

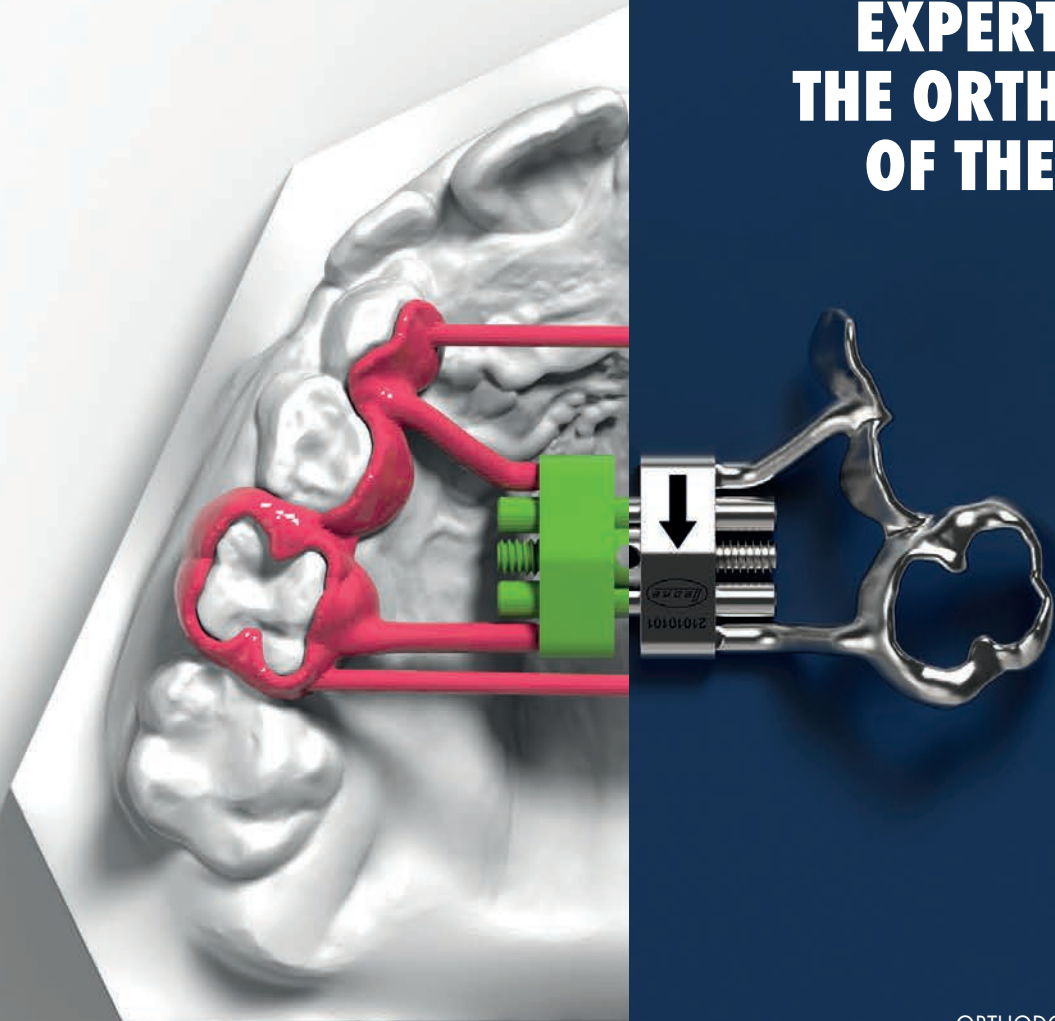
ORTHO NEWS

FALL/WINTER 2022
VOL 1 #42

LEONEAMERICA

A PERIODICAL FOR
ORTHODONTIC PROFESSIONALS

**TRADITION
EXPERTISE MEETS
THE ORTHODONTICS
OF THE *FUTURE*...**



MANUFACTURING
ORTHODONTIC PRODUCTS SINCE 1934

LEONEAMERICATM



PATENTED

CAD·CAM

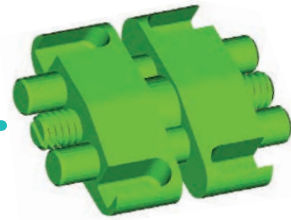
EXPANDER

**FIRST RPE SCREW SERIES
DESIGNED FOR A
FULL DIGITAL WORKFLOW**



RPE FULLY DIGITAL DESIGNED

CAD-CAM expanders allow the manufacturing of totally customized appliances with dental anchorage, hybrid (teeth and TADs) and bone borne in a full digital workflow, by using **3DLeone Designer** software.



SQUARED SLOTS

The CAD-CAM expanders bodies feature, instead of the standard arms, squared slots that allow a correct oriented coupling of digitally designed customized laser melted framework and, thanks to their geometric shape, the fully transmission of the expansion forces to the teeth and/or TADs



THE STRONGEST RPE OF THE RANGE

CAD-CAM expanders are manufactured by biomedical stainless steel with increased mechanical properties and a dedicated geometry of the male screw head that allow us to declare, based on in-vitro tests performed, a strengthness higher than 60kgf, about 50% higher than standard RPE.

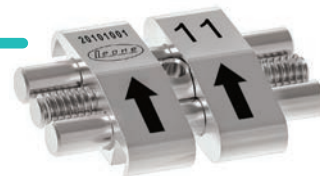


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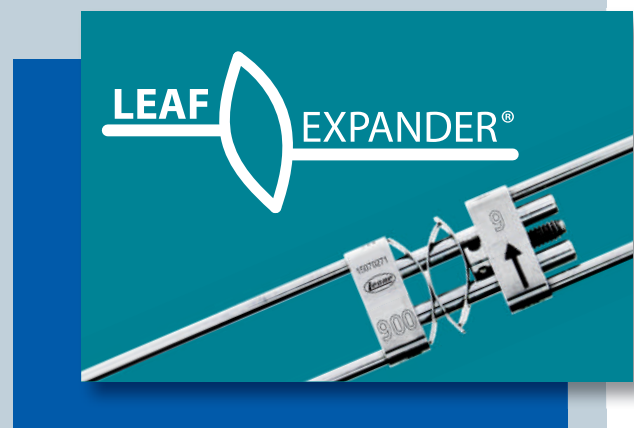
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Leone MAD



Designed to allow for early treatment of patients with mixed or deciduous teeth.

MEMORIA® Leaf Spring Activated Expander



Nickel Titanium MEMORIA® Leaf Springs allow the release of calibrated and continuous forces to promote the expansion of the maxillary arch.

RPE: from analogic to digital. Our experience

Dr. Fabio Giuntoli

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Introduction

Rapid Palatal Expander is the widely used appliance to treat one of the most common occlusal disorder: the upper arch transversal deficit, independently by the presence of related complications as unilateral or bilateral crossbite.

