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Post-operative hilotherapy in SMAS-based facelift surgery: A prospective, randomised, controlled trial

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KEYWORDS
Hilotherapy;
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Summary *Background:* Ecchymosis, oedema, haematoma and pain after SMAS-based facelift surgery are all the direct result of the physical trauma of surgery and subsequent inflammatory response. Hilotherapy is a novel form of cryotherapy that purports to minimise these events through single-use face masks circulating cooled, sterile water. This study was performed to assess the validity of Hilotherapy in this population of patients.
Methods: Over 14 weeks fifty consecutive patients were randomised to post-operative facial cooling with Hilotherapy or management with standard dressings alone, while fifteen subsequent, consecutive patients were randomised to cooling of one side of the face but not the other. Assessment of ecchymosis, oedema, haematoma and pain was performed independently by clinical staff and patients. The second analysis was undertaken to better delineate pain relief using each individual patient as their own control.
Results: The Hilotherapy mask produced a statistically significant difference in facial skin temperature ($p = 0.01$). In the second limb of the study patients reported a statistically significant increase in facial swelling 6–8 days post surgery in the half of the face that was treated with the mask ($p = 0.05$) but there was no significant difference in ecchymosis, haematoma and pain between comparison groups ($p > 0.10$) in either limb of the study. Subjectively the majority of patients found the cooling masks to be comforting.
Conclusion: In this randomised, controlled trial the Hilotherapy mask produced significant facial skin cooling after SMAS-based facelift surgery at the expense of a statistically significant increase in patient reported post-operative swelling. No objective benefits were derived in terms of reducing ecchymosis, haematoma or pain.

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Introduction

SMAS-based facelifts are commonly used operations for surgical rejuvenation of the face. This descriptive term encompasses numerous different operative techniques, however common to all is the use of the SMAS (superficial musculo-aponeurotic system) as a vehicle for redistributing the soft tissues of the face into a more youthful position. Surgery inevitably induces a local inflammatory response accompanied by bleeding, ecchymosis, oedema and pain. Whilst usually short lived, these features may hinder a patient returning to full activity.

Recent advances in the peri-operative management of facelift patients have been directed towards speeding recovery and limiting complications but they will all still occur to some degree.[1,2] Cryotherapy is a generic term applied to any form of cooling including the topical application of ice. Cryotherapy is a well accepted technique in sports medicine and orthopaedic surgery which employs the cooling of tissues to reduce the adverse effects of inflammation, including bleeding, ecchymosis, oedema and pain.[3,4] A universal feature of SMAS-based facelifts is the development of large, thin, facial skin flaps whose vascularity may be compromised by excessive, uncontrolled cooling. Hilotherapy is an innovative form of cryotherapy that circulates sterile, cooled water through a purpose designed mask. The temperature of the water can be adjusted to avoid the risk of cold injury to tissues.

This randomised, controlled study was undertaken to assess the usefulness of Hilotherapy in SMAS-based facelift surgery.

Methods

This trial was designed using the guidelines published in the CONSORT 2010 statement.[5] The study population consisted of consecutive patients undergoing SMAS-based facelift surgery for facial rejuvenation by the two senior authors in a single institution. The only exclusion criterion for the trial was extensive facial scarring which applied to one patient, having had multiple previous deep facial resurfacing procedures. Random allocation to treatment groups was performed using Research Randomizer random number generating freeware (http://www.randomizer.org/form.htm). The surgeons were only informed of the patient allocation to treatment group at the commencement of the operation.

Over a 14 week period, from February to May 2010, patients were recruited for the trial. The proposed benefits and potential risks of Hilotherapy were explained pre-operatively and informed consent obtained. In the first limb of the study 50 consecutive patients were randomised to post-operative Hilotherapy or standard post-operative care (Figure 1). In the treatment group the single-use Hilotherapy mask was applied to the skin of the face and held in place by adjustable, elasticated Velcro straps, followed by the standard post-operative dressing. Sterile water cooled to 14° celcius was circulated through the mask according to the manufacturers recommendations. In the second limb of the study a subsequent 15 consecutive patients were randomised to post-operative Hilotherapy treatment to one side of the face or the other. Given the subjective nature of pain this second analysis was performed to further quantify the analgesic effect of the mask

