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RESEARCH ARTICLE

EFFECT OF TENS IN RELIEVING SYMPTOMPS OF XEROSTOMIA

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ABSTRACT

Introduction: Saliva plays a significant role in oral homeostasis. Nevertheless, its diminution or absence can cause significant morbidity and a reduction in a patient's perceptions of quality of life.
Aims and Objectives: The study aimed at finding the effects of transcutaneous electrical nerve stimulation (TENS) on whole salivary flow rates and comparison between healthy adult subjects and patient with xerostomia.
Materials and Methods: Un-stimulated whole saliva and TENS stimulated whole saliva was measured in control as well as study (xerostomia) groups. Data obtained was subjected to statistical analysis using the student t test.
Results: 75 % of patients in control group and 61 % of patients in study group responded to TENS therapy by increase in stimulated whole saliva flow rate [p value of 0.001]. Comparison between control and study groups in regards to the un-stimulated and stimulated whole saliva showed high statistically significant difference (p value 0.000) in flow rates.
Conclusion: In this study extra oral transcutaneous electric nerve stimulation was found to be effective in stimulating whole saliva. The results presented here in healthy and xerostomia subjects warrant further studies in future on the aspects using TENS modality of treatment for xerostomia.

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INTRODUCTION

Saliva plays a significant role in oral homeostasis (Navazesh *et al*., 1996). It performs important functions by virtue of its constituents (Kaufman *et al*., 2002). Nevertheless, its diminution or absence can cause significant morbidity and a reduction in a patient's perceptions of quality of life (Guggenheimer *et al*., 2003). The saliva circulating in the mouth at any given time is termed whole saliva and comprises of secretions from the major & minor salivary glands, gingival crevicular fluid, oral bacteria, desquamated epithelial cells, and food debris (Vilas *et al*., 2009). At rest, secretion ranges from 0.25 to 0.35 ml/min and is mostly produced by the sub-mandibular and sublingual glands. Sensory, physiological, electrical or mechanical stimuli can raise the secretion rate to 1.5 ml/min (Carmen Llena Puy *et al*., 2006).

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When no exogenous or pharmacological stimulation is used it is termed as un-stimulated saliva, where as stimulated saliva is the one resultant secretion promoted by mechanical, gustatory or pharmacological stimuli (Dawes *et al*., 1987). The greatest volume of saliva is produced before, during and after meals, reaching its maximum peak at around 12 a.m., and falls considerably at night, while sleeping (Carmen Llena Puy *et al*., 2006). Xerostomia or dry mouth is one of the oldest recorded symptoms by man in ancient times (Sreebny *et al*., 2000). Many research workers have described this condition as 'Xerostomia or dry mouth, is the abnormal reduction of saliva and can be a symptom of certain diseases or be an adverse effect of certain medications (Porter *et al*., 2004). And also as 'xerostomia is subjective feeling of dry mouth, a symptom that may or may not be accompanied by hypo salivation, an objective decrease in salivary flow (Napeñas *et al*., 2009). The symptoms of oral dryness described as xerostomia is therefore considered to have a significant effect on individual's quality of life as well as his or her oral health (Carmen Llena Puy *et al*., 2006).

Various management protocols ranging from palliative management to systemic drug administration, acupuncture and others treatment modalities have been utilized with moderate success but still requires a safe and efficient modality of management. Use of TENS in production of saliva has been studied in the past which showed promising results (Vilas *et al*., 2009). The mechanism by which TENS unit worked on parotid gland is not clear. The early investigators of electro stimulation postulated that normal physiologic salivary reflexes are augmented on electro-stimulation (Hargitai *et al*., 2005). Electric stimulation of parasympathetic nerves of salivary glands produce copious amounts of watery saliva at low frequencies, and it is this voluminous, serous saliva of parotid gland that would be clinically most useful for management of xerostomia (Garret *et al*., 1987). Therefore TENS possibly thought to act by directly stimulating the auriculotemporal nerve that supplies secretomotor drive to the parotid gland (Hargitai *et al*., 2005). Results of preliminary investigations of non-invasive electronic stimulation of reflex salivation in xerostomic patients have been encouraging (Steller *et al*., 1988). Very few studies are conducted so far to find out the effects of transcutaneous electrical nerve stimulation in patients with xerostomia. Research in this area has been sparse thus requiring further study in this regard. The purpose of the present study was to find out the difference between the whole saliva flow rates in healthy adult subjects and patients with xerostomia and to determine the efficacy of transcutaneous electric nerve stimulaton (TENS) in stimulation of the whole saliva in these subjects. As an increase in salivary flow rate in these patients with xerostomia, may be helpful in reducing the symptoms and risks associated with xerostomia, like increased plaque formation, dental caries, opportunistic fungal infections, difficulty in eating and swallowing, malnourishment, oral pain and others.

