Hilotherm Efficacy in Controlling Postoperative Facial Edema in Patients Treated for Maxillomandibular Malformations

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Background: A cooling system based on polyurethane preshaped masks for postoperative cryotherapy, named Hilotherm, has been recently introduced. The purpose of this study was to evaluate the effectiveness of this equipment in controlling postoperative edema and compare the results with those obtained with a group treated with conventional cryotherapy and a group not treated with cryotherapy.

Methods: Ninety patients were included in this randomized controlled trial. The 90 patients were divided into 3 groups. Group A was treated with Hilotherm. Group B was treated with conventional cryotherapy. Group C was not treated with cryotherapy. Using a tape measure, we measured for both sides of the face the distances in centimeters between point 0 and external canthus (α), most lateral point on the ala of the nose (β), commissura labialis (γ), and Pos (δ). We performed a Kruskal-Wallis test comparing the average variation of edema on the right and left sides of the face for each facial segment of patients of the 3 groups from time 0 to time 24 hours.

Results: No cryotherapy is the worst treatment for every segment studied. In anatomic regions defined β, γ, and δ, Hilotherm was more effective in containing edema than the ice pack 24 hours after the first measurement. Opposite results were seen on district α, the site not completely enclosed in the mask.

Conclusions: The substantial difference between different treatments probably consisted in the greater reliability of the Hilotherm system, which is characterized by easy handling, constant temperature control, comfort, and practicality of the masks.

Key Words: Hilotherm, postoperative swelling, edema, facial edema, postsurgical swelling, cryotherapy, hilotherapy, maxillofacial surgery, Le Fort, osteotomy, swelling control

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Combined use of glucocorticoids and nonstreoidal anti-inflammatory drugs is the therapy of choice for edema. In addition to drug therapies, compression bandages, massage therapy, and cryotherapy are also used.

Cryotherapy is the application of ice packs to decrease local temperature. This causes vasoconstriction of the precapillary arterioles, decreased tissue perfusion, and diminution of metabolic reactions. Temperature between 12.8°C and 15.6°C is estimated to be most effective in reducing edema.[1,2] Cryotherapy administered by ice packing is definitely an effective antiedemigenic method, although it is difficult to quantify its efficacy. Probably, that is the reason why the protocols used by different authors differ significantly in time and mode of administration.

The main differences are as follows:

- freezing mixture (ice, frozen gel, frozen mixture of water and alcohol)
- details of application (whether to place an ice pack directly on the skin)[1,3]
- timing of application and duration of treatment

A new equipment for cryotherapy at constant temperature (Hilotherm, Argenbühl-Eisenharz, Germany) has recently been introduced. It consists of a polyurethane mask connected to a circuit in which the coolant flows (demineralized water). The masks provided with the device are modeled to fit the different regional anatomies (Fig. 1).

The purpose of this study was to evaluate the effectiveness of this equipment in controlling postoperative edema and compare the results with those obtained with a group treated with conventional cryotherapy and a group not treated with cryotherapy.

MATERIALS AND METHODS

Ninety patients were included in this randomized controlled trial. Patients were admitted to our institution from April 2009 to April 2010. Fifty-eight patients were affected by progenic syndrome, 30 by prognathism, and 14 by maxillomandibular asymmetry. The sample consisted of 38 women and 52 men aged between 19 and 41 years, with an average age of 29 years. These patients underwent orthognathic surgery under general anesthesia. All patients underwent Le Fort I osteotomies + bilateral sagittal split osteotomy of the mandible. The 90 patients were divided into 3 groups (groups A–C). The 3 groups differed for the method of application of cryotherapy.

Group A was treated with Hilotherm, applied in the operating room and maintained for 48 hours. Therapy was periodically interrupted to allow meals and personal hygiene. The cryotherapy protocol with Hilotherm consisted in wearing a mask of polyurethane, preshaped to fit the middle and lower thirds of the face. The mask was connected by tubes to a portable structure, which makes

FIGURE 1. A, Hilotherm system. B and C, Application of the polyurethane mask.

use of demineralized water as coolant. The temperature was adjustable between +10°C and +30°C and was constantly kept at + 15°C. In this study, we exclusively applied the mask model for the middle and lower thirds of the face (Fig. 2).

Group B was treated with conventional cryotherapy, which involved local application of ice for 30 minutes every 90 minutes during the vigil period, as described by many authors.[4] Ice packing started within an hour after the end of the surgery and was maintained for 48 hours.

Group C was not treated with cryotherapy.