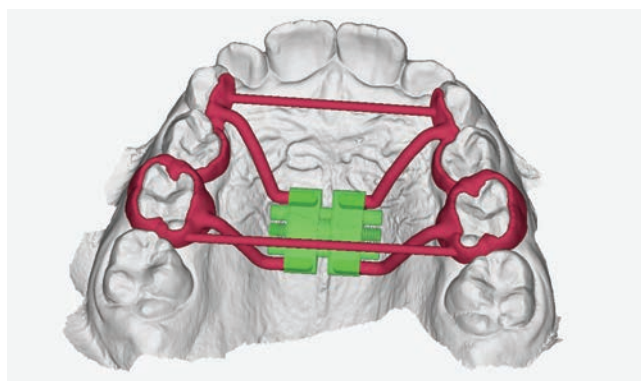
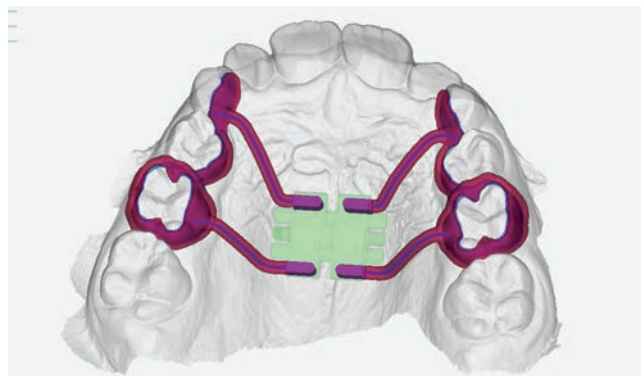
The aim of this article has been, by showing clinical pictures of two real cases, to offer some critical insights to compare two different designing and manufacturing methods for the Rapid Palatal Expander.

In the first case the lab has used a conventional method for the RPE appliance construction, while in the second case the technician has used a CAD-CAM digital technology by means of the recently released 3DLeone Designer software.

CASE 1 - CONVENTIONAL ANALOGIC METHOD



CASE 2 - CAD-CAM DIGITAL METHOD AND 3DLEONE DESIGNER



CASE 1 Conventional analogic method

The first patient, L.P. 9 years and 2 months old, showed a maxillary transversal contraction with -5 mm of transversal discrepancy plus a left unilateral crossbite and consequent left mandibular shift.

A standard RPE, manufactured with the conventional method and based on an alginate impression taken after the bands fitting has been applied. Elastic separators have been placed a week before the bands fitting and a week before the expander cementation.

The 13 mm Leone A0620 expander has been used and was performed a daily activation for 32 consecutive days to solve the transversal discrepancy including an overcorrection of about 30% to compensate the possible relapse.

RPE has been removed after 12 months, by the end of the active phase.

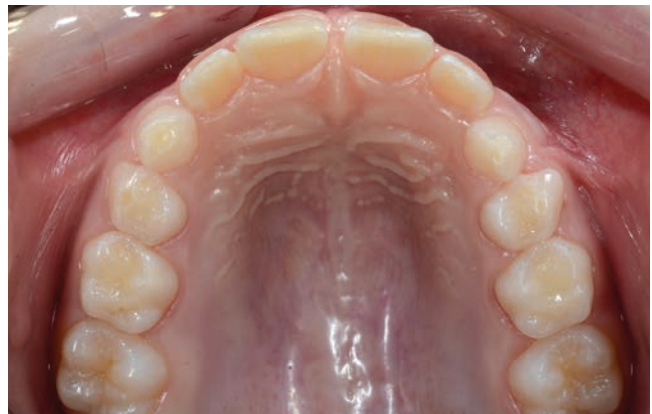


Fig. 1a-d - Intraoral pictures before

RPE: from analogic to digital. Our experience



Figg. 2a-d - Intraoral pictures of rpe at the end of activation



Figg. 2a-d - Intraoral pictures after rpe

CASE 2 **CAD-CAM digital method** **and 3DLeone Designer**

The second patient, C.G. 9 years and 4 months old, showed a maxillary transversal contraction with -4 mm, anterior crowded teeth, class II occlusal relationship with absence of crossbite. In this case an impression by means of an intra-oral scan has been taken, avoiding the need of placing elastic separators. A palatal expander Leone 9 mm A0620 CAD-CAM, manufactured by 3DLeone Designer Software was placed. Daily activation was performed for 26 days consecutive to solve the transversal discrepancy including an overcorrection of about 30% to compensate the possible relapse as the previous case.



