

Evaluation of pain associated with facial injections using CoolSkin[®] in rhytidectomy

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Purpose: To evaluate the use of the CoolSkin[®] (Elbio, Seoul, Korea) skin-cooling device to reduce injection pain during rhytidectomy.

Method: Nineteen patients underwent rhytidectomy using the CoolSkin at -4°C on the first side lateral injection. The second side was then started without the cooling. Patients were offered cooling if they desired it on the second side. Surveys were administered 24 hours after the procedure, comparing pain (scale 0–5) and investigating treatment preferences. Patient healing was tracked for 6 weeks.

Results: Mean pain score for the untreated side was 4.63 versus 2.37 for the CoolSkin-treated side ($P < 0.001$). All patients asked for the second side to be cooled, and 89% were in favor of the chilling procedure when surveyed 24 hours afterwards. Sixty eight percent of patients stated that this device reduced fear of future injections. No flap loss or healing sequelae were noted from device use.

Conclusion: The CoolSkin device is an effective tool to reduce injection pain laterally during rhytidectomy.

Keywords: pain, cooling, rhytidectomy, CoolSkin[®], facial injections, face lift

Introduction

While pain is a subjective feeling related to many physiologic and personal factors, fear of discomfort can be a large impediment to patients receiving esthetic procedures. Many adults experience anxiety when undergoing needle-based procedures.¹ Topical anesthetics can be used to reduce pain with injectables,² but such options can be prohibitive when doing larger facial esthetic procedures; for example, using injected lidocaine as the topical may interfere with proper dosing calculations.³ In the last decade, there has been a shift towards performing facial esthetic procedures like face lifts with less invasive techniques. These techniques are often performed with less sedation and more regional blocks,⁴ bringing pain-control issues to the forefront.

Cooling the skin is one strategy that has been employed to reduce injection pain, as studies have shown that it changes sensory and motor-nerve conduction.^{5–10} While ice is not comparable with the application of topical anesthetic creams,¹¹ it can be very effective in reducing pain thresholds during needle injections.¹² Of the different modalities for cold application, ice massage more closely resembles reduced nerve sensory conduction velocities of cold water immersion than simple ice packs.¹³ To this end, having a focalized and stable cooling source is paramount to proper preinjection icing.

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The CoolSkin® (Elbio, Seoul, Korea) is a skin-cooling device that uses the Peltier effect to focus thermoelectric refrigeration on a single metal paddle, maintaining a constant temperature down to -16°C regardless of skin contact time and surface area touched by the paddle. The device has been shown to reduce injection pain for injectables like botulinum toxin.¹⁴ In this study, the effect of this device on reducing injection pain during rhytidectomy (face lift) was evaluated.

Patients and methods

Twenty-two patients undergoing a 5–6 cm flap-length rhytidectomy (high-superficial muscular aponeurotic system with deep plane imbrications and medial platysmaplasty) consented to participate in the trial over a 3-month study period. Consents followed established good clinical practice guidelines. Nineteen patients underwent the treatment protocol and three patients were control patients. The surgical procedure began with the administration of oral valium, variably dosed from 15 to 20 mg. The patients were then marked for the stated rhytidectomy procedure, along with other supplemental procedures, such as neck liposuction, platysmaplasty, blepharoplasty, and fractional carbon dioxide laser resurfacing. The patients were mildly sedated at the start of the procedure and were able to converse and provide feedback for the injection process.

The procedure commenced with the patient getting the right side injected. The CoolSkin device was set to -4°C and the skin in the temporal and upper preauricular marked crease was cooled for a total of 5 seconds and then injected with 0.25% bupivacaine hydrochloride (Marcaine; AstraZeneca plc, London, UK) with 1:100,000 epinephrine (Amphastar IMS Limited, South El Monte, CA). Bicarbonate buffer (Hospira Inc, Lakeforest, IL) was added to all injections. The remaining preauricular sulcus was then injected after subsequent skin cooling for 5 seconds. This injection proceeded into the postauricular sulcus and then along a hair-sparing incision line, using the same cooling and injection technique. A total of 10 mL of the bupivacaine hydrochloride mixture was injected initially. Then, using 0.5% lidocaine (Hospira Inc) with 1:200,000 epinephrine, the remaining marked flaps were injected, all with 5-second skin cooling of the surface area prior to injection. At this point, the patient's head was turned so that the right injected side was facing down and the left uninjected side was facing upward. The second side proceeded with the temporal and upper preauricular crease injection being performed with 0.5% bupivacaine hydrochloride with 1:100,000 epinephrine but no chilling. After the

first injection the patient was asked if they wanted to proceed without the chiller or if they wanted the injection done with chilling, similar to the right side. After the left side was injected, the central neck was injected. The laser procedures were performed at case end without the chiller.

