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INNOVATIVE COOLING AND COMPRESSION SYSTEM TO DECREASE SWELLINGS ON FRACTURES AT EXTREMITIES

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ABSTRACT

If there is a break in a bone, the surrounding tissue swells due to protein influx, bleeding and lymphatic influx. If an operation takes place in this period, it may cause a rupture of the surgical suture material and the operation must be repeated. To support the process of the swelling reduction active, it should be tried to exploit the principles in the occurrence of a chemical reaction, in this case an inflammatory reaction. By the use of a concerted, regulated cooling influence on the tissue, the metabolism at the fracture area should be slowed down. At the same time the excess accumulation of fluid can be removed from the fracture area by simulating a technical lymphatic drainage. The operation can be arranged at an earlier point in time.

1. INTRODUCTION

Fig. 1: Ankle fracture on the left ankle [27]

The most common injuries in traumatology include the ankle fracture and the wrist fracture. They belong to the fractures of extremities, which have the highest incidence with 80 % related to the totality of all fractures [4]. Shortly after the injury process, a swelling of the skin and soft tissue envelope occurs in the fracture area, as shown in Fig. 1. A chirurgical operation in the area of the fracture cannot be carried out in this time. 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 injured are not able to spend the waiting time outside the hospital, but are treated fully inpatient.

After the injury process the broken extremity should be immobilized and relieved as soon as possible. In the trauma surgery this is realized by the application of a support bandage, typically with cast, which is used both preoperative and postoperative. 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 (see Fig. 2(a)). Another possible alternative is to put on an orthosis, an anatomically shell system mostly made of hard plastic, as shown in Fig. 2(b). If the tissue is swelling in such an environment, there may be pressure ulcers because of insufficient padding, which in turn can lead to partial or complete circulatory disorders. Pressure damage to nerves, muscle degeneration due to immobilization of the extremity in the support bandage, deep vein thrombosis and pulmonary embolism are other problems that may occur.

The aim of the project is to design a smart bandage for the application in the area of swelling at fractures of extremities, which can be mounted between the human tissue and the material for the stabilization of the fracture. It should profit to reduce and accelerate the local inflammatory reaction, to prevent or reduce the swelling and to accelerate the decrease of the posttraumatic swelling. This allows an early surgery of the fracture and by the way a reduction of the pain and the tendency to muscle spasms of the patient at the same time.


(a) Gap cast [26] (b) Orthosis [28]

Fig. 2: Different types of support bandages

2. COOLING SYSTEM

2.1 Biological background of cooling systems on human tissue

For the decline of the swelling by inhibition of the local inflammatory reaction and acceleration of the decrease of the swelling, the effect of gentle local hypothermia, i. e. undercooling of the tissue by cold treatment, was studied. 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 [18]. This occurs from a skin temperature of less than 20°C [1]. From a temperature of less than 18°C, however, it may comes to a decrease in the efficiency of the muscles already [9].

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%. Due to the resulting reduced energy consumption and the associated decrease in the requirement of oxygen and nutrient in the fracture area an adaption to the posttraumatic reduced local supply of oxygen and nutrient occurs in the tissue, which is a result of the bleeding in the fracture area. Furthermore, the supply of proteins, which would release an edema generation by their ability to bind large amounts of liquid, decreases. [5]

The cooling also leads to a reduction of the nerve conduction velocity of about 2.4 m/s per K [6, 12] and an increase of the refractory period. Thus, the threshold of pain is reduced from tissue temperatures of about 10 to 15°C [11], which in turn can cause reductions of muscle spasms based on an uncomfortable position.

In a study of Stöckle et al. [16] investigations about the efficiency of cooling on fractures have already been carried out. In this case a reduction of swelling of the ankle of 18% with the use of cooling pads and of 36% with the use of continuous cooling could be measured preoperatively over a period of 24 hours. Postoperatively the swelling had decreased on the third day by 20% with the cooling pads and by 27% with continuous cooling, on the sixth day even by 38% with the cooling pads and by 64% with the continuous cooling. Thereby the cooling pads, which were taken out of the refrigerator, were changed four times a day. The continuous cooling was carried out by a hydraulic system with a fixed water temperature of 12°C.

