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Extended Abstract

Three-dimensional evaluation of postoperative swelling in treatment of zygomatic bone fractures using two different cooling therapy methods: a randomized, observer-blind, prospective study

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Abstract

Background: Surgical treatment and complications in patients with zygomatic bone fractures can lead to a significant degree of tissue trauma resulting in common postoperative symptoms and types of pain, facial swelling and functional impairment. Beneficial effects of local cold treatment on postoperative swelling, edema, pain, inflammation, and hemorrhage, as well as the reduction of metabolism, bleeding and hematomas, have been described.

The aim of this study was to compare postoperative cooling therapy applied through the use of cooling compresses with the water-circulating cooling face mask manufactured by Hilotherm in terms of beneficial impact on postoperative facial swelling, pain, eye motility, diplopia, neurological complaints and patient satisfaction.

Methods: Forty-two patients were selected for treatment of unilateral zygomatic bone fractures and were divided randomly to one of two treatments: either a Hilotherm cooling face mask or conventional cooling compresses. Cooling was initiated as soon as possible after surgery until postoperative day 3 and was applied continuously for 12 hours daily. Facial swelling was quantified through a three-dimensional optical scanning technique. Furthermore, pain, neurological complaints, eye motility, diplopia and patient satisfaction were observed for each patient.

Results: Patients receiving a cooling therapy by Hilotherm demonstrated significantly less facial swelling, less pain, reduced limitation of eye motility and diplopia, fewer neurological complaints and were more satisfied compared to patients receiving conventional cooling therapy.

Conclusions: Hilotherapy is more efficient in managing postoperative swelling and pain after treatment of unilateral zygomatic bone fractures than conventional cooling.

Trial registration number: German Clinical Trials Register ID: DRKS00004846

Keywords: Zygomatic bone fracture, Three-dimensional optical scanner, Hilotherm, Conventional cooling

Background

The face represents the most prominent position in the human body and is often involved in trauma injur-ies. The zygomatic bone is particularly prone to facial injuries due to its prominence [1] and is the second most common mid-facial bone affected. The fracture of the zygomatic bone can pose considerable func-tional complications such as restricted mouth opening. Disruption of the zygomatic position can also carry psychological, aesthetic and functional significance, causing impairment of ocular and mandibular func-tions. Therefore, a prompt diagnosis of fracture and soft tissue injuries is important for both cosmetic and functional reasons [2].

In most cases the treatment of unilateral zygomatic bone fractures leads to a significant degree of tissue trauma that again causes an inflammatory reaction [3]. As a result, patients display common postoperative symptoms and types of pain, facial swelling and func-tional impairment [4]. Pain is typically brief and peaks in intensity in the early postoperative period. In con-trast, facial swelling reaches the characteristic max-imum 48 to 72 hours after surgery [5]. These symptoms can affect the patient's quality of life and well-being. To increase patient satisfaction after treatment of uni- and bilateral zygomatic bone fractures, it is a necessary goal to minimize side effects as much as possible [6]. One way do so is to prescribe medication such as corticoste-roids [7], non-steroidal anti-inflammatory drugs [8], a combination of corticosteroids and non-steroidal anti-inflammatory drugs [9] or enzyme preparations such as serrapeptase [10]. Furthermore, there are also non-medication methods to treat the above side effects. These can include manual lymph drainage [11], soft laser [12,13] and cryotherapy [14]. Historically, the therapeutic use of local or systemic cryotherapy was first described by Hippocrates [15]. Beneficial effects of cold treatment on postoperative swelling have been de-scribed previously [16-20] as well as the positive impact on edema, pain and inflammation [21-23]. The activity of inflammatory enzymes rises with increasing tempera-tures [21]. On reviewing the

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literature, there is a lack of scientific evidence and trials in oral and maxillofacial surgery which show positive as well as no effect of cold therapy [24]. Cooling therapy varies from the conven-tional, such as ice packs, gel packs or cold compresses, to mechanically supported continuous cooling with face masks. Both positive and negative side effects have been previously discussed [16,20]. The aim of this study was to examine the effect of hilotherapy in comparison with a conventional cooling method using cold compresses on swelling, pain, eye motility, diplopia, neurological complaints and overall patient satisfaction following treatment of unilateral zygomatic bone fractures.

Methods

The study was approved by the local ethics committee at the University Aachen, Germany (EK 142/2008). Before the beginning of the study, written informed consent was obtained from each patient.