Fig. 1a-d - Intraoral pictures before

RPE: from analogic to digital. Our experience

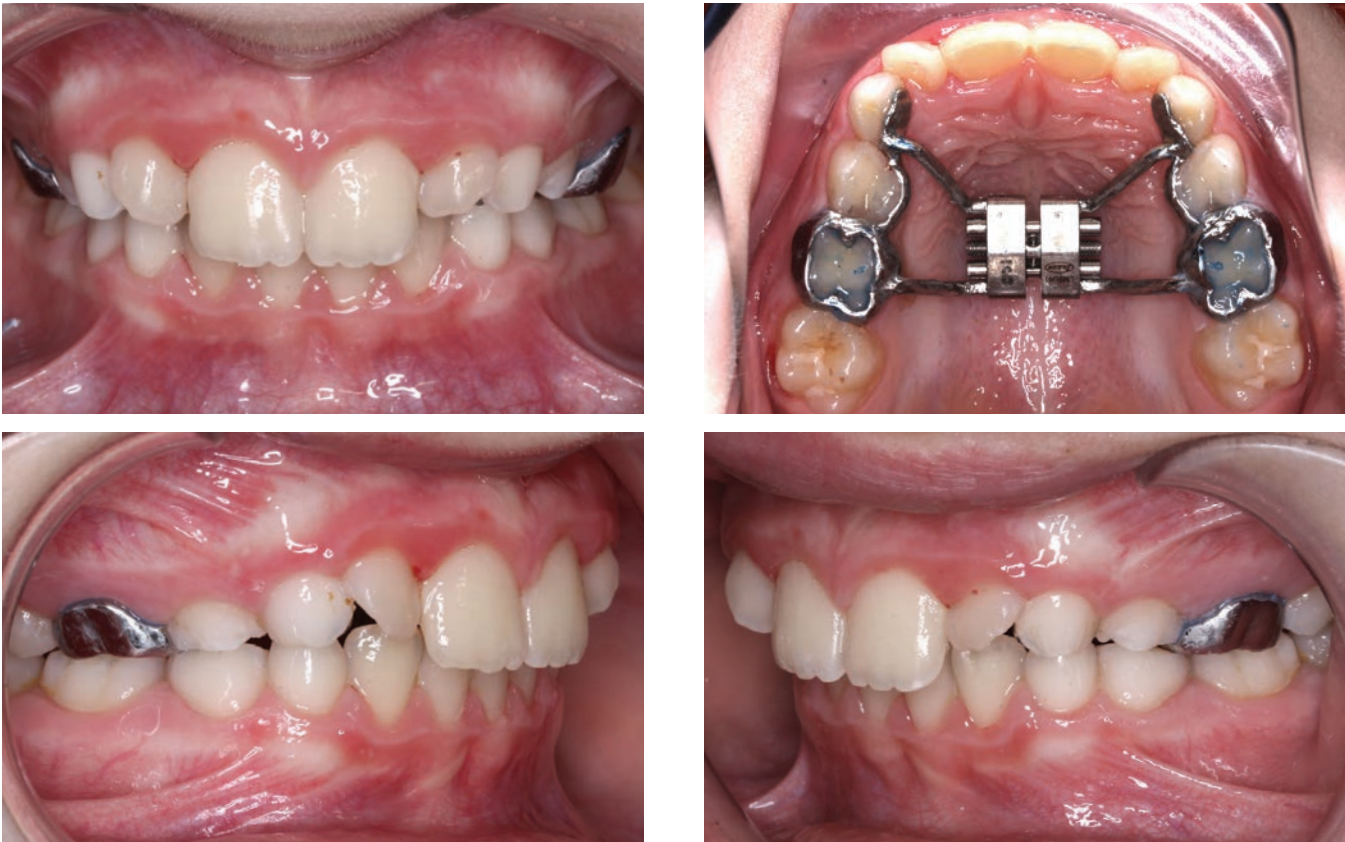


Fig. 2a-d - Intraoral pictures with RPE

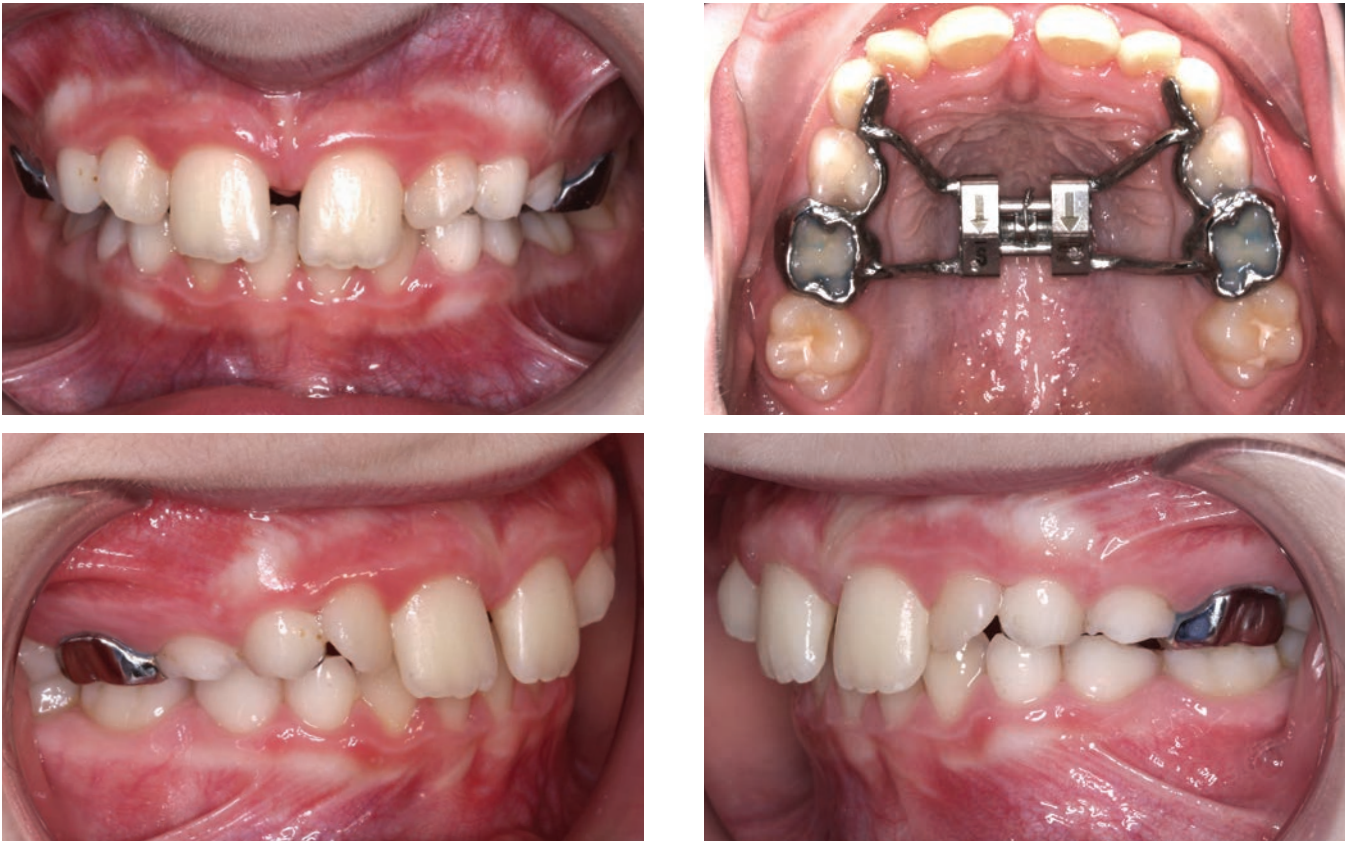


Fig. 3a-d - Intraoral pictures of rpe at the end of activation

Comparison method

It has been analysed the manufacturing and delivery time of both the workflows.

Some important clinical aspects have been compared: the precision and ease of expander placement as well as the eventual interferences between the soft tissue and the arms of the RPEs on both methods.

Working phases have been analysed: placement of elastic separators, impression taking method, eventual necessity to create plaster or printed model, designing, manufacturing and delivery.

Results

Both manufacturing methods result were effective since the appliances have determined the orthopaedic upper arch expansion. The full-digital manufacturing method, however, were more efficient since we have observed an important time saving both in dental office, due to 3 appointments less, and dental laboratory manufacturing phases with an estimation of 50% less time.

We have also observed better patient comfort, due to the 3DLeone Designer A.I. that allows an automatic and precise digital configuration, thus the expander designing become also less operator dependant.

Moreover, a 50% reduction of a detaching issue with the use of digitally customized bands compared with the use of the preformed ones was observed.

To sum up, the clinician advantages of a "full digital" method have been:

- no to place elastic separators;
- it has been possible to validate and/or modify the project by the clinician before the effective appliance production;
- patient discomfort greatly reduced, since the bands do not overrun the interproximal spaces, as well as the metal framework being designed with an ideal distance from the soft tissue, perfectly rounded and placed as high as possible in the palatal vault. In addition, the bands designed with a full digital method detach from the teeth pretty seldom and can be placed easier and faster than traditional bands and with less patient discomfort during the adaptation phase, thus avoiding the soft tissues compression. Dental Lab advantages have been:
 - to avoid some manufacturing steps;
 - being able to reduce the construction pases and delivery time;
 - and the option to work without printing any model.

The clinician disadvantages have been represented only by the slight higher cost of the appliance, while for the dental technician mainly, is the learning curve for use the software and the need, just in case a 3D printer was not already present at the lab, to find a metal printing service company.

Conclusions

A full digital method to manufacture a rapid palatal expander has the only disadvantage of slightly higher costs than standard analogic method. However, reducing clinical phases thus saving time as well as the increased patient comfort makes this method effective, efficient and predictable, totally justifying the slightly higher costs.

