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Phototherapy versus Occlusal Splint to control painful symptoms in Temporomandibular Disorder: controlled, randomized cost-effectiveness clinical trial

Fototerapia versus Placa Oclusal no controle da sintomatologia dolorosa na Disfunção Temporomandibular: Estudo clínico controlado randomizado e de custo-efetividade

Fototerapia versus Placa Oclusal para controlar los síntomas dolorosos en la Disfunción Temporomandibular: Estudio clínico aleatorizado controlado y de rentabilidad

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Abstract

Objective: To compare the efficacy of photobiomodulation and occlusal splint in patients with TMD-associated myofascial pain. Material and methods: 23 patients were randomized into 2 groups: laser group (LG) (n = 12) and occlusal splint group (OSG) (n=11). For the LG, laser was applied to 3 points on each side of the face. Twelve applications were made, 2 sessions per week. In the OSG, patients were instructed to use the device during sleep, 8 hours per night, for a period of 6 weeks, and 12 adjustment and follow-up sessions were performed. Patients in both groups were reevaluated 30 days after the end of the treatments. Results: There was a decrease in pain intensity, according to a visual analogue scale, in both groups before and after 1 month (LG, p = 0.008 and OSG p = 0.002), but with no difference between groups. For the quality of life, both treatments had a positive impact, with this impact being higher in the LG compared to the OSG (p <0.05). Regarding the cost-effectiveness analysis, laser was more cost-effective than the occlusal splint in the clinical trial. The incremental cost of the laser was $3,483.45 compared to the splint, but it had a cost ratio of $4,569.02 for controlled pain intensity while the splint showed $6,691.91 ratio for controlled pain intensity. Conclusion: The photobiomodulation was more cost-effective in controlling painful symptoms in patients with TMD and myofascial pain.

Keywords: Low-level light therapy; Temporomandibular joint disorders; Occlusal splints; Cost-effectiveness evaluation.

Resumo

Objetivo: Comparar a eficácia da fotobiomodulação e da placa oclusal em pacientes com dor miofascial associado à DTM. Material e métodos: 23 pacientes foram randomizados em 2 grupos: grupo laser (GL) (n = 12) e grupo placa oclusal (GPO) (n = 11). Para o GL, o laser foi aplicado em 3 pontos de cada lado da face. Doze aplicações foram feitas, 2 sessões por

semana. No GPO, os pacientes foram orientados a usar o aparelho durante o sono, 8 horas por noite, por um período de 6 semanas, sendo realizadas 12 sessões de ajuste e acompanhamento. Os pacientes de ambos os grupos foram reavaliados 30 dias após o término dos tratamentos. Resultados: Houve diminuição da intensidade da dor, de acordo com a escala visual analógica, nos dois grupos antes e após 1 mês (GL, p = 0,008 e GPO p = 0,002), mas sem diferença entre os grupos. Para a qualidade de vida, ambos os tratamentos tiveram impacto positivo, sendo esse impacto maior no GL em relação ao GPO (p <0,05). Em relação à análise de custo-efetividade, o laser foi mais custo-efetivo do que a placa oclusal no ensaio clínico. O custo incremental do laser foi de $ 3.483,45 em comparação com a tala, mas teve uma relação de custo de $ 4.569,02 para intensidade de dor controlada, enquanto a tala apresentou relação de $ 6.691,91 para intensidade de dor controlada. Conclusão: A fotobiomodulação foi mais custo-efetiva no controle da sintomatologia dolorosa em pacientes com DTM e dor miofascial.

Palavras-chave: Laser de baixa intensidade; Síndrome da disfunção da articulação temporomandibular; Placas oclusais; Avaliação de custo-efetividade.

