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Трета меѓународна конференција ЕТИМА Third International Conference ETIMA

PREFACE

The Third International Conference "Electrical Engineering, Technology, Informatics, Mechanical Engineering and Automation – Technical Sciences in the Service of the Economy, Education and Industry" (ETIMA'25), organized by the Faculty of Electrical Engineering at the "Goce Delchev" University – Shtip, represents a significant scientific event that enables interdisciplinary exchange of knowledge and experience among researchers, professors, and experts in the field of technical sciences. The conference was held in an online format and brought together 78 authors from five different countries.

The ETIMA conference aims to establish a forum for scientific communication, encouraging multidisciplinary collaboration and promoting technological innovations with direct impact on modern life. Through the presentation of scientific papers, participants shared the results of their research and development activities, contributing to the advancement of knowledge and practice in relevant fields. The first ETIMA conference was organized four years ago, featuring 40 scientific papers. The second conference took place in 2023 and included over 30 papers. ETIMA'25 continued this scientific tradition, presenting more than 40 papers that reflect the latest achievements in electrical engineering, technology, informatics, mechanical engineering, and automation.

At ETIMA'25, papers were presented that addressed current topics in technical sciences, with particular emphasis on their application in industry, education, and the economy. The conference facilitated fruitful discussions among participants, encouraging new ideas and initiatives for future research and projects.

ETIMA'25 reaffirmed its role as an important platform for scientific exchange and international cooperation. The organizing committee extends sincere gratitude to all participants for their contribution to the successful realization of the conference and its scientific value.

We extend our sincerest gratitude to all colleagues who, through the presentation of their papers, ideas, and active engagement in discussions, contributed to the success and scientific significance of ETIMA'25.

The Organizing Committee of the Conference

ПРЕДГОВОР

Третата меѓународна конференција "Електротехника, Технологија, Информатика, Машинство и Автоматика — технички науки во служба на економијата, образованието и индустријата" (ЕТИМА'25), организирана од Електротехничкиот факултет при Универзитетот "Гоце Делчев" — Штип, претставува значаен научен настан кој овозможува интердисциплинарна размена на знаења и искуства меѓу истражувачи, професори и експерти од техничките науки. Конференцијата се одржа во онлајн формат и обедини 78 автори од пет различни земји.

Конференцијата ЕТИМА има за цел да создаде форум за научна комуникација, поттикнувајќи мултидисциплинарна соработка и промовирајќи технолошки иновации со директно влијание врз современото живеење. Преку презентација на научни трудови, учесниците ги споделуваат резултатите од своите истражувања и развојни активности, придонесувајќи кон унапредување на знаењето и практиката во релевантните области.

Првата конференција ЕТИМА беше организирана пред четири години, при што беа презентирани 40 научни трудови. Втората конференција се одржа во 2023 година и вклучи над 30 трудови. ЕТИМА 25 продолжи со истата научна традиција, презентирајќи повеќе од 40 трудови кои ги отсликуваат најновите достигнувања во областа на електротехниката, технологијата, информатиката, машинството и автоматиката.

На ЕТИМА 25 беа презентирани трудови кои обработуваат актуелни теми од техничките науки, со посебен акцент на нивната примена во индустријата, образованието и економијата. Конференцијата овозможи плодна дискусија меѓу учесниците, поттикнувајќи нови идеи и иницијативи за идни истражувања и проекти.

ЕТИМА'25 ја потврди својата улога како значајна платформа за научна размена и интернационална соработка. Организациониот одбор упатува искрена благодарност до сите учесници за нивниот придонес кон успешната реализација на конференцијата и нејзината научна вредност. Конференцијата се одржа онлајн и обедини седумдесет и осум автори од пет различни земји.

Изразуваме голема благодарност до сите колеги кои со презентирање на своите трудови, идеи и активна вклученост во дискусиите придонесоа за успехот на ЕТИМА'25 и нејзината научна вредност.

Организационен одбор на конференцијата

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

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Abstract

Xerostomia is a common condition that often affects patients undergoing radiotherapy for head and neck cancers. The condition arises primarily due to damage to the salivary glands, leading to a significant reduction in saliva production. This not only impacts oral health but also diminishes the quality of life for patients, making it essential to explore effective treatment options. One such innovation is the SaliPen electrostimulator, a device designed to stimulate salivary gland function. Several clinical trials have investigated the efficacy of the SaliPen electrostimulator in patients suffering from xerostomia due to radiotherapy. 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. 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. The electrical impulses stimulate the afferent nerve fibbers in the oral mucosa, particularly those linked to the parasympathetic nervous system. 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. 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. 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. As healthcare continues to evolve, innovations like the SaliPen demonstrate the potential for improved outcomes in the management of complex postradiation-related symptoms.

Key words:

electrostimulation, xerostomia, radiotherapy, salivary glands, head and neck cancer

Introduction

Xerostomia resulting from radiation therapy markedly impairs quality of life in individuals treated for head and neck cancer. Neuro-electrostimulation of the salivary glands represents a promising and safe modality to enhance physiological salivary output and mitigate the clinical manifestations of dry mouth. Radiotherapy is a cornerstone in the management of head and neck cancers, but it often results in collateral damage to the surrounding healthy tissues, particularly the salivary glands.