FULL DIGITAL METHOD

ADVANTAGES CLINICIAN

- possibility to validate the project before the production;
- less chair time;
- no need to place elastic separators;
- higher patient comfort;
- less unwanted deattachments, therefore better safety

TECHNICIAN

- reduced construction time;
- better precision;
- less technical skill

DISADVANTAGES CLINICIAN

- higher costs

TECHNICIAN

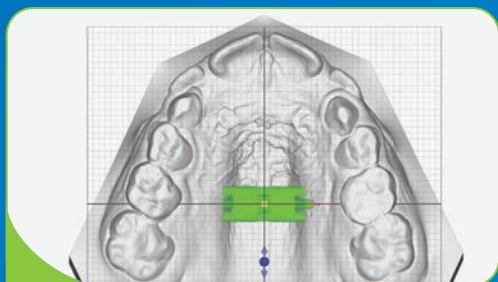
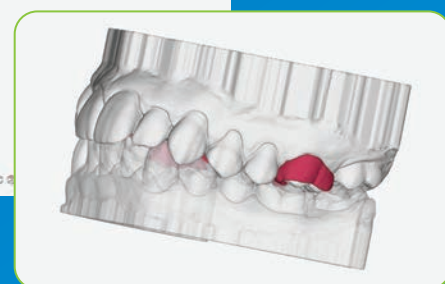
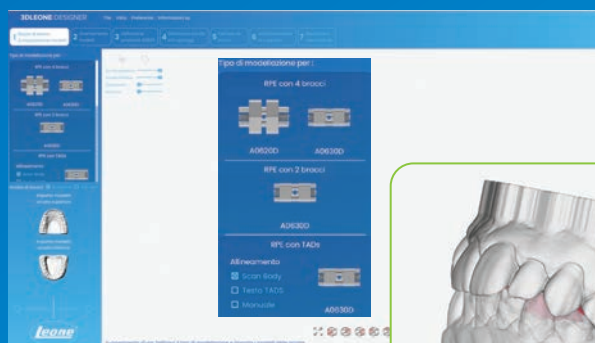
- purchase software;
- learning curve to work with software

3DLEONE DESIGNER updated version

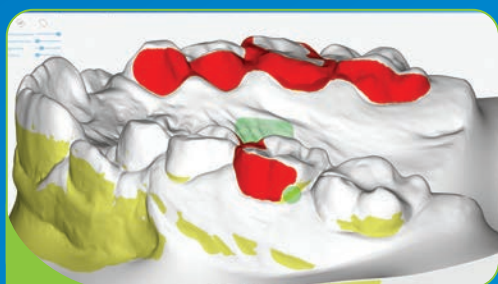
An updated version 2.0 of **3DLeone Designer** is available.

This new version implements many new features: new look, new tools and new workflows.

- The look of the "home page" is new with the implementation of some **icons** that are the 3D representations of the Expansion screws together with the related type of orthodontic appliance, in order to make easier the choice of the right workflow. Further there are in addition some icons of the lower jaw and of the upper jaw in order to guide the upload of the intraoral scan or the lab scanning of the models.



- One of the new features is the possibility, by flagging the proper command, to show the **reference grid** as an aid for the operator to the positioning of the expansion screws on the base of the automatic default position given by the software.

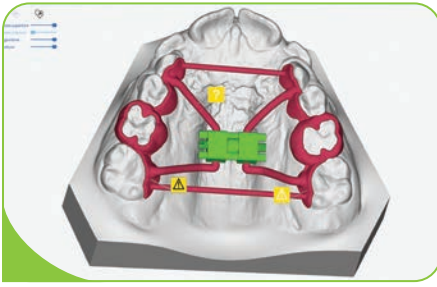


- Another new feature is the ability to show the **undercuts** of the model during the design of the bands surfaces and supports in order to include or not in the selection the undercuts area.

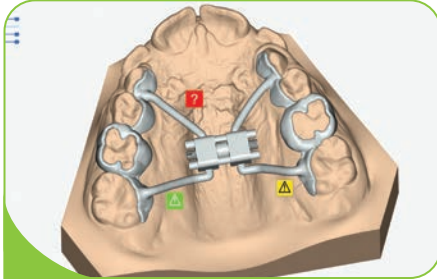


- An additional function is to allow the digital position of the **single tube on each band**. This feature permits to automatic design on the band with the proper slot for the tube base at the end of the workflow during the exportation phase. The dedicated slot on the band surface will ensure the perfect positing of the tube with no errors possibility; the tube will be laser or spot





- Based on customer requests we added the possibility to insert labels, when necessary, to write **annotations** for communicating warning or asking questions to the Clinician in an easy way just to click in the chosen area. The updated viewer will be able to show these annotations.



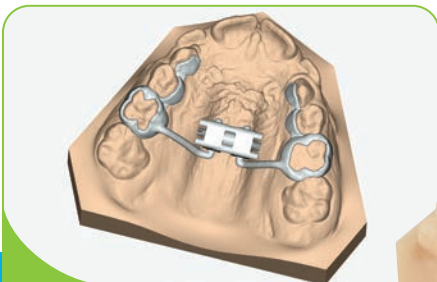
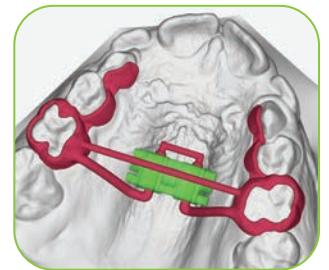
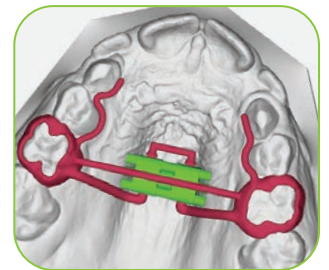
- The **3DLeone Designer Viewer** is a free software to improve the communication between Technician and Clinician: The Clinician can import the project file (.3dl) with all the data regarding the design done by laboratory, to control the designed appliance and all the necessary information such as the designer name, the catalog reference and the dimensions of the expansion screw and any annotations added by the Technician.

- Regarding the workflows, we highlighted the use the **A0630 CAD/CAM** anatomic expander in hybrid and bone borne cases. This expansion screw is well-known for its unique technical features:
 - the **design** due to its small size allows a comfortable positioning;
 - the **mechanical strength** is the strongest of the RPE range because it is manufactured in biomedical stainless steel, and also because the size of the expansion swivel key and consequently of the activation hole are increased;
 - the **large longitudinal squared slots** allow a perfect fit with the laser melting framework making the expansion screw body to be joined permanently by laser welding with the customised arms.



These unique and innovative features make the expander suitable for many uses: dental anchorage both permanent and permanent/deciduous teeth, hybrid (teeth and 2 TADs) and bone borne (4 TADs).

- The **3DLeone Designer 2.0** introduces the possibility to use the A0630 CAD/CAM anatomic expansion screw also with **only two posterior arms** that will be joined to the "connections", the squared slots in the two screw bodies, without being forced to design the two anterior arms. Summing up, the orthodontic expander will be provided only with 2 arms that will be connected to the bands and anatomic supports or alternatively to a round arms. This feature allows to further reduce the size of the orthodontic appliance and at the sometime increase the comfort of the patient without losing stability and expansion strenght, that are the main features of this expander.



ACTIVATE YOUR
FREE TRIAL



Me and the 3DLeone Designer

Dental technician Stefano Negrini

Founder & CEO ORTODONZIA ESTENSE Srl - Orthodontics specialized laboratory

My phone ringing...incoming call from Gabriele Scommegna Leone. To be honest with you I must underline that between me, Founder & CEO of Ortodonzia Estense srl, and Leone company there are not any agreements or contracts, but just simply a professional collaboration based on transparency and mutual respect. With Leone company and especially with Gabriele, the relationship has always been great, we have discussed together and shared opinions about many different technological matters that, in the last years, have brought both of us to a professional growth.

