research article

A NEW AID IN TMD THERAPY: THE UNIVERSAL NEUROMUSCULAR IMMEDIATE RELAXING APPLIANCE "UNIRA"

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SUMMARY

A new aid in TMD therapy: the Universal Neuromuscular Immediate Relaxing appliance "UNIRA".

Among the various treatment options currently indicated for the temporomandibular joint disorders (TMD) tackle an important role is played by occlusal devices which can be used in an individualized and or universal.

At the Service of Clinical Gnathology of the Head-Neck Department of the Umberto I Polyclinic at the Sapienza University of Rome, has been tested a new universal occlusal appliance, invented and patented by dott. Rampello.

To assess the applicability and efficacy was carried out a preliminary study on a sample of 50 patients selected according to the criteria RDC-TMD and divided in random into two groups, the patient group (PG), treated with the device, and a control group (CG) does not undergo any treatment.

The two groups were evaluated according to an analysis of segmentation by comparing the clinical data. Were considered some aspects of the application of the device using a self-evaluation questionnaire administered to the PG.

Considerations derived from this initial application are: none of the 25 patients in the sample PG has worsened the initial situation. 6 patients (24%) were healed and were included in a protocol of regular six-monthly visits. 16 patients (64%) have improved and incorporated into treatment to complete the treatment cycle. 3 patients (12%) were stationary and subjected to a diagnostic reassessment.

The patients in the CG have all been included in the multidisciplinary treatment program.

The findings of our preliminary study are favorable to this new device occlusion, however, requires further verification in time and on a sample of patients numeroso.

Key words: therapy for TMD, TM appliance, immediately appliance therapy.

RIASSUNTO

Un nuovo ausilio nella terapia dei DTM, Splint Universale "UNIRA": (Universal Neuromuscular Immediate Relaxing Appliance).

Tra le varie opzioni di trattamento attualmente indicato per affrontare i disturbi dell'articolazione Temporomandibolare (TMD) un ruolo importante è giocato dai dispositivi occlusali utilizzati che possono essere individualizzati e / o universali.

Presso il Servizio di Gnatologia clinica del Dipartimento testa-collo del Policlinico Umberto I presso Sapienza Università di Roma, è stato testato un nuovo dispositivo universale occlusale, ideato e brevettato dal dott. Rampello.

Per valutare l'applicabilità e l'efficacia è stato effettuato uno studio preliminare su un campione di 50 pazienti selezionati in base ai criteri RDC-TMD e suddiviso in modo random in due gruppi, il gruppo di pazienti (PG), trattati con il dispositivo, e un gruppo di controllo (CG) che non è stato sottoposto ad alcun trattamento.

I due gruppi sono stati valutati in base ad un'analisi di segmentazione comparando i dati clinici.

Sono stati considerati alcuni aspetti dell'applicazione del dispositivo utilizzando un questionario di autovalutazione somministrato ai PG.

Le considerazioni che derivano da questa prima applicazione sono: nessuno dei 25 pazienti del campione PG ha peggiorato la situazione iniziale. 6 pazienti il 24% sono guariti e sono stati inseriti in un protocollo di controlli periodici nei sei mesi consecutivi. 16 pazienti il 64% hanno migliorato, ed inseriti nel trattamento per completare il ciclo terapeutico. 3 pazienti il 12% sono rimasti stazionari e sottoposti ad una nuova valutazione diagnostica.

I pazienti in CG sono stati tutti inseriti nel programma di trattamento multidisciplinare. I risultati del nostro studio preliminare sono favorevoli sul nuovo dispositivo occlusale.

Si richiedono comunque, ulteriori verifiche nel tempo e su un campione numerico maggiore.

Parole chiave: terapia dei DTM, dispositivi temporo mandibolari, terapia con dispositivi immediati.

Introduction

The indications and efficacies of therapies for temporomandibular joint disorders (TMDs) are currently a study topic of great importance. The treatment models applied today are directly related to the symptoms, the time over which they have developed, and some of the factors affecting these symptoms and their development. Moreover, the data emerging from studies have demonstrated the possibility of treating patients with TMDs using conservative methods that are chosen and individualized over time for each patient and altered appropriately for any changes in their lifestyle.
The purpose of this study was to evaluate a new type of occluding device that is ready-to-used. The technical, mechanical, physical, and construction characteristics of this device, the Universal Neuromuscular Immediate Relaxing Appliance (UNIRA by Rampello), are presented herein, along with the outcome of preliminary trials in several patients (compared with a control group).

