



Efficacy of Hilotherapy face mask in improving the trend of edema after orthognathic surgery: a 3D analysis of the face using a facial scan app for iPhone

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Abstract

Purpose Cryotherapy after orthognathic surgery is essential for the control of facial edema. The aim of our study is to evaluate the efficacy of Hilotherapy face mask in reducing facial edema after orthognathic surgery, studying facial surfaces with an innovative, fast, economical 3D facial scan system based on an iPhone app.

Methods Eighty-four patients with Class III were included: 35 patients treated with Hilotherm after orthognathic surgery (Group 1), 32 patients with ice packs (Group 2), 7 patients who refused cryotherapy (not 1 - not Group 2). Their facial scans performed immediately after surgery (T0), at 24 (T1), 48 (T2) and 72 h (T3) after surgery, were acquired in specific software, and the discrepancies between them were studied in an accurate 3D volumetric method.

Results We measured a significantly better edema trend in Group 1 in the tragus–nasal wingline and in the tragus–labial commissure line at T1, and also in the tragus–menton line at T2 and T3.

Conclusions In conclusion, Hilotherapy represents a more comfortable and more effective cryotherapy system in controlling the trend of facial edema after orthognathic surgery. The method we used for the facial scans is accurate, cheap, smart, and fast. As demonstrated by the 3D volumetric study of the face, the regions of the middle third of the face are those in which the difference is most noticeable.

Keywords Orthognathic surgery · Hilotherapy · 3D application · Maxillofacial surgery

Introduction

Cryotherapy after orthognathic surgery represents the most basic and widely used method for the reduction of postoperative edema: cold therapy together with an adequate medical therapy is essential for the improvement of the surgical outcome [1]. In fact, edema and pain are the main symptoms in the early postoperative days after orthognathic surgery, and giving good cryotherapy can make a difference for the patient.

The usefulness of ice at 0 °C is controversial, because it causes an excessive vasoconstriction and a reduction of

lymphatic drainage [2], and temperatures between 12.8 °C and 15.6 °C are estimated to be most effective in reducing edema [3].

Hilotherapy is an alternative cryotherapy system, which provides controlled and stable temperatures, through masks that are designed to adhere well to the patient's face [4]. Compared to traditional ice packs, it allows the administration of cold by precisely controlling the temperature and the duration.

The edema-reducing effect of Hilotherm face mask compared to traditional ice packs has been described in the literature, and its efficacy after oral, facial trauma, and orthognathic surgery has been documented. However, given the difficulty in measuring facial edema, to our knowledge, there is little evidence of precise three-dimensional (3D) analyses of the facial edema trend in patients treated with this cryotherapy system after orthognathic surgery.

The aim of our study is to evaluate the efficacy of Hilotherapy face mask in reducing facial edema after

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orthognathic surgery, studying facial surfaces with an innovative, fast, economical, and self-made 3D facial scan system based on an iPhone app.

Patients and method

This is a prospective comparative clinical study, conducted at the Department of Oral and Maxillofacial Surgery of the University Hospital *Federico II* of Naples, Italy.

In the period between January 2018 and December 2020, 81 patients who underwent orthognathic bimaxillary surgery for correction of Class III were studied. All enrolled patients voluntarily joined the trial and signed a written consent, as requested by our Local Ethics Committee. The trial was conducted in accordance with the Declaration of Helsinki.

We included only adult patients with Class III undergoing orthognathic surgery in good general health. The following were excluded: patients with Class II, patients simultaneously undergoing genioplasty or other ancillary treatments, patients operated on only one jaw, underage patients, patients who developed erythema or purpura or urticaria following placement of ice on the skin.

A total of 74/81 patients who met the selection criteria were enrolled: 35 patients who received cryotherapy using the Hilotherapy face mask after surgery constitute *Hilotherm Group*; 32 patients who received ice therapy after surgery constitute *Conventional Therapy Group*. Finally, 7 patients enrolled refused any form of cryotherapy due to lack of compliance: they were therefore excluded from each group and were considered separately in *No Intervention Group*.

Regardless of the underlying malocclusion and the extent of the planned surgical movements of the jaws, all patients received the same surgical technique (maxilla-first Le Fort I osteotomy, bilateral sagittal splint by Epker) and were operated on by the same surgical team. Patients undergoing other osteotomies were not considered for our study.

