# Vibration-assisted Anesthesia in Eyelid Surgery

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***Purpose:*** To investigate whether a vibrating device applied in a circular motion to the forehead reduces the pain of local anesthetic injection in upper eyelid surgery.

***Design:*** Prospective, interventional, cross-over, randomized, controlled clinical trial.

***Participants:*** Eighty patients undergoing bilateral upper eyelid surgery under local anesthesia.

***Intervention:*** A vibrating device was applied in a circular motion to participants' foreheads while local anesthetic was injected into 1 eyelid. During injection of anesthetic on the contralateral lid, the device was applied to the forehead in static fashion with the vibration switched off (placebo). The order of intervention was randomized.

***Main Outcome Measures:*** After both injections had been given, participants were asked to specify their pain ratings for each injection on a scale of 0 to 10, with 0 representing no pain and 10 indicating the worst pain imaginable. Participants were also asked to qualitatively compare the 2 sides.

***Results:*** The mean pain scores were 3.3 for the vibration-assisted side and 4.5 for the placebo. This difference was statistically significant ($P=0.0003$); 73% of participants found the vibrated side to be better than the placebo, with 35% finding it a lot or quite a bit better.

***Conclusions:*** Vibration-assisted anesthesia during upper eyelid surgery has a beneficial effect that is highly statistically significant and is clinically significant in terms of patients' qualitative assessment of pain. Further research is needed to determine whether this constitutes a quantitatively clinically significant improvement in pain management.

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In many surgical procedures performed under local anesthetic, the most frightening and painful aspect of the procedure for patients is the anesthetic injection. Various techniques have been advocated to address this.

Gentle verbal reassurance and hand-holding may relax and distract patients but may not reduce the discomfort of the injection.[1] Simple, widely practiced measures to reduce injection pain include slow administration and use of a fine-bore needle (e.g., 30 or 32 gauge). Other effective techniques include warming and buffering the local anesthetic.[2–7] Diluting lidocaine with 0.9% bacteriostatic saline (containing benzyl alcohol) has been shown to reduce injection pain in eyelid surgery.[8]

Cooling the skin immediately before treatment reduces the pain of dermatologic laser procedures[9–11] but may be difficult to perform in the periocular region because of the risk of corneal injury. Similarly, topical anesthetic agents, such as eutectic mixture of local anesthetic cream, applied to the skin 1 hour before injection are commonly used on the limbs of infants and children, but inadvertent ocular application when used on the eyelids has been reported to cause corneal de-epithelialization.[12]

Sedative agents, such as midazolam, may be useful in anxious patients, but this requires the input of an anesthetist and it is often difficult to finely control the level of sedation; it is arguably preferable not to have patients sedated during eyelid surgery if patient cooperation is required intraoperatively to assess the height of the eyelids.

Vibration, pinching, and the application of pressure have long been recognized as methods of reducing concurrent pain, and there is much anecdotal evidence of the use of such techniques to reduce the pain of anesthetic injection, mostly in dentistry and dermatology,[13–17] but there is a dearth of evidence from randomized controlled trials. There are no reports of vibration anesthesia in an ophthalmic setting.

The aim of this study was to investigate the effect of vibration-assisted anesthesia in reducing the pain of local anesthetic injection for upper eyelid surgery.

## Patients and Methods

This interventional, cross-over, randomized, controlled clinical trial was carried out in the Eye Care Centre in Vancouver between November 2008 and March 2009. The study protocol was approved by the University of British Columbia Clinical Research Ethics Board and adhered to the tenets of the Declaration of Helsinki. The study was registered before enrollment at http://www.clinicaltrials.gov (registered 18 November 2008).

The tip of a small, battery-powered, hand-held vibrator (Waterproof Mini-G, manufactured by California Exotic Novelties, Chino, CA, costing ~$20) was rested on the middle of the forehead 1 cm above the mid-brow point (Fig 1) and rotated in a clockwise circle of 2 cm diameter at a speed of approximately 1 cycle every 2 seconds. The vibrator was held such that it balanced on the forehead with a uniform light pressure (as opposed to the operator exerting any downward force). This particular protocol



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**Figure 1.** Participant receiving vibration-assisted local anesthesia. The second vibrator (seen in the operator's right hand) was used for auditory stimulation during the injection on the placebo side.

was chosen on the basis of the results of a pilot study in which we tested the efficacy of several different vibrating devices in various sites around the eyelids (including over the supraorbital notch, along the eyebrow above the injecting needle, and in the mid-brow point) and on the hand, using several different techniques (holding the vibrator still, lifting it on and off the test site, and circling it).

