Intraoral device APNiA (DIA)

Treatment of sleep apneas and roncopathy

STEP BY STEP

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"When we thought we had all the answers,
suddenly, all the questions changed."

***Mario Benedetti** (1920-2009)*
Writer, poet and Uruguayan playwright

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APNiA INTRAORAL DEVICE (DIA)

1. PREVIOUS EVALUATION OF THE PATIENT

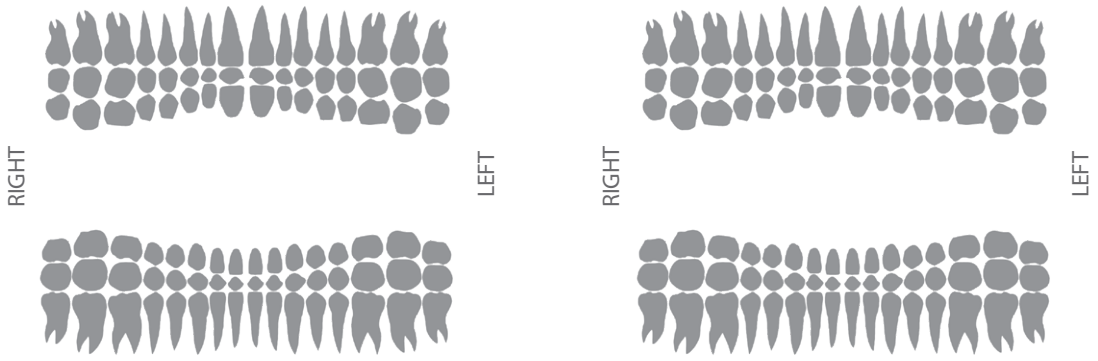
The following issues should be evaluated for a correct process when preparing the intraoral device for treating the SAHS patient:

1. Confirm the presence of an DIA therapeutic indication. Previously, the patient will have carried out a sleep test and presence of an obstructive apnea and/or roncopathy will have been checked for. Another possible indication is the intolerance to continuous positive pressure in the airway (CPAP) and in this case, the patient will be referred to the dentist by a sleep unit.

2. Oral Examination: teeth condition, prosthesis (if there is any), and soft tissues are revised to detect the presence of pathological changes and to retrieve data on the following important parameters in order to prepare the DIA. The use of an odontogram is recommended to record dental findings.

Odontogram

Name _____ Patient number _____



Hygiene _____ Scalings ☐ Upper ☐ Lower REV C/ _____

Smoker ☐ YES ☐ NO Dose _____ CAT ☐ Upper _____ _____

Ex-smoker _____ ☐ Lower _____ _____

Night-guard splint _____ Colour _____

Orthodontic treatment _____

The following information is also obtained from the intraoral examination which is important for the preparation of the intraoral device in the treatment of SAHS:

Number of teeth on each dental arch ≥8	☐ Yes	☐ No
Presence of teeth with infection, mobility or breakage	☐ Yes	☐ No
Presence of prosthetic with mobility and / or breakage	☐ Yes	☐ No
Presence of active periodontal disease	☐ Yes	☐ No
Presence of third molars	☐ Yes	☐ No
Presence of tooth wear	☐ Yes	☐ No

☐ Mild ☐ Moderate ☐ Severe

To begin preparing an DIA, a treatment plan must be developed so that the patient has sufficient teeth/ prosthesis for the DIA retention. Also, it is necessary to treat periodontal disease and all those teeth with pathologies.

The occlusion will also be examined as to take some references of the initial stage of the patient. This information will help us to notice changes in the occlusion during treatment with DIA.

- Overbite (mm)
  - ☐ Yes
  - ☐ No
- Overjet (mm)
  - ☐ Yes
  - ☐ No
- Malocclusion Angle classification
  - ☐ Class I ☐ Molar ☐ Canine
  - ☐ Class II ☐ Molar ☐ Canine
  - ☐ Class III ☐ Molar ☐ Canine

3. It is essential to carry out and to analyze a panoramic x-ray and intraoral radiographs, and it is highly recommended to have a CAT (com-bean) to be able to see the airway and to rule out any associated pathologies.

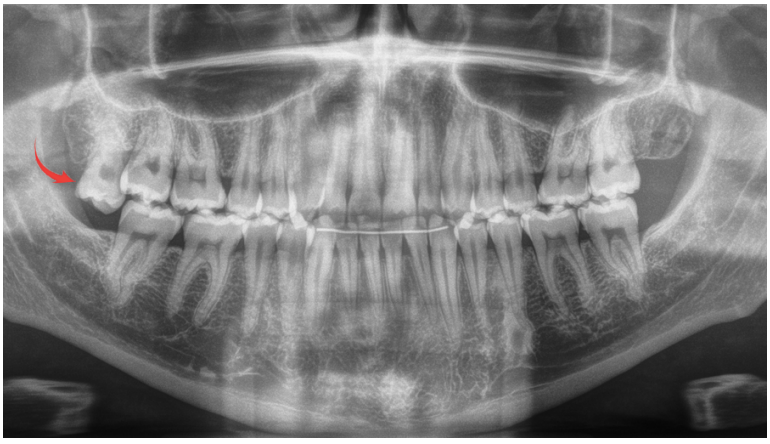
4. It is recommended to perform a cephalometry to record the initial state of occlusion and to obtain the following information: mandibular plane, ANB angles, overbite, overjet, lower facial height. The type of bite and the malocclusion Angle classification will be recorded.

5. Assess the presence of improper function and mandibular mobility (limited protrusion or limited mouth opening) and study of the occlusion.

Presence of clicks during opening, closing and lateral movements must be observed. Maximum mouth opening, laterality and protrusion are also measured in millimeters. Normal values of these movements are a maximum mouth opening ≥ 40 mm, lateral movements ≥ 7 mm and a protrusion ≥ 7 mm.

If severe pain in the ATM or history of temporomandibular joint disorders, then an DIA cannot be used. The presence of disorders of moderate-severe ATM may contraindicate treatment with the DIA or at least be very alert.

In case of suspected ATM-related problems, an occlusion and TMJ specialist should be consulted. The presence of third molars or extruded molars out of plane must be evaluated, in order to know if we can proceed with the construction of DIA.



In this panoramic radiograph the presence of 18 out of plane it can be observed, creating an occlusal interference. Before preparing an DIA, a extraction will be needed.

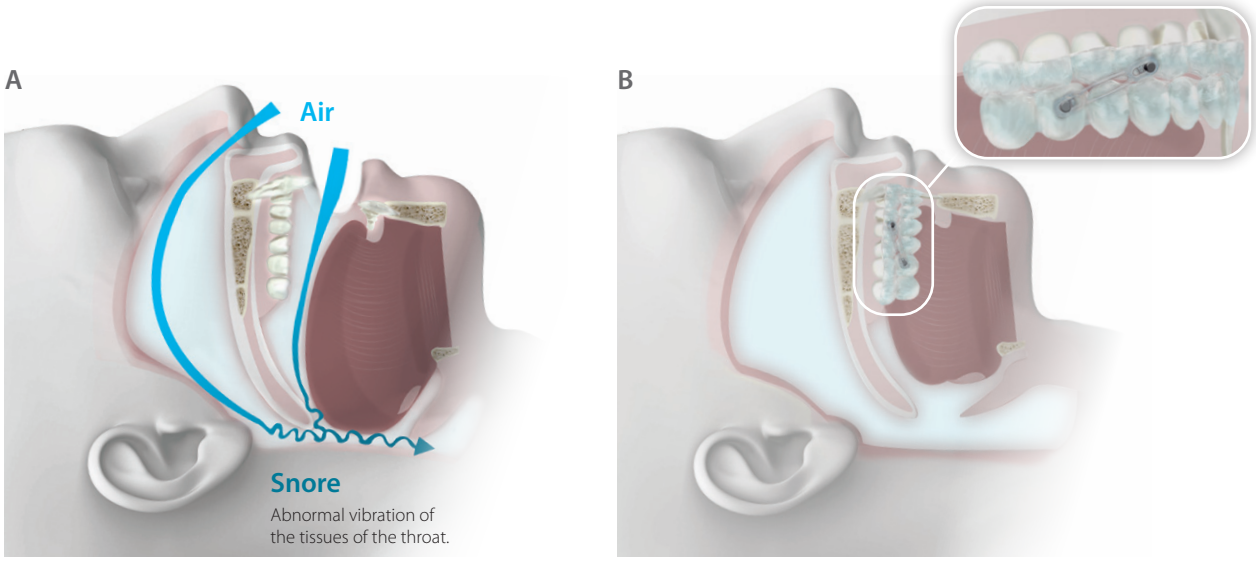
2. MANDIBULAR ADVANCEMENT DEVICES DEVELOPMENT IN THE TREATMENT OF SAHS

The use of different systems to treat problems of obstruction of the upper airway dates back to 1902 when Pierre Robin advocated the use of a device that achieved advancing the maxilla, clearing the way by moving the tongue forward and so avoiding its fall backward, thus treating patients with the syndrome that takes his name. Therefore, this system referred to as monoblock, can be considered the precursor of the intraoral devices (IODs).

The first publications related to IOD for the treatment of SAHS appear in the 80s to get alternative treatments to the continuous positive upper airway pressure (CPAP) or surgery. From these beginnings, more than 50 types of devices have been described for this purpose, considering the IOD a valid alternative for some specific cases of SAHS such as mild or mild-moderate cases with low body mass index, or for patients who do not respond or reject the positive pressure devices.

The American Academy of Sleep Medicine (AASM) defines the IODs as "devices that are placed into the mouth and modify the position of the mandible, tongue and other upper airway supporting structures to treat snoring and/or SAHS ".

The mode of action of mandibular advancement devices (MAD) is based on a system that slightly moves the mandible a few millimeters forward. This advancement generates an increase in the tone of muscles of the oropharynx, preventing them from vibrating, thus increasing the retropharyngeal space. Both facts result in a reduction of snoring and apneas. The conducted studies have shown a reduction of apneas of more than 50% in most patients, with a decrease of snoring in over 80% of cases.



Mode of action of the intraoral device IOD. A) In a relax position, the lingual muscles fall backward collapsing the upper airway. B) With the APNiA intraoral device (DIA) the mandible is slightly pulled forward, thus clearing of the airway, or in case that the mandible advancement would not be necessary, it is prevented from going backwards.

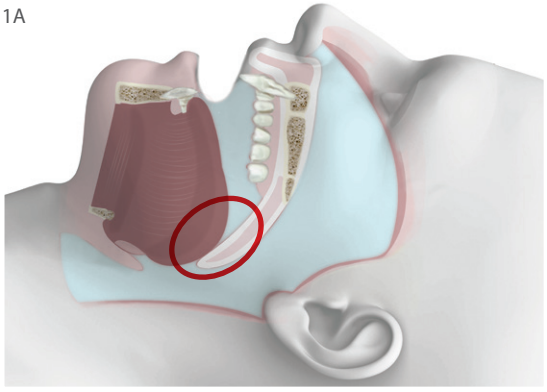
3. TYPES OF INTRAORAL APPLIANCES IN THE TREATMENT OF SAHS AND SNORING

Depending on the mechanism of action, we can divide the intraoral devices in the following groups:

1. Tongue retaining device (TRD)

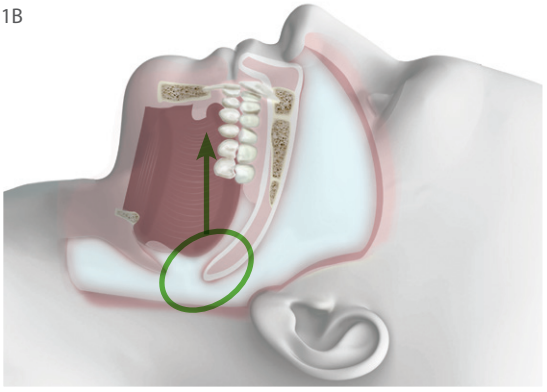
Acts by holding the tongue in a forward position to avoid the mandible advancement. This way, the distance between the tongue and the pharyngeal wall increases, thus generating a greater airway space.

