

Salivary Pacemakers and Its Role in Management of Xerostomia: A Review

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ABSTRACT

Saliva is an essential oral fluid that plays a vital role in maintaining both oral and dental health. Xerostomia, commonly referred to as dry mouth, is a condition characterized by a noticeable reduction in salivary flow. It can significantly impact a patient's quality of life by affecting nutrition, impairing denture function, compromising oral hygiene, and increasing the risk of dental caries and oral infections such as candidiasis. Managing xerostomia remains a significant clinical challenge in dental care. Effective prevention and treatment require a proactive and collaborative approach. Salivary pacemakers, through neuroelectro-stimulation, activate salivary glands and optimize the use of any remaining functional glandular capacity. This review aims to emphasize the role and clinical relevance of salivary pacemakers in modern dentistry.

Keywords: Neuroelectrostimulation, Saliva, Salivary Pacemaker, Xerostomia

INTRODUCTION

Xerostomia, commonly known as dry mouth, refers to the feeling of dryness in the oral cavity and is often linked to decreased saliva production, also called hyposalivation.^[1] Xerostomia is estimated to affect between 10% and 29% of the general population, with women experiencing it more frequently than men. While xerostomia symptoms are more frequently observed in older adults, aging itself is not the direct cause. Normally, the flow of unstimulated or resting saliva is about 0.3 mL per minute. During sleep, this rate drops to approximately 0.1 mL per minute but can rise significantly to around 4.0–5.0 mL per minute during activities like chewing.^[2]

A decrease or lack of saliva can lead to considerable health issues and negatively impact a person's quality of life.^[3,4] Saliva is mainly composed of water, along with proteins and electrolytes.^[5] These elements play a vital role in enhancing taste, aiding speech and swallowing, and maintaining moisture and protection of the mucosal surfaces in the upper digestive system.^[3] Additionally, saliva serves important physiological purposes, including

antimicrobial defence and buffering actions that help safeguard teeth against cavities.

Individuals experiencing xerostomia frequently report difficulties with eating, speaking, swallowing, and wearing dentures. Those who use dental prostheses may face challenges such as poor denture retention, inflammation of the oral mucosa, and the tongue sticking to the roof of the mouth. Common complaints also include altered taste (dysgeusia), burning sensations in the tongue (glossodynia), and increased thirst at nighttime. Xerostomia is associated with a heightened risk of dental caries, swelling of the parotid glands, lip inflammation and cracking, tongue inflammation (glossitis), oral mucositis, fungal infections like candidiasis, salivary gland infections (sialadenitis), and halitosis.^[6,7]

Approximately 90% of saliva is secreted by the three main pairs of salivary glands, while the remaining portion is produced by 600 to 1000 minor salivary glands.^[8] Salivary flow rate ranges between 0.3–0.4 mL/min when unstimulated and increases to about 1.5–2.0 mL/min when stimulated.^[9] Salivary gland hypofunction (SGH) is defined as a reduction in saliva production, with flow rates dropping below 0.1–0.2 mL/min in an unstimulated state and below 0.7 mL/min when stimulated. Xerostomia is managed by alleviating symptoms, often using sugar-free gum, lozenges, or frequent sips of water. SGH treatment involves two main approaches: (a) using artificial saliva substitutes—though their effectiveness is limited—and (b) stimulating natural saliva production, which is generally the preferred method.^[9,10,11] For this reason, muscarinic receptor stimulants like pilocarpine and cevimeline are commonly prescribed. Additionally, agents like lemon juice or citric acid that activate taste receptors may promote saliva flow. However, muscarinic agonists can cause side effects such as excessive sweating, nasal discharge, nausea, and fatigue, while acidic solutions might irritate oral tissues or lead to enamel erosion.^[9] In a recent study, people suffering from xerostomia indicated a desire for an effective

non-pharmacological treatment option; however, current therapies do not fully meet these expectations.

This review aims to highlight recent developments in neuroelectrostimulation as a treatment for xerostomia, drawing upon existing understanding of the neurological regulation of saliva production.

