Comparison between Simple Planas Indirect Tracks and occlusal splints for treatment of temporomandibular disorder-related headache: a randomized controlled clinical trial

Comparação entre Pistas Indiretas Planas Simples e placas miorrelaxantes para tratamento de dor de cabeça relacionada à disfunção temporomandibular: ensaio clínico randomizado

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ABSTRACT

BACKGROUND AND OBJECTIVES: Temporomandibular disorder-related headache (TMDH) is a very common clinical condition which manifests as pain around the temples. The treatment recommended in dentistry is occlusal splint. However, there is a device generally used in functional jaw orthopedics, called simple Planas indirect tracks (SPIT), which has been shown to be efficient in managing these headaches. This clinical trial aimed to compare SPIT and occlusal splints in the treatment of TMDH patients.

METHODS: This randomized clinical trial included thirty-seven women who had TMDH for more than one year into three groups: GPIT treated with SPIT, GSPLINT treated with a Michigan splint, and a control group (CG) submitted to no treatment. The randomization was paired, that is, each new individual was assigned to a group sequentially. The number of headache days per month, average pain intensity, pain response to masseter and temporalis palpation, and days of pain drug use were collected and analyzed. The follow-up lasted for 3 months.

RESULTS: Thirty-seven patients were included but 4 dropped out during treatment and 33 underwent intervention. Patients in GPIT exhibited superior results compared to GSPLINT and CG, with significant differences between groups for almost all variables. In GPIT, the number of headache days was reduced by 87.43%, pain intensity by 66.67%, and days of drug use by 88.42%, with significant improvement in all parameters compared to CG. In GSPLINT, the number of headache days decreased by 44.46% and days of drug use by 36.63%, while pain intensity increased by 46.67%; however, there was no significant difference in any of the parameters compared to CG.

CONCLUSION: SPIT may be a good treatment option for patients with TMDH since these appliances have shown much more consistent results than occlusal splints. Further studies and with more individuals will be needed to confirm these findings.

Keywords: Headache, Headache disorders, Occlusal splints, Planas Indirect Tracks, Secondary headache disorders, Temporomandibular joint dysfunction syndrome.

RESUMO

JUSTIFICATIVA E OBJETIVOS: A cefaleia secundária à disfunção temporomandibular (CDTM), é uma condição clínica muito comum, com dores nas têmporas. O tratamento padrão na odontologia são as placas miorrelaxantes, entretanto um aparelho da ortopedia funcional dos maxilares, chamado de Pistas Indiretas Planas Simples (PIPS), tem se demonstrado eficiente no controle dessas cefaleias. Este estudo clínico visou comparar as PIPS com as placas miorrelaxantes, no quadro álgico de CDTM.

MÉTODOS: Este ensaio clínico randomizado incluiu 37 mulheres portadoras de CDTM há mais de um ano, que foram distribuídas aleatoriamente em três grupos: o GPIPS, no qual as pacientes foram tratadas com PIPS, o GPLACA, com uso de placas miorrelaxantes de Michigan e o grupo controle (GC), sem qualquer tratamento. A aleatorização foi pareada, sendo que cada participante era consecutivamente alocada em um grupo diferente. Foram coletados e analisados dias de cefaleia por mês, intensidade de dores, resposta álgica à palpação de masseter e temporal, bem como os dias de uso de fármacos. O acompanhamento foi de três meses.

RESULTADOS: Das 37 pacientes iniciais, 4 desistiram do tratamento e apenas 33 foram submetidos a alguma intervenção. As pacientes do GPIPS apresentaram resultados muito superiores às do GPLACA e do GC, com diferenças significativas entre os

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HIGHLIGHTS

- Planas Indirect Tracks performed better than occlusal splints in the treatment of headache secondary to temporomandibular disorder.
- Planas Indirect Tracks reduced the number of days with headache, the intensity of pain and use of analgesics.
- Planas Indirect Tracks may be a viable alternative for headache control.

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grupos em quase todas as variáveis. No GPIPS, os dias de dor diminuíram 87,43%, a intensidade 66,67% e os dias de uso de fármacos analgésicos 88,42%, sendo estatisticamente significante a melhora em todos os parâmetros em relação ao GC. Já no GPLACA, os dias de dor diminuíram 44,46% e os dias de uso de fármacos 36,63%, mas a intensidade da dor aumentou 46,67%, porém sem diferença estatisticamente significativa em nenhum parâmetro quando comparado ao GC.