Resumen

Objetivo: Comparar la eficacia de la fotobiomodulación y la férula oclusal en pacientes con dolor miofascial asociado a DAT. Material y métodos: 23 pacientes fueron aleatorizados en 2 grupos: grupo láser (GL) (n = 12) y grupo de férula oclusal (GFO) (n = 11). Para el LG, se aplicó láser en 3 puntos a cada lado de la cara. Se realizaron doce aplicaciones, 2 sesiones por semana. En el GFO, se indicó a los pacientes que utilizaran el dispositivo durante el sueño, 8 horas por noche, durante un período de 6 semanas, y se realizaron 12 sesiones de ajuste y seguimiento. Los pacientes de ambos grupos fueron reevaluados 30 días después del final de los tratamientos. Resultados: Hubo una disminución en la intensidad del dolor, según una escala analógica visual, en ambos grupos antes y después de 1 mes (LG, p = 0,008 y GFO p = 0,002), pero sin diferencias entre los grupos. Para la calidad de vida, ambos tratamientos tuvieron un impacto positivo, siendo este impacto mayor en el LG que en el GFO (p <0,05). En cuanto al análisis de rentabilidad, el láser resultó más rentable que la férula oclusal en el ensayo clínico. El costo incremental del láser fue de $ 3.483,45 en comparación con la férula, pero tuvo una relación de costo de $ 4.569,02 para la intensidad del dolor controlado, mientras que la férula mostró una relación de $ 6.691,91 para la intensidad del dolor controlado. Conclusión: La fotobiomodulación resultó más rentable en pacientes con DAT y dolor miofascial.

Palabras clave: Terapia por luz de baja intensidad; Trastornos de la articulación temporomandibular; Ferulas oclusales; Evaluación de costo-efectividad.

1. Introduction

According to the American Academy of Orofacial Pain, temporomandibular disorder (TMD) is defined as a set of disorders involving the masticatory muscles, the temporomandibular joint (TMJ) and associated structures. The most common symptoms include facial pain, pain in one or both TMJs and/or pain in the masticatory muscles, headache and earache. As for the signs, they include muscle and TMJ tenderness to palpation, limited and/or impaired mandibular movements and joint noise (Okeson, 2013; Leeuw, 2010).

Orofacial pain is any pain associated with soft and mineralized tissues (skin, blood vessels, bones, teeth, glands or muscles) of the oral cavity and face. This pain can be referred to the head and/or neck region or even be associated with cervical pain, primary headache and rheumatic diseases such as fibromyalgia and rheumatoid arthritis (Leeuw, 2010). TMDs are the most common non-dental cause of orofacial pain (Pozzebon, 2015), and muscle pain is the main complaint reported by patients with TMD, being associated with the feeling of fatigue and muscle tension, ranging from mild to extreme discomfort (Okeson, 2013). Having to live with pain is a very uncomfortable condition for any individual. Pain impairs physical and mental function and results in costly treatments and reductions of productivity and quality of life (Basto et al, 2017).

Several factors are identified as causes of TMD, among which: occlusion disorders and trauma that overload the temporomandibular joint, deleterious habits, poorly adapted prostheses and/or restorations, muscle changes, degenerative problems, functional changes, emotional problems and stress (Barreto et al., 2010). Identifying and controlling etiological factors are directly associated with treatment success. Conservative and non-invasive treatment is the one initially recommended, combining guidelines, occlusal splint therapy, pharmacotherapy and physiotherapy (Godinho et al., 2019).

Occlusal splints are widely used to treat patients with TMD, as they are considered a reversible therapy that temporarily promotes a more stable orthopedic joint positioning, reestablishing optimal functional occlusion, reorganizing the abnormal neuromuscular reflex activity, while providing a more adequate muscle function and protecting the teeth and support structures from abnormal forces that can erode or destroy them (Portero et al., 2009).

Low-level laser therapy (LLLT) has been shown to contribute to the symptomatic

treatment of TMD-related pain due to its analgesic and anti-inflammatory effects (Morais Maia et al., 2012; Dostalová et al., 2012; Cavalcanti et al., 2016; Melchior et al., 2016; Panhoca et al, 2013). A major advantage of LLLT for TMD is that it is a non-invasive, low-cost therapy that is currently being widely used in dental practice, reducing the need for surgery or the use of drugs for pain relief and tissue regeneration (Kato et al, 2006; Fikackova et al., 2006).

2. Materials and Methods

The purpose of this study was to carry out a comparative analysis of the effectiveness and costs of phototherapy and occlusal splint therapy in patients with TMD through a controlled and randomized clinical trial.

This is a prospective trial with a clinical and economic approach. Study activities were carried out on the premises of Nove de Julho University Clinical School of Dentistry. The study followed regulatory and ethical standards for human research and was submitted to the Research Ethics Committee of Nove de Julho University, having been given a favorable opinion (Opinion Number: 2.014.339). For being a clinical trial, the study was also registered in the ClinicalTrials.gov Identifier: NCT03096301 (March 9, 2017). Patients were instructed on study procedures and data collection was started after subjects had signed the informed consent form.