DISCUSSION

Etiology of Xerostomia:

Xerostomia can be categorized based on its origin as either systemic or local.^[12] Systemic factors include endocrine disorders like diabetes mellitus and autoimmune thyroid conditions, autoimmune diseases such as Sjögren's syndrome, rheumatoid arthritis, and systemic lupus erythematosus, as well as infections like hepatitis C and granulomatous conditions including tuberculosis and sarcoidosis. Local causes involve the use of multiple medications, exposure to aggressive radiotherapy for head and neck cancers, and lifestyle habits such as the intake of alcohol, tobacco, and caffeine.^[13,14,15] A link between xerostomia and COVID-19 has also been observed. In a study by Fantozzi et al.^[16], 45.9% of individuals with confirmed COVID-19 reported experiencing dry mouth, with 76.5% stating it was their first time encountering the condition.

Neurological Regulation of Saliva Secretion:

The process of salivation is predominantly governed by autonomic pathways, involving both sympathetic and parasympathetic nerve fibres. Signals are transmitted through parasympathetic nerves to the otic and submandibular ganglia. As a result, the parotid and submandibular glands are stimulated, leading to saliva production through mechanisms involving acinar cell activation and increased blood flow (vasodilation).

Sympathetic activation leads to the narrowing of blood vessels (vasoconstriction), resulting in limited saliva production from the submandibular gland. In contrast, parasympathetic stimulation

promotes vasodilation, enhancing blood flow and causing abundant secretion of watery saliva that has a low concentration of organic components.^[17]

Theoretically, stimulating one or more elements of the salivary reflex pathway through electrical means can enhance saliva production and may help reduce the long-term impact of xerostomia.

Challenges associated with various pharmacological treatments have prompted interest in an intrinsic method known as salivary neuro-electrostimulation. Early efforts involved the use of transcutaneous electrical nerve stimulation (TENS), which relies on external devices with electrodes placed on the skin near the parotid glands. This technique was found to enhance salivary output from the parotid gland, particularly in individuals who had a low but detectable baseline flow. However, the stimulation effect was short-lived, typically lasting only about 30 minutes after application.

Despite initial success, TENS devices came with several drawbacks, such as involuntary facial muscle movements, temporary numbness or itching of the skin, and reduced effectiveness in older adults—factors that ultimately limited their clinical usefulness.^[18,19]

The initial use of intraoral stimulation devices dates back to 1986 in the United States, with the introduction of the Salitron device by Biosonics, based in Fort Washington, Pennsylvania.

SALIVARY PACEMAKERS

First-Generation:

Initial attempts at using neuroelectrostimulation to boost saliva production led to the creation of a device called Salitron, which was introduced in the United States (Biosonics Inc, USA) which was approved by U.S. Food and Drug Administration in 1988. This device [FIGURE-1] required the user to apply a probe daily to the mucosal surfaces inside the mouth—specifically between the palate and the tongue—for a few minutes. The device delivered electrical signals that activated

sensitive oral neurons to stimulate salivary flow.^[20,21] Repeated application of this device resulted in both an immediate increase in saliva production and a longer-term improvement in baseline salivary flow. Users also reported relief from symptoms of dry mouth (xerostomia). Clinical studies demonstrated its potential benefits without causing any significant local or systemic side effects.^[20,21,22] However, its practical use was limited due to factors such as its large size, high cost, and lack of ease of use. To overcome these issues, the European Commission supported the development of more advanced intraoral electrostimulators through the Saliwell project. This initiative led to the creation of two improved devices: one integrated into a removable oral appliance (second-generation) and another designed to be anchored to a dental implant (third-generation).^[23]

Second Generation:

GenNarino: A Miniature Intraoral Neuroelectrostimulation Device

GenNarino is a compact, intraoral neuroelectrical stimulator developed to enhance salivary secretion. It [Figure-2] includes two main components: a mouthpiece and a remote-control button to switch the device on and off. It is intended for use on an as-needed basis—specifically when the user experiences oral dryness—but usage should not exceed five times daily. The total permitted duration of use extends up to 50 months cumulatively.

Clinical studies^[24,25,26] have shown that GenNarino effectively increases saliva output, enhancing oral moisture through both mechanical and electrical stimulation. The mechanical action results from the mouthpiece's contact with the oral tissues, while electrical stimulation is delivered via low-voltage biphasic pulses to the mucosa, targeting the lingual nerve. The electrodes are strategically positioned near the lower third molars, close to the lingual nerve, as this nerve is significantly involved in controlling salivary gland secretion. The stimulation settings are optimized to ensure

effective salivation while remaining well below the thresholds for pain and sensory discomfort.

It is contraindicated in patients who are allergic to platinum, iridium, polyurethane and polycarbonate materials of device and under 18 years of age.

