

Comparison of oral health-related quality of life after lower third molar extraction following preemptive administration of Traumeel S® vs dexamethasone

Comparaç o da qualidade de vida de pacientes submetidos   exodontia de terceiros molares inferiores ap s administraç o preemptiva de Traumeel S® vs dexametasona

Comparaci n de la calidad de vida en pacientes sometidos a extracci n del tercer molar mandibular tras la administraci n preventiva de Traumeel S® frente a dexametasona

Received: 01/00/2022 | Reviewed: 01/00/2022 | Accept: 02/13/2022 | Published: 02/20/2022

Yaser Al-Sharaee

ORCID: <https://orcid.org/0000-0002-4225-7360>

Thamar University, Yemen

E-mail: yaseryahmed@gmail.com

Essam Ahmed Al-Moraissi

ORCID: <https://orcid.org/0000-0002-3649-9662>

Thamar University, Yemen

E-mail: dressamalmoraissi@gmail.com

Saulo Gabriel Moreira Falci

ORCID: <https://orcid.org/0000-0001-9438-5199>

Universidade Federal dos Vales do Jequitinhonha e Mucuri, Brazil

E-mail: saulofalci@hotmail.com

Ighor Andrade Fernandes

ORCID: <https://orcid.org/0000-0002-3767-5197>

Universidade Federal dos Vales do Jequitinhonha e Mucuri, Brazil

E-mail: ighor.af@gmail.com

Glaciele Maria de Souza

ORCID: <https://orcid.org/0000-0002-3303-072X>

Universidade Federal dos Vales do Jequitinhonha e Mucuri, Brazil

E-mail: glacieledtna@gmail.com

K ssia Nara Andrade Sales

ORCID: <https://orcid.org/0000-0001-6103-3242>

Universidade Federal dos Vales do Jequitinhonha e Mucuri, Brazil

E-mail: sales.kessia@gmail.com

Marcos Luciano Pimenta Pinheiro

ORCID: <https://orcid.org/0000-0001-9939-1045>

Universidade Federal dos Vales do Jequitinhonha e Mucuri, Brazil

E-mail: marcospimenta2@gmail.com

Endi Lanza Galv o

ORCID: <https://orcid.org/0000-0002-5648-3932>

Universidade Federal dos Vales do Jequitinhonha e Mucuri, Brazil

E-mail: endilanza@yahoo.com.br

Abstract

Purpose: To compare the effect of intramuscular administration of dexamethasone versus *Traumeel S*® on patients' oral health-related quality of life (OHRQoL) after surgical extraction of impacted lower third molars (3M). **Patients and methods:** A randomized, triple-blinded clinical trial was conducted. The sample was composed of 17 patients with asymptomatic bilateral lower 3M positioned as class IIB according to the Pell and Gregory classification. The patients were randomly assigned into 2 groups: intramuscular dexamethasone or *Traumeel S*®. The OHRQoL was assessed using the Oral Health Impact Profile (OHIP) version 14. It was considered patients' perception regarding different quality of life dimensions, in the first seven postoperative days. **Results:** There was a significant OHRQoL improvement in the dexamethasone group when compared to *Traumeel S*® group. It was noted a significant decrease of psychological disability and psychological discomfort in patients receiving dexamethasone vs those receiving *Traumeel S*®. **Conclusion:** Intramuscular injection of dexamethasone showed a greater improvement of the OHRQoL following 3M surgeries when compared to *Traumeel S*® injection.

Keywords: Dexamethasone; Homeopathy; Oral surgery; Third molar; *Arnica Montana*.

Resumo

Objetivo: Comparar o efeito da administração intramuscular de dexametasona *versus* Traumeel S® na qualidade de vida (QoL) de pacientes após a extração cirúrgica de terceiros molares inferiores impactados (3M). **Metodologia:** Foi realizado um ensaio clínico randomizado, triplo-cego. A amostra foi composta por 17 pacientes com 3M bilateral assintomático posicionado em classe IIB de acordo com a classificação de Pell e Gregory. Os pacientes foram distribuídos aleatoriamente em 2 grupos: dexametasona intramuscular ou Traumeel S®. A QoL foi avaliada por meio do *Oral Health Impact Profile* (OHIP) versão 14. Considerou-se a percepção dos pacientes em relação às diferentes dimensões da qualidade de vida, nos primeiros sete dias de pós-operatório. **Resultados:** Houve melhora significativa da QoL no grupo dexametasona quando comparado ao grupo Traumeel S®. Observou-se uma diminuição significativa da incapacidade psicológica e desconforto psicológico em pacientes que receberam dexametasona comparado àqueles que receberam Traumeel S®. **Conclusão:** A injeção intramassetérica de dexametasona mostrou uma melhora maior da QoL após cirurgias de 3M quando comparada à injeção de Traumeel S®.