CONCLUSÃO: O uso do PIPS pode ser uma boa escolha de tratamento da CDTM, tendo apresentado resultados mais consistentes do que as placas miorrelaxantes. Mais estudos e com mais participantes são necessários para confirmar estes achados.

Descritores: Cefaleia, Distúrbios de cefaleia, Distúrbios secundários de cefaleia, Pistas Indiretas Planas, Placas miorrelaxantes, Síndrome de disfunção da articulação temporomandibular.

INTRODUCTION

Headaches are one of the most common complaints of the general population and are among the ten most symptomatic conditions seen in the clinical practice[1]. The International Classification of Headache Disorders proposed in 2018 by the International Headache Society distinguishes between primary and secondary headaches, whereas patients can have both primary and secondary headaches simultaneously[2].

According to the literature, headaches are the main symptom in patients with temporomandibular disorders (TMD), if not the only one[1-4]. Peripheral and central factors have been recognized to play a role in the pain that occurs in TMD[5], which is often confused with primary headaches such as tension-type headache. A study[6] reported a TMD prevalence of 56.1% in a population of patients with primary headaches, with no significant differences between primary headache groups.

However, the prevalence tended to be higher among patients who had a combination of migraine and tension-type headache[7,8]. Moderate to severe depression was present in 54.1% of patients with TMD[6,9]. On the other hand, about 70% of individuals with TMD have headaches, which are the most common symptom and the complaint most frequently reported by patients with TMD[10]. One explanation for this finding would be the presence of parafunctional habits such as bruxism, which can lead to hyperfunction of the masticatory muscles and consequently to headaches[11,12]. Simple palpation tests of the muscle and joint can be performed to assess the relationship between primary and TMD-derived headaches[13].

The headache observed in TMD exhibits a characteristic pattern. It occurs in the temporal, frontal and retro-ocular regions and can be unilateral or bilateral, whose intensity ranges from mild to severe. This type of headache occurs more frequently at the end of the day. Studies have reported a moderate relationship with changes in emotional state and fatigue, as well as a preponderance in females[3,14,16].

Several treatments have been proposed, including the use of drugs[17], physical therapy[18], osteopathy and cognitive-behavioral therapy[19,20], as well as other alternative approaches such as meditation, relaxation techniques[21], or stress management[22]. In dentistry, the gold standard treatment are occlusal splints. These appliances consist of an acrylic orthosis that prevents contact between the upper and lower teeth, altering occlusal proprioception. Tooth clenching would not be eliminated but the damage to the muscles will be less intense, reducing headaches associated with TMD. The mechanism underlying the effect of splints is still unclear but the appliance is able to reduce muscle pain[23,24].

A treatment commonly used in functional jaw orthopedics for headaches associated with TMD are simple class II Planas indirect tracks (SPIT II), which were initially developed to treat retrognathia in children. These appliances consist of acrylic tracks which, in addition to promoting disocclusion like occlusal splints, have the advantage that they enable free lateral movement of the mandible and promote mandibular protrusion. There are currently no investigations that evaluated the results of SPIT II for the management of headaches associated TMD in adults. This is why the present study was conducted.

METHODS

This is a randomized clinical trial that involved patients attended at NEOMSP-Health Education and Research (NEOMSP-*Ensino e Pesquisa em Saúde)*, São Paulo, Brazil. This study was approved by the local Ethics Committee (Ethical Clearance Certificate 31985920.7.0000.5485) and all participants signed the Free and Informed Consent Term (FICT).

Criteria for inclusion were age between 20 and 50 years, headache duration of more than one year, at least one pain episode per week, and pain upon palpation of cranial and/cervical muscles. Patients who had been submitted to other headache treatments were excluded.

Primary outcome was the number of days with pain, before starting treatment (initial) and 3 months afterwards (final). Secondary outcomes were initial and final pain intensity (in the last 30 days). Pain intensity upon the palpation of the masseter and the temporalis, as well as the number of days of drug use (in the last 30 days) were also evaluated.

The sample size was determined statistically based on other studies, with 13 individuals by group.

Thirty-three women participated in the study. The mean age was 38.46 (sd 9.9) years. All subjects were randomly and consecutively assigned by a blind assistant to one of the following three groups: GSPLINT, consisting of 11 women who received an upper acrylic (Michigan) splint; GPIT consisting of 13 women who were treated with SPIT II, and a control group consisting of 9 women who were not submitted to any treatment. The recruitment and follow-up period were from August 2020 to January 2021.