The placebo consisted of a switched-off vibrating device applied to the test site and a second, identical, switched-on vibrating device held close (but not touching) to the first device, which made the same buzzing sound as the test intervention. Thus, on the placebo side the patient felt an object on his/her forehead and heard the vibrating sound but did not have the sensation of vibration. Although the "active" vibrator was circled on the forehead, the placebo was held still because the purpose of the placebo was to overcome the potential distracting effect of the instrument, in terms of physical presence on the forehead and auditory stimulation. Care was taken to ensure that the devices were out of the participants' view so they could not see the nature of the placebo set-up.

Inclusion criteria were adult patients (≥18 years) who had not undergone previous upper eyelid surgery and were undergoing bilateral anterior levator resections or bilateral blepharoplasties under local anesthetic. Each patient acted as his/her own control, receiving the test intervention on one side and the placebo on the other side. The order of test intervention and placebo was randomized using a computer-generated binary sequence, with 40 patients receiving the intervention first and 40 patients receiving the placebo first; the right eyelid was injected first in all participants. Allocation was concealed from the surgeon performing the anesthetic until the time of intervention.

Potential participants were given an information sheet explaining the aim of the study without describing the specific effects of the vibrating device and placebo to reduce the risk of biasing their perception. They were advised beforehand that they would be required to verbally rate their pain score on a scale of 0 to 10 immediately after both sides were anesthetized, with 0 being no pain and 10 being the worst imaginable pain. They were asked if the first or the second injection hurt more or if they felt the same. Those who reported a difference between the 2 sides were asked by how much: a lot, quite a bit, a little, or no difference. The questions were asked by the oculoplastics consultant (PJD), and the results were documented by the oculoplastics fellow (TF or DM). Patients were asked to provide their assessment after both injections had been given, as opposed to after each injection, to allow them to make a relative comparison between the 2 sides.

All anesthetic injections followed topical corneal anesthesia with tetracaine and consisted of Xylocaine 1% with 1:100,000 adrenaline at room temperature administered through a short 30-gauge needle at a constant slow speed (0.1 ml per 5 seconds) at multiple (6–8) subcutaneous sites along the upper lid by the same surgeon throughout the study (PJD). Verbal cues were standardized, and other background noise was minimized during the injections.

The vibration device and placebo were operated by 2 oculoplastics fellows (TF for 51 patients and DM for 29 patients); the instruments were placed on the test site 1 second before the anesthetic injection was commenced. The 2 operators practiced applying the instruments to staff members to ensure a standardized technique.

When the anesthetist thought that the patient would benefit from light sedation to alleviate his/her heightened anxiety, 1 dose of intravenous midazolam was given 5 to 10 minutes before the first anesthetic injection so that the sedative effect would have reached a steady plateau level for the duration of the 2 injections.

### Statistical Analysis

For the purpose of the power calculation, we decided that on a scale of 0 to 10, a difference in pain score of 1.5 could be considered clinically significant. The power calculation for a paired *t* test with 90% power and $P=0.05$ demonstrated a sample size of 80 patients to be more than sufficient.

A paired *t* test was used to compare the pain scores between the side receiving vibration and the side receiving placebo. Distribution of the residuals (unexplained variation) was found to be normally distributed, and an analysis of variance for a 2×2 cross-over study was used to analyze the results according to order of intervention (period effect), operator (TF/DM), and intravenous sedation. Statistical analysis was carried out using STATA (Version 10, StataCorp LP, College Station, TX).

## Results

Twenty-two men and 58 women participated in the trial, with an average age of 62 years (range 27–87 years). Fourteen participants received intravenous sedation. This number is too small to make any statistical inferences about differences between participants receiving and not receiving sedation.

### Quantitative Analysis

The mean pain scores were 3.3 for the vibrated side (95% confidence interval, 2.9–3.7) and 4.5 for the placebo side (95% confidence interval, 4.0–4.9) (Table 1), which is highly statistically significant (paired *t* test, $P=0.0003$).

### Qualitative Analysis

The vibrated side was reported as better than the placebo in 72.5% of participants (58/80), with 35% (28/80) finding it either a lot better or quite a bit better (Fig 2). No difference in pain scores between the 2 sides was found in 3.8% of participants (3/80). The vibrated side was found to be worse than the placebo in 23.8% of participants (19/80), of whom all but one found it only a little worse; no participants found the vibrated side a lot worse.