2.2 State of the art of cooling systems on human tissue

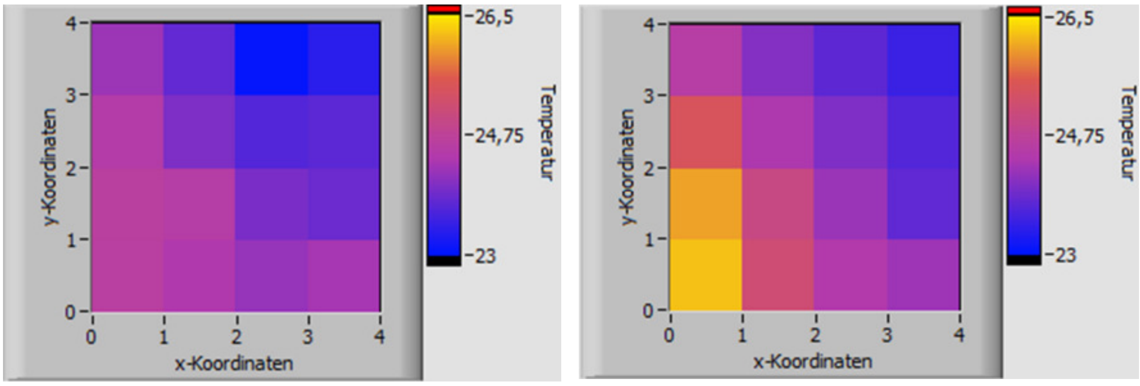
Cooling systems for human tissue can be distinguished in two categories previously. On the one hand, there are systems with passive cooling. It involves cooling pads, also known as ice packs or cooling bandages, which are decreased to a low temperature by storage in a refrigerator. Although they are 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 in 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.

2.3 Innovative cooling system

A system adapted to the human thermoregulation enables an individual adaption to the single patients and their specific fracture by temporally and spatially variable cooling. To insert the hypothermia specifically, the local distribution of the inflammation at the fracture area should be known. For a continuous, two-dimensional measurement of this distribution a possibility must be created to measure the skin temperature without an intervention in the human organism under the plaster cast. The temperature of the injured tissue is increased about 2 to 5°C [2]. Conventional methods of temperature measurement, such as by the use of infrared cameras, cannot be used, because the plaster cast prevents the inflammation measurement through its low thermal conductivity. 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, 17]. For the fracture cooling a textile-based temperature sensor mat should be developed for the use under the support bandage. As initial tests of a functional demonstrator on a copper-cladded, flexible circuit board with 16 sensors and sensor intervals of 1 cm showed, that a temperature distribution in the fracture area is already well detectable. To measure the temperature distribution, negative temperature coefficient SMD thermistors are used at first, which produce a maximum total error of ± 0.84°C by consulting the tolerances of the measuring section. This would be quite sufficient for the application. Furthermore for the system test tissue warming was induced by sportive exercises or application of ointment, which is used for local heating of tissue. For example, skin warming up to 2°C based on temperature measurements both before and after ointment application is noticeable well resolved in Fig. 3 (a) and (b). The ointment application was arranged in the sector x=0…2 and y=0…2.

A second sensor mat made of jersey fabric (see Fig. 4) is implemented with textile circuits of electrically conductive yarn. Through a matrix of 5 x 8 sensors at a distance of 3 cm a high resolution is reached and simultaneously room is left for cooling channels, which can be integrate additionally. Due to the large surface of the mat of 15 x 24 cm^2 it can be concluded on different regions of activity and inflammatory around the area of the fracture. The measurement of the individual voltage values, that is time-clocked over multiplexer, is realized through a bridge circuit by a „NI myDAQ“ measurement card from National Instruments [25]. For reconditioning and evaluation of the measurement values, the software „LabVIEW 2012” [24] was used. With this, the temperature distribution is represented



(a) Measurement sector before applying the skin warming ointment

(b) Measurement sector after applying the skin warming ointment

Fig. 3: Temperatures on the upper side of the hand at a room temperature of 20°C

Fig. 4: Textile temperature sensor mat with 40 SMD thermistors

graphically. A very good assessment of the situation of the center of inflammation is possible through the high measurement resolution and the close meshed measured value recording. Even measurement errors (e. g. due to the failure of single sensors) can be detected by evaluating surrounding sensors and considered accordingly.

