Henriette Luise Bock, Jens Johannes Bock, Fabian Karbach, Björn Ludwig, Werner Schupp, Julia Funke, Julia Haubrich

Material properties and first clinical applications of CA Pro, a novel aligner foil

KEY WORDS aligner, aligner material, biomaterials, digital orthodontics, materials

The present article describes the material properties of CA Pro (Scheu Dental, Iserlohn, Germany), a novel aligner foil, and demonstrates its performance in the orthodontic treatment of two cases with different characteristics.

Introduction

The first aligner treatment dates back to 1944¹⁻³. Since the mid-1990s, orthodontic therapy with sequential aligners has experienced a significant boom owing to the introduction of CAD/CAM-supported processes. Recent study results, especially for Invisalign treatments (Align Technology, San Jose, CA, USA), can be summarised as follows⁴⁻⁹:

Henriette Luise Bock University of Würzburg, Würzburg, Germany

Jens Johannes Bock, Dr med dent Private practice, Fulda, Germany

Fabian Karbach, PhD Scheu Dental, Iserlohn, Germany

Björn Ludwig, PhD, PD Dr med dent Private practice, Traben Trabach, Germany

Werner Schupp, Dr med dent Private practice, Cologne, Germany

Julia Funke, Dr med dent Private practice, Cologne, Germany

Julia Haubrich, Dr med dent Private practice, Cologne, Germany

Correspondence to: Dr Jens Johannes Bock, Am Schlossgarten 1, 36037 Fulda, Germany. Email: drbock@web.de

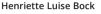
- therapy for more complex malocclusions is possible;
- the effectiveness of aligner treatments is, within specific limits, comparable to that of fixed appliances;
- some individual tooth movements are more difficult (e.g., extrusions and derotations);
- use of attachments and approximal enamel reduction is often necessary;
- a high level of patient compliance is required (aligners worn for 20 to 23 hours a day).

Various thermoplastics have been recommended as the basic materials for aligner production. The requirements for the material properties of thermoforming foils have proven to be diverse and dependent on indications¹⁰⁻¹². The standard materials that have been used to date are single- or multilayer polyethylene (polyethylene terephthalate glycol copolyester [PET-G]) or polyurethane foils (Table 1).

As well as commercial providers, Kim and Stückrad¹⁰ developed a concept in 1998 to plan and implement chairside-fabricated sequential aligner treatments in the dental office. The basic principles were as follows:

- use of foils of different thicknesses (0.50/0.65/0.75 mm);
- use of PET-G aligner material;
- setup creation on a plaster cast;
- vacuum and pressure thermoforming;
- regular impression taking;
- activation using specific forceps, if necessary.







	 Three-layered ABA foil Outer layers (A): copolye Inner layer (B): thermople 			Hard laySoft laye		
	A: Copolyester (hard)	Foil thickness, mm	0.50	0.65	0.75	
		A layer thickness	0.17	0.21	0.25	
	B: Thermoplastic elastomer (soft)	B layer thickness	0.17	0.21	0.25	
	A: Copolyester (hard)	A layer thickness	0.17	0.21	0.25	
annon and a second	 Hygroscopic material: foils a Must be processed within Processing temperature: 150 Indication: correction of mal Contraindication: CA Pro is r 	n 15 minutes after ope)°C–175°C occlusion using aligne	r therap	ру	U	

Fig 1 The new CA Pro film: three-ply structure. The outer layers are composed of abrasion resistant copolyester material and the core of thermoplastic elastomer.

Table 1 Materials used for aligner productio	n
--	---

Aligner	Manufacturer	Material
CA Clear Aligner	Scheu Dental	PET-G
Invisalign	Align Technology	Multilayer thermoplastic polyurethane
CA Pro	Scheu Dental	Three-layer copolyester elastomer

Further development and clinical applications were continued by Echarri¹¹ and supplemented by both analogue and digital planning aids.

During treatment implementation, various factors have proven decisive for success¹¹⁻¹⁴. In addition to precise and clinically orientated planning, variables such as material type, processing technique, material thickness and accuracy of fit have been found to be particularly important¹¹⁻¹⁴.

Seo et al¹² used simulated tooth movements in a finite element model to show that both 0.50- and 0.75-mm-thick aligner foils applied effective forces for dentoalveolar transformation processes, and found that approximately 6% more stress is expected in the periodontal ligament when using a stronger foil.

Using 3D microcomputed tomography (microCT), Lombardo et al¹³ indicated that aligner fit depends on the material used and showed a significant variance between different products. In contrast, Mantovani et al¹⁴ demonstrated a comparably accurate fit for Invisalign aligners (Align Technology) and CA Clear Aligners (Scheu Dental, Iserlohn, Germany).

Despite the technological developments that have occurred in aligner therapy, there are clinical limitations to achieving specific tooth movements. For instance, extrusion of the anterior teeth, derotation of rounded teeth and torque movements are accomplished using aligners with lower predictability^{15,16}. One important step towards solving these common problems is seeking new aligner materials that are under consideration through scientific evaluation and critical clinical testing.

Aim

In the following sections, the mechanical properties of a new aligner material (CA Pro, Scheu Dental) are described and compared with those of standard materials. Its integration into a digital workflow is demonstrated in two clinical cases.

Mechanical properties of the novel aligner material CA Pro

A three-layer composite of abrasion-resistant copolyester material and a thermoplastic elastomer is presented as a new development (Table 1 and Fig 1). For improved clinical use in comparison with conventional PET-G materials, the following properties were specified:

- high elasticity;
- good wearability;
- continuous force output;
- low force level.