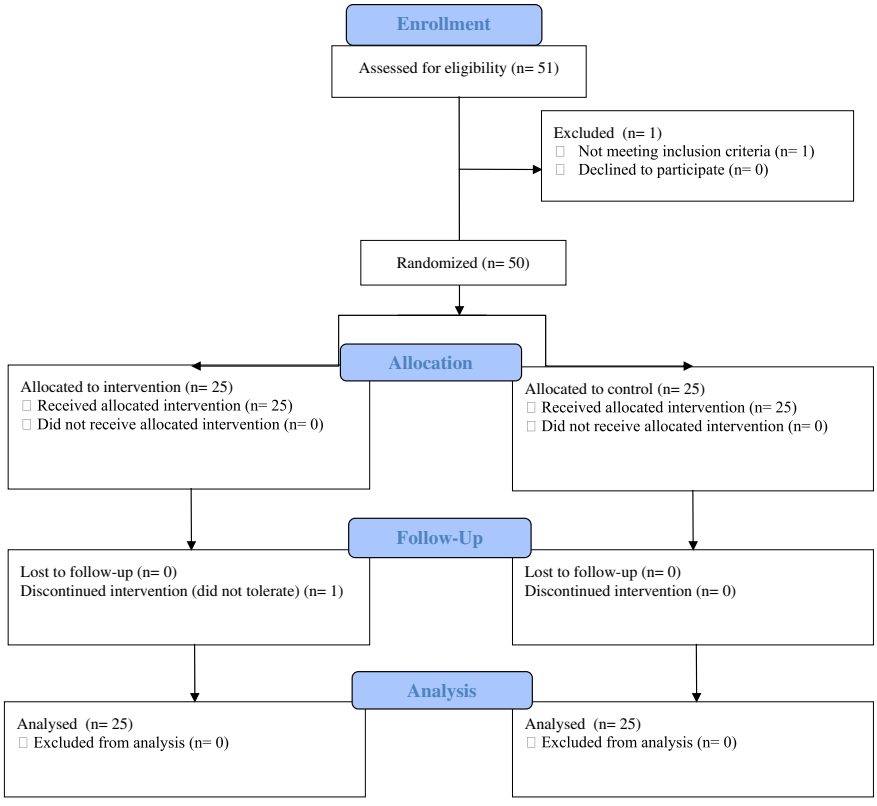

Figure 1 Hilotherapy entire face flow diagram.

using each patient as their own control. Half of the Hilotherapy mask was applied to the randomly allocated half of the patient's face, followed by the standard facelift head dressing. The remaining half of the mask was externalised through the midline of the dressing which insulated it from the control side of the face (Figure 2). In the recovery suite GE Disposable Skin Temperature Probes placed directly against the skin measured the skin temperature on both sides of the face. All dressings and Hilotherapy masks were removed on the 1st post-operative day.

Surgery was carried out under general anaesthesia or local anaesthesia with sedation administered by one of four senior anaesthetists. After induction of anaesthesia 200 ml of tumescent solution was instilled into both sides of the face. The solution contained 25 ml of 0.25% bupivicaine, 25 ml of 1% lignocaine, 1.25 ml of triamcinilone (40 mg/ml) and 1 ml of hyaluronidase (1500IU) in 500 ml of Ringer's lactate solution. Surgery always commenced on the left side of the face and concluded on the right[1] with the same SMAS intervention applied to both sides of the face in each respective patient. Low suction concertina drains were used. Patients receiving Hilotherapy had the masks applied to the skin of the face as described above. Standard dressings consisting of jelonet, dry gauze, cotton wool and Surginet were used to hold the masks in place.

