Direct-Printed Aligners: A Clinical Status Report

BJÖRN LUDWIG, DMD, MSD, PhD
KENJI OJIMA, DMD
JONAS Q. SCHMID, DMD
VANESSA KNODE, DMD
RAVINDRA NANDA, BDS, MDS, PhD

As three-dimensional printing has become more widely available in private-office settings, interest in 3D-printed aligners has rapidly increased. Research groups, scientists, and companies have recently been moving away from vacuum-forming processes, instead investigating new materials for 3D-printing of aligner shells.[1-3] Among these materials, Graphy's Tera Harz TC-85,* which was approved in 2022 by the U.S. Food and Drug Administration, the European Union (CE marking), and other official bodies, has gained routine use in offices worldwide.[4-7]

This article outlines the clinical uses and material properties of aligners fabricated from TC-85 resin, and it presents a workflow for designing and manufacturing them in the orthodontic office.

Clinical Uses

The unlimited design possibilities of 3D-printed aligners offer a significant advantage to clinicians (Fig. 1). Biomechanics can be fine-tuned not only by incorporating cutouts or bite ramps (Fig. 2), but also by adjusting the thickness of the plastic at any part of the aligner, which enables precise force delivery and the production of countermoments for root movement. Class II advancement wings can be added; a design similar to a Twin Block appliance is also possible. For retention in anterior open-bite cases or to close gaps

KRAVITZ KEYS

- Tera Harz Clear* (TC-85DAC*), a methacrylate-based photopolymer resin, can be used to print clear aligners directly.
- Production of 3D-printed aligners involves four steps: digital setup and staging; adjusting the aligner shells in slicer software, then 3D-printing them; cleaning the aligners in a centrifuge and removing the supports; and post-processing with light-curing and ultrasonic cleaning.
- Among the greatest advantages of TC-85 are the design possibilities it introduces, including the option to alter the thickness at any part of the aligner.

Dr. Ludwig

Dr. Ojima

Dr. Schmid

Dr. Knode

Dr. Nanda

Dr. Ludwig is an Associate Editor of the *Journal of Clinical Orthodontics;* an Instructor, Department of Orthodontics, University of Homburg, Saar, Germany, and Institute of Odontology, Sahlgrenska Academy, University of Gothenburg, Sweden; and in the private practice of orthodontics, Am Bahnhof 54, 56841 Traben-Trarbach, Germany; bludwig@kieferorthopaedie-mosel.de. Dr. Ojima is in the private practice of orthodontics at Smile Innovation Orthodontics, Tokyo. Dr. Schmid is Full-Time Faculty, Department of Orthodontics, University of Münster, Münster, Germany. Dr. Knode is in the Department of Orthodontics, University Medical Center of Johannes Gutenberg University Mainz, Mainz, Germany. Dr. Nanda is an Associate Editor of the *Journal of Clinical Orthodontics* and Professor Emeritus, University of Connecticut School of Dental Medicine, Farmington, CT.

