would be a fluid accumulation because of lymphatic influx, protein influx and bleeding in the fracture area. The mean extent of the amount of bleeding in different fracture areas can be seen in Fig. 1. If an operation takes place in this period, it may cause a rupture of the surgical suture material, the arranged bones can be directed against each other and the operation must be repeated. Therefore the swelling must decrease first, which in experience may take 7 to 14 days [4]. This leads to high treatment costs, long delay times and persistent pain periods for the patients. The aim of this project is therefore to significantly shorten this process with a suitable novel equipment technology. The main focus is on the fractures of the extremities, which have the highest incidence with 80 % related to the totality of all fractures [4].

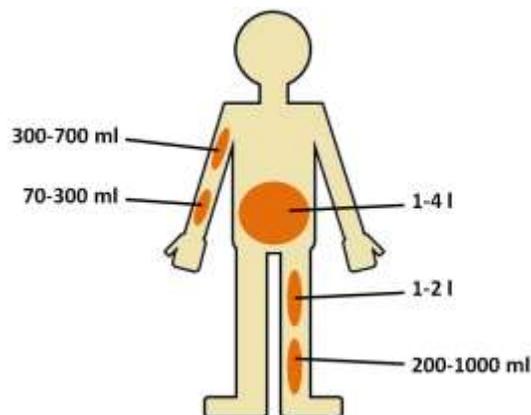


Fig. 1: Mean amount of bleeding in different fracture areas (according to [24])

2. RICE – A mnemonic trick in the emergency medicine

Referring to the medical mnemonic „RICE“, which is used to treat soft tissue injuries by paying attention to the words Rest, Ice, Compression and Elevation. These words were introduced by Gabe Mirkin in Sportmedicine Book [11] in the year 1978 and are used as acronyms for the first-aid treatment of soft tissue injuries. In the following sections the individual methods are presented.

2.1. Rest

Rest is one of the prerequisites of the onset of the self-healing powers of the body [12]. In order to avoid the uncontrolled displacement of bone fragments, so that a later merging of the bone is made possible and no other vessels are injured, a fixed bandage is usually sufficient to hold the bone in place. The bandage material varies. The present bandages consist rather of synthetic fibers (glass wool) than gypsum, because gypsum is heavier and less solid. But even gypsum still occurs frequently because of its easy handling. In order that the tissue has place to spread in the further swelling, an artificial gap in the plaster cast is usually produced, which allows an extension. This type of plaster cast is called a gap cast. Another possible alternative is to put on an orthosis, an anatomically shell system mostly made of hard plastic. The period of the rest should be long enough that the patient is able to use the affected extremity with the main work functions again and the most of the pain is gone.

2.2. Ice

At a fracture or a tissue injury the so-called acute phase reaction occurs. This is the name of the immediate systemic response, in which the body uses proinflammatory cytokines as messengers [1]. The cytokines enter the liver with the bloodstream, where they together with cortisol stimulate the organ to produce about 30 different acute phase proteins (APP) at the beginning of an inflammatory response [7]. The APPs benefit wound healing processes at the area of the immunological event, counteract the tissue damage and should prevent infections. At this stage, however, as a side-effect it comes to a change of the body temperature setpoint in the hypothalamus. The metabolic activity in the body is increased. As a result, the symptom of fever is subsequently released and the temperature in and around the damaged tissue is increased by about 2 to 5°C [15]. Also due to the increased metabolism a rapid swelling of the tissue is caused.

The task is to prevent the formation of a tissue swelling or at least to limit it. By the use of a concerted, regulated cooling influence on the tissue, the metabolism at the fracture area should be slowed down. According to the Q_{10} temperature coefficient, a rule of thumb in the biochemistry, a temperature reduction of 10 K tends to a reduction of the metabolic rate of approximately 50 % [6].

$$Q_{10} = \left(\frac{R_2}{R_1} \right)^{\frac{10}{T_2 - T_1}} \quad (1)$$

Here, R_1 and R_2 designate the respective reaction rates at temperatures T_1 and T_2 .