Materials and methods

Pattern and study protocol

A cohort of 158 patients with temporomandibular articulation pathologies were observed at the Service of Clinical Gnathology of the Head-Neck Department of the Umberto I Polyclinic in Rome, between January and May 2008. All of these patients were studied using our clinical, anamnestic, and instrumental protocols in order to evaluate the stage of their dysfunctional pathology and/or the presence of any structural deterioration of osteoarticular and muscular components, fulfilling the diagnostic research criteria for TMDs.
The UNIRA device was designed to address the painful and dysfunctional symptoms associated with TMDs. The cohort in the present study was thus divided into two groups using the following inclusion and exclusion criteria:

Inclusion criteria

- Muscular pain – visual analog scale (VAS) score of >30
- Articular pain – VAS score of >30
- Violent headache and/or migraine – VAS score of >30
- Nonreducing dislocations of the articular disk in acute cases of Miocene
- Parafunctions associated with muscular and/or articular pain
- Limited opening of the mouth of muscular origin
- Agree to participate in the study

Exclusion criteria

- Nonreducing dislocations of the articular disk in the acute form of TMD
- Consequences of condoyle fractures and/or fracture of another maxillofacial zone
- Undergone surgery for ATM
- In therapy for the same pathologies
- Articular pathologies of systemic nature (e.g., rheumatoid arthritis, arthrosis, psoriasis arthritis)
- Well-known pathologies of neurologic and/or psychic nature and other forms of migraine
- Absence of more than six teeth (three in the inferior arch and three in the superior arch) necessary for the correct function of the splint

Of the 158 patients examined, 92 were excluded for the following reasons: affected by chronic lock (n=24); consequences of a fracture (n=8); a pain VAS score of <30 (n=49); absence of more than six teeth necessary for the correct function of the splint (n=11). Of the remaining 66, 16 declined to be part of the study.
The selected sample of 50 was divided randomly into two subgroups: the patient group (PG) and the control group (CG). Subjects in the PG, who were fitted with the UNIRA splint, comprised a consecutive series of 25 patients (20 women and 5 men; age 20–46 years old, average 30.8 years) who were selected according to the aforementioned inclusion criteria (Table 1). Subjects in the CG comprised 25 patients (22 women and 3 men; age 20–45 years old, average 30.2 years) who have the same characteristics as those in the PG, but who were given no treatment during the therapy period (Table 2).

Table 1 - Table f the signs and symptoms of the patient group before therapy T0.

	Sex	Age	Muscular pain VAS before	Migraine VAS before	Cervical pain VAS before	TMJ Pain VAS before	TMJ Noise before	TMJ Block mm. before	Stress before	Clench before
1	f	23	70	60	30	60	none	27	yes	yes
2	f	28	0	30	30	100	none	50	yes	none
3	f	26	60	0	45	0	none	45	yes	yes
4	f	33	0	90	90	0	none	50	none	none
5	m	38	0	0	0	60	yes	45	none	yes
6	f	25	30	0	0	30	none	23	none	none
7	f	42	0	70	60	60	none	32	yes	yes
8	f	21	100	70	70	60	none	40	yes	yes
9	f	26	70	70	0	0	none	45	yes	yes
10	m	31	70	0	0	50	none	43	none	yes
11	f	40	40	0	0	50	none	48	none	yes
12	f	45	60	60	60	0	none	42	none	yes
13	f	43	0	0	0	50	none	40	yes	yes
14	f	24	0	0	0	40	yes	47	none	none
15	m	46	80	50	0	30	none	41	none	yes
16	f	30	0	0	50	30	none	27	none	none
17	m	37	70	70	0	0	none	43	none	yes
18	f	35	70	0	50	0	none	40	yes	yes
19	f	27	30	0	0	30	none	25	yes	yes
20	f	24	60	0	50	0	yes	45	none	none
21	f	21	0	70	60	60	none	45	yes	yes
22	f	20	0	90	90	0	none	52	none	none
23	m	29	0	70	50	0	yes	48	yes	yes
24	f	25	100	50	50	80	none	43	none	yes
25	f	33	50	30	30	50	yes	44	none	yes

The distribution of pain symptoms for the PG was as follows: muscular pains, n=15 (60%); migraine, n=14 (56%); cervical pain, n=15 (60%); ATM pains, n=16 (64%). The distribution of dysfunctional pathology among this group was as follows: disc displacement with reduction (DDwR), n=5 (20%); disc displacement without reduction (DDw/oR) of the muscular type, n= (%); functional blockage of maximum mouth opening, n=5 (20%). The anamnesis revealed that 11 subjects (44%) live with stress, 18 (72%) were aware that they regularly clench their teeth, and 7 (28%) grind their teeth.

The distribution of pain symptoms among the CG patients is as follows: muscular pain, n=15 (60%); migraine, n=19 (76%); cervical pain n=5 (20%);

Table 2 - Table of the signs and symptoms of the control group before therapy T0.