Patients

Forty-two healthy patients were scheduled for treatment of unilateral zygomatic bone fractures (Figure 1). Only pa-tients who required open reduction and internal fixation using a 3 point fixation technique were divided randomly into two treatment groups. One group of 21 patients were treated with conventional cooling and the other group of 21 patients received continuous cooling using hilotherapy after repositioning of unilateral zygomatic bone fractures. The observer was not aware of the kind of therapy that was applied at the time of the patient examinations and during analysis of the data. The patients were not blinded and were informed that the study was designed to compare the effect of the Hilotherm cooling face mask and conventional cooling compresses on swelling, pain, eye motility, diplopia, neurological complaints and patient satisfaction.

Fixation methods

The fracture sites were exposed using different standard incisions. Frontozygomatic suture was approached using an eyebrow incision, zygomatico maxillary buttress was exposed using an intraoral buccal sulcus incision and add-itional exposure of the infraorbital rim was accomplished using an infraorbital approach. In all cases, plating was attempted along frontozygomatic suture, infraorbital mar-gin and zygomatico maxillary buttress (Figure 2). The osteosynthesis was performed with 2.0 mm or 1.5 mm plates (Stryker, Duisburg, Germany) per fracture line.

Cooling methods

Hilotherapy refers to the water-circulating external cooling device Hilotherm Clinic (Hilotherm GmbH, Argenbühl-Eisenharz, Germany) that consists of a preshaped thermo-plastic polyurethane mask and the Hilotherm cooling device control unit (Figure 3A,B). The temperature setting is adjustable from +10°C to +30°C and was set to 15°C immediately after surgery. Conventional cooling was per-formed through cool compresses. Both cooling methods were initiated as soon as possible after surgery until post-operative day 3 continuously for 12 hours daily.

Study protocol and inclusion criteria

Only patients with a unilateral zygomatic bone fracture were included in this study. Potential participants were ex-cluded from the study because of missing operability, the possibility of missing the follow-up examination, preg-nancy, nursing, drug addiction, recent operations, diseases of the heart, metabolism and central nervous system, infec-tious disease, and diseases affecting the circulation, sys-temic, malignant and immune systems, as well as blood coagulation disorders and allergic reactions to pharmaceu-ticals and antibiotics. The clinical inclusion and exclusion criteria are shown in Table 1. All patients were examined and scanned on fixed dates using standardized methods and techniques. Thus, each patient received the same post-operative analgesic drug therapy which included 1000 mg paracetamol intravenously twice daily for 3 days, 600 mg ibuprofen orally (day 1, ibuprofen 600 mg three times per day; day 2, ibuprofen 600 mg twice daily; day 3, ibuprofen 600 mg once daily; day 4, ibuprofen 600 mg once daily). Antibiotic prophylaxis consisted of 600 mg clindamycin intravenously three times daily for 3 days. A single peri-operative dose of 250 mg steroids was administered to each patient intravenously. During a first visit, the physician col-lected information about past illnesses and diseases and conducted a standard blood test. The operation took place using general anesthesia and oral intubation.

During the study the following parameters were assessed: pain, swelling, eye motility, diplopia, neurological com-plaints and patient satisfaction. To minimize bias through patient contact, the patients were examined and hospital-ized in separate rooms.

Measurement of facial swelling

This study used the three-dimensional optical scanner, FaceScan3D (3D Shape GmbH, Erlangen, Germany), to measure facial swelling in volume (ml) as described previ-ously [18-20]. The three-dimensional optical scanner con-sists of an optical range sensor, two digital cameras, a mirror

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construction and a commercial personal computer. The sensor is based on a phase-measuring triangulation method [25]. There is no need for special safety precau-tions for the patient, since the advantage of this optical sensor is its contactless data acquisition accompanied by its high accuracy in the z-direction with 200 µm and a short measurement time of 430 ms. The mirror construc-tion permits the capture of over 180° of the patient's face. The computer program Slim 3D (3D Shape) automatically triangulates, merges and postprocesses the data [26]. The final output is a triangulated polygon mesh that is visual-ized as a synthetically-shaded or wire-mesh representation

[27]. For the volume calculation all patients were pho-tographed with a standard technique for frontal views of the face. Adjustment occurred on the Frankfurt horizontal line, parallel to the floor. Patients sat on a self-adjustable stool and were asked to look into a mirror with standard horizontal and vertical lines simulating a red cross marked

Neurological analysis

The neurological analysis was utilized in order to enable the evaluation of nerve dysfunctions. The results were recorded on a score that ranges between 0 and 9, with 9 being the worst neurological score. The skin of the upper lip was checked using a cotton test for touch sensation (regular = 0; hypesthesia = 1; anesthesia = 2), a pinprick test using a needle for sharp pain (regular = 0; hypalgesia = 1; analgesia = 2), and a blunt instrument for testing sharp-blunt-discrimination (regular = 0; partly = 1; none = 2). Additionally, a two-point discrimination test (0 to 0.9 cm = 0; 1 to 2.5 cm = 1; 2.6 to 4 cm = 2; >4 cm = 3) was exe-cuted on the lip. The neurological score was assessed at five points in time: before surgery (T0), on day 1 (T1), day 7 (T2), day 28 (T3), and day 90 (T4) postoperatively.

