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A Novel Device for Alleviating Postoperative Transient Xerostomia: Analysis of Patient-reported Outcome Measures

Research Article

Zion Zibly[1,2], Ehud Nagler[3], Ari Zimran[4], Alexander Ioscovich[5,*]

[1] Department of Neurosurgery, Sheba Medical Center, Ramat Gan,5262000, Israel.
[2] Raphael Hospital, Tel Aviv, 6158101, Israel.
[3] IMD tech, Ltd, Tivon, 3604442, Israel.
[4] Gaucher Clinic, ShaareZedek Medical Center, Jerusalem, 9103102, Israel.
[5] Department of Anesthesiology, Perioperative Medicine, and Pain Treatment, Shaare Zedek Medical Center, and Faculty of Medicine, Hebrew University of Jerusalem, 9103102, Israel.

Abstract

Background: Postoperative transient xerostomia (dry mouth) is a very common phenomenon after general anesthesia, yet, no adequate treatment is currently available. Lipsus, an FDA-approved disposableface-mounted device, was shown in a proof-of-concept study involving 10 patients to be safe and effective in alleviating such xerostomia. The goal of the current audit was to investigate the effectiveness and safety of this device in a larger cohort in real-life clinical practice.
Methods: This observational audit included patients(n= 62) who underwent surgery, used the device as part of postoperative care, and reported their xerostomia-associated discomfort before and after mounting the device using a 0-10 scale (0, no discomfort; 10, unbearable discomfort).
Results: The median (range) age of the patients was 50 (15-77) years, 54.8% were women, and the most common surgery was knee replacement (19.4%). Before mounting the device, 53.3% of the patients characterized their xerostomia-associated discomfort as 10, and the mean (SD) level of reported discomfort was 8.5 (2.1). Within 15 minutes of mounting the device, the mean (SD) dropped to 0.05 (0.2), and within 30 minutes to 0.03 (0.2). From 45 minutes on, all patients characterized their discomfort as 0 (none).The device was safe; no adverse events were reported and no patient requested to remove it.
Conclusion: The Lipsus device is a safe and effective modality for alleviating postoperative transient xerostomia.

Keywords: Anesthesia; Complication; Dry Mouth; Postoperative; Xerostomia.

Introduction

Xerostomia (defined as a subjective feeling of oral dryness) has numerous etiologies. These include adverse effects of certain medications, radiotherapy to the head and neck, and certain autoimmune disorders (e.g., Sjogren's syndrome, diabetes mellitus) (reviewed in [1]). The main goal of xerostomia management is symptom relief along with addressing the underlying cause, if possible. Currently, treatment modalities for xerostomia include mainly local measures such as sprays, lozenges, gels, frequent sips of water, chewing sugar-free gum, etc [1]. In addition, a few sialogogue drugs are currently available for xerostomia management (e.g., pilocarpine and cevimeline), and transcutaneous electrical nerve stimulation (TENS) has also been assessed as a treatment modality for this condition [1, 2].

Transient xerostomia is an extremely common phenomenon in the peri and postoperative setting occurring (at some level) in the majority of patients [3-5]. Multiple factors potentially contribute to postoperative xerostomia including abstaining from food/water prior to, during, and for several hours after surgery, the use of certain anesthetic and analgetic drugs, as well as methods of airway management (e.g., face mask, laryngeal mask airway, and tracheal intubation)[6, 7]. Although transient xerostomia could be

***Corresponding Author**:
Alexander Ioscovich,
Department of Anesthesiology, perioperative medicine, and pain treatment, Shaare Zedek Medical Center, and Faculty of Medicine, Hebrew University of Jerusalem, 9103102, Israel.
Tel: 972-50-8685052
Fax: 972-2-6555003
E-mail: aioscovich@gmail.com

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as uncomfortable as non-transient xerostomia, it is not adequately addressed by current treatment modalities. The only treatment approach used in routine clinical practice is temporarily moistening the lips and oral mucous membranes with warm water by the nursing staff, who may not be immediately available to assist. Thus, transient postoperative xerostomia clearly constitutes an unmet clinical need.

We previously described a novel treatment modality for postoperative transient xerostomia, named the Lipsus® device (Figure 1). It is a disposable device (up to 24 h use) mounted on the face of the patient after surgery like spectacles. The front part of the device is made from a soft cloth and is placed above the patient's lips touching or almost touching them. A plastic bag (300 mL) supplies a low water flow rate (up to 12 mL/h) to the cloth. The flow rate is low, so only the lips are wet and the patient can speak freely [8]. In a proof-of-concept study, the device was applied in 10 patients post operatively and was found to be effective and with no adverse events [8]. The device received approval by the United States Food and Drug Administration (FDA) and a CE certification in the EU (both in 2019).