1A



Upper airway collapse by the contact of the tongue with the soft palate.

1B

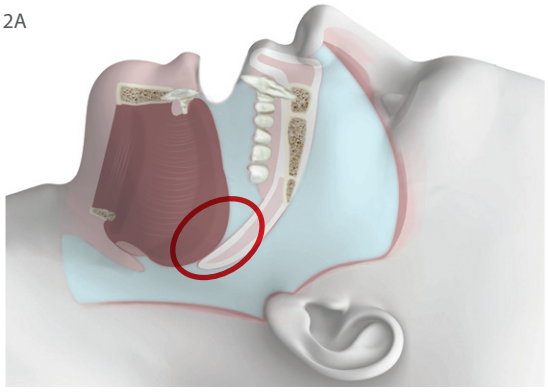


Mode of action of the tongue retaining device clearing the air passage in the upper airway.

2. Devices for lifting of the soft palate and uvula repositioning

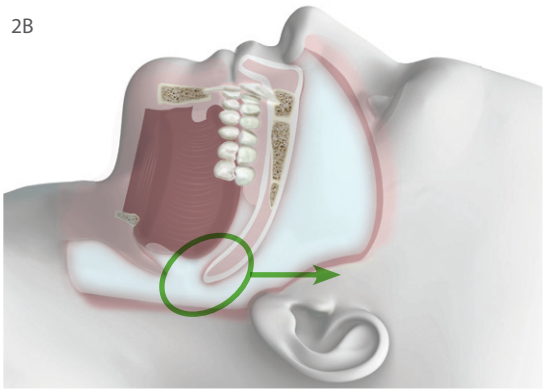
This type of device operates by raising the soft palate and taking the uvula to a higher position. They are therefore effective in cases of snoring being generally ineffective in cases of SAHS.

2A



Position of the tongue in contact with the soft palate causing a collapse of the upper airway.

2B



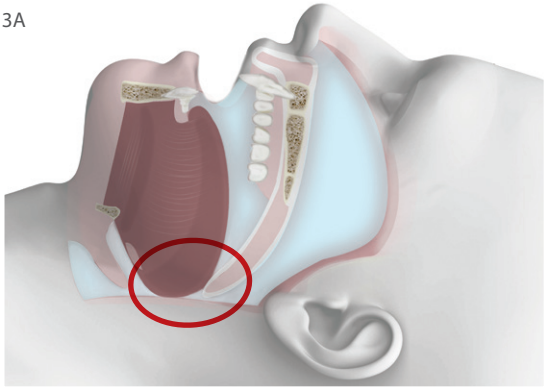
Palate lifting by the lifting device.

3. Mandibular advancement devices

The reposition devices are the largest group of intraoral devices available for the treatment of snoring and sleep obstructive apnea-hipopnea. All of them generate a functional mandibular advancement that results in a posterior airspace increase at the height of the oro-hypopharynx.

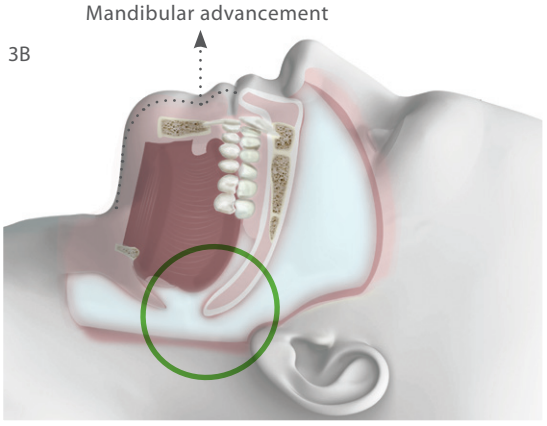
The mandibular advancement in turn generates a lingual traction by its insertion in the geni apophysis of the tongue and also a hyoid bone advancement that favors an increase in volume and permeability of the upper airway.

3A



Upper airway collapse due to obstruction by contacting the tongue with the oropharyngeal area.

3B

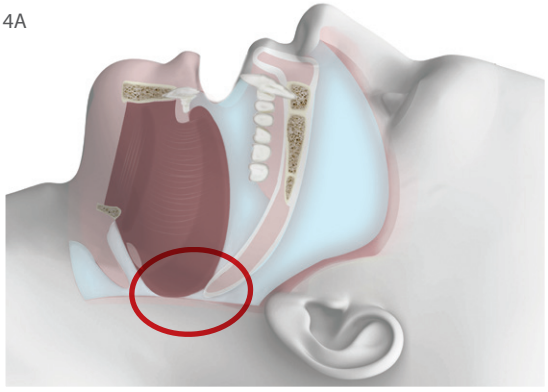


Mode of action of the mandibular advancement device.

4. OPAP devices (Oral Pressure Appliance)

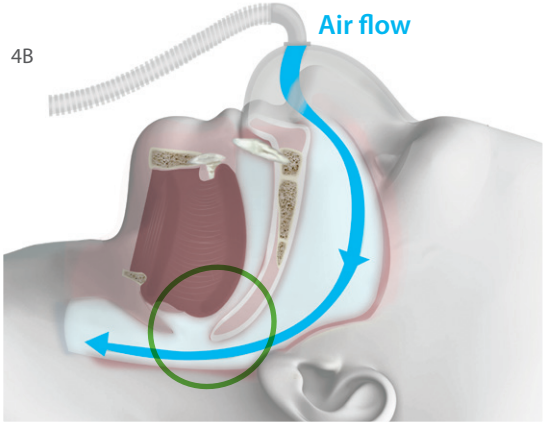
Systems that provide a combination therapy between a mandibular advancement device and a continuous positive airway pressure device (CPAP). They are indicated for patients with severe SAHS who require a CPAP together with a mandibular advancement to achieve a correct permeability of the upper airway. These devices can be replaced by an DIA combined with a much more comfortable nasal mask.

4A



Upper airway collapse similar to the previous case.

4B



The combination of the mandibular advancement device together with the use of an air flow mantains the upper airway permeable.

COMPLICATIONS

Complications resulting from intraoral devices are frequent and they are described in most studies that monitor patients treated with IOD for long periods of time. These complications can be divided into different groups:

A) Cephalometric changes: mandibular movements are registered (advancement 0.1 mm, 0.3 mm decrease), posterior mandibular rotation (0.5 °), mandibular length increase (0.4 mm) although the latter figure corresponds to cases with great advancements.

B) Occlusal changes: Changes in the occlusal contacts are described in most studies, as well as the overbite reduction (even reaching edge-to-edge overbite or class III in some cases) and problems in the temporomandibular joint. Devices with a large acrylic volume in the occlusal area can also generate anterior or posterior open overbites (unilateral or bilateral), existing a correlation between the previous oral opening and the occurrence of these disorders. (Vertical dimension excess opening).

C) Device derived problems: In most studies, problems related to the device similar to those ones of the patients with an orthodontic device are described: increased salivation, mouth dryness, mucosal irritation. Another problem reported by patients is the sensation of "Claustrophobia" caused by the mandibular movements and mouth opening impossibility, as in most of the devices maxilla and mandible stay together preventing the mandible and mouth from moving during sleep.

D) Problems in the temporomandibular joint (TMJ): Most often, the occurrence of myofascial pain usually disappears when removing the IOD although sometimes it can be perpetuated. Most authors have found a higher incidence of these events in the non-adjustable devices than in the adjustable ones.

4. APNIA INTRAORAL DEVICE (DIA)

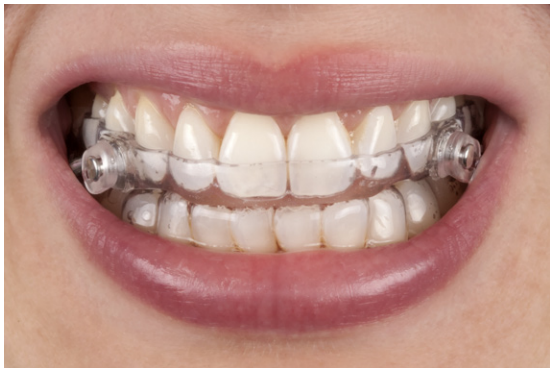
4.1. Differential aspects

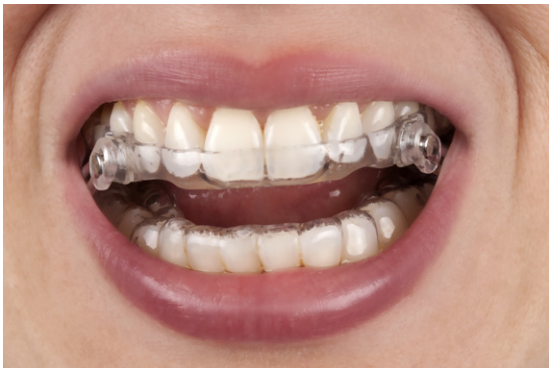
In order to minimize the above-described side effects associated with other intraoral devices, especially the non-adjustable ones, an intraoral device has been developed that tries to diminish these effects and improves patient´s comfort.

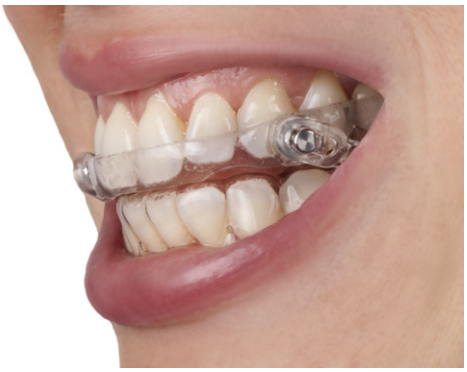
1. Occlusal and cephalometric changes resulting from excessive opening of the vertical dimension by the large volume of acrylic reported by other devices (which they are greater, when the greater the amount of acrylic at the back) are minimized by having a device with a minimum acrylic height: 1.2 mm for the lower model and the minimum height allowed by the occlusal anatomy for the top one.

2. The connection system of both splints allows opening and lateral movements without setting both dental arches. Mobility allowed by the device ensures mandible freedom during the hours of treatment minimizing joint problems thus greatly improving the adaptability of the patient.

3. At the same time, the protrusion used in the device is minimal when compared with that described in the literature, thereby largely avoiding the mandibular advancement side effects. **This way we get from the maximum tolerated protrusion to the minimum effective one**. This essential concept is another differential point of APNIA intraoral device (DIA) with respect to the intraoral mandibular advancement devices (MAD and IOD).This is the concept that has driven us to develop an efficient automated device, so that a dentist can titrate (to assess the DIA effectiveness) comfortably at his clinic and thus to set the protrusion, if necessary, as "the minimum effective" (its effectiveness can be measured and quantified objectively). Snoring and postural apneas will be corrected in many cases without the need of advancing the mandible, just preventing the retraction.