196* 2	
Q Cserv	
Ved Start	
ressenz	
-ssene	

Characteristic	Notes
Indications	Sequential aligner therapy to correct malocclusion
Contraindications	Known incompatibilities with the used materials, no adhesive buildup possible with acrylates
Procedure	Vacuum and pressure moulding at 150°C to 175°C, insulating foil or CA Pro+ for 3D printed models, block out undercut areas if necessary, must be processed within 15 minutes after opening the barrier bag, trimming and finishing with specific instruments
Cleaning/care	No oxidising agents or solvents; optimal: specific cleaning powders for daily use
Available material thicknesses	0.50, 0.65, 0.75 mm

Table 2 Brief description of the novel aligner material

The processing of the new CA Pro aligner material was based on a previously known workflow. The basic procedure is outlined in Table 2.

Material tests on the thermoformed foils were carried out using a universal testing machine (ZwickRoell 1445, ZwickRoell, Ulm, Germany) equipped with a 100-N force transducer (Xforce, ZwickRoell) and a miniaturised threepoint flexural strength test apparatus in a water bath (inhouse customisation). To adapt the standard commonly used to determine the flexural properties of plastics (DIN EN ISO 178), a miniaturised test fixture was designed with a support distance of L = 8 mm. The support and compression fin radii of the structure corresponded to 0.5 mm. The water bath, which was filled with distilled water, was controlled using an external thermostat (Julabo, Seebach, Germany) via a spiral heat exchanger. Prior to the test, the water bath was preheated to 37°C (± 0.1 K). During the tests, the temperature of the water bath was recorded digitally and maintained within a specified range.

Specimen preparation and conditions

The thermoforming foils (thickness 0.75 mm) were heated according to the manufacturer's instructions (BIOSTAR, Scheu Dental) and moulded over a smooth strip of polypropylene (thickness 2.00 mm, 90×60 mm). From the central area of the resulting block, sample strips (40×105 mm) were cut using a lever cutter (IDEAL 1058, Krug & Priester,

Balingen, Germany). The prepared samples were stored in water at 37°C for 24 hours prior to testing and then placed in the previously described test machine and allowed to rest for another hour before testing began.

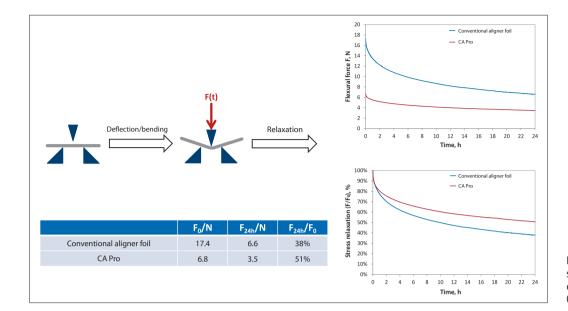
A bending test was performed at a traverse speed of v = 1 mm/minute. The starting point (deflection 0.0 mm) was the initial contact between the fin and the specimen, which was manifested by the increase in the measured force and registered by the testing software (testXpert II, ZwickRoell).

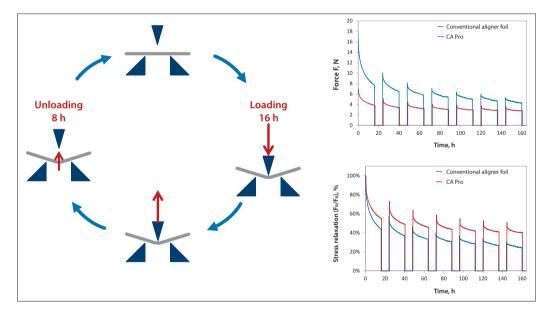
After reaching the initial contact, the fin was shifted to the stress point of the specimen (deflection 0.3 mm), and the initial bending force F0 was determined. The course of the bending force Ft was recorded over the following 24 hours. Stress relaxation, S, was the ratio of the bending force to the initial bending force (S = Ft/F0).

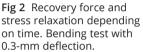
Cyclic loading and unloading tests were performed using the same parameters as the fatigue loading test; however, in contrast to the latter, only the stress point (deflection 0.3 mm) was maintained for 16 hours.

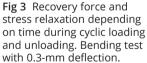
After this loading phase, the fin was moved back to the starting point of the test and the specimen was unloaded for 8 hours. This was followed by a subsequent loading phase. Each specimen was subjected to seven cycles of loading and unloading, during which the bending force curve was recorded. Additionally, the analysis of the force-displacement data from the loading cycles allowed the permanent deformation of the foil caused by deflection to be determined.









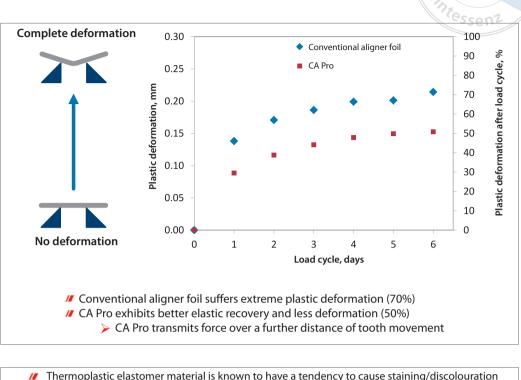


Test results

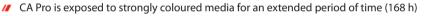
The results of static fatigue loading are presented in Fig 2. The conventional aligner material exhibited a very high initial bending force that decreased rapidly during the loading test. After 24 hours, only 38% of the initially measured bending force remained. In contrast, the three-layer CA Pro sheet exhibited a lower initial bending force that decreased less rapidly during the testing period. At the end of this period, the CA Pro sheet retained 51% of its initial bending force. Based on these results, CA Pro aligners should have a more constant force output over the treatment period than conventional aligner foils. A lower initial force also increases patient comfort.