All patients received the same postoperative medical therapy: ceftriaxone 2 gr i.v. intraoperative and for 2 days after surgery, betamethasone 8 mg i.v. for 3 days and then gradually reduced over the next 6 days, gastric protection, analgesic therapy with ondansetron 8 mg/4 mL + ketorolac trometamine 60 mg/2 mL + tramadol 200 mg/2 mL through elastomeric pump for the first 24 h. All patients received the same amount of postoperative intravenous hydration (1500 cc of fluids for the first 3 days after surgery) and the same postoperative hospital care. All patients in all groups were instructed for face care and oral hygiene measures, including the use of 0.2% chlorhexidine digluconate mouthwash at least twice daily.

Patients of the Hilotherm Group had cryotherapy through the Hilotherapy system face mask, with a controlled temperature of 12 °C. The face mask was placed inside the

operating theater immediately after surgery, between 10 and 30 min, and maintained for at least 24 h. It was periodically interrupted to allow patients their personal hygiene and to feed themselves.

The Conventional Therapy Group received ice in specific bags on the face bilaterally. The ice packs were also placed inside the operating theater immediately after surgery, between 10 and 30 min and maintained for at least 24 h with small interruptions for the pack substitution every 2 h.

The Hilotherapy system consisted of Hilotherm cooling machine, cooling transferring tube, face mask, and accessories (used to fix the face mask, represented by elastic bands and fixing bandages).

Each patient underwent a 3D face scan 4 times: 1 h after the intervention (T0), after 24 h (T1), 48 h (T2), and 72 h (T3). To get fast and accurate scans, we used the Bellus3D Face Camera Pro System© (model number FCP01, Bellus 3D Face App, Bellus 3D Inc.) available for iPhone X, XS, XS Max, XR, 11, 11 Pro, or 11 Pro Max. The app provides a face scan wizard very simple to run. At the end of the procedure, an Object file (OBJ), containing the downloadable face scan, was generated. The type of scan that we set up was an HD 24 MB file size with 250,000 triangles and 4 K color texture map.

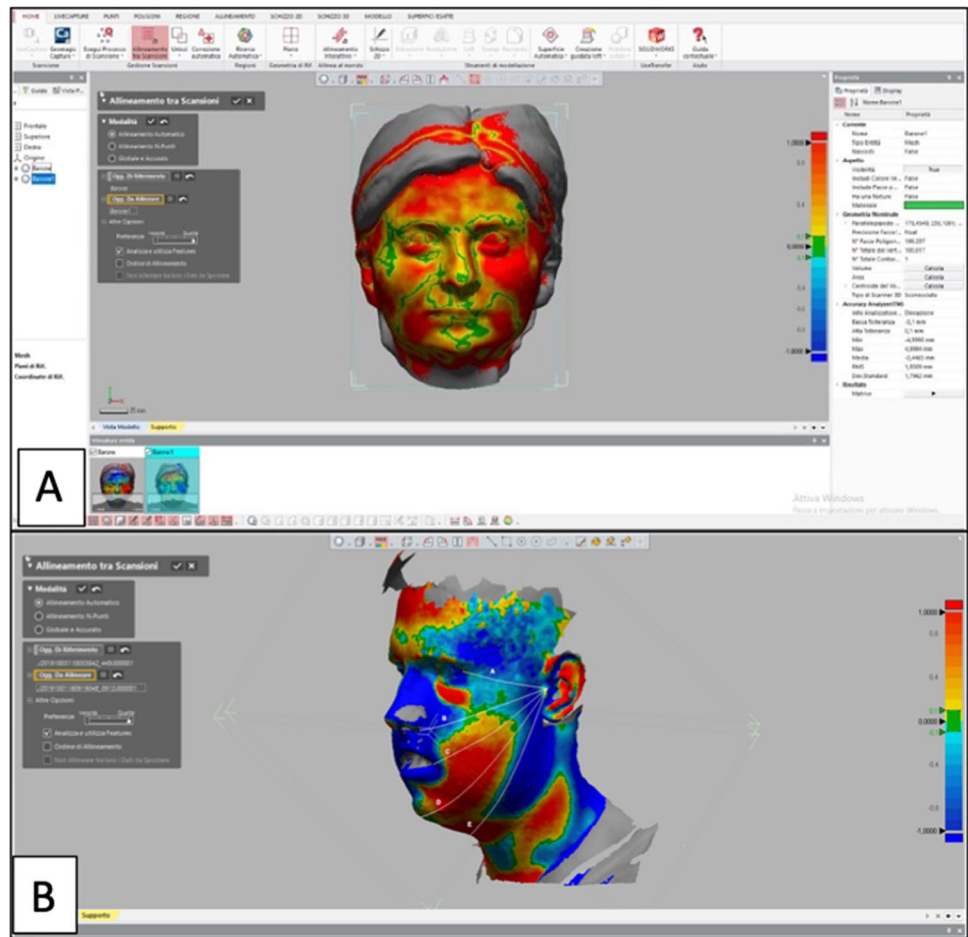
Each face scan was imported into the Geomagic Design X 3D software (2019, 3D Systems, Raindrop Geomagic GmbH, NC, USA). With this software, we superimposed the virtual scans of each patient at various times, and we measured the average discrepancy (in millimeters) between the overlapping volumes (Fig. 1a).

