



# A Randomized Controlled Trial on The Efficacy of Transcutaneous Electric Nerve Stimulation in Control of Complications After Surgical Removal of Impacted Mandibular Third Molar

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## Abstract:

**Introduction:** Impacted Mandibular third molars are the major oral health problem. Despite the introduction of modified surgical techniques and improved precision in control of soft and hard tissues, that reduces post operative sequelae; there still exists various unavoidable complications after surgery. Impacted lower third molar surgery is commonly associated with trismus, swelling and pain. **Material and Method:** In this study, 50 cases with bilaterally impacted third molars have been randomly divided into two groups irrespective of caste, creed and gender. Group A- Cases for TENS therapy Group B- Control group **Result:** TENS therapy and control group showed almost equal effect on pain at each day, as P value >0.05. On comparing both the groups for swelling, TENS group showed better results as compared to Control group with P value <0.05, on horizontal measurement of swelling and vertical measurement of swelling at each day. TENS therapy showed better results on mouth opening during the course of therapy on day 1, day 3 and day 7 when compared with control group, with the P-value <0.05, On day 15 difference of mean was zero that means complete mouth opening was achieved. **Conclusion:** In our study it has shown that groups are equally effective in managing pain after extraction of impacted lower third molar. TENS therapy showed better results in controlling postoperative sequelae during course of healing.

**Keywords:** TENS, Postoperative pain, third molar, Impaction, Extraction.

## Introduction:

Surgical extraction of impacted 3<sup>rd</sup> molar is the most ubiquitous procedure performed by Oral and Maxillofacial Surgeons. It usually involves postoperative complications

including bleeding, pain, trismus, infection, edema, alveolar Osteitis, delayed healing and sensory disturbances in the distribution of the inferior alveolar and lingual nerves<sup>1</sup>. These complications can majorly be attributed to the consequences after direct

trauma to the bone, muscular attachments, blood and lymph vessels<sup>2</sup>. Edema is significantly present because of fluid accumulation in interstitial area due to transudates escaping from injured blood vessel and fibrin obstruction of lymph drainage. Most surgeons have used many techniques to reduce the postoperative sequelae by analgesics, non-steroidal drugs, or corticosteroids, but the side effects of these drugs cause problems for some patients who are contraindicated to these medications<sup>3</sup>. In majority of the cases it is used for control of pain, although it is also being used as an antiemetic and to increase the blood flow to ischemic tissue and wounds<sup>4-6</sup>. Many studies have been conducted in past to find out better modalities for management of surgical outcomes following surgical extraction of lower impacted third molars but we have not come across any study so far comparing TENS and NSAIDs on surgical outcome following surgical extraction of lower impacted third molar.

**Statement of problem:** literature reports hypothesize that TENS can have an effect on reduction of pain and other postoperative complications and diminish the length of wound healing by preventing release of mediators and reduction of sensory nerve conduction Hence, there is an ongoing interest in developing alternative or complimentary methods for reduction of post operative sequelae.

**Material and Methods:** The present study was approved by the Institutional ethical committee and review board.

**Study Design:** Comparative Split Mouth Randomized Controlled Trial.

**Sample:** A total of fifty patients within the age group of 18-30 years, indicated for surgical removal of bilateral impacted mandibular third molar teeth were included based on the following inclusion and exclusion criteria. The patients were randomly divided into two groups. Patients in the study modality group Transcutaneous electric nerve stimulation (TENS) were allocated in Group A (50 impacted third molars) and patients in the control group who were prescribed NSAIDs only were allocated in Group B (50 impacted third molars). **Inclusion Criteria** were, age between 18-30years, Bilaterally impacted mandibular third molars (Class B and Type 2 of Pell and Gregory Classification), the willingness (informed consent) of subjects to comply for the operative procedure as well as the entire duration and availability for post-operative follow-up. **Exclusion Criteria** were Patients with acute inflammation, cardiac pace-maker, psychiatric disorders, and uncontrolled seizures. Individuals who used analgesics were not included, since variability in the effects of drugs on subsequent pain levels could not be assessed accurately. **Methodology:** A complete history of all the patients was taken, patients were examined clinically; radiographic evaluation was done using Pell and Gregory classification and the difficulty was assessed using Pederson's difficulty Index. The patients who were willing were enrolled for the study. Informed consent was taken for each patient. Procedure was done following aseptic precautions. All the patients were anesthetized by 2% lignocaine hydrochloride with adrenaline in 1:80000 concentrations. Access was gained through a Modified Ward's Incision and a muco periosteal flap was raised. With adequate ostectomy, elevation of the tooth was carried out and