The objective of the current study was to evaluate the safety and effectiveness of the Lipsus device in alleviating transient postoperative xerostomia, and to assess the feasibility of its use in a hospital setting.

Methods

This observational audit involved patients who underwent surgery in Raphael hospital between December 2020 and January 2021, and for whom Lipsus was used to alleviate postoperative xerostomia as part of routine patient care. Since Lipsus was used as part of its introduction into the hospital setting, patients were asked about their experience with it and their responses were documented. Patients were asked to indicate their level of discomfort from xerostomia using a scale of 0 (no discomfort) to 10 (most severe discomfort), at the recovery room (post anesthesia care unit) immediately before the Lipsus device was mounted, and 15, 30, 45, 60, 90, 120, 180, and 240 minutes thereafter, or until they were able to drink. Patients were also asked about their overall impression of the device, using a 1 (minimally helpful) to 10 (very helpful) scale. Descriptive statistics was used to analyze the results.

Ethical review and approval were waived for this study, as this was an audit of pre-collected data related to FDA/CE approved device in standard-of-care commercial use.

Results

Patient Characteristics

Overall, 62 patients are included in the current analysis. Patient demographics are presented in Table 1. The majority of patients were women (54.8%), the median (range) age was 50 (15-77) years. Approximately a third of the patients were 21-40 years of age and another third were 41-60 years of age. The cohort included patients who underwent a variety of surgery types. The most common type was knee replacement (19.4%), followed by spinal surgery (16.1%), and laparoscopic cholecystectomy (9.7%).

Effect of the Lipsus device on xerostomia

Data on the level of discomfort from postoperative xerostomia before mounting the Lipsus device was available for 60 patients. Thirty-two patients (53.3%) characterized their level of discomfort as 10 (in a scale of 0-10 where 10 is the most severe discomfort and 0 is no discomfort), 8 patients (13.3%) characterized it as 9, and 6 (10.0%) characterized it as 8. The rest of the patients characterized their level of discomfort between 7 and 1; none characterized it as 0 (Figure 2).

The mean (SD) level of discomfort immediately before mounting the Lipsus device was 8.5 (2.1) (Figure 2, time 0). Within 15 minutes, the level of discomfort dropped to a mean (SD) of 0.05 (0.2), and within 30 minutes it dropped further to a mean (SD) of 0.03 (0.2). From 45 minutes on, all patients characterized their discomfort as 0 (none). The number of patients using the Lipsus device dropped over time (from 60 minutes on), as patients started to drink normally (Figure 3).

No adverse events (e.g., irritation, allergic reaction) were reported and no patient requested to remove the Lipsus device.

Lastly, when asked to grade their overall impression from the device (0-10 scale; 0, minimally helpful; 10, very helpful), 50 patients (80.6%) graded it as 10; 2 (3.2%) as 9; 1 each (1.6%) graded it as 8 and 6, and 2 (3.2%) as 5. Responses were not available for 6 patients (9.7%).

Discussion

This observational audit demonstrated the feasibility, safety, and effectiveness of the Lipsus device in alleviating postoperative transient xerostomia. The findings also suggest that the device alleviates xerostomia very quickly (within 15 minutes of mounting it).

Figure 1. Schematic illustration of the Lipsus device.

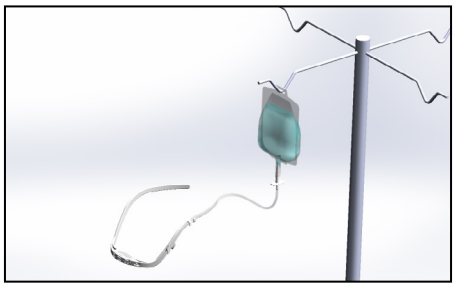


Table 1.Patient demographics.

Characteristic	N = 62
Sex, n (%)	
Women	34 (54.8)
Men	28 (45.2)
Age	
Median (range), years	50 (15-77)
Age category, n (%)	
≥20 years	7 (11)
21-40	20 (32)
41-60	21 (34)
61-80	14 (23)
Surgery type, n (%)	
Knee replacement	12 (19.4)
Spinal surgery	10 (16.1)
Laparoscopic cholecystectomy	6 (9.7)
Breast surgery (including breast implant revision surgery)	5 (8.1)
Gynecologic surgery (including hysteroscopy)	4 (6.5)
Plastic surgery	3 (4.8)
Prostate biopsy	3 (4.8)
Hip replacement	3 (4.8)
Other knee surgery	3 (4.8)
Arthroscopy	2 (3.2)
Rectocele	2 (3.2)
Other*	6 (9.7)
Unknown	3 (4.8)

*One each of Carpal tunnel release surgery, ear surgery, radical neck dissection, radius fracture surgery, re-operation due to bleeding, and tonsillectomy.