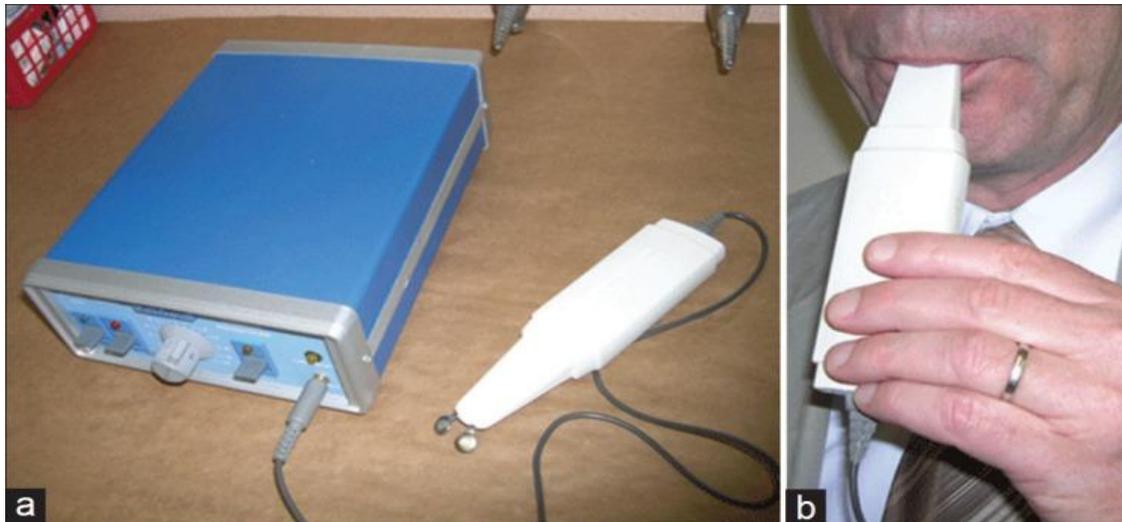


FIGURE -1(a)&(b) The first-generation neuroelectrostimulation device featured a handheld probe equipped with stainless steel electrodes and was connected to a console that contained a battery and the signal-generating electronics.

Figure courtesy: - Sarapur S, Shilpashree HS. Salivary Pacemakers: A review. Dent Res J (Isfahan). 2012 Dec; 9:20-5.



FIGURE-2 The second-generation removable device includes three main parts (a) a compact electronic stimulator containing a signal generator, power supply, and conductive circuits; a removable intraoral appliance; and an infrared remote control. (b) The remote control, which triggers the stimulation process (c) Device is inserted into the mouth non-invasively for use.

Figure courtesy: - Sarapur S, Shilpashree HS. Salivary Pacemakers: A review. Dent Res J (Isfahan). 2012 Dec; 9:20-5.

SaliPen

SaliPen is an electrostimulation device designed to stimulate the salivary glands. It features two flexible arms, each ending in an electrode, which are positioned under the tongue inside the oral cavity.^[27] This device [FIGURE-3] helps relieve dry mouth symptoms gradually, without causing any

discomfort or noticeable electrical sensation. Its safety and effectiveness have been confirmed through multiple clinical studies conducted across various countries. SaliPen is user-friendly and noninvasive—simply place it in the mouth several times a day for a few minutes during each use.^[26,28]



FIGURE-3 Salipen

Figure courtesy: - Rao RS, Akula R, Satyanarayana TS, Indugu V. Recent advances of pacemakers in treatment of xerostomia: A systematic review. *J Int Soc Prevent Communit Dent* 2019; 9:311-5.