Patients were then wrapped and discharged home and returned for a follow-up 24 hours later. At this point, the patients took a survey asking them to give a 0–5 analog pain score for the treated and untreated sides, whether they preferred treatment, and whether the experience would reduce fear of future injections. Data were then compiled and statistical analysis was performed using paired *t*-tests. The charts and photos were also viewed at 6 weeks to evaluate any wound healing or flap issues related to the procedure.

Finally, three patients were evaluated for future study designs. One patient had botulinum toxin (Botox®, Allergan, Irvine, CA) using a split forehead protocol, and two patients had central neck procedures only with no lateral injections. One patient had only central neck laser lipolysis, and another patient had a T-neck operation (a direct midline skin excision with platysmalplasty) in the central neck with laser lipolysis. In these two patients, the right half of the neck was chilled and the left half was not chilled during the injection. The patient who received botulinum toxin was asked the survey questions the day of the procedure, while the central neck procedure patients were asked the questions the day following their procedures.

Results

Of the 19 patients who underwent the CoolSkin procedure, there were 18 female and one male, with the mean age of all patients being 61.5 years. The three control patients were all female with a mean age of 64.7 years. Of the treated patients, all 19 asked that the chiller be applied to their skin during the second side injection. Table 1 lists each patient and their 24-hour pain scores for the treated side and the untreated side before the request was made to apply the chiller. Control patients all described injection pain as level 5 on both sides, while the study group described the average pain as 4.63 (± 0.83) on the untreated side. This score dropped to an average pain level of 2.37 (± 1.6) on the treated side, which was statistically significant (Figure 1; $P < 0.001$). When asked if they preferred to be treated or untreated, 17/19 study patients preferred treatment, with the remaining two failing to answer the question (Table 2). One control patient answered that they preferred to be “treated”: this was an indication of their desire for discomfort reduction rather than an indication that they received any treatment. Patients were asked if the CoolSkin

Table 1 Pain scores after injections for facial aesthetic procedures

Patient	Age	Sex	Diagnosis	Cooled side score	Control side score
1	67	F	FL	4	5
2	64	M	FL, PL	0	5
3	65	F	FL, Lipo, PL	2	3
4	62	F	FL, PL, CO ₂	5	5
5*	67	F	FL, PL, Lipo, CO₂	5	5
6	58	F	FL, Lipo, PL, CO ₂	5	5
7	57	F	FL, Lipo, PL, CO ₂	1	4
8*	71	F	FL, Lipo, PL, CO₂	5	5
9*	56	F	FL, PL, CO₂	5	5
10	59	F	FL, CO ₂	1	2
11	57	F	FL, Lipo, PL	1	5
12	71	F	FL	2	5
13	47	F	FL, Lipo, PL	2	4
14	64	F	FL, PL, UE, CO ₂	5	5
15	63	F	FL, Lipo, PL	4	5
16	76	F	FL, Lipo, PL	3	5
17	61	F	FL, LaserLipo, PL	3	5
18	74	F	FL, PL, Lipo	2	5
19	47	F	FL, LaserLipo	1	5
20	61	F	FL, PL, Laserlipo	3	5
21	55	F	FL, PL, LaserLipo	0	5
22	60	F	FL, PL, LaserLipo	1	5
Average (n = 19)	61.5			2.37 ± 1.6	4.63 ± 0.83

Notes: Nineteen patients underwent a rhytidectomy using CoolSkin® on the first side lateral injection. The second side was started without chilling. Patients ranked pain on a scale of 0–5 comparing the chilled and unchilled sides. Three patients (highlighted in bold and marked with an asterisk) experienced no chilling on either side of the face during their procedure. The mean age of the 19 study patients, along with their pain scores on 24-hour surveys, standard deviation, and paired *t* test between the treated and untreated sides is listed. Averages reflect only treated patients' data. Paired *t*-test ($P < 0.001$). *Control patients (no chilling).

Abbreviations: FL, face lift; Lipo, liposuction; LaserLipo, laser liposuction; PL, platymalplasty; UE, upper eye blepharoplasty; CO₂, fractional carbon dioxide laser resurfacing; n, number.

use would reduce their fear of future injections, and 68% answered yes (Table 3).

All patient skin flaps were evaluated at 24 hours, 1, and 6 weeks after the procedure, with no clinical evidence of flap loss or delayed skin healing.