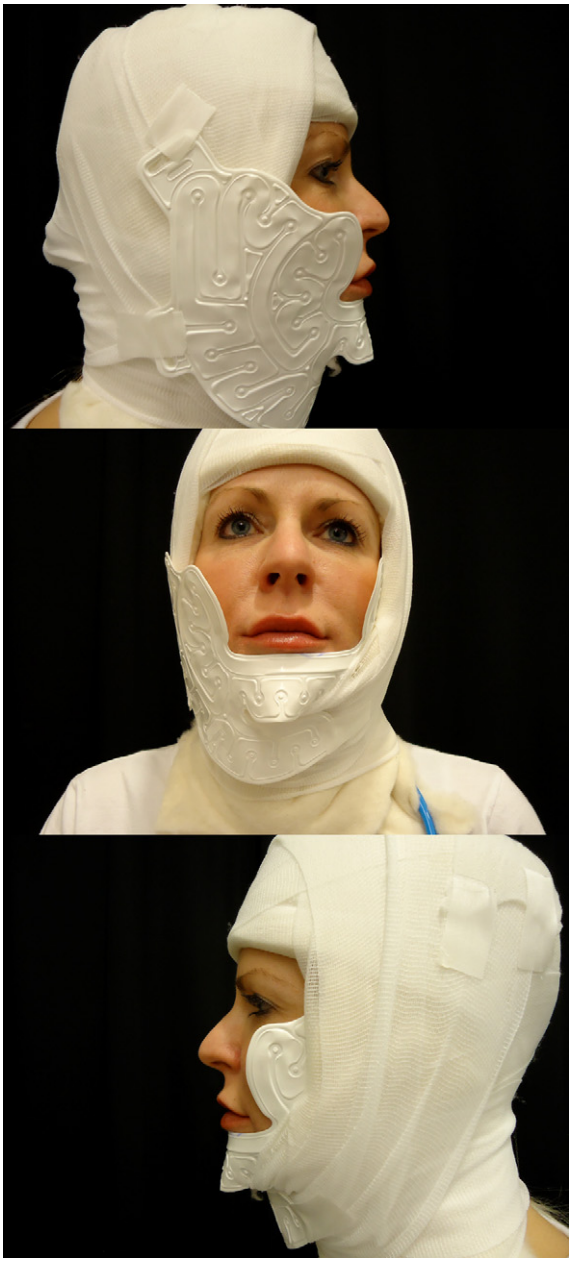

Figure 2 Application of hilotherapy mask to a randomly assigned half of the face.

A non-blinded, clinical assessment of ecchymosis, oedema and haematoma was made independently at day 1 post surgery and again at day 6—8 by the consultant surgeon, clinical fellow and practice nurse with a summary score generated for each outcome. Where there was wide variability amongst scorers a mean score was generated and, if necessary, rounded up to the nearest whole number for consistency. The patient made a subjective assessment of swelling, bruising and pain at the same time points. Outcomes were graded 1 (least severe) to 4 (most severe) using a previously published grading system.[2,6] patients used a modified version of the same grading system for self-assessment (Table 1). The final aesthetic outcome was assessed at 3 months.

An intention-to-treat analysis was performed. Results of the initial 50 patients were analysed using the Mann Whitney *U* test for unpaired, non-parametric data, while results from the final 15 patients were analysed using the Wilcoxon signed rank test for paired, non-parametric data.

Results

All but one patient had general anaesthesia. The exception, appearing in the second limb of the study, had sedation and local anaesthesia owing to her advanced age (78 years) and co-morbidities. Of the 65 patients only one was male. Two were active smokers. The mean age was 56 years with a range of 45—79 years. There was no significant difference between the patient groups after randomisation (Table 2). The total number of procedures, preformed in both limbs of

Table 1 Patient grading system (1—4) for bruising, swelling and pain.

Bruising
Grade 1: nil to barely perceptible
Grade 2: present but minimal (around wound only)
Grade 3: moderate with some tracking (into neck)
Grade 4: extensive with marked tracking (onto chest)
Sweling
Grade 1: nil
Grade 2: minor
Grade 3: moderate
Grade 4: marked
Pain
Grade 1: nil
Grade 2: mild
Grade 3: moderate
Grade 4: severe

Table 2 Characteristics of Patients Randomised to Entire Face Mask or No Mask.

Characteristics	Mask	No Mask
Background		
Mean age (range)	59 (46—79)	58 (45—76)
Sex (no. patients)	Female (25)	Female (25)
Co-morbidities		
Smoking	1	1
Hypertension	3	2
Anicoagulant/-platelet	0	0
Rhytidectomy		
SMASectomy	15	12
SMAS plication	9	11
Short scar	1	1
Skin only	0	1
Total	25	25
Adjunctive Procedures		
Blepharoplasty	7	9
Endoscopic brow lift	5	4
Submental liposuction	5	5
Corset platysmaplasty	2	3
Rhinoplasty	1	2
Upper lip shortening	1	1
Fat transfer	1	1

the study, are listed in Table 3. Patients wore the Hilotherapy mask for an average of 14 h. Only one patient did not tolerate the mask for the minimum 8 h recommended by the manufacturer, asking to have it removed after 3 h. In the first hour post surgery the mean facial skin temperature was 22.9° celcius (range 18.1—30.2) beneath the mask compared with 32.6° celcius (range 30.3—35.8) without the mask ($p = 0.01$). A single patient in the face mask group suffered a small haematoma which was managed by aspiration (Table 4). It was re-aspirated at one week which was followed by complete resolution. There were no expanding haematomas necessitating return to the operating theatre for evacuation.