Palavras-chave: Dexamethasone; Homeopathy; Oral surgery; Third molar; *Arnica Montana*.

Resumen

Objetivo: Comparar el efecto de la administración intramuscular de dexametasona *versus* Traumeel S® en la calidad de vida (QoL) de los pacientes después de la extracción quirúrgica de terceros molares inferiores impactados (3M). **Metodología:** Se realizó un ensayo clínico aleatorizado, triple ciego. La muestra estuvo compuesta por 17 pacientes con 3M bilateral asintomático posicionados en clase IIB según la clasificación de Pell y Gregory. Los pacientes fueron asignados aleatoriamente a 2 grupos: dexametasona intramuscular o Traumeel S®. La calidad de vida se evaluó mediante el *Oral Health Impact Profile* (OHIP) versión 14. Se consideraron las percepciones de los pacientes con respecto a las diferentes dimensiones de la calidad de vida en los primeros siete días del postoperatorio. **Resultados:** Hubo una mejora significativa en la calidad de vida en el grupo de dexametasona en comparación con el grupo Traumeel S®. Se observó una disminución significativa de la discapacidad psicológica y el malestar psicológico en los pacientes que recibieron dexametasona en comparación con los que recibieron Traumeel S®. **Conclusión:** La inyección intramassetérica de dexametasona mostró una mayor mejora en la calidad de vida después de cirugías 3M en comparación con la inyección de Traumeel S®.

Palabras clave: Dexametasona; Homeopatía; Cirugía oral; Tercer molar; *Arnica Montana*.

1. Introduction

Quality of life (QoL) is a multidimensional concept that involves the patient ability to accomplish daily activities (Galvão et al., 2018; Sancho-Puchades et al., 2012). The QoL assessment consists of questionnaires aiming to measure the efficacy and efficiency of treatments. This measurement is based on physical, psychological, and social aspects in each individual's life. Thus, health-related disabilities can change the QoL as well. On the other hand, it is a subjective analysis and thereby, the results of this evaluation may present differences depending on each individual perception (Sancho-Puchades et al., 2012).

Third molar surgical removal is a common procedure in dentistry because of its high impaction prevalence. This tooth extraction is indicated when there are pathologies associated with its presence such as caries (Falci et al., 2012), pericoronitis (Galvão et al., 2019), cysts, and tumors (Mello et al., 2019). Specifically, lower third molar (L3M) surgeries can lead to high postoperative inflammatory consequences such as pain, swelling, and trismus. These postoperative inflammatory parameters can disable the patients, compromising their quality of life in the early postoperative days (Alcântara et al., 2014; Duarte-Rodrigues et al., 2018).

Postoperative inflammation is mainly controlled through drug protocols, aiming to reduce the patients' discomfort and morbidity. The pharmacological strategy consists of blocking the formation or inhibiting the effects of acute inflammation mediators through the administration of steroidal and non-steroidal anti-inflammatory drugs (NSAIDs) (Lima et al., 2018).

Dexamethasone is the most used anti-inflammatory drug in the prevention of pain after L3M surgeries (Fernandes et al., 2019). The effectiveness of this allopathic drug has been proven in previous studies (Alcântara et al., 2014; Lima et al., 2018; Falci et al., 2017; Bhargava et al., 2014). On the other hand, there are other drug classes used alternatively to the traditional ones for L3M surgery. Currently, the searching for alternative drugs over the allopathic ones is on the raise.

Traumeel S[®] is a homeopathic formulation (Biologische Heilmittel Heel GmbH, Baden Baden, Germany) resulted from a mixture of 12 botanical substances and two minerals (Scientifics Bio-Logics-Heel). It has anti-inflammatory properties and has already shown a good performance on third molar surgeries (de Souza et al., 2021). However, no studies have searched whether homeopathic medications improve QoL after L3M surgeries.

