

A New Modality to Alleviate Transient Xerostomia Post-Surgery

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ABSTRACT

Autoimmune disorders such as Sjogren's syndrome, Diabetes Mellitus, various medications, radiation to the head/neck, smoking, post-anesthesia and post-surgery period, aging are recognized as associated with salivary gland hypofunction which colloquially is termed "dry mouth" or Xerostomia. To combat the long-term side effects of xerostomia, therapeutic regimens include increasing oral hydration using over-the-counter oral comfort agents or alternative medical approaches in addition to the use of systemic cholinergic drugs to stimulate salivary output. The purpose of this report is to present safety and efficacy outcomes in the first patients to use a new device, the Lipsus set-up, which was developed specifically meet this unmet need and alleviate dry mouth in postoperative period.

Key words: Postoperative, complication, xerostomia, dry mouth, anesthesia

INTRODUCTION

Autoimmune disorders such as Sjogren's syndrome, diabetes mellitus, various medications, radiation to the head/neck, smoking, and aging are recognized as associated with salivary gland hypofunction which colloquially is termed "dry mouth."^[1] Beyond the subjective uncomfortable feeling and verbal communication difficulties, long-term xerostomia can significantly diminish oral health and may indirectly result in decreased dietary intake and as a nexus for infections. To combat the long-term side effects of xerostomia, therapeutic regimens^[2] include increasing oral hydration using over-the-counter oral comfort agents or alternative medical approaches^[3] in addition to the use of systemic cholinergic drugs^[4] to stimulate salivary output.^[5] Most recently, a third-generation, implant-supported neuroelectrostimulating device has been devised.^[6] However, these options are inappropriate for transient dryness in the oral cavity that characterizes the post-anesthesia post-surgery period. Whereas the symptoms

are equally uncomfortable, to date, there has been no attempt to relieve this condition.

The purpose of this report is to present safety and efficacy outcomes in the first patients to use a new device, the Lipsius setup, which was developed specifically meet this unmet need and alleviate dry mouth after general anesthesia.

METHODS

Patients

Patients who were candidates for surgery under general anesthesia were randomly approached in the presurgery clinic by one of the investigators and offered the use of the Lipsius [Figure 1] setup for relief of post-anesthesia dry mouth in the context of a clinical trial with this new system. The equipment was shown to the patient and written informed consent was requested.

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Post-surgery, one of the investigators awaited the patient in the recovery unit after surgery. In the case of the patient complaining of dry mouth, the nurse on-call in the recovery unit alerted the investigator who would then ask the patient to score the degree of dryness on a 0–10 scale where zero was no sense of dryness and 10 was the worst case of oral dryness imaginable; the investigator would then attach the Lipsius setup. Approximately 1 h after continuous use of the Lipsius setup, the patient was again requested to rate oral dryness and then a 3rd time after 2 h and/or at the end of the stay in the recovery room whichever occurred first.

The Lipsius setup description

The Lipsius device was developed after the developer suffered from a dry mouth after surgery.

The device is disposable and can be used up to 24 h.

This device is placed on the patient's face after surgery like spectacles.

The front part of the device is placed above the patient's lips touching or almost touching them.

The part touching the lips is made from soft tissue giving the patient a pleasant feeling.

A plastic bag (similar to an infusion bag) supplies a low water flow rate to the soft tissue.

The flow rate is about half of the normal saliva production (about 12 cc/h). This flow rate is safe from a medical point of view and does not wet the patient's face (only his or her lips). The patient can speak freely during the treatment. The device does not prevent the use of other medical devices.



Figure 1: Lipsius device.

RESULTS

The Institutional Review Board (Helsinki Committee) approval was received for this study.

Of the 15 randomly approached patients, one patient (6.7%) refused to participate in the clinical trial. Of the remaining 14 patients who all signed informed consent, there were 8 males: Mean age was 58.5 years (range 21–77 years) and 6 females: Mean age 58.3 years (range 43–78 years) [Table 1].

One of the patients underwent two surgeries under general anesthesia during the trial period. After the first surgery, the patient did not complain of oral dryness but did complain of dryness after the second surgery so that the Lipsius setup was applied after the second surgery only.

Of the remaining 13 patients, one patient was transferred directly from the operating theater to the intensive care unit. Four other patients did not complain of oral dryness after surgery and therefore did not need to avail themselves of the Lipsius setup. In all, 10 patients used the Lipsius setup because of complaints of oral dryness after general anesthesia.