Patients aged 15 to 25, screened at UNINOVE Clinical School of Dentistry entered the study. Thirty patients were screened following the sample calculation based on studies with LLLT and occlusal splint, using DINAM 1.0 software (Godoy et al., 2013). For the diagnosis of TMD, the Research Diagnostic Criteria for Temporomandibular Disorders (RDC/TMD) (Pereira-Júnior et al., 2004) questionnaire was applied before any intervention.

The inclusion criteria included young people aged 15 to 25 years, with a diagnosis of TMD in group I (myofascial pain according to RDC-TMD) and also with a diagnosis of TMD in group I associated with group IIa (disc displacement with reduction). Individuals with dentofacial anomalies, who were undergoing maxillary orthodontic or orthopedic treatment, or under psychological and/or physical therapy were excluded. Subjects using myorelaxant or anti-inflammatory medications were also excluded. Subjects screened were assigned to 2 groups: Laser Group (LG) (n = 15) and Occlusal splint Group (OSG) (n=15). For the random distribution of subjects with TMD, randomization was carried out by draw, using research randomizer software.

2.1 Clinical Procedures

For low-power laser therapy, indium-gallium-aluminum phosphate (In-Ga-Al-P) device, by THERAPY EC, (DMC®, São Carlos, SP, Brazil) was used, with infrared wavelength of 808 nm ± 10 nm and 100 mW power, properly calibrated. Twelve laser applications were performed, two sessions per week. The 808nm wavelength with 100mW power was used for 60 seconds per point, resulting in a total energy of 6J per point (Table 1). Application was specific, in contact with the skin and with a conventional tip, according to the protocol suggested by Shobha et. al (2017) and Ahrari et al. (2013). Laser was applied to 3 points of the masseter muscle (upper, middle and lower bundles) and 1 point in the anterior temporal muscle on each side of the face (Venezian et al., 2010; Carvalho et al. 2009).

Table 1. Parameters of Photobiomodulation.

PARAMETERS	INFRARED LASER
Wavelength [nm]	808
Operating mode	Continuous
Power [mW]	100
Opening diameter [cm]	0.354 (beam diameter with spacer)
Aperture irradiance [mW/cm^2]	1,016
Beam profile	Gaussian
Beam area [cm^2]	0.0984 (with spacer)
Target irradiance [mW/cm^2]	1,016
Exposure time [s]	60
Fluency [J/cm^2]	61
Energy [J]	6
Number of irradiated points	8
Irradiated area [cm^2]	0.7872
Application technique	Contact
Number of sessions	12
Treatment frequency	2 times a week

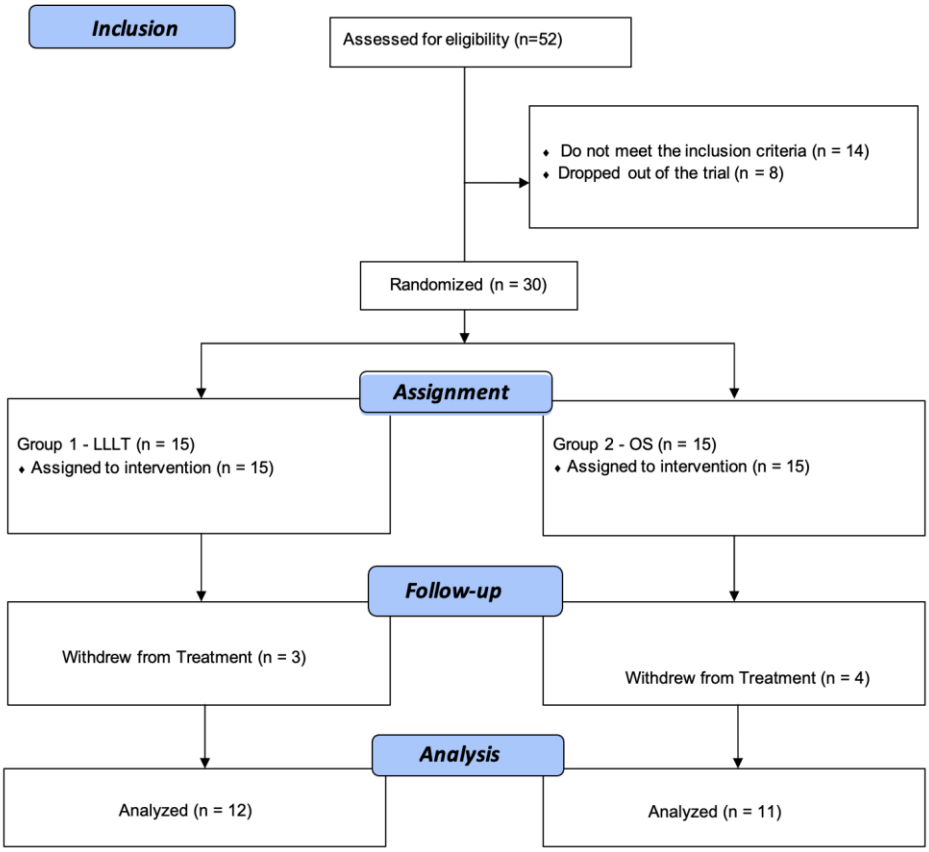
Source: Authors.