Compared to the results of static permanent loading, CA Pro is characterised by a less noticeable force decay than the conventional aligner material (Fig 3). Throughout all the loading and unloading phases, the force exerted by CA Pro dropped less dramatically. In addition to the reduction in force over time, the cyclic test provided information





Thermoplastic elastomer material is known to have a tendency to cause staining/discolouration



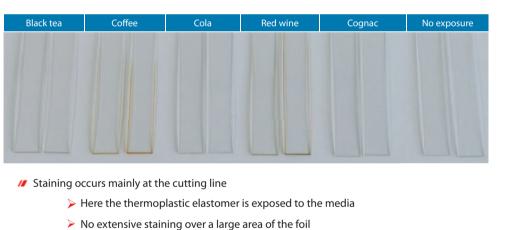


Fig 5 Discolouration of CA Pro foil after immersion in various solutions.

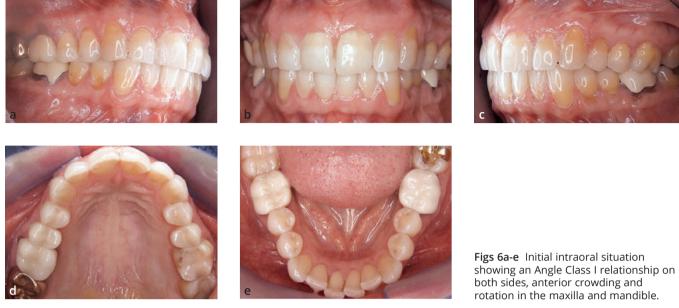
about the plastic deformation of the foils under a physical load. Figure 4 illustrates that after the first loading phase, the conventional aligner foil already exhibited 50% plastic deformation, whereas CA Pro retained only 30% of the deflection; this trend continued over all testing cycles. After six cycles of loading and unloading, the conventional material retained 70% of its deflection, whereas CA Pro only underwent 50% plastic deformation. Applied to aligner therapy, this indicates that CA Pro exerts a force on the teeth over a

longer distance and period of time and can thus contribute to more efficient tooth movement.

Thermoplastic elastomers are known to tend to stain upon contact with coloured substances and media, and in the present study, CA Pro samples were exposed to various coloured drinks for a prolonged period of time. The results are shown in Fig 5. For CA Pro, discolouration only occurred at the edges of the material, and was not widespread.

Fig 4 Deformation of the foil material as a percentage of the initial value, depending on the number of cycles. Bending test with 0.3-mm deflection.





Clinical use of CA Pro

Case 1

A 36-year-old woman presented to the office run by BL with the following complaints (Fig 6):

- Angle Class I malocclusion in the permanent dentition;
- generalised attachment loss with wedge-shaped defects;
- mandibular incisor protrusion;
- anterior crowding in the maxilla and mandible.

The patient was provided with comprehensive information about the possibilities of orthodontic treatment with aligners (wearing time 22 hours/day) and approximal enamel reduction to prevent further attachment loss. The intraoral situation was recorded using a CEREC Primescan intraoral scanner (Dentsply Sirona, Charlotte, NC, USA) and the initial data processing was carried out using Medit Link software (Medit, Seoul, South Korea). The resulting stereolithographic data were transferred to OnyxCeph Lab software (Image Instruments, Chemnitz, Germany) for further planning. The necessary steps within this software include creation and orientation of the digital model (Fig 7), planning of the necessary tooth movements and approximal enamel reduction (Figs 8 and 9), and output of printable dental arch models (Fig 10).

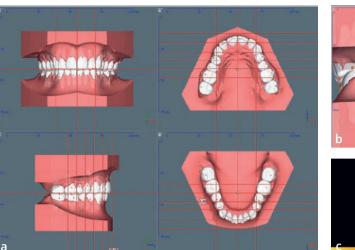
The calculated dental arches were output as a stereolithography file and seven alignment models were produced through 3D printing (Grey Resin V4, Form 3, Formlabs, Somerville, MA, USA). The thermoforming process was conducted according to the manufacturer's instructions (BIOSTAR, Scheu Dental) to obtain a total of seven CA Pro foils for both arches. The processing of the aligner material was based on known working steps and proved to be unproblematic. To improve the clinical hold, the foils were not cut in a garland shape.

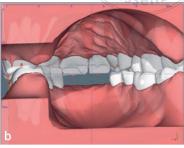
Approximal enamel reduction of up to 0.3 mm per tooth and creation of space between the anterior teeth were planned and carried out prior to the start of active aligner treatment (Figs 9 and 10).

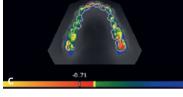
Compared with conventional aligner materials, the new material was noticeably more elastic (Fig 11). Both insertion and patient comfort when wearing the aligners were improved. The course of treatment was monitored clinically, then after 10 weeks, the following results were recorded (Figs 11 and 12):

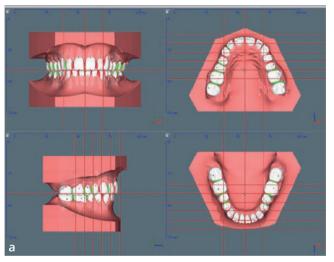
MATERIAL PROPERTIES AND FIRST CLINICAL APPLICATIONS OF CA PRO

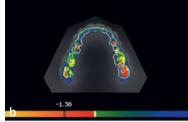
Figs 7a-c Initial intraoral situation in the digital model. The mandibular right central and lateral incisors were removed virtually to show significant enamel defects and the red colouring in the occlusogram indicates traumatic deep bite relations (OnyxCeph).