We have chosen 5 linear references on the facial scans: *line A* (from the tragus to the palpebral commissure), *line B* (from the tragus to the base of the nasal wing), *line C* (from the tragus to the oral commissure), *line D* (from the tragus to the menton), *line E* (from the tragus to the cervicomandibular fold) (Fig. 1b).

For each facial line examined, we have calculated the average millimetric discrepancy obtained by the overlapping of two consecutive facial scans. We called the values of these discrepancies “*D*.” In particular, we called *D1* the discrepancy between T1 and T0, *D2* between T2 and T0, and *D3* between T3 and T0. This mean discrepancy is indicative of the progression of facial edema, and its positive/negative sign corresponds to an increase/decrease in edema respectively.

The data were tabulated into the statistical software SPSS (IBM SPSS Statistics for Windows, Version 20.0. IBM Corp., Armonk, NY, USA). A *Shapiro–Wilk* test was carried on evaluating the normal distribution of all *D* in Groups 1 and 2, and a *T Student* test was carried out to assess the significance of *D* values between these two groups for each line of reference, with the aim to study the trend of facial edema Hilotherm *versus* ice packs.

Fig. 1 Superimposition of the 3D facial scans relative to a female subject (a). Measure process of the average discrepancy between the overlapping volumes following 5 linear references on the facial scans in a male subject (line A: from the tragus to the palpebral commissure; line B: from the tragus to the base of the nasal wing; line C: from the tragus to the oral commissure; line D: from the tragus to the menton; line E: from the tragus to the cervicomandibular fold) (b)



Finally, the values obtained from the facial scans of the 7 patients who refused cryotherapy were reported without interfering with the statistical tests. Values of $p < 0.05$ were considered statistically significant.

Results

Overall, 74 patients were included: 35 in the Hilotherapy Group with a mean age of 25.6 years (15 males and 20 females); 32 in the Conventional Therapy Group with a

mean age of 24.1 years (14 males and 18 females); finally, the 7 patients of the No Intervention Group had a mean age of 23 years (3 males and 4 females).

For each group, we measured D1, D2, and D3 for 5 facial lines of reference. The average values obtained for these lines are summarized in Table 1. Overall, on the average of the 5 lines, the average D we measured were as follows: $D1 = 6.65 (\pm 0.87)$ mm for the Hilotherapy Group, $D1 = 7.53 (\pm 0.91)$ for the Conventional Therapy Group, and $D1 = 9.94 (\pm 0.97)$ for the No Intervention Group; $D2 = 7.17 (\pm 0.74)$ mm for the Hilotherapy Group, $D2 = 8.59 (\pm 1.08)$ for the

Table 1 Mean values of discrepancy in mm (D1=discrepancy at 24 h, D2 at 48 h, and D3 at 72 h) in the three groups. A: measurement on the tragus–palpebral commissure line. B: tragus–nasal wing line;

C: tragus–labial commissure line; D: tragus–menton line; E: tragus–cervicomandibular sulcus line

Area	D1 (T1-T0)					D2 (T2-T0)					D3 (T3-T0)				
	A	B	C	D	E	A	B	C	D	E	A	B	C	D	E
Hilotherapy	0.3	5.4	11.8	12	3.8	0.4	6.1	12.5	12.6	4.2	0.3	6.3	12.5	12.8	4.5
Conventional Therapy	0.3	6.4	13.3	13.4	4.1	0.5	7.8	15.1	15.1	4.4	0.6	7.6	16.1	16.2	4.67
No Intervention	1	7.1	18.4	19	4.2	1.1	8.5	18.9	19.9	5	1.1	8.9	9.2	20.1	5.4

Conventional Therapy Group, and $D2 = 10.68 (\pm 1.22)$ for the No Intervention Group; $D3 = 7.17 (\pm 0.8)$ mm for the Hilotherm Group, $D3 = 9.05 (\pm 1.15)$ for the Conventional Therapy Group, and $D3 = 10.94 (\pm 1.29)$ for the No Intervention Group (Table 2).