Eye motility and diplopia

For the analysis of eye motility and diplopia the patient was required to fix on a light source at a distance of 30 cm. While the head was fixed, the light source was guided in different directions of view. The relative dis-placement of the reflected images to each other and the movement of the eye were analyzed. Meanwhile, the pa-tient was asked about diplopia. The data were collected at four points in time: before surgery (T0), on day 1 (T1), day 7 (T2) and day 28 (T3) postoperatively.

Patient satisfaction

Each patient was asked to complete a questionnaire on the postoperative day 10, subjectively rating their comfort and satisfaction with the applied postoperative cooling therapy. The grading scale ranged from 1 to 4, where 1 de-noted "very satisfied" and 4 "not satisfied".

Statistical analysis

To check for statistical significance of quantitative vari-ables, the Student t-test for unrelated samples was used. All data are expressed as mean values ± standard devi-ation, with a P-value ≤0.05 taken as significant. For analyz-ing gender, eye motility and diplopia, a $\chi 2$-test was utilized, and a P-value ≤ 0.05 was taken as a level of significance. The statistical analysis was conducted using SPSS for Windows version 14.0 (SPSS Inc., Chicago, IL, USA).

Results

Baseline characteristics

Forty-two patients were randomly enrolled in the study. After reposition and osteosynthesis of unilateral zygomatic bone fractures, 21 patients were assigned to conventional cooling therapy and 21 patients were treated with hilo-therapy. The clinical and demographic characteristics of patients in both groups are shown in Table 2. Both groups showed no statistical significances regarding gender, age, body mass index, surgery duration, hospitalization duration, preoperative pain and neurological score as well as preoperative limited eye motility and diplopia.

Postoperative swelling

Swelling was measured in terms of volume (ml) as de-scribed in the methodology section. On the day 1 follow-ing surgery a statistically significant reduction in swelling could be seen by applying the Hilotherm cooling device compared to conventional cooling therapy (Hilotherm 9.45 ± 4.42 ml versus conventional 20.69 ± 9.05 ml, P =

0.00002) (Figure 5). Maintaining this tendency on day 2 following surgery, a statistically significant reduction in swelling could be seen (Hilotherm 13.20 ± 7.71 ml versus conventional 22.97 ± 8.50 ml, P = 0.00036). On day 3 (Hilotherm 14.44 ± 8.21 ml versus conventional 23.52 ± 9.69 ml, P = 0.00217) and on day 7 (Hilotherm 7.06 ± 4.97 ml versus conventional 11.51 ± 6.70 ml, P = 0.01907) the measured swelling was also significant. On the postopera-tive day 28, the measured swelling was almost equal in both groups (Hilotherm 3.62 ± 4.02 ml versus conven-tional 4.80 ± 4.43 ml, P = 0.36980). Maximal swelling was noticed on postoperative day 3 (Figure 5).

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Postoperative pain score

Pain was quantified in terms of a 10-point visual analogue scale ranging from 0 to 10, based on subjective analysis. On postoperative days 1 and 2, a significantly reduced pain score was obtained by hilotherapy compared to conven-tional cooling (day 1, Hilotherm 2.38 ±1.36 versus conven-tional 4.10 ± 1.76, P = 0.00105; day 2, Hilotherm 2.34 ± 1.49 versus conventional 4.38 ± 1.32, P = 0.00003). No statistically significant difference could be seen on postop-erative day 7 (Hilotherm 1.43 ± 0.68 versus conventional 1.90 ± 1.18, P = 0.11627) (Figure 6).

Postoperative neurological score

Hilotherapy obtained a significantly reduced neuro-logical score at day 1 compared to conventional cooling (Hilotherm 2.57 ±1.29 versus conventional 3.90 ± 1.76, P = 0.00775). There were no statistically significant differ-ences between groups concerning the neurological score at postoperative days 7, 28 or 90 (day 7, Hilotherm 2.05 ± 0.80 versus conventional 2.90 ± 1.97, P = 0.07642; day 28, Hilotherm 1.76 ± 1.81 versus conventional 2.06 ± 1.79, P = 0.55187; day 90, Hilotherm 0.48 ± 0.87 versus conventional
0.67 ± 1.02, P = 0.51947) (Figure 7).

and health status as well as patient independent factors such as surgeon experience, duration of surgery time, ex-tent of trauma and fragment dislocation as well as use of antibiotics [3,18,19,30]. Since in this study the use of antibiotics and the duration of surgery time were not sig-nificantly different among both groups, and since health-compromised patients were excluded from the study, these factors are considered not to have influenced the ob-served results.