	Sex	Age	Muscular pain VAS before	Migraine VAS before	Cervical pain VAS before	TMJ Pain VAS before	TMJ Noise before	TMJ Block mm. before	Stress before	Clench before
1	f	20	40	30	0	0	none	45	yes	yes
2	f	22	0	40	0	0	none	43	yes	yes
3	f	23	0	0	0	0	yes	50	yes	yes
4	f	26	60	30	30	60	none	45	yes	yes
5	m	36	0	30	30	50	yes	50	none	none
6	m	27	100	40	0	0	none	48	none	yes
7	f	27	80	80	0	50	none	43	yes	yes
8	f	20	0	50	0	30	none	32	none	none
9	f	27	80	80	50	0	none	40	yes	yes
10	f	42	0	50	30	50	yes	43	none	none
11	f	30	70	30	0	0	none	48	yes	none
12	f	25	50	30	0	30	yes	42	yes	none
13	f	34	0	30	0	0	yes	43	yes	none
14	f	42	30	0	20	0	yes	40	none	none
15	f	40	80	70	0	50	none	45	none	none
16	f	33	0	0	0	0	yes	43	none	none
17	f	33	0	0	0	30	yes	40	yes	yes
18	f	35	50	60	0	20	none	48	yes	yes
19	m	21	0	30	0	0	yes	47	yes	yes
20	f	26	60	50	0	0	yes	38	none	yes
21	f	27	0	0	0	30	yes	42	none	yes
22	f	39	30	30	0	0	yes	45	none	yes
23	f	45	100	100	0	50	yes	43	yes	yes
24	f	28	50	50	0	30	none	30	none	none
25	f	28	40	0	0	0	yes	45	yes	yes

ATM pain n=12 (48%). The distribution of dysfunctional pathology among this group is as follows: DDwR, n=14 (56%); DDw/oR of the muscular type, n= (%); functional blockage of maximum opening, n=3 (12%). The anamnesis revealed that 14 subjects (56%) in this group live with stress, 15 (60%) were aware that they clench their teeth, and 7 (28%) grind their teeth.

Before describing the treatment method used for the clinical study, it is important to explain the design of the project and the realization of the UNIRA dental appliance.

Design and description

Construction, design, and functional characteristics of the UNIRA.

The majority of occlusive immediate splints used for TMD therapy are designed to resist the occlusive forces determined by the strength of the vertical muscles (masseters, internal pterygoids and temporal). We believe that in order to obtain a complete functional recovery and pain relief, it is necessary to establish the balance of all masticatory and facial muscles. Thus, we have designed a new splint that acts not only on the vertical muscles, but also on the horizontal muscles, improving the connection between the tongue, the hyoid bone, and the rachis. The design of the UNIRA is the result of a combination of clinical considerations associated with the following technical prerequisites: small dimensions and reduced trauma, good comfort, easily managed, and low economic and biological cost.

It was decided that the expansion, thickness, and general structure of this appliance must have a good retention and be firm. Thus, a polyvinyl (polypropylene) material was chosen, which is biocompatible, nontoxic, hypoallergenic, and has a hardness of about 60–70 Shore, in accordance with European Union directives (Class 1a 93-42 CE). After some technical tests including compression, torsion, traction, and cut executed in the laboratory, and from an analysis of similar commercially available devices and the results of a first-phase clinical study with different prototypes over a 2-year period, a first set of UNIRA splints with a thickness of 3 mm in the occlusive active portion and 2 mm in the other parts was constructed, and used in the present study.

The UNIRA is made of some parts that are considered active and others that have a prevailing "stabilizing" action. The so-called active parts are:

1) Two lateral genal shields that are vertical and symmetric, and have a right- and left-of-oval form
2) Two interocclusive levels with a roughly triangular form, but with round angles; also right and left symmetric
3) Palatal arch linking the two horizontal, triangular, occlusive levels passing near the palatal vault

The stabilizing parts are:

1) An arched string connecting the two lateral shields placed in the vestibular fornix inferior and front
2) Two small vertical and semilunar wings that are detachable at the lower part in a right angle from the two occlusive horizontal levels, encircling the mouth on the molar and premolar teeth (Figs. 1, 2, 3).

Figure 1
Higher view of the splint UNIRA.

Figure 2
Rear view of the splint UNIRA.