Maxilla															
Tooth*	17-16	16-15	15-14	14-13	13-12	12-11	11-21	21-22	22-23	23-24	24-25	25-26	26-27		Total
Amount of interproximal	0.00 +	0.00 +	0.00 +	0.00 +	0.00 +	0.00 +	0.00 +	0.00 +	0.00 +	0.00 +	0.00 +	0.00 +	0.00 +		
reduction (mm)	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00		
Total (mm)	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00		0.00
Distance (mm)	0.00	0.00	0.00	-0.03	0.00	-0.17	-0.42	-0.08	-0.10	-0.09	-0.03	0.00	0.00		-0.92
Mandible															
Tooth*	47-46	46-45	45-44	44-43	43-42	42-41	41-31	31-32	32-33	33-34	34-35	35-36	36-37		Total
Amount of interproximal	0.00 +	0.00 +	0.00 +	0.00 +	0.00 +	0.00 +	0.00 +	0.00 +	0.00 +	0.00 +	0.00 +	0.00 +	0.00 +		
reduction (mm)	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00		
Total (mm)	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00		0.00
Distance (mm)	0.00	0.00	0.00	-0.30	-0.31	-0.56	-0.49	-0.65	-0.29	-0.23	0.00	0.00	0.00		-2.83
Distance (mm)	0.00	0.00	0.00	0.50	0.51	0.50	0.45	0.05	0.25	0.25	0.00	0.00	0.00		2.0

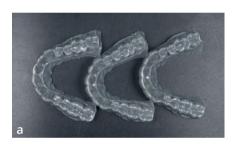
С

Figs 8a-c Virtual treatment plan: balancing crowding with the help of approximal enamel reduction and compensation of misaligned teeth through virtual tooth movements. *According to FDI notation.













Figs 9a-e Intraoral situation after interproximal reduction in the maxilla and mandible before insertion of the first aligners.







Figs 10a-b After the virtual models were created, the dental arches were 3D printed, then three maxillary (a) and four mandibular aligners (b) were fabricated using CA Pro.





Figs 11a-e Interim intraoral results after 10 weeks. The tooth positions were improved. A slight residual gap can be seen in the maxilla, along with incomplete derotation.



MATERIAL PROPERTIES AND FIRST CLINICAL APPLICATIONS OF CA PRO



Figs 13a-b Virtual treatment planning in the Visual Treatment Objective module. The shaded grey-blue area indicates planned fine adjustment with additional aligners.





- **Figs 14a-b** Final adjustments were made with additional aligners, two in the maxilla and two in the mandible.
- significant improvement of the dental arches;
- significant improvement of the occlusal relations;
- alignment of the maxillary and mandibular anterior teeth;
- slight midline diastema;
- incomplete derotation in both arches.

Treatment continued with another intraoral scan and the planning of two more aligners per arch (Figs 13 and 14). After a total of 16 weeks, a very good treatment result was achieved (Fig 15), and was secured with fixed retainers in the maxilla and mandible (Figs 16 and 17).



















Figs 15a-e Final intraoral results after a total of 16 weeks. Significant improvements of the anterior tooth positions can be observed.



Figs 16a-e The treatment result was secured using fixed retainers in the maxilla and mandible.

MATERIAL PROPERTIES AND FIRST CLINICAL APPLICATIONS OF CA PRO



Figs 17a-j Comparison of the initial and final intraoral situation.

Case 2 with in-office aligner treatment

A 31-year-old man presented to the office run by WS, JF and JH with a desire for aesthetic improvement. Intraoral images showed a molar Class I relationship with moderate crowding in the maxilla and mandible. Figure 18 presents the extra- and intraoral situations during treatment planning. The orthopantomogram showed adult dentition with restorations and a mucocele in the maxillary left sinus which was referred to the dental surgeon for treatment (Fig 18I). Figure 19a shows the aesthetic analysis with 4 mm of the surface of the maxillary central incisors being visible in the resting position, congruent midlines and no excessive gingival display. The incisal edges demonstrated a straight relation to the lower lip, and a slight dark buccal corridor was visible on the left side (see also Fig 18c). A thorough diagnosis, including a short screening test, revealed no signs of craniomandibular dysfunction (Fig 19b).