The condition arises primarily due to damage to the salivary glands, leading to a significant reduction in saliva production. This damage leads to a significant decrease in saliva production, resulting in xerostomia. Patients with xerostomia experience a range of symptoms, including

difficulty swallowing (dysphagia), increased risk of dental curries, oral infections, and a diminished sense of taste. The psychosocial impact of these symptoms can be profound, leading to anxiety and depression. Traditional management strategies, including saliva substitutes and stimulants like pilocarpine, have demonstrated limited effectiveness, highlighting the need for innovative approaches [1] [2].

This not only impacts oral health but also diminishes the quality of life for patients, making it essential to explore effective treatment options [3]. One such innovation is the SaliPen electrostimulator, a device designed to stimulate salivary gland function. The SaliPen electrostimulator is a handheld device that utilizes low-level electrical stimulation to activate the salivary glands. By applying electrodes to the oral mucosa, the device delivers electrical impulses that mimic the natural signals sent by the nervous system to stimulate saliva production. Research has shown that this stimulation can enhance the secretion of saliva from the remaining functional salivary tissue, providing a non-invasive alternative to pharmacological treatments.

The mechanism by which the SaliPen operates is grounded in neuromuscular stimulation principles. The electrical impulses trigger the release of neurotransmitters that promote glandular activity, thus facilitating saliva production. Studies have indicated that patients using SaliPen experience a significant increase in saliva flow, leading to improved oral comfort and overall quality of life.

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

Materials and Methods

For this narrative review article about the benefits of using electrostimulation for xerostomia after radiation therapy, an 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. Articles focusing on materials, methods, techniques, and advancements in using intraoral electrostimulator for xerostomia relief. The selected articles were carefully reviewed, and key information was gathered and integrated to offer a thorough understanding of the subject. Furthermore, clinical guidelines, and manufacturer documentation were used to support and enhance the findings from the literature and the use of saliPen by our patients. This narrative review presents an integrative analysis of recent findings and analysis of the techniques, innovations, clinical results, and patient advantages linked to the use of intraoral electrostimulators for stimulating salivary gland function and promoting saliva production.

Evaluation and results

The SaliPen electrostimulator has emerged as a revolutionary device in the management of xerostomia, or dry mouth, particularly in patients who have undergone radiotherapy for head and neck cancers. Xerostomia significantly affects not only oral health but also overall quality of life. Traditional treatments have often proven inadequate, prompting the development of innovative solutions like the SaliPen.

At the core of the SaliPen's functionality is the principle of electrical stimulation, specifically neuromuscular electrical stimulation (NMES). NMES involves the application of electrical impulses to stimulate nerves or muscles, thereby inducing a physiological response. In the

context of the SaliPen, the goal is to activate the salivary glands through targeted electrical impulses, mimicking the natural stimulation provided by the body's autonomic nervous system [3], [4].

Alajbeg and al. in their research they conclude that the positive impact of a removable intraoral electrostimulation device has been demonstrated and continues to increase with regular use [4]. 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 [5].

Other study conducted by Strietzel, Frank P et al. the results suggest that consistent daily use of the device enhanced saliva production and reduced symptoms of oral dryness and discomfort, as well as certain complications associated with xerostomia, including difficulties with speech and sleep. Over the course of the study, the device demonstrated a progressive and sustained beneficial effect, with improvements observed from the initial baseline through to the conclusion of the trial [6].

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. Together, these processes support the regeneration of the salivary glands [7].

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 [8], [9], [10], [11], [12].

These outcomes support the potential efficacy of peripheral intraoral electrostimulation in reactivating residual salivary gland function, possibly through neuromodulation and/or glandular recruitment mechanisms. Results demonstrated a statistically significant increase in both unstimulated and stimulated salivary flow rates (p < 0.05), along with marked reductions in patient-reported dryness scores. Improvements were noted as early as week 2 and sustained throughout the intervention period [13].

Components of the SaliPen Electrostimulator (Figure 1):

- 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.

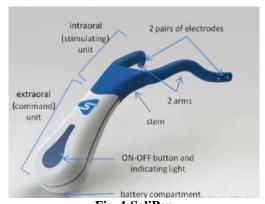


Fig. 1 SaliPenSource: www.saliwell.com

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.

Several clinical trials have investigated the efficacy of the SaliPen electrostimulator in patients suffering from xerostomia due to radiotherapy. A landmark study published in the Journal of Clinical Oncology found that patients using SaliPen reported a marked improvement in their symptoms compared to a control group receiving placebo treatment. Participants noted enhanced saliva production, improved swallowing function, and greater satisfaction with their oral health.

Furthermore, SaliPen has been shown to have a favorable safety profile, with minimal adverse effects reported. The non-invasive nature of the device also makes it an attractive option for patients who may be hesitant to pursue pharmacological interventions due to side effects or contraindications.