Due to the resulting reduced energy consumption and the adjunctive decrease in the oxygen demand in the fracture area, an adaptation to the post-traumatic reduced local oxygen supply in the tissue takes place. The local oxygen supply arises from the blood loss in the fracture area. The local hypothermia reduces the metabolism and blood circulation. It results in a decrease in the posttraumatic swelling because of the inhibition of the local inflammatory response. Also the cold treatment results in a vasoconstriction, i. e. a stenosis of the blood vessels, in the cooled tissue. Thus, the extension of the blood vessels (vasodilation) is counteracted, which would occur due to the decrease of the oxygen partial pressure based on the blood leaked from the vessels. A lower tendency to swellings and edemas because of the reduction of blood flow to about 60 to 80 % of the blood circulation at rest is the result [17]. This occurs from a skin temperature of less than 20°C [2]. From a temperature of less than 18°C, however, it may come to a decrease in the efficiency of the muscles already [9].

2.3. Compression

Is a swelling of tissue formed, it should be removed as quickly as possible. In physiotherapy the so-called manual lymphatic drainage is used. Manual lymphatic drainage is used to stimulate accumulated fluid in the tissue (lymph) to drain off and to prevent the same time that more fluid flows into. This can be achieved by the massage therapist by gently brushing his fingertips on the skin in the direction of the lymphatics. With various grip techniques the lymphatic system should be activated by the notably improving of the pumping capacity of the lymphatic vessels. The pump frequency of lymphatic vessels is at rest about 10 to 12 contractions per minute [18]; this can be increased to up to 20. The therapist generates by the changing pressure of the grips a stimulus

for the tissue. The smooth (involuntary) muscles of the lymphatics answer this stimulus with an increased pumping frequency [3]. An increased flow rate follows a frequent repetition of the grips. The direction of massage is always toward the extremity root. As a result, protein-rich edema or swelling liquid move through the superficial lymphatic system, which encases the body like a net, from a congested area of the body into a healthy area. The swelling is reduced.

According to a report by Schröder [13] local compression in a range of 30 to 40 mmHg (this roughly corresponds to 4.0 to 5.3 kPa) ensures a decrease in blood flow of 50 to 60 % in the subcutaneous tissue and of 25 to 40 % in the muscle tissue. Through the lymphatic drainage an increased blood flow in the extremities is not achieved, as it would be the case with a traditional massage. For example, a deep vein thrombosis could thereby be prevented. The disadvantage here is only the increased risk of pain.

2.4. Elevation

The elevation of the limb is used to prevent a further accumulation of swelling fluid by the force of gravity. The heart augmented must pump blood upward. The flow rate decreases because more heartbeats and therefore more time for the transport of the same volume are required. At the same time the venous return of blood to the systemic circulation increases. Thus, the rate of swelling of the fractured limb is significantly reduced. Dangerous, however, in this situation is the risk of an occurring thrombosis and a conditioned pulmonary embolism, which appears when there is a congestion of blood. These effects are also tried to be prevented by the application of pressure pulses.

3. Technical combination of ice and compression

Of the four methods mentioned cooling and compression should be reproduced by technical implementation to realize a contemporary operation. This is done by adaption to the human individual parameters of the single patients.

3.1. Gentle local hypothermia

Cooling systems for human tissue can be distinguished in two categories previously. On the one hand, there are systems with passive cooling. It involves cooling pads, also known as ice packs or cooling bandages, which are decreased to a low temperature by storage in a refrigerator. Although they are inexpensive, the cooling temperature cannot be regulated over a longer period of time because they heat up again by the body temperature and the ambient temperature. A regular change of the cooling pads must be executed and therefore this method is elaborate. This type of cooling is also not suitable for the use under cast. If a gap cast is used, a slight cooling in the gap can be generated by applying the cooling pads, but you will not be able to cool the actual location of the inflammation of the fracture area, because it is located under the plaster cast. On the other hand, there are systems with active, unregulated cooling. In such systems, such as the Cryo Cuff [23] or the Polar Care 500 [21], with ice cubes chilled water is transported from a reservoir by a pump into a hydraulic bandage. With such systems it is possible to maintain a prolonged cooling time. However, the cooling temperature is also not adjustable and a refilling with ice water is necessary. These systems may also not be fixed under a plaster cast of a fracture.

