

# Evaluation of the efficacy of transcutaneous electrical nerve stimulation (TENS) on salivary flow rate in patients with xerostomia - A case control study

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## ABSTRACT

**Introduction:** In oral cavity, saliva is a physiological fluid present in the oral cavity. Oral fluid is an absolute media exploring for health and disease surveillance. Saliva is a complex fluid. Xerostomia is the subjective complain of dryness in the oral cavity due to decreased salivary flow. Transcutaneous electrical nerve stimulation (TENS) is an established physical therapy, which is useful for the pain relief. **Materials and Methods:** A total of 25 subjects of xerostomia and 25 age and sex matched normal subjects visiting the Department of Oral Medicine and Radiology, Pacific Dental College and Hospital were included in the study. For patients with positive mirror stick test unstimulated saliva were collected with 'low forced spitting' method in a graduated test tube for 5 minutes. Individuals with unstimulated salivary flow equal to or less than 0.5 mL per 5 min were included in the study group (xerostomia) and individuals with salivary flow more than 0.5 mL per 5 min were included in the control group (age and sex matched). The TENS unit were then activated and intensity control switch were gradually increased to tolerable level of patient for 15 min. At this optimal intensity, stimulated saliva were collected for 5 min with same method in a separate graduated test tube and flow rate were compared with unstimulated salivary flow rate. Same were done with 25 control patients. **Results:** The data thus obtained was subjected to statistical analysis. The following findings were observed in the study. There was increase salivary flow rate in xerostomic individuals after TENS application. More improvement was found in inter appointment salivary flow than two follow-ups. Healthy group showed more improvement than xerostomia after TENS therapy. Known cases of diabetes mellitus patients with xerostomia revealed more improvement than other etiologies of xerostomia included in this study. **Conclusion:** This present study has an important therapeutic value in the treatment of patients with xerostomia. TENS therapy was highly effective in stimulating whole salivary flow. The encouraging results of this present study indicate that TENS has the potential to increase salivary flow rate and can be an important alternative in the xerostomia treatment.

**Keywords:** Saliva, Salivary flow rate, salivary glands, TENS, xerostomia

## Introduction

This is especially true for saliva. In oral cavity, saliva is a physiological fluid present in the oral cavity. It cleanses the oral cavity, keeps the mouth moist, lubricates food for swallowing and chewing, helps during speech and taste sensation, digestion, uses

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for the buffering purpose to neutralize acid attack of bacteria and mineralizes the teeth and uses as an antimicrobial agent.<sup>[1]</sup>

Oral fluid is an absolute media exploring for health and disease surveillance.<sup>[2]</sup> Saliva is a complex fluid. It consists of enzymes, hormones, antibodies, antimicrobial substances and cytokines (Zelles *et al.*, 1995, Rehak *et al.*, 2000). Most of these entering in the saliva from the blood via cells by transcellular, passive intracellular diffusion and active transport, or paracellular routes by extracellular ultrafiltration within the salivary glands or through the gingival sulcus (Drobitch and Svensson, 1992, Haeckel and Hanecke, 1993, Jusko and Milsap, 1993). Many compounds are found in blood are also present in saliva. So saliva also reflecting the physiological state of the body. For this purpose, saliva can also be used to evaluate the oral and systemic health.<sup>[2]</sup>

Xerostomia is the subjective complain of dryness in the oral cavity due to decreased salivary flow. The major reasons of xerostomia are medications, mainly diuretics, opioids, antihistamines, anticholinergic drugs and radiation therapy for the treatment of head and neck cancers and autoimmune disorders like Sjögren's syndrome.<sup>[3]</sup> High prevalence of xerostomia are mainly seen in cancer patients.<sup>[4]</sup>

Secretion of saliva is regulated by three components reflex arch consisting: (a) afferent nerves and receptors, (b) a processing nucleus (salivation center) and central connection, and (c) an efferent reflex arm comprised by sympathetic and parasympathetic nerves bundles.<sup>[5]</sup> The sensory nerves carry sensation from the periphery to the salivation center in the medulla oblongata, which in turn conducts signals to the motor part of the reflex arch leading to salivation.<sup>[6]</sup> The autonomic control of salivary secretion is given, the electrical activation of one of the part of the salivary reflex arch can potentially lead to increased salivary secretion.<sup>[5]</sup>

