

## **Effectiveness of the use of therapeutic bandage method in the third molar surgery: a randomized, controlled, single-blind, split-mouth**

**Eficácia do uso do método de bandagem terapêutica na cirurgia do terceiro molar: um método randomizado, controlado, simples-cego, boca dividida**

**Eficacia del uso del método del vendaje terapéutico en la cirugía del tercer molar: un estudio aleatorizado, controlado, simple-cego, de boca dividida**

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### **Abstract**

**Objective:** Extraction of semi-impacted or impacted, lower, third molars is one of the most performed procedures in the maxillofacial surgery, and inherent to it, there may be post-operative inflammatory response. Among the most common factors related to this response, pain, swelling, and trismus are the main ones. In this sense, therapeutic bandage has been used in the post-operative physiotherapy for several specialties so that muscular functions can be fully resumed and swelling, muscle spasms and pain reduced. **Materials and Methods:** The randomized, split-mouth, clinical trial was to assess 20 post-operative patients who underwent extraction of lower third molars with therapeutic bandage. Seven days after the extraction, swelling and trismus were the variables evaluated and pain was assessed according to the visual analogue scale (VAS). The Student's t-test was used for comparison at significance level of 5% ( $\alpha = 0.05$ ). **Results:** With the results found, it was not possible to state that the therapeutic bandage protocol used in this study, given the evaluated signs and symptoms, were favorable, even providing greater comfort to patients. **Conclusion:** Therefore, we suggest that further studies should be performed in order to develop a protocol for application of therapeutic bandage for stomatognathic system. Clinicaltrials.gov NCT03393533. 12/05/2017 retrospectively registered.

**Keywords:** Third molar; Oral surgery; Pain; Bandage.

### **Resumo**

**Objetivo:** A extração de terceiros molares inferiores semi-impactados ou impactados é um dos procedimentos mais realizados na cirurgia bucomaxilofacial, e inerente a ele, pode haver resposta inflamatória pós-operatória. Dentre os fatores mais comuns relacionados a essa resposta, a dor, o edema e o trismo são os principais. Nesse sentido, o curativo terapêutico vem sendo utilizado na fisioterapia pós-operatória para diversas especialidades para que as funções musculares possam ser totalmente retomadas e o inchaço, os espasmos musculares e a dor sejam reduzidos. **Materiais e Métodos:** O ensaio clínico randomizado, de boca dividida, avaliou 20 pacientes em pós-operatório que foram submetidos à exodontia de terceiros molares inferiores com curativo terapêutico. Sete dias após a extração, edema e trismo foram as variáveis avaliadas e a dor foi avaliada de acordo com a escala visual analógica (EVA). O teste t de Student foi utilizado para comparação ao nível de significância de 5% ( $\alpha = 0,05$ ). **Resultados:** Com os resultados encontrados, não foi possível afirmar que o protocolo de curativo terapêutico utilizado neste estudo, diante

dos sinais e sintomas avaliados, foi favorável, mesmo proporcionando maior conforto aos pacientes. Conclusão: Portanto, sugerimos que mais estudos sejam realizados a fim de desenvolver um protocolo para aplicação de curativo terapêutico para o sistema estomatognático. Clinicaltrials.gov NCT03393533. 12/05/2017 registrado retrospectivamente.

**Palavras-chave:** Terceiro molar; Cirurgia oral; Dor; Bandagem.

### Resumen

**Objetivo:** La extracción de terceros molares inferiores semi-impactados o impactados es uno de los procedimientos más realizados en cirugía oral y maxilofacial, y inherente a ella, puede existir una respuesta inflamatoria postoperatoria. Entre los factores más comunes relacionados con esta respuesta, el dolor, el edema y el trismus son los principales. En este sentido, el apósito terapéutico se ha utilizado en fisioterapia postoperatoria de varias especialidades para que las funciones musculares se recuperen por completo y se reduzcan la hinchazón, los espasmos musculares y el dolor. **Materiales y métodos:** el ensayo clínico aleatorizado de boca dividida evaluó a 20 pacientes postoperatorios que se sometieron a la extracción de terceros molares inferiores con un apósito terapéutico. Siete días después de la extracción, el edema y el trismo fueron las variables evaluadas y el dolor se evaluó según la escala analógica visual (EVA). Se utilizó la prueba t de Student para la comparación a un nivel de significación del 5% ( $\alpha = 0,05$ ). **Resultados:** Con los resultados encontrados, no se pudo afirmar que el protocolo de vendaje terapéutico utilizado en este estudio, dados los signos y síntomas evaluados, fue favorable, incluso brindando mayor comodidad a los pacientes. **Conclusión:** Por lo tanto, sugerimos que se realicen más estudios con el fin de desarrollar un protocolo para la aplicación de vendajes terapéuticos al sistema estomatognático. Clinicaltrials.gov NCT03393533. 12/05/2017 registrado retrospectivamente.