Figure 2. Distribution of levels of discomfort from xerostomia as reported by the patients immediately post-surgery (and before mounting the Lipsus device), using a 0-10 scale (0, no discomfort; 10, most severe discomfort). N = 60 (data were unavailable for 2 patients).

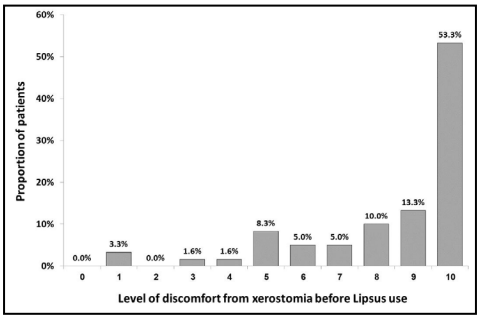
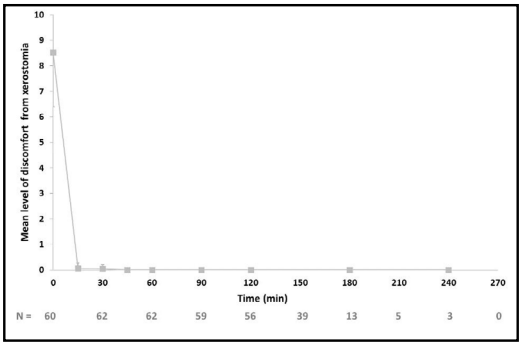


Figure 3. Mean level of discomfort from xerostomia over time. Patients reported their perceived level of discomfort using a 0-10 scale (0, no discomfort; 10, most severe discomfort) just before the application of the Lipsus device (time 0) and after 15, 30, 45, 60, 90, 120, 180, and 240 minutes. Patients stopped using the device when they were able to drink. The number of patients using the device at each time point is presented below the graph. Error bars represent standard deviation.



Notably, although postoperative xerostomia is transient, the discomfort it causes can be substantial, as shown in the current report. Furthermore, xerostomia could impact communication due to difficulties in pronunciation and voice production [9] and thus could lead to frustration, as patients may not be able to communicate their needs clearly after their surgery.

Currently, postoperative transient xerostomia constitutes an unmet clinical need, as the phenomenon is extremely common, yet the routine treatment (moistening the lips/oral mucous membranes with warm water by the nursing staff) is inadequate and no other treatment modalities are available. To the best of our knowledge, the only other treatment modality evaluated thus far is a spray derived from Phyllanthus embilica (Indian gooseberry), which was shown in a recently published randomized controlled trial involving 64 female patients after gynecologic surgery under general anesthesia to be significantly more effective than warm water spray for treating postoperative xerostomia [4].

The results of our findings are consistent with an earlier proof-of-conceptstudy showing that Lipsus was safe and effective in alleviating postoperative transient xerostomia in 10 patients (aged 21-77 years) [8]. Notably, in the proof-of-concept study, the first time-point after mounting the Lipsus device was 60 minutes [8]. The current analysis, in which the first evaluated time-point was 15 minutes after mounting the device, demonstrates that the device alleviates xerostomia quickly.

Notably, healthcare-acquired infections (HAIs) constitute a major challenge in the healthcare system, and even more so since the emergence of the COVID-19 pandemic [10] The main HAI-prevention strategy involves increasing hand hygiene [11]. Thus, an automated device that addresses postoperative xerostomia without hand contact between the patient and the nursing staff could also, indirectly, support HAI prevention.

The study is limited by the relatively small sample size, and its unrandomized design. Also, this study evaluated the subjective sensation of "dry mouth" as reported by the patients and no objective measures (e.g., salivary flow, oral mucosa moisture [12]) were evaluated.

In conclusion, the Lipsus device is a safe and effective approach to alleviating postoperative transient xerostomia.

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Conflicts of Interest: Zion Zibly declares no conflict of interest. Ehud Nagler reports having stock ownership and intellectual property interest in IDM tech, Ltd. Ari Zimran and Alexander Ioscovich declare having stock ownership in IDM tech Ltd.

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