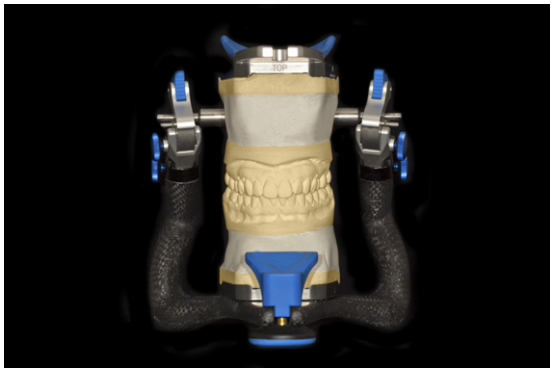


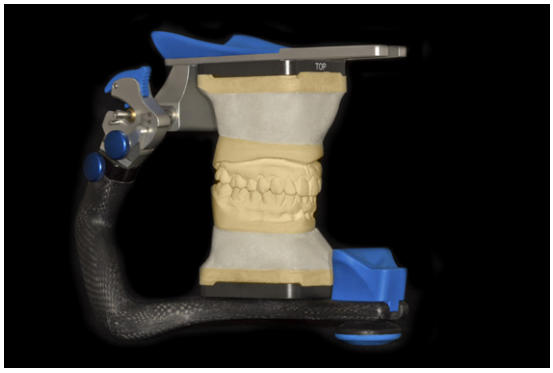
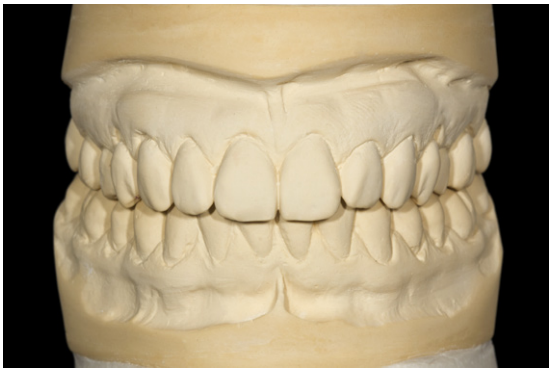
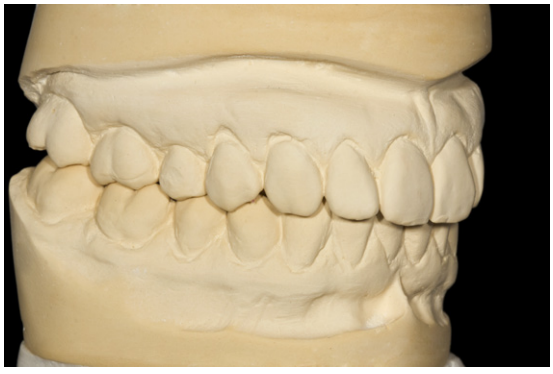
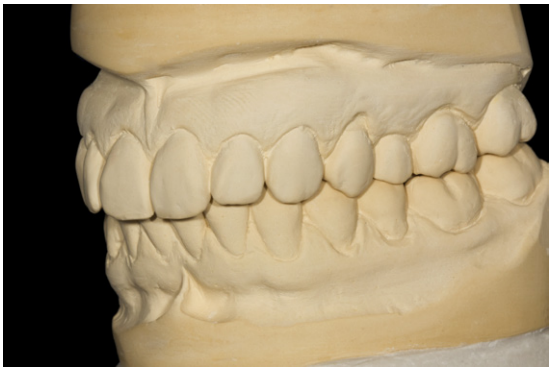


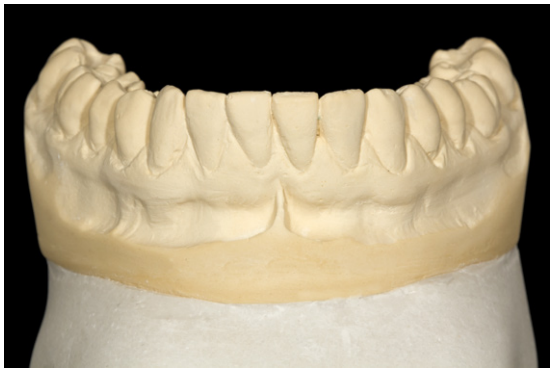


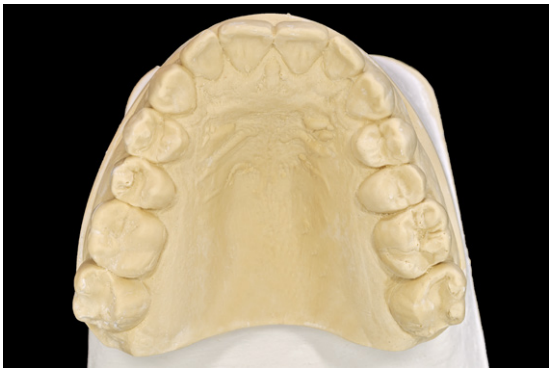
4.2. Step by step DIA preparation

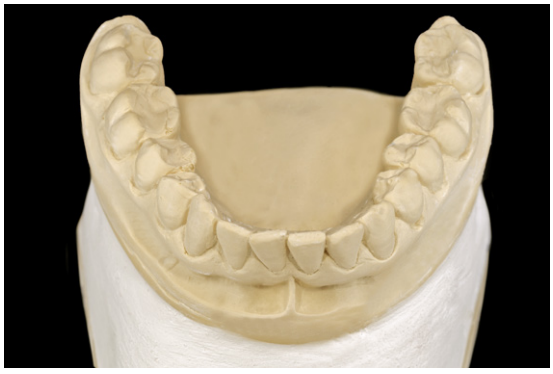
1. We started with perfectly trimmed study models that allow a background display of the complete passage. These models are mounted on an articulator in centric relation. We make sure there are no bubbles, drop zones or retentions that were not blocked when making the printing.





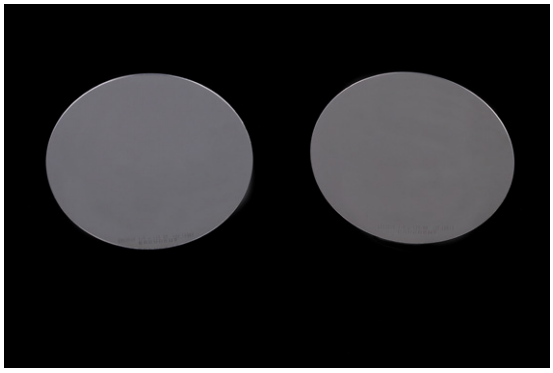
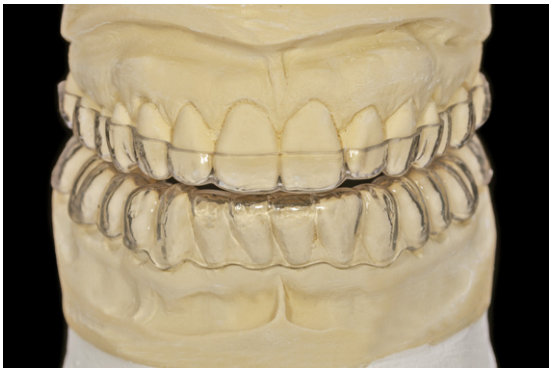
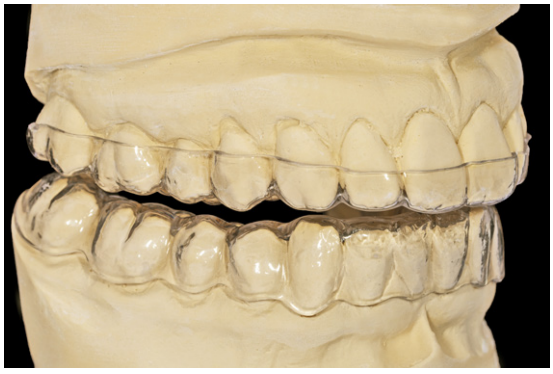
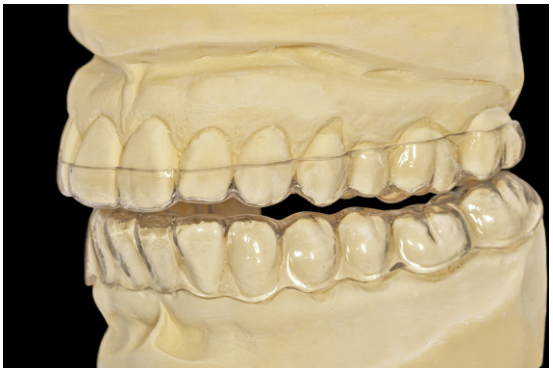
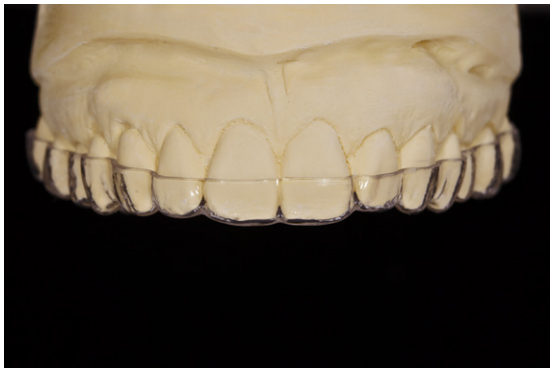
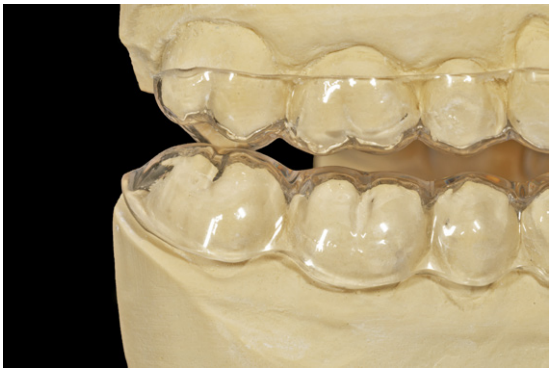


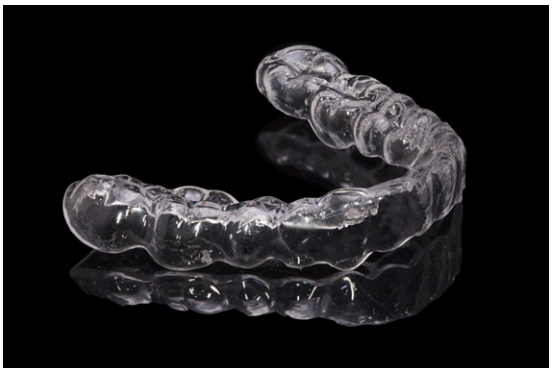


2. Vacuum thermoplastic plates are made following the gingival outline in the lower arch and leaving the top one slightly below the dental equator. The dental equator should not be exceeded to avoid excessive mechanical retention of the splint. The thickness of the material used will be of **2 mm for the lower one and 1 mm for the upper one.**

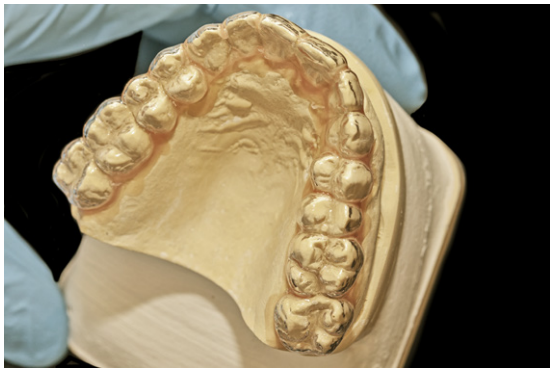
The final thickness which will help us to identify the points of occlusion is 1.2 mm for the lower one and 0.6 mm for the upper one, which we will slightly load it in order to obtain a flat surface and to correct discrepancies using self-polymerizable resin (thermo-plastic).