was followed by thorough debridement of the extraction socket. Sectioning of the tooth was carried out whenever necessary. Extraction was performed and post-operative instructions were given. The duration of procedure was measured by the time lapse between incision and completion of suturing. After removal of third molar, Patients in group-A received TENS Therapy extra orally in the region of third molar that was extracted at Frequency of 50Hz and Pulse Duration of 400 $\mu$ S for 10 min as per the manufacturer's specifications, starting on the day of the extraction and continued for next 7 post-operative days. Silicon pads were placed with the help of Velcro. Amperage was set according to patient's comfort.



**Figure 1: Showing application of TENS therapy device**

2. Patients in group-B - Immediately at the completion of the procedure, Tab. Diclofenac was given and patients were advised to take tablet EnzoFlam (Diclofenac 50 mg, Paracetamol 325mg, Serratiopeptidase 15mg) three times in a day. The patient was advised to take the rescue medication (Tablet Tramadol 50mg) if required.

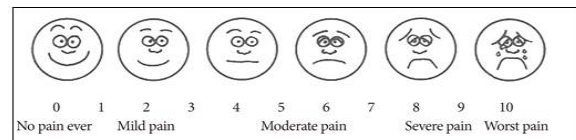
The extractions on both the sides were performed by the same operator. The patients were handed over the Performa and asked to fill it with the necessary information. The patient was given the rescue medication

(Tablet Tramadol 50mg). The second extraction procedure was done following the protocols followed by the first extraction.

**Follow up Protocol:** The patient was recalled on the 1<sup>st</sup>, 3<sup>rd</sup>, 5<sup>th</sup> and 7<sup>th</sup> postoperative days after extraction. The filled Performa was collected on 7<sup>th</sup> postoperative day of extraction. Follow up was done till the 14<sup>th</sup> post-operative day.

#### **Evaluation Criteria:**

**Pain:** self-evaluation by the patient for pain at intervals of 24 hours, 3<sup>rd</sup> and 5<sup>th</sup> day using Visual Analogue Scale was done using a VAS.



**Edema:** The outer contour of the cheek was measured using the method described by Amin and Laskin<sup>7</sup>. In this method, horizontal and vertical distance was measured.



**Fig 2: showing edema on Day 1 and Day 7**

**Trismus:** Inter-incisal opening was measured by the distance of maximal opening between the right maxillary and mandibular central incisor with a caliper.



**Fig 3: showing trismus on Day 1 and Day 7**

**Results:**

In this study fifty cases(100 impacted third molars) ,16 were female and 34 were male and based on the distribution of mean age among different sex, the mean age for male was 26.18 years and for female was 21.96 years. Based on the Pederson Difficulty Index among the two groups, 56 were having minimally difficult index, 44 were having moderately difficult index. The effect of TENS therapy at 50 Hz, keeping the amplitude according to patients comfort for 10 min showed immediate effect of the therapy on pain, the result for each

assessment day by application of Paired t-test came to be significant. The results showed that both the groups, Group A(TENS therapy) and Group B(Control Group) were effective on reducing pain after single day. Hence, immediate effect on pain is same for both the groups on each day. It is evident from the analysis table that, statistically both the groups have equal effect on pain at each day, as P value is greater than 0.05. Both groups showed same immediate effect in pain on each day when ANOVA test was applied (table 1). The effect of TENS therapy on mouth opening just after the first cycle showed immediate effect of the therapy on mouth opening. The result for each assessment day by application of Paired t-test came to be comparable. The results showed that the TENS therapy is more effective in improving mouth opening. In Control group, since the mouth opening did not show any improvement, we can say that TENS is beneficial. Chi square is used pre therapy to check whether the allotment of modalities is independent. It is found that there is no relationship between pain and therapy given.