Transcutaneous electrical nerve stimulation (TENS) is an established physical therapy, which is useful for the pain relief. With TENS, electrical activation is leading to chronic pain areas through surface electrodes, and current travelled via these areas decrease or removes pain.<sup>[7]</sup> It is safe, noninvasive, easily operated and patients can accepts it very gracefully.<sup>[8]</sup> In the past electro activation to make saliva was learned and manifested moderate promise but it can never be a part of main treatment modality. Outcome of current preparatory examination of non-invasive electronic activation of reflex salivation in xerostomia patients have been motivating.<sup>[9]</sup> Transcutaneous electrical nerve stimulation (TENS) comprises of implementation of pulsed electrical currents, reduced frequency. The transmission of electrical current via surface electrode pads are placed on the surface of skin and potentially activate the peripheral nerves to make many types of physiological effects.<sup>[10]</sup> The development of first TENS units were done in the year of 1965 after the gate control theory publication by Melzack and Wall.<sup>[11]</sup>

## Materials and Methods

A total of 25 subjects of xerostomia and of equal age and sex matched normal subjects visiting the Department of oral medicine and radiology, Pacific Dental College and Hospital were included in the study. Inclusion criteria includes. Twenty five subjects age (from 18 to 70 years) of xerostomia and 25 age- and sex-matched healthy adults as control will be selected, Diagnosed cases of autoimmune salivary gland disorders, drug induced xerostomia, Aged patients, selected medical disorders (like diabetes mellitus, psychogenic disorder), Radiation therapy of head and neck cancer, Smoking. Exclusion criteria includes Patients under 18 years of age, those with pacemakers, those patients who have taken medications which increase salivary flow (Or patient is advised to stop the medications till the effect of the medications is subsided), any clinically diagnosed cases of salivary gland aplasia parotidectomy, obstructive salivary gland disorders (strictures and stenosis).

A total of 25 subjects of xerostomia and 25 age and sex matched normal subjects visiting the Department of Oral Medicine and Radiology, Pacific Dental College and Hospital were included in the study. 25 clinically confirmed cases of xerostomia were included in the study and 25 healthy adult subjects as control. Subjects were asked to refrain from eating, drinking, chewing gum, smoking, and oral hygiene procedures for at least 1 hour prior to the appointment. Patients who gives history of xerostomia were checked for 'mirror stick' test. For patients with positive mirror stick test unstimulated saliva were collected with 'low forced spitting' method in a graduated test tube for 5 minutes. Individuals with unstimulated salivary flow equal to or less than 0.5 mL per 5 min were included in the study group (xerostomia) and individuals with salivary flow more than 0.5 mL per 5 min were included in the control group (age and sex matched). The electrode of TENS unit were placed externally on skin overlying the parotid gland region bilaterally with TENS unit in off position. The TENS unit were then activated and intensity control switch were gradually increased to tolerable level of patient for 15 min (intensity ranging from 20-50 Hz). At this optimal intensity, stimulated saliva were collected for 5 min with same method in a separate graduated test tube and flow rate were compared with unstimulated salivary flow rate. Same were done with 25 control patients to measure the flow rate before and after giving TENS and compare the flow rate with xerostomia patients. The calculation of the salivary flow rate was done by dividing the amount of collected saliva (volume in mL) by the duration of collection period (five minutes). Every patient (healthy and xerostomic) were called twice in a week (four times) for TENS stimulation. Patient were followed up for 1 month every 15 days.

## Results

This study [Table 1] showed the mean salivary flow rates of all 4 appointments before and after TENS in healthy patients are  $1.120 \pm 0.540$  mL./min and  $1.38 \pm 0.54$  mL./min and in xerostomia patients are  $0.4909 \pm 0.399$  mL./min and  $0.688 \pm 0.459$  mL./min, respectively.

It revealed increase in mean salivary flow rate after TENS application in both the groups (Healthy and Xerostomia). Statistical evaluation showed this increase to be Highly Significant. ( $P < 0.001$ ). Here more improvement were revealed in each successive appointment (1<sup>st</sup>, 2<sup>nd</sup>, 3<sup>rd</sup>, 4<sup>th</sup>) in healthy individuals in comparison with xerostomia patients [Table 2]. The mean difference were statistically highly significant value.

The present study showed higher amount of mean salivary flow rate in healthy group than xerostomia group which was statistically significant. Improvement were revealed in each follow-up (first and second) from base value in both the groups [Table 3] but the mean difference were statistically not significant.

Comparison was done between the etiologies of xerostomia patients such as diabetes mellitus, chemotherapy and tobacco habits (smokable and chewable) [Table 4] in this study. Of these etiologies more improvement was seen in mean salivary flow rates after TENS application in diabetes mellitus patients compared to tobacco and chemotherapy patients, respectively, in four appointments (first, second, third, fourth).

In this present study the mean difference salivary flow rates in first, third and fourth appointment of three etiologies of

xerostomia were not significant and in second appointment the mean difference of three etiologies were statistically significant.