Four individuals from the control group withdrew from the project for personal reasons and two individuals from the GSPLINT group withdrew because they did not have positive results.

The Michigan occlusal splint is a mobile appliance made of acrylic resin with canine guides that fit perfectly in the upper or lower arch. It is designed to allow maximum contact between antagonist teeth while creating total disocclusion (Figure 1). This appliance is considered the gold standard treatment for TMD in dentistry[26].

SPIT II is based on the law of minimum vertical dimension, as described by study[25]. This law states that the mandible will

Figure 1. Lateral and occlusal view of the Michigan splint.

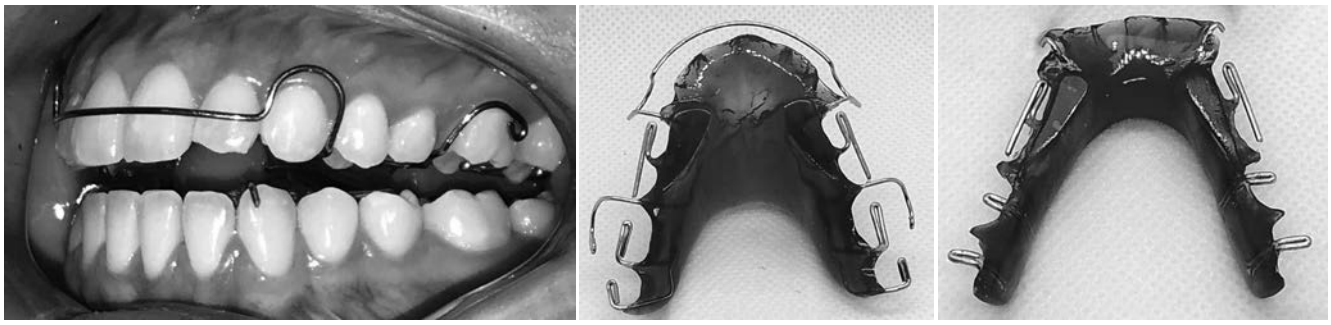

Figure 2. Lateral and occlusal view of simple class II Planas indirect tracks (SPIT II).

always seek the smallest possible vertical dimension and not the maximum habitual intercuspation. Based on this law, the maximum habitual intercuspation becomes a consequence of the minimum vertical dimension, a key fact to understand the function of this device. SPIT II is composed of two parts, an upper and a lower one, equipped with tracks made with an ascending inclination in the posteroanterior direction (Figure 2)[25].

When the mouth is closed seeking dental occlusion, the mandible recedes and the "upper" part of the lower track touches the "upper" part of the upper track, increasing the vertical dimension. Since the organism tends always to seek the smallest vertical dimension, this retruded position causes discomfort and induces the mandible to assume a more anterior position. The consequence is protrusion of the mandible, in addition to an innate vertical lift of the appliance. For this reason, the device received the denomination II, i.e., it was initially designed to treat patients with class II malocclusion or mandibular retrognathism[25].

Another characteristic of SPIT II is that it prevents the upper and lower teeth from touching since contact only occurs between tracks. The absence of interferences permits free lateral movement of the mandible[25].

All participants in the study had a first appointment that included the application of the questionnaire recommended by the American Academy of Orofacial Pain[11], as well as specific clinical examination of TMD-related headache, with emphasis on tender points in the temporalis and masseter muscles. Clicking, deviation during movement, and pain upon direct palpation of the temporomandibular joints were also evaluated. To assess the frequency, laterality, average intensity (0 = no pain, 1 = mild pain, 2 = moderate pain, and 3 = severe pain), triggers, and drugs used, each participant completed an electronic headache diary in the first month (baseline) in order to evaluate headache behavior before any intervention (application for iOS or Android developed by *Libbs Farmacêutica* Ltd.).

In the first appointment, molds were taken from the participants in GPIT and GSPLINT for fabrication of their respective appliances. No intervention was performed within the first 30 days after the first appointment to obtain a reference for future intragroup comparison.

After 30 days, patients in GSPLINT received the occlusal splints, which were adjusted with correctly distributed contact points and well-defined canine guides. In the GPIT, SPIT II was installed and the necessary adjustments of the tracks were made using Bausch 200 Micron Articulating Paper, with at least 75% of the contact area between them being marked. Photographs were also taken for clinical control and measurement of the inclination of the tracks in relation to Camper's plane and the occlusal plane. Participants in CG were not submitted to any instrumental in-

tervention and their follow-up was the same as that used in the groups receiving the intervention.