Of the clinician assessed outcomes for the initial 50 patients comparing Hilotherapy with no cooling treatment

Table 3 Operative Procedures (Total Patient Population).

Operation	No. of Patients (%)
Rhytidectomy	
Lateral SMASectomy/platysmaplasty	35 (54)
SMAS plication	26 (40)
Short scar	3 (4)
Cutaneous	1 (2)
Total	65 (100)
Adjunctive Procedures	
Blepharoplasty	22 (34)
Endoscopic brow lift	14 (22)
Submental liposuction	13 (20)
Corset platysmaplasty	7 (11)
Rhinoplasty	4 (6)
Upper lip shortening	3 (5)
Fat transfer	4 (6)

Table 4 Complications.

Complication	Mask	No Mask	*p* value
Minor haematoma	1	0	<0.32
Expanding haematoma	0	0	
Seroma	0	0	
Infection	0	0	
Motor nerve injury	0	0	
Alopecia	0	0	

there was no difference in the incidence of bruising, oedema and haematoma at day 1 ($p = 0.81$, 1.0 and 0.32 respectively) or at days 6—8 ($p = 0.17$, 0.59 and 0.31 respectively). Once again there was no difference in bruising, oedema and haematoma amongst the subsequent 15 patients who had only one side of their face cooled at day 1 ($p = 1.0$ for all outcomes) or at days 6—8 ($p = 0.26$, 0.56 and 1.0 respectively).

In the second limb of the study there was a statistically significant increase in patient reported swelling at 6—8 days post surgery ($p = 0.05$) in the mask treated halves of the face. Remaining results for the patient assessed outcomes of bruising, swelling and pain failed to demonstrate a statistically significant difference between treatment groups in both limbs of the study. In first limb of the study *p*-values at day 1 were 0.37, 0.12 and 0.79 and at day 6—8 were 0.33, 0.15 and 0.39 respectively. For patients in the second limb of the study *p*-values at day 1 were all 0.66, 1.0 and 0.74 while at day 6—8 were 0.71 for bruising and 0.32 for pain. Although there were no detectable differences in pain levels between groups in the two parts of the study 53% of patients having one side of their face cooled found the experience to be comforting. Many of these patients described the mask as "reassuring" or "soothing".

There was no difference in the final aesthetic result between any of the comparison groups at the three month post-operative assessment.

Discussion

Post-operative oedema, ecchymosis and pain are all manifestations of inflammation induced by surgical trauma. After an initial period of vasoconstriction in an effort to limit bleeding, damaged blood vessels dilate with further bleeding causing ecchymosis and haematoma, while post-capillary venules become leaky leading to the egression of plasma into the extracellular space causing oedema.[7,8] Vasoactive mediators potentiate the inflammatory process and the coagulation cascade is initiated, while leukocytes are attracted to the site by chemotaxis.[7,8] Macrophages and fibroblasts subsequently are responsible for initiating the process of healing by repair.[7,8] Limiting oedema, ecchymosis and pain are crucial goals in facelift surgery since this facilitates a more rapid recovery and return to normal social activities. The avoidance of haematoma is critical for not only can haematoma result in prolonged post-operative inflammation and bruising, it can compromise the viability of skin flaps and produce delayed healing of wounds.

Hilotherapy is a novel form of cryotherapy, recently introduced into clinical practice. The application of this

technology is analogous to first aid recommendations for the use of ice in the management of soft tissues strains and sprains. Cooling the site of trauma minimises the inflammatory process thereby reducing oedema, bleeding, ecchymosis and pain.[9] Systematic reviews of randomised, controlled trials into the use of ice in acute soft tissue injury and following orthopaedic surgery confirm that ice both reduces swelling and pain in addition to hastening return to normal activity.[3,4] To date only one previous publication has studied outcomes of the Hilotherapy mask.[10] In a series of 10 orthognathic patients undergoing Le Fort I osteotomy and bilateral sagittal split osteotomies for the correction of class II and III malocclusion. No statistical analysis was performed but clinicians and patients noted minimal oedema, good pain relief and good jaw mobility post-operatively.[10] We set out to explore the validity of Hilotherapy in SMAS-based facelift surgery patients using a randomised, controlled trial.