**Palabras clave:** Tercer molar; Cirugía oral; Dolor; Vendaje.

## 1. Introduction

Third molar extraction is the most commonly performed maxillofacial surgery in the world. Its execution may result in the emergence of several post-operative events in which pain, swelling and trismus are the most observed in greater or lesser degree. Therefore, there is a constant search for procedures providing less post-operative discomfort to patients undergoing this type of surgery (Brignardello-Petersen et al., 2012; Ristow et al., 2014).

Developed in Japan in 1996 by Kenzo Kase, the elastic bandage must have direct application on the muscle that needs to be stimulated, and can be used on the body or facial muscle (González-Iglesias et al., 2009). Among its benefits, we can mention the correction of muscle functions, the reduction of swelling, muscle spasms and pain, including the ability to open lymphatic vessels in the affected area, thus facilitating the pathway of the local exudate towards the main drainage system (Artioli & Bertolini, 2014).

When the area covered by the bandage is submitted to a tension resulting from muscle contraction, the lymphatic vessels located between muscle plane and covering tissue undergo variations in pressure, which allows pumping the exudate similarly to that occurring during a massage (Tsai et al., 2009).

Knowing that the therapeutic bandage can improve the local lymphatic drainage, studies found that this material could be used in dentistry as it was reported to conceivably decrease the morbidity caused to the surrounding tissues during a third molar surgery (Ristow et al., 2014).

Therefore, the objective of this clinical, randomized trial was to assess the effectiveness of the use of therapeutic bandage in the relief of post-operative signs and symptoms inherent to the extraction of lower third molars.

## 2. Methodology

The present study used a methodology based on the norms set by the 2010 COSORT Statement (Moher et al., 2012) and was registered at the ClinicalTrials.gov website (NCT03393533), in addition to being submitted to and approved by the Research Ethics Committee of the Institute of Science and Technology (ICT) of the São Paulo State University (UNESP) according to protocol number CAAE 79503817.8.0000.0077. Patients voluntarily seeking Maxillofacial Surgery Clinic for extraction of lower third molars, regardless of being semi-impacted or impacted teeth, were evaluated and treated. Molar

impaction had to be similar on both sides. Detailed anamnesis with the patients was performed after the surgery, including panoramic radiograph.

## **Subjects**

This is a randomized, controlled, single-blind, split-mouth clinical trial whose sample consisted of patients requiring extraction of semi-impacted or impacted lower third molars. The patients were divided into two groups simultaneously as follows:

- Control group: without therapeutic bandage on the face
- Study group: with therapeutic bandage on the face

### **2.1 Eligibility criteria**

1. Patients requiring third molar extraction regardless of gender;
2. Patients having no pathology associated with the eruptive process;
3. Patients having no previous health problem;
4. Patients having teeth in similar position and classifications on the opposite sides (Winter, 1926; Pell & Gregory, 1933).

### **2.2 Exclusion criteria**

1. Patients with local or systemic alterations contra-indicating surgical procedure;
2. Patients taking anti-inflammatory medication in the past 15 days;
3. Patients who were pregnant or lactating;
4. Patients with lower third molars in different positions and different impaction types on both sides;
5. Patients with erupted lower third molars.

The initial sample consisted of 56 patients, but after applying the inclusion and exclusion criteria, 20 (i.e. 40 teeth) were selected for the final sample (Figure 1).

## **Randomization**

After clinical evaluation, the patients meeting the inclusion criteria were randomly divided into two groups by using numbers and envelopes and to verify whether they would undergo the initial surgery in the control or study group. The first surgery was performed on the right side (i.e. tooth 48) in all patients. Randomization was performed by a researcher not involved in the recruitment and treatment of the patients, who were then assigned to the above-cited groups. Both surgeon and assistant were blinded to the groups. In the second surgery, the tooth 38 of each patient was immediately treated after the procedure compared to tooth 48 on the opposite side. In this way, all patients took part in both groups, which characterized a split-mouth protocol.

### **2.3 Surgical procedures and evaluation**

The surgeries were performed on each side of the patient's face by an experienced surgeon and an assistant at a 20-day interval. The surgical protocols were applied according to biosafety standards.