MATERIALS AND METHODS

A total of 100 subjects consisting of 50 healthy individuals with no history of salivary gland disorders and 50 individuals with xerostomia in the age groups of 18-60 years including both males and females, attending out-patient department of Vishnu Dental College and Hospital, Bhimavaram. All these subjects participated in the study voluntarily after signing a written consent form. The demographic data was collected from each subject & the purpose of the study was explained to all the subjects.

Inclusion Criteria

Control group: Healthy patients with no history of systemic diseases or medications and no history of salivary gland disorders were included.

Study group: Xerostomia patients due to various causes having subjective complaint of dry mouth.

Subjective evaluation of xerostomia was done asking following questions and was modified.

- Do you have difficulty in swallowing any foods?
- Does your mouth feel dry while eating a meal?
- Do you sip liquids to aid in swallowing dry foods?
- Does the amount of saliva in your mouth seem to be too little?
- Dryness of lips and buccal mucosa and difficulties in speech?

Exclusion Criteria

Patients wearing active pacemakers, defibrillator, hearing aids, cochlear implants, and pregnant female patients were excluded and patients taking medications to increase salivary secretion in the past 6 months were also excluded from the study.

Procedure: Saliva was collected between 9.30 to 12 pm and following instructions were provided to patient to be followed before and during the procedure. All participants were asked to refrain from eating, drinking, chewing gum, smoking and oral hygiene practices for at least one hour prior to the investigation.

Subjects were made to sit in an upright position, with the head inclined forward and with minimal body and oro-facial movements. Patients are then asked to swallow saliva first and stay motionless, with 'low forced spitting' un-stimulated saliva was collected every minute for five minutes in a test tube fitted with funnel. Collected saliva is measured using the micropipette and recorded (Figure 1).

Figure 1.

Then the TENS unit was used to stimulate saliva using following protocol

- Clean the surface over the parotid gland bilaterally with alcohol or spirit wipes to remove makeup and facial oils.
- Then dry the areas with clean pieces of gauze.
- Apply self-adherent electrode patches over the cleansed areas
- Make sure the TENS unit's amplitude controls are set to the "off" position.
- Attach the electrode leads from the patch to the TENS unit.
- Set the timer to C (continuous) and the mode selector to C (conventional).
- The pulse rate is fixed at 50 Hz and amplitude will be gradually increased to maximum tolerable level of patient .
- Adjust pulse width and pulse rate so they are comfortable for the patient.

- Stimulated whole saliva is collected in similar manner as the un-stimulated saliva, measured and recorded.
- At completion of the procedure, turn off the unit, disconnect the leads and remove the electrode patches from the patient.
- Any discomfort felt during and after procedure is recorded.
- Patients are then asked to stay motionless, with 'low forced spitting' stimulated saliva was collected every minute for five minutes in a test tube fitted with funnel. Collected saliva is measured using the micropipette and recorded (Figure 2). Data recorded in Microsoft excel and analyzed using SPSS software. The comparative analysis was carried out using 'paired t test' for intra-group comparison and 'unpaired t test' for inter-group comparison.

Figure 2.

RESULTS

Out of the 50 patients included in the control group 25 were males and 25 were females with minimum age of patient as 20 years and maximum age of patient included as 50 years. Thirty nine patients out of 50 (75 %), responded to TENS therapy by increase in stimulated whole saliva flow rate. The mean un-stimulated whole saliva in the control group was found to be 2.01±0.61 ml/ 5 minutes and stimulated whole salivary flow rate after application of TENS was found to be 2.26±0.68 ml/ 5 minutes, with p value of 0.000 indicating high statistical significance in the whole saliva flow rate which showed an increase 0.25±0.07 ml/ 5 minutes (12.4% increase) on application of TENS and stimulation of whole saliva in control group (Table 1 and 2).