## Discussion

The mechanism of action of the TENS unit on the parotid gland is by activating the auriculotemporal nerve supplying secretomotor impulse to the parotid gland. This impulse is carried by sensory nerve to the salivary nuclei situated in the medulla which gives signals to the motor part of reflex causing beginning of salivation.<sup>[7]</sup> For Electrical activation of sympathetic salivation, increased frequencies and prolonged pulse duration is needed. For the parasympathetic nerve stimulation, which produces thin, watery saliva from the parotid gland at reduced frequencies which is very large volume serous saliva that can be more useful in the treatment of xerostomia.<sup>[9]</sup>

In present study the mean salivary flow rates of all 4 appointments before and after TENS in healthy patients were  $1.120 \pm 0.540$  mL/min and  $1.38 \pm 0.54$  mL/min and in xerostomia patients are  $0.4909 \pm 0.399$  mL/min and  $0.688 \pm 0.459$  mL/min, respectively.

Mean salivary flow rate of first appointment before TENS and mean salivary flow rate of fourth appointment after TENS were considered as base value in this study. The base value at first appointment before TENS mean salivary flow rates in healthy and xerostomia patients were  $0.45 \pm 0.16$  mL/min and  $0.09 \pm 0.07$  mL/min, respectively. The base value at fourth appointment after TENS mean salivary flow rates in healthy and xerostomia patients were  $2.008 \pm 0.30$  mL/min and  $1.23 \pm 0.32$  mL/min, respectively. The mean difference of salivary flow rates from the base value of first appointment before TENS mean salivary flow rate to after TENS salivary flow rate

**Table 1: Mean unstimulated (Before TENS) and stimulated (After TENS) salivary flow rate in healthy and xerostomia patients of 4 appointments**

Groups	Mean salivary flow rate of 4 appointments		P
	Before tens (BT) (mL/min)	After tens (AT) (mL/min)	
Healthy	$1.120 \pm 0.540$	$1.38 \pm 0.54$	$<0.001$
Xerostomia	$0.4909 \pm 0.399$	$0.688 \pm 0.459$	$<0.001$

\* $P < 0.001$  = Highly Significant (HS) By using Students Unpaired \*t test

**Table 2: Comparison of mean difference of salivary flow rates at each appointment (1<sup>st</sup>, 2<sup>nd</sup>, 3<sup>rd</sup> and 4<sup>th</sup>) between xerostomia and healthy patients from base value of mean salivary flow rate before TENS on the first appointment to mean salivary flow rate after TENS at each appointment**

Groups	Mean difference salivary flow rate of 1 <sup>ST</sup> appointment (mL/min)	Mean difference salivary flow rate of 2 <sup>nd</sup> appointment (mL/min)	Mean difference salivary flow rate of 3 <sup>rd</sup> appointment (mL/min)	Mean difference salivary flow rate of 4 <sup>th</sup> appointment (mL/min)
Xerostomia (Experimental)	$0.12 \pm 0.11$	$0.41 \pm 0.24$	$0.73 \pm 0.26$	$1.14 \pm 0.30$
Healthy (Control)	$0.30 \pm 0.14$	$0.74 \pm 0.24$	$1.12 \pm 0.25$	$1.56 \pm 0.28$
P	$<0.001$	$<0.001$	$<0.001$	$<0.001$

HS=Highly Significant. By using Unpaired Student's \*t test

**Table 3: Comparison of mean difference of salivary flow rates at first and second follow-ups between xerostomic and healthy individuals from base value of mean salivary flow rate after TENS on the 4<sup>th</sup> appointment to unstimulated mean salivary flow rate at each follow-up (1<sup>st</sup> and 2<sup>nd</sup>)**

Row Labels	Mean salivary flow rate of 4 <sup>th</sup> Appointment (mL/min)	Mean difference from 4 <sup>th</sup> appointment after TENS salivary flow rate and unstimulated mean salivary flow rate at 1 <sup>st</sup> follow-up (mL/min)	Mean difference from 4 <sup>th</sup> appointment after TENS mean salivary flow rate and unstimulated mean salivary flow rate at 2 <sup>nd</sup> follow-up (mL/min)
Xerostomia (Experimental)	$1.228 \pm 0.32$	$0.07 \pm 0.15$	$0.13 \pm 0.16$
Healthy (Control)	$2.008 \pm 0.30$	$0.11 \pm 0.12$	$0.18 \pm 0.13$
P	$<0.001$	$>0.05$ (NS)	$>0.05$ (NS)

NS=Not Significant. By using Unpaired Student's \*t test

**Table 4: Comparison of mean salivary flow rates of xerostomia patients with different etiologies in four appointments**