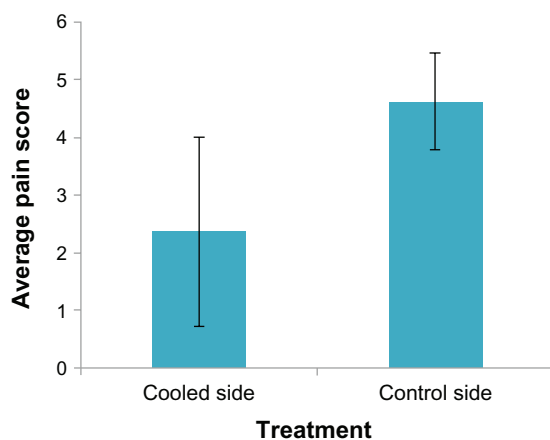


Figure 1 Average pain score (±SD) on cooled side and unchilled side of treated patients.

Notes: Nineteen patients underwent a rhytidectomy using CoolSkin® on the first side lateral injection. The second side was started without chilling. Patients ranked pain on a scale of 0–5, comparing the chilled and unchilled sides. Average response of 19 treated patients is shown.

Abbreviation: SD, standard deviation.

Finally, three patients who had the CoolSkin treatment with nonface-lift procedures were evaluated (Table 4). The patient who received botulinum toxin had a diminution of pain, while the central neck–injected patients showed no difference in pain scores. All three patients preferred to have been treated with the CoolSkin device.

Comment

Industry data clearly show that “fear of discomfort both during and after treatment” is a major reason why consumers remain undecided about undergoing cosmetic surgery.¹⁵ The trend toward more minimally invasive styles of face lifting, with patient desire for faster recovery, has made injection pain a significant potential impediment to modern facial plastic practices. To this end, this study was undertaken to evaluate newer techniques to reduce injection pain without complicating injection–dose toxicity risks.

During face-lift injections, distribution of the auriculotemporal and great auricular nerve fibers make pre- and postauricular blocks especially painful. These are often the injections performed first and, from the authors' experience, they are the ones most cited by patients as being uncomfortable. The failure of ice packs to maintain a con-

Table 2 Patient response to the question of whether they preferred treatment

Patient	Age	Sex	Diagnosis	Treated/untreated
1	67	F	FL	Treated
2	64	M	FL, PL	N/A
3	65	F	FL, Lipo, PL	Treated
4	62	F	FL, PL, CO ₂	N/A
5	67	F	FL, PL, Lipo, CO₂	N/A
6	58	F	FL, Lipo, PL, CO ₂	Treated
7	57	F	FL, Lipo, PL, CO ₂	Treated
8	71	F	FL, Lipo, PL, CO₂	N/A
9	56	F	FL, PL, CO₂	Treated
10	59	F	FL, CO ₂	Treated
11	57	F	FL, Lipo, PL	Treated
12	71	F	FL	Treated
13	47	F	FL, Lipo, PL	Treated
14	64	F	FL, PL, UE, CO ₂	Treated
15	63	F	FL, Lipo, PL	Treated
16	76	F	FL, Lipo, PL	Treated
17	61	F	FL, LaserLipo, PL	Treated
18	74	F	FL, PL, Lipo	Treated
19	47	F	FL, LaserLipo	Treated
20	61	F	FL, PL, Laserlipo	Treated
21	55	F	FL, PL, LaserLipo	Treated
22	60	F	FL, PL, laserLipo	Treated

Notes: Nineteen patients underwent a rhytidectomy using CoolSkin® on the first side lateral injection. The second side was started without chilling. Three patients (highlighted in bold) experienced no chilling on either side of the face during their procedure. Patients received a survey asking for a 0–5 analog pain score for the treated and untreated sides, along with a question on whether they preferred treatment, and a final question on whether the experience would reduce fears of future injections. Answers to whether they preferred treatment are shown. N/A represents blank survey responses. One control patient stated “treated” as a suggestion of future desire for pain reduction.

Abbreviations: FL, face lift; Lipo, liposuction; LaserLipo, laser liposuction; PL, platymalplasty; UE, upper eye blepharoplasty; CO₂, fractional carbon dioxide laser resurfacing.

sistent temperature can reduce skin cooling efficacy in this area along with the discomfort of water condensation around the ear. The authors’ prior work using air-based chilling systems proved problematic as patients complained of cold air blowing around the ear canal as well as temperature regulatory problems and surface area cooling inconsistencies. The theory of “ice massage”¹³ seemed most compelling, leading the authors to further investigate the CoolSkin device.