Table 1.

Particulars	No. of Cases (M&F)	USF (ml/5min)	SSF1 (ml/5min)	Mean difference (ml/5min)	% of Mean difference	Significance	
						t*-value	p value
Mean ± SD	50	2.01±0.61	2.26±0.68	0.25±0.07	12.4%	-7.072	0.000 HS
Range(Min Max)	-	0.60-3.60	0.8-4.20	-	-	-	-

t*: paired t test; statistically significant if p<0.05; if p<0.001: Highly significant (HS).

Table 2.

Particulars	No. of Cases	USF (ml/5min)	SSF1 (ml/5min)	Mean difference (ml/5min)	% of difference	Significance	
						t*-value	p value
Male	25	2.02±0.65	2.25±0.69	0.23±0.04	11.4%	-5.074	0.000 HS
Female	25	2.01±0.59	2.27±0.70	0.26±0.11	12.9%	-4.885	0.000 HS
Male vs Female	t**	0.046	-0.102	-	-	-	-
	p value	0.964 NS	0.919 NS	-	-	-	-

t*: paired t test; t**: independent sample t-test; statistically significant if p<0.05; if p<0.001: Highly significant (HS); S: significant NS: not significant

Out of the 50 patients included in the study group 14 were males and 36 were females with minimum age of patient as 29 years and maximum age of patient included as 60 years. Thirty two out of 50 (61 %), responded to TENS therapy by increase in stimulated whole saliva flow rate. The mean un-stimulated whole saliva in the study group was found to be 0.49±0.29 ml/ 5 minutes and stimulated whole salivary flow rate 0.59±0.35 ml/ 5 minutes, with p value of 0.001 indicating statistical significance in the whole saliva flow rate which showed an increase 0.10±0.06 ml/ 5 minutes (20% increase) of saliva on application of TENS and subsequent stimulation (Table 3 & 4).

Table 3.

Particulars	No. of Cases (M&F)	USF	SSF1	Mean difference	% of difference	Significance	
						t*-value	p value
Mean ± SD	50	0.49±0.29	0.59±0.35	0.10±0.06	20%	-3.678	0.001 S
Range (Min-Max)	-	0.10-1.40	0.10-1.50	-	-	-	-

t*: paired t test; statistically significant if p<0.05; if p<0.05; if p<0.001: Highly significant (HS)

Table 4.

Particulars	No. of Cases	USF	SSF1	Mean difference	% of difference	Significance	
						t*-value	p value
Male	14	0.57±0.34	0.71±0.47	0.14±0.13	25%	-2.610	0.022 S
Female	36	0.46±0.27	0.55±0.28	0.09±0.01	20%	-2.705	0.010 S
Male vsFemale	t**	1.139	1.190	-	-	-	-
	p value	0.268 NS	0.251 NS	-	-	-	-

t*: paired t test; t**: independent samplet t-test; statistically significant if p<0.05; if p<0.001: Highly significant (HS); S: significant NS: not significant.

Table 5.

Particulars	No. of Cases (M&F)	USF (ml/5min) Control group	USF (ml/5min) Study group	Mean difference (ml/5min)	Significance	
					t-value	p value
Mean ± SD	50	2.01±0.61	0.49±0.29	1.52±0.32	15.810	0.000 HS
Range (Min-Max)	-	0.60-3.60	0.10-1.40	-	-	-

t: independent sample t- test; statistically significant if p<0.05; if p<0.001: Highly significant.

Comparison between control and study groups: the un-stimulated whole saliva in control group was found to be 2.01±0.61ml/5 minutes whereas study group had 0.49±0.29 ml/ 5 minutes. High statistical significant difference (p value 0.000) was found in flow rate with mean difference as 1.52±0.32 ml/ 5 minutes (Table 5). The TENS stimulated whole saliva on in control group was 2.26±0.68 ml/5 minutes and in study group was 0.59±0.35 ml/ 5minutes. High statistically significant difference (p value 0.000) was found in flow rate with mean difference as 1.67±0.33 ml/ 5 minutes (Table 6).

Table 6.