A scan was performed using an intraoral scanner (Trios, 3Shape, Copenhagen, Denmark) and transferred into Onyx-Ceph (Fig 20a). The treatment plan comprised 20 stages with arch alignment (Fig 20b). Attachments were planned on the maxillary central and lateral incisors and canines as well as on the mandibular canines and left first premolar. Interproximal reduction was necessary for alignment in the mandible up to 0.32 mm, and mesially in the maxilla for the central incisors (0.37 mm) to reduce black triangles (Fig 20c). The material chosen for each stage 2 aligner was CA Pro, with a thickness of 0.500 or 0.625 mm. The initial occlusion



Figs 18a-I Extra- and intraoral situation with crowding in both arches. The orthopantomogram revealed a mucocele in the maxillary left sinus and the patient was referred to the dental surgeon for medical evaluation.

showed a physiological dental relationship in the molars, which therapeutically does not require improvement or improvement is not possible; the molar occlusion should therefore not be changed. Fixed and unmoved teeth also offer better anchorage than teeth that are actively being moved, and can be marked in OnyxCeph using the fixation tool. Figure 21 shows the lateral detailed and occlusal view of the maxilla and mandible, demonstrating an occlusal pattern in the molar region and penetration of -0.63 mm at the beginning of treatment. Figure 22 illustrates the planned virtual situation without movement of the molars, and offers an occlusal view of the maxilla and mandible and

Yes

Yes

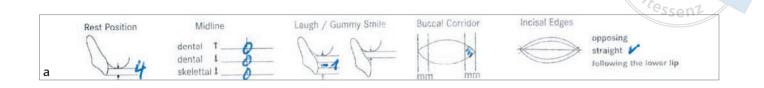
Yes

mo

0000000 Yes Yes

0

phy 1. 1



HORT SCREENING TEST 1.4.

6) CR + CO Cotton Roll Test

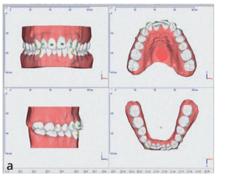
) Pain or cle pal

ical mouth on

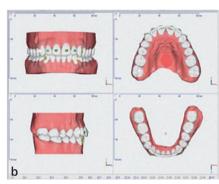
ds/joint pain

Figs 19a-b (a) The aesthetic analysis shows 4 mm of the surface of the maxillary central incisors in the resting position, congruent midlines and no excessive gingival display. The incisal edges demonstrated a straight relation to the lower lip and a slight buccal black corridor was visible on the left side. (b) The short screening test revealed no pathologies or signs of craniomandibular disorder.

Figs 20a-d Beginning of the first treatment phase. (a) Intraoral scan transferred into OnyxCeph. (b) The virtually planned treatment outcome. (c) Interproximal reduction up to 0.32 mm in the mandible and up to 0.37 mm in the maxilla was required to align the arches and reduce black triangles. (d) The number of planned movements in both arches. *According to FDI notation.



b



57

60 yes

TMJ-e

TML

ф

i-15 15-14 00 + 0.00 + 00 0.00 00 0.00 00 0.00	- 0.00 + 0. 0.00 0. 0.00 0.	1-13 13-1 .00 + 0.00 .00 0.00 .00 0.00 .00 0.00 .02 0.00		11-21 0.00 + 0.00 0.00	21-22 0.00 + 0.00 0.00	22-23 0.00 + 0.00 0.00	23-24 0.00 + 0.00 0.00	24-25 0.00 + 0.00 0.00	25-26 0.00 + 0.00 0.00	26-27 0.00 + 0.00		Total
00 0.00	0.00 0.	00 0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00		
00 0.00	0.00 0.	.00 0.00	0.00	0.00	0.00							
						0.00	0.00	0.00	0.00			
0.00	0.00 -0.	02 0.00	-0.21	0.07					0.00	0.00		0.00
				-0.37	-0.19	-0.22	-0.22	-0.03	-0.05	0.00		-1.31
-45 45-44	45-44 44	1-43 43-4	42-41	41-31	31-32	32-33	33-34	34-35	35-36	36-37		Total
00 + 0.00 + 00 0.00	+ 0.00 + 0.	.00 + 0.00		0.00 + 0.00	0.00 + 0.00	0.00 + 0.00	0.00 + 0.00	0.00 + 0.00	0.00 + 0.00	0.00 + 0.00		Total
00.00	0.00 0.	.00 0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00		0.00
	-0.23 -0.	25 -0.26	-0.24	-0.32	-0.20	-0.22	-0.19	-0.23	-0.21	0.00		-2.56
00)	0.00 0.00 0.00 0.0	0.00 0.00 0.00 0 0.00 0.00 0.00	0.00 0.00 0.00 0.00 0 0.00 0.00 0.00 0.00	0 0.00 0.00 0.00 0.00 0 0.00 0.00 0.00 0.00	0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00	0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00	0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0 0.00 0.00 0.00 0.00 0.00 0.00 0.00	0.00 0.00 <th< td=""><td>0.00 <th< td=""><td>0.00 <th< td=""><td>0.00 <th< td=""></th<></td></th<></td></th<></td></th<>	0.00 0.00 <th< td=""><td>0.00 <th< td=""><td>0.00 <th< td=""></th<></td></th<></td></th<>	0.00 0.00 <th< td=""><td>0.00 <th< td=""></th<></td></th<>	0.00 0.00 <th< td=""></th<>

