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CAD-based functional therapy during aligner treatment – the "En-Nova"-protocol (technical report)

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ABSTRACT

Functional orthodontic therapy represents a fundamental element of orthodontic therapy, intending to correct skeletal discrepancies of growing patients by changing their neuromuscular patterns on the long run. To date, consequent functional orthodontic therapy is the first part of a two-phase treatment protocol, which is followed by subsequent dental alignment. For aligners several features are present, which aim to integrate functional therapy into aligner treatment. Examples include inclined planes ("precision wings") incorporated into the aligners or elastics, both trying to force a mandibular advancement. However, all of them suffer from a rather small skeletal effect, which is why the development of new approaches, which allow for more growth control during aligner therapy, is justified. Against this background, the present article describes a new treatment concept which consists of a CAD-based functional orthodontic appliance overlaying over the aligners during the entire treatment time. By increasing the skeletal control, it is intended to guarantee a consequent functional orthodontic treatment while saving treatment time.

Introduction

The challenge of orthodontic therapy is primarily its duration, which is why patients must be motivated to wear their appliance throughout the course of treatment.[1] This applies in particular to functional orthodontic appliances, which can only unfold their skelettal effect if they are worn regularly.[2] However, a high level of patient compliance is also required in the second phase of treatment, weather this consists of consistent aligner wear or maintenance of good oral hygiene during multibracket therapy.[3] One aim of orthodontic therapy is therefore to shorten its duration while minimizing the risk of adverse effects and maximizing the therapeutic result. With regard to aligners, several options for a one-phase therapy have been provided in order to combine functional orthodontic elements with dental alignment. In 2017, Align Technology (San José, CA, USA) introduced the Mandibular Advancement (MA) feature which aims to replicate the effect of functional appliances. MA is composed by two pairs of lateral inclined planes ("precision wings"), positioned buccally in the posterior area of the aligners, guiding the mandibular forward each time the patient closes his mouth. This feature aims to combine the concept of growth regulation with tooth movement in order to support simultaneous dental arch expansion, tooth alignment and mandibular advancement. To be precise, however, functional elements on aligners often suffer from rather minimal skeletal effect,[4-6] which might be mostly because the MA elements are incorporated in the aligner, consequently leading all protrusive forces on a small segment of flexible material. Using elastics with aligners can be used either as a supplement or as a replacement for MA elements. However, when using elastics, one should consider that these can have adverse effects mostly because of their vertical force component.[7]

Using conventional functional orthodontic appliances upon aligners is limited to impossible, since their fit continuously decreases due to the dental movement during the aligner therapy. CAD-based functional appliances might provide a remedy here due to their individual design capabilities. In this context, we recently introduced CAD-based versions of the functional regulator III (FR3),[8] the functional regulator II (FR2), the Sander II appliance[9] and various other removable CAD/CAM appliances.[10] Using CAD-based functional orthodontic appliances during aligner therapy might be the key to a shorter duration of overall orthodontic therapy. However, for this purpose further developments in the field of design have been required. In order to combine functional orthodontic CAD-appliances with aligners, the following article presents a new therapy concept which aims to enable a single-phase therapy, intending to shorten the overall duration of therapy.

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Fig. 1. The En-Nova concept – It basically represents a functional orthodontic appliance which is worn above the aligners. Since it considers all of the different aligner steps, the En-Nova appliance can be worn throughout the entire aligner treatment with no adaptions required.

A new concept in functional orthodontic therapy combined with aligner therapy – "En-nova"

The En-Nova-concept (3DO, Naples Italy) represents basically a CAD-based functional orthodontic appliance which is worn above the aligners. In contrast to MA features on aligners, En-Nova appliances are built from rigid materials with various design capabilities in order to provide a higher skelettal control during the aligner treatment (Fig. 1).

The overlaying appliance considers all movements which are carried out during the aligner therapy. It can therefore be worn through the entire aligner treatment without any adaptation required. This is made possible by its design which is based on a so called "Boolean operation". This is a digital tool through which separate single STL files can be fused together to a final STL file. Boolean operations are feasible with multiple CAD-programs like Blender (Blender Institute B.V., Amsterdam, Netherlands), Meshmixer (Autodesk, San Francisco, USA), Blue Sky Plan (Blue Sky Plan, Libertyville, USA), OnyxCeph (Image Instruments, Chemnitz, Germany), OrthoAnalyzer (3Shape, Copenhagen, Denmark) and several others. Overlapping all individual aligner steps allows for the creation of a final model which considers all movements of the respective aligner therapy. This final model then serves as the basic "impression" for the inside of the overlaying functional appliance, which in turn can then be further designed with various elements in order to generate a maximal skeletal control according to the clinicians demands. Examples include two separate plates with lateral inclined planes according to jumping plates. According to the type of malocclusion the planes can be reversely inclined for example to prevent anterior mandibular movement in a Class III patient (Fig. 2).