The hydraulic system, which is currently under development, is used to transport chilled water from the place of the cold source to the center of the inflammation in the fracture area. The cold sink is made possible by a parallel connection of Peltier elements, which deprive an adjacent finned heat sink the heat and thus cool the water flowing around this heat sink. The heat sink is positioned in an already to the hydraulic system associated enclosure. The cooled water is channeled via a pump to different partial circuits located behind, whereby on the basis of the measured temperature distribution only the areas were flow through, in which a cooling is required. Because a plurality of circuits is provided in the bandage, several types of fractures can be cooled with only one bandage. The not required cooling regions are detected by the temperature measurement and disconnected from the system by valves. Thus, a temporally and spatially regulated cooling can be realized. The cooling tubes were first sewn onto the temperature sensor mat in parallel to the sensors. That way, the skin temperature can be measured directly on the fabric and the cooling can be coupled directly to the skin surface. The cooling temperatures are between 18 and 20°C. The different partial circuits are formed of specially designed U-shaped polyethylene tubular films to permit a cold transfer over as large an area as possible with simultaneous return to the heat exchanger. They can reach, in contrast to tubes with circular cross sections, a larger collective surface area for heat transfer with the human skin. The tubular film is filled with plastic balls to prevent squeezing with parallel application of the compression system and to exert stimulation on the tissue at the same time. The surrounding areas, lying on the same height on which the temperature sensors are mounted, are also filled with plastic balls in order to enable a smooth supporting surface. All materials are biocompatible according to DIN EN ISO 10993 and harmless to humans even at long-term use.

Based on medical findings, that a constant temperature plateau is formed after a cooling operation of 20 to 30 min [18, 5] and this level persists after cooling breakup over 20 to 30 min [18], 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].

3. COMPRESSION SYSTEM

3.1 Biological background of compression systems on human extremities

A targeted increase in pressure on the swelling tissue reduces the swelling spread, because the liquid outflow is hampered in its spread. According to a report by Schröder [15] 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. A well-known example of such a treatment constitutes the compression stocking, which is available to purchase in various levels of pressure. Compression is also used in the treatment of patients with lymphatic drainage. Starting with pressure on the human tissue in the distal region, i. e. on the sole of the foot or on the palm, and leading to the proximal region, i. e. towards the thigh or upper arm, lymph, protein accumulations and blood are returned to the large lymphatic ducts or to the heart. 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.

In the already mentioned study by Stöckle et al. [16] 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. In this case, a preoperative reduction of the swelling volume over a period of 24 hours of 56% was measured, the swelling was reduced by 36% on the third postoperative day and on the sixth day by 63%. In comparison to the swelling reduction by cooling the use of compression achieved better results. 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.

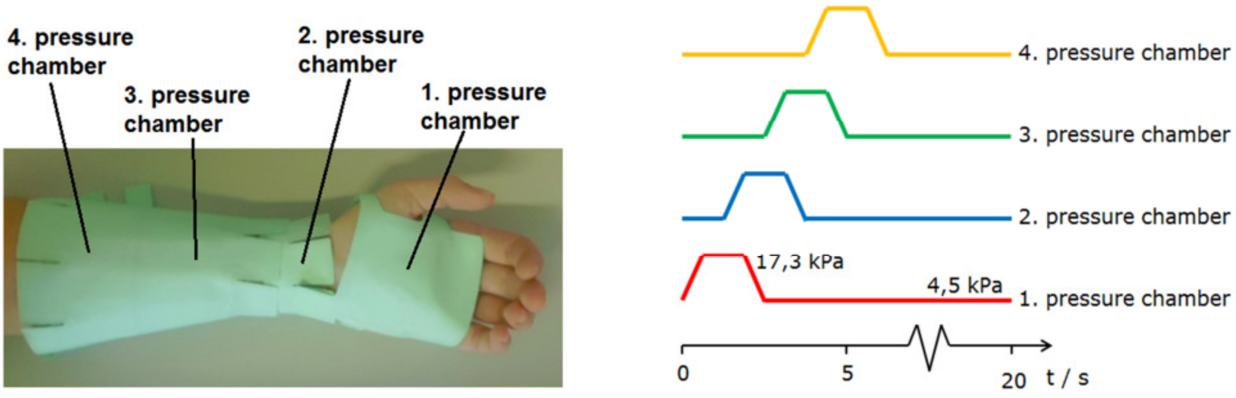
3.2 State of the art of compression systems on human extremities

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 Artic 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 lympha-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 lympha-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.