A purpose designed Hilotherapy mask is applied directly to the face after surgery and is held in place by elasticated, Velcro straps. A standard facelift dressing can then be applied over the top of the mask. In a closed system sterile water cooled to 14° celcius is circulated continuously through the mask cooling the underlying tissues. In both limbs of the trial the mean temperature of the face in the recovery suite after the first post-operative hour was 22.9° celcius (range 18.1—30.2) beneath the mask compared with 32.6° celcius (range 30.3—35.8) beneath the standard dressing but without the mask. This difference in recorded temperature was statistically significant ($p = 0.01$). The skin temperature difference of the mask treated faces confirmed the cooling ability of the mask, although the skin temperature did not fall to the 14° setting on the Hilotherapy machine. A randomised controlled trial measuring skin temperature during cryotherapy after anterior cruciate ligament repair recorded a minimum skin temperature of 28° celcius.[11] In this trial patients were divided into four groups and had their operated knees cooled with either cooling pads set to either 4—10°celcius or 21—27° celcius or ice packs or placebo. The study reports a statistically significant ($p < 0.001$) difference in skin temperature achieved using the colder cooling pads or ice packs compared to placebo but no difference comparing the warmer cooling pads to placebo. The authors reported no objective benefits as a result of the post-operative cryotherapy. It was interesting to note that the mean temperature of the faces not treated with the mask in the recovery suite was 32.6 °celcius. The temperatures measured can most likely be accounted for by the use of large volume, room temperature, tumescent, local anaesthetic solution at the commencement of the operation and an effect of elevating the surgical flaps, separating them from the underlying tissue.

Our study has demonstrated a statistically significant increase in self reported 6—8 day post-operative swelling in patients treated with the Hilotherapy mask while failing to show any significant improvement in post-operative ecchymosis, haematoma and pain relief. Subjectively, a small majority of patients reported that the mask felt comforting. Why should a therapeutic modality that makes physiological sense fail to achieve what it promised in practice? Of the outcomes assessed in the study, haematoma is the least likely to have been affected by observer bias. Although the one small haematoma which occurred was in a patient wearing the mask it was not statistically relevant. Other dressings have been shown to have no influence on haematoma incidence.[1,19] There were no expanding haematomas requiring return to theatre for evacuation in either group of both limbs of the study. The increased incidence of patient reported swelling at 6—8 days post surgery in the mask treated patients may simply be a statistical quirk reflecting the small sample size. It is likely that many adjuvent interventions applied to the patient population were acting to minimise the afore mentioned adverse outcomes. The injection of tumescent local anaesthetic solution has been proven to minimise post-operative oedema, ecchymosis and haematoma.[12—14] The local anaesthetic in the tumescent solution no doubt contributes to post-operative analgesia. Also it may be suggested that the physical effect of better delineating tissue planes with tumescent infiltration may result in a less traumatic dissection thus minimising the outcomes that we were measuring. The addition of steroid to the tumescent solution further minimises post-operative oedema, a fact that has been well demonstrated in the craniofacial and aesthetic surgery literature.[14—16] Systemic steroids were not administered to the patients in this trial given evidence of the inefficacy of this form of steroid treatment in facelift patients.[17,18] The omission of adrenaline from the tumescent solution and the use of post-operative drains both act to minimise ecchymoses while the former also reduces the risk of haematoma.[2,19] Other measures instituted to minimise the measured adverse outcomes include hypotensive anaesthesia, strict peri-operative blood pressure control, physically elevating the head of the operating table and subsequently the patient's bed plus withholding medications and herbal remedies that predispose to bleeding for 2 weeks prior to and 2 weeks after surgery.[20,21]

The potential role of Hilotherapy in SMAS-based facelift patients may be confined to the subjective provision of post-operative comfort, although this would be recommended with caution given our findings. Hilotherapy may find a place in the management of patients after subperiosteal facial surgery but this question was beyond the scope of our trial.

Conclusion

This randomised, controlled trial has demonstrated that Hilotherapy is effective in cooling the face after SMAS-based facelift surgery. Patients reported a statistically significant increase in swelling at one week. There was no objective benefit in terms of minimising bruising, haematoma and pain. Subjectively a majority of patients found the cooling masks to be comforting.

Conflicts of interest

Not applicable.

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