### **Application of Therapeutic Bandage**

A functional elastic bandage (TherapyTex®, São Paulo, Brazil), measuring 5 meters long by 5 cm wide, made of elastane threads, acrylic polymers and cotton fibers was used in this clinical trial. This material is also characterized for being hypoallergenic, water-resistant, free of drug components and adhering easily to the skin. In addition, it is certified by the International Standard Organization 9001, Food and Drug Administration (FDA, USA), European Community Free Trade Association (EFTA), Korea Testing Certification (KTC) and Brazilian Agency for Sanitary Surveillance (ANVISA) under register number 80 784 640 001.

The therapeutic bandage was applied to patients of the study group, according to previous randomization and protocol used by Morini-Junior (2016) immediately after the surgery and before termination of the anesthetic effect. The skin was cleaned with 70% alcohol and trichotomy was performed if necessary. The bandage was applied to the regions of interest by a professional not involved in the other steps of the study, in which no additional cutting on the tape was made (i.e. I-shaped cutting was used). The length of the bandage was adjusted according to each patient's facial size (Morini-Júnior, 2016).

The patient was asked to bite down so that the dimension of the masseter muscle could be determined by means of palpation, which was performed by selecting point A in the lower portion of the zygomatic arch to point B close to the angle of the mandible. The tape was placed onto the skin accompanying the orientation of the muscle fibers. A second tape was placed from the mandibular angle to the mental symphysis accompanying the entire mandibular body in its medial portion, covering the mylohyoid muscle and anterior belly of the digastric muscle.

After its application, the bandage was gently scrubbed in order to activate the acrylic components and thus provide adhesiveness, remaining on the face for three days.

### **Clinical Evaluation of Pain, Swelling and Trismus**

The patients undergoing the surgical procedures evaluated their own painful experience during the post-operative period until the third day by using the VAS scale, whose score ranged between zero (no pain) and ten (the worst pain ever felt) (Maxwell, 1978).

Facial swelling was measured which is based on the distance from the lateral corner of the eye to the gonion, distance from the tragus to the labial commissure and distance from the tragus to the soft pogonion (Ustün et al., 2013). The measurements in each side were compared to the same distances obtained in the post-operative period, thus evidencing the presence and magnitude of edema in each one of the periods when the evaluations were made. The measurements were made by using a flexible ruler on the third and seventh days.

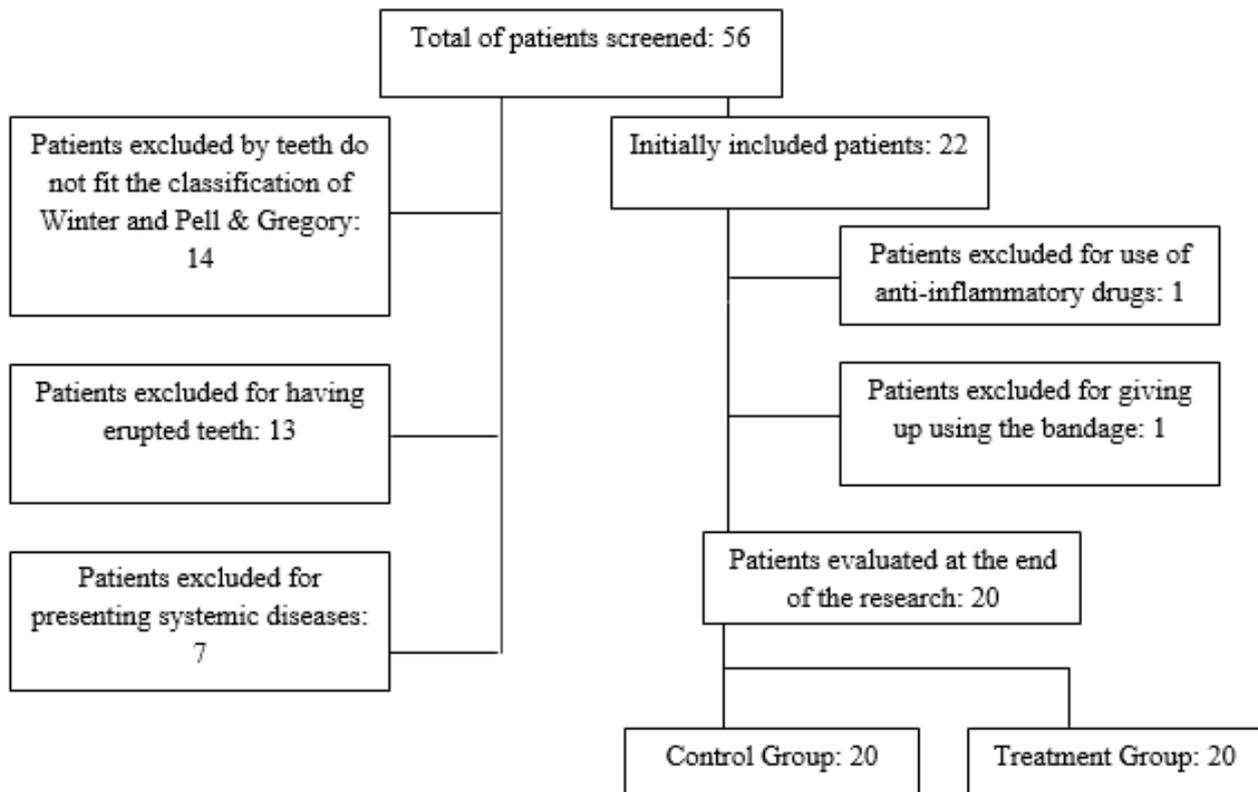
Trismus was measured during the post-operative period on the third and seventh days by using a flexible millimeter ruler placed between incisal ridges of the upper and lower central incisors.