Between groups Hilotherm and Conventional Therapy, the Shapiro–Wilk test showed a normal distribution of D1, D2, and D3 for each facial line we measured, with $p < 0.001$ in all cases.

Between groups Hilotherm and Conventional Therapy, Student’s *T* test revealed that the difference for D1 was statistically significant for lines C ($p < 0.001$) and D ($p = 0.011$); the difference for D2 was statistically significant for lines B ($p < 0.001$), C ($p = 0.005$), and D ($p = 0.005$); the difference for D3 was statistically significant for lines B ($p = 0.028$), C ($p < 0.001$), and D ($p < 0.001$). The *T* test calculated on the mean of all 5 lines (see Graph 1) showed a $p < 0.001$ for D1, a $p < 0.001$ for D2, and a $p < 0.001$ for D3 between groups Hilotherm and Conventional Therapy.

Discussion

The measurement of facial edema is often a controversial method in maxillofacial surgery: some authors have used linear measurements [4], other optical scanners [5], still others

more complex methods that generally require waste of time and money. The iPhone app we used is a smart, low-cost, fast, repeatable, and self-made tool for face scanning.

We acquired a 3D photo at T1, T2, and T3, and through the Geomagic software, we evaluated the discrepancy between these scans and the T0 scan. In this way, we were able to accurately assess the trend of facial edema in the various areas of the face for each group.

Studies have reported that a therapeutic skin surface temperature is accepted ranging from 10 to 15 °C, which allows comfort of the patient during cryotherapy and increases patient compliance with the treatment [3, 6, 7].

During Hilotherapy, a water-circulating cooling device is applied directly to the face after surgery maintaining the right temperature for a continuous, slowing down cellular metabolism, decelerating biochemical reactions, and determining vasoconstriction [4].

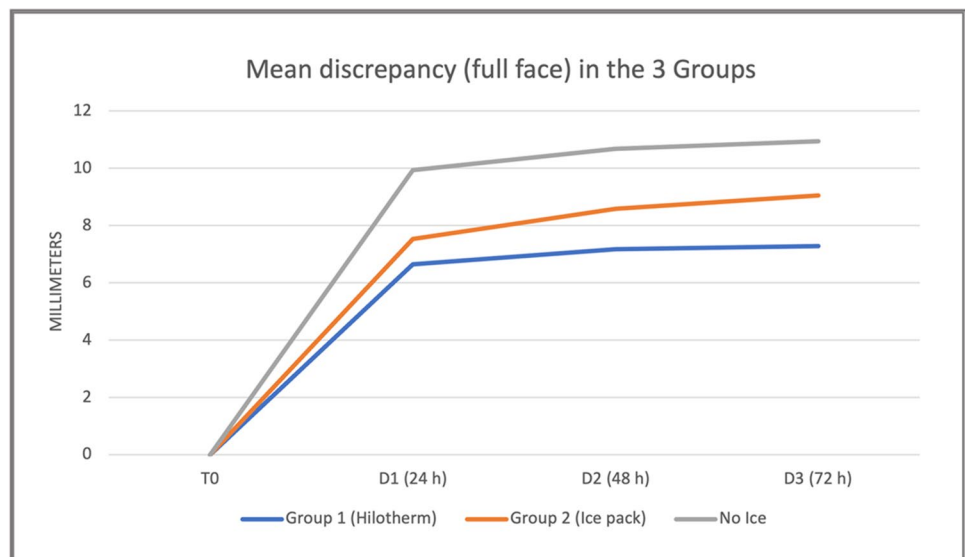
It is demonstrated that Hilotherm, compared to traditional ice, also has better effects on pain control [8, 9] and it is associated with high levels of patient satisfaction [2, 10]. Chadha et al. [11] noted that the hospitalization time was further reduced when patients were offered Hilotherapy, and that opiate analgesia requirement was less in the Hilotherapy group. Barca et al. [12] in their comparable trial study between patients treated with ice bag and patients treated with the Hilotherm cooling system reported a more rapid edema reduction after 48 h of the Hilotherm treatment. Other authors have shown that the best vasoconstriction effect with Hilotherm is around 15 °C [13, 14].

A temperature close to 0° like ice reduces peripheral nerve conduction: for lower temperatures, nerve conduction is disabled, and vasoconstriction loses efficacy, with negative results in the reduction of edema [15–17].

