

SAFETY OF A NOVEL NITROUS OXIDE DELIVERY SYSTEM TO PROVIDE PATIENT ANALGESIA AND COMFORT DURING COSMETIC PROCEDURES

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Disclosures

Jordan V Wang, MD, MBE, MBA

- Allergan
- Alastin
- Cynosure
- Lutronic
- Novoxel
- Sofwave
- Solta

Background

- Cosmetic medicine had tremendous growth with in-office procedures
 - Expanding indications, improved technology, increased accessibility, society's greater acceptance
- Many cosmetic treatments are associated with periprocedural discomfort
 - Topical anesthetics
 - Local anesthetics
 - NSAIDs
 - Benzodiazepines
 - Opioids
 - Inhaled nitrous oxide

Background

- Inhaled nitrous oxide has received more recent attention
 - Rapid onset
 - Short half-life
 - Low side-effect profile
 - Ease of clinical integration
 - Can reduce or eliminate need for systemic pain medication
 - Following final inhalation, neurologic effects diminish within minutes

Background

- Pro-Nox is a novel nitrous oxide delivery system
 - Provides patient analgesia during cosmetic procedures
 - Cleared by FDA as an analgesic device
- Delivers nitrous oxide 50%/oxygen 50% to be inhaled by patients
 - Given this fixed blend, there is low risk for losing consciousness
- Only delivers nitrous oxide on-demand through a one-way valve
 - Patients must actively breathe to inhale the mixture
 - Reduces many risks attributed to continuous systems



Background

- Due to COVID-19, additional safety measures have been implemented
- Pro-Nox now incorporates an anti-viral filter
 - Reduces risk of exhalation of viral particles into examination room
 - Offers comfort and confidence for safety of physicians and patients
 - 99.99% filtration efficiency
 - Independently verified

Methods

- Online survey was distributed to physician practices
 - Dermatology, plastic surgery, and aesthetics
 - Currently using Pro-Nox in their practice
- Survey was sent in January 2021 to February 2021
 - Demographic data
 - Experiences using Pro-Nox
 - Perspectives on Pro-Nox

Results

- 204 respondents
 - 14.3 years working in aesthetic medicine
 - 2.6 years using Pro-Nox
- Cosmetic treatments per week:
 - 11-20 (23.5%)
 - 31-40 (22.6%)
 - >50 (19.6%)
 - 21-30 (12.8%)
 - 1-10 (10.3%)
 - 41-50 (10.3%)

Results

- Cosmetic treatments with Pro-Nox per week:
 - 1-3 (42.7%)
 - 4-6 (27.9%)
 - 7-9 (12.3%)
 - 10-12 (8.8%)
 - 13-15 (3.4%)
 - >15 (1.0%)

Results

- 64.2% combined Pro-Nox with other oral, intravenous, or intramuscular medications to increase patient comfort
 - NSAID (47.1%)
 - Benzodiazepine (22.1%)
 - Opioid (12.8%)
 - Midazolam/ketamine/ondansetron (MKO) melt (3.4%)
- 84.8% have patients actively breathe Pro-Nox during laser and other energy-based procedures on the head, neck, and chest
 - No one has experienced a flammable situation

