

# Discomfort during Periorbital and Lateral Temporal Laser Vein Treatment: A Double-blind Randomized Controlled Trial

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**Background:** Treatments for cosmetically displeasing periorbital and lateral temporal veins are limited. The purpose of this study was to test the hypothesis that the application of topical lidocaine before the cosmetic treatment of periorbital and lateral temporal veins with a neodymium-doped yttrium aluminum garnet (ND:YAG) laser will result in a significant reduction in subjective pain compared with placebo as assessed using a visual analogue scale.

**Methods:** Twenty patients who required bilateral treatment of facial veins were randomly assigned to receive either placebo or 30% lidocaine gel applied topically over the veins, a split-body design. Both the investigator and the patient were blinded to the treatment. An ND:YAG laser was used to treat the veins. Patients completed a visual analogue scale to assess the pain on each side of the face. Data were analyzed using nonparametric data testing.

**Results:** There was a 64.0% reduction in pain on the treatment side compared with the placebo side ( $P < 0.001$ ). There was no significant difference in patient-assessed subjective efficacy between sides ( $P = 0.2$ ). Complications were minimal and mild.

**Conclusions:** Patients undergoing periorbital and temporal vein ablation using ND:YAG laser should be offered topical lidocaine as the pain levels are moderate. The use of topical 30% lidocaine results in a significant reduction in pain levels. (*Plast Reconstr Surg Glob Open* 2014;2:e159; doi: 10.1097/GOX.000000000000106; Published online 29 May 2014.)

**C**osmetically displeasing periorbital and lateral temporal veins are a common complaint in facial plastic surgery practices.

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Proposed treatments include direct cautery through a small incision,<sup>1</sup> sodium tetradecyl sulfate sclerotherapy,<sup>2</sup> and phlebectomy.<sup>2</sup> However, all require either direct access to the vein or an invasive venipuncture. Although very rare, sclerotherapy carries the additional risk of blindness; thus, it is uncommonly practiced near the orbit.<sup>3</sup>

Recently, our clinical team<sup>4</sup> described the use of the neodymium-doped yttrium aluminum garnet (ND:YAG; 1064 nm) laser for treatment of facial veins. Due to its absorption profile and its wavelength, this technique has the advantage of being able to penetrate deeper into the tissue, resulting in less epidermal damage due to minimal or no melanin competition.<sup>5,6</sup> Even though noninvasive, patients commonly report significant pain and discomfort when undergoing the treatment.<sup>4,7</sup>

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Eremia and Li<sup>6</sup> conducted a study on facial periorbital reticular veins using the ND:YAG laser. Although they achieved excellent results, patients reported moderate pain, with a small number indicating that they would not have a second procedure due to the pain levels. Similarly, Lai and Goldman<sup>8</sup> noted similar findings with 5 of the 14 patients reporting moderate pain. Unfortunately, none of these studies quantified or subjectively assessed pain levels in an unbiased manner.

The application of topical lidocaine is used in many medical fields for minor procedures on the skin and mucosa. At this time, it is unclear if the use of a topical lidocaine gel would reduce the pain associated with ND:YAG laser therapy. As noted, it is believed that the long wavelength of the laser results in no or minimal epidermal/dermal heating; thus, theoretically, all the pain should be a result of deep tissue heating. The absorption of lidocaine into these deeper structures is unlikely; thus, it remains unclear if it is of benefit.

Therefore, the purpose of this study was to test the hypothesis that the application of topical lidocaine before the cosmetic treatment of periorbital and lateral temporal veins will result in a significant reduction in subjective pain compared with placebo as assessed using a visual analogue scale (VAS).

## METHODS

We conducted a split-body, double-blind randomized controlled trial between June 2013 and July 2013 at a private cosmetic surgery clinic affiliated with the University of Toronto. The institutional ethics review board of The University of Toronto reviewed and approved the study. Written informed consent was obtained from all patients. One blinded surgeon was responsible for enrollment, randomization of patients, and administration of interventions, whereas another blinded surgeon was responsible for performing all of the laser treatment procedures and for performing data collection.

All patients presenting to the facial plastic surgery clinic who were interested in temporal and periorbital vein treatment were asked to volunteer for the study.

### Participants

All patients 18 years old or older who presented to our facial cosmetic surgery clinic and who were interested in having their periorbital/lateral temporal veins treatment were asked to participate in the study.