One patient complained of mild dripping of the water from the Lipsius setup onto her jaw and the setup was replaced to the satisfaction of the patient. However, in the 10 min before, the second setup was inserted, the patient applied a wetted tongue depressor and wet gauze pads.

There were no adverse events and no patient requested that the Lipsius setup be removed and not replaced.

No patient requested alternative options of wetting the lips while the Lipsius setup was in place. All patients felt that the oral dryness was completely relieved by the Lipsius setup.

The recovery unit staff was comfortable with the installation of the Lipsius system on an individual basis without requiring additional monitoring.

DISCUSSION

One serious repercussion of dry mouth, even if it is transient, is impeded speech. With inadequate saliva production, pronouncing words become difficult and people cannot “swallow” and start talking normally.^[7] Lubrication of the mouth is essential to proper speech and the sense of dryness often stymies efforts to communicate. The frustration of being unable to speak because of dry mouth is exemplified by the finding that xerostomia is the domain that most reduces quality of life in patients who have undergone chemoradiotherapy for oropharyngeal cancers.^[8] Thus, patients who feel a need to communicate while still in the recovery unit but are hampered

Table 1: Demographic characteristics and outcome of scores (0–10) of the participants

Age	Sex	Surgery type	Score before surgery	Score at 60'	Last score and time	Comments by patient
56	M	Laparoscopic cholecystectomy	9	0	0 at 70'	Significantly less oral dryness; easy to use
71	F	Laparoscopic cholecystectomy	6-7	0	0 at 65'	Easy to use
54	F	Laparoscopic gastropexy/ gastric bypass	7	0	0 at 70'	Nothing to report
62	M	Open radical dissection of the prostate	7	0	0 at 120'	Easy to use; hopes not to suffer from latent oral virus post-recovery as he usually does
64	M	Stoma reversal	7	0	0 at 80'	Easy to use; completely eliminated sense of oral dryness
51	M	Nephrectomy	6	0	0 at 120'	Very satisfied
60	M	Open radical dissection of the prostate	7	1-2	0	Nothing to report
44	F	Laparoscopic large bowel dissection	5	0	0	Patient with the mild dripping whose setup was switched
21	M	Orthopedic procedure	8	0	0	Very satisfied
77	M	Nissen fundoplication	8	Not done	Not done	Initially complained of severe oral dryness, but then became confused and could not provide scores after 60'

by dry mouth might benefit functionally and psychologically if able to ease the oral dryness. The Lipsius system is a means to preclude dryness and allay concerns that the patient might not be able to communicate properly post-surgery because of the inability to produce words properly.

The paradigm used in the study whereby the Lipsius system was employed post-surgery post-anesthesia in patients complaining of transient xerostomia proved to be adequate to evaluate both safety and efficacy. Safety was shown over a period of up to 2 h, with no adverse events. Efficacy was shown in reduction of the (subjective) estimation of the sensation of dry mouth in all participants.

One of the limitations of the study was that estimation of dry mouth was only requested 60' after the Lipsius system was put in place. Since all the patients had rated oral dryness at 60' as 0, it would be of interest to assess the time interval when the Lipsius system engenders sufficient lubrication to allow a dramatic drop in the dryness estimation, a time point that may have been well before the 60' protocol-driven evaluation. Similarly, the use of a single open-ended question regarding the participants' satisfaction while still in the recovery unit might have not been optimal and perhaps would have been better documented using a structured visual analog scale of 0–10 points as is used in dialysis patients who rate thirst and xerostomia before

and after treatment^[9] once the patient was back in the departmental ward.

The complaint of dry mouth was universally present among a cohort of patients undergoing orthopedic surgery with peripheral nerve blockade, or neuraxial or regional or general anesthesia, all of whom also received oral opioid analgesics.^[10] In a comparison of anesthesia for emergency cesarean sections, the group receiving hyperbaric bupivacaine and 45 µg clonidine had significant incidence of dry mouth.^[11] The use of intravenous dexmedetomidine very short-term for tympanoplasty^[12] and for laparoscopic gynecological surgeries^[13] also induces significant dry mouth. Thus, the occurrence of dry mouth because of anesthesia is a non-trivial symptom for the patient and occurs with predictably high-frequency consequent to the use of certain drugs. Thus, proof of concept of the utility of the Lipsius system is a novel and user-friendly means to alleviate dry mouth post-surgery because of the use of certain anesthesia medications.

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