Surgical procedures were identical in all groups. The surgical team was the same during every surgical intervention. No complications occurred during surgery and postoperative stage. Anesthetic procedures were identical in all patients. Titanium plates and screws were used for the rigid fixation of the maxilla; mandibular fixation was obtained with 3 bicortical screws for each side.

Every patient started soft diet on the morning after surgery. The 3 groups were administered the following medications during the postoperative period:

- piperacillin sodium (2085 g) + tazobactam sodium (268.3 mg) intravenously (IV) every 12 hours for 10 days
- esomeprazole 40 mg IV every 12 hours for 5 days
- betamethasone 4 mg IV every 12 hours on the first day, 1.5 mg every 12 hours on the second day, suspended on the third day

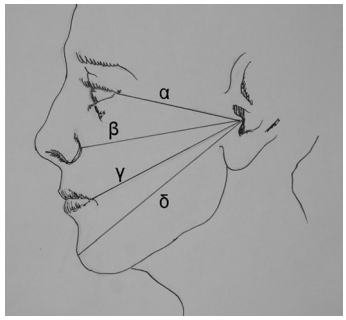

FIGURE 2. Anatomic regions studied. α: external canthus-tragus; β: most lateral point on the ala of the nose-tragus; γ: commissura labialis-tragus; δ: pos (most prominent point of the chin skin-tragus).

In all groups, no other antiedemigenic aids were used. To evaluate the efficacy of the therapy with Hilotherm, we measured distances between defined points on the skin with a tape measure, as described by Laureano et al.[2] We stained those points with an indelible marker and used them as landmarks.

Before surgery, 5 landmarks were marked on each side:

- point 0 (lowest point in the pit between tragus and antitragus)
- external canthus
- most lateral point on the ala of the nose
- commissura labialis
- Pos (most prominent point of the chin skin)

Using a tape measure (extension: 1 m, definition: 0.1 cm), we measured for both sides of the face the distances in centimeters between point 0 and

- external canthus
- most lateral point on the ala of the nose
- commissura labialis
- Pos

We named the following:

- α: distance between point 0 and the external corner of the eye
- β: distance between point 0 and the most lateral point on the wing of the nose
- γ: distance between point 0 and the corner of the lips
- δ: distance between point 0 and Pos

Each measurement was repeated at least 3 times to minimize the operator's errors in detection. Measurements were made after 30 minutes, after 24 hours, and after 48 hours from the end of surgery (time 0). Then we calculated the variations of these lengths in centimeters after 24 hours from time 0.

Finally, we calculated for each patient the average of the sums of the values found on the right and left sides of the face for each facial segment, and we called these values α1, β1, γ1, and δ1; for example, α1 = (α on the left side + α on the right side) / 2.

Statistical Analysis

To evaluate the differences between the results of the treatment with Hilotherm, with ice and without cryotherapy, we performed a Kruskal-Wallis test comparing the variation of the values α1, β1, γ1, and δ1 of the patients of groups A, B, and C from time 0 to time 24 hours.

RESULTS

The average variations in swelling from time 0 to time 24 hours of α1 were found to be 0.237 cm in group A (indicating an average increase of edema), 0.227 cm in group B, and 0.36 in group C; this difference was statistically significant (Kruskal-Wallis test $P = 0.002$) (Fig. 3).

Average variations in swelling from time 0 to time 24 hours on β1 were 0.357 cm in group A and 0.62 cm in group B and 0.783 in the group C. Significant differences were found (Kruskal-Wallis test $P < 0.001$) (Fig. 3).

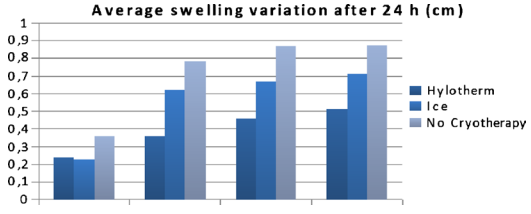

FIGURE 3. Average variation of the swelling on α1, β1, γ1, and δ1 after 24 hours from time 0 in patients treated with ice versus patients treated with Hilotherm.

On γ1, there was a mean value of 0.457 cm in patients of group A, a mean value of 0.667 cm in those of group B, and a mean value of 0.867 cm in patients of group C. The Kruskal-Wallis test confirmed the presence of statistically significant difference (Kruskal-Wallis test $P < 0.001$) (Fig. 3).

As for the comparison of the values of δ1, we recorded an average variation of swelling of 0.513 cm in patients of group A, a mean change of 0.71 cm in group B, and a mean value of 0.873 cm in the group C. The Kruskal-Wallis test found statistically significant differences between the 3 treatments on δ1 (Kruskal-Wallis test $P < 0.001$) (Fig. 3).