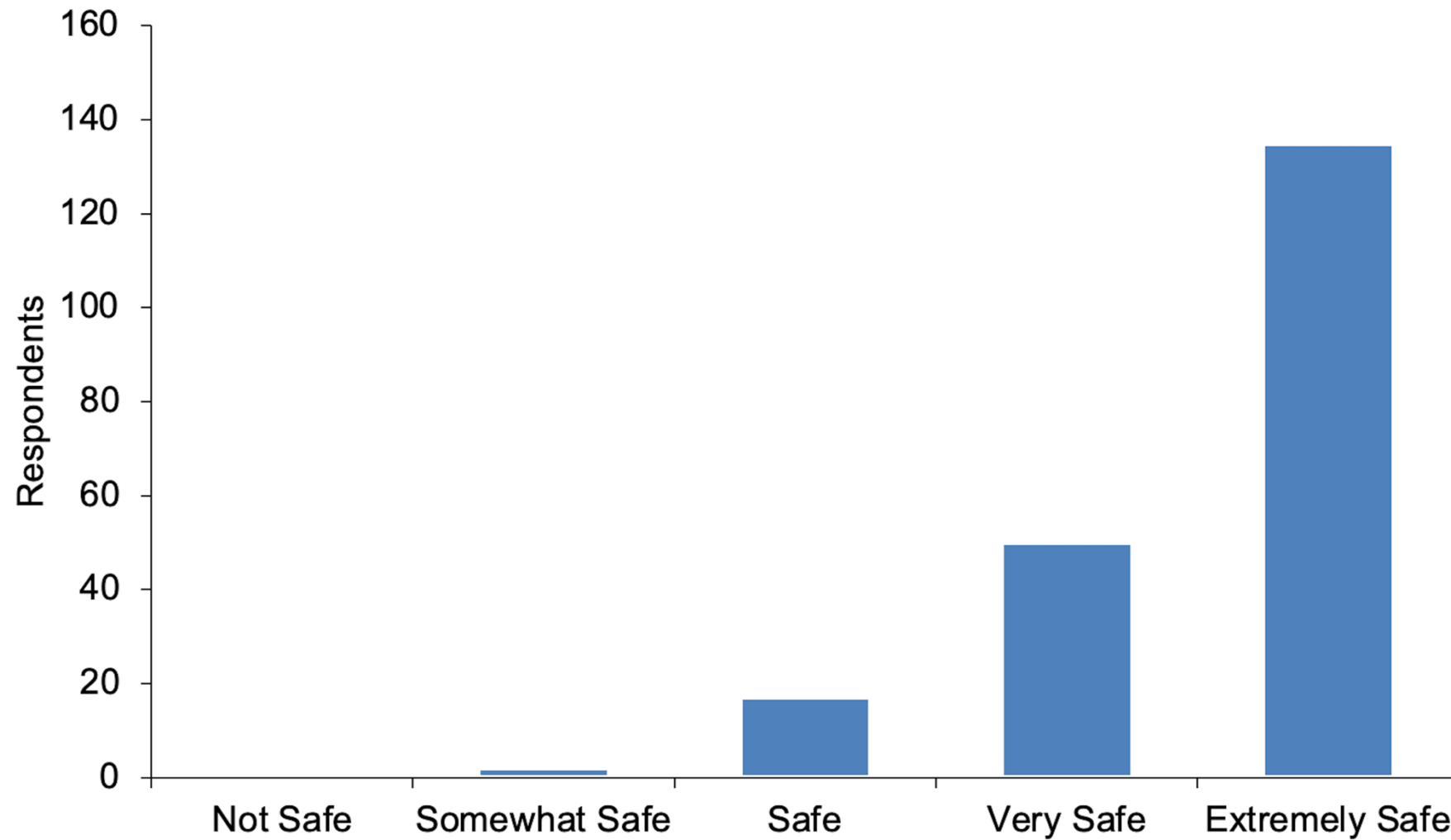
Results

- Top 10 procedures performed with Pro-Nox:
 - Radiofrequency microneedling (61.3%)
 - Ablative resurfacing laser (51.5%)
 - Non-ablative resurfacing laser (45.1%)
 - Ultrasound device (32.8%)
 - Cosmetic injectable (29.4%)
 - Surgical procedure (27.0%)
 - Platelet-rich plasma (PRP) (23.5%)
 - Other radiofrequency device (18.1%)
 - Facilitation of local or tumescent anesthesia (16.2%)
 - Microneedling (13.2%)

Results

- Of all respondents, 7.8% experienced any side effects
 - Headache, dizziness, nausea and vomiting
- 3 respondents may have had a patient with loss of consciousness
 - “Over inhalation”; “very brief and reversed quickly once Pro-Nox stopped”
 - More information required to determine if true loss of consciousness or over-sedation
 - Conservative estimate for incident rate of 0.002% of all treatments
- 1 respondent referred a patient to hospital for headache and sense of doom caused by excessive inhalation

Perceived Safety of Pro-Nox



Results

- 99.0% believed Pro-Nox to be effective at making cosmetic procedures more comfortable for patients
- 100.0% believed Pro-Nox to be easy to use
- 98.5% were satisfied with their use of Pro-Nox
 - 99.0% believed that their patients were satisfied

Supplemental Results

- Supplemental databases were also reviewed to determine safety
- Internal safety data from CAREstream America
 - No significant adverse events from 3,000+ Pro-Nox users over 3 years
 - No formal incident reports filed to the FDA
- Retrospective billing database review
 - Laser & Skin Surgery Center of New York
 - No significant adverse events over 2 years

Conclusions

- Pro-Nox is an FDA-cleared device
 - Safely, reliably, and predictably provides analgesia during cosmetic treatments
- Practical adjunctive agent for pain control during several common procedures in aesthetic medicine
 - Lasers
 - Other energy-based devices
 - Cosmetic injectables
 - Surgical procedures
 - Tumescence anesthesia

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