During that call Gabriele informed me that Leone was involved in a project to create and sell a software for custom-made expander CAD-CAM designing, the 3DLeone Designer software. The project was at that time still in a Beta phase so my help would have been useful to get feedback on the software, based on my strong knowledge on software and digital technologies in general. Starting from that call, we began to test all the 3DLeone Designer potentials through the digital workflows daily did inside my laboratory.

I decided to involve some of my collaborators that work daily with others' software, in order to evaluate their first impression and collect their feedbacks. With great amazement,

almost all of my collaborators had a good approach and were completely confident since the software was developed with a straightforward workflow, for a fast but controlled utilization, evidenced by the fact that it was developed around the word "SIMPLICITY" of utilization.

Obviously the first Beta version presented improvements to do but from the beginning this software showed great potential. Step by step the software was improved to give it a "new shape"; new tools and functions were integrated as well as new dedicated workflows, with the chance to design RPEs also anchored on TADs.

I even took opportunity and recorded some videos and shared on my website "HUB3DOrthodontics", dedicated digital orthodontics platform, in order to get feedbacks and show it to all the people that follow me. Here below some pictures about some RPE and MARPE manufactured inside my lab, starting from digital designing through 3DLeone Designer software.

- 1) RPE with Leone expander A0620D with additional hooks for Delaire's Mask (Figg. 1a-b)

Courtesy by Dr.a Karmen Verhovec ZoboEstetika

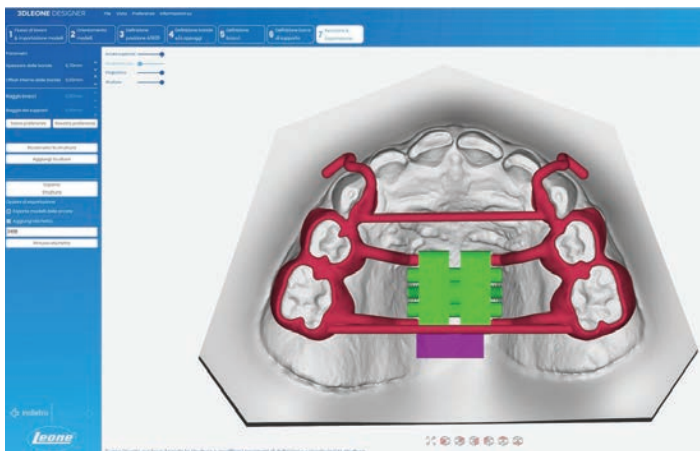


Fig. 1a



Fig. 1b

Me and the 3DLeone Designer

2) RME with Leone A0630D (Figg. 2a-b)

Courtesy by Dr.a Karmen Verhovec ZoboEstetika

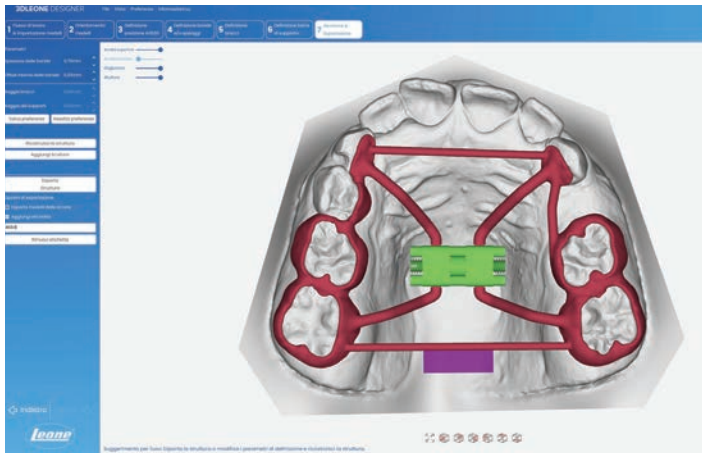


Fig. 2a



Fig. 2b

3) MARPE with Leone A0630D (Figg. 3a-f)

Courtesy by Dr. Riccardo Riatti

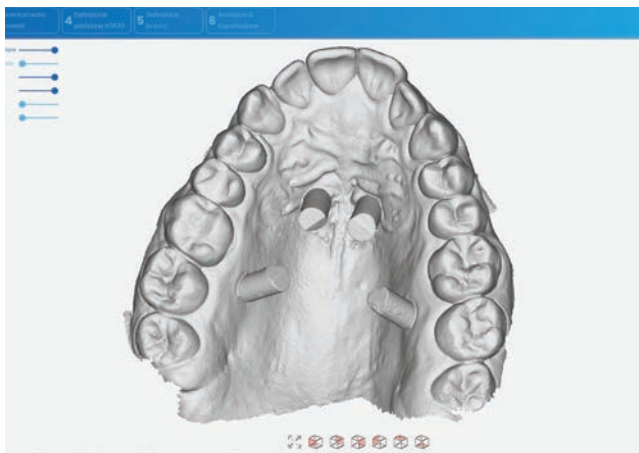


Fig. 3a

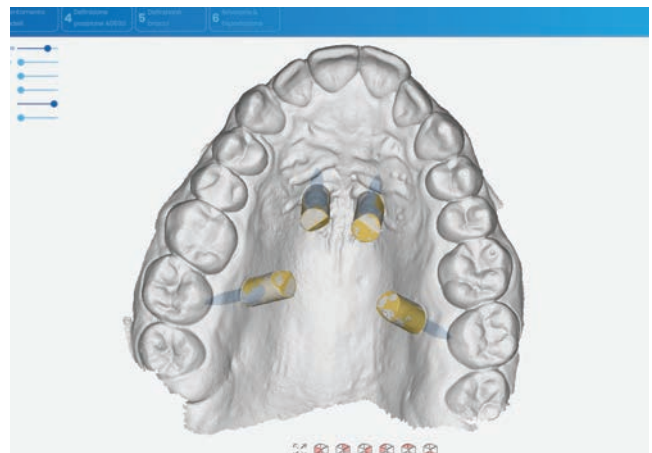


Fig. 3b

Me and the 3DLeone Designer



Fig. 3c

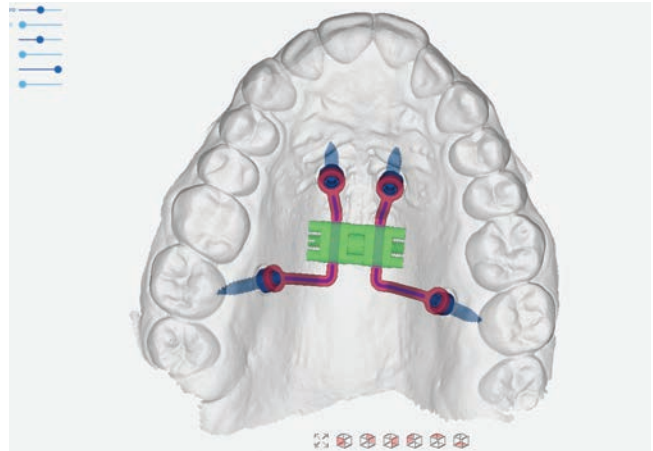


Fig. 3d



Fig. 3e



Fig. 3f

A case where I recently collaborate has been this of the Dr. Riatti, performed completely in collaboration with the 3DLeone Dept. After a planned TADs insertion they were placed into the patient's palate by Dr. Riatti, with the help of surgery guide, and afterwards was acquired a digital impression of the upper arch thanks to PSM Scan Body (distributed in US by LeoneAmerica) and a digital intra-oral scanner. The impression was uploaded on the 3DLeone Designer software to design the custom-made RPE. Even in this case, considering the TADs anchored workflow, the key word of 3DLeone Designer software was "simplicity": starting from the

upper arch uploading, just in a few minutes it was possible to design a custom-made structure completely anchored on 4 TADs with Leone A0630D expander. Once this structure had been sintered and verified the perfect fitting on the model, I really appreciated the precision of it that was also appreciated by Dr. Riatti during the mouth cementation, since he did not need to make any adjustments. This perfect precision can be achieved even thanks to the Leone Scan Body alignment method, automatic process inside the software that reports the correct position of the TADs without introducing any type of mistakes.