The group receiving occlusal splint therapy was instructed to use the device during sleep, 8 hours a night, for a period of 6 weeks, plus 1 month after treatment. The splints were made following the principles established by Okenson (2013). In the upper model, a 2 mm

acetate splint was made to be subsequently produced with acrylic resin (Botelho, 2012). and was centrically adjusted to promote occlusal stability and disocclusion guidance. Monitoring and adjustments were performed whenever necessary, during the evaluation period until the end of treatment (Botelho, 2012; Pomponio, 2010). Muscle pain was assessed using the clinical criteria of the Research Diagnostic Criteria for Temporomandibular Disorders (RDC/TMD). Clinical examination was performed at baseline and 1 month after treatment. To assess the impact of treatment on the subjects' quality of life, an EQ-5D-3L instrument was used, which consists of two stages, a questionnaire and a visual analogue scale (VAS). The instrument was applied at baseline and 1 month after treatment. Responses were compared between groups.

Because it is a controlled clinical trial and seeking greater transparency and high research standards, CONSORT (Consolidated Standards of Reporting Trials) recommendations, Figure 1, were followed.

Figure 1. Clinical study flowchart.



Source: Consort flowchart (Consolidated Standards of Reporting Trials).

2.2 Economic Procedures

In this study, a cost-effectiveness analysis of both groups studied was carried out and for that, it was necessary to obtain the cost-effectiveness data of each therapy. The study followed the Consolidated Health Economic Evaluation Reporting Standards (CHEERS), which are specific for reporting economic evaluation studies. Direct costs in both groups were calculated by adding the amount of each material used in each group (Silva et al., 2017) plus the cost of the visit. The cost of the visit (laser application session) was based on data presented by healthcare operators in Brazil, following information from TUSS (Unified Terminology for Supplementary Health - Medical Procedures), with code and description: 31602215- LASER - PER SESSION and description: 10101012 - OFFICE VISIT (http://www.ans.gov.br/images/stories/Legislacao/in/anexo_in34_dides.pdf). An average of 2 sessions per week was considered, with 6 weeks of laser therapy, according to what was observed in the protocol by Sobral et al. (2017).

In order to make it possible to compare TMD treatment costs and generalize the results of this economic study to other countries, US dollar was used as common reference (calculated based on the Central Bank website on November 1, 2019, of US$ 39,786). The effectiveness of both treatments will be measured by assessing pain and quality of life.

2.3 Data Analysis

To analyze clinical trial data, data distribution was assessed using the Kolmogorov-Smirnov test and it was found that the variables had a normal distribution. To compare both groups studied before and after treatment, t-paired and two-way ANOVA tests were used, complemented by Bonferroni. For all analyses, a statistically significant difference of $\alpha = 0.05$ was considered. Data were analyzed using the SPSS 23.0 statistical package (IBM Corporation).

3. Results

Thirty patients were included in the study, of which 7 patients withdrew from treatment and 23 patients completed the study (LG = 12 and OSG = 11). Of these patients, 91.3% (21) are female and the mean age of the subjects was 22.91 years.