Likewise, additional buccal elements like telescopes according to the Herbst appliance or a single Monoblock design according to an Activator are possible. For maximal skelettal control, the lingual or palatal shields can be extended (Fig. 3). The final design can then be manufactured by 3D-printing using resins like Dental LT clear, Biomed Clear (both Formlabs, Massachusetts, USA), Keysoft (Keystone Industries, Singen, Germany), Freesplint (Detax, Ettlingen, Germany), Dima Print (Kulzer, Hanau, Germany) or recently released more flexible resins like Freeprint Splintmaster taff or flex (both Detax). When printing the functional appliance, care should be taken that a Class IIa resin is used, which is certified for long term intraoral use. Wearing the En-Nova appliance does not prolong the aligner therapy or change its replacement frequency.

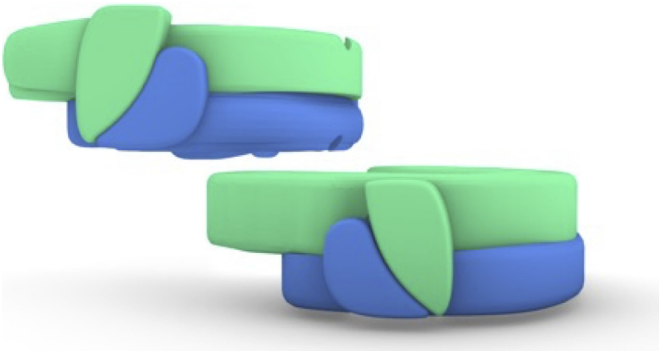

Fig. 2. Separate plates with inclined plates - The present concept allows for multiple designs like for example separate plates with lateral wings according to jumping plates. If required, the lateral wings can be reversely inclined.

Clinical case

A 13-years-old male patient presented with skeletal and dental class II malocclusion. Family history revealed that also both parents had a skeletal class II anomaly. There were no general or syndromic diseases and no history of parafunctional habits. The clinical examination revealed a convex facial profile which a lower concave element through a protruded chin. Vertical facial height was reduced, upper lip was predominant.

Intraoral examination revealed a permanent dentition, a narrow upper triangular arch, a Class II division 1 malocclusion with a deep bite (9 mm), an accentuated curve of Spee, an increased overjet (11 mm) and a mild crowding in the upper and lower front (Fig. 4). The cephalometric analysis showed a skeletal Class II discrepancy with an SNB-angle of 5° due to mandibular retrognathia. According to Baccetti et al.'s stages of cervical vertebral maturation,[11] the patient was in CVM stage 4 at his peak pubertal growth spurt.

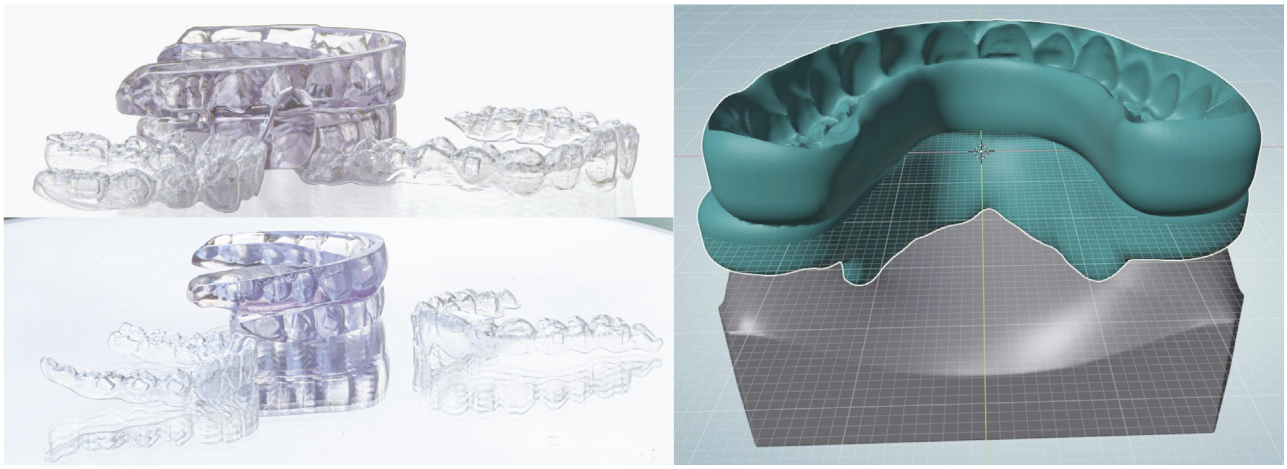

Fig. 3. Different En-Nova appliances – The present concept allows for multiple designs of the overlaying appliance according to the clinician demands.

