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A novel universal device "LINGUAL RING Ri.P.A.Ra" for TMDs and cranio-cervico-mandibular pains: preliminary results of a randomized control clinical trial

A. RAMPELLO, P. PAPI, G. POMPA, A. RAMPELLO, A. POLIMENI, C. DI PAOLO

Department of Oral and Maxillo-Facial Sciences, "Sapienza" University of Rome, Rome, Italy

Abstract. – OBJECTIVE: The aim of this study was to evaluate functionality and clinical application of a novel immediate device in the treatment of temporomandibular disorders (TMDs). To address the research purpose, authors developed and implemented a randomized control clinical trial.

PATIENTS AND METHODS: Eighty patients were enrolled in this study and were randomly divided into two subgroups based on the treatment applied: patient group (PG) and control group (CG). The CG was not subjected to any kind of treatment, even placebo, in order to be able to assess the spontaneous development of the pathology over time. The PG was treated applying the novel device for a maximum of three months. The following parameters were evaluated at baseline (T0) and at the end of therapy (T1): presence/absence of articular noises, painful symptomatology (articular pains, muscle pains, headache, cervicalgia), parafunctional habits and duration of symptoms. The x^2-index of association was performed, with a p-value < 0.05 considered as statistically significant.

RESULTS: No patient in the PG worsened its symptomatology. Thirteen patients (33%) declared themselves cured from their symptoms and were included in a monitoring protocol. Twenty-seven patients (67%) improved their symptoms and were treated with other conservative conventional methods to complete the therapeutic cycle. Therefore, 100% of PG obtained benefits from the application of the new therapeutic approach. In contrast, among patients of CG, eighteen subjects (45%) worsened their symptoms, while eighteen (45%) were defined as stationaries compared to T0 and only four (10%) were defined as improved.

CONCLUSIONS: The device presented the following advantages: immediacy of use, reduction of waiting times for its application, good tolerability and comfort and specificity in the execution of tongue rehabilitation exercises.

Key Words

Temporomandibular disorders, TMJ, headache, Reducible dislocation.

Introduction

The tongue is an important organ for the harmonious development of the maxilla and regulation of mandibular movements[1,2]. An alteration of its functional and biomechanical patterns may involve occlusion, skeletal bases, TMJ (Temporomandibular Joint) functions and oral and perioral muscles[3,4]. This organ is generally concerned by rehabilitation treatment for the correction of atypical swallowing in orthodontic therapy[5]. In the multidisciplinary management of TMDs, however, the myofunctional therapy of the tongue is still rarely considered, and traditional gnathological *occlusal splints* typically do not provide specific activities involving the tongue[6,7].

Implant therapy is still controversial in patients affected by TMDs and parafunctional habits[8,9]: several authors[10-12] have reported lower success and survival rates, when compared with standard patients, with a higher frequency of mechanical failures[12,13] over implant-related biologic complications[14-18].

The aim of this work is to evaluate functionality and clinical application of a novel immediate device. This Bite originates from the evolution of a similar apparatus that has already been studied, experimented and published by the same authors[19,20]. "The Lingual Ring Ri.P.A.Ra.", therefore, represents the development of this research. This device distinguishes itself from the previous one by its peculiar and innovative structural characteristics. "THE UNIRA" is a neuromuscular deconditioning indirect splint[20], the "Ri.P.A.Ra." has the purpose to re-educate either the mandibular and tongue position in an active way through a specific functional ring.

Constructional, technical, mechanical, physical and functional characteristics of this novel

Corresponding Author: Piero Papi, MD; e-mail: piero.papi@uniroma1.it

device are reported, presenting the preliminary results of its use on a sample of dysfunctional patients, compared with an untreated homologous control group.

Patients and Methods

Study Design

To address the research purpose, the authors developed and implemented a randomized control clinical study, to be conducted at the Department of Oral and Maxillo-Facial Sciences, at "Sapienza" University of Rome (Rome, Italy).

From February to December 2014, a consecutive series of 299 patients came to our observation at the Clinical Gnathology Unit. The Ethical Committee of the Department of Oral and Maxillo-Facial Sciences approved the study on 01-10-2014. All patients included in the study signed the informed consent form. Subjects underwent either clinical and instrumental examinations to analyze the presence of temporomandibular disorders (TMDs) in accordance with the Research Diagnostic Criteria for Temporomandibular Disorders (DC/TMD)[21,22]. Patients were selected based on the following inclusion and exclusion criteria.

Inclusion criteria:
- Reducible dislocation of the articular disk
- Sub-acute and chronic myalgia ≥ 30
- Arthralgia ≥ 30 values NVS (Numeric Verbal Scale)
- Parafunctional habits associated with muscular and/or articular pains
- Comorbidity with tensive headache and/or migraine ≥ 30 NVS values
- Comorbidity with cervicalgia and/or spine pain of tensive origin ≥ 30 NVS values
- Committed to participate to the entire duration of the study and signed the informed consent form.

Exclusion criteria:
- Other disorders inserted in the DC
- Axis II positivity
- Outcomes or consequences of condylar fractures and/or of any other maxillofacial district
- Patients subjected to surgical therapy of TMJ
- Patients already under therapy for the same disorders
- Articular disorders of systemic nature (rheumatoid arthritis, arthrosis, psoriatic arthritis)
- Known pathologies of a neurological and/or psychic nature including other forms of headache
- More than 8 missing teeth

Out of the 299 visited patients, 219 were not included because they did not meet the above-mentioned criteria. In detail, reasons for exclusion were the following: 32 suffered from chronic lock; 27 were Axis II positive; 13 were outcomes of fractures; 59 had pain with NVS values < 30; 13 had multiple missing teeth; 14 refused to be enrolled in the study, and 89 were subjected to other treatments.

The selected sample, therefore, consisted of 80 patients, randomly divided into two subgroups: patient group (PG) and control group (CG). All subjects signed the informed consent form and agreed to be included in the study.

The CG was not subjected to any treatment, even placebo, in order to be able to assess the spontaneous development of the pathology over time. All patients were carefully examined in order to obtain comparable results. To decrease the inter-examiner variability, all examinations were performed by the same two expert operators.

Study Variables

The following parameters were evaluated before the beginning of therapy, defined as baseline (T0) and at the end of therapy (T1):
- Presence/absence of articular noises, compatible with a reducible dislocation of the disk
- Painful symptomatology (articular pains, muscle pains, headache, cervicalgia) divided into 4 categories based on the value conferred upon them in terms of the NVS scale (Numeric Verbal Scale): mild (0-30); moderate (30-50); strong (50-80); severe (80-100).
- Presence/absence of parafunctional habits
- Duration of symptoms (months/years)
- Medical examinations were planned every 25 days, for either group.
- The following parameters were assessed at the end of therapy (T1):
- duration of treatment (hours of application/ months of therapy)
- Result of treatment expressed through the following categories:

H: healed, no sign no symptom
I: improved, at least one symptom improved and none worsened
S: stationary, no symptom improved no sign worsened
W: worsened, at least one symptom or one sign worsened and none improved.

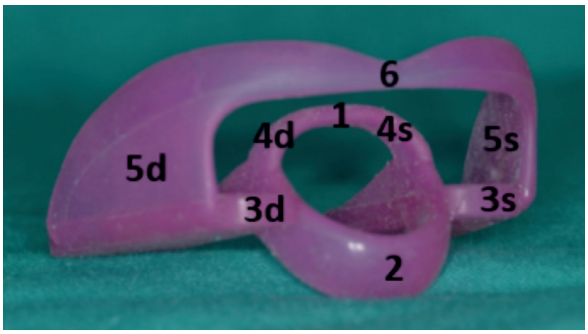

Figure 1. Lingual ring Ri.P.A.Ra (front view).

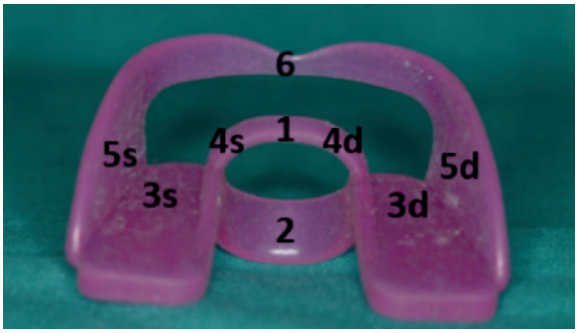

Figure 2. Lingual ring Ri.P.A.Ra (rear view).

Statistical Analysis

Descriptive statistics (mean, range) was computed for each variable of the study, collected at baseline (T0) and at end of therapy (T1). The Chi-square index of association was performed to check that frequencies of values observed adapted to the theoretical frequencies of a predetermined probability distribution, with a p-value < 0.05 considered as statistically significant.

Functional characteristics of the new device

All patients were informed of the aims of the study and authors specified them that a novel device would be applied free of charge.

A medical platinic silicone, non-toxic, hypoallergenic, biocompatible, in compliance with regulation (UNI EN ISO 10993 1:2010) and the EU directives 93-42 EC (Class 1 medical devices), hardness 55 Shore, was selected to fabricate the novel device (Lingual Ring Ri.P.A.Ra.). Its thickness is 3 mm in the occlusal portion subjected to loads and 2 mm in the remaining parts. It is made of three different components (Figures 1-2):

1) Central part A, i.e., the real and proper Lingual ring.
2) Part B, i.e., the reinforcement, anchoring, balancing, fitting and stabilization systems.
3) Part C, i.e., the functional reference rehabilitation systems.
   - Part A is composed of two arches: Arch "1" below and arch "2" above, that extend laterally on two horizontal planes which are placed between the teeth: the "3d" plane on the right, and the "3s" plane on the left which are symmetrical (Figures 1-2), all this constitutes the most important "Active" universal functional unit.
   - Part B is formed by two symmetrical palatal vertical reinforcement edges "4d" on the right and "4s" on the left, two vertical lateral symmetrical balance cheek shields "5d" to the right and "5s" to the left, a front connection band "6";
   - Part C is the functional reference rehabil-

Figure 3. Patient with the lingual ring Ri.P.A.Ra inserted.

itation system to stimulate active collaboration on the part of the patient by means of specific exercises, can be inserted or not as follows: one or more reeducative circular buttons or similar elements depending on the size and morphology of the oral cavity and also according to the required rehabilitative action.

Therefore, the illustrated device, by means of the Lingual Ring, basically aims at the positional rehabilitation of the tongue, the mandible and all components of the stomatognathic apparatus.

Therapeutic indications

1. The therapeutic protocol of the Universal Splint "RI.P.A.RA." is articulated in the following manner:
2. Standardized prescription of application of the device from a minimum of night only and rest (6-8h), to a maximum of 12 hours per day, including night and rest, with the indication to put the tongue at the top of the spot and the cognitive information to not tighten on the horizontal planes (3d and 3s);
3. For the entire PG, the only therapeutic presidium was the RI.P.A.RA. device, which was not associated with any other form of therapy during the treatment period (1-3 months);

The maximum duration established for an entire cycle of treatment was 3 months.

Results

The PG study sample was represented by a consecutive series of 40 patients: they were either males (6) and females (34), with a mean age of 34 years (range: 20-58 years).

The CG control group was composed by 40 patients: 35 females and 5 males aged between 25 and 51 years with a mean age of 38 years, with the same characteristics of the PG, but not subjected to any treatment for all intervention period.

All patients of the two groups (Table I and Table II) were suffering from a reducible dislocation of the articular disk.

As the novel device is an immediate splint, application times were consistent with the type of splint and the evaluation of the expected results could not exceed three months.

TMJ noises, present in the totality of PG sample (40 patients; 100%), disappeared in 38 patients (95%) and were stationary in the remaining 2 (5%). TMJ noises, in the CG, were present in the totality of sample at T0 (40 patients; 100%), and were unchanged at T1 in 39 patients (98%), disappearing only in 1 patient (3%).

As for the algic symptomatology, the following characteristics were found out in the PG: TMJ pains, n=32 (80%); muscular pains, n=30 (75%); cervical pains, n=22 (55%); headache, n=33 (82.5%); parafunctional habits, n=33 (82.5%).

While for the CG, the following data were registered: TMJ pains, n=26 (65%); muscular pains, n=24 (60%); cervical pains, n=17 (43%); headache, n=28 (70%); parafunctional habits, n=32 (80%).

The "articular pains" in the PG, initially present in 32 patients, representing 80% of the sample, disappeared after application of the novel device in 25 patients (63%), being therefore absent in 33 patients (83%) and remaining only in 7 patients (17%) at T1. However, all patients reported an improvement of their symptomatology and none any worsening. As for the CG (Table 4), the articular pains present at T0 in 26 patients (65%) were stationary at T1 in 22 of these (85%), while 4 patients (15%) had worsened.

The "muscular pains", initially present in the PG in 30 patients (75%), disappeared in 17 patients (43%) and were present only in 13 patients (33%), with 10 indicating they had mild pain (77%) and 3 moderate pain (23%). As regarding the CG (Table 4), articular pains present at T0 in 24 patients (60% of the sample), were stationary at T1 in 23 of these (96%), while one patient (4%) reported a worsening.

As for comorbidity, "headache", present in the PG in 33 patients, 82.5% of the sample, had disappeared in 16 patients (40%), and among the 17 patients who still presented headache, 13 (76%) reported mild symptoms and 4 (24%) moderate. A headache in the CG was present in 28 patients (70%) at T0 and in 31 patients (78%) at T1, with a worsening of the previous symptomatology in 3 patients (7.5% of the sample).

The "cervical pains", initially present in PG in 22 patients (55%), had disappeared in 12 patients (30%). Among the 7 patients who still presented cervicalgia (18%), all had mild symptoms (100%) with no worsening. As for the CG (Table 4), cervical algias present at T0 in 17 patients (43%) remained stationary at T1 with worsening in 1 patient (6% of patients with cervicalgia).

As for "parafunctional habits" in PG: 27 patients (82%) reported feeling a weaker and different feeling when tightening their teeth and waking up in the morning with a lower muscular tension, which remained virtually unchanged in

Table I. Patients group at T0.

Patients	Age	Gender	Articular noises	Articular pains	Muscle pains	Head-ache	Cervi-calgia	Parafun-ctional habits	Duration of symp-toms (months/ years)
11	37	F	YES	90	70	50	50	YES	4
2	45	F	YES	0	70	70	0	YES	2
3	50	F	YES	50	50	0	0	YES	1
4	30	M	YES	0	60	60	0	NO	3
5	27	F	YES	0	40	0	40	YES	1
6	32	F	YES	50	0	80	0	YES	3
7	25	F	YES	0	50	50	70	NO	6
8	28	F	YES	30	0	50	0	YES	1
9	43	F	YES	30	0	40	60	YES	1
10	51	F	YES	50	50	50	0	NO	4
11	37	F	YES	30	0	80	80	YES	1
12	38	F	YES	0	60	40	0	YES	2
13	41	F	YES	0	80	80	0	NO	3
14	50	F	YES	60	0	0	50	YES	1
15	43	M	YES	60	0	0	0	YES	9
16	33	F	YES	40	40	40	30	YES	1
17	28	F	YES	60	0	0	0	YES	1
18	47	F	YES	30	0	0	0	NO	6
19	42	F	YES	50	0	30	20	YES	8
20	26	F	YES	70	0	80	30	NO	1
21	42	F	YES	0	70	70	0	YES	8
22	41	F	YES	0	40	50	40	YES	1
23	28	F	YES	50	0	50	0	YES	2
24	33	F	YES	60	40	0	0	YES	1
25	43	M	YES	40	40	40	30	YES	2
26	50	F	YES	80	50	0	50	YES	9
27	43	F	YES	80	0	0	0	YES	1
28	38	F	YES	0	80	60	0	NO	3
29	37	M	YES	0	60	40	70	YES	2
30	51	F	YES	30	0	30	0	YES	1
31	44	F	YES	50	50	50	90	YES	4
32	28	F	YES	30	0	0	0	YES	1
33	25	F	YES	30	0	50	0	YES	1
34	32	F	YES	0	50	50	70	NO	6
35	27	F	YES	50	0	80	0	YES	3
36	29	F	YES	0	40	0	40	YES	1
37	51	F	YES	0	60	90	0	YES	3
38	46	F	YES	50	50	0	0	YES	1
39	38	M	YES	0	70	70	0	YES	2
40	31	F	YES	40	70	50	50	YES	4

6 cases (18%). For the CG, this parameter was present in 32 patients (80%) at T0 and at T1 had remained stationary in the same 32 patients.

As for treatment duration, expressed as "hours of daily application": the average daily application was 7 hours (range: 4-12 hours). As for "Application Time", expressed as months of therapy: the average time was 1.8 months in 22 patients (range: 1-3 months).

The following results ($p<0.05$) were expressed through segmentation analysis at T1 comparing both groups:

	PG		CG
Worsened	0 = 0%	-	18 = 45%
Stationary	0 = 0%	-	18 = 45%
Improved	27 = 68%	-	4 = 10%
Cured	13 = 33%	-	0 = 0%

Discussion

The vast majority of universal occlusal splints used in TMD therapy are designed to be simple "pads", that counteract the load determined by the strength of the vertical muscles (masseters,

Table II. Control group at T0.

Patients	Age	Gender	Articular noises	Articular pains	Muscle pains	Head-ache	Cervi-calgia	Parafun-ctional habits	Duration of symp-toms (months/ years)
11	37	F	YES	90	70	50	50	YES	4
2	45	F	YES	0	70	70	0	YES	2
3	50	F	YES	50	50	0	0	YES	1
4	30	M	YES	0	60	60	0	NO	3
5	27	F	YES	0	40	0	40	YES	1
6	32	F	YES	50	0	80	0	YES	3
7	25	F	YES	0	50	50	70	NO	6
8	28	F	YES	30	0	50	0	YES	1
9	43	F	YES	30	0	40	60	YES	1
10	51	F	YES	50	50	50	0	NO	4
11	37	F	YES	30	0	80	80	YES	1
12	38	F	YES	0	60	40	0	YES	2
13	41	F	YES	0	80	80	0	NO	3
14	50	F	YES	60	0	0	50	YES	1
15	43	M	YES	60	0	0	0	YES	9
16	33	F	YES	40	40	40	30	YES	1
17	28	F	YES	60	0	0	0	YES	1
18	47	F	YES	30	0	0	0	NO	6
19	42	F	YES	50	0	30	20	YES	8
20	26	F	YES	70	0	80	30	NO	1
21	42	F	YES	0	70	70	0	YES	8
22	41	F	YES	0	40	50	40	YES	1
23	28	F	YES	50	0	50	0	YES	2
24	33	F	YES	60	40	0	0	YES	1
25	43	M	YES	40	40	40	30	YES	2
26	50	F	YES	80	50	0	50	YES	9
27	43	F	YES	80	0	0	0	YES	1
28	38	F	YES	0	80	60	0	NO	3
29	37	M	YES	0	60	40	70	YES	2
30	51	F	YES	30	0	30	0	YES	1
31	44	F	YES	50	50	50	90	YES	4
32	28	F	YES	30	0	0	0	YES	1
33	25	F	YES	30	0	50	0	YES	1
34	32	F	YES	0	50	50	70	NO	6
35	27	F	YES	50	0	80	0	YES	3
36	29	F	YES	0	40	0	40	YES	1
37	51	F	YES	0	60	90	0	YES	3
38	46	F	YES	50	50	0	0	YES	1
39	38	M	YES	0	70	70	0	YES	2
40	31	F	YES	40	70	50	50	YES	4

internal and temporal pterygoids); while, in this case, the lower part of the device (Lower Arch), guides the front repositioning of the mandible[23-25]. The new posture, in addition to altering the vertical dimension, stimulates the elongation of all muscles, both vertical (Masseters, internal and temporal Pterygoids) and horizontal (external Pterygoids and Buccinators) and consequently causes the variation of the lever arm and force arm, guiding at the same time the tongue position to remain higher and more forward[1,20]. The new posture of the mandible and tongue consequently favours an alteration of the position of the hyoid bone and of the paravertebral muscles of rachis. The lingual ring Ri.P.A.Ra., therefore, influences and affects all these components in a more complete manner.

No patient out of the 40 inserted in the PG sample has worsened its symptomatology and no patient has remained stationary. Thirteen patients (33%) declared themselves cured from their symptoms and were included in a monitor-

Table III. Patients group at T1.

Patients	Rumor	Articular noises	Muscle pains	Head-ache	Cervi-calgia	Para-function	Duration of symptoms (months/ years)		Results
1	NO	0	0	0	0	NO	8	2	G
2	NO	0	0	0	0	NO	6	1.5	G
3	NO	0	0	0	0	NO	10	3	G
4	NO	40	40	40	0	NO	7	2	M
5	NO	0	30	30	0	NO	5	1.5	M
6	NO	30	20	20	0	NO	6	1	M
7	NO	0	0	0	0	YES	8	2.5	M
8	YES	0	0	50	0	NO	12	3	M
9	NO	0	0	0	0	YES	10	2	M
10	NO	30	20	0	0	NO	8	2	M
11	NO	0	0	20	0	YES	8	1	M
12	NO	0	0	10	0	NO	4	2	M
13	NO	30	20	0	20	NO	6	2.5	M
14	NO	50	0	0	0	NO	8	3	M
15	NO	0	0	0	0	NO	8	2	G
16	NO	0	0	0	0	NO	7	2	G
17	NO	0	0	50	0	NO	9	1.5	M
18	NO	0	0	0	20	NO	8	2.5	M
19	NO	30	20	0	0	NO	10	2	M
20	NO	0	0	10	0	NO	9	2	M
21	NO	0	0	0	0	NO	8	1	G
22	NO	20	20	20	10	NO	8	2	M
23	NO	0	10	0	0	NO	6	2	M
24	NO	0	20	0	0	NO	4	1	M
25	YES	0	0	20	20	NO	6	3	M
26	NO	0	10	10	10	NO	8	2	M
27	NO	0	0	0	0	NO	10	2	G
28	NO	70	50	20	0	YES	6	2	M
29	NO	30	0	20	0	NO	4	1	M
30	NO	0	0	0	0	NO	5	1	G
31	NO	0	0	20	0	YES	9	2	M
32	NO	0	0	0	0	NO	5	1	G
33	NO	50	20	20	20	NO	6	1	M
34	NO	0	0	0	0	NO	5	1	G
35	NO	0	0	0	0	NO	4	1	G
36	NO	0	10	0	0	YES	6	1	M
37	NO	0	0	0	0	NO	5	1	G
38	NO	0	0	20	0	NO	6	1	M
39	NO	0	0	20	30	NO	8	3	M
40	NO	0	0	0	0	NO	8	2	G

ing protocol with periodic examinations every 6 months. Twenty-seven patients (67%) improved their symptoms and were treated with other conservative conventional methods to complete the therapeutic cycle. Therefore, 100% of the PG obtained benefits from the application of the new therapeutic approach.

In contrast, among patients of CG, eighteen subjects (45%) worsened their symptoms, while eighteen (45%) were defined as stationaries compared to T0. Only four patients (10%) were defined as improved, while no patient was categorized as Healed. These results showed an unfavourable evolution of the symptoms in patients who were not subjected to treatment. This represents a further point for reflection on the evaluation of the progression of TMDs over time, which is still controversial in literature[26-32]. In our sample, only a few untreated subjects improved while the majority remained stationary or worsened. All subjects of the CG were subsequently inserted in a multidisciplinary therapeutic program.

Table IV. Control group at T1.

Patients	Rumor	Articular noises	Muscle pains	Head-ache	Cervi-calgia	Para-function	Duration of symptoms (months/ years)	Results
1	YES	30	70	50	50	YES	2	S
2	YES	0	70	70	60	YES	1	P
3	YES	50	50	0	0	YES	3	S
4	YES	60	60	80	0	YS	1	P
5	YES	40	40	100	0	YES	3	P
6	YES	0	0	60	0	YES	6	S
7	YES	50	50	50	70	NO	1	S
8	YES	0	0	50	0	YES	1	M
9	YES	30	0	70	0	YES	4	S
10	YES	50	50	50	20	YES	1	P
11	YES	30	0	70	0	YES	2	M
12	YES	0	60	40	0	YES	3	S
13	YES	0	80	40	50	NO	1	P
14	YES	80	0	0	50	YES	9	P
15	YES	60	0	60	0	YES	1	P
16	YES	40	40	40	60	YES	2	P
17	YES	60	0	0	0	YES	6	S
18	YES	3	0	50	70	NO	8	S
19	YES	60	0	40	0	NO	1	P
20	YES	60	0	0	0	NO	8	M
21	YES	0	70	70	0	YES	1	S
22	YES	0	40	50	40	YES	2	S
23	YES	50	0	50	0	YES	1	S
24	YES	60	60	0	60	YES	2	P
25	YES	40	40	40	30	YES	9	S
26	YES	80	50	80	50	YES	1	P
27	YES	80	0	0	0	YES	3	S
28	NO	0	80	60	0	NO	2	S
29	YES	0	60	40	100	YES	1	P
30	YES	30	0	80	30	YES	4	P
31	YES	50	50	50	0	YES	1	M
32	YES	30	0	0	0	YES	1	S
33	YES	60	0	50	0	YES	6	P
34	YES	0	50	50	70	NO	3	S
35	YES	70	0	60	0	YES	1	P
36	YES	0	40	0	0	YES	3	S
37	YES	0	60	30	50	NO	1	P
38	YES	80	50	0	0	YES	2	P
39	YES	0	70	70	0	YES	4	S
40	YES	80	70	50	50	YES		P

According to our findings, the Universal Splint "Ri.P.A.Ra." has proven to be a valid garrison for immediate treatment.

Conclusions

After analysing these preliminary data, Ri.P.A.Ra present the following advantages: immediacy of use for either patient and operator, reduction of waiting times for its application compared to other therapeutical approaches (particularly helpful in public hospitals, with a reduction of waiting lists), good tolerability and comfort and specificity in the execution of tongue rehabilitation exercises.

In addition, it may be administered to patients who underwent rehabilitative dental treatments to obtain deconditioning and/or occlusal protection.

The inconveniences of this new apparatus are mainly related to the increased request for collaboration from the patient. It is necessary their cooperation in learning how to hold the device through a different posture of their tongue. Main

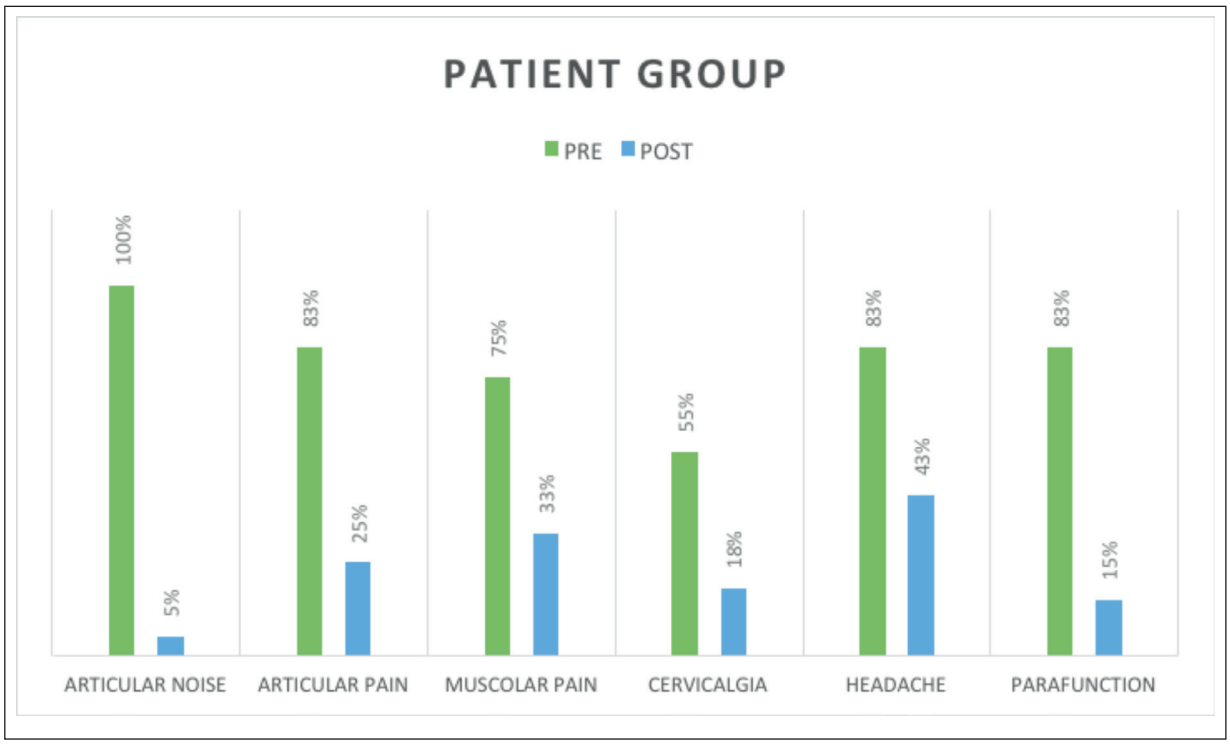

Chart 1. Patient group pre-post treatment comparison.

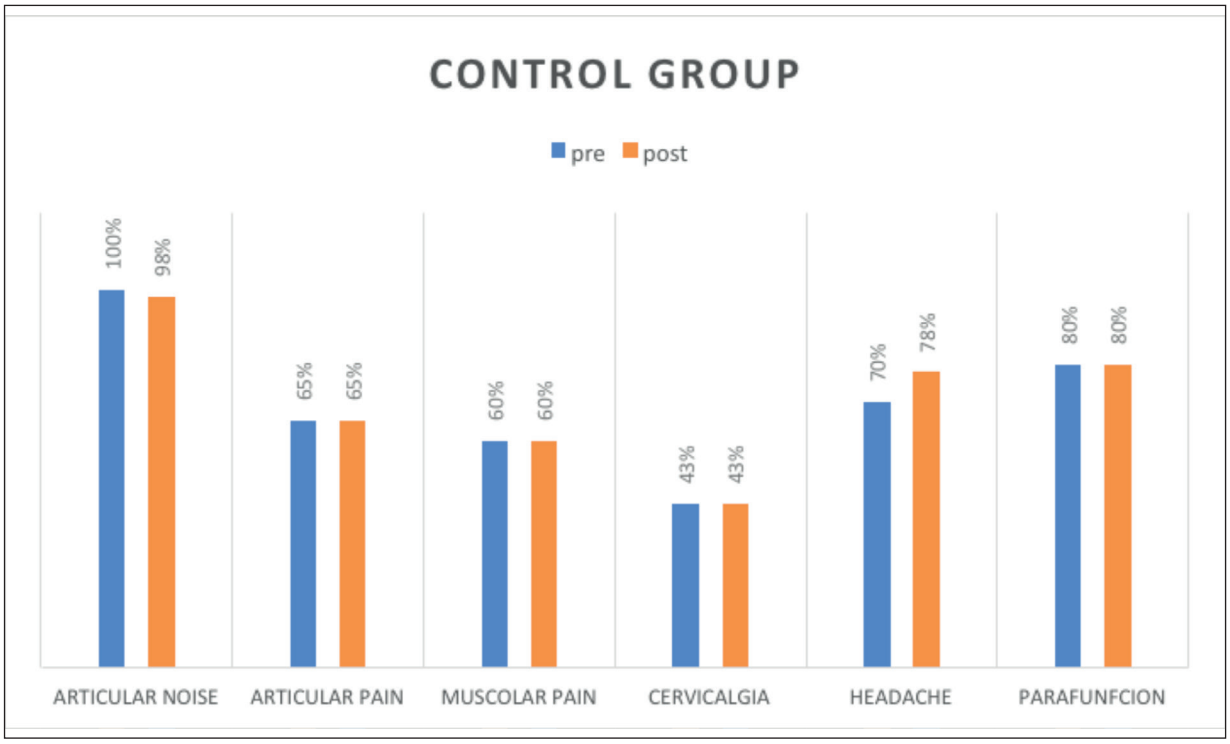

Chart 2. Control group pre-post treatment comparison.

limitations of this study are represented by the small sample and the short period of clinical observation. Therefore, further studies, with larger sample and follow-up are required to confirm our findings.

Conflict of Interest

The Authors declare that they have no conflict of interests.

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