Particulars	No. of Cases (M&F)	SSF1 (ml/5min) Control group	SSF1 (ml/5min) Study group	Mean difference (ml/5min)	Significance	
					t-value	p value
Mean ± SD	50	2.26±0.68	0.59±0.35	1.67±0.33	15.361	0.000 HS
Range (Min-Max)	-	0.8-4.20	0.10-1.50	-	-	-

t: independent sample t test; statistically significant if p<0.05; if p<0.001: Highlysignificant (HS)

DISCUSSION

The range of normal flow rates in unstimulated condition is from 0.2 to 0.5 mL /min, and that of the stimulated flow rate is from 0.9 to 2.6 mL/ min (Ami *et al*., 2010). The secretion of saliva is regulated by autonomic nervous system, with minor role played by hormones. While both autonomic divisions act synergistically to produce salivation by the salivary glands, the parasympathetic system is mostly responsible for water and electrolyte secretion, and the sympathetic system mainly regulates the protein secretion (Garret *et al*., 1987). Within this dual autonomic system it is clear that salivation is primarily under the parasympathetic control. Electric stimulation of parasympathetic nerves of salivary glands produce copious amounts of watery saliva at low frequencies, and it is this voluminous, serous saliva of parotid gland that would be clinically most useful for management of xerostomia (Hargitai *et al*., 2005). The symptom of oral dryness described as xerostomia is considered to have a significant effect on individual's quality of life as well as his or her oral health (5) (Figure 3).

Figure 3.

Various management protocols ranging from palliative management to systemic drug administration, acupuncture and others treatment modalities were useful and use of TENS in production of saliva has been studied in the past which showed moderate promising results. Therefore this study was conducted to evaluate the efficacy of TENS therapy in whole saliva stimulation in healthy adult subjects and patients with xerostomia.

As an increase in salivary flow rate in these xerostomia patients, may be helpful in reducing the symptoms and risks associated with xerostomia, like –increased plaque formation, dental caries, opportunistic fungal infections, difficulty in eating and swallowing, malnourishment, oral pain and others. In the present study of 100 patients, two groups were divided as control and study groups having 50 patients each, from whom the whole saliva was collected before and after stimulation using TENS.

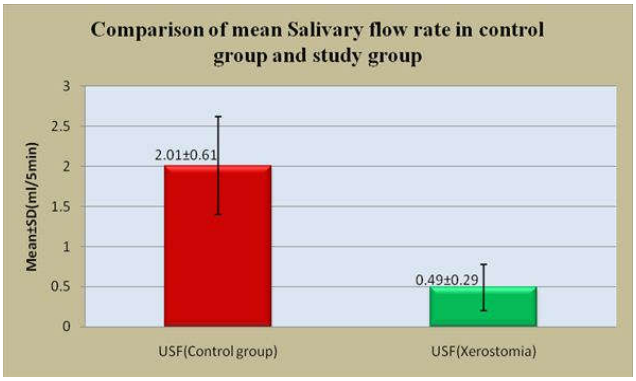

Figure 4.

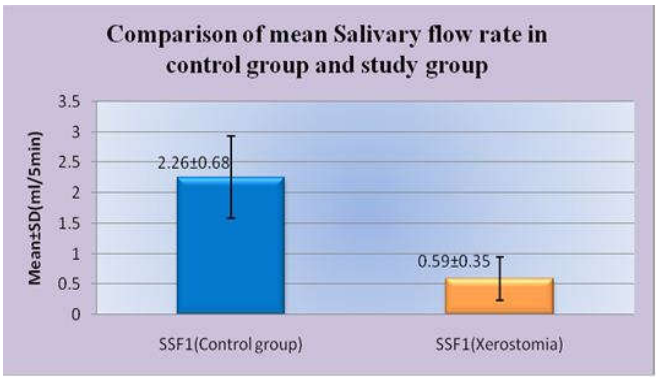

Figure 5.