Etiologies of Xerostomia	Mean difference of salivary flow rate at 1 <sup>st</sup> appointment (mL/min)	Mean difference of salivary flow rate at 2 <sup>nd</sup> appointment (mL/min)	Mean difference of salivary flow rate at 3 <sup>rd</sup> appointment (mL/min)	Mean difference of salivary flow rate at 4 <sup>th</sup> appointment (mL/min)
Chemotherapy (n=3)				
Mean	0.02	0.13	0.43	0.77
SD	0.01	0.005	0.10	0.06
Diabetes mellitus (n=4)				
Mean	0.11	0.60	0.82	1.12
SD	0.11	0.43	0.50	0.43
Tobacco habits (n=11)				
Mean	0.11	0.36	0.70	1.11
SD	0.09	0.16	0.21	0.25
ANOVA test				
P	>0.05 (NS)	<0.05 (S)	>0.05 (NS)	>0.05 (NS)

in each successive appointment (first, second, third, and fourth) were statistically significant between healthy and xerostomic individuals which revealed more improvement in healthy than xerostomia group but the difference was not significant in both the groups in first and second follow-ups which showed similar improvement in healthy and xerostomia group.

A study conducted by Bhasin *et al.*<sup>[12]</sup> on 100 xerostomic individuals showed the mean unstimulated whole saliva flow rate was 0.52 mL/min during stimulation it increased to 0.72 mL/min. Findings of Jagadhri *et al.*<sup>[13]</sup> and Weiss *et al.*<sup>[5]</sup> were also in accordance with the finding to our study. In this present study the comparison of salivary flow rate was done in xerostomia patients of different etiologies after TENS application. More improvement were seen in diabetes mellitus patients compared to tobacco and chemotherapy patients, respectively. In first, third and fourth appointment the mean difference of before and after TENS therapy of these etiologies were not significant except second appointment where the difference was statistically significant. A study conducted by Jagadhri *et al.*<sup>[13]</sup> which revealed improvement in diabetes mellitus patients with decreased salivary secretion which was statistically significant. This finding was in accordance with this present study. In our study, there was 23.22% and 40.05% increase in whole salivary flow rates in healthy and xerostomic individuals after TENS therapy, respectively. A study done by Kumud *et al.*<sup>[14]</sup> there was 70.28% increase in whole salivary flow of xerostomia patients which was statistically significant.

Ramesh, *et al.*,<sup>[15]</sup> concluded that there was an increased salivary flow rate observed with conventional settings of TENS unit in majority of patients. TENS, thus, comes out to be a safer, nonpharmacological therapeutic option for treating patients with xerostomia wherein systemic drug therapy is contraindicated or, found to be associated with severe side effects.

Significant improvement was noted in salivary flow rates in both inter-appointments and first and second follow-ups of both xerostomia and healthy group. The mean difference at fourth appointment in healthy and xerostomia patients were

1.56 ± 0.28 mL/min and 1.14 ± 0.30 mL/min, respectively, and at first follow-up in healthy and xerostomia patients were 0.11 ± 0.12 mL/min and 0.07 ± 0.15 mL/min, respectively, in second follow-up in healthy and xerostomia groups were 0.18 ± 0.13 mL/min and 0.13 ± 0.16 mL/min, respectively. More improvement was seen in inter-appointments salivary flow rates than two follow-ups in unstimulated salivary flow rates of both xerostomia and healthy patients.

## Conclusion

This study comprises with the statement “Neuro-electro stimulation of salivary glands takes the still remaining salivation reserves into therapeutic use”<sup>[16]</sup> There is many types of uneasiness and morbidity in xerostomia patients so the need of the alternative device over other variants which is having no side effect, noninvasive, economical and.<sup>[13]</sup>

Electrical stimulation of salivary glands has an important role in therapeutic salivary stimulation among patients who required long term treatment and has low quality of life. The result of this study showed increased salivary secretion and progressive improvement of xerostomia symptoms are demonstrating the effectiveness of these extra-oral devices for neuro-electro-stimulation.<sup>[17]</sup> This present study has an important therapeutic value in the treatment of patients with xerostomia. This study has demonstrated that TENS can be an effective therapy to increase the salivary flow rate among the xerostomia patients. TENS therapy was highly effective in stimulating whole salivary flow. The encouraging results of this present study indicate that TENS has the potential to increase salivary flow rate and can be an important alternative in the xerostomia treatment. More research should be needed to evaluate the possibility of using TENS to give relief from the symptoms of xerostomia. it could be concluded that TENS therapy is also safer, nonpharmacological therapeutic treatment for treating medically compromised patients with xerostomia.

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## Conflicts of interest

There are no conflicts of interest.

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