This was a masked cross-over study because the participants were randomized to the intervention or placebo first. We therefore explored whether there was a cross-over effect, for example, if patients tend to respond differently to the second injection compared with the first. The analysis of variance showed a period effect that was only just statistically significant ($P=0.03$), consistent with the view that the second side was more painful than the first; however, there was no evidence that this in any way altered the treatment effect of vibrated side versus the placebo ($P=0.10$).

The cross-over analysis of variance was extended to allow for the effect of operator (TF/DM) and sedation. Neither of these was significant ($P=0.68$ and $P=0.12$, respectively), nor did they materially affect the estimates.

Table 1. Results of Participant Pain Scores (From 0 = No Pain to 10 = Worst Pain Imaginable) for Vibrator Compared with Placebo

| Variable | No. of Observations | Mean Pain Score | Standard Deviation | 95% Confidence Interval |
|---|---|---|---|---|
| Vibrator | 80 | 3.3 | 1.9 | 2.9–3.7 |
| Placebo | 80 | 4.5 | 2.0 | 4.0–4.9 |

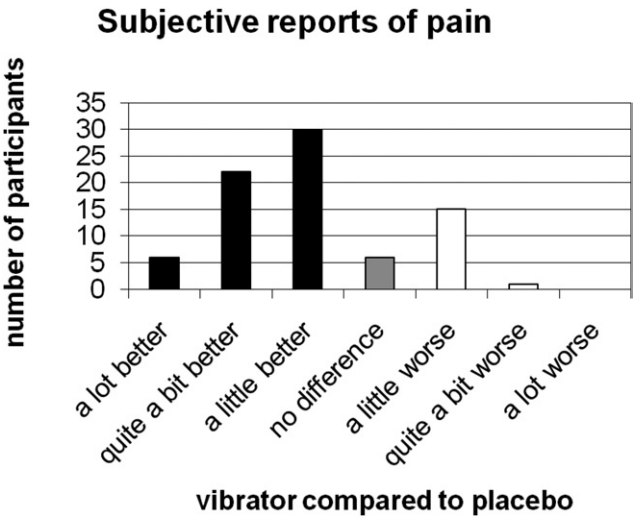


**Figure 2.** Bar chart showing the qualitative results of participant pain reports for the vibrator compared with the placebo.

## Discussion

In 1965 Melzack and Schecter[18] demonstrated that the itch produced by application of cowage to the wrist was reduced in intensity by vibration of the stimulated area and of the opposite wrist. Later that year, Melzack and Wall[19] published their famous gate control theory of pain in which they asserted that the stimulation of vibration or touch receptors in the skin causes stimulation of inhibitory interneurons in the spinal cord that can in turn inhibit the transmission of pain signals to the brain. It has since been recognized that this theory is not sufficient to explain all types of pain, for example, phantom limb phenomena or chronic pain syndromes.[20] Although the consensus view is that the gate theory is partly relevant, pain transmission is now believed to be more complex. In 2004 Melzack[20] presented a novel neuromatrix theory of pain in which he proposed that pain is a multidimensional experience produced by characteristic "neurosignature" patterns of nerve impulses generated by a widely distributed neural network in the brain. The neuromatrix, which is genetically determined and modified by sensory experience, is the primary mechanism that generates the neural pattern that produces pain, as opposed to the traditional view that pain is directly produced by sensory input evoked by injury or inflammation.

In 2008, Coelho[21] presented the results of a series of experiments using sophisticated acupuncture-like needles and a custom-built "stroking machine" and found that pain sensation was most effectively reduced when the skin was stroked at a speed of 5 cm per second and with little pressure—equivalent to the weight of a third of a 5 pence coin (approximately equivalent to a US 10 cent coin). His explanation was that there is a subset of the pain-transmitting C-fibers that, instead of inducing a pain signal, act as pleasure receptors. Stimulation of these "pleasure nerves" can alleviate the discomfort caused by a painful stimulus in a nearby part of the body, as well as accounting for the pleasant feeling of being stroked.

Other simpler hypotheses that have been proposed to explain the pain-reducing effect of vibration or stroking include an acupuncture-type effect, distraction, self-hypnosis, or suggestion in credulous patients,[21] but none of these provide useful insight into the pathophysiology of the mechanism of action.