3.1 Pain Outcome Analysis

Pain was assessed using RDC/TMD at the baseline (before treatment) and 1 month after the end of treatment. Pain data of patients with TMD included in the study had a normal distribution. Table 2 shows comparison data for both treatments, where we observed a statistically significant difference in terms of pain reduction between the laser and the splint groups before and 1 month after treatment for the following parameters: overall facial pain (1.455* / p<0.0001), right side pain (1.455* / p<0.0001) and left side pain (1.000 / p=0.009), with laser therapy showing superior results compared to the occlusal splint. Laser therapy also showed superior and statistically significant results compared to occlusal splint therapy for the following parameters: maximum mouth opening without (4.727* / p<0.0001) and with assistance (4.000* / p<0.0001), and joint pain (1.091 * / p=0.010). The occlusal splint group showed superior results compared to the laser group for the following parameters: muscle pain (0.909* / p=0.047) and VAS right temporal muscle (0.364 * / p=0.048).

Table 2. Comparison between groups at different times of assessment.

						95% CI	
	Group	Time		Mean difference	p-value	Lower limit	Upper limit
Facial pain	Laser	1	2	1.455*	p<0.0001	0.745	2.164
	Splint	1	2	0.455	0.196	-0.255	1.164
Right side pain	Laser	1	2	1.455*	p<0.0001	0.745	2.164
	Splint	1	2	0.455	0.196	-0.255	1.164
Left side pain	Laser	1	2	1.000*	0.009	0.275	1.725
	Splint	1	2	0.636	0.082	-0.088	1.361
Maximum opening without assistance	Laser	1	2	-4.727*	p<0.0001	-6.708	-2.747
	Splint	1	2	-1.727	0.084	-3.708	0.253
Muscle pain	Laser	1	2	0.818	0.071	-0.077	1.714
	Splint	1	2	0.909*	0.047	0.014	1.805
Joint pain	Laser	1	2	1.091*	0.010	0.289	1.893
	Splint	1	2	0.182	0.642	-0.620	0.984
Maximum opening with assistance	Laser	1	2	-4.000*	p<0.0001	-5.748	-2.252
	Splint	1	2	-1.364	0.119	-3.112	0.385
VAS – Temporal -	Laser	1	2	0.000	1.000	-0.360	0.360

Right	Splint	1	2	0.364*	0.048	0.004	0.723
VAS – Temporal - Left	Laser	1	2	-0.091	0.534	-0.391	0.209
	Splint	1	2	0.182	0.220	-0.118	0.482
VAS – Masseter - Right	Laser	1	2	0.455	0.070	-0.040	0.949
	Splint	1	2	0.182	0.452	-0.313	0.676
VAS – Masseter - Left	Laser	1	2	0.091	0.775	-0.563	0.745
	Splint	1	2	0.545	0.097	-0.109	1.200
VAS - Pterygoid muscle - Right	Laser	1	2	0.636	0.065	-0.045	1.317
	Splint	1	2	0.091	0.784	-0.590	0.772
VAS - Pterygoid muscle - Left	Laser	1	2	0.364	0.410	-0.538	1.265
	Splint	1	2	0.364	0.410	-0.538	1.265

Source: Authors

3.2 Outcome of Quality of Life Analysis

The impact of treatment on the quality of life of patients with TMD was measured using the EQ-5D-3L instrument, where 0 represents the worst health status and 100 the best one. Table 3 shows data regarding comparison between groups before and 1 month after treatments.

When treatments were compared, an improvement in patients' health status was observed in both treatment groups, the laser group (17,500*) and the occlusal splint group (11,818*), before and 1 month after treatment. Laser therapy (p=0.011) showed a superior and statistically significant improvement when compared to the occlusal splint group (p=0.084). Therefore, both treatments were effective in improving patients' quality of life. However, laser therapy provided a more significant improvement.

Table 3. Comparison of health status between groups before and 1 month after treatment.

