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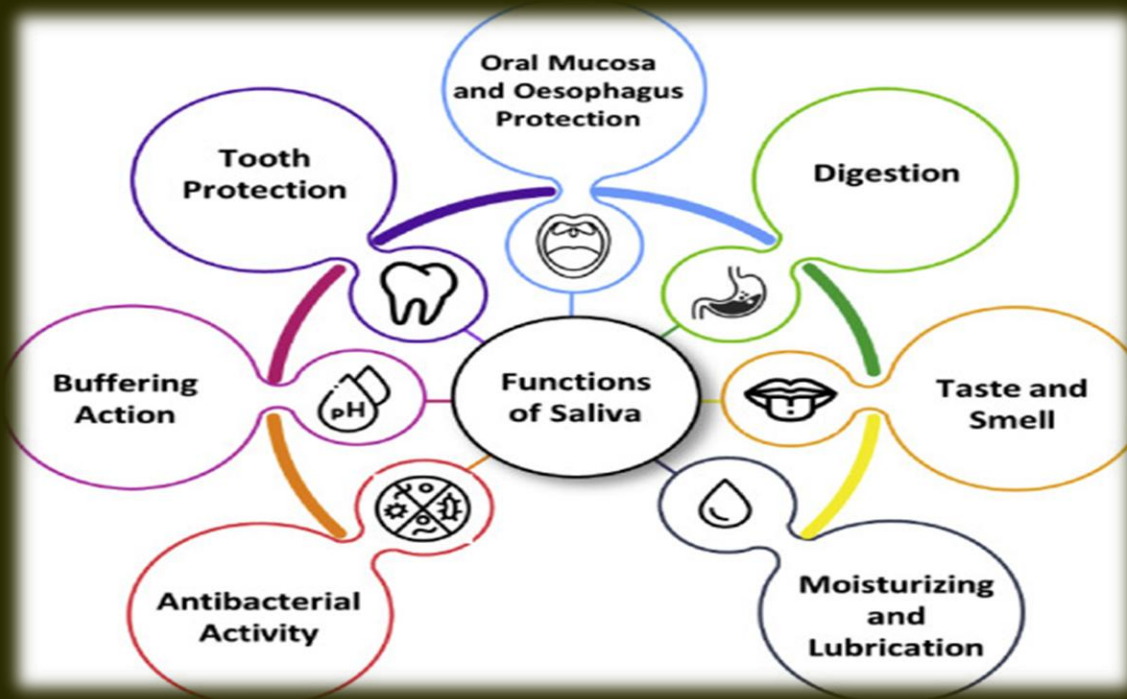
# **INTRAORAL ELECTROSTIMULATOR FOR RADIATION INDUCED XEROSTOMIA IN PATIENTS WITH HEAD AND NECK CANCER**

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**Ljupka Arsovski, Verica Toneva Stojmenova, Lenche Kostadinova, Sanja Nashkova, Marko Mladenovski**

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# Introduction

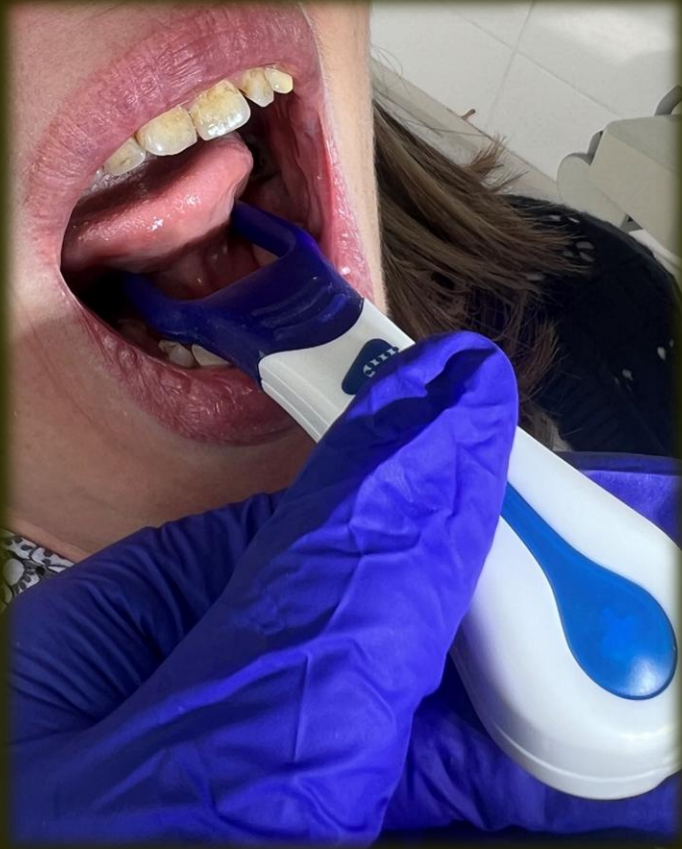


Xerostomia is the result of a decrease in the volume of saliva secreted because of salivary gland hypofunction



Patients with salivary gland hypofunction typically complain of dry mouth, difficulty chewing, swallowing and/or speaking; they hardly tolerate spicy, acidic, and crunchy food and often report taste changes or difficulty wearing dentures

This article review will examine the efficacy of the SaliPen in treating xerostomia following radiotherapy, its mechanisms of action, clinical implications, and potential limitations.