Despite its promise, the SaliPen is not without limitations. The need for patient compliance in using the device regularly may pose a challenge, particularly for those with cognitive impairments or those who are less motivated. Additionally, the initial cost of the device may be prohibitive for some patients, and insurance coverage may vary.

Discussion

The SaliPen electrostimulator has emerged as a promising device for the treatment of xerostomia, particularly in patients who have undergone radiotherapy for head and neck cancers. Xerostomia, characterized by dry mouth due to reduced saliva production, poses significant challenges to oral health and quality of life. Traditional treatments often fall short in efficacy and patient compliance, leading to the exploration of innovative solutions like SaliPen. To understand the functionality of the SaliPen, it is essential to first comprehend the physiology of salivary gland secretion. Saliva is produced by three major pairs of salivary glands: the parotid, submandibular, and sublingual glands. The process of saliva production is primarily regulated by the autonomic nervous system, which consists of the sympathetic and parasympathetic branches. The parasympathetic nervous system is particularly crucial for stimulating saliva secretion, as it activates the glands in response to stimuli such as food intake or the thought of eating [10], [11], [12].

Use of the GenNarino device resulted in statistically and clinically significant improvements in xerostomia, as evidenced by both subjective patient-reported outcomes and objective measures of salivary flow rates (p < 0.05). These findings suggest that peripheral electrostimulation may play a therapeutic role in managing salivary gland hypofunction.

GenNarino refers to a prior-generation device that utilizes similar intraoral electrostimulation technology as the SaliPen system [13].

When the salivary glands are stimulated, they secrete a fluid rich in enzymes, electrolytes, and mucins, which play vital roles in digestion, oral hygiene, and maintaining the integrity of oral tissues. However, damage to these glands—often caused by radiotherapy—can disrupt this delicate balance, leading to xerostomia. The SaliPen seeks to address this issue by mimicking the natural stimulation of the salivary glands through electrical impulses.

The SaliPen electrostimulator operates on the principle of neuromuscular electrical stimulation (NMES). It consists of a handheld device equipped with electrodes that deliver low-frequency electrical impulses to the oral mucosa. Here's a detailed breakdown of its mechanism:

- 1. Electrode Placement: The device is designed for easy use, allowing patients to place it on specific areas of the oral cavity, often near the cheeks or gums, where the salivary glands are located. Proper placement is crucial for effective stimulation.
- 2. Electrical Impulse Delivery: Once activated, the SaliPen emits controlled electrical impulses that penetrate the oral mucosa. These impulses are typically low-frequency and designed to be comfortable for the patient. The electrical stimulation mimics the natural signals sent by the autonomic nervous system, specifically the parasympathetic branch, which is responsible for saliva production.
- 3. Neurotransmitter Release: The electrical impulses stimulate the nerve endings in the oral mucosa, leading to the release of neurotransmitters such as acetylcholine. Acetylcholine plays a vital role in activating the salivary glands, promoting the secretion of saliva.
- 4. Salivary Gland Activation: The stimulation of the nerve endings results in increased activity of the remaining functional salivary gland tissue. As a result, the glands begin to produce saliva, alleviating the symptoms of xerostomia.
- 5. Patient-Controlled Usage: The SaliPen is designed for patient-friendly use, allowing individuals to control the duration and frequency of stimulation sessions. This autonomy enhances patient engagement and compliance, which are critical factors for successful treatment outcomes.

Clinical studies have demonstrated the efficacy of the SaliPen electrostimulator in increasing saliva production among patients with xerostomia. Research published in reputable journals

indicates that patients using SaliPen experience significant improvements in salivary flow rates compared to those receiving placebo treatments. The device not only enhances saliva production but also improves patients' overall oral health and quality of life.

Furthermore, the SaliPen has a favorable safety profile, with few reported side effects. This aspect is particularly important for patients who may be wary of pharmacological interventions due to potential adverse effects or contraindications [10], [11].

The electrical mechanism of the SaliPen not only provides a novel means of treating xerostomia but also offers several clinical advantages. The ability to stimulate salivary production non-invasively and without pharmacological agents is particularly beneficial for patients who may be sensitive to medications or who have contraindications to traditional treatments.

Moreover, the SaliPen's customizable settings allow healthcare providers to tailor treatment to individual patient needs. Patients can adjust the intensity and duration of stimulation based on their comfort levels, enhancing compliance and overall satisfaction with the treatment [13], [14], [15].

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. By employing the principles of neuromuscular electrical stimulation, the device effectively mimics the natural processes of saliva production, offering a non-invasive and patient-friendly solution to a common and distressing condition. As research continues to validate its efficacy and optimize its use, SaliPen may become an integral part of the therapeutic arsenal for managing xerostomia, ultimately enhancing the quality of life for countless patients. Understanding the mechanisms of SaliPen not only highlights its innovative approach but also underscores the potential for future advancements in the treatment of oral health complications arising from cancer therapies and underscores the importance of technological advancements in addressing complex health challenges.

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