DESCRIPTIVE STATISTICS					ANOVA		
PAIN	GROUP	MEAN	STD. DEVIATION	STD. ERROR	F	P VALUE	RESULT
Pain_Pre_DO	TENS	1.56	1.879	0.889	0.256	0.688	Non-Significant
	Control	1.11	1.324	0.234			
	Total	1.08	1.141	0.778			
Pain_Pre_D1	TENS	3.86	1.729	0.306	0.908	0.546	Non-Significant
	Control	5.4	2.292	0.567			
	Total	4.88	2.02	0.378			
Pain_Pre_D3	TENS	2.098	0.78	0.189	2.897	0.187	Non-Significant
	Control	16.09	1.087	0.245			
	Total	2.98	0.987	0.189			
Pain_Pre_D5	TENS	0.8	0.789	0.109	0.765	0.987	Non-

	<b>Control</b>	<b>0.9</b>	<b>0.690</b>	<b>0.151</b>			<b>Significant</b>
	<b>Total</b>	<b>0.65</b>	<b>0.654</b>	<b>0.123</b>			
<b>Pain_Pre_D7</b>	<b>TENS</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>Test statistic cannot be computed because the difference of means is 0</b>		
	<b>Control</b>	<b>0</b>	<b>0</b>	<b>0</b>			
	<b>Total</b>	<b>0</b>	<b>0</b>	<b>0</b>			
<b>Pain_Post_D0</b>	<b>TENS</b>	<b>0.18</b>	<b>0.478</b>	<b>0.197</b>	<b>0.654</b>	<b>0.765</b>	<b>Non- Significant</b>
	<b>Control</b>	<b>0.08</b>	<b>0.245</b>	<b>0.87</b>			
	<b>Total</b>	<b>0.3</b>	<b>0.546</b>	<b>0.054</b>			
<b>Pain_Post_D1</b>	<b>TENS</b>	<b>2.43</b>	<b>1.876</b>	<b>0.236</b>	<b>0.454</b>	<b>0.564</b>	<b>Non- Significant</b>
	<b>Control</b>	<b>3.98</b>	<b>1.643</b>	<b>0.567</b>			
	<b>Total</b>	<b>2.44</b>	<b>1.789</b>	<b>0.56</b>			
<b>Pain_Post_D3</b>	<b>TENS</b>	<b>0.78</b>	<b>0.176</b>	<b>0.189</b>	<b>0.198</b>	<b>0.456</b>	<b>Non- Significant</b>
	<b>Control</b>	<b>0.28</b>	<b>0.987</b>	<b>0.235</b>			
	<b>Total</b>	<b>0.92</b>	<b>0.786</b>	<b>0.167</b>			
<b>Pain_Post_D5</b>	<b>TENS</b>	<b>0.4</b>	<b>0.546</b>	<b>0.177</b>	<b>2.675</b>	<b>0.198</b>	<b>Non- Significant</b>
	<b>Control</b>	<b>0</b>	<b>0</b>	<b>0</b>			
	<b>Total</b>	<b>0.2</b>	<b>0.456</b>	<b>0.08</b>			
<b>Pain_Post_D7</b>	<b>TENS</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>Test statistic cannot be computed because the difference of means is 0</b>		
	<b>Control</b>	<b>0</b>	<b>0</b>	<b>0</b>			
	<b>Total</b>	<b>0</b>	<b>0</b>	<b>0</b>			

**Table 1: ANOVA applied on pain between Group A and Group B**

Statistically TENS therapy have better effective in immediate mouth opening on effects on mouth opening when measured each day. just after the therapy at each day, as P-value is less than 0.05. TENS therapy is more

<b>Mouth Opening</b>	<b>Group</b>	<b>Mean</b>	<b>Deviation</b>	<b>F</b>	<b>P value</b>
<b>MO_Post_D0</b>	TENS	40.22	2.675	1.125	0.296
	Control	41.56	2.837		

	Total	29.99	8.217		
<b>MO_Post_D1</b>	TENS	33.53	7.193	2.113	0.012
	Control	30.13	7.832		
	Total	32.45	7.007		
<b>MO_Post_D3</b>	TENS	36.12	6.95	1.442	0.037
	Control	33.78	7.018		
	Total	34.65	2.72		
<b>MO_Post_D7</b>	TENS	39.92	2.636	0.171	0.682
	Control	38.83	2.65		
	Total	39.05	2.982		

**Table 2: Comparing the difference between effectiveness of both therapies in increasing mouth opening in mm by applying ANOVA test.**

It is evident that Transcutaneous electric nerve stimulation (TENS) has shown the effectiveness on swelling on all the days. TENS showed its effect on swelling during the course of therapy on day 1, day 3, and day 5 when compared with day 0. The P-value came less than 0.05. On day 7 P-value came non-significant when compared to day

0 as difference of the mean was less, that means it almost reached normal mouth opening on day 7. On day 15 difference of mean was zero. TENS stands more effective when compared to Control group in management of trismus and swelling because statistically the difference was significant.