The distinct advantage of this system was that the machine maintained a preset temperature that did not change as the hand piece contacted the skin. The skin thus cooled rapidly and consistently with minimal moisture being added to the field. The authors did not find the need to check skin temperatures with an infrared source, but, during the product evaluation, a period of 5 seconds was found to be adequate for the device cool the skin surface area to a reduced pain state. The temperature of –4°C was found to be a good temperature to minimize potential risk to flaps from

Table 3 Patient response to the question of whether the CoolSkin® device reduced concerns about future injections

Patient	Age	Sex	Diagnosis	Yes/no
1	67	F	FL	Y
2	64	M	FL, PL	Y
3	65	F	FL, Lipo, PL	N
4	62	F	FL, PL, CO ₂ (UE/LE)	N
5	67	F	FL, PL, Lipo, CO₂	N*
6	58	F	FL, Lipo, PL, CO ₂	N
7	57	F	FL, Lipo, PL, CO ₂	Y
8	71	F	FL, Lipo, PL, CO₂	N*
9	56	F	FL, PL, CO₂	N*
10	59	F	FL, CO ₂	Y
11	57	F	FL, Lipo, PL	Maybe
12	71	F	FL	Y
13	47	F	FL, Lipo, PL	Maybe
14	64	F	FL, PL, UE, CO ₂	N
15	63	F	FL, Lipo, PL	Y
16	76	F	FL, Lipo, PL	Y
17	61	F	FL, LaserLipo, PL	Y
18	74	F	FL, PL, Lipo	Y
19	47	F	FL, LaserLipo	Y
20	61	F	FL, PL, Laserlipo	Y
21	55	F	FL, PL, Laserlipo	Y
22	60	F	FL, PL, Laserlipo	Y

Notes: Nineteen patients underwent a rhytidectomy using CoolSkin® on the first side lateral injection. The second side was started without chilling. Three patients (highlighted in bold) experienced no chilling on either side of the face during their procedure. Patients received a survey asking for a 0–5 analog pain score for the treated and untreated sides, along with a question on whether they preferred treatment, and a final question on whether the experience would reduce fears of future injections. Answers to whether their fear of injection was reduced are shown.

Abbreviations: FL, face lift; Laser Lipo, laser liposuction; PL, platymalplasty; UE, upper eye blepharoplasty; CO₂, fractional carbon dioxide laser resurfacing.

over cooling. The follow-up data showed this to be a safe temperature for flaps. Future studies using infrared checks may find more ideal temperatures. Patients found the device comfortable with no specific complaints of discomfort using it around the ear.

The three control patients had the injections done without any chilling and they reported discomfort, all rating the pain as 5 in their surveys 24 hours later. Similarly, the study group patients rated the pain level average as 4.6, prior to all of them getting the remainder of the site of their second side injection chilled. The comparison of pain was between the initial chilled side and the second side temporal injection starting unchilled. Once the second side was chilled, the patients experienced pain relief from the skin cooling. Interestingly, one control patient mentioned they desired to have some pain reduction, and 68% of patients stated that the cooling reduced their fear of future injections. This factor is key, as patients may be more receptive to other procedures in the future if their fear is reduced. Finally, 24 hours afterward, 17/19 treated patients responded that they would prefer treatment,

Table 4 Response to questions from additional three patients

Patient	Age	Sex	Diagnosis	Cooled side score	Control side score
Pain scores after injections for lifestyle lift procedures					
23	62	F	LaserLipo	3	3
Patient	Age	Sex	Diagnosis	Yes/No	
Did treated side reduce concerns of future injections?					
23	62	F	LaserLipo	Y	
Patient	Age	Sex	Diagnosis	Treated/Untreated	
If given a choice would you prefer to be treated or untreated?					
23	62	F	LaserLipo	Treated	

Notes: Three patients were evaluated for further study designs. The three patients had three unique procedures. For patients 23 and 25 with neck procedures, the right half of the neck was chilled and the left was not during injection. The patient who had botulism toxin had one side of the face chilled and the other unchilled using the split forehead protocol. Patients were asked the same three questions as the 22 rhytidectomy patients. Questions and answers are shown.

Abbreviations: LaserLipo, laser liposuction; Botox, botulinum toxin.

with two failing to answer the question. These two patients, however, did want to be chilled on the second side.

While future studies with higher patient numbers will be needed, it was found that the central neck injections seemed more resistant to pain reduction. The two patients in this study preferred being treated with the device, but the impact seemed less. The patient who received botulism toxin who was treated with the CoolSkin device had pain reduction similar to those in previous studies¹⁴ using the device.

In summary, the CoolSkin device is a safe and effective tool for lateral pain reduction during rhytidectomy injections. The device is well tolerated by patients with no flap loss at -4°C .

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Disclosure

The authors declare that there are no real or potential conflicts of interest in relation to this paper. The machine used for the study was purchased. None of the authors have any financial ties to Elbio.

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