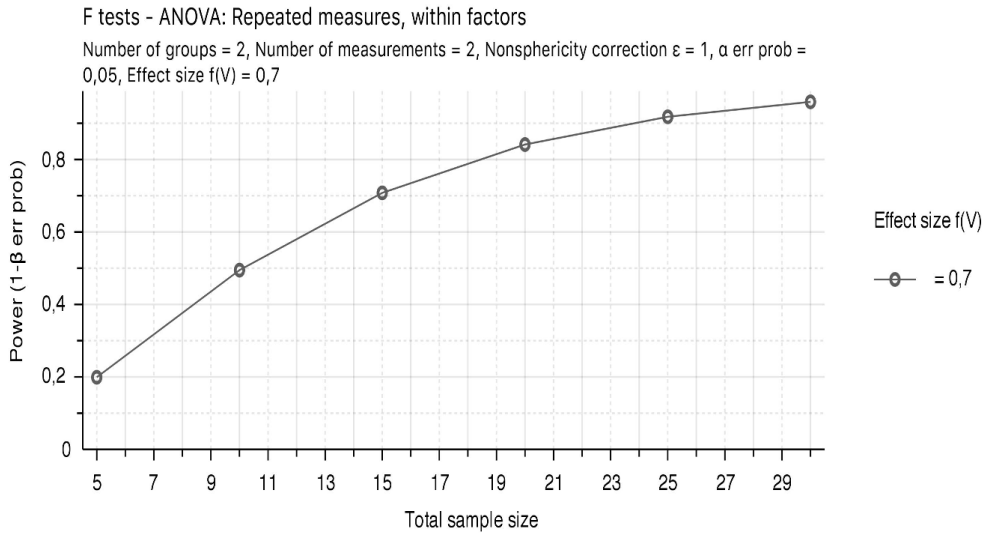
Group	Time	Mean	Mean difference	Sig.	95% CI Lower limit	95% CI Upper limit
Laser	Before	68.33			-30.461	-4.539
	1 month after	85.83	17.500*	0.011	4.539	30.461
Splint	Before	72.72			-25.356	1.719
	1 month after	84.54	11.818	0.084	-1.719	25.356

Source: Authors.

3.3 Sample Effect Size

The size of the sample effect reflects the magnitude of the difference between the experimental and control groups. Effect measurements were defined by Cohen at three levels: small if 0.20 < d < 0.50, satisfactory if 0.50 < d < 0.80 and great if 0.80 < d. Sample calculation defined n of 15 patients for each group. As in this clinical trial the final score was n=12 for the laser group and n=11 for the splint group, the sample effect was calculated and yielded 0.7.0 (d=0.7), showing a satisfactory level (Figure 2).

Figure 2. Sample Effect Size.



Source: Authors.

3.4 Cost-Effectiveness Analysis: Pain and Quality of Life

For the cost-effectiveness calculations, US dollar ($) was used and for the effectiveness calculations, pain and quality of life outcomes were used.

In this paper, the measurement unit of effectiveness was characterized by the clinical performance of treatments; for the Pain and Quality of Life Outcomes, the difference in the mean scores before and 1 month after treatments was considered "Clinical Success": Laser Group - Pain = 1.33 / Quality of life = 17.50 and Occlusal splint Group - Pain = 0.45 / Quality of Life = 11.81

The randomized clinical trial provides accurate information for calculating the cost-effectiveness ratio. Table 4 shows treatment costs in the laser and occlusal splint groups for the Pain outcome.

Table 4. Description of treatment costs in the laser and splint groups.

	Laser group	**Occlusal splint group Splint handed in + 11 Outpatient Visits**
Cost of 12 sessions*		
Cycle per patient	$506.40	$273.76
Cost of 12 sessions*	$6,076.8	$3,011.36
Total N cycle	n=12	n=11

* 12 sessions = TMD treatment cycle.
Source: Authors.

ICER (incremental cost-effectiveness ratio), that is, the incremental cost per unit of benefit obtained, was calculated for both groups studied with the Pain and Quality of Life Outcomes. ICER was calculated considering the cost of treatment in 12 sessions and considering the difference in the mean scores before and 1 month after treatment in the Laser Group and Occlusal splint Group.

The incremental cost for the Pain outcome in this study is $3,483.45; whereas for the Quality of Life outcome, it is $538.74. The cost-effectiveness ratio in the laser and splint groups was $4,569.02 and $6,691.91 / per controlled pain intensity, respectively. This shows that laser therapy was more cost-effective than splint treatment in controlling pain in patients

with TMD. As for Quality of Life, cost-effectiveness in the laser group was $347.24 and in the splint group it was $254.98 / per impact on quality of life. Although the splint group is more cost-effective regarding the positive impact on patients' quality of life, we can see that for the same time interval, the laser group had a greater number of patients with clinical success when compared to the splint group.

4. Discussion

The American Academy of Orofacial Pain defines TMD as a set of disorders involving the masticatory muscles, the TMJ and associated structures. TMD is the second most common type of orofacial pain, with an estimated prevalence of 3 to 15% of the population (Bender, 2014).