The Student's t-test was used for comparison between the mean values at a significance level of 5% ( $\alpha = 0.05$ ).

## **3. Results**

The screening was carried out in 6 months. Initially, a sample consisted of 56 patients who needed dental extraction of the lower third molar. After the initial examination, 34 patients were excluded, with 22 patients remaining. After this selection, 2 more exclusions occurred, one for use of anti-inflammatory and another for withdrawal. The final number was 20 patients, 17 women and 3 men (Figure 1). The resulting data were statistically analysed by using the SPSS software, version 11 (IBM Corp., Somers, NY, USA). Sample power was calculated and normality test performed as well (Anderson-Darling test). As the sample was parametric, the Student's t-test was used for comparison between the mean values at a significance level of 5% ( $\alpha = 0.05$ ).

**Figure 1** - Flowchart of patient selection for the study.



Source: Own authorship.

Statistical analysis showed that the sample was significant for the present study at a significance level of 10% and sample power of 80% (Ristow et al., 2014).

### Pain

With regard to this variable, it was possible to observe that pain intensity was greater in both study and control groups for zero and two-hour periods, respectively, but no statistically significance was found between these periods of time (Table 1).

**Table 1** - Pain (VAS) in mm between the control and treatment group in the evaluated periods (0 to 72 hours).

Pain	Control Group	Treatment Group	p-value
0h	1.15 ± 1.50	2.3 ± 2.67	0.104
2h	3.05 ± 3.14	2.1 ± 2.33	0.860
4h	3 ± 2.73	3.05 ± 2.54	0.859
6h	2.2 ± 2.21	2.65 ± 2.47	0.820
8h	2.3 ± 2.43	2.5 ± 2.33	0.813
24h	1.15 ± 2.11	1.4 ± 1.93	0.721
48h	1.5 ± 2.12	1.35 ± 1.87	0.776
72h	1.25 ± 2.05	1.15 ± 1.56	0.786

Source: own authorship.

## Swelling

With regard to swelling, it was possible to observe that this variable was present in both groups on the third day of evaluation compared to the other two days. However, again, no statistically significant difference was found between the study and control groups in any of the periods of evaluation for this variable (Table 2).

**Table 2** - Swelling (in mm) between the control and treatment group in the evaluated periods (1<sup>st</sup>, 3<sup>rd</sup> and 7<sup>th</sup> day)

Swelling		Control Group	Treatment Group	p-value
1 <sup>st</sup> Day	G - CP	10.64 ± 0.46	10.70 ± 0.59	0.721
	T - C	11.23 ± 0.66	11.23 ± 0.64	0.880
	T - PG	14.65 ± 0.74	14.75 ± 0.73	0.685
3 <sup>rd</sup> Day	G - CP	11.18 ± 0.57	11.07 ± 0.58	0.568
	T - C	11.82 ± 0.62	11.70 ± 0.57	0.526
	T - PG	15.03 ± 0.88	15.13 ± 0.71	0.695
7 <sup>th</sup> Day	G - CP	10.83 ± 0.57	10.76 ± 0.62	0.692
	T - C	11.43 ± 0.68	11.32 ± 0.63	0.598
	T - PG	14.76 ± 0.72	14.85 ± 0.77	0.721

Source: own authorship.

## Trismus

Trismus had no statistically significant difference between the study and control groups in any of the periods of evaluation (Table 3).