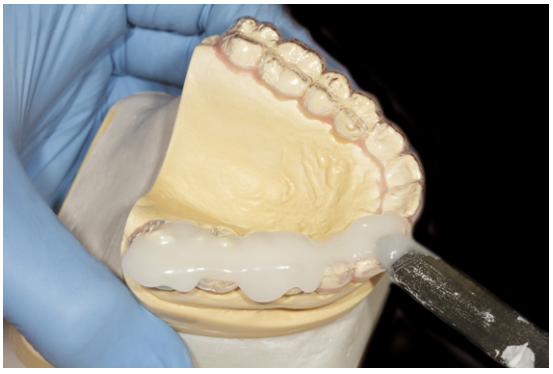
It is important that the lower plastic be placed as close as possible to the gum of the last molar. On the last molar, leave an oval visor-shaped surface, as seen in the image, using a wax block. If the distance between the gum and the cusp is 4 mm, this step will not have to be carried out, although its conduct is always advisable in order to ensure a better distribution of the pressure loads exerted on the lower arch.

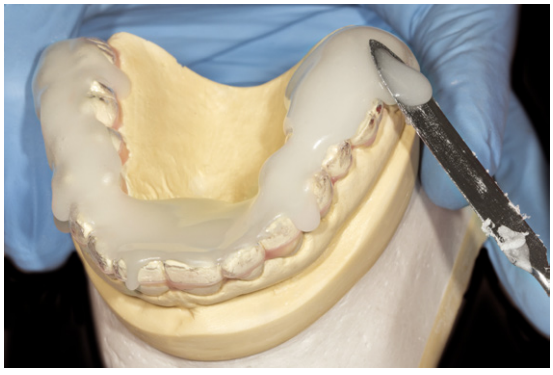







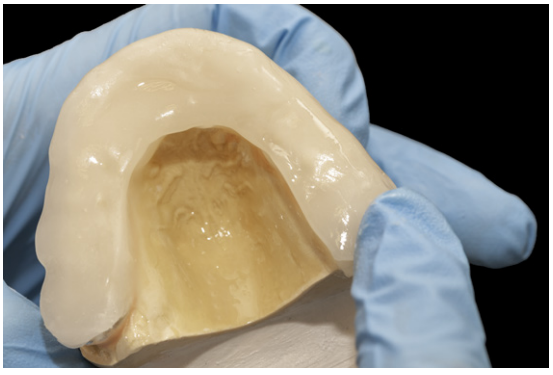


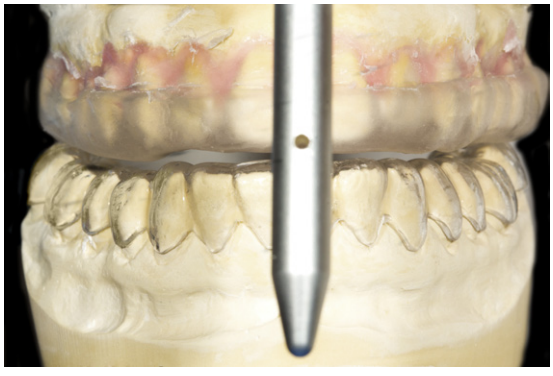
3a. Once the plates are prepared, a minor upper plate load is performed with thermpolymerizable transparent acrylic, assembling itself with the inferior plate in a centric relation. The lower splint is kept only with the vacuum plate unless some correction is required. If the lower anchorage falls to a proximal level between 6 and 7, a flat area will be created to increase the anchorage bonding surface.

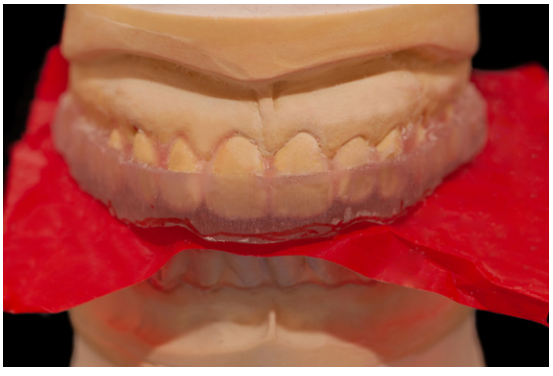








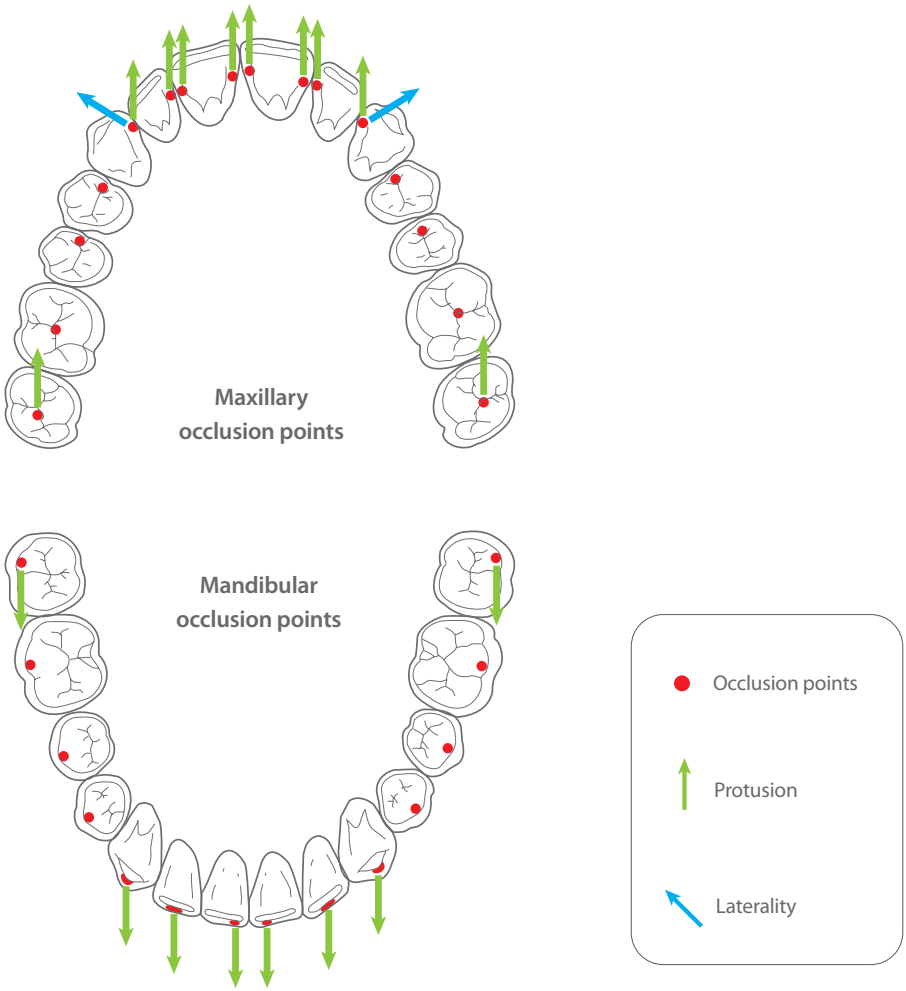


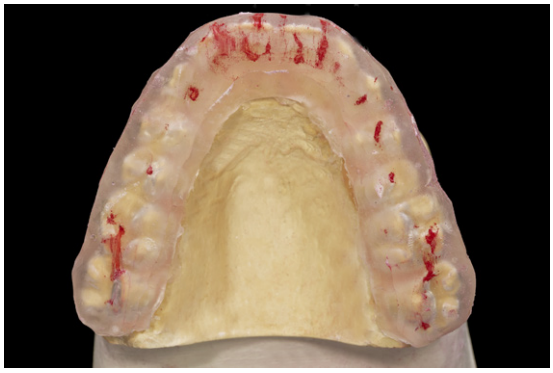


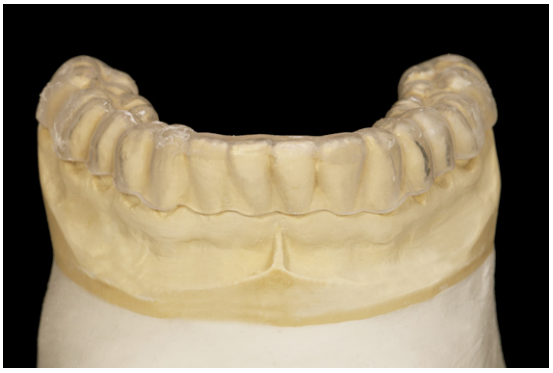
3b. The acrylic load of the upper plate must meet the following occlusal requirements: flat surface, occlusion of all functional apex and lower incisor edges on a flat surface **without indentations**, and laterality in canines. This way, when doing the protrusion, contact will exist in the incisor edges and in the molars active apex to ensure a stable position when the jaw is moved forward. We seek a protrusive, with contacts in the last molars.

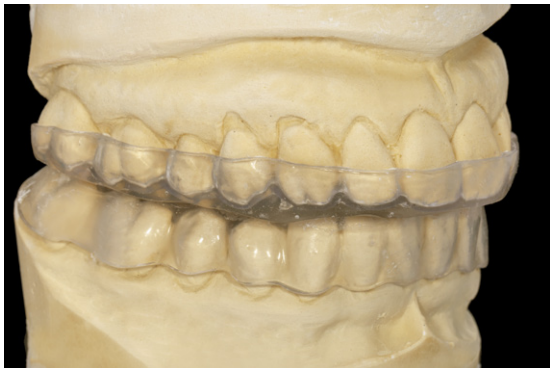
Ensure that the splint is in full contact with the vertical walls of the last molar around all of its free perimeter corresponding to all but the interproximal region.

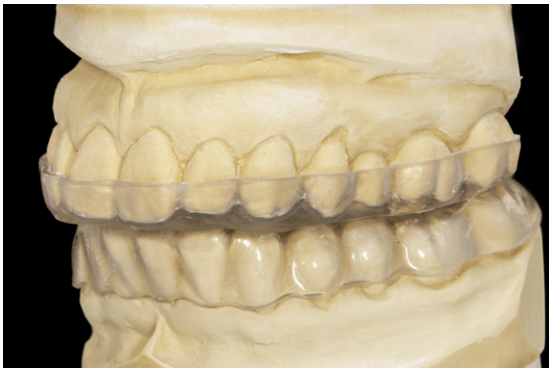
- This contact can be ensured from the centre of the mandible up to the optimal placement of the advancement device. This contact must be maintained throughout the entire band with at least 4 contact points (2 IN THE MOLAR REGION AND 2 IN THE INCISORS), taking advantage of the increased thickness of the plastic at the level of the lower arch, adding the resin in the upper splint, and flattening the areas that will come into contact. This way we ensure a uniform contact with any advancement device.
- In order to improve the patients' comfort and avoid overloading the dental pieces involved, to the extent possible, it must be avoided that an advancement device only be in contact with the mouth in 1 or 2 points.