Fig. 4. Dental and profile improvements.

Table 1 shows the measurements before (T0) and after treatment (T1). After 17 month of treatment dental (Fig. 4) and skeletal improvements (Fig. 5) could be achieved. With regard to dental parameters, an improvement of the Overbite (4.4 mm to 1.8 mm) and Overjet (9.7 mm to 2.9 mm) was observed. The interincisal angle changed from 119.7° to 126.5°. With regard to skeletal parameters, ANB showed an improvement of 3.1°, with changes in SNA (80.4° to 79.5°) and SNB (76,0° to 78.2°).

Table 1
Measurements before (T0) and after (T1) therapy

	T0	T1
Sagittal skeletal Relations		
Maxillary Position SNA	80.4°	79.5°
Mandibular Position SNB	76.0°	78.2°
Mandibular Base Position SNPog	79.7°	81.1°
Sagittal Jaw Relation ANB	4.4°	1.3°
Sagittal Jaw Relation ANPog	0.7°	-1.6°
WITS	3.8	0
Vertical skeletal Relations		
Maxillary Inclination	8.1°	6.9°
Mandibular Inclination	22.6°	24.5°
Vertical Jaw Relation	14.5°	17.6°
Dento Basal Relations		
Maxillary Incisor Inclination	124.9°	117.6°
Mandibular Incisor Inclination	101°	98.3°
Mandibular Incisor Compensation	-3.9	-2.3
Dental Relations		
Overjet	9.7	2.9
Overbite	4.4	1.8
Interincisal Angle	119.7°	126.5°

Discussion

To the best of our knowledge, this is the first article, which describes a hybrid form of a functional CAD-therapy and an aligner therapy at the same time. Using this new protocol allows to treat both malocclusions and skeletal discrepancies in a single-phase instead of a two-phase protocol. Thus, aligners can realign the teeth while the overlaying functional appliance concentrates on repositioning the lower jaw. This might lead to a considerable reduction in treatment time which in turn might reduce adverse effects and have beneficial effects on costs and patient compliance.[12-15] One example includes Class II deep bite cases in which mandibular advancement leads to a lateral open bite which has to be subsequently closed by the extrusion of the premolars and molars. Conventional functional orthodontic appliances have to be continuously adapted by removing the lateral posterior sectors in order to allow for a physiological extrusion of the laterals. Using aligners instead allows for a forced driven extrusion but suffers from less skeletal control.[4-6] Using the present En-Nova protocol might offer better opportunities by combining the advantages of both appliances. Apart from a reduction in overall treatment time and an enhanced skeletal control, the overlaying functional appliance can serve as an anchoring appliance, which might become useable, when performing dental movements that have previously been limited by the flexibility of the aligner.[16] Examples include symmetric or asymmetric contraction or expansion of both arches.[17] Being positioned upon the aligners, the new concept might be capable in strengthening the aligners action while dispersing their undesired forces. Consequently, movements that could not been carried out by aligners or which required a long treatment time due to sequential procedure, might be facilitated and faster through the anchoring capabilities of the overlaying stiff functional appliance.