С

Maxilla																
Tooth*	18	17	16	15	14	13	12	11	21	22	23	24	25	26	27	28
Mesial interproximal reduction (mm)																
Distal interproximal reduction (mm)																
Inclination (degrees)		-3.70	-9.20	-14.00	-13.70	-0.60	4.80	13.40	10.10	5.00	0.20	-16.10	-14.40	-15.80	-8.90	
Inclination +/- (degrees)					5.00	12.20	3.40	14.0	6.80	3.90	12.00	3.60				
Angulation (degrees)		8.30	0.40	1.50	-1.70	0.60	13.20	0.60	3.50	8.00	10.10	1.80	4.50	5.80	0.40	
Angulation +/- (degrees)				-2.40	-5.90	-16.90	-5.30	-0.90	-2.50	-16.30	-0.90	-8.20	-3.50			1
Rotation +/- (degrees)				0.10	-18.70	-18.40	-11.80	-0.20	-5.50	-18.50	-3.90	-12.80	0.30			
Mesial +/- (mm)				0.20	0.59	-0.13	-0.16	0.43	-0.32	-0.93	-0.12	0.71	0.10			
Vestibular +/- (mm)				1.03	1.06	0.84	-0.11	2.05	0.17	-0.12	0.61	1.26	1.04			
Occlusal +/- (mm)					0.10	1.11	0.78	1.20	0.96	0.94	0.79	0.16	0.01			
Mandible												-				
Tooth*	48	47	46	45	44	43	42	41	31	32	33	34	35	36	37	38
Amount of mesial interproximal reduction (mm)																
Amount of distal interproximal reduction (mm)																
Inclination (degrees)		-35.50	-38.40	-38.40	-24.50	-14.40	-3.60	-2.30	0.30	2.40	-5.60	-22.80	-31.10	-25.70	-25.20	
Inclination +/- (degrees)						4.40	8.40	7.80	4.30	9.40	0.20	-6.30				
Angulation (degrees)		6.50	2.70	5.80	2.70	2.00	-3.50	8.20	-3.90	-3.90	-2.30	-3.80	-1.70	11.30	0.50	
Angulation +/- (degrees)						-0.70	0.70	0.90	-6.30	-1.10	5.90	-5.80				
Rotation +/- (degrees)				-0.10		-10.30	4.50	31.10	-2.00	-10.00	2.50	30.20				
Mesial +/- (mm)				0.05		-0.10	-0.20	-1.29	-0.32	-0.34	-0.79	-1.07	0.06			
Vestibular +/- (mm)				1.22	0.15	0.13	1.17	2.07	0.76	0.35	-0.93	0.03	0.55			
Occlusal +/- (mm)						-0.31	0.08	-0.01		-0.61	-0.31	-0.28	0.64			

*According to FDI notation.

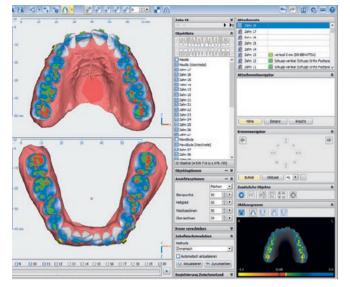


Fig 21 Beginning of the first treatment phase. The occlusal contact tool revealed good initial posterior occlusion.

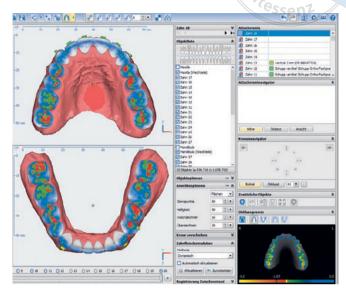


Fig 22 Planned end of the first treatment phase. The occlusal view of the maxilla and mandible demonstrated an occlusal pattern in the molar region compared to the initial situation without movement of the molars.

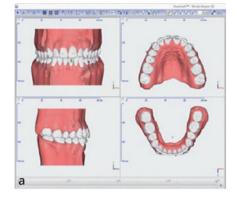


Figs 23a-f Intraoral situation after the first treatment phase and 20 aligners. The arches have been aligned. Further root angulation was planned for the mandibular left central incisor; thus, additional scans were taken. The initial molar support and occlusal contacts remained. No posterior change or intrusion of molars with posterior open bite had occurred.

shows the distribution and penetration of the occlusal contact pattern after the planned first phase. The red contact points demonstrate that the overall maximal penetration (maxillary and mandibular teeth) was -0.68 mm.

Figure 23 shows the intraoral situation after placement of 20 aligners and arch alignment. The mandibular right

central incisor was scheduled for further root angulation; thus, an additional scan was performed. Figure 24a shows the transfer of the scan into OnyxCeph once again. An additional vertical rectangular attachment was added to the mandibular right central incisor for root angulation of the mandibular left first premolar for anchorage for extrusive **Figs 24a-c** Second treatment phase. (a) Transferral of the scan into OnyxCeph for finishing. (b) Planned end of the second treatment phase. Additional attachments were placed on the mandibular left central incisor and first premolar. Four additional stages were planned in the mandible for finishing. (c) Planned movements in the mandible; interproximal reduction was not planned in this phase. *According to FDI notation.





Mandible	1.0					10										
Tooth*	48	47	46	45	44	43	42	41	31	32	33	34	35	36	37	38
Mesial interproximal reduction (mm)																
Distal interproximal reduction (mm)																
Inclination (degrees)		-39.50	-47.40	-42.20	-22.10	-17.60	-4.40	-4.70	-0.80	-3.40	-8.70	-20.30	-38.60	-37.30	-24.10	
Inclination +/- (degrees)								-0.30	0.40							1
Angulation (degrees)		7.00	3.70	0.70	4.50	-0.90	-3.20	3.20	-0.80	-5.40	-7.60	-2.90	6.20	16.50	3.60	Ι
Angulation +/- (degrees)								0.70	-5.00							
Rotation +/- (degrees)								3.10	-2.80							Ι
Mesial +/- (mm)								-0.01	0.09			0.10		0.02	0.02	Ι
Vestibular +/- (mm)							0.20	0.25	-0.01							Ι
Occlusal +/- (mm)									0.26	-0.25		1.30		0.20	0.20	

С

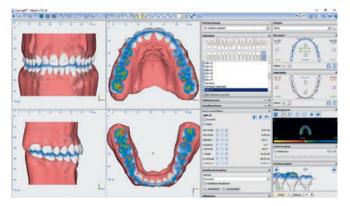


Fig 25 Situation at the beginning of the second treatment phase transferred into OnyxCeph showing the fixed and unmoved position of occlusal contacts in the molar region compared to the beginning of treatment. As the molars were not moved during the first phase, the occlusal contacts showed a penetration of -0.41 mm after the first phase and at the beginning of the second phase compared to the treatment plan after an initial penetration of molars prior to treatment of -0.68 mm. Penetration of molar occlusion was maintained. Despite the planned overcorrection, the maxillary left first premolar showed only slight occlusal contact without penetration.