To use the hypothermia specifically, however, the local distribution of the inflammation at the fracture area must be known. For continuous, two-dimensional measurement of this distribution in the area, a way to measure the skin temperature without intervention in the human organism even under a potential cast must be found. Conventional temperature measuring methods, such as infrared cameras, cannot be used. The cast prevents the inflammation measurement because of its low thermal conductivity. Furthermore, the sensor mats must be handled as inexpensive disposables. Until now mats with a matrix-like temperature sensor arrangement for the continuous measurement were used only with low spatial resolution at distances of 10 to 20 cm in the medical field [8, 16]. With the help of an innovative textile temperature sensor mat it is not only possible to measure the temperature two-dimensional, but also to adapt it flexible to the individual human anatomy. It allows an

increased mobility compared to conventional cast. The used NTC thermistors (Negative Temperature Coefficient Thermistors) are sewn matrix-like at distances of 3 cm into the mat. They enable a two-dimensional evaluation of the skin temperature. The mat can be used even in case of a breakdown of single thermistors. Possible measurement errors could be detected by evaluating the surrounding sensors and could be excluded from the analysis. As a heat sink and thus to carry away the heat from the inflammation area of the fracture, polyethylene tubes are used. Chilled water is conducted through them. The materials are biocompatible and safe for humans even in long-term use. In order to enable a good thermal coupling to the human skin, blown films can be used. These are tubes which have not a circular cross section but a more elliptic one. In contrast to tubes with circular cross sections, they offer a larger joint surface area for heat transfer with the human skin. The tubes are combined to groups. This enables a temporally and spatially controlled cooling of areas by the use of valves and a control system is realized. Hence, it can selectively impact to the area of inflammation without dealing with an undercooling. The cooling of the medium is carried out in a re-usable device console by the use of Peltier elements. These are very well suited for the implementation in medical devices because they are small and light, free of wear and noise. They can realize the small temperature differences in this application.

Based on medical findings, that a constant temperature plateau is formed after a cooling operation of 20 to 30 min [17, 5] and this level persists after cooling breakup over 20 to 30 min [17], the cooling could be adjusted by a microcontroller such that cooling cycles could be carried out medical advisable. In the period, in which the low temperature level is maintained upright by the body, the cooling function can be interrupt, for example, to increase the battery life and not to burden the body with further cooling. Cooling processes over longer time periods, e.g. 24 h, can cause injuries by undercooling [10]. Cooling cycles are recommended of 10 min with breaks in the meantime, thus injuries by undercooling and other great interference effects can be avoided [9].

The most important technical details of the cooling system are shown in Tab. 1.

Table I: Technical Details of the System for Gentle Local Hypothermia

Principle:	heat exchange	
Cold generation:	Peltier elements	
Heat to be dissipated:	max. 30 W	
Cooling medium:	water	
Cooling temperature:	19°C	
Cooling period:	10 min	
Break time between cooling periods:	20 ... 60 min (occur not during sleep)	
Transport:	hydraulic pump	
Temp. measurement:	thermistors on smart textiles	
Coupling elements:	tubular films filled with plastic balls	
Biocompatibility:	DIN EN ISO 10993	
Legend:		