All participants in the three groups had monthly appointments for 3 months. Headache behavior was monitored via the application that continued to be completed monthly by all participants. The devices and splints were adjusted according to the information collected by the electronic diary.

In GPIT, in the absence of pain relief, the inclination of the tracks was increased in the anteroposterior direction. In GSPLINT, the most frequent adjustments involved the canine guides or the wear of premature points. Participants in CG had clinical appointments for pain monitoring.

Three months after installation of the devices, the participants again filled out the questionnaire and were submitted to a new clinical examination (palpation) and collection of the app data.

As determined by the Ethics Committee, molds were taken from patients in CG for fabrication of the device that provided the best results.

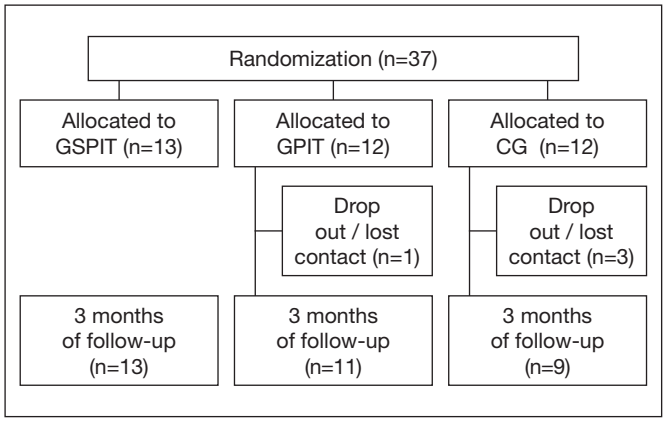

Figure 3. Participant flow diagram

Table 1. Age (years) of the participants according to group

[1]Group	Mean (standard deviation)	Median (interquartile range)
GPIT	37.8 (10.2)	38.0 (31.0; 44.0)
GSPLINT	39.7 (9.9)	42.0 (35.5; 47.0)
CG	37.9 (9.6)	42.0 (36.0; 44.0)

p=0,8744. [1]GPIT = dental treatment using SPIT II; GSPLINT: dental treatment using occlusal splints; GC: without the use of any intraoral appliance.

Statistical analysis

All analyses were performed using the R statistical program. The age of the participants was compared using one-way Analysis of Variance (ANOVA). The variables number of pain days, pain intensity and number of days of drug use did not meet the assumption of parametric analysis. Thus, the Kruskal-Wallis and Dunn tests were used for comparison between groups and the paired Wilcoxon test for comparison between time points. Pearson's correlation test was used to correlate track inclination of the SPIT II with headache intensity. A level of significance of 5% was adopted for all analysis.

RESULTS

Thirty-seven patients were included in this research, but four dropped out during treatment and 33 underwent intervention There was no significant difference for participant age between groups. The age of the sample ranged from 20 to 59 years, with a mean age of 38.33 years (p=0.874).

At baseline, no significant difference in the number of pain days, pain intensity or number of days of drug use was observed between the three groups (p > 0.05 - tables 1 and 2 - figures 4 to 8).

Table 2. Intra and intergroup comparison of number of pain days, pain intensity (scale from 0 – no pain to 3 – intense pain), pain response to masseter and temporalis muscle palpation, and days of drug use at baseline and after intervention.

Variables	[1]Group	Time					p-value
		Baseline		After intervention			
		Mean (SD)		Mean (SD)		Difference	
Number of pain days	GPIT	18.3 (7.9)	Aa	2.3 (2.6)	Bb	-87.43%	0.0015*
	GSPLINT	20.6 (5.9)	Aa	11.4 (6.6)	Ba	-44.66%	0.0033*
	CG	16.9 (7.5)	Aa	18.8 (8.5)	Aa	11.24%	0.5286
Monthly average pain intensity	GPIT	1.8 (0.5)	Aa	0.6 (0.5)	Bb	-66.67%	0.0019*
	GSPLINT	1.5 (0.3)	Ba	2.2 (0.6)	Aa	46.67%	0.0234*
	CG	1.8 (0.3)	Aa	1.6 (0.4)	Aa	-11.11%	0.1508
Masseter palpation	GPIT	2.2 (0.8)	Aa	0.8 (0.7)	Bb	-63.64%	0.0051*
	GSPLINT	1.8 (1.0)	Aa	1.4 (0.9)	Aab	-22.22%	0.3254
	CG	2.0 (1.0)	Aa	2.0 (1.0)	Aa	0.00%	1.0000
Temporalis palpation	GPIT	2.2 (0.7)	Aa	0.8 (0.7)	Bb	-63.64%	0.0022*
	GSPLINT	2.1 (0.7)	Aa	1.4 (0.8)	Bab	-33.33%	0.0277*
	CG	2.0 (0.9)	Aa	2.0 (0.9)	Aa	0.00%	1.0000
Drug use (days)	GPIT	9.5 (10.1)	Aa	1.1 (1.8)	Bb	-88.42%	0.0076*
	GSPLINT	10.1 (8.2)	Aa	6.4 (8.1)	Ba	-36.63%	0.0129*
	CG	6.7 (4.0)	Aa	7.8 (5.6)	Aa	16.42%	0.4990

Different letters (uppercase in rows and lowercase in columns) indicate statistically significant differences (p≤0.05). [1]GPIT = dental treatment with SPIT II; GSPLINT = dental treatment with occlusal splint; CG = no intraoral appliance; SD = standard deviation. * Statistically significant.

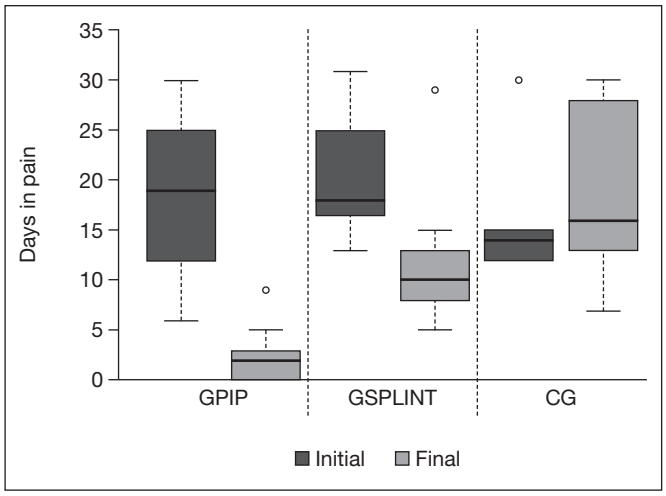

Figure 4. Box plot of the number of pain days (last 30 days)

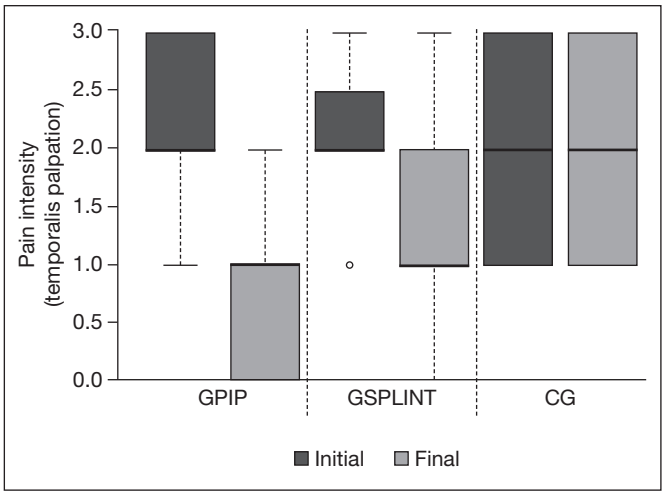

Figure 7. Box plot of initial and final pain intensity per temporal palpation

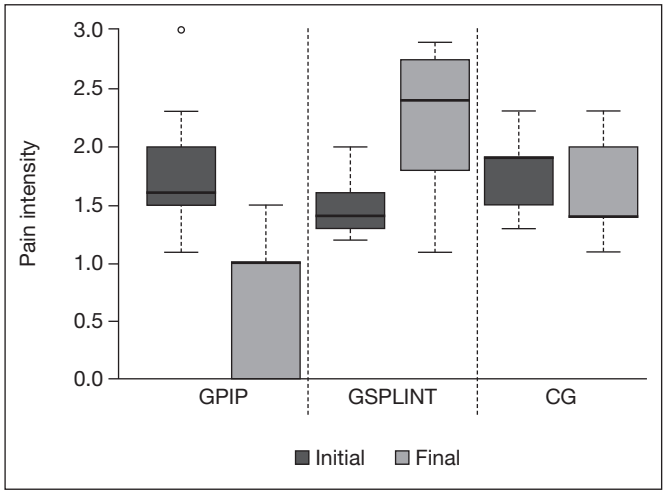

Figure 5. Box plot of initial and final pain intensity (in last 30 days)

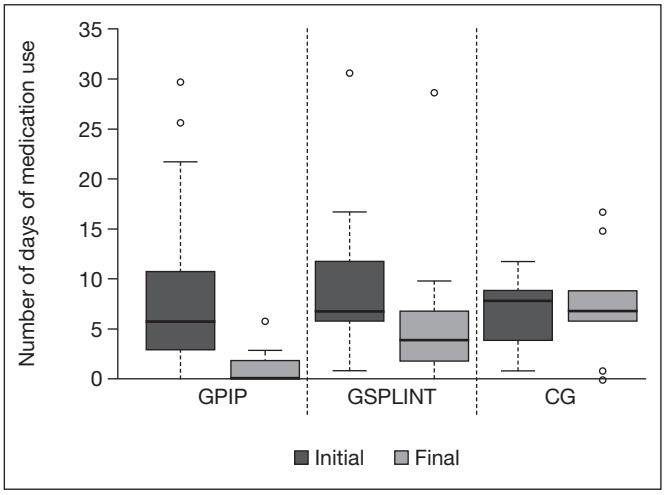

Figure 8. Box plot of the number of days of drug use (in the last 30 days)

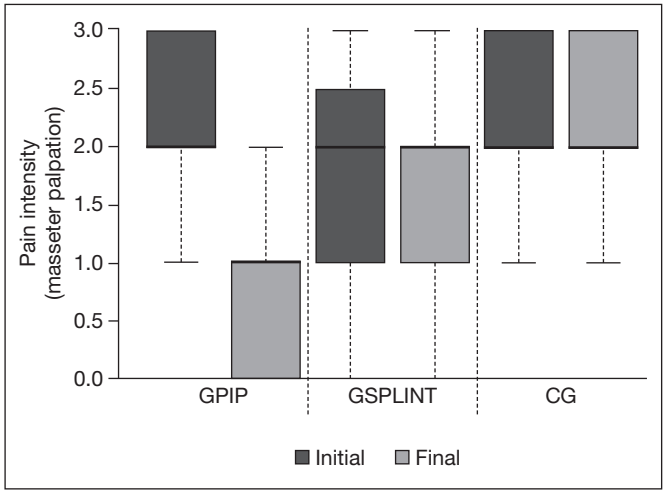

Figure 6. Box plot of initial and final pain intensity per masseter palpation

Patients in GPIT showed a significant reduction in the number of pain days (-87.43%), monthly average pain intensity (-66.67%), pain upon masseter (-63.64%) and temporalis palpation (-63.64%), and number of days of drug use (-88.42%) ($p < 0.05$ for all) after the intervention. In GSPLINT, there was a significant reduction in the number of pain days (-44.66%), pain upon temporalis palpation (-33.33%), and number days of drug use (-36.63%), but not in pain upon masseter palpation ($p = 0.3254$). However, average pain intensity was significantly increased in GSPLINT by 46.67% ($p = 0.0234$). No significant differences compared to baseline were observed in CG.

Intergroup comparison showed that GPIT was statistically superior compared to CG for all variables.

Compared to GSPLINT, GPIT was statistically superior in terms of the number of pain days, monthly average pain intensity, and number of days of drug use. No significant dif-

ference in pain upon masseter or temporalis palpation was observed between groups. However, there was no significant difference in any variable analyzed between GSPLINT and CG. Figures 4 to 8 illustrate these differences.

Table 3 shows the descriptive analysis of track inclination and incisor distance.

A directed and moderate correlation (r=0.68) was observed between track inclination and pain intensity (Figure 9).

Table 3. Inclination of the tracks in relation to Camper's plane and occlusal plane and vertical distance between upper and lower central incisors with the use of SPIT II.

Variables	Mean (standard deviation)	Median (interquartile range)
Track inclination – Camper's plane (in degrees)	9.35 (4.77)	10.50 (7.00; 11.0)
Track inclination – occlusal plane (in degrees)	10.31 (2.85)	10.50 (8.50; 12.00)
Incisor distance (in mm)	4.85 (2.30)	4.00 (3.00; 6.00)

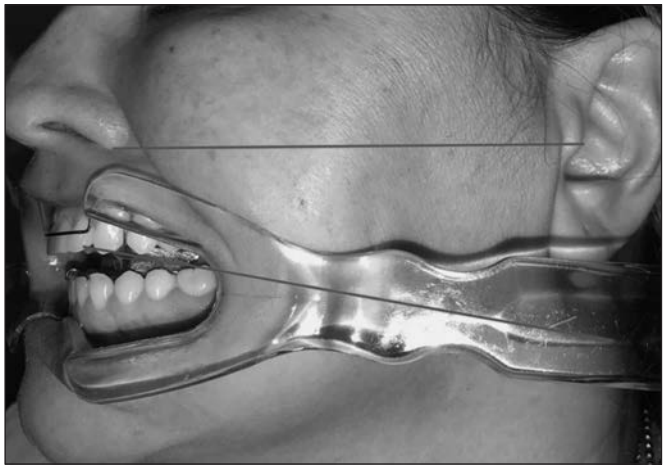

Figure 9. Angle formed by the inclination of the tracks and Camper's plane. The upper line (nose to ear) is the Camper's Plane e the lower line, is the inclination of the tracks.

DISCUSSION

A study using occlusal splints in patients with headache associated with TMD found that 25% of the patients with severe pain started to have mild pain, 10% started to have moderate pain, and 10% no longer experienced pain; a strong pain intensity persisted in only 5%. There was also significant improvement from moderate to weak or absent pain in all participants, thus validating the treatment that provided significant headache pain relief[13]. In another study that evaluated the treatment outcome of occlusal splints, 60% of the patients reported cure or marked improvement, 25% reported only improvement, and 15% reported that the therapy was ineffective or had little effect on pain relief[25].

In the present study, similar results were observed regarding the frequency of pain. Patients in GSPLINT exhibited a significant reduction in the number of pain days per month from 20.6 ± 5.9 to 11.4 ± 6.6 ($p < 0.05$), corresponding to a reduction of 44.66%. These patients also experienced significant improvement in pain upon temporalis palpation from 2.1 ± 0.7 to 1.4 ± 0.8 and in the number of days of drug use from 10.1 ± 8.2 to 6.4 ± 8.1 ($p < 0.05$). However, pain intensity increased significantly in this group from 1.5 ± 0.3 to 2.2 ± 0.6 ($p < 0.05$), in contrast to the results reported in the literature.

In GPIT, once the appliances were installed, some patients felt that they would not get used to the device since it is bulkier and occupies more intraoral space than occlusal splints. However, at the end of treatment, all patients were well adapted. There was a significant reduction in all parameters in this group, particularly in the number of pain days from 18.3 ± 7.9 to 2.3 ± 2.6, corresponding to a reduction of 87.43%.

Comparison of the groups showed that patients who used SPIT II obtained much better results for all variables studied than those using splints. Regarding pain upon masseter and temporalis palpation, despite considerable improvement in GPIT, no statistically significant difference was observed.

In the present study, most of the tracks installed in GPIT patients did not require changes. However, in the absence of considerable headache relief, their inclination was increased, which provided good pain relief in the following months. A correlation was observed between the inclination angle and pain intensity in GPIT participants. The greater the inclination, the lower the pain intensity (r=0.58).

The most likely theory for the mechanism of action of SPIT is that the inclination of the tracks induces greater mandibular protrusion through contraction of the lateral pterygoid muscle (in the anterior and inferior direction), consequently promoting relaxation of its antagonists and of the masseter, temporalis and medial pterygoid muscles, reducing headaches.

The present results demonstrate the positive impact of SPIT II and validate the technique as a safe and effective option for the management of headaches associated with TMD. Limitations of this study include the relatively small sample size and the lack of a cross-over design.

CONCLUSION

In the present study, SPIT II were found to be a more effective treatment option of headaches associated with TDM than occlusal splints for all parameters studied, as well as compared to the control group. Further studies are necessary to reproduce these findings and to confirm the usefulness of these appliances for headache treatment. However, SPIT II seem to be more effective than the gold standard treatment currently used in dentistry for the management of headaches associated with TDM.

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AUTHORS' CONTRIBUTIONS

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Methodology, Writing - Review and Editing

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