Fig 26 Situation at the end of the second treatment phase compared to the virtual plan. Occlusal contacts were planned virtually on all the posterior teeth from the first premolars to the second molars with maximal penetration of -0.32 mm. The canines were in minimal occlusal contact and the incisors just out of contact. On the maxillary left first premolar, planning of overcorrection for penetration might have been more successful.

movement. Four additional stages (CA Pro 0.500 and 0.625 mm) were planned in the mandible only (Figs 24b and c).

The beginning of the second phase showed the fixed and unmoved positions of the occlusal contacts in the molar region (Fig 25). As the molars were not actively moved during the first phase, the occlusal contacts showed a penetration of -0.41 mm after the first phase and at the beginning of the second phase compared to the virtual treatment plan after an initial penetration of molars prior to treatment of -0.68 mm. Penetration of the molar occlusion remained. At the end of the second phase, occlusal contacts were



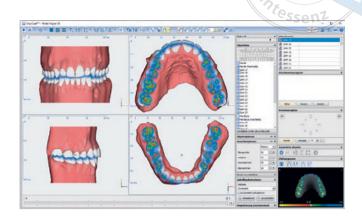
Figs 27a-I Extra- and intraoral situation with aligned arches. The radiograph revealed no pathologies and the mucocele was being treated by the dental surgeon.

planned virtually on all posterior teeth from the first premolars to the second molars with a maximal penetration of -0.32 mm. The canines were in minimal occlusal contact, with the incisors just out of contact (Fig 26).

Figure 27 shows the extra- and intraoral situations with aligned arches after treatment. Radiographs revealed no

pathologies, and the mucocele was being treated by the dental surgeon (Fig 27I). The final scan showed equal occlusal contact points on all posterior teeth in relation to the virtual treatment plan (Fig 28). The premolars and molars showed a maximum penetration of -0.35 mm (Fig 28). Canine guidance was achieved with minimal contact between

Fig 28 Final scan transferred into OnyxCeph showing equal occlusal contact points on all posterior teeth according to the virtual treatment plan. The premolars and molars showed maximal penetration of -0.35 mm. Canine guidance was achieved with minimal contacts on the mandibular canines and first premolars. The occlusal contact point situation of the molars was maintained over the entire course of treatment.





Figs 29a-f Comparison of treatment before (a to c) and after (d to f) in-office aligner treatment.

the mandibular canines and first premolars. The occlusal contact point was maintained over the entire treatment period.

The total treatment duration was 9 months and comprised 24 stages. For retention, a lingual retainer was bonded on the mandibular left first premolar to the right first premolar (stainless steel, Penta-One wire, Masel, Carlsbad, CA, USA), and a removable retainer was worn at night in the maxilla. A comparison of the pre- and posttreatment intraoral conditions is provided in Fig 29.

Discussion

The development of new materials for aligner therapy requires intensive material testing and should be confirmed by clinical studies¹⁷⁻¹⁹. Elkholy et al²⁰ defined the standards for biomechanical measurements of aligner foils as follows:

- specimen length ≥ 40 mm;
- thermoforming process according to manufacturer's instructions;
- three-point-bending test with 8 mm distance between the lateral supports;
- tests of specimens after water immersion performed under long-term loading for ≥ 24 hours.

The authors demonstrated the advantages and disadvantages of different testing conditions for aligner materials and illustrated their behaviours depending on material thickness, initial power load, time and storage conditions. These results are comparable to those obtained for the PET-G material.

For standard aligner materials, Jaggy et al²¹ reported comparable stress relaxation over time. The PET-G specimens lost a substantial amount of their initial high force within the first few hours and continued to decrease steadily in force thereafter²¹. In contrast to these findings, CA Pro demonstrated a different behaviour in the present study, with a comparable lower initial force and a significantly smaller decrease under the same conditions. Stress relaxation of up to 50% of the standard material was also reported by Lombardo et al²², who pointed out that an optimal aligner foil has a lower initial force that does not decrease over time. The two-layer materials in their study exhibited a very constant stress release, but at absolute values up to four times lower than those of the single-layer samples tested²². In comparison, the three-layer foil in the present study might perform better in a clinical setting, starting with a force that is two to three times lower with minimal stress relaxation over the next 24 hours in relation to the standard material. The advantages of CA Pro were also demonstrated under cyclic loading and unloading.

Discolouration of aligner material was reported in another study and could be a clinical problem when using long-term thermoplastic retainers²³. Daniele et al²³ used different methods to analyse the translucent material over time and loaded it with specific substances such as coffee and red wine. Such substances tend to reduce the aesthetic features of standard aligner materials, as also shown in the present results.

The advantages of the in vitro tested CA Pro material could also be beneficial for clinical use. In two cases with different orthodontic treatment complexities, the planned goals were achieved without additional scanning processes or any other manipulation. The lower initial forces of the three-layer foil could contribute to improved patient compliance, better patient comfort and continuous alignment. The combination of new and well-known materials, as well as individual software planning, allows for more diverse options, especially when using in-office aligners.