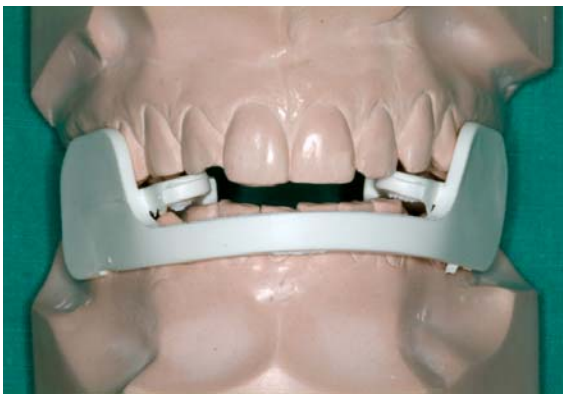

Figure 3
Front view of the splint UNIRA.

It is also important to note that the connecting parts have an effect upon the tissues that they come into contact with, but for the present description we preferred to divide the different parts of the splint into active and stabilizing.
The aim and functions performed by the described elements are:

1) The two lateral genal shields balance and equilibrate the perioral muscles (horizontal) and stabilize the splint horizontally.
2) The two triangular interocclusive and horizontal parts increase the vertical dimension and space the teeth. Indeed, they equilibrate the vertical muscles, protecting the teeth and the temporomandibular structures from inadequate parafunctional forces. They also function to stabilize the vertical parts.
3) Particularly novel in the present model is the palatal arch, which commences from the internal superior pole of the two horizontal interocclusive levels and continues crosswise to encircle the palatine vault at the back of the tongue. It has various functions: (1) it links elements 1 and 2, (2) it retains the entire splint, opposing its expulsion from the mouth sagittally, and (3) it induces postural tongue rehabilitation and, as a consequence, rehabilitation of the lower jaw, the hyoid bone, and the cervical column, aiding the correct head posture.
4) The front lower string, the front arch, is positioned in the lower vestibular fornix, between the front lower teeth and the lower lip, linking the lateral 1 and 2 elements to stabilize and retain the splint sagittally.
5) The two small semilunar wings help the retention and intra-oral stabilization of the splint, in order to maintain the two interocclusive levels firm between the antagonist teeth.

The surfaces of all described elements are smooth, and thus should cause no trauma. Only the surfaces of the two interocclusive levels could eventually develop small holes or retentions, or become rough. Thus, autopolymerizing and resinous materials can be added to compensate for some issues attributable to the occlusive curves, or to balance and/or personalize the splint.

Therapeutic protocol

The therapeutic protocol for our study of the UNIRA splint was as follows:

1) The splint was applied for a minimum of 1 night, followed by rest to a maximum of 12 h/day (including night and rest) for patients with intense pain.
2) For all patients, the UNIRA splint was the only therapeutic aid used. No other form of therapy was used during the treatment period (0.25 months).
3) The maximum period of treatment was fixed at 4 months.

The patients provided informed consent to participate in this study, agreeing to use the UNIRA splint. All of the patients were aware of the trouble afflicting them and so were able to obtain a real perception of the problem, thus assuring us of the best possible compliance.
Patients were examined every 25 days during the study period. All of the patients in the two groups (PG and CG) were chosen by comparison of their pain levels, as measured using a VAS scale. This is a quantitative analysis that utilizes periodic comparison of mill metric values of mouth-opening fluidity, symmetry, and absence of pain during mandibular movements. To reduce interexamination variability, all of the patients (i.e., both PG and CG) were examined by the same two operators who were well trained for this study. The pain levels were measured for the PG at two time intervals: before therapy, and at the end of therapy (T1). For the CG, examinations were carried out at the beginning of the study period and then again after 4 months (T1).
A segmentation analysis between the two groups was carried out for results obtained before and after the therapy. They were evaluated as follows:

1) G: Cured, no sign, no symptoms
2) M: Getting better, with at least one symptom improved and none worsening
3) S: Stationary situation, no symptom improvement, but no symptom worsening
4) P: Worsening, at least one symptom worsening and none improving

Considering the innovation of this appliance and

as part of the evaluation of its clinical effectiveness, the level of comfort while wearing the splint was evaluated by asking the patients to respond to a set of easily understood questions:

1) Did the splint cause any problems in your mouth? Yes/no. This question was asked in order to evaluate the degree of trauma induced by the splint (if any), and to determine whether it induced problems for the teeth or/and gums.
2) Did you have any problems with the appliance? Yes/no. This question was designed to ascertain whether the patients had any problems inserting or removing the UNIRA from the mouth, and to assess its wearability.
3) Given your initial condition, would you chose to use this appliance? Yes/no. This question allowed us to assess the level of patient satisfaction with the treatment.

Expected functional characteristics

The expected functional responses to treatment with the UNIRA splint were:

1) Improvement of muscular and articular pain
2) Improvement in migraine
3) Improvement in the quality and quantity of mandibular movement
4) Absence of real changes in the teeth at the three levels of space perceptible by the patient and the doctor.