**Table 3** - Trismus (in mm) between the control and treatment group in the evaluated periods (1<sup>st</sup>, 3<sup>rd</sup> and 7<sup>th</sup> day).

Trismus	Control Group	Treatment Group	p-value
1 <sup>st</sup> day	4.36 ± 0.75	4.62 ± 0.87	0.321
3 <sup>rd</sup> day	3.38 ± 0.96	3.62 ± 1.03	0.443
7 <sup>th</sup> day	4.14 ± 0.99	4.26 ± 0.83	0.693

Source: own authorship.

The present study demonstrated that the application of therapeutic bandage did not influence significantly the tissue reactions and the presence of swelling, pain and trismus in the post-operative period. In fact, very similar results were found between the study and control groups regarding all these variables.

## 4. Discussion

In our study, despite the lower results, patients report feeling more comfortable on the affected side in the postoperative period. This can be explained by the placebo effect, by the patient's view on healing (Ristow et al., 2014) or due to effects and benefits not totally based on scientific literature (da Silva et al., 2014). However, the most accepted idea so far is the theory in which the mechanical stimulus used by the therapeutic bandage triggers electrical traction mechanisms that, upon reaching the gelatinous substance in the posterior horn of the spinal cord, perform synapses with inhibitory interneurons not allowing the passage of stimuli nociceptive (Gosling, 2012).

But Ristow et al. (2014) unlike our study, it concluded that the use of therapeutic dressing after extraction of third molars is beneficial and cheaper to reduce pain, swelling and trismus. However, we found that trismus was less present in the study group on the first, third and seventh day compared to the control group, but no statistical difference was observed.

In the present study, there was no statistically significant difference between groups regarding pain, although already reported that the use of therapeutic bandage can decrease the intensity of pain in their study (González-Iglesias et al., 2009; Thelen, Dauber & Stoneman, 2008). It was possible to find a low amount of pain in our study group in the period of two hours, despite the lack of statistical differences, a result also observed by Ristow et al. (2014) in his bandaged group. However, when comparing patients using a bandage with those using a drain in the postoperative period, reporting the most severe pain in the first group (Genc et al., 2019).

Manual lymphatic drainage has already been proven to be effective in the decrease of swelling resulting from the surgical removal of third molars (Szolnoky et al., 2007). Assuming that therapeutic bandage stimulates the pumping of lymph through the pressure from muscle contraction the swelling was also chosen as a parameter for assessment of the effectiveness of the bandage (Tsai et al., 2009). By comparing both groups (i.e. study x control), one can observe that the swelling was similar in the post-operative period, however another study reported that patients using bandage showed more swelling than those with drain during the post-operative period (Genc et al., 2019). However, in another study, with extraction of third molars, it was concluded that patients with bandages had the least swelling (da Rocha et al., 2020).

In our study, despite the non-statistically significant results, patients report feeling more comfortable on the affected side in the postoperative period. This can be explained by the placebo effect, by the patient's view on healing (Ristow et al., 2014) or due to effects and benefits not totally based on scientific literature (da Silva et al., 2014). However, the most accepted idea so far is the theory in which the mechanical stimulus used by the therapeutic bandage triggers electrical traction mechanisms that, upon reaching the gelatinous substance in the posterior horn of the spinal cord, perform synapses with inhibitory interneurons not allowing the passage of stimulus nociceptive (Gosling, 2012).

It was found that trismus was less present in the study group on the first, third and seventh days compared to the control group, but no statistical difference was observed. Genc et al. (2019) also reported no statistical difference regarding the presence of trismus in patients with bandage, whereas Ristow et al. (2014) concluded that the use of bandage was beneficial for trismus in the post-operative period.

Due to the recent use of therapeutic bandage in dentistry, it is difficult to determine the optimal protocol for its application. For this reason authors compared the classic technique, in which three tapes are extended from the region of supraclavicular lymph nodes to the region of perioral nodes, to the new technique in which two other tapes are also applied to the masseter region, which resulted in better outcomes, although both techniques had positive results (Gözlüklü et al., 2020). Da Rocha et al. (2020) assessed only the classic technique and reported good results, and according to Artioli and Bertolini (2014) this therapy should be considered for reducing pain on an adjunct or complementary basis.

## 5. Conclusion

The results found, it was not possible to state that the therapeutic bandage protocol used in this study, given the evaluated signs and symptoms, were favorable, even providing greater comfort to patients. Therefore, we suggest that further studies be carried out to develop a therapeutic bandage application protocol in the stomatognathic system.

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