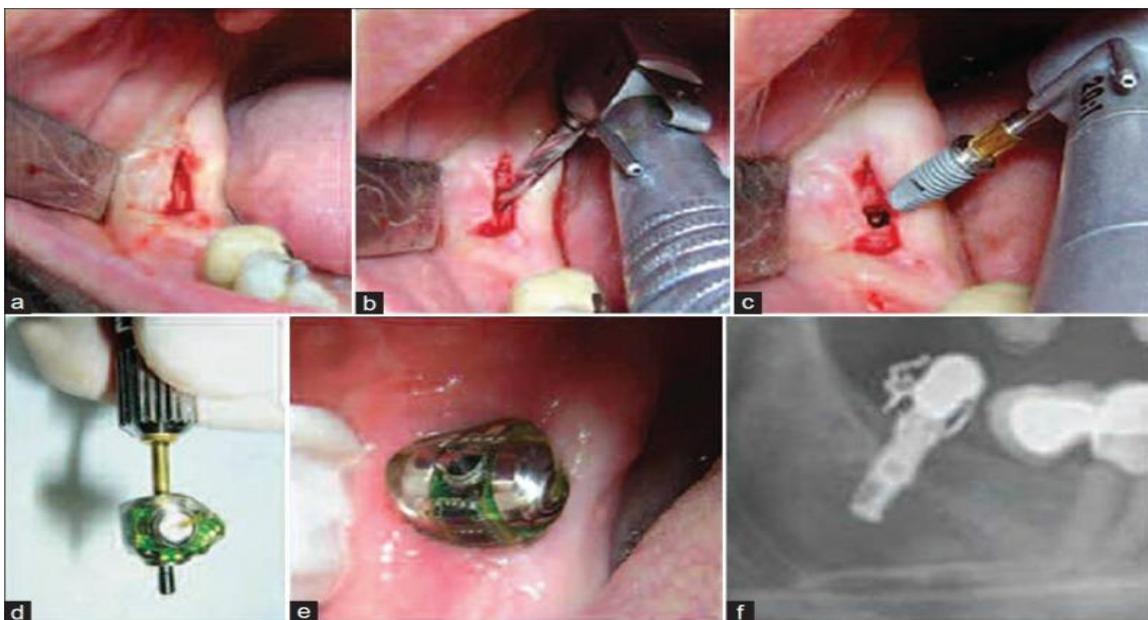


Figure-4: The third-generation neuroelectrostimulation device, which is supported by a dental implant, can be permanently placed in the oral cavity by securing it onto an osseointegrated implant positioned in the region of the third molar. The accompanying figure illustrates the steps involved in the implantation and application process. The procedure begins with (a) exposing the mandibular bone through the mucosa, (b) followed by the preparation of the implant site within the bone, and (c) placement of the dental root implant. (d) The neuroelectrostimulation unit (e) Neuroelectrostimulation unit attached to the dental implant. (f) Radiographic image of implant-supported device.

Figure courtesy: - Sarapur S, Shilpashree HS. Salivary Pacemakers: A review. *Dent Res J (Isfahan)*. 2012 Dec; 9:20-5.

Third Generation: Saliwell Crown (Implant-Supported Miniature Device)

The Saliwell Crown is a compact neuroelectric stimulator designed to be supported by dental implants, intended for continuous salivary stimulation in severe cases of xerostomia. This fixed device [Figure-4] eliminates the discomfort and inconvenience often associated with removable devices.

The components of the earlier removable version have been miniaturized and embedded into a module shaped like a molar tooth, which fits onto standard osseointegrated dental implants. It is equipped with a built-in sensor that detects changes in oral dryness. The Saliwell Crown provides consistent salivary stimulation without interfering with routine oral functions. The stimulation intensity automatically adjusts based on the dryness

level and can also be manually controlled by the user through an on/off switch. The implant is typically placed near the second molar area, close to the lingual nerve, which plays a key role in stimulating salivary glands.

It fulfils multiple functions: (a) it delivers either continuous or periodic stimulation, (b) it can be placed within the mouth without disrupting normal oral activities, (c) it can detect moisture levels in the oral cavity and automatically adjust the stimulation accordingly within a predefined range (self-regulating function), and (d) it allows patient control through a remote device.

The implant, which is anchored to the bone, is typically placed near the lower wisdom tooth area. This site offers close access to the lingual nerve, responsible for transmitting both incoming and outgoing salivary signals, and helps maintain normal oral operations. The surgical procedure required is relatively simple, and the posterior placement of the device means it does not pose any cosmetic issues.^[29]

The MICROSAL device (MD)

It is a third-generation, implant-supported system with a unique design [Figure-5]. It is an advanced, intelligent unit that incorporates two newly developed nano-sensors; one for detecting moisture and another for measuring pH. This device adjusts salivary stimulation based on the oral cavity's moisture level and pH, enabling personalized regulation of saliva flow. Real-time data is transmitted to the patient's smartphone via Bluetooth Low Energy (BLE) technology through a dedicated application. When the oral pH drops, indicating increased acidity, the body requires additional saliva to neutralize it and maintain a stable oral environment. The device responds to this by boosting saliva production based on feedback from the integrated wetness sensor. Notably, if both saliva volume and pH levels are below normal, the device triggers an even greater stimulation response.^[29]