In terms of the anodyne effect of vibration in a clinical setting, there have been several empirical reports in the dermatologic literature using battery-operated vibrating devices during local anesthetic injection.[13,15] Anecdotal evidence from dentists advocates the beneficial pain-relieving effect of manually pinching, shaking, or vibrating the cheek while administering local anesthetic.

Eleven-point pain intensity numeric rating scales, such as the validated Brief Pain Inventory,[22] are frequently used to rate pain intensity, where 0 = no pain and 10 = worst possible pain. However, it is difficult to interpret the clinical importance of changes, such as a 1- or 2-point change, on this scale. Farrar et al[23] presented an analysis to determine the change in a pain intensity numeric rating scale that is most closely associated with improvement on the commonly used and validated measure of the patient's global impression of change in 2879 patients being treated with pregabalin for chronic pain. They found that, on average, a reduction of approximately 2 points or approximately 30% in the pain intensity numeric rating scale represented a clinically important difference. However, such chronic pain situations are different from the brief, acute pain experienced during anesthetic injections; thus, the results are not necessarily applicable. Further research is needed to determine what constitutes a clinically significant change in anticipated, short-lasting pain.

In our study, for the power calculation, we arbitrarily chose a difference of 1.5 on a pain score between 0 and 10 as being clinically significant. Thus, one could argue that our finding of a mean difference of 1.2, or 27%, between the vibrated and placebo sides may not be clinically significant. However, convincing evidence that the difference is clinically significant derives from the qualitative analysis. In particular, approximately three quarters of the participants subjectively described the vibrated side as hurting less, with more than one third of all participants finding it hurt quite a bit less or a lot less. Less than a quarter of the participants found the vibrated side hurt more, and of those nearly all reported the difference as being only a little worse rather than quite a bit or a lot worse.

Notably, 6 participants scored both sides equally on the pain scale, yet of those only 3 qualitatively described the 2 sides as being of no difference. The other 3 participants all reported the vibrated side as hurting a little more than the placebo side. One participant commented that the second [vibrated] side hurt a little more, but she enjoyed the distraction of the vibration. Another said that the second [vibrated] side was generally better, but there was a particular point at which it was more painful [medially], and therefore overall she found that side a little worse.

Another interesting finding from this study was that participants seem to find the second side more painful than the first, regardless of the order of intervention (there was no evidence of a statistical interaction between the intervention and the order of application of vibrator and placebo). This may be because having received injections on one side, patients are aware of the discomfort and therefore more anxious with a heightened awareness and anticipation of pain for the second side. Also, the total length of time the pain has been endured is longer by the time of the second injection, and therefore patients' tolerance of it may be lower.

An editorial in the *Lancet* in 1992 on vibration therapy for pain concluded that vibration is simple, safe, highly effective, and inexpensive to establish and maintain, but that battery-operated vibrators have sexual connotations that can embarrass some patients.[24] We informed our patients that we were using hand-held vibrating tools, and none complained or appeared embarrassed by this.

The intervention we chose used both mechanical vibration and stroking. The reason we chose this particular protocol was that this seemed to provide the most beneficial effect in a pilot study, and there was evidence that both interventions were beneficial. To distinguish whether both of these acts were equally effective, if one was more effective, or if they act synergistically, an additional study would be necessary to analyze each of these situations in turn. Other variables that are likely to be influential and that could be studied are the frequency of vibration, the frequency of stroking, the pattern of stroking (circular or linear), and the location of the intervention in relation to the site of injection.

Having demonstrated proof of concept, we are now exploring alternative methods to facilitate the application such that an assistant is not required. We are currently testing manual vibration or stroking of the skin using the index finger of the surgeon's non-injecting hand. Other ideas we plan to test are using a fingertip vibrator (analogous to a vibrating thimble) and a vibrating needle (we have anecdotal reports of the use of such a device by dentist colleagues).

In conclusion, this study demonstrated that circling a vibrator on the forehead during administration of local anesthetic into the upper eyelids reduced the pain of the injection and that this effect was highly statistically significant. In terms of clinical significance, further research is needed to determine the change in pain intensity rating that can be deemed clinically significant in this setting. However, our qualitative analysis demonstrated that the majority of patients subjectively preferred the vibrated side. This is an intervention that is inexpensive to purchase and maintain. It is easy to use and may have a particularly beneficial effect in patients who are anxious about the anesthetic injection or have a low pain tolerance.

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