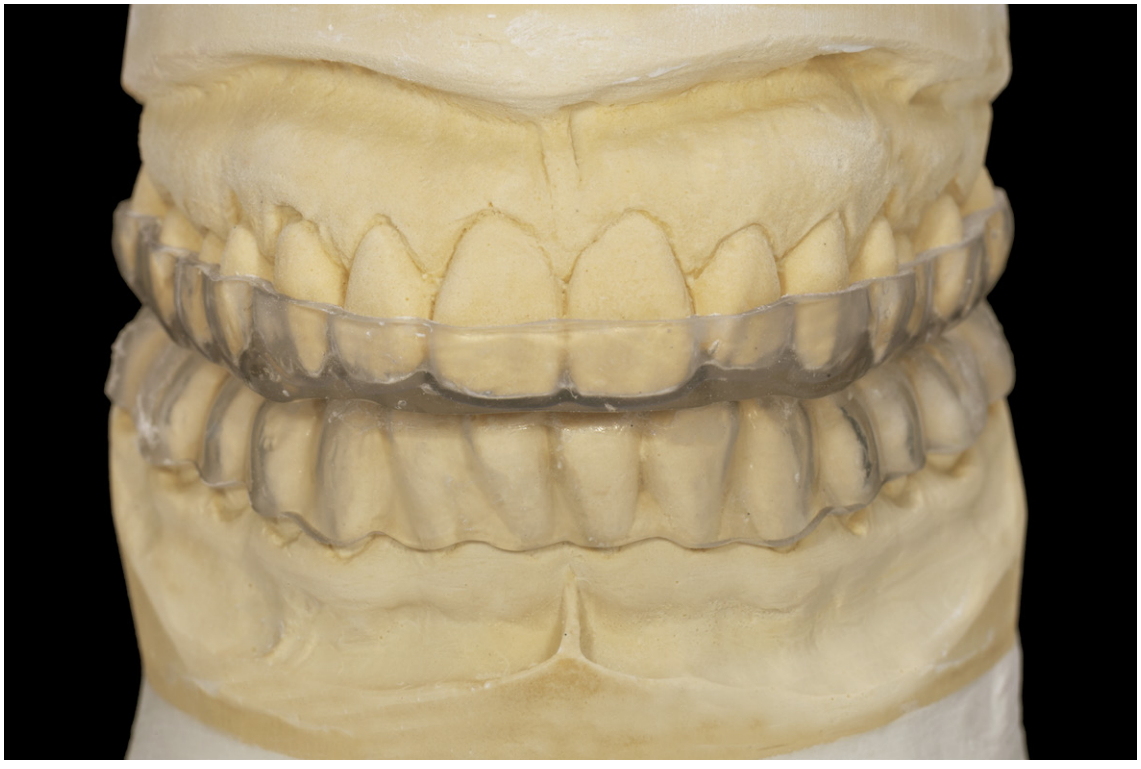






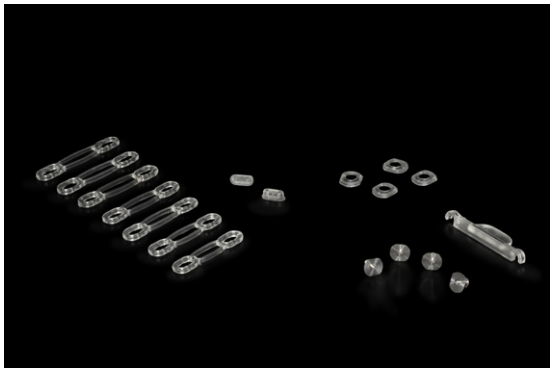






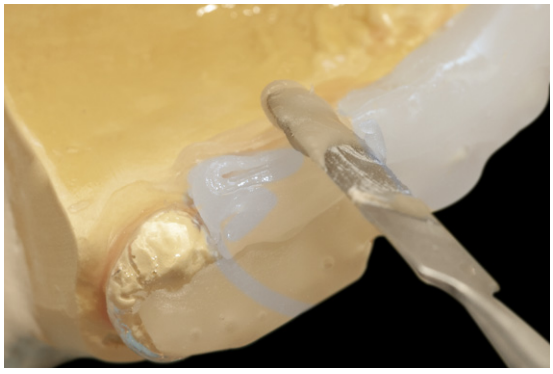
4. Commercial kit for splints preparation. The accessories required are sold in boxes of 4 or 12 kits.

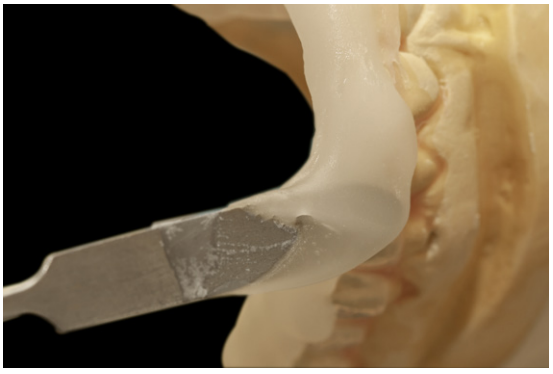
The use of adhesive Loctite 4061 (used for both anchors and the washers) and Loctite 4305 (light-curing sealing gel that will be used to seal the metal-splint-washer interface) is recommended. Both of these products must be kept in the refrigerator before and after use.

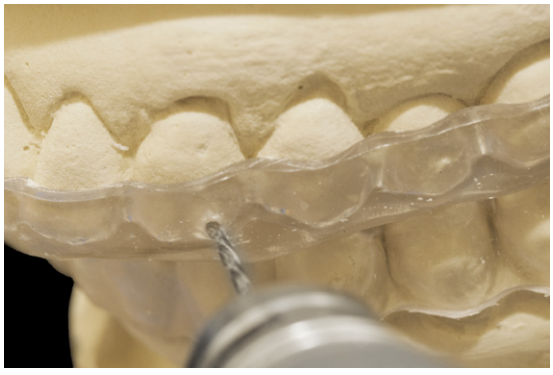


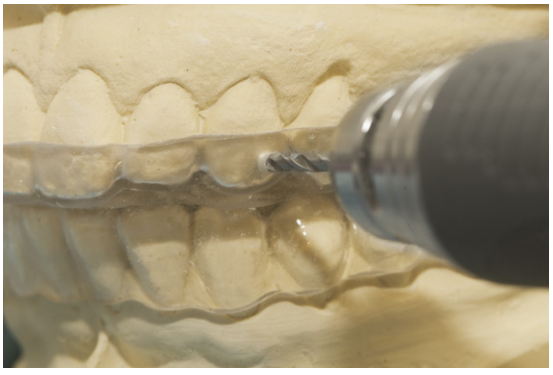
5. Before making the perforations where the titanium anchors shall be placed, and with a small amount of resin, a flat surface will be created in the area where the lower anchors will be placed, in order to favors its adhesion. In this way, the whole area around the anchor strengthens while increasing the support platform.

A perforation is made (using the smaller caliber drill that comes in the kit) distally of both upper canines near the apex (incisal third) for insertion of the anchors of the restraint and mandibular advancement of both splints. If the location and angulation are suitable, the diameter will be increased with the larger drill.

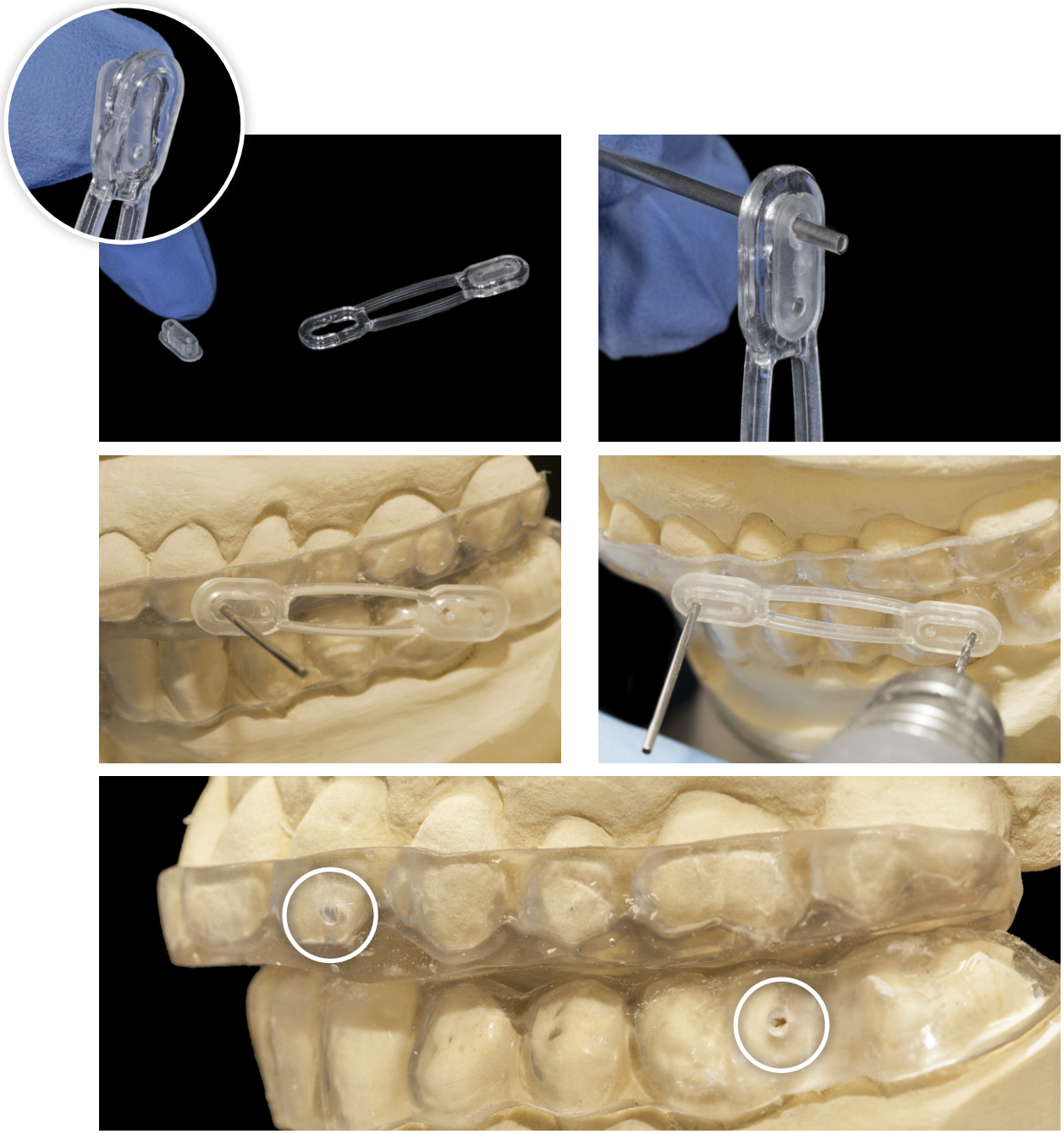








6. The tensor that will join both splints together is selected, so the one that covers the distance from the point made in the upper canine area to the distal area of the lower first molar canine must be found. Generally we use the tensor of 27 mm and otherwise that one of 26 mm. The tensor will be placed in position and we will attach it to the upper canine perforation with the 1 mm fastener with the help of the guides and the pin for the subsequent anchors drilling. Once the tensor is positioned, we will proceed to do the perforation in the lower molar. The same will be repeated in the contra lateral side.



7. The anchors that will be attached to the splint and where the tensors will be introduce into, comprise two parts:

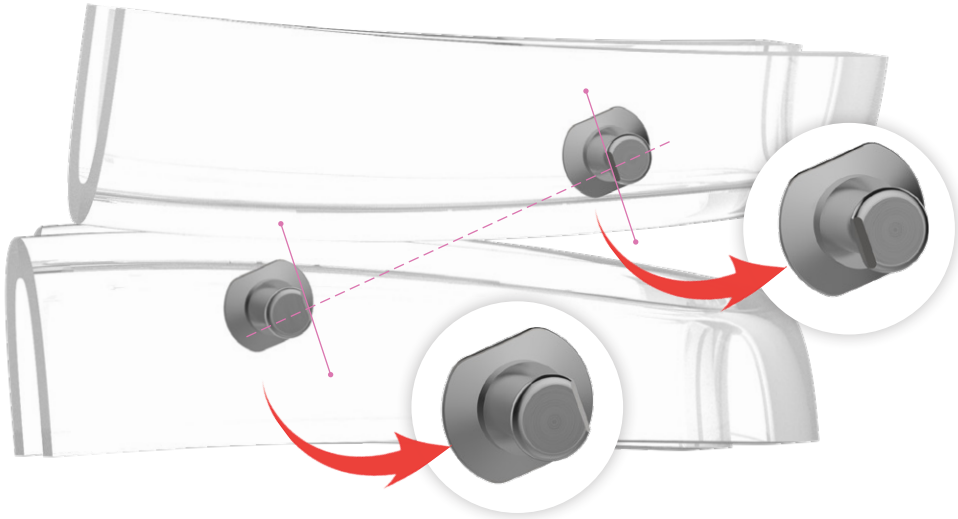
- A titanium anchor that adheres to the splint and then leaves the tensor insertion surface once positioned.