Results

The main findings of this study are presented in Table 3. As regards to "application time," the minimum was 1 month (n=4), while the maximum was 4 months (n=1). The application time for the remaining 20 patients ranged from 2 to 3 months. The average reaction time for UNIRA therapy was 2.2 months.

With regard to "daily application time," the minimum was 8 h (n=13) and the maximum was about 12 h (n=2), with an average of 9.30 h.

The results of the analysis of factors considered to influence the clinical effectiveness of the UNIRA splint are presented in Table 3 (pre-/posttreatment comparison).

A quantitative improvement in the mandibular movement was observed in three of the five patients who had an initial mouth opening inferior to 30 mm (12% of the entire PG). These patients had an end-of-study mouth opening of 40 mm. The remaining two patients (8%) did experience a slight improvement, but the data remained pathologic (i.e., under 40 mm). The movement quality, with regard to symmetry (as evaluated by the doctor) and fluidity (as evaluated by the patient), improved in 20 PG patients (80%). All 25 PG patients (100%) had no sensation of change in the three space levels of the teeth.

Seven of the 15 patients in the PG (28% of the entire group) who reported muscular pain were cured of that pain after the treatment. An improvement in VAS score was observed in eight PG patients (32%). No change was observed in muscular pain in 14 out of the 15 CG patients who initially reported this symptom (Table 4); only 1 CG patient noted any improvement.

Migraine

In the PG, 14 of the 25 patients (56%) presented with migraine. Of these, 12 (48%) recovered during the study period; there was no change in condition in the remaining 2 patients. In the CG, of the 19 patients who complained of migraine, 17 (68% of the entire group) maintained their condition. In one of the remaining two, migraines became worse, while the condition of the other slightly improved, achieving a high VAS score of 40–60. Overall, there was no significant variation in migraine symptoms between the two groups.

Cervical pain

Of the 15 PG patients who presented with cervical pain, an improvement was observed in 10 patients (40% of the entire group), complete recovery was observed in 2 (8% of the entire group), and no

Table 3 - Table of the signs and symptoms of the patient group pre-/posttreatment comparison T1.

	Hours	Time of application months	Muscular pain VAS before	after	Migraine VAS before	after	Cervical pain VAS before	after	TMJ Pain VAS before	after	TMJ Noise before	TMJ Block mm. before	after	Stress before	Clench before	Bruxism before	G:Cured M:Going better S:Stationary P:Getting worse
1	8	1	70	0	60	0	30	0	60	0	none	none	27 45	yes	none	yes	none G
2	10	2	0	0	30	0	30	0	100	0	none	none	50 50	yes	none	none	yes none G
3	8	2	60	20	0	0	45	30	0	0	none	none	45 45	yes	yes	yes	yes yes M
4	12	3	0	0	90	20	90	20	0	0	none	none	50 50	none	none	none	none none M
5	8	2	0	0	0	0	0	0	60	0	yes	yes	45 45	none	none	yes	none none M
6	8	1	30	0	0	0	0	0	30	0	none	none	23 46	none	none	none	none none M
7	10	3	0	0	70	70	60	60	60	60	none	none	32 32	yes	yes	yes	yes yes S
8	12	2	100	20	70	20	70	20	60	0	none	none	40 40	yes	none	yes	none none M
9	8	1	70	0	70	0	0	0	0	0	none	none	45 45	yes	none	yes	none none G
10	8	2	70	0	0	0	0	0	50	0	none	none	43 43	none	none	yes	none none G
11	8	2	40	0	0	0	0	0	50	20	none	none	48 48	none	none	yes	none none M
12	10	3	60	20	60	20	60	20	0	0	none	none	42 42	none	none	yes	yes none M
13	8	1	0	0	0	0	0	0	50	10	none	none	40 40	yes	yes	yes	none none M
14	8	2	0	0	0	0	0	0	40	0	yes	none	47 47	none	none	none	none none G
15	8	2	80	40	50	30	0	0	30	10	none	none	41 41	none	none	yes	yes none M
16	10	3	0	0	0	0	50	50	30	30	none	none	27 30	none	none	none	none none S
17	10	2	70	20	70	30	0	0	0	0	none	none	43 43	none	none	yes	yes yes M
18	10	2	70	20	0	0	50	30	0	0	none	none	40 40	yes	yes	yes	yes yes M
19	10	3	30	0	0	0	0	0	30	0	none	none	25 42	yes	yes	yes	none G
20	10	3	60	20	0	0	50	30	0	0	yes	none	45 45	none	none	none	none none M
21	10	2	0	0	70	10	60	10	60	10	none	none	45 45	yes	none	yes	none none M
22	10	3	0	0	90	10	90	20	0	0	none	none	52 52	none	none	none	none none M
23	8	4	0	0	70	70	50	50	0	0	yes	yes	48 48	yes	yes	yes	none none S
24	8	2	100	20	50	10	50	10	80	0	none	none	43 43	none	none	yes	none none M
25	8	2	50	0	30	30	30	30	50	20	yes	yes	44 44	none	none	yes	none none M

change was observed in 3 (12% of the entire group) over the study period. In the CG, those who presented with cervical pain experienced no change in their symptoms throughout the study period.

ATM pain

Of those patients in the PG who presented with ATM pain, improvement of symptoms was observed in five patients (20% of the entire group), and complete recovery was observed in nine patients (36% of the entire group) over the study period. No change in this symptom was observed in the remaining two patients. The ATM noises experienced by 14 patients in the CG improved during the study period in only 1 patient, while for the remaining 13 patients the symptom was unchanged.

Table 4 - Table of the signs and symptoms of the control group before no therapy T1.

	Muscular pain VAS		**Migraine** VAS		Cervical pain VAS		TMJ Pain VAS		TMJ Noise	TMJ Block mm.		Stress	clench	Bruxism	**G**: Cured **M**: Going better **S**: Stationary **P**: Getting worse
	before	after	before	after	before	after	before	after	before after	before	after	before after	before after	before after	
1	40	40	30	30	0	0	0	0	none none	43	43	yes yes	yes yes	none none	S
2	0	0	40	40	0	0	0	0	none none	44	44	yes yes	yes yes	none none	S
3	0	0	0	0	0	0	0	50	yes none	50	32	yes yes	yes yes	none none	P
4	60	60	30	30	30	30	60	6 0	none none	45	45	yes yes	yes yes	none none	S
5	0	0	30	40	30	40	50	30	yes yes	50	50	none none	none none	none none	P
6	100	100	40	60	0	0	0	30	none yes	48	48	none yes	yes yes	yes yes	P
7	80	60	80	50	0	0	50	30	none none	43	43	yes yes	yes yes	none none	M
8	0	0	50	50	0	0	30	30	none none	32	32	none none	none none	none none	S
9	80	100	80	100	50	60	0	50	none none	40	40	yes yes	yes yes	yes yes	P
10	0	0	50	50	30	30	50	50	yes yes	42	42	yes yes	none none	none none	S
11	70	70	30	30	0	0	0	0	none none	45	45	yes yes	none none	none none	S
12	50	80	30	50	0	0	30	30	yes yes	44	44	none none	none none	none none	P
13	0	0	30	30	0	0	0	50	yes none	40	35	none none	none none	none none	P
14	30	30	0	0	20	20	0	0	yes yes	40	40	none none	none none	yes yes	S
15	80	20	70	40	0	0	50	50	none none	45	45	none none	none none	yes yes	M
16	0	0	0	0	0	0	0	0	yes yes	43	43	none none	none none	none none	S
17	0	0	0	0	0	0	30	30	yes yes	40	40	yes yes	yes yes	none none	S
18	50	50	60	60	0	0	20	20	none none	48	48	yes yes	yes yes	none none	S
19	0	0	30	30	0	0	0	0	yes yes	47	47	yes yes	yes yes	none none	S
20	60	60	50	50	0	0	0	0	yes yes	38	38	none none	yes yes	none none	S
21	0	0	0	0	0	0	30	30	yes yes	42	42	none none	yes yes	yes yes	S
22	30	30	30	30	0	0	0	0	yes yes	45	45	none none	yes yes	none none	S
23	100	70	100	60	0	0	50	20	yes yes	43	43	yes yes	yes yes	yes yes	M
24	50	50	50	50	0	0	30	30	none none	30	30	none none	none none	yes yes	S
25	40	40	0	0	0	0	0	0	yes yes	43	43	yes yes	yes yes	none none	S

Dysfunctional pathology

Five PG patients presented with DDwR; over the study period, two of these improved, while this symptom remained unchanged in the remaining three patients. The DDw/oR symptom experienced by five patients in the PG recovered during the study period in three patients; this symptom remained unchanged for the remaining two.

The CG patients who presented initially with muscular block (n=3) experienced no improvement throughout the study period.

Stress

As regards stress, of the 11 PG patients who professed to live with stress at the beginning of the therapy protocol, 5 patients reported "disappearance" of that stress by the end of the study period; the remaining 6 patients reported no change in this parameter. The number of patients reporting to be stressed in the CG increased from 14 to 15 during the study period.
The number of patients in the PG who clench their teeth decreased from 18 to 11 over the study period. This number for the CG remained unchanged (15 patients, 60% of the entire group). The symptom of bruxism also improved in the PG in three cases during the study period, remaining unchanged in the other four patients who reported this symptom initially. The patients in the CG who suffer from bruxism (n=7) experienced no change in this symptom during the study period.

Segmentation analysis
A segmentation analysis of the findings at T1 for the two groups is presented below.

	PG	CG
Worsening	0%	24%
Unchanged	12%	64%
Improved	64%	12%
Recovered	24%	0%

The answers to the three appliance evaluation questions presented to the PG patients were as follows:

- Question 1 (Did the splint caused you any problems in your mouth?): three patients (12%) answered yes, because they developed inflammation on the median raphe as a result of compression of the palatal string.
- Question 2 (Did you have any problems with the appliance?): two patients (8%) reported a lack of firmness – they would wake up in the morning and find the splint in the bed.
- Question 3 (Given your initial condition, would you chose to use this appliance?): 22 patients (88%) answered yes, if they had the same condition they would chose the treatment again.

Discussion and conclusions

We have been treating diseases of the stomatologic apparatus for the past 25 years at our center, and we are continually striving to develop diagnostic and therapeutic strategies that will provide more rapid, comfortable, and less expensive ways of treating our patients. Following this logic, treatment strategies have advanced over the years, allowing us to be consistently up-to date, both clinically and as regards the literature. Patients with TMDs are treated with a combination of occlusive, conservative, behavioral, and physiotherapy solutions, involving cooperation between disciplines and practitioner multidiscipline training. Patients with structural and nonreversible diseases of the osteoarticular components are seen, following diagnosis, by a maxillofacial surgeon, who will apply the correct therapy.
There are many different commercially available, "ready-to-use" appliances for the solution of specific parafunctions. Unlike the UNIRA, these are less versatile and are not individualized. The evaluation of this new type of splint in this preliminary study has revealed that it did not result in worsening of symptoms in any of our PG patients; rather, it resulted in a resolution of symptoms in 24% (these patients are now being followed up every 6 months), and an improvement of symptoms in 64% (these patients are continuing their therapy). Only three of the PG patients experienced no change as a result of using the splint. These three patients were submitted to a diagnostic reevaluation, and a more therapeutic program more appropriate to their specific pathology was provided. Following the study period, the CG patients were all entered into a therapeutic multidisciplinary program.
Thus, in conclusion, a positive treatment effect of the UNIRA was observed in 22 (88%) of the study PG cohort. The findings regarding improvement of cervical pain are not conclusive, and it is neces-

sary to further analyze this problem.
The main limit of this device appears to be mechanical. There are issues with dental anchorage, since there are no supporting elements. It may sometimes be impossible to place the palatal spring optimally in jaws that are particularly arched or particularly low, or those with a large arch. Furthermore, this splint is often prescribed for those patients with particularly dysfunctional and painful forms of the disease who have a characteristic tensive musculature, in whom immediate control of pain is necessary. Finally, the sample number of this study is low; further studies are required with a larger sample.
The benefits of the UNIRA are its immediacy of use by the doctor, the low cost of the appliance, the ease of control by the patient and doctor, the reduction of the sometimes long waiting times in public health systems when it is important to treat the patients as soon as possible. Another benefit is its versatility; it can be used to treat not only patients with TMDs, but also by the doctor for any patient immediately after an odontostomatologic or rehabilitative treatment that requires occlusive protection. The shims we utilize in this splint provide the best resilience to the material, optimize the resistance to forces, and are less traumatic for the oral tissues.

References

1. Abraham J, Pierce C, Rinchuse D et al. Assestment of buccal separators in the relief of bruxism activity associated with myofascial Paindysfunction. Angle Orthod. 62:177-184, 1992.
2. Capurso U. Il riposizionamento mandibolare: progettazione ed esecuzione di una placca occlusale. Minerva Stomatol. 37:721-728, 1988.
3. Capurso U. Le placche occlusali: classificazione, utilizzo e limiti. Minerva Stomatol. 35:51-56,1986.
4. Carrisi JE, Mc Glynn FD, Parker EM. Occlusal Splint effects on nocturnal bryxism an emerging paradigm and some early risults, in J. Cranio. Pract. 1:64-68, 1987.
5. Cascone P. Terapia chirurgica della lussazione anteriore del menisco Parte I/II, in Dental Cadmos Dossier 17-26, 11/1987; 9-26,12/1987.
6. Cascone P, Di Paolo C, Rampello A, et al. Valutazione Neuromuscolare ed esame posturale in pazienti affetti da incoordinazione condilo meniscale dell'A.T.M., in Minerva Stomatologica, 41: 79-90, 1992.
7. Cassisi J, Mc Glynn FD, Mahan PE. Occlusal Splint Effects on Nocturnal bruxing: an emerging paradigm and some early results, in J.Cranio.Mand. Pract 5:65-68, January 1987.
8. Collesano V, Pessina E, Bosco M. Le placche occlusali nella terapia dei disordini Cranio-Cervico-Mandibolari. Quaderni di protesi N°8 Masson 1997.
9. Collesano V, Bosco M, Pessina E. T-Scan: potenzialità applicative. Verifica sperimentale. Dental Cadmos 2:72-78, 1990.
10. Colonnelli P, Di Paolo C, Rampello A, Pennacchini N, Cascone P. Valutazione neuro muscolare ed esame posturale in pazient affetti da incoordinazione condilo-meniscale dell'ATM. Estratti primo congresso Internazionale su: Postura-Occlusione-Rachide. Venezia 28,29,30 Giugno 1991.
11. Dawson EP.Evaluation, diagnosis, and treatment of occlusal problems. The C.V. Mosby Company; 2nd Ed.: 1989.
12. Di Paolo C, Baldoni E. La placca di riposizionamento nell'incoordinazione condilomeniscale dell'ATM. XXII Congresso Nazionale della Società Italiana di Odontostomatologia e Chirurgia MaxilloFacciale, Roma 69 Dic. IV 157-60, 1989.
13. Di Paolo C, Rampello A, De Luca S. Terapia non chirurgica del Closed Lock: metodiche a confronto, in RIS Settembre 1991.
14. Di Paolo C, Rampello A, De Luca S. Valutazione dell'occlusione nella incoordinazione Condilo Discale dell'A.T.M., in RIS Febbraio 1992.
15. Di Paolo C, Rampello A. Lock articolare dell'ATM. Terapia non chirurgica. Dental Cadmos 18:48-74, 1993.
16. Di Paolo C, Conti M, Massaccesi B. Ruolo degli eventi stressanti nei disordini dell'ATM. "Valutazione mediante questionario". Dental Cadmos 19: 63-69, 1998.
17. Farrar WB, McCarty W.L. A clinical Outline af Temporomandibolar joint diagnosis and treatment, in Montgomery Walker Printing Co. 1983.
18. Fraccari F, Bogini A, Spangaro F. L'uso di placche di distrazione nella patologia dell'articolazione temporomandibolare. Minerva Stomatol. 3/89,38,3:345-351, 1989.
19. Krogh-Poulsen, WG. Orthofunktion und Pathofunktion des mastikatorischen Systems unter Berücksichtigung der beteiligten Muskelgruppen. Kiefergelenk und Okklusion. Quitessenz Berlin 1980.
20. Lerman M.D. The hydrostatic appliance: a new approach to treatment of the TMJ pain-dysfunction syndrome. A complete hydrostatically derived treatment procedure for the TMJ pain-dysfunction syndrome. JADA 89:1343, 1981.
21. Martignoni M. Le turbe funzionali delle articolazioni temporo-mandibolari: loro diagnosi e terapia, in Rivista Italiana di Stomatologia, anno XXII, n°8, 1967.
22. Mongini F. Funzioni e disfunzioni dell'apparato stomatognatico, Ed. scientifiche internazionali. 1984.
23. Okeson P. Jeffrey. Il trattamento delle disfunzioni del-

l'occlusione e dei disordini temporomandibolari Ed. Martina Bologna, 1996.
24. Palla S. La diagnosi e la terapia delle mioartropatie del sistema Stomatognatico. Università di Zurigo, Sillabo, 1989.
25. Rampello A, Falisi G, Lorenzano F, Di Paolo C. Diagnosi e terapia. Terapia delle patologie dell'ATM. "Valutazione dei fattori occlusali"Atti del V Congresso Naz. Del Collegio Docenti: Roma 22/25 Aprile II/985-990, 1998.
26. Rampello A, Di Paolo C, Cascone P. Limitazione dell'apertura della bocca: Diagnosi Differenziale e terapia: "Atti del III Congresso Naz. Del Collegio Docenti: Roma 27/30 Marzo I/147-152, 1996.
27. Rampello A, Falisi G, Lorenzano F, Di Paolo C. Diagnosi e terapia. Terapia delle patologie dell'ATM. "Valutazione dei fattori occlusali"Atti del V Congresso Naz. Del Collegio Docenti: Roma 22/25 Aprile II/985-990, 1998.
28. Rampello A, Falisi G, Panti F, e al. Terapia del Locking. Ortognatodonzia Italiana: vol. 8, n°4 : 527-531, 1999.

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