Me and the 3DLeone Designer

4) FAST BACK TADs (Figg. 4a-b)

Courtesy by Dr. Alessandro Gianolio, Gianolio-Cherchi Dental office

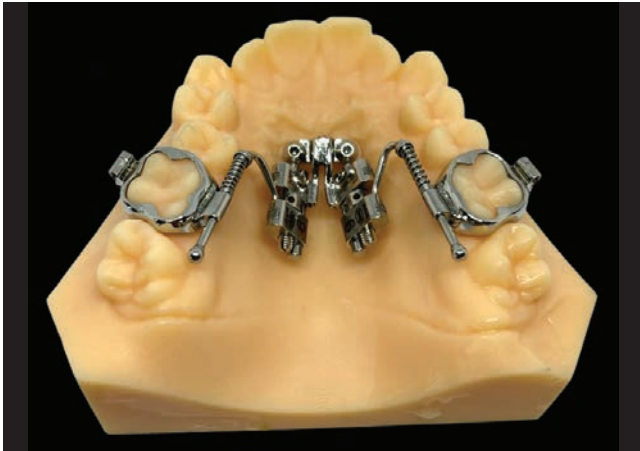


Fig. 4a



Fig. 4b

"Lately I have been using the new Leone TADs in association with Fast Back distalizer, a known product that I have been using for the last 20 years. My feedback is completely positive from both surgery side, thanks to the easy coupling system between the handpiece adapter and TADs and the precision of the surgery guide, and the clinical side since the perfect oral adaptation of the CAD-CAM cemented appliance. I had the chance to digitally plan the TADs insertion: I can say completely satisfied that digital precision will be reflected in the absolute correspondence with surgery and clinical reality. The collaboration with Leone company and my trusted dental technician, Stefano Negrini, allows me to deal with even the worst cases in total serenity. A great teamwork."

Dr. Alessandro Gianolio

RAPID EXPANDER WITH ORTHOGONAL ARMS



The new Leone anatomical expander is the ideal solution for patients who need orthopedic maxillary expansion, as it allows the manufacture of devices with limited dimensions, maximum stability, comfort and safety. The small size of the body and the orthogonal arrangement of the bending arms allow an optimal positioning of the expander even in case of severe contraction and favor the biomechanical control of the expansion.

The unique self-centering system of the guides ensures a symmetrical and stable expansion. The package includes a swivel key with handle and instructions for use to facilitate the home endoral activation.

The arm bending and self-locking instrument REF P0630-00 is also available.

Pack of 1

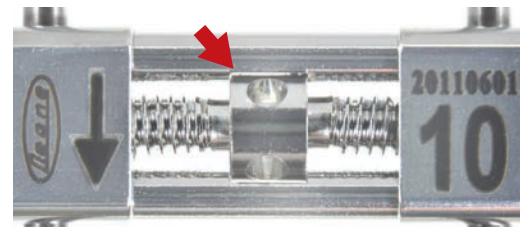


Swivel key included in the package












- The orthogonal position of the arms reduces the overall size of the device.
- The arms are placed within a through-hole into the body and the external laser welding make them to form an integral part of the expander, thus ensuring maximum safety and comfort for the patient.
- Compared to the previous version, the outer position of the arms inside the bodies works on further reducing the overall size and facilitates the adaptation of the expander by the technician.

- The presence of a special slot on the guide pins allows the head of the male screw to keep the guides centered throughout the treatment, ensuring a symmetrical, stable expansion and minimizing the possibility of spontaneous deactivation during therapy.



- Two different placements are possible thanks to the marking of the arrows on both sides of the screw.
- Available in three expansion capacities for every therapeutic need.

	 6 mm	 4,5 mm	 arms	 body		 activation turns	for maximum expansion limit
 A0631-08			1,5 mm	12 mm	8 mm	0,8 mm	40
 A0631-10			1,5 mm	14 mm	10 mm	0,8 mm	50
 A0631-12			1,5 mm	16 mm	12 mm	0,8 mm	60

GIVES SWEET DREAMS

THE IDEAL DEVICES IN RONCOPATHIC PATIENTS OR
SUFFERING FROM MILD-TO-MODERATE OSA SYNDROME



FORWARD!*



**FORWARD!
MAX RETENTION***



**TELESCOPIC
ADVANCER***

*PATENTED

TWIN WING: modern re-interpretation of Clark functional appliance

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**Leone S.p.A. Research and Development Director - Florence, Italy



Twin Block appliance was conceived by Dr. Clark in 1977 and was published for the first time on AJO-DO in 1988 with a paper written by the same inventor; during the years it has become one of the most used appliances to treat Class II skeletal malocclusion with mandibular deficit¹ (Fig. 1). Scientific evidences have shown the unquestionable improved effectiveness of functional appliances, in order to solve cases with mandibular deficit, as long as they be used during the growth peak.² One of the most used systems to establish mandibular growth peak is the "Cervical Vertebra method", made out by Professor Baccetti and by Professor Franchi³ (Fig. 2).



Fig. 1 - Twin Block appliance

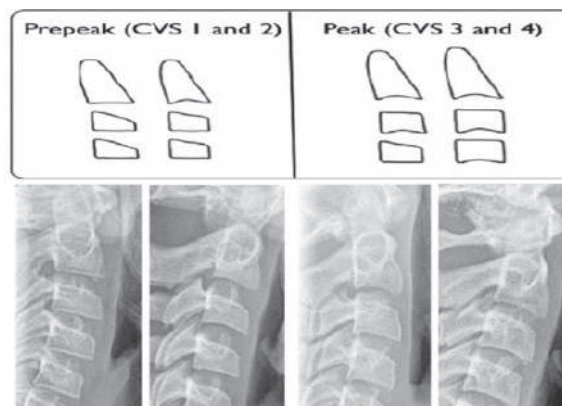


Fig. 2 - Cervical Vertebra method

Recently this method has been analysed by many groups of researchers that have shown some difficulties on the identification of mandibular growth peak and, furthermore, underlined the fact that sometimes phases lasted much more than a year.⁴⁻⁵

Some years ago, Dr. Perinetti who has collaborated with Baccetti and Franchi, has developed a system that could overcome these limits and it is based on the maturation evaluation of middle phalanx of the third finger⁶ (Fig. 3).

As previously claimed, based on a wide literature, Twin Block can be defined as the elective appliance for the treatment of Class II with mandibular deficit, thanks to its proven mechanism, based on the interaction between the two occlusal acrylic blocks, angulated at 70° respect the occlusal plane (Fig. 4).