Conclusions

The development of new materials for aligner therapy requires intensive material testing and should be confirmed by clinical studies. Initial clinical experience shows that CA Pro appears to be useful and offers some advantages compared to conventional materials, especially for individual in-office planning using modern orthodontic 3D software. Further clinical studies are necessary to confirm these initial clinical results.

Acknowledgements

Figures 6 to 17 are based on those found in the article previously published (in German) in KFO 2021;35(3):223–235.

Declaration

During the study, Dr Karbach was employed by Scheu Dental (Iserlohn, Germany) and was responsible for the development of new aligner materials. The other authors declare that they have no competing interests.

References

- 1. Kesling HD. The philosophy of the tooth positioning appliance. Am J Orthod 1945;31:297–304.
- Weir T. Clear aligners in orthodontic treatment. Aust Dent J 2017;62(suppl 1):58–62.
- 3. Hennessy J, Al-Awadhi EA. Clear aligners generations and orthodontic tooth movement. J Orthod 2016;43:68–76.
- Rossini G, Parrini S, Castroflorio T, Deregibus A, Debernardi CL. Efficacy of clear aligners in controlling orthodontic tooth movement: A systematic review. Angle Orthod 2015;85:881–889.
- Iliadi A, Koletsi D, Eliades T. Forces and moments generated by aligner-type appliances for orthodontic tooth movement: A systematic review and meta-analysis. Orthod Craniofac Res 2019;22: 248–258.
- Galan-Lopez L, Barcia-Gonzalez J, Plasencia E. A systematic review of the accuracy and efficiency of dental movements with Invisalign®. Korean J Orthod 2019;49:140–149.
- Papageorgiou SN, Koletsi D, Iliadi A, Peltomaki T, Eliades T. Treatment outcome with orthodontic aligners and fixed appliances: A systematic review with meta-analyses. Eur J Orthod 2020;42:331–343.
- Charalampakis O, Iliadi A, Ueno H, Oliver DR, Kim KB. Accuracy of clear aligners: A retrospective study of patients who needed refinement. Am J Orthod Dentofacial Orthop 2018;154:47–54.
- Buschang PH, Ross M, Shaw SG, Crosby D, Campbell PM. Predicted and actual end-of-treatment occlusion produced with aligner therapy. Angle Orthod 2015;85:723–727.
- Kim TW, Stückrad P. Das Clear-Aligner Konzept. https://www.zwp-online.info/fachgebiete/kieferorthopaedie/aesthetik/das-clear-alignerkonzept-nach-dr-kim. Accessed 1 February 2022.
- 11. Echarri P. Clear Aligner. Madrid: Ripano Médica, 2011.
- 12. Seo JH, Eghan-Acquah E, Kim MS, et al. Comparative analysis of stress in the periodontal ligament and center of rotation in the tooth after

orthodontic treatment depending on clear aligner thickness-Finite element analysis study. Materials (Basel) 2021;14:1–17.

- Lombardo L, Palone M, Longo M, et al. MicroCT x-ray comparison of aligner gap and thickness of six brands of aligners: An in-vitro study. Prog Orthod 2020;21:1–12.
- 14. Mantovani E, Castroflorio E, Rossini G, et al. Scanning electron microscopy evaluation of aligner fit on teeth. Angle Orthod 2018;88:596–601.
- Robertson L, Kaur H, Fagundes NCF, Romanyk D, Major P, Flores Mir C. Effectiveness of clear aligner therapy for orthodontic treatment: A systematic review. Orthodontics Craniofac Res 2020;23:133–142.
- Haouili N, Kravitz ND, Vaid NR, Ferguson DJ, Makki L. Has Invisalign improved? A prospective follow-up study on the efficacy of tooth movement with Invisalign. Am J Orthod Dentofacial Orthop 2020;158: 420–425.
- 17. Elkholy F, Lapatki BG. Recommendation of a novel film-thickness sequence, 0.4, 0.5 and 0.75 mm, for aligner systems. J Aligner Orthod 2018;2:295–304.

- Krey KF, Behyar M, Hartmann M, Corteville F, Ratzmann A. Behaviour of monolayer and multilayer foils in the aligner thermoforming process. J Aligner Orthod 2019;3:139–145.
- 19. Wheeler T, Patel N, McGorray S. Effect of aligner material on orthodontic tooth movement. J Aligner Orthod 2017;1:21–27.
- 20. Elkholy F, Schmidt S, Amirkhani M, Schmidt F, Lapatki BG. Mechanical characterization of thermoplastic aligner materials: Recommendations for test parameter standardization. J Healthc Eng 2019;2019: 8074827.
- 21. Jaggy F, Zinelis S, Polychronis G, et al. ATR-FTIR analysis and one-week stress relaxation of four orthodontic aligner materials. Materials (Basel) 2020;13:1–9.
- 22. Lombardo L, Martines E, Mazzanti V, Arreghini A, Mollica F, Siciliani G. Stress relaxation properties of four orthodontic aligner materials: A 24-hour in vitro study. Angle Orthod 2017;87:11–18.
- 23. Daniele V, Macera L, Taglieri G, Spera L, Marzo G, Quinzi V. Color stability, chemico-physical and optical features of the most common PETG and PU based orthodontic aligners for clear aligner therapy. Polymers (Basel) 2021;14:1–18.