This study aimed to compare the impact of the preoperative injection of dexamethasone *vs* *Traumeel S*[®] on the QoL of patients following L3M surgeries, in a short-term follow up.

2. Methodology

This study is a randomized split-mouth triple blinded clinical trial. The *Consolidated Standards of Reporting Trials* (CONSORT) checklist for clinical trials was followed (Moher et al., 2010). This randomized clinical trial (RCT) is a branch of the same research already published, comparing *Traumeel S*[®] *vs* dexamethasone on postoperative pain, edema, and trismus (de Souza et al., 2021), and was registered in (<https://www.clinicaltrials.gov>), NCT03567369. The present study shows the QoL results of this comparison. The surgeries were performed on the authors' university after ethical committee approval (2.341.947). A total of 34 patients underwent third molar surgery based on the results of a sample size calculation.

The following eligibility criteria were applied to patients' selection. Inclusion: 1) health individuals, 2) older than 18 years, 3) patients who gave their writing consent to participate in the study, 4) patients with bilateral asymptomatic impacted or included L3M. Exclusion: 1) patients who have allergy to dexamethasone or *Traumeel S*[®], 2) patients who have taken anti-inflammatory drugs within 15 days prior to surgery (*washout period*).

The randomization process was performed through sealed opaque envelopes. The randomization was performed to know which side the third molar would be extracted first (right or left) and which medication would be applied in the first surgery (protocol 1 or protocol 2). The other side was operated 45 days after the first surgery and the other drug protocol was applied. To assure the triple blind design (surgeon, patient, and evaluator), a fourth person who was not involved with the research, was responsible to manipulate and deliver the drugs. Thus, the patient acted as his/her own control. The drug in each protocol was revealed only at the end of all surgeries and after all the statistical analyzes were complete. The protocol 1 consisted in *Traumeel S*[®] 2,2mg/2mL and protocol 2 was dexamethasone 8mg/2mL. The route of administration was the intramuscular and the medication was injected into the masseter muscle.

Surgical procedure

All surgeries were performed under local anesthesia (2% lidocaine with epinephrine 1:100000) blocking the inferior alveolar, lingual, and buccal nerves. After anesthesia, according to the randomized process already described, the drugs were administered to the patient. The medications were injected in three different points of the masseter muscle (Messer and Keller, 1975).

All surgeries were performed by the same experienced oral and maxillofacial surgeon. The surgical technique was conducted in accordance with Hupp (Hupp et al., 2008). Osteotomy and tooth sectioning were performed, when necessary, always under irrigation with a 0.9% sterile saline solution. Stiches were performed with 4-0 silk suture. At the end of each surgery, patients received postoperative instructions and rescue medication (18 tablets of acetaminophen 500mg). They were informed to take one tablet, every four hours for up to three days in case of pain. They were also advised to avoid taking other medications that were not provided by the study protocol. Besides that, the patients should inform the researcher if they took any additional medication.

Data collection

The QoL was assessed using the Oral Health Impact Profile (OHIP) version 14, adapted and validated to the Portuguese language (Afonso et al., 2017). The questionnaire includes the following items related to the oral condition: 1) functional limitation, 2) physical pain, 3) psychological discomfort, 4) physical disability, 5) psychological disability, 6) social disability, and 7) social disadvantage. The scores for each condition ranged from 0 to 4, where zero corresponded to “never” and 4 to “always”. The questionnaire was applied preoperatively (baseline) and seven days postoperatively (test) in both surgeries, right and left sides.

Statistical analysis

Statistics were performed using the software Statistical Package for Social Science (SPSS), version 22.0. The mean of the OHIP scores given for each medication, at the baseline and the postoperative moment, was calculated. The higher the mean value the worse was the QoL. The normality test Shapiro-Wilk was used to check data distribution. Then, the association parametric or non-parametric tests were performed according to the normality test. To assess the difference between the means of the groups, the Wilcoxon test for paired samples was used when the data distribution was non-normal, and the paired t test was used for data with normal distribution. A value of $p < 0.005$ was adopted for statistical significance. In case of loss of patient during follow-up, in the allocated groups, an intention-to-treat analysis was performed in order to preserve the random distribution.