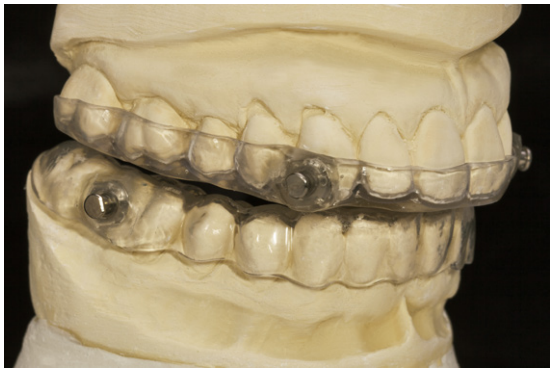
- A plastic washer (made of polymer) placed on the titanium anchor and reaffirms the anchor attachment to the splint thus increasing anchoring sealing and retention.

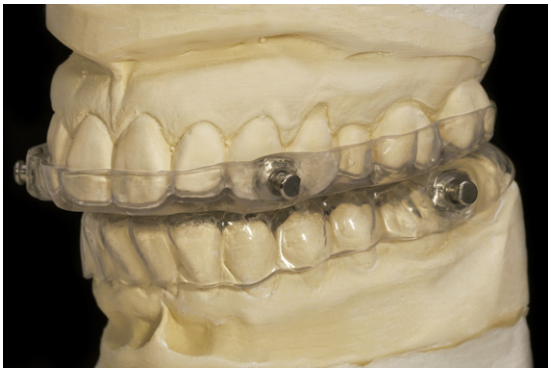
The upper anchors are positioned in the upper holes which will serve to insert the tensors. These anchors are attached with a special self-curing adhesive (Loctite 4061). To properly place the anchors, we must have a frontal view of both models mounted on the articulator so that both upper buttons are in the same plane along the circumferential arc standing in the outermost possible position. In order to do this action we use the anchors positioning guide which is included in the kit. If they are placed leaned or one innermost than the other, this could hinder the protrusive and laterality advancement, causing breakage of the anchors and tensors, as well as enabling mobility and therefore the opening. It should be kept in mind that upper anchor bevels should face a distal position when placing them.

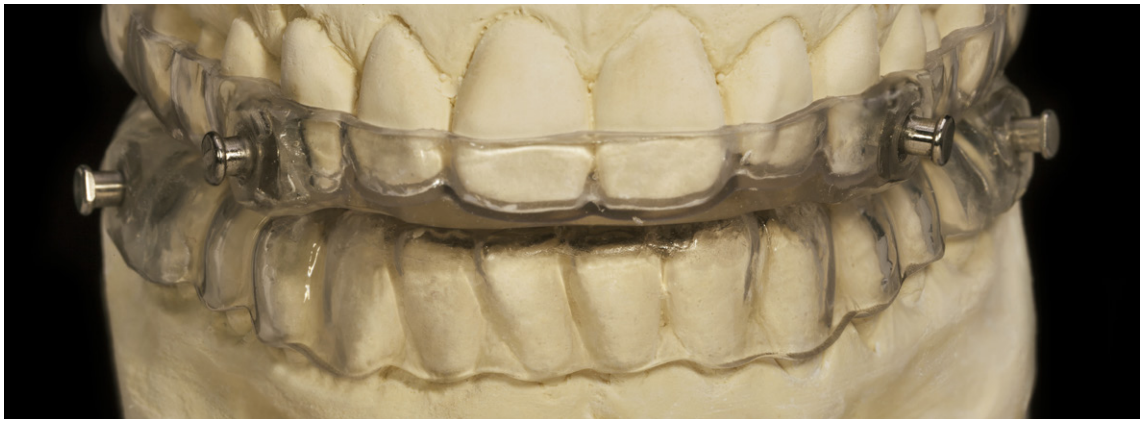
8. The lower anchors are positioned with the bevels facing mesial and also facing the upper anchors using the anchors positioning guide.

Both anchors must be on the same spatial level and the anchoring bezel facing each other, to favor the tensor insertion and to prevent it from coming out when rotating.



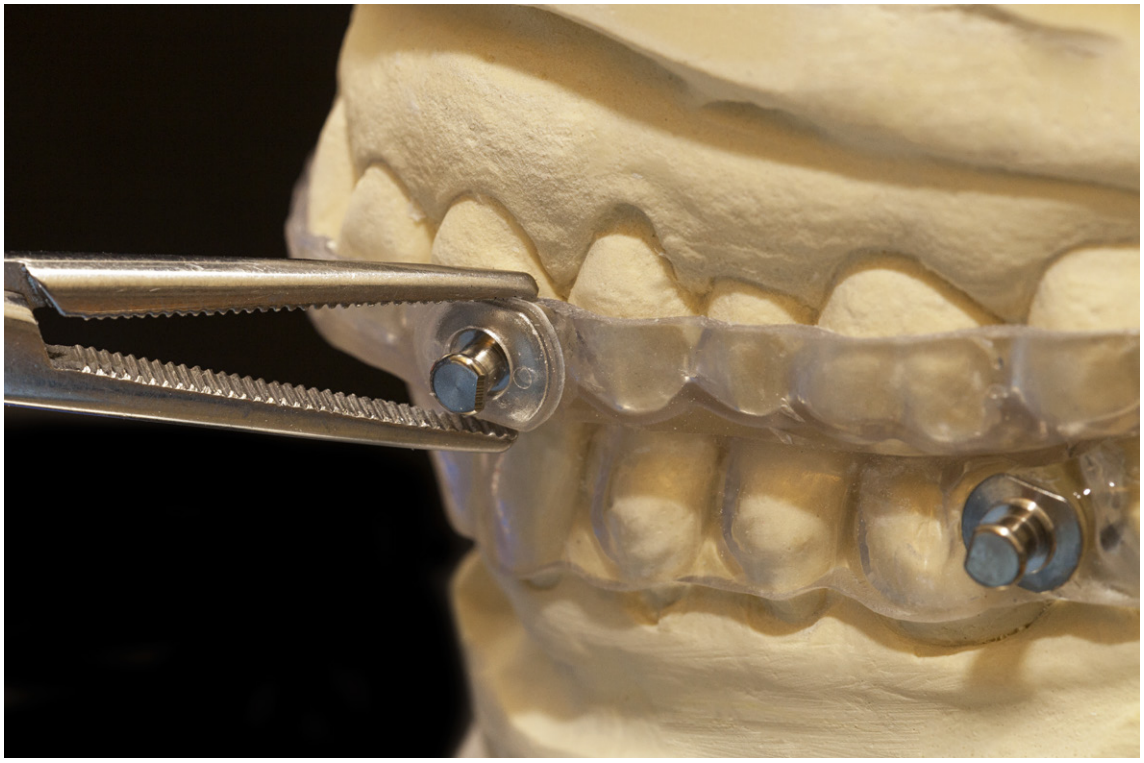


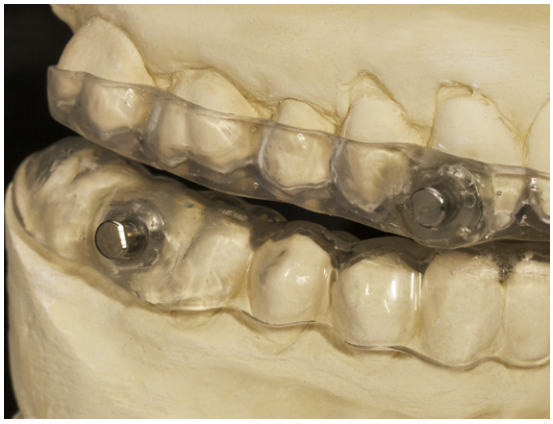


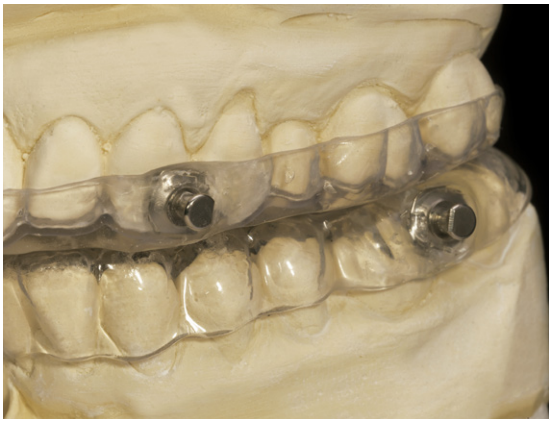


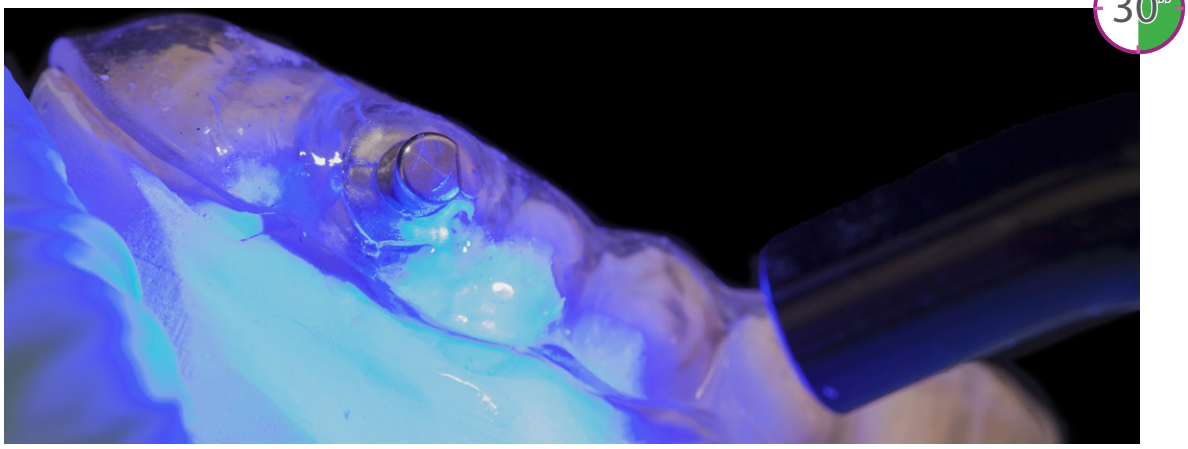
9. Once secured, it is essential to ensure that the anchors are in the same level, otherwise it's time to get them off and correct their position. After verification, the washer will be inserted over the anchor and this will reinforce the union. The washer must be positioned carefully, and once oriented in its final position, adhesive will be applied on top of the metal and the anchor washer. Pressure is put on both materials for proper adhesion. Finally, the light-curing sealing gel (Loctite 4305) shall be applied to seal the metal-splint-washer interface, creating a firm and reinforced bond.

The purpose of the sealing gel is to ensure the absence of pores once the anchors and washers have been fixed with the adhesive, and to ensure that the metal-splint-washer interface is perfectly sealed.