The studies by Dantas et al. (2015) and Cordeiro et al. (2012) showed that more women than men look for a specialized service in orofacial pain and that the patients evaluated showed TMD and high emotional tension. These findings support the data found in this study, where 91.3% of the patients included in the research study are female.

The studies by Maia et al. (2012); Fikáckova et al. (2007); Shirani et al. (2009); and Ahrari et al. (2013) confirm the results of this study regarding significant improvement in muscle pain in patients of the laser group (12 treatment sessions) when the periods before and after treatment are compared. Reduced pain sensitivity can be justified due to the cumulative effect of low-power laser and modulation of the inflammatory process (Carrasco et al. 2008).

In this clinical study, both laser and occlusal splint treatments improve patient's pain and mouth opening when comparing the periods before and 1 month after treatment, but there was no statistical difference between the groups.

Demirkol et al. (2015) evaluated the effects of LLLT and the use of occlusal splints in patients showing signs and symptoms of TMD with myofascial pain according to RDC/TMD. Thirty subjects were screened and assigned to 3 groups: occlusal splint, LLLT, and placebo. Pain intensity values were observed to have been reduced after treatment in both groups (LLLT and occlusal therapy) compared to the placebo group that did not show statistical differences. The authors concluded that the specific dosage in LLLT was as effective as the occlusal splint therapy in reducing pain in individuals with TMD who had myofascial pain.

The study by Oz et al. (2010) evaluated the effects of low-level laser and occlusal splint to treat patients with signs and symptoms of myofascial TMD. A total of 40 patients were randomly assigned to 2 groups: laser and control (occlusal splint). Comparisons were

made within and between groups before and after treatment. Vertical movements showed statistically significant improvements after treatments in both groups, but when the groups were compared, there was no significant difference between them. In both groups, tenderness to muscle palpation decreased significantly. Assessments of pressure pain thresholds and VAS scores also revealed similar results. It was possible to conclude that laser therapy is as effective as the occlusal splint therapy in improving pain and jaw movements in patients with myofascial TMD.

Maia et al. (2012) carried out a systematic review of the literature to investigate the effect of laser therapy on pain levels in individuals with TMD. Studies were surveyed from January 2003 to October 2010 and the authors stated that in most of the studies LLLT has been shown to be effective in reducing pain in patients with TMD.

The study by Biasotto-Gonzalez et al. (2009) was intended to classify TMD patients and find a relationship between the condition and the impact on quality of life. This study showed a direct influence of the TMD degree on the quality of life of symptomatic subjects, with harm mainly to mental characteristics such as Vitality and Emotional Aspects.

Kuroiwa et al. (2011) evaluated the Quality of Life of patients with temporomandibular disorders and/or orofacial pain and concluded that the aspects of pain and functional capacity interfere with the general health status. They also identified that patients with TMD and Orofacial Pain had a negative impact on quality of life due to physical and mental aspects being impaired.

This clinical trial showed that laser therapy improved patients' quality of life, and proved to be superior and statistically significant when compared to the improvement offered by the occlusal splint treatment.

Cost-effectiveness calculation showed that laser therapy was more cost-effective than the splint treatment in controlling pain in TMD patients. Regarding Quality of Life, cost-effectiveness of the laser group showed a higher value for impact on quality of life than the occlusal splint group. Although the splint group is more cost-effective in relation to positive impacts on patients' quality of life during the same time interval, laser therapy showed a greater number of patients with clinical success when compared to the occlusal splint group.

5. Conclusions

The controlled and randomized clinical trial conducted found that laser and occlusal splint treatments were effective in reducing pain in patients with myofascial TMD. It also

found that there was no statistically significant difference in some of the variables related to pain reduction in patients with TMD when comparing laser and occlusal splint therapies. In the Quality of Life outcome, both treatments (laser and occlusal splint) were effective in improving patients' quality of life. However, when treatments were compared, laser therapy was more effective than the occlusal splint. Regarding the cost-effectiveness analysis, laser therapy was more cost-effective than the occlusal splint in this clinical trial.

A limitation of the present research was to evaluate the patients only 01 month after the end of the treatments, as TMD is complex, we could have followed the patients for a longer period of time, which could better reflect some difference between the groups.

As a suggestion for future research, we have the measurement of pain with VAS, immediately after each laser application.

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