3. Results

The descriptive analysis was the same reported in the previous published study by the same research group (de Souza et al., 2021). The similarity between the two groups can be proved by the results about surgery duration ($p=0.19$) and postoperative analgesic intake ($p=0.15$) (Table 1).

Table 1. Descriptive analysis.

	Traumeel S® (2.2mg) Mean ± SD	Dexamethasone (8mg) Mean ± SD	p-value
Surgery time (minutes)	14.48 ± 7.33	16.56 ± 5.49	0.19
Number of taken analgesics	9.44 ± 5.73	6.88 ± 5.41	0.15

Source: Authors.

In the postoperative moment, the patients who had their third molar extracted and were treated with *Traumeel S*® (23.05±11.46) experienced worse QoL than baseline values (10.05±6.10), $p < 0.001$. This worsening on QoL is attributed to functional limitation (2.41±1.69), physical pain (5.23±2.61), physical disability (3.64±2.62), psychological disability (3.05±2.24), and social disability (3.52±4.09). On the other hand, the patients who had their third molar extracted and were treated with dexamethasone showed the same postoperative QoL (total OHIP) than baseline, $p=0.212$. However, the functional limitation was worse in the dexamethasone group when comparing baseline to postoperative values ($p=0.005$). The direct comparison between *Traumeel S*® and dexamethasone showed better overall QoL in the dexamethasone group ($p=0.02$). This result can be attributed to psychological discomfort ($p=0.007$) and psychological disability ($p=0.012$) (Table 2).

Table 2. OHIP evaluation by each domain.

Variable	Preoperative Traumeel	7 days after Traumeel	p-value	Preoperative Dexamethasone	7 days after Dexamethasone	p-value	p-value
						7 days after Traumeel	7 days after Dexamethasone
OHIP total	10.058 (6.10)	23.05 (11.46)	<0.001*	11.87 (9.34)	16.12 (10.17)	0.212	0.020*
Functional limitation	0.352 (0.70)	2.41 (1.69)	<0.001*	0.68 (1.07)	2.25 (1.80)	0.005*	0.322
Physical pain	2.94 (1.78)	5.23 (2.61)	0.023*	3.06 (1.69)	4.06 (1.87)	0.138	0.114
Psychological discomfort	2.76 (1.88)	3.05 (2.24)	0.64	3.12 (2.18)	1.83 (1.56)	0.053	0.007*
Physical disability	1.11 (1.40)	3.64 (2.62)	0.003*	1.43 (1.45)	2.75 (2.54)	0.129	0.172
Psychological disability	1.83 (1.97)	3.05 (2.24)	0.022*	1.81 (1.90)	1.93 (1.56)	0.467	0.012*
Social disability	0.64 (0.99)	3.52 (4.09)	0.003*	1.18 (1.64)	1.93 (1.84)	0.127	0.234
Handicap	0.41 (0.79)	1.17 (1.18)	0.086	0.56 (0.96)	1.31 (1.66)	0.082	0.943

Source: Authors.

4. Discussion

The aim of this study was to compare preemptive intramuscular injection of dexamethasone with intramuscular homeopathic preparation *Traumeel S*[®] in patients who underwent lower third molar surgery in respect of QoL at the seventh postoperative day. The main findings include: 1) There was a significant improvement of QoL following dexamethasone administration when compared to *Traumeel S*[®]; 2) There was no statistically significant difference between the two groups regarding the following outcomes: functional limitation, physical pain, psychological discomfort, physical disability, psychological disability, and social disability.

Dexamethasone acts differently from *Traumeel S*[®]. Thus, all the procedures and interventions in this study were standardized at a maximum level. In this way, the different results between the groups would only be addressed to the drugs' effects.

The previous published article resulted from this same research (de Souza et al., 2021), showed no statistically significant differences in rescue analgesic intake. However, as a result of the randomization, dexamethasone was administered mostly in the second surgery for each patient. Therefore, it could be suggested that the mean analgesic consumption for the second surgery might have been decreased if patients had not used this drug to avoid the same pain experience of the first surgery. This directly impact the results on QoL, since rescue analgesic consumption is linked to postoperative pain, which is strictly associated with QoL.