Exclusion criteria included patients who were not willing to be randomized to the interventions, patients who only wanted treatment on one side of

the face, or patients with a known sensitivity to any topical analgesic.

### Interventions

Intervention 1 consisted of 1 mL of topical 30% lidocaine in Lipothene gel (treatment), and intervention 2 consisted of 1 mL of standard lubricating gel (placebo).

### Randomization

All randomization was performed after the patient volunteered for the study. A computerized random number generator (Research Randomizer, Online)<sup>9</sup> was used by the research coordinator to randomize the patients' side to each intervention group. The random number generator generated a unique number for each patient. If an even number was generated, the treatment was applied to the right periorbital/temporal region, whereas odd numbers resulted in the treatment being applied to the left periorbital/temporal region. All patients received both the treatment and placebo. Once randomization was performed, there was no change to randomization after beginning the trial. Randomization was stored on a computer and concealed from both the patient and the individual doing the treatment and outcome assessment. Subjects were asked not to communicate any subjective differences in sensation until the treatment was complete to ensure the treating physician remained blinded to the treatment sides. Allocation data were stored on a secured computer in the clinic and were not available until completion of the trial.

Both the treatment and control had a similar gel consistency, color, and temperature (8°C). Before performing the intervention, the gel was removed so that the treating physician was not able to see any residual gel. The study conforms to the CONSORT 2010 recommendations.<sup>10</sup> The study was registered with the Australian New Zealand Clinical Trials Registry (ACTRN#: 12613000996763).

### Protocol

After signing an informed consent, 0.25 mL of either the treatment or placebo was applied on the skin along the prominent veins on each side of the patient. A cotton tip applicator was used to "paint" the skin overlying the identified veins. This resulted in a total topical dose of 150 mg of topical lidocaine. If further topical lidocaine was required, we would measure out an additional 0.25 mL and apply as needed up to a maximum dose of 1.0 mL per side. The gel remained on the veins for 15 minutes before removing and cleansing the skin with an alcohol wipe.

All laser treatments began within 5 minutes of gel removal.

To remove the veins, we used a Cutera (Brisbane, Calif.) ND:YAG laser (1064 nm) with a fluence of 130 J/cm<sup>2</sup>, 30 ms pulse duration with 0 Hz repeat, and a 5-mm spot size. A procedure was considered successful if the vein appeared to contract along its course, and no further fluid motion could be observed in the vessel during manual compression. To ensure the temporal artery was not targeted, the treating physician continuously palpated the vessels to ensure there was no pulse. If a vein was located over the artery, this site was not treated.

### Outcome Measures

Demographic data including gender, age, and Fitzpatrick skin type were collected before randomization. The total impulses required for each side to achieve adequate results were recorded.

This study used the definition of pain based on International Association for the Study of Pain.<sup>11</sup> Specifically, we defined pain as an unpleasant sensory and emotional experience associated with actual or potential tissue damage. Patients were advised to rate their pain based on their experience during the examination only.

A 100-mm VAS, with 0 mm corresponding to no pain and 100 mm corresponding to extreme pain, was used to quantify the outcome of the examination.<sup>6</sup> To minimize the possibility of installing bias during data collection, a standardized information sheet was prepared with instructions outlining the VAS for each outcome measure. This instruction sheet was read to each patient before completion of the data collection. If a patient had a question regarding a specific outcome measure, the information in the standardized instructions was repeated to the patient. No additional information or clarification was provided to limit potential bias. A Vernier digital caliper with an accuracy of 0.001 cm was used to measure patients' assessments on the VAS. Patients completed the data collection within 10 minutes of completion of the procedure.

As a secondary objective, an assessment of efficacy was conducted 2 weeks after treatment. Patients were asked to grade their subjective level of improvement using a VAS. A zero on the scale was considered no change with a score of 100 mm corresponding to complete resolution of the vein. At this time point, patients were no longer blinded to intervention sides.

Adverse events were recorded during the study. All patients were seen at 2-week intervals after the initial treatment for a minimum of 6 weeks.

Any adverse event reported over this time was recorded.

To determine if patients were unblinded during the testing, we asked patients to attempt to identify their knowledge of blinding at 2 time points. The first was immediately after the removal of the gel solutions before the laser testing and the second was after completion of the laser treatment.