3.3 Innovative compression system

In parallel to the already explained cooling system a compression system should be designed for the fracture area. This is adjusted by a plurality of properly shaped pressure chambers, for example of polyamide, to the anatomy of the human wrist or ankle (see Figure 5 (a)). The pressure chambers are used to maintain a constant pressure on the tissue around the fracture area and have an analog effect to the principle of a compression bandage. If a corresponding pressure on the skin is applied, the liquid mixture of blood, lymph and proteins cannot freely spread in all directions and the swelling may develop only partially. However, in order to avoid squeezing and thus pain, the pressure chambers adapt to the swelling-dependent shape changes of the tissue by release or supply of pressure air. For this purpose, the pressure chambers are provided with pressure sensors. To support the venous activity and thus for removal of the swelling liquid, the pressure chambers are also provided with higher pressures in a particular frequency, so-called intermittent pressure pulses. They take place in a size of 130 mmHg (approximately 17.3 kPa) for 1.5 s every 20 to 30 s. Thereby, the surrounding veins could be stretched and compressed active and thus the collected blood-quantity, which depends on the fracture location, could be removed [16]. By using a membrane pump and solenoid valves, it is possible to provide the individual pressure chambers, which are serially attached to the axis of the extremity, in such a way successively with a short-time pressure pulse that the blood is expressed in venous plexus and channeled in a directed movement out of the extremity back towards the body core. The pressure pulses run from the pressure chamber with the most distance to the heart through all the pressure chambers up to the pressure chamber closest to the heart. The appearance of such occurring pressure pulses is illustrated in Figure 5 (b). There is an imitation of the natural processes of walking and grasping, as it would appear in normal tissues without support bandages. Between the pulses usual maximum pressures of conventional compression bandages should exist, which may occur in the range of 30 to 40 mmHg (approximately 4 to 5.3 kPa) [13, 14]. The swelling spread is reduced by a curtailed liquid outflow and actively degraded by the supported removal of tissue fluid. The pressure chambers are mounted around the hydraulic system to accelerate the swelling reduction parallel.



(a) Pressure chambers adapted to the anatomy of the human wrist

(b) Time-shifted pressure pulses of 4 pressure chambers

Fig. 5: Pressure chambers of the compression system and their time-dependent activation

4. FUSION OF COOLING AND COMPRESSION SYSTEM

By the linking of the two systems, an optimization of the active swelling combating should be achieved. On the one hand it is tried to displace and to reduce the swelling by compression mechanisms, and on the other hand to prevent the swelling from spreading by cooling.
Both systems should be linked activity-dependent using an algorithm and operate adapted to the swelling state of the fracture. The swelling tendency of the tissue in the fracture region is highly dependent on the individual thermal regulation of the human. This is influenced by body surface area, BMI, clothing, activity, time of day, and more [3]. Thus, the measured values of the temperature sensor mat and the temporal rate of pressure changes will not only be evaluated in the chambers of the compression system, but, for example, also the movements of the patient via an accelerometer, the ambient temperature, time and point in time of the beginning of the therapy should give information about the patient's condition. Is the patient asleep and needs rest, only minimal functions of the cooling and compression system will run. If the patient is active, stronger influences may be exerted on the fracture area. For the implementation of such an algorithm, the fuzzy logic is used. This makes it possible to describe complex systems with nonlinear behavior due to so-called expert knowledge, as it occurs very often in medicine. Human experience is transferable to engineering systems. Such algorithms are well usable, because the fuzzy rules can be adjusted to the application areas, and they have a high traceability of the results. However, they are not capable of learning and do not automatically adapt to environmental changes. All time the patient should be in a position to even intervene in the regulatory cycle in order to counteract discomfort, for example.

5. SUMMARY

The proposed cooling and compression bandage should enable an active counteracting to a swelling after a fracture and thus a necessary operation clearly formerly. Thereby the patient should receive a greatest possible mobility. Even patients with cast, external fixator or surgical wounds on the whole leg can be supplied. This is also possible after the time of the operation. Furthermore through the elimination of ice cooling and cooling pads it comes to a relief of the nursing stuff and thus to significant cost savings. Investigations in relation to a possible beneficiary sequence of the different therapies and possible mutual interferences must still be conducted.

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