Although the effects of different cooling methods have been investigated for a number of maxillofacial and plastic surgery treatment procedures, there is so far no study comparing conventional cooling versus hilotherapy follow-ing treatment of zygomatic bone fractures [18,19,31-33].

Consistent with our results, Belli and colleagues [31] reported the safe use of hilotherapy as well as a postopera-tive decrease in pain and swelling intensity and duration after Le-Fort-I osteotomy and bilateral sagittal osteotomy of the lower jaw. While they investigated only 10 patients without a comparison to other cooling techniques, Jones and colleagues [32] recorded differences between hilo-therapy and conventional groups in a greater cohort of 50 patients following face-lift surgery procedures. In contrast to our results, Jones and colleagues [32] described a statis-tically significant increase in patient-reported postopera-tive swelling in the Hilotherm group with no significant differences regarding ecchymosis, hematoma or pain be-tween groups. However, subjectively the majority of pa-tients found the cooling masks to be comforting. In order to overcome the lack of significance of subjective assess-ments versus objective evaluation methods, Moro and col-leagues [33] measured the distance of multiple anatomic landmarks for swelling purposes. In so doing, 90 patients operated on for maxillomandibular malformations were di-vided into three groups and treated either with hilotherapy, conventional cooling or left untreated as a control group.

As expected, no cryotherapy treatment led to the worst re-sults whereas cooling with the hilotherapy method showed the least degree of swelling.

With the aim of improving measurement accuracy of different swelling stages, our study group used three-dimensional evaluation by the means of an optical face scanner [18-20]. Hence, three-dimensional volumes could be measured instead of two-dimensional lines.

Although cryotherapy is a relatively safe way to treat complications after oral or maxillofacial surgeries, cold therapy should only be employed with caution. Above all, very young or very old patients can react with intol-erances to external cooling [34].

Topographical considerations make it difficult to quan-tify the facial volume of swelling. However, there are some limitations of this measurement technique which have to be discussed. The volume measurement with this tech-nique is limited to localized facial swelling, since facial areas which have not been affected by the swelling are ne-cessary for surface matching [18,19]. Some methods are described to predict soft tissue via cephalograms, which are able to create three-dimensional images. Ethically, the benefit of cephalograms might not justify the patient's ex-posure to ionizing radiation [35].

In summary, use of the cooling device by Hilotherm reduces postoperative swelling and pain compared to conventional cooling. Biological effects of cooling ther-apy on vascular, neural, metabolic and muscular sites are known. Cryotherapy decelerates cell metabolism be-cause, according to Van't Hoff law, it slows down bio-chemical reactions. Regarding vascular effects, cold therapy constricts blood vessels. The intensity of vaso-constriction reaches the highest value at a temperature of 15°C. Furthermore, a decrease in body temperature slows down peripheral nerve conduction. For tempera-tures below 15°C, nerve conduction is completely disabled and the vasoconstriction turns into a vasodila-tation. These biological effects influence postoperative symptoms. Meanwhile, the anti-

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edema effect is caused by the vasoconstriction and the pain reducing effect of the cold is related to a blocking of nerve endings. This blocking decelerates nerve conduction, and conse-quently the inflammation phenomena. Ice packs or similar conventional cooling methods use a temperature of around 0°C. Such a low temperature constrains lymph drainage and cell metabolism [36]. The effects of a treatment with overly low temperatures have already been mentioned. The inference is that a system is needed that maintains the desired temperature over a fixed period of time. To fulfill this requirement, this study worked with the cooling device Hilotherm Clinic (Hilotherm GmbH) [37]. Further studies are needed to investigate the benefits of this technique in other clin-ical research areas.

Conclusions

Hilotherm is easy to use for both, patients and medical staff. Constant cooling with the possibility of adjusting temperature are important advantages. This is why hilotherapy is expected to play a greater role in oral and maxillofacial surgery as well as other clinical fields in the future.

Ethical approval

Approval for the study was obtained from the relevant ethics committee at the University of Aachen, Germany (EK 142/2008). Before the beginning of the study, written informed consent was obtained from each patient. The study was registered with the Trial Registration Number: DRKS00004846.

Competing interests

The authors declare that they have no competing interests.

Authors' contributions

AM and MR were responsible for the study concept and design. AM was responsible for data acquisition and writing the paper. AM and MADR carried out the statistical analysis. All authors were responsible for data analysis and interpretation. AM and MR drafted the manuscript. MR, FH, NCG, AG and MG were involved in revising the manuscript. All authors reviewed the manuscript. All authors read and approved the final manuscript.

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