DISCUSSION

Cryotherapy reduces local temperature (between 10°C and 15°C), and it has different effects on postoperative edema:

- decrease of the cellular metabolism that allows the cells to survive with less oxygen consumption and less secondary hypoxic damage[1,6]
- vasoconstriction that reaches its maximum intensity at 15°C[7]
- reduction of the microvascular permeability and leakage of macromolecules[8]
- decrease of the conduction speed of peripheral motor and sensory nerves that causes reduction of local pain and muscle spasm[9]

The traditional cryotherapy application protocols differ in timing and types of application. There are several types of freezing mixtures: ice packs, ice massage, gel packs, ice chips in a plastic bag, ice in a wash clot, frozen mixture of alcohol and water, prepackaged chemical ice packs, ice wrapped in a paper towel, and melted ice water through wet towels.[10]

Some authors suggest applying ice packs directly on the skin, whereas other authors propose to apply oil on the skin or a cloth between the skin and the ice pack to prevent injury from hypothermia.[1,4]

Different authors propose a variety of administration timings. The most widely used protocol is the ice pack application at intervals of 10 to 20 minutes for 48 to 72 hours,[10] but there is no clear evidence about the most effective cryotherapy protocol.[1,5,11,12]

Many studies compared the efficacy of intermittent therapy to continuous therapy, leading to contradictory results.[13,14] Moreover, according to the literature, we demonstrated that a treatment with cryotherapy is capable of decreasing edema better than a treatment without cryotherapy. Conventional cryotherapy has some drawbacks, partly due to the patient, partly due to the method.

Patients often disregard the intervals of time of application and cannot continue the application when they sleep (night interruption). The correct placement of the ice pack is neither controllable nor constant, and patient cooperation might be poor. Moreover, ice pack cannot provide uniform heat conduction. What is well known is that rapid changes in temperature and extreme low temperatures should be avoided. It is also apparent that cryotherapy should start early after injury at temperatures between 10°C and 15°C.

Patients undergoing conventional cryotherapy might incur different adverse effects: damage from hypothermia,[6,9,15] vasodilatation caused by block of nerve conduction, paralysis of the contractile mechanism of the vascular walls,[7,16] and intense perception of cold.[7]

Unlike traditional cryotherapy, therapy with Hilotherm is not subject to interruptions (possibility to keep the mask during the night); it is not affected by the state of consciousness or the cooperation of the patient and ensures a uniform temperature distribution on the involved soft tissues.

Application temperature can be chosen between 10°C and 30°C. The preshaped polyurethane mask adapts easily to the morphology of the patient and restricts the hypothermic effect to the areas affected by injury. It also ensures uniform cooling and avoids abrupt temperature gradients. The mask can be placed directly in the operating room at the end of surgery and constantly worn for several days. An element of discomfort is related to the formation of water droplets on the polyurethane masks, by condensation of the surrounding air.

In our study, we set Hilotherm at 15°C. At this temperature, we could not detect any damage from hypothermia, but obtained a local analgesic effect. Belli et al[10] evaluated comfort in using Hilotherm with a questionnaire in a group of 10 patients who underwent orthognathic surgery. People involved in this study were asked to assign a score within 0 and 2 to the following parameters: pain, comfort at application, and comfort during therapy.

They stated that therapy with Hilotherm reduced the intensity and duration of edema and soothed pain. According to these authors, Hilotherm granted better and faster recovery of mandibular function, greater comfort, and easier patient management by the nursing staff.

According to literature, there are various methods of measuring edema. These methods include techniques that make use of computed tomography scans, magnetic resonance imaging, ultrasonography, three-dimensional range camera, optical scanners, photographic support, and individual perceptions of the patient.[17,18]

Among the existing procedures, we chose to use direct measurement of the distances between landmarks on the skin for the handiness, lack of cost, and lack of invasiveness of this method. We choose to assess the variation of edema after 24 hours from time 0 because we noticed that after the surgical intervention, edema is more important at that time.

Some of the facial segments studied were completely covered by the mask (β, γ, δ), whereas segment α coincided with the upper border of the mask. Data provided by the analysis of segment α indirectly suggests that cryotherapy with Hilotherm is effective on the regions that are fully enclosed by the mask. The results showed that the shape of the premodeled mask is a major determinant of the effectiveness of cryotherapy with Hilotherm. No cryotherapy is worst treatment for every segment studied. In anatomic regions defined β, γ, and δ, 24 hours after the first measurement, Hilotherm was more effective in containing edema than the ice pack. Opposite results were seen on district α (joining tragus-external corner of the eye), the site not completely enclosed in the mask, where treatment with ice contained swelling in 24 hours better than Hilotherm. Patients treated with Hilotherm had a reduction in swelling after 24 hours from time 0 more than those treated with ice on anatomic regions β,γ, and δ.