### Ethical Considerations

To ensure any patient with a possible allergy to topical anesthetic was informed, all patients were told that lidocaine would be administered to one side of their face. In addition to this, we informed patients that it was unclear as to the levels of pain at both baseline and with topical lidocaine applied as this is a new treatment and no data are available suggesting the level of pain patients experience. Based on our pilot testing, most patients' rate pain between 4 and 6 out of 10, thus a reduction in pain would be beneficial to patients.

### Statistical Analysis

All statistics were analyzed using MINITAB (version 16.1.1; Minitab, State College, Pa.) statistical software.

Primary outcome measure data were assessed for a normal distribution using the Anderson-Darling Test. Normally distributed data were assessed using a paired *t* test, whereas data not fitting a normal distribution were assessed using nonparametric Wilcoxon signed-rank test. A significant difference was defined as a *P* value < 0.05. An intention-to-treat analysis was used.

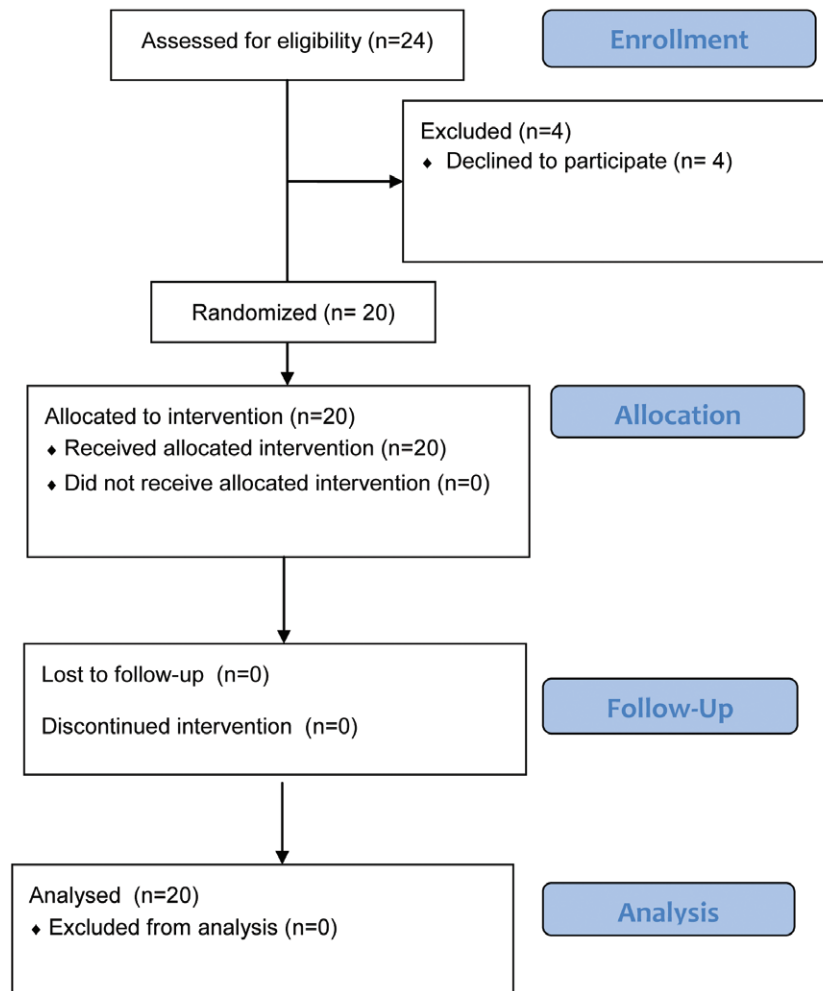
### Power Considerations

A sample size calculation was conducted to determine the minimum sample required to answer the primary objective. Based on a previous pilot study,<sup>1,3</sup> we estimated a minimal difference in pain between treatment and control of 2 cm (2 of 10 on a VAS), with a standard deviation (SD) of 2 cm. Based on these data, this study required a minimum of 10 patients to achieve the desired power of 80% at an  $\alpha$  of 0.05.

## RESULTS

A total of 24 patients were approached for inclusion, with 20 patients enrolling in the study (Fig. 1). The mean age of the patients was 46.5 (10.1) years, with 95% being female. The median Fitzpatrick skin type was 2. The average (SD) number of pulses required for both the treatment and placebo sides were 26.7 (8.2) and 25.1 (6.9), respectively (*P* = 0.019).