3.2. Technical lymphatic drainage

In the case of the compression system, two different types of implementation are known to date. On the one hand, there are manual systems, such as the Arctic Air Kälte-Kompressions-Bandage [22], which allows a manual inflation of a flexible pneumatic bandage by a hand air pump. With such a bandage, it is not possible to set a precise pressure or to reproduce a lymphatic drainage without considerable effort. It is also unsuitable for use under a support bandage. On the other hand, there are automated systems, such as the lympho-mat [20] or the A-V Impulse System [19], which can generate a pulsed compression by the activation of pressure chambers and thus adjust a manual lymphatic drainage. The chambers, which exhibit a pressure become less and less to the top of the leg, are successively filled by the lympho-mat with air and retain their pressure until the last chamber is filled. The pressure values are between 20 and 120 mmHg, which corresponds to 2.7 and 16.0 kPa. The air escapes then simultaneously from all three chambers and after a short break of 5 to 90 s, the cycle begins again. The previously existing systems in this area are, however, neither under a support bandage applicable, nor do they support the mobility of the patient, because an exclusive use is necessary in resting position.

As the second part of the system, a compression system is used in parallel to the cooling system. It is fitted to the human anatomy of the patient by four or five suitable shaped pressure chambers made of polyamide, which are woven of laminated jacquard fabric. There are diverse hand and ankle cuffs and they can be made in different sizes. The pressure chambers are used to maintain a constant pressure on the tissue around the fracture area. They work analog to the principle of a compression bandage. If a suitable pressure on the skin is applied, the liquid mixture of blood, lymph and proteins cannot freely propagate in all directions and the development of the swelling may be reduced. However, in order to avoid bruises and pain, the pressure chambers adapt to the shape changes caused by swelling of the tissue by deflating the compressed air or inflating ambient air. For this purpose pressure sensors are added to the pressure chambers. Moreover, higher pressures are applied to the pressure chambers in a specific frequency, so-called pressure pulses. This supports of the venous activity and thus removes the liquid of the swelling. Thereby, the pressure pulses run from the pressure chamber at the most distal position in a peristaltic sequence to the pressure chamber at the most proximal position. By these extrinsic compressions of the vessels, the blood is actively transported back into the cardiovascular system to the heart and the swelling is decreased.

In the already mentioned study by Stöckle et al. [14] also the swelling reduction at the ankle was examined by intermittent pneumatic compression with pulses compared to the use of cooling pads or continuous cooling. The compression was carried out using compression pulses of 130 mmHg, that is about 17.3 kPa, over a period of 1 s at intervals of 20 s in a pressure chamber at the sole of the foot. These values were used as an orientation.

The most important details of the system for technical lymphatic drainage are shown in Tab. 2.

3.3. Combination

Both systems should be connected with each other depending on the activity of the patient by a fuzzy logic algorithm or an artificial neuronal network. They should be driven in adaptation to the swelling state of the fracture. Thus, not only the measured values of the temperature sensor mat and the temporal pressure changes in the chambers of the compression system are evaluated. Also the movements of the patient are detected using an acceleration sensor and may provide information of the patient's condition for logging. If the patient is asleep or needs rest, the cooling and compression system can be switched to a reduced activity. In contrast if the patient is active, the influences to the fracture area can be more intensive.

4. Summary

This project is used to develop a mobile cooling and compression system, which enables the surgeon to significantly earlier execute a necessary intervention. Hence, the patient has to suffer less pain and overall cost of the treatment can be reduced significantly.

Table II: Technical Details of the System for Technical Lymphatic Drainage

Principle:	pulsed compression	
Pressure chambers:	≥ 2	
Constant pressure:	4.0 ... 5.3 kPa	
Pressure pulses:	18 kPa	
Pressure pulse period:	≤ 5 s (one pressure chamber)	
Break time between pressure periods:	20 ... 60 s (from last to first pressure chamber activation)	
Time offset of the time-shifted pulses:	~ 2 s	
Compression medium:	air	
Transport:	pneumatic pump	
Pressure measurement:	pressure sensors near the pressure chambers	
Legend:		
		<p>... control unit consisting of electronic and software</p> <p>... distribution and collection element</p> <p>... flow control by hydraulic or pneumatic valves</p> <p>... hydraulic or pneumatic pump system</p> <p>... pressure sensor</p> <p>... pressure element</p> <p>... pneumatic feeding</p> <p>... electric feeding</p>

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