Following the same idea, dexamethasone may have shown better results on postoperative QoL than *Traumeel S*[®] because of psychological influences. A previous experience with pain, discomfort, and disabilities may prepare the individual to similar experiences that are to come. Thus, individuals may react in a lighter way to bad feelings that are not new anymore (Scherer, 2009). Also, individuals can react differently to similar situations and that supports a floating characteristic of a quality-of-life evaluation.

Pain is one of the symptoms that most influence the QoL. In this way, following the results of this study, pain was higher in the *Traumeel S*[®] group in the 48-hour follow-up (de Souza et al., 2021). This is explained by the half-life of dexamethasone, which is probably longer than the *Traumeel S*[®] (de Souza et al., 2021; Al-Dajani, 2017; Troiano et al., 2018). Thus, a lower impact on QoL is expected for those patients treated with dexamethasone.

Owing to the current literature, this is the first randomized clinical trial that compared effect of intramuscular injection of dexamethasone vs *Traumeel S*[®] after lower third molars surgery. Therefore, it was not possible to compare the recent findings to previous studies.

The limitations of the present study include the absence of a placebo/ control group to assess a real effect of both medications. On the other hand, the strengths of this study include: 1) all patients acted as his/her own control; 2) both surgeon, patients and assessor were blinded; 3) an intention-to-treat analysis was performed in order to preserve the random distribution. Further well-designed with larger sample size randomized clinical trials are suggested to compare and better elucidate the present results.

5. Conclusion

Preemptive intramassetric injection of dexamethasone was associated with better postoperative QoL than the homeopathic complex *Traumeel S*[®] after lower third molar surgeries at the 7th postoperative day.

Acknowledgments

The authors declare that there are no competing interests or any funding sources.

References

- Afonso, A., Silva, I., Meneses, R., Frias-Bulhosa, J., & Castro Afonso, A. (2017). Oral health-related quality of life: Portuguese linguistic and cultural adaptation of ohip-14. *Psicologia, Saúde & Doença*, 18, 374–88. [10.15309/17psd180208](https://doi.org/10.15309/17psd180208).
- Alcântara, C. E. P., Falci, S. G. M., Oliveira-Ferreira, F., Santos, C. R. R., & Pinheiro, M. L. P. (2014). Pre-emptive effect of dexamethasone and methylprednisolone on pain, swelling, and trismus after third molar surgery: a split-mouth randomized triple-blind clinical trial. *Int J Oral Maxillofac Surg*, 43(1), 93–8. [10.1016/j.ijom.2013.05.016](https://doi.org/10.1016/j.ijom.2013.05.016).
- Al-Dajani, M. (2017). Can preoperative intramuscular single-dose dexamethasone improve patient-centered outcomes following third molar surgery? *J Oral Maxillofac Surg*, 75, 1616–1626.
- Bhargava, D., Sreekumar, K., & Deshpande, A. (2014). Effects of intra-space injection of Twin mix versus intraoral-submucosal, intramuscular, intravenous and per-oral administration of dexamethasone on post-operative sequelae after mandibular impacted third molar surgery: a preliminary clinical comparative study. *Oral Maxillofac Surg*, 18(3), 293–6. [10.1007/s10006-013-0412-7](https://doi.org/10.1007/s10006-013-0412-7).
- de Souza, G. M., Fernandes, I. A., Pinheiro, M. L. P., & Falci, S. G. M. (2021). Comparative Effectiveness of the Homeopathic Preparation Traumeel S in Third Molar Extraction Surgery: A Preliminary Triple-Blind Clinical Trial. *Homeopathy*, 110(4), 229-235. [10.1055/s-0041-1725038](https://doi.org/10.1055/s-0041-1725038).
- Duarte-Rodrigues, L., Miranda, E. F. P., Souza, T. O., de Paiva, H. N., Falci, S. G. M., & Galvão, E. L. (2018). Third molar removal and its impact on quality of life: systematic review and meta-analysis. *Qual Life Res*, 27(10), 2477–89. [10.1007/s11136-018-1889-1](https://doi.org/10.1007/s11136-018-1889-1).
- Falci, S. G. M., de Castro, C. R., Santos, R. C., de Souza Lima, L. D., Ramos-Jorge, M. L., Botelho, A. M., & dos Santos, C. R. R. (2012). Association between the presence of a partially erupted mandibular third molar and the existence of caries in the distal of the second molars. *Int J Oral Maxillofac Surg*, 41(10), 1270–4. [10.1016/j.ijom.2012.03.003](https://doi.org/10.1016/j.ijom.2012.03.003).
- Falci, S. G. M., Lima, T. C., Martins, C. C., Santos, C. R. R. D., & Pinheiro, M. L. P. (2017). Preemptive Effect of Dexamethasone in Third-Molar Surgery: A Meta-Analysis. *Anesth Prog*, 64(3), 136–43. [10.2344/anpr-64-05-08](https://doi.org/10.2344/anpr-64-05-08).
- Fernandes, I. A., de Souza, G. M., Pinheiro, M. L. P., & Falci, S. G. M. (2019). Intramuscular injection of dexamethasone for the control of pain, swelling, and trismus after third molar surgery: a systematic review and meta-analysis. *Int J Oral Maxillofac Surg*, 48(5), 659–68. [10.1016/j.ijom.2018.09.014](https://doi.org/10.1016/j.ijom.2018.09.014).