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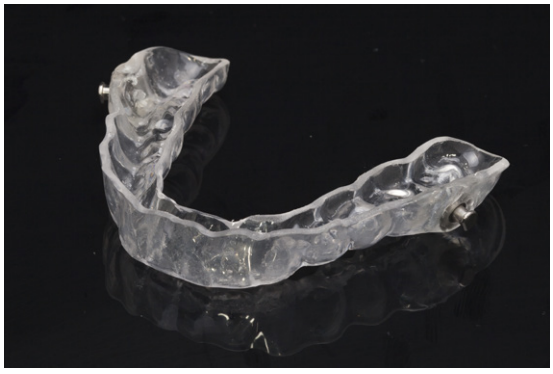
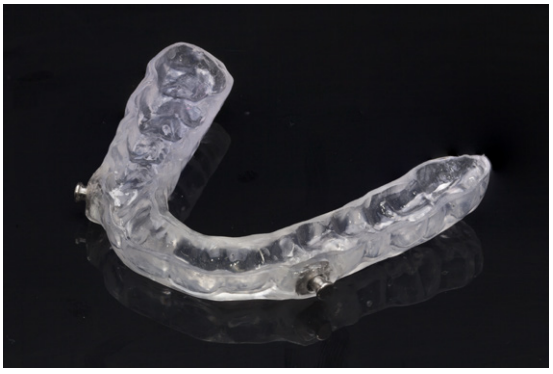
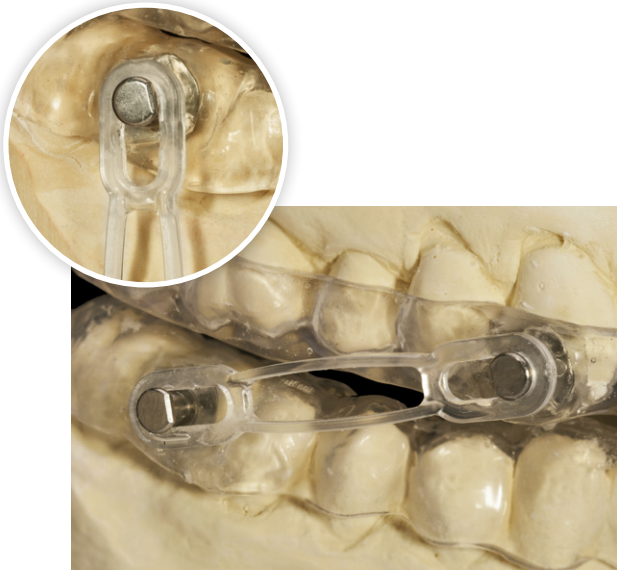
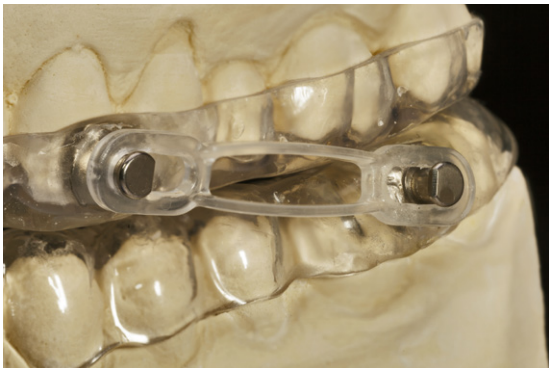




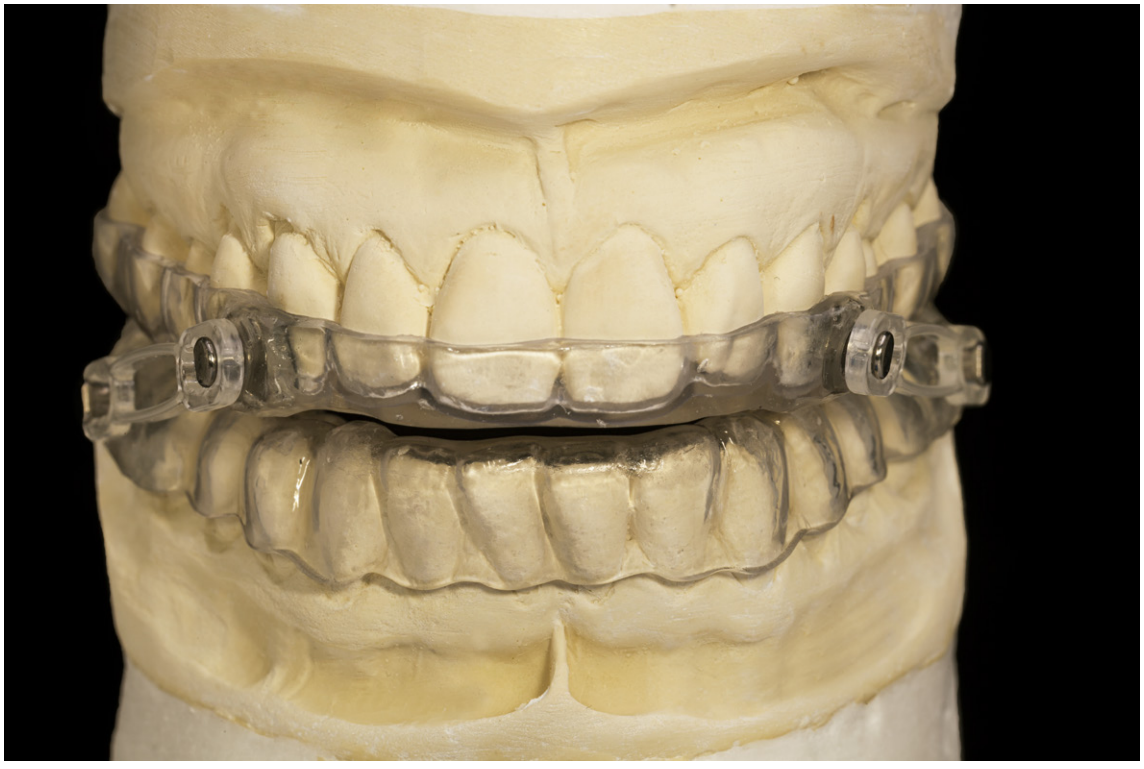
10. Finally, the chosen tensor is affixed to the anchors, being able now to select the tensors length, and the splint is ready for use.

Tensors are inserted in a 90º position, using the anchor bezel to facilitate its insertion or removal.

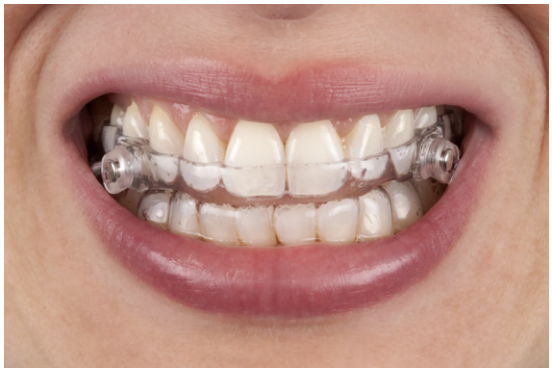


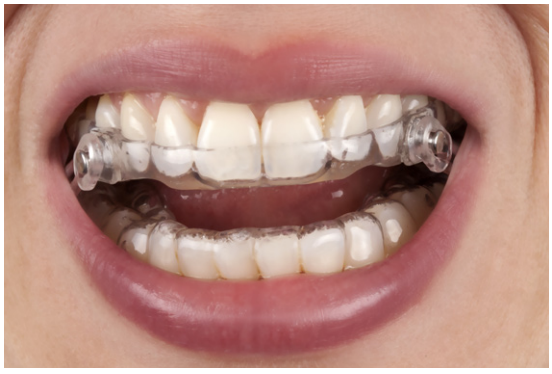


We use the tensioner nº27 for the assembly.



11. The splint reaches the clinician with the tensor that has been used and the clinician must try the splints in the mouth removing the tensors and ensuring a perfect adaptation and comfort as well as adjusting the occlusion. It be will assessed whether the patient should stayed a few days without tensors to be able to get adapted to the splint and then the tensor will be placed showing the patient how to insert it with the hand. If the splint has been done with a number 27 tensor, then it is recommended to use a number 26 for the first treatment. If after two weeks the patient feels comfortable with its use, the first APNiA treatment will be carried out.





12. Splint cleaning should be daily following these steps:

- Brush the splint while rinsing it
- Fill the box with 80% water and add a prosthesis cleaning tablet
- Immerse the splint for a couple of hours and then rinse it with water

This way the DIA will remain in perfect conditions for a long period of time, depending on the severity of bruxism and its parafunctions.






5. HOW TO EVALUATE (TREAT) THE APNIA INTRAORAL DEVICE

At the time a patient is offered the possibility of initiating treatment with the intra oral device (IOD), it is necessary to foresee a number of sleep studies that reliably show us each advancement results. This process of successive advancements and sleep studies is what we call "Treatment". Although it is a dynamic process that varies in each patient, there are general recommendations to follow which algorithm we detail below. First of all, we will have encountered this situation:

Patient that responds positively to two of these six questions:

1. Snores habitually
2. Suffers from hypertension
3. Is obese
4. Suffers from cv or cerebrovascular
5. Excessive unexplained daytime sleepiness disease
6. Dental wear

APNiA

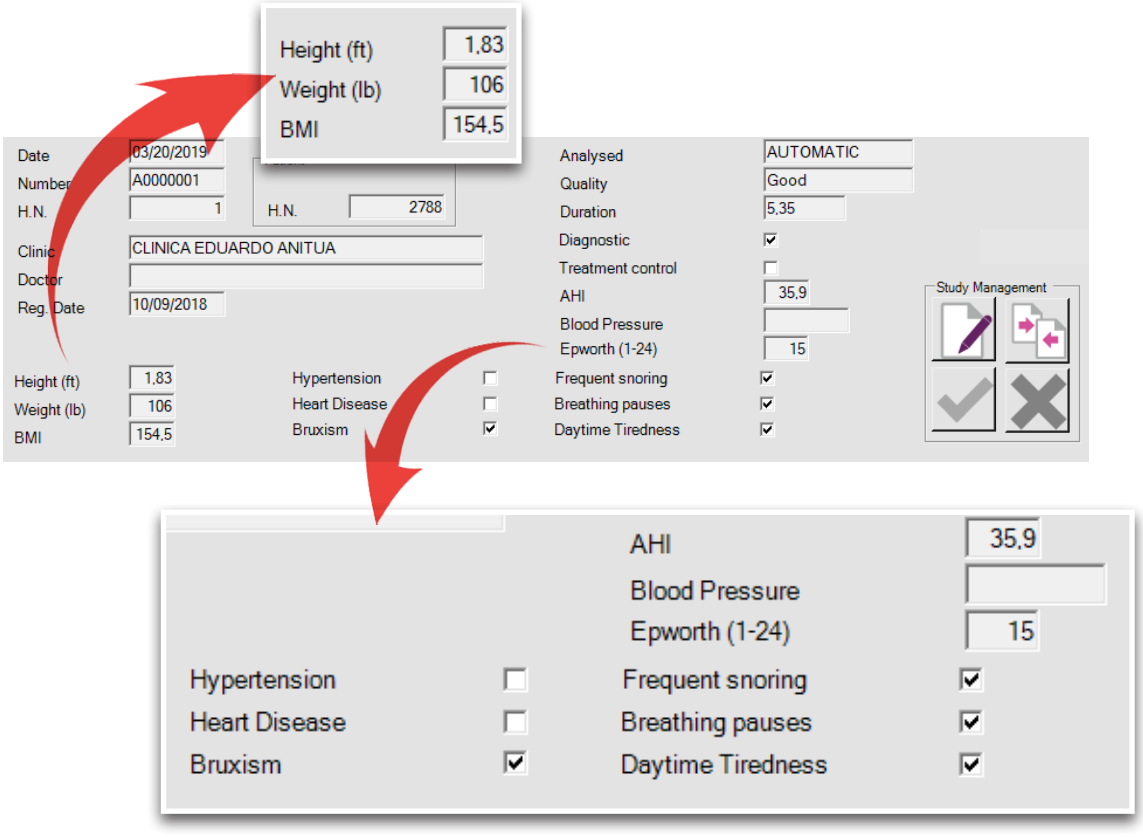
1. AHI between 5-15
2. AHI between 15-30 without associated comorbidity
3. AHI > 30 who refuses or can not tolerate CPAP after having being assessed by a sleep unit
4. Simple snoring that generates coexistence problems

DIA

EFFICIENCY EVALUATION (TREATMENT)

That is, in the presence of a number of symptoms and after a diagnostic test, evidence is obtained of the existence of a breathing disorder during sleep susceptible of being treated with an intraoral device. As seen in the algorithm, we consider candidates for treatment with an intraoral device those who show an apnea-hypopnea index between 5 and 15, between 15-30 without associated co morbidity and severe cases, that is, with AHI rates above 30 but who reject treatment with CPAP or who presents CPAP intolerance after being assessed by a sleep unit. We must not forget patients with simple snoring who, despite not suffering SAHS, they do present a coexistence problem derived from snoring.