TWIN WING:

modern re-interpretation of Clark functional appliance

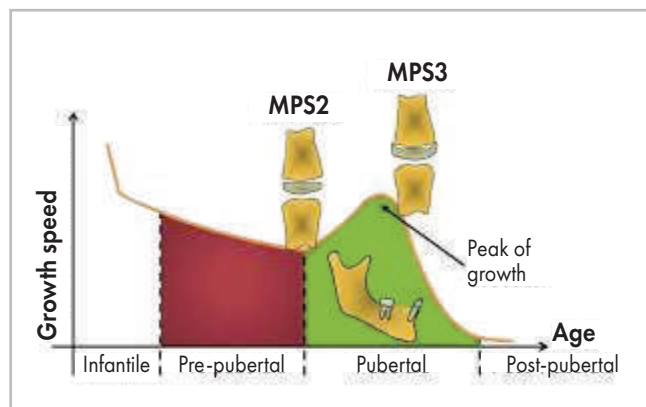


Fig. 3 - Middle phalanx method

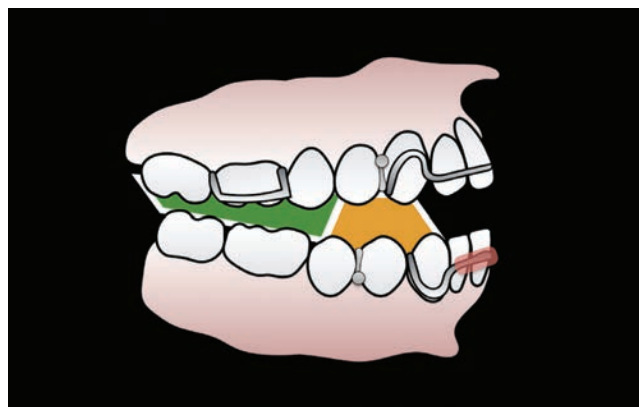


Fig. 4 - 70° Acrylic blocks action mechanism

Dr. Clark, has even defined the protocols for the Twin Block clinical management both for the vertical and sagittal problems improvement. He has shown how to promote and guide the posterior teeth extrusion, beneficial for the quite common Class II deep bite cases, thanks to a progressive reduction of the occlusal contact with the internal side of the appliance (Fig. 5).

The Twin Block is made according to a patient protrusive bite, if more mandibular forwarding position is needed, Dr. Clark suggested to add some acrylic/composite on both the upper and lower blocks.

Since some years Leone has introduced a unique activable device to be embedded in appliances designed to treat nocturnal obstructive apnea syndrome, based on the same angulated plane at 70° principle, with the aim to forward the lower jaw achieving a better patency of the posterior airways. The OSAS appliances with this design are commonly defined Dorsal featuring angulated planes placed in the free spaces between the arches and the inner side of the cheeks, with lower wings that go in contact with upper blocks (Fig. 6).



Fig. 5 - Posterior extrusion promoted by the trimming of Twin Block appliance



Fig. 6 - Dorsal type appliance for OSAS treatment

TWIN WING:

modern re-interpretation of Clark functional appliance

According to the AADSM (American Academy of Dental Sleep Medicine) guidelines a MAD (Mandibular Advancer Device) for OSAS treatment has to be a custommade appliance, based on a construction bite taken up to 70% of the maximum achievable protrusive of the patient, and must allow a progressive further titration, generally obtained thanks to a screw mechanism that the patient has to activate at home.

Based on this Leone has developed the Forward! device (Fig. 7) that's based on two upper dedicated 70° angulated screw and 2 lower wings, that allows to put the mandible in a forward position up to solve the breathing obstruction during that affect the OSAS patients. In the upper splint will be placed the two 70° angulated screws while in the lower splint will be placed the lower wings, perfectly shaped and pre-formed in order to be put in contact with the anterior angulated part of the upper screws: the appliance made out in this way has shown to be really tough but at the same time comfortable for its utilization during the night.

Since the Forward! MAD has several analogies with the Twin Block appliance principle, Leone has made a miniaturized Forward! version, therefore allowing its use on Class II growing patients with mandibular deficit.

This new device, called **Twin Wing**, make simpler and more precise the appliance manufacture for dental technician while clinically, differently from the original Clark's Twin Block, allows a progressive sagittal activation thanks to the presence of the upper screws, thus to favourites the portability and the patient's compliance (Fig. 8).



Fig. 7 - Forward! appliance for OSAS treatment



Fig. 8 - Twin Wing appliance for Class II treatment

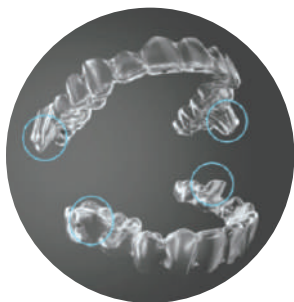


Fig. 9 - Recently it has been shown a specific aligners treatment called ITMA that has the purpose to advance the lower jaw by using an aligners sequence that, thanks to vestibular wings, try to reproduce the 70° angulated planes of Twin Block appliance: based on our experience the aligner poor consistency, the difficult management in case of deep bite and the cost make this as no-optimal to treat growing patients, considering that often we face mixed dentitions.



About this appliance even Kevin O'Brien on his blog talked about: kevinobrienorthoblog.com/whatever-happened-to-invisalign-mandibular-advancement/

TWIN WING:

modern re-interpretation of Clark functional appliance

Another important advantage is that, thanks to the lateral placement of both screws and wings, it is possible to trim both the upper and lower posterior splints in order to promote and guide the posterior teeth extrusion, helpful for cases with vertical height deficiency. There is even the chance to avoid or limit the presence of retentive clasps since the appliance can be manufactured with bi-laminated thermoforming material that features an inner soft side that ensures both comfort and, by using the teeth undercuts, stability.

We can point the features of the **Twin Wing** appliance that make it innovative despite it is fully in accordance with Dr. Clark principles:

- easy manufacturable with high precision thanks its preformed screws and wings perfectly angulated at 70° (Fig. 10a)
- clinical proven effectiveness
- progressively activable (Fig. 10b)
- aesthetic, since it can be manufactured transparent and without metallic clasps
- comfortable, thanks to its reduced palatal extension of the upper splint
- can be produced, as the Twin Block, with design variation in order to be used on both patients with open bite or deep bite.

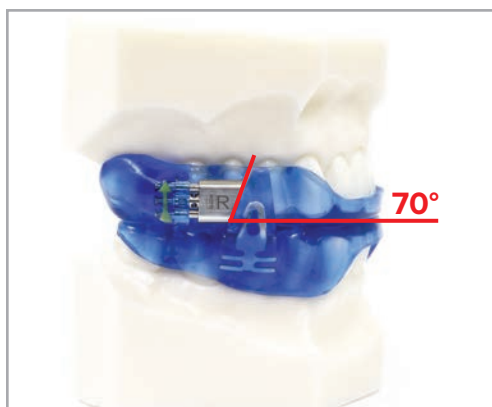


Fig. 10a - Protrusive screw and lower wing angulated at 70°



Fig. 10b - Twin Wing appliance activation simulation

Mainly the **Twin Wing** can be considered different from Clark's appliance for the following reasons:

1. acting on the upper screws we can progressively gain the mandibular advancement needed, with a gradual muscular adaptation and a consequent bone re-shaping.

It is no longer requested take a construction bite in a full mandibular forward position (Fig. 11), since it is possible to activate progressively the appliance.