- Galvão, E. L., da Silveira, E. M., de Oliveira, E. S., da Cruz, T. M. M., Flecha, O. D., Falci, S. G. M., & Gonçalves, P. F. (2019). Association between mandibular third molar position and the occurrence of pericoronitis: A systematic review and meta-analysis. *Arch Oral Biol*, 107, 104486. 10.1016/j.archoralbio.2019.104486.
- Galvão, E. L., Pedras, M. J., Cota, G. F., Simões, T. C., & Rabello, A. (2018). Development and initial validation of a cutaneous leishmaniasis impact questionnaire. *PLoS One*, 13(8), e0203378. 10.1371/journal.pone.0203378.
- Hupp, J. R., Ellis, E., Tucker, M. R. (2008). Contemporary oral and maxillofacial surgery. St. Louis: Elsevier.
- Lima, T. C., Bagordakis, E., Falci, S. G. M., Dos Santos, C. R. R., & Pinheiro, M. L. P. (2018). Pre-Emptive Effect of Dexamethasone and Diclofenac Sodium Associated With Codeine on Pain, Swelling, and Trismus After Third Molar Surgery: A Split-Mouth, Randomized, Triple-Blind, Controlled Clinical Trial. *J Oral Maxillofac Surg*, 76(1), 60–6. 10.1016/j.joms.2017.06.012.
- Mello, F. W., Melo, G., Kammer, P. V., Speight, P. M., & Rivero, E. R. C. (2019). Prevalence of odontogenic cysts and tumors associated with impacted third molars: A systematic review and meta-analysis. *J Craniomaxillofac Surg*, 47(6), 996–1002. 10.1016/j.jcms.2019.03.026.
- Messer, E. J., & Keller, J. J. (1975). The use of intraoral dexamethasone after extraction of mandibular third molars. *Oral Surg Oral Med Oral Pathol*, 40(5), 594–8. 10.1016/0030-4220(75)90369-2.
- Moher, D., Hopewell, S., Schulz, K. F., Montori, V., Gotzsche, P. C., Devereaux, P. J., Elbourne, D., Egger, M., & Altman, D. G. (2010). CONSORT 2010 explanation and laboration: updated guidelines for reporting parallel group randomised trials. *BMJ*, 340, c869
- Sancho-Puchades, M., Valmaseda-Castellón, E., Berini-Aytés, L., & Gay-Escoda, C. (2012). Quality of life following third molar removal under conscious sedation. *Med Oral Patol Oral Cir Bucal*, 17(6), e994-999. 10.4317/medoral.17677.
- Scherer, K. R. (2009). The dynamic architecture of emotion: Evidence for the component process model. *Cognition and Emotion*, 23(7), 1307-1351.
- Scientific Bio-Logics—Heel. Traumeel®. Accessed December 14, 2020 at: <http://www.healingedge.net/pdf/traumeel.pdf>
- Troiano, G., Laino, L., Cicciù, M., Cervino, G., Fiorillo, L., D'amico, C., Zhurakivska, K., & Lo Muzio, L. (2018). Comparison of Two Routes of Administration of Dexamethasone to Reduce the Postoperative Sequelae After Third Molar Surgery: A Systematic Review and Meta-Analysis. *Open Dent*, 12, 181-188.