**CONSORT 2010 Flow Diagram**



**Fig. 1.** Consort flow diagram for study.

The data for the primary outcome were significantly different from a normal distribution ( $P < 0.001$ ); thus, nonparametric testing was used. There was a significant reduction in pain at the treatment side compared with the placebo ( $P < 0.001$ ). When comparing the treatment with the placebo, the median (95% CI) reduction in pain on the 100-mm VAS was 23.6mm (7.9–30.5). The mean (median)  $\pm$  SD VAS pain score for the treatment and control was 31.45 (24.8) mm  $\pm$  18.28mm and 57.82 (65.6) mm  $\pm$  26.1 mm, respectively.

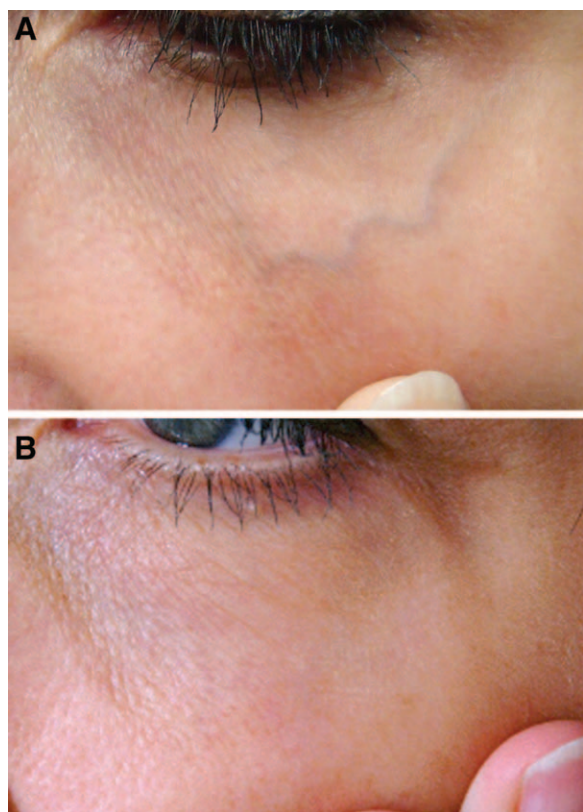
For overall subjective patient-assessed efficacy, there was no significant difference between treatment and control sides ( $P = 0.254$ ). The mean (median)  $\pm$  SD was 64.8 (71.5)  $\pm$  30.5 and 70.5 (77.5)  $\pm$  28.2 for the treatment and control sides, respectively (Fig. 2). Four of the 20 patients did not have a response to treatment, and the prominent veins re-

turned requiring a second treatment. Of these, 75% (3 of 4) were on the treatment side.

When asked if the patient was able to determine which side was treated, 60% of patients correctly identified the intervention side before the laser treatment. Ninety percent of patients predicted which side had the active treatment after the laser therapy and data collection.

**Safety**

All patients completed the testing. Four patients required a second treatment to complete the treatment as one or more veins did not respond to the initial treatment. Table 1 lists side effects and complications of the procedure. All side effects were classified as mild and temporary and occurred within the first 24–48 hours of treatment. One patient developed temporary eyelid edema that resolved with no intervention within 4 days.



**Fig. 2.** Typical results of periorbital/lateral temporal vein treatment in patient. Photographs taken immediately before treatment (A) and again at 1 month posttreatment (B).

**Table 1. Complications**

Side Effect	Treatment	Placebo
Transient Erythema (<48h)	18	19
Transient Edema (<48h)	19	19
Prolonged Erythema (>48h)	2	1
Prolonged Edema (>48h)	2	2
Superficial Skin Desquamation	6	3
Superficial Burn	2	1
Eyelid edema >48h	0	1
TOTAL	49	46

## DISCUSSION

The results of this study confirm our initial clinical observation that the pain associated with the treatment of temporal and orbital superficial veins can be significantly reduced by applying topical lidocaine gel. The application of this gel does not seem to affect the efficacy of the treatment nor does it alter the potential complications or side effects of the procedure. The effect of lidocaine is both statistical and clinically significant as it results in nearly a 50% reduction in pain scores. Given this finding, our team believes that topical lidocaine must be offered to all patients undergoing this procedure. Reducing the discomfort of the procedure would likely result in an improved overall satisfaction with the treatment.

It is difficult to compare the pain levels in this current study with other published research. One important point relates to the energy levels used for each study and the location of treated veins. The majority of studies assessed veins treated on the legs of patients<sup>6,10,12</sup>; thus, clinical equivalence in terms of pain is unlikely.

Initially, our team used a shorter pulse duration (20–25 ms) and a slightly lower fluence (100–120 J/cm<sup>2</sup>). Over the course of our experience, we noted that treatment was more effective with a slightly longer pulse duration (30 ms) and a slightly higher fluence (130 J/cm<sup>2</sup>). However, this was also associated with an increase in discomfort. A study by Lai and Goldman assessed the ND:YAG for treatment of facial reticular veins. These authors used a much higher fluence (180–210 J/cm<sup>2</sup>) and a longer pulse duration (25–50 ms). These authors used a cryogen spray to cool the skin before treatment; however, they did not describe any details regarding this treatment. Of the 14 patients treated, 5 experienced mild to moderate pain. Unfortunately, there was no formal quantification of pain levels nor was there any comparison to pain levels when the cryogen spray was not used. A study by Bevin et al<sup>7</sup> used a significantly higher fluence (226–425 J/cm<sup>2</sup>), using even higher fluencies for smaller vessels. Interestingly, patients were reported to experience only minor pain; however, this was not quantified.

One of the primary difficulties with this study was ensuring adequate blinding of participants and the treating physician. After the trial was completed, patients were able to correctly identify the treated side in 60% of cases. Although this is close to that one would expect with chance alone, it is likely that some patients were able to correctly identify the treatment due to the paresthesia that can be associated with topical lidocaine. However, this number increased after the laser treatment. It is likely that the large effect of the lidocaine was noted as the patients perceived a significant amount of pain reduction between sides. Given that patients were aware that one side would have a numbing agent and another a placebo, they likely deduced that the less painful side contained the active ingredient. It is unlikely that this unblinding influenced the data as the effect size was so great.

Although this study demonstrated a significant effect of the laser treatment, it is important to note that this was a secondary objective and thus not designed to assess this in a blinded manner. Currently, there is no standardized grading scale of infraorbital and lateral temporal veins that has been assessed for validity and reliability. Due to this, it is difficult to adequately grade the baseline vessels and the effect to treatment. This study attempted to capture a gross assessment of effect

using a VAS; however, it must be noted that this has not been validated nor has it been assessed for reliability. It does provide basic evidence suggesting that both groups were comparable in terms of efficacy. Future research is required to both develop a grading scale and ensure the application of lidocaine does not influence treatment effects. In addition to this, there is no blinded research comparing different fluence levels or pulse durations on efficacy. Future research ideally would also assess for optimal treatment parameters.

With respect to complications, all were mild and temporary. Two patients had superficial burns that did not seem to be a result of the intervention groups. Both healed with no scarring or other long-term sequelae. Both these patients had their veins traced with a blue-purple surgical marking pen on the skin to aid in identification of the veins when the patient was lying flat. Although we washed this off before treatment, there was a small blue-purple tint remaining on the skin and we feel as though the laser was absorbed by the pigment in the marking pen and caused superficial heating of the skin. Once we identified the cause, this did not occur in any other patients.

One remaining question relates to the safety of a high concentration of topical lidocaine. Lidocaine toxicity is possible due to its narrow therapeutic window. However, a study by Campbell et al<sup>11</sup> assessed the toxicity of topically applied lidocaine in the head and neck in both healthy individuals and patients with herpes zoster. The authors assessed 5 g of the gel (750 mg of lidocaine) applied for up to 8 hours. The authors noted that the bioavailability of the lidocaine was 3% when applied topically, thus demonstrating that absorption is minimal. This dose was more than double the dose used in this study. Furthermore, our team ensured that the minimal total skin area required was covered such that the topical lidocaine was only applied to the skin directly overlying the vessels to be treated. In all cases, this was less than 0.5 mL of 30% lidocaine.

## CONCLUSIONS

The use of topical 30% lidocaine gel applied directly over treated temporal and infraorbital veins results in a clinically significant reduction in pain levels. Clinicians should offer topical lidocaine to all patients undergoing this procedure.

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