Whole saliva measurements are simple to perform and are useful as an indicator of general salivary performance, also provide meaningful information concerning the quantitative aspects of gland function and can be obtained easily in a dental office (Vilas *et al*., 2009). Out of the 50 patients included in the control group 25 patients were males and 25 patients were females with minimum age of patient as 20 years and maximum age of patient included as 50 years. As the age advances individuals would be prone to suffer from various systemic diseases, as well as use various medications for the treatment of underlying diseases (Gerdin *et al*., 2005), so we could not find patients of age beyond 50 years to include (as per inclusion criteria) in the control group within the stipulated period of study. Thirty nine patients out of 50, responded to TENS therapy by increase in stimulated whole saliva flow rate which on average ranged to 75% of patients responding to TENS with increase in quantity of stimulated saliva. This result was in agreement with previous studies which showed similar response in healthy individuals to TENS therapy for saliva stimulation (Vilas *et al*., 2009; Hargitai *et al*., 2005). The mean un-stimulated saliva was 2.01±0.61 ml/ 5 minutes and TENS stimulated saliva as 2.26±0.68 ml/ 5 minutes. It resulted in 12.4% increase in the saliva flow rates (Figure 4). In our study the quantity of un-stimulated saliva was more in males (2.02±0.65 ml/ 5 minutes) than females (2.01±0.59 ml/ 5 minutes) which can be attributed to smaller size of salivary

glands and degree of hydration (Kaufman *et al*., 2002; Napeñas *et al*., 2009). Contrary to previous studies TENS stimulated saliva flow rate was higher for females than males in our study (Vilas *et al*., 2009; Hargitai *et al*., 2005; Ikebe *et al*., 2002). In previous studies it was observed that TENS was unable to stimulate the parotid saliva and it was interpreted that TENS may act more efficiently as an accelerator of salivary flow rather an initiator and further suggested that it is likely to be more effective in cases of decreased in salivary function than the absolute absence of function as observed among six subjects in our study (Vilas *et al*., 2009 and Hargitai *et al*., 2005). In five patients there was decrease in quantity of TENS stimulated saliva, this finding was similar to previous studies where the cause for this reduction in saliva was attributed to the frequency and intensity settings of TENS. The stimulus perceived by brain may be painful and salivary reflex is enhanced when nociceptive input reaches the brain via trigeminal sensory nuclei (Vilas *et al*., 2009 and Hargitai *et al*., 2005).

Out of the 50 patients included in the study group 14 patients were males and 36 patients were females with minimum age of patient as 29 years and maximum age of patient included as 60 years. A female predominance was observed which reflects that prevalence of xerostomia to be higher among females could be suggested. Thirty two out of 50, responded to TENS therapy by increase in stimulated whole saliva flow rate which on average ranged to 61% of patients responding to TENS with increase in quantity of stimulated saliva. The mean un-stimulated saliva was 0.49±0.29 ml/ 5 minutes and TENS stimulated saliva as 0.59±0.35ml/ 5 minutes, resulted in 20% increase in saliva flow rates (Figure 5). In our study the quantity of stimulated saliva was more in males (0.71±0.47 ml/ 5 minutes) than females (0.55±0.28 ml / 5 minutes), Which can be attributed to smaller size of salivary glands and degree of hydration in females (Vilas *et al*., 2009 and Hargitai *et al*., 2005). Nine patients out of 50, responded to TENS therapy by decrease in stimulated whole saliva flow rate. The mechanism for this may involve the frequency and intensity settings and whether brain perceived the stimulus as being painful, not all pre-ganglionic parasympathetic fibers are necessarily facilitated some may be inhibited (Vilas *et al*., 2009 and Hargitai *et al*., 2005). On the other hand nine patients out of 50, responded to TENS therapy by no change in stimulated whole saliva flow rate. These different responses may be due to the amount of remaining parenchyma of salivary glands to respond to stimulation (11). In previous studies it was observed that TENS was unable to stimulate the parotid saliva and it was interpreted that TENS may act more efficiently as an accelerator of salivary flow rather an initiator and further suggested that it is likely to be more effective in cases of decreased in salivary function than the absolute absence of function (Vilas *et al*., 2009 and Hargitai *et al*., 2005). The comparison between the control and study groups revealed: The un-stimulated whole saliva in control group was found to be 2.01±0.61ml/5 minutes whereas study group had 0.49±0.29 ml/ 5 minutes. High statistical significant difference (p value 0.000) was found in flow rate with mean difference as 1.52±0.32 ml/ 5 minutes. Where it was evident that control group had higher baseline saliva flow when compared with the study group. When TENS was applied the stimulated whole saliva obtained in control group was 2.26±0.68 ml/5 minutes and in study group was 0.59±0.35 ml/5minutes. High statistically significant difference was found in flow rate with mean difference as 1.67±0.33 ml/ 5 minutes.