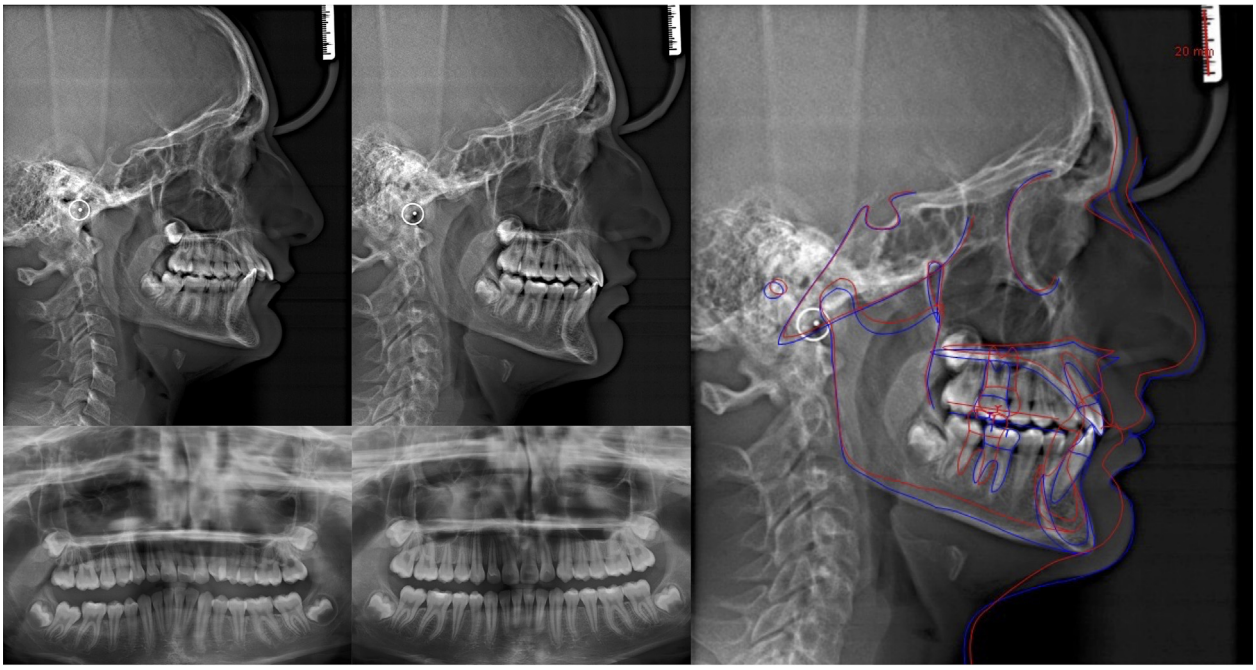

Fig. 5. Skeletal improvements.

The present protocol is fully based on CAD/CAM production and might therefore offer several additional benefits. Loosened or damaged appliances are a common problem in orthodontic therapy.[18] This is especially the case for functional orthodontic appliances as these are worn by particular young patients. Since the design can be stored digitally, an indefinite replication of the appliance is possible even on the same day without the requirement of a new impression. Faster reintegration of the appliance might therefore have a positive effect on therapy.[19, 20] As another aspect, one should keep that apart from a fully CAD/CAM workflow for the production of the En-Nova appliance, also the production of aligners is also already fully integrated in CAD/CAM.[21] Due to the rapid development of new resins like Graphy "Tera Harz TC-85" (Graphy Inc., Seoul, Republic of Korea) a joint production of the En-Nova appliance and the corresponding aligners might be feasible by one 3D-print in the future.

From an economical point, one should consider that chair time is considerably reduced since no adaption or activation of the overlaying functional appliance is required. Instead, dental movements are entirely generated by the aligners. For example, patients suffering from an anterior crossbite might benefit from an aligner controlled proclination of the upper incisors while reversely inclined lateral wings of the overlaying appliance serve for a maximal skeletal control. Various other elements such as tubes for extraoral traction, hooks for intermaxillary elastics attached to the rigid overlaying appliance or even skeletal anchorage connective elements are feasible.

With regard to the En-Nova protocol, several limitations have to be considered to date. One of them includes the bulky design which is required to guarantee a sufficient stability. In order to provide higher patient comfort, the aim is to create slimmer designs of the overlaying appliance. New upcoming resins might offer a solution for this purpose. Furthermore, building the En-Nova appliance still requires some affinity for CAD-based construction yet. However, due to the development of artificial intelligence, automated design options may arise in the future, making it easier for practitioners to fabricate the respective appliance in everyday practice.

Conclusions

The present article presents a new hybrid therapy concept which combines aligner treatment with functional orthodontic therapy. It consists of an overlaying functional appliance that is wearable throughout the entire aligner therapy. Due to a one-phase therapy it aims to shorten the time of overall treatment. In contrast to aligner based functional elements like lateral wings and elastics, the present concept aims to maximize the skeletal control by the stiff constructure of the overlaying functional appliance. Since it is fully based on CAD/CAM technology it allows furthermore for infinite replication, higher individual design capabilities and rapid availability.

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Patient consent

Patient consent was obtained.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

CRediT authorship contribution statement

Cristiano Segnini: Conceptualization, Methodology, Visualization, Writing – review & editing. **Vincenzo D'Anto:** Supervision. **Rosa Valletta:** Supervision. **Christopher J. Lux:** Supervision. **Christoph J. Roser:** Methodology, Visualization, Writing – original draft, Writing – review & editing.

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