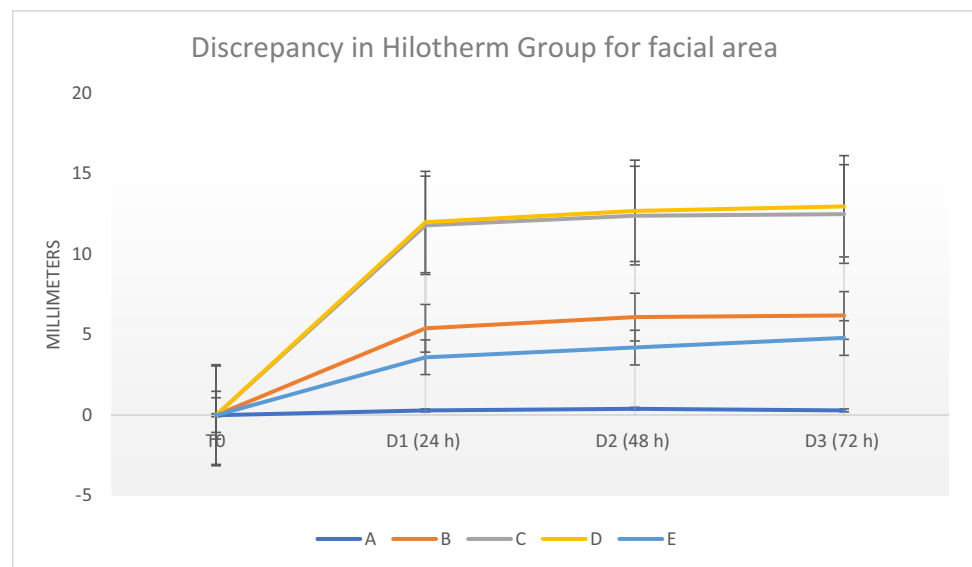
Table 2 Mean discrepancy in mm at the full face in the three groups

	D1 (24 h)	D2 (48 h)	D3 (72 h)
Hilotherm	6.65	7.17	7.29
Conventional Therapy	7.53	8.59	9.05
No Intervention	9.94	10.68	10.94

Graph 1 Mean discrepancy in mm at the full face in the three groups (Group 1: Hilotherm Group; Group 2: Conventional Therapy with ice packs group, No Ice: No Intervention Group patients that refused cryotherapy)



Graph 2 Discrepancy in mm in Hilotherm Group for the 5 different facial lines of reference—A: measurement on the tragus–palpebral commissure line. B: tragus–nasal wing line; C: tragus–labial commissure line; D: tragus–menton line; E: tragus–cervicomandibular sulcus line



The results of our study have demonstrated an efficacy of the Hilotherapy system in the reduction of facial edema following orthognathic surgery, compared to traditional cryotherapy. The analysis of the results showed a $p < 0.001$ for the differences of D1, D2, and D3 in the average of the 5 measurements between groups Hilotherm and Conventional Therapy, demonstrating that the difference between the Hilotherm and the ice bags is very significant in all T. The Student test calculated for each line of reference showed that for lines A and E the difference is not significant between groups Hilotherm and Conventional Therapy. For line B, the difference is significant in D2 and D3, and for lines C and D, the difference is significant in D1, D2, and D3.

Hilotherapy showed greater effectiveness in the central reference lines, when compared with the Conventional Therapy Group. This is probably due to the face mask's elastic which, passing behind the ears, compresses the mask against the cheekbone region. The lower portion of the face mask is also fixed through an elastic that passes behind the neck, but in the malar region, the adhesion between the face mask and the skin is certainly greater. Another interesting consideration that can be deduced from our results is that facial edema progresses downwards with each passing day: the discrepancies on the E line progressively increase, while it decreases on the A line (as shown in Graph 2), due to the gravitational descent of the edema.

Although we have also used Hilotherm face masks for other types of surgery (e.g., for trauma surgeries), we selected only orthognathic patients to consider equal and reproducible osteotomies with the aim to avoid influencing the results as much as possible.

In conclusion, Hilotherapy represents a more comfortable and more effective cryotherapy system in controlling the trend of facial edema after orthognathic surgery. The method

we used for the facial scans is accurate, cheap, smart, and fast. As demonstrated by the 3D volumetric study of the face, the regions of the middle third of the face are those in which the difference is most noticeable.

Declarations

Ethical approval No general ethical approval was needed, with only a signed patient required by the hospital.

Conflict of interest The authors declare no competing interests.

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