Where it was evident that control group had higher stimulated saliva flow when compared with the study group. In control group 12.4% increase in stimulated saliva with an increase of 0.25±0.07 ml/ 5 minutes was observed when compared to study group which had 20% increase in stimulated saliva with an increase of 0.10±0.06 ml /5 minutes. The increase in percentage of stimulation in study group explains that salivary glands having residual flow can have better stimulation when TENS is applied. Xerostomia often considered multi-factorial, the causes include salivary gland disorders such as sjogren's syndrome, radiation to head and neck region, chemotherapy uncontrolled diabetes mellitus and number of commonly used medications, occasionally associated with psychological factors (Bergdahl *et al*., 2000). In our study thirty two patients from study group (64%) had history of various drug usages for treatment of underlying diseases such as hypertension, diabetes mellitus, asthma, epilepsy and others. Thus drug induced xerostomia was predominantly found and was similar to previous studies (17, 18). Out of these 32 cases 18 patients were on anti hypertensive therapy which is known for its potential to cause dry mouth (19). Following drug induced xerostomia the next predominant cause found in the study was treatment of various carcinomas including radiation and chemotherapy, accounting for 18 cases out of 50 patients, remaining patients had anaemia, habits like -smoking, alcoholism and others representing 10 cases out of 50 study patients. All these factors are known to induce xerostomia (Bergdahl *et al*., 2000). In our study among 50 patients with subjective sensation of dry mouth thirty patients had an objective signs and symptoms of xerostomia. It was seen in previous studies that oral dryness may occur despite normal salivary gland activity (20). Though most common symptom of hypo salivation is xerostomia, studies have shown that former does not necessarily guarantee later (Napeñas *et al*., 2009). However, patients have the finding of mouth dryness when an individual's baseline salivary output falls by 50 % (Napeñas *et al*., 2009; Hargitai *et al*., 2005). Subjective evaluation regarding the perception of mouth wetness after TENS therapy revealed that 61% of subjects had increase in saliva and mouth wetness.

When asked for any untoward or side effects experienced by the patients in both the groups only eight patients, five from study group and three from control group complained of itchy and tingling sensation in the area of electrode placement. These side effects seen with TENS therapy in our study, itching and tingling sensation were pertained to the areas of electrode placement, which were transient and ceased within few minutes after TENS unit was switched off and electrode pads removed. The modifications suggested to avoid the side effects include use of small sized electrodes to make the electro stimulation of parotids more effective (Vilas *et al*., 2009). TENS has a long proven safety records and has been used in physical therapy for quite a long time (Lodaya *et al*., 2010 and Munshi *et al*., 2002). The main advantage offered by TENS over other measures, such as chewing gum or citric lozenges is that it is an extra oral device, with minimal or no side effects. It can be used while eating food and it does not affect the normal mastication process. Thus, the salivary production while eating would be beneficial, which is not the case with the intraoral devices (Hargitai *et al*., 2005). Chewing gum bases may need to be avoided in those with temporomandibular disorders, it has had favorable and unfavourable results in previous studies (Hargitai *et al*., 2005). Artificial saliva preparations can be used, but they have some limitations.

A majority of the commercial products available are based on carboxymethylcellulose (CMC). However, these products do not stimulate all properties of saliva and they do not contain specific antibacterial components (including antibodies) and enzyme and other components of saliva (Hargitai *et al*., 2005). The results presented here in healthy subjects and subjects with xerostomia warrant further studies in future on the aspects of how long the increase in saliva flow lasts after turning off the TENS unit, the ability of TENS to stimulate parotid salivary flow specifically when there is none at baseline, patient acceptance and usefulness of TENS alone versus in combination with other sialogogues. Thus in near future TENS may be included as an additional modality in ever-growing armamentarium to manage xerostomia.

Conclusion

Thus in this study an extra oral transcutaneous electric nerve stimulation over parotid gland was used to stimulate saliva in xerostomia patients and also compared the whole salivary flow rates in healthy and patients with xerostomia. In our study, the effect of TENS on whole salivary flow rate was evaluated and it was found to be effective in stimulating whole saliva in normal, healthy subjects and also in the xerostomia patients.

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