## □ Extraoral and intraoral devices



The first attempt to exploit neurostimulation to increase salivary secretion was made in the USA, through the design and commercialization of the Salitron device (Biosonics, Fort Washington, PA, USA)

# SaliPen



# Methods and materials

- extensive literature search was performed using online databases such as NCBI (US National Library of Medicine), Webmd, PubMed and Google scholar.
- Keywords such as electrostimulation, xerostomia, radiotherapy, salivary glands, head and neck cancer were used to find relevant articles published in peer-reviewed journals.
- The inclusion criteria encompassed studies, clinical trials, and reviews published in the English language from the past 10 years.
- clinical guidelines, and manufacturer documentation were used to support and enhance the findings from the literature and also the use of SaliPen by our patients.

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Case Reports > Med Oral Patol Oral Cir Bucal. 2018 Sep 1;23(5):e552-e559.  
doi: 10.4317/medoral.22597.

**Electrostimulation of the lingual nerve by an intraoral device may lead to salivary gland regeneration: A case series study**

A Wolff <sup>1</sup>, M Koray, G Campisi, F-P Strietzel, G-I Lafaurie, B-Z Beiski, J Ekström

Affiliations + expand  
PMID: 30148471 PMCID: PMC6167107 DOI: 10.4317/medoral.22597

**Abstract**

**Background**  
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Clinical Trial > Int J Radiat Oncol Biol Phys. 2024 Jan 1;118(1):142-153.  
doi: 10.1016/j.ijrobp.2023.03.047. Epub 2023 Mar 17.

**Salivary Electrostimulation in the Treatment of Radiation Therapy-Induced Xerostomia (LEONIDAS-2): A Multicenter, Randomized, Double-Masked, Sham-Controlled, Phase 3 Trial**

Valeria Mercadante <sup>1</sup>, Arwa Al Hamad <sup>2</sup>, James McCaul <sup>3</sup>, Christopher Nutting <sup>4</sup>, Kevin Harrington <sup>5</sup>, Dawn Carnell <sup>6</sup>, Teresa Guerrero Urbano <sup>7</sup>, Nicholas Kalavrezos <sup>8</sup>, Julie A Barber <sup>9</sup>, Stephen R Porter <sup>10</sup>, Stefano Fedele <sup>11</sup>

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PMID: 36933846 DOI: 10.1016/j.ijrobp.2023.03.047

**Abstract**

**Purpose:** Radiation therapy-induced xerostomia significantly affects quality of life in head and neck

# Evaluation and results

- In the research by Strietzel, Frank P et al. the conclusion showed that electrostimulation led to a marked reduction in oral dryness, contributing to an overall improvement in patients' perceived well-being. No notable adverse effects were reported
- Wolf, A et al. present possibility of salivary gland regeneration after electrostimulation, and they conclude that recovery is likely attributed to a combination of increased functional glandular tissue and the restoration of neural regulation over the secretory components and associated blood vessels.
- Clinical studies have demonstrated that lingual nerve stimulation can restore salivary secretion in patients previously exhibiting complete absence of salivary output, enabling them to recover the ability to expectorate



## *Components of the SaliPen Electrostimulator:*

1. **Electrodes:** The SaliPen is equipped with electrodes that deliver electrical impulses to the oral mucosa. These electrodes are designed to ensure effective contact with the tissue, allowing for optimal stimulation.
2. **Power Source:** The device is powered by a battery, which generates the electrical current required for stimulation. This power source is crucial for the device's portability, allowing patients to use it conveniently in various settings.
3. **Control Unit:** The SaliPen contains a control unit that regulates the frequency, intensity, and duration of the electrical impulses delivered. This unit allows for customization based on individual patient needs and comfort levels.