It is extremely important to have taken sufficient clinical data of our patients in order to know potential associated pathologies. A number of key issues should be registered. APNiA software itself allows us to register anthropometric data, as well as the fundamental questions that we should take into account when taking therapeutic decisions.



We need to know that if a patient with hypertension or cardiovascular disease also shows an AHI index superior to 15 in the diagnostic test, he should be referred to a sleep unit for further assessment.

At the same time, we must take into account a number of dental recommendations to be assessed during the treatment:

EVENTS

- ☐ Pain or dental/gingival pressure
- ☐ TMJ pain
- ☐ Oral intolerance
- ☐ Dry throat (mouth)
- ☐ Dental repairs damage
- ☐ Change in the occlusion
- ☐ Hypersalivation
- ☐ Bad dental occlusion
- ☐ Neck pain
- ☐ Cephalea
- ☐ Insomnia
- ☐ Device breakdown
- ☐ Non-specific discomfort
- ☐ It is used everyday
- ☐ It is used at all times

TREATMENT

- ☐ Conservative
- ☐ Change of strap
- ☐ Advancement reduction
- ☐ DIA interruption
- ☐ Referral or TMJ consultation

Regarding sleep, it is important to collect data from their sleepiness through the Epworth scale (described on page 35 of this manual) to evaluate the changes and to observe the evolution.

In general, we can say that a patient shows excessive daytime sleepiness if the sum of the results of all questions is over 12, with a maximum of 24. This questionnaire is very useful and in patients with severe symptoms can verify the benefit treatment and, if it occurs, a worsening of symptoms, usually because of insomnia due to DIA maladjustment, which should be taken into account.

Consider that in addition to all patients with apnea-hypopnea syndrome, in our clinics we will see many others who come because of simple snoring, this is that they do not present a pathological apnea-hypopnea index but they do complain of snoring (themselves, their partners or relatives whom they live with). Snoring, although it is not considered a clinical pathology, it can nevertheless be considered as it would be one from a social point of view and it can generate serious problems of coexistence. Therefore, it is very important to have in mind the assessment that the patient makes about his snoring, aided by information from their close relatives. An example of questions that should be answered during the treatment is the following:

SPLINT SYMPTOMS CHANGES GLOBAL IMPRESION

Comparing the current situation with what it was before starting this treatment, how would you say that the following issues have changed?

Mark with an (x) the most appropriate response and remember that you can only mark one.

1. How do you sleep?

☐ Much worse ☐ A little worse ☐ No changes ☐ Something better ☐ Much better

2. How do you feel during the day?

☐ Much worse ☐ A little worse ☐ No changes ☐ Something better ☐ Much better

The next question is for you to give us your impression regarding whether your snores have changed when wearing the splint (ask your bed partner or close relatives, if possible).

You nightime snores:

- ☐ Have increased a lot
- ☐ Have increased a bit
- ☐ No changes
- ☐ Have reduced a bit
- ☐ Have reduced a lot

Once the DIA device has been placed, an adaptation time must pass before the second sleep test. In general, this time can vary from patient to patient and is usually shorter in those who already use an occlusal splint, but it should not last more than two or three weeks.

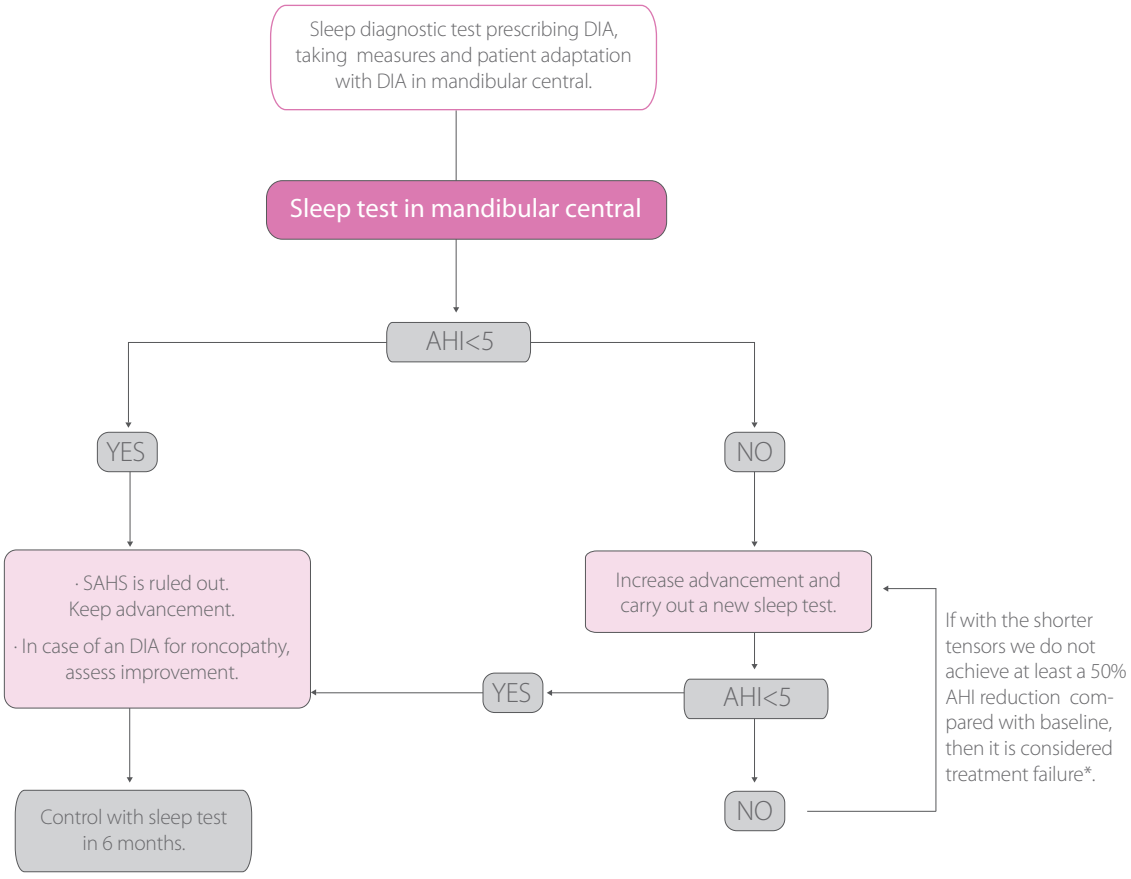
After the adaptation time, a sleep test is carried out to assess results with the device in the mandibular central area, as very good results have been achieved like snoring and AHI reduction. If the problem is only the snoring, then it is not necessary to carry out a mandibular advancement, but a treatment to corroborate snoring reduction. If not, the patient will be given a shorter tensor (it is preferably to advance in consecutive numbers, this means, little by little), and again an adaptation time is needed, which in this case is usually shorter (one week should be enough). Once again, the APNiA diagnostic device is handed to the patient and the results of the new advancement are assessed.

This dynamic is followed until the apnea-hypopnea index is less than five per hours of sleep (that is, until it is not pathological) or until we can achieve reducing this rate at least by half compared with the diagnostic test. Remember that not all patients respond the same way to treatment. As a general measure, it is important to note that **we seek the maximum benefit with the minimal advancement**. In those patients to whom 4-5 treatments are carried out and the desired effect is not achieved even using the shortest tensors, we will consider that the treatment is not being effective and other therapeutic options will be needed. The scientific literature even mentions a percentage of 10% of patients who worsened with the treatment with DIA. This gives us an idea of the importance of the treatment process and ongoing evaluation.

Once the patient is comfortable, symptoms have decreased, and the study provides us with satisfactory values, then the patient will be assessed at 3 -6 months. The test will be repeated 1 or 2 times a year not only to evaluate the AHI and the T-90, but also to assess the occlusal situation, TMJ, anthropometric data, as well as snoring and patients´ feelings.

As we have observed, and this is just an introduction, the development, adaptation and optimization of the intraoral device it is not a simple matter and it requires close monitoring.

Finally, we summarize everything said in a treatment basic algorithm:



** Literature data show an AHI reduction with the intraoral devices of around 50-60% compared to baseline. However, the variability is large, from patients who can be "cured" (AHI <5) to patients whose AHI reduction is less than 50%. Not optimal results, that is, when the AHI is not <5, or at least less than 50% from baseline, should be evaluated carefully and individually. In addition, the need to consult a sleep unit will be taken into consideration if the residual AHI is > 15.*

6. ADVERSE EVENTS WITH THE APNiA DEVICE

During its use, APNiA intraoral device may suffer adverse events that may fracture or detach some parts of it.

The main issues that we have found so far in our experience with the device are described below:

6.1. Tensors breakage

Tensors consist of a plastic material which has a breaking limit. When this limit is exceeded the tensor may fracture, generally, by the narrow area that joins the flanges which are inserted into the anchors.

When these type of fractures happen, the way to proceed should be to replace the tensor by one of the same size. Sometimes when the fracture was due to a movement restriction in that area, then the tensor can be replaced by one tensor that is 1 mm longer, thereby allowing greater freedom of movement.

6.2. Anchors detachement

It is possible that when removing the tensors, a detachment of the anchors may happen. When this happens, we must insert new anchors to allow the placement of the splint again with the tensors in position, and pay special attention to the spatial arrangement of the anchors and the proper bonding of the washers.

6.3. Splint perforation/tear

The patient must be alerted about the appearance of perforations in the occlusal surface of the upper or lower splint due to occlusal pressure.

These perforations, if detected, must be repaired to prevent improper contact areas on both splints that generate interference or prematurities thus disarranging contacts sought initially.

In parafunctional patients even splint breakage can happen. In these cases, the splint should be created again, thus being able to reinforce with resin the border areas where the break had occurred.

7. RECOMMENDATIONS

7.1. LOCTITE products handling and storage

The following recommendations for handling and storage LOCTITE adhesives are detailed below:

Storage:

- LOCTITE adhesives should be stored in a dry place and refrigerated at a temperature between 2º and 8ºC.
- LOCTITE 4305 adhesive is sensitive to light, so exposure to sunlight or artificial light should be limited to the maximum during handling and storage.
- They should always be stored in a vertical position inside the refrigerator.

Precautions for use:

- LOCTITE adhesives are to be used in a well-ventilated area. When handling the product in poorly ventilated environments a mask or respirator fitted with an organic vapor filter (Type A filter) should be used.
- The use of chemical resistant gloves such as nitrile gloves is recommended. No PVC, rubber or nylon gloves should be used.
- To protect the eyes against adhesive splashes, using a face shield or safety glasses are recommended when using the LOCTITE adhesive.
- To prevent skin damage we recommend using appropriate protective clothing.

Ultimately, the usual precautions when handling cyanoacrylate adhesives.

CAT180 BTI APNIA ENG - SBS TREATMENT - V. 01

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