Horizontal	Group	Mean	Deviation	F	P value
<b>Day 0</b>	TENS	110.8	5.952	0.288	0.595
	Control	109.6	5.543		
	Total	109.9	5.665		
<b>Day 1</b>	TENS	116.1	5.77	0.865	0.035
	Control	129.3	6.4		
	Total	123.2	6.111		
<b>Day 3</b>	TENS	114.65	6.277	1,064	0.030
	Control	126.65	5.985		
	Total	120.65	6.138		
<b>Day 7</b>	TENS	111.7	5,868	0.288	0.594
	Control	120.7	5.913		
	Total	115.2	5.836		

**Table 3: Comparing the difference between effectiveness of both the groups in reducing horizontal measurement in mm for swelling by applying ANOVA test.**

**Discussion:** Third molar surgeries are mainly associated with some unavoidable postoperative sequelae, such as pain,

swelling and trismus. These symptoms can affect the quality of life of patients during initial days of the postsurgical process<sup>8</sup>.

Trismus could be managed medically and surgically but results are unpredictable, whereas physiotherapy treatment has shown better and speedy recovery<sup>8-10</sup>. In this study, a total of 50 patients who needed surgical removal of bilaterally impacted mandibular third molars were treated. Pederson Difficulty Index is a method to score the difficulty of a lower third molar surgery. This difficulty score gives us an estimated amount of trauma and time taken during the surgery. Based on the Pederson Difficulty Index among the two groups, 56 were having minimally difficult index, 44 were having moderately difficult index. Kitchen S<sup>14-15</sup> concluded in his study that placebo and TENS showed same effect. In our study, statistical test applied on pain were Chi-square, ANOVA and Paired-t. VAS score was recorded before and after the surgery. The day of the surgery was the first day when the therapy was started and data was recorded. Then on 1st, 3rd, 7th and 15th day VAS score was recorded before and after the therapy. This helped us to conclude immediate effect of the therapy. Both the groups, be it control and TENS were equally effective in reducing pain. Swelling is common after any surgery be it in oral cavity or anywhere else in the body. After impacted lower third molars were extracted swelling is prominent in the masseteric and buccal region of the mandible. Mostly there is no evident swelling intra-orally<sup>11</sup>. Trismus is associated with swelling mostly<sup>12</sup>. With reduction of swelling trismus subsides too. TENS manages swelling and trismus with the help of its contraction and relaxation effect on muscles. Paired t-test was applied to measure swelling during the course of therapy by comparing the swelling on baseline day to other post-operative days

(day-1, day-3, day-7 and day-15). In group-A, TENS group it was evident that, only on day-15, the P-value was more than 0.05, whereas on other days P-value came out to be less than 0.05, results were significant. It suggests that most of the swelling reduced within 7 days of TENS therapy. In group-B, Control group it was evident that on all days, the P-value was greater than 0.05, result were non-significant. Results from ANOVA and Paired t-test help us to access the effectiveness of TENS therapy on swelling after surgical extraction of impacted lower third molar. During the course of TENS most of the effect came during first 7 sittings of therapy. TENS was more effective in reducing swelling. Paired t-test was applied to compare effect of both the modalities on mouth opening each day. Control group modality was not effective in improving mouth opening after day 1, day 3 and day 5, as the difference of mean was zero for control group. ANOVA was applied to compare effectiveness of both the groups on mouth opening each day. TENS therapy showed good results as compared to control group. Paired t-test was applied to compare effects between both the groups on mouth opening and swelling during the course of treatment. TENS was more effective in managing postoperative trismus and swelling in comparison to control group and statistically the differences were significant.

**Conclusion:** To perform this procedure in atraumatic manner, extensive training, skill, and experience is a must. Postoperative pain, trismus and edema are common phenomenon particularly frequent after surgical removal of impacted third mandibular molars. In our



study it has shown that TENS is equally effective in managing pain after extraction of impacted lower third molar when it is given for single sitting to the patient, as control group. It has shown in this study that TENS is more effective in managing swelling and trismus after extraction of impacted lower third molar during postoperative course of healing. So, further studies are needed for more accurate suggestion with larger sample size.

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