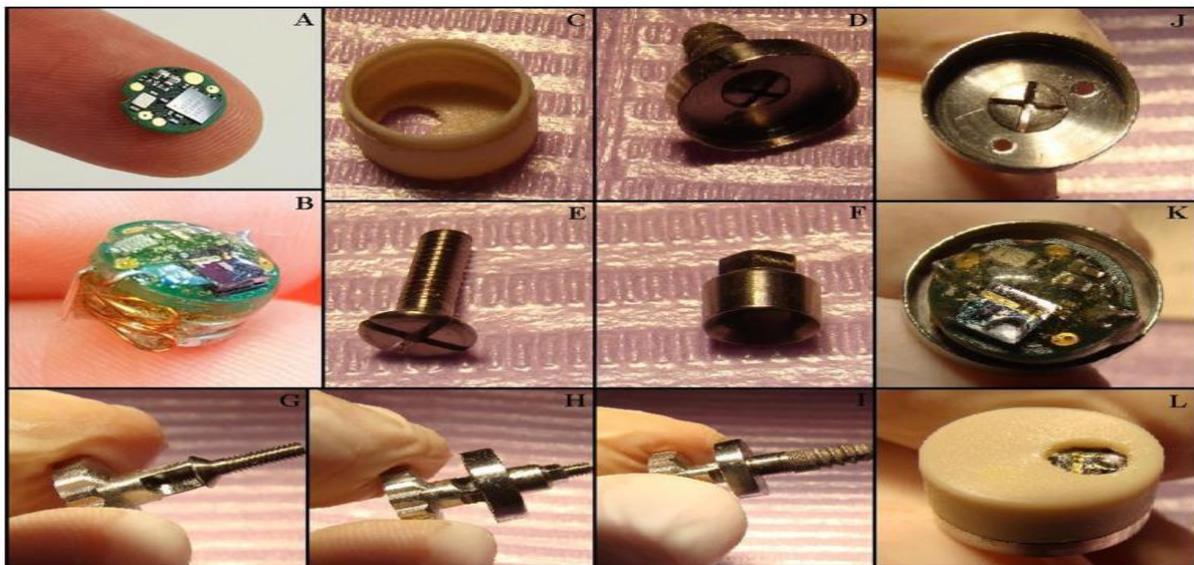


Figure-5: Assembly of the MICROSAL device (MD) involves the following components and steps: (A) the printed circuit board (PCB); (B) the MD unit outside its housing; (C) the top section of the casing, constructed from polypropylene; (D) the bottom section, made from a titanium alloy; (E) the central cover screw for the implant; (F) a titanium alloy metallic extension; (G) the central screw along with its corresponding Tehnomed™ screwdriver; (H,I) the titanium casing and metallic extension are attached to a model dental implant; (J) the bottom casing section, which contains two openings for electrode placement; (K) the internal view of the MD; (L) the procedure concludes with the attachment of the upper casing, completing the assembly.

Figure courtesy: - Funieru C, Tudose DȘ, Dobrică B, Săndulescu M, Popovici IA, Slușanschi EI, Croitoru SM, Vrînceanu D, Bănică B, Nicolescu MI. A New Model of Salivary Pacemaker-A Proof of Concept and First Clinical Use. *Medicina* (Kaunas). 2023 Sep 12; 59:1647.

The latest MD device advances earlier models like GenNarino™ and Saliwell Crown™ by using an algorithm that analyzes real-time wetness and pH sensor data to automatically regulate stimulation, mimicking natural saliva secretion. It is particularly useful for managing dry mouth in autoimmune conditions like Sjögren's Syndrome, with placement guided by gland function, and ongoing research explores how one submandibular gland can compensate when the other is impaired or absent.^[30] The MD device shows potential in alleviating dry mouth caused by conditions such as COVID-19, neurological disorders like Parkinson's, and especially in patients receiving radiotherapy for head and neck cancers.^[31,32,33]

Looking ahead, biotelemetry-based devices like the MD are poised to revolutionize diagnostic processes and patient monitoring, offering significant advantages to both patients and healthcare providers.^[34]

CONCLUSION

Xerostomia, impacting 5.5% of the population, poses serious health risks in adults. Management options include natural remedies, drugs, and electrostimulation devices. Future advancements in salivary pacemakers should focus on miniaturization, wireless technology, and improved materials for better performance and patient comfort.

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