Cryotherapy with Hilotherm has proven an effective antiedemigenic aid, superior to application of ice packs. In this study, the reduction of edema induced by Hilotherm resulted higher than that obtained with other methods.

The substantial difference between different treatments probably consisted in the greater reliability of the Hilotherm system, which is characterized by easy handling, constant temperature control, comfort, and practicality of the masks. This allows starting cryotherapy immediately after surgery, avoiding sudden changes in temperature, excessive hypothermia, or damage by freezing; Hilotherm can also be applied regardless of patient's cooperation. Cryotherapy with Hilotherm has proven effective in all anatomic areas included in the mask we used.

REFERENCES

1. Greenstein G. Therapeutic efficacy of cold therapy after intraoral surgical procedures: a literature review. *J Periodontol* 2007;78:790–800

2. Laureano Filho JR, de Oliveira e Silva ED, Batista CI, et al. The influence of cryotherapy on reduction of swelling, pain and trismus after third-molar extraction. A preliminary study. *J Am Dent Assoc* 2005;136:774–778
3. Nusair YM. Local application of ice bags did not affect postoperative facial swelling after oral surgery in rabbits. *Br J Oral Maxillofac Surg* 2007;45:48–50
4. Hochberg J. A randomized prospective study to assess the efficacy of two cold-therapy treatments following carpal tunnel release. *J Hand Ther* 2001;14:208–215
5. Barber F. A comparison of crushed ice and continuous flow cold therapy. *Am J Knee Surg* 2000;13:97–101
6. Deal DN, Tipton J, Rosencrance E, et al. Ice reduces edema: a study of microvascular permeability in rats. *J Bone Joint Surg Am* 2002;84:1573–1578
7. Guyton AC. *Medical Physiology.* Philadelphia, PA: WB Saunders Co, 1991
8. Llewelyn J, Ryan M, Santosh C. The use of magnetic resonance imaging to assess swelling after the removal of third molar teeth. *Br J Oral Maxillofac Surg* 1996;34:419–423
9. Stillwell K. *Handbook of Physical Medicine and Rehabilitation*. 2nd ed. Philadelphia, PA: WB Saunders, 1971:268–272
10. Belli E, Rendine G, Mazzone N. Cold therapy in maxillofacial surgery. *J Craniofac Surg* 2009;20:878–880
11. Knight KL. *Cryotherapy in Sports Injury Management*. Champaign, IL: Human Kinetics, 1995:95–98
12. Chotani MA, Flavahan S, Mitra S, et al. Silent α2C adrenergic receptors enable cold-induced vasoconstriction in cutaneous arteries. *Am J Physiol Heart Circ Physiol* 2000;278:1075–1083
13. Dolan MG, Thomton RM, Fish DR, et al. Effects of cold water immersion on edema formation after blunt injury to the hind limbs of rats. *J Athl Train* 1997;32:233–237
14. McDonald WD, Guthrie JD Jr. Cryotherapy in postoperative setting. *J Foot Surg* 1985;24:438–441
15. Sunderland S. *Nerve and Nerve Injuries*. New York: NY: Churchill Livingstone, 1978:186–1 88; further review: *Nerve Injuries and Their Repair*. 2nd ed. New York, NY: Churchill Livingstone, 1991
16. Kanlayanaphotporn R, Janwantanakul P. Comparison of skin surface during the application of various cryotherapy modalities. *Arch Phys Med Rehabil* 2005;86:1411–1415
17. Knight K. *Cryotherapy-Theory, Technique and Physiology.* 1st ed. Chattanooga, TN: Chattanooga Corporation, 1985:17–26
18. Milles M, Desjardins PJ, Pawel HE. The facial plethysmograph: a new instrument to measure facial swelling volumetrically. *J Oral Maxillofac Surg* 1985;43:346–352
19. Malone TR, Engelhardt DL, Kirkpatrick JS, et al. Nerve injury in athletes caused by cryotherapy. *J Athl Train* 1992;27: 235–237
20. La Velle BE, Snyder M. Differential conduction of cold through barriers. *J Adv Nurs* 1985;10:55–61
21. Taber C Contryman K, Fahrenbruch J, et al. Measurement of reactive vasodilatation during cold gel pack application to nontraumatized ankles. *Phys Ther* 1992;72:294–299
22. Lowitzsch K, Hops HC, Gallard J. Changes of sensory conduction velocity and refractory periods with decreasing tissue temperature in man. *J Neurol* 1977;216:181–188