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This feature, since in the literatures there is a bit of confusion about the protrusion quantity necessary for an ideal construction bite (Fig. 12), allows to limit the construction bite to about 4 mm and to reach the advancement needed, progressively acting on the screws, adding up to 5 mm of titration.

2. The lower wings, being higher than standard acrylic splints, ensure a contact with the metallic angulated screws even if the patient does not perfectly keep the occlusion or sleeps with the mouth open, limits the chance to lose contact between blocks that, really, cancel the effect of lower jaw anterior growth stimulus.

The wings, as previously explained, have the same 70° angulation of the screws thus allowing the functional effect of the well proven Twin Block appliance. The occlusal planes overall, being free from the "block" presence, can be adapted to solve facial height problems.



Fig. 11 - Construction bite

Study	Appliance	Initial Mandibular advancement
1. Tulloch et al. 1997	Bionator	4 - 6 mm
2. Baccetti et al. 2000	Twin-Block	End-to-end (< 7mm) or 70% (> 7 mm)
3. Faltin et al. 2003	Bionator	Not reported
4. O'Brien et al. 2003	Twin-Block	7 - 8 mm
5. Quinãto et al. 2006	Twin-Block	4 mm
6. Almeida-Pedrin et al. 2007	Bionator	Not reported
7. Cui et al. 2010	Twin-Block	Not reported
8. Singh et al. 2010	Twin-Block	10 mm
9. Baysaland Uysal 2013	Twin-Block	70%
10. Martina et al. 2013	Sander	4 mm
11. Perillo et al. 2013	FR-2	< 3 mm

Fig. 12 - Indication about the advancement amount on construction bite

Clinical cases example

Based on the lateral position of both screws and wings, it is possible to manufacture a **Twin Wing** with the design needed to solve a Class II with deep bite, therefore capped to control the anterior eruption while facilitating the posterior extrusion, or to solve an open bite Class II, promoting anterior teeth extrusion and controlling the posterior ones.

Activations can even be performed by the clinician chairside who, activating unilaterally the appliance, can compensate a light midline deviation as well as increase the protrusion, testing the portability or, in the opposite way, decrease the activations in case of discomfort due to muscular overstress.



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Based on the literatures, we know that almost the totality of the final effects by using this type of appliances are dentoalveolar, anyway dental and profile changing effects are always relevant and often, if the appliance was used with a correct timing and with a good patient's compliance, resolute even at skeletal level.⁷



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Leone S.p.A., the Italian orthodontic manufacturing company founded in 1934, is happy to announce that as of March 1, 2022, it is the sole shareholder of LeoneAmerica Dental Products, Inc. after having purchased the remaining shares from American Tooth Industries (ATI).

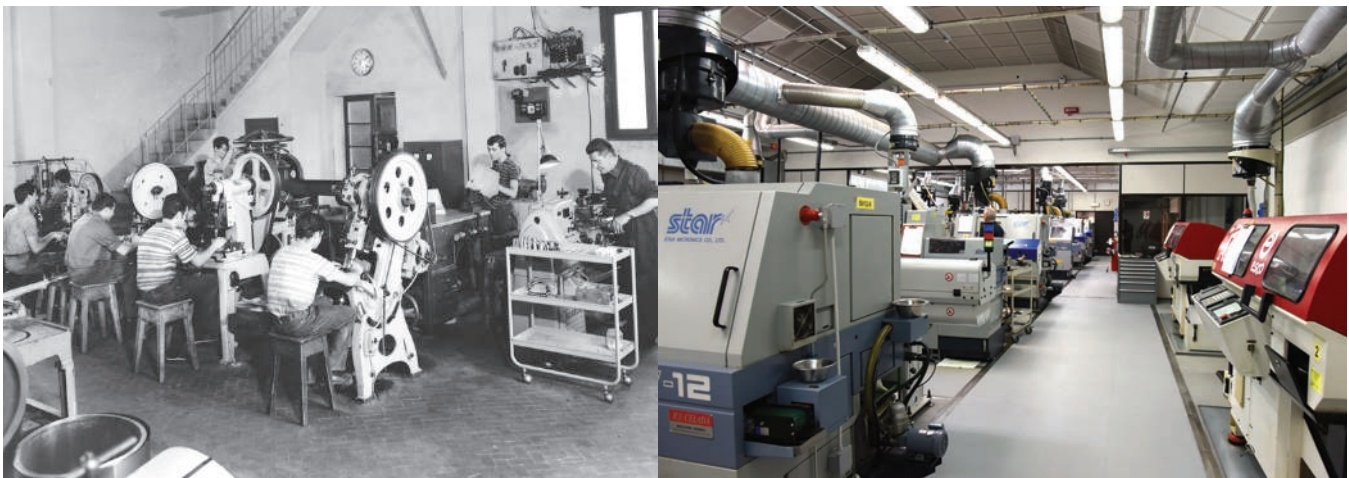
LeoneAmerica Dental Products is a California corporation established in 2016 which distributes exclusively Leone branded orthodontic products. It was born as the spin-off company of American Tooth Industries (ATI), historical distributor of Leone in the USA, Canada, and Puerto Rico.

Five years ago, the Italian company Leone S.p.A. decided to directly invest in the US market by acquiring some shares of the new company and, since LeoneAmerica has shown sustainable sales growth since 2017, in 2022 Leone decided to purchase the total of the shares.

As a consequence of the agreement between ATI and Leone, Emilio Pozzi retired from the role of Company Director and CEO of LeoneAmerica. We would like to thank Emilio for his work during this time and the passion he has shown to have the Leone brand recognized, grown and succeed in the US orthodontic market.

The history of Leone S.p.A., located in Florence, began in the workshop of Mario Pozzi, a resourceful craftsman, and today continues as cutting-edge orthodontic manufacturing. When Mario passed away in 1961, his son Alessandro took over the business, by developing the production and the marketing of products in Italy and abroad. The company's achievements have been continuing since the late 1990s with the support of Alessandro's daughter Elena, who is the current CEO of the company. The family is a founding value for Leone which, in 2021, saw the fourth generation join the administration.

Research and development are at the core of Leone, and significant investments are made each year in the analysis, design, production, and clinical testing of new additions to the product line.



The manufacturing in the 50s and today

On the other side of the globe, LeoneAmerica proudly sells the Leone orthodontic line carrying on and spreading the parent company's values.

Elena Pozzi has now taken up the role of President and CEO of LeoneAmerica. Gabriele Scommegna, Leone's R&D and Product Manager will continue to be a member of the Board of Directors.



LeoneAmerica Dental Products Board of Directors

As part of the objective to invest in the US market and improve LeoneAmerica capabilities and operations, Jasmine Marjouee, Leone's Quality and R&D Engineer since 2016, will serve as COO because of her experience and deep knowledge, gained cooperating thoroughly with the US company. She will take a leadership role in the Technical and R&D arena, purchasing, and operations management activities. Together with her Olivia Viti, Elena's daughter, and Board of Directors new member, will help LeoneAmerica in sales, marketing, and operations management activities.



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Our Sales Representatives Kory Carman and Rinaldo Pallamari will continue to be the commercial reference for customers, providing their important assistance and support. Together with our historical and experienced team we want to make certain that we are going to sustain the repute and standing that we have managed to build in these past years.

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