**SaliPen** 

## *The Mechanism of Electrical Stimulation in the SaliPen*

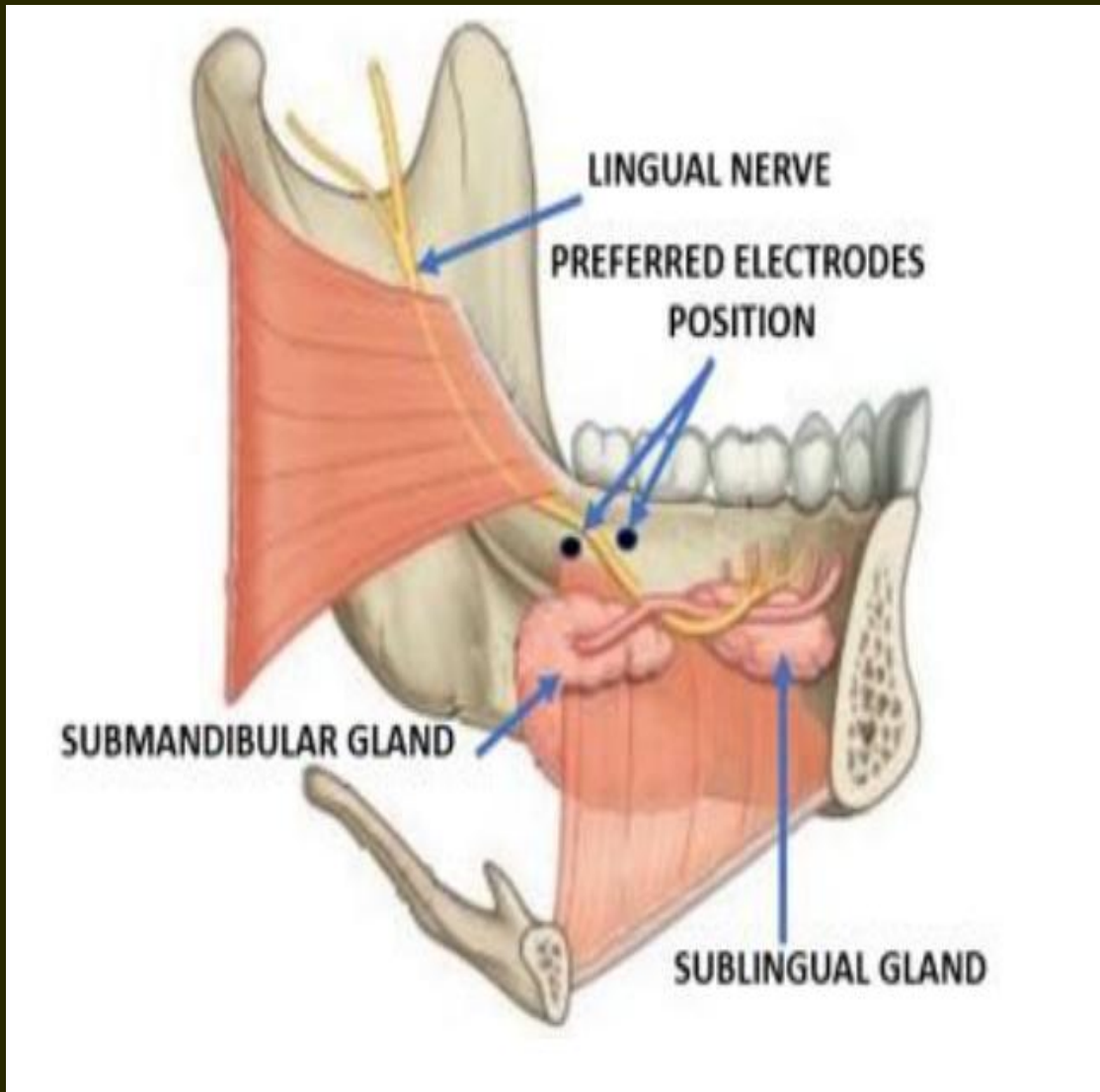
**1. Electrical Impulse Generation:** When the SaliPen is activated, the control unit generates low-frequency electrical impulses. These impulses are typically in the range of 1 to 100 Hz, which is optimal for stimulating the salivary glands without causing discomfort to the user.

**2. Transmission of Electrical Signals:** The generated impulses are transmitted through the electrodes to the oral mucosa. The design of the electrodes ensures that the electrical current penetrates the tissue effectively, reaching the nerve endings associated with the salivary glands.

**3. Activation of Nerve Endings:** The electrical impulses stimulate the afferent nerve fibers in the oral mucosa, particularly those linked to the parasympathetic nervous system. This stimulation mimics the natural physiological signals that would typically prompt saliva production.

**4. Release of Neurotransmitters:** As a result of the electrical stimulation, neurotransmitters such as acetylcholine are released at the synapses of the salivary glands. Acetylcholine is a key neurotransmitter in the stimulation of saliva secretion, activating the glandular cells responsible for producing saliva.

**5. Saliva Production:** The activation of the salivary glands leads to an increase in saliva production. The SaliPen effectively enhances the function of the remaining viable salivary tissue, allowing patients to experience relief from the symptoms of xerostomia.



## Conclusion

**SaliPen electrostimulator** represents a novel and effective approach to managing xerostomia in patients following radiotherapy for head and neck cancers.

By stimulating salivary gland function, the device offers a non-invasive solution to a condition that significantly impacts patient quality of life.

As further research elucidates its benefits and optimizes treatment protocols, the SaliPen may become a standard element in the care of patients suffering from the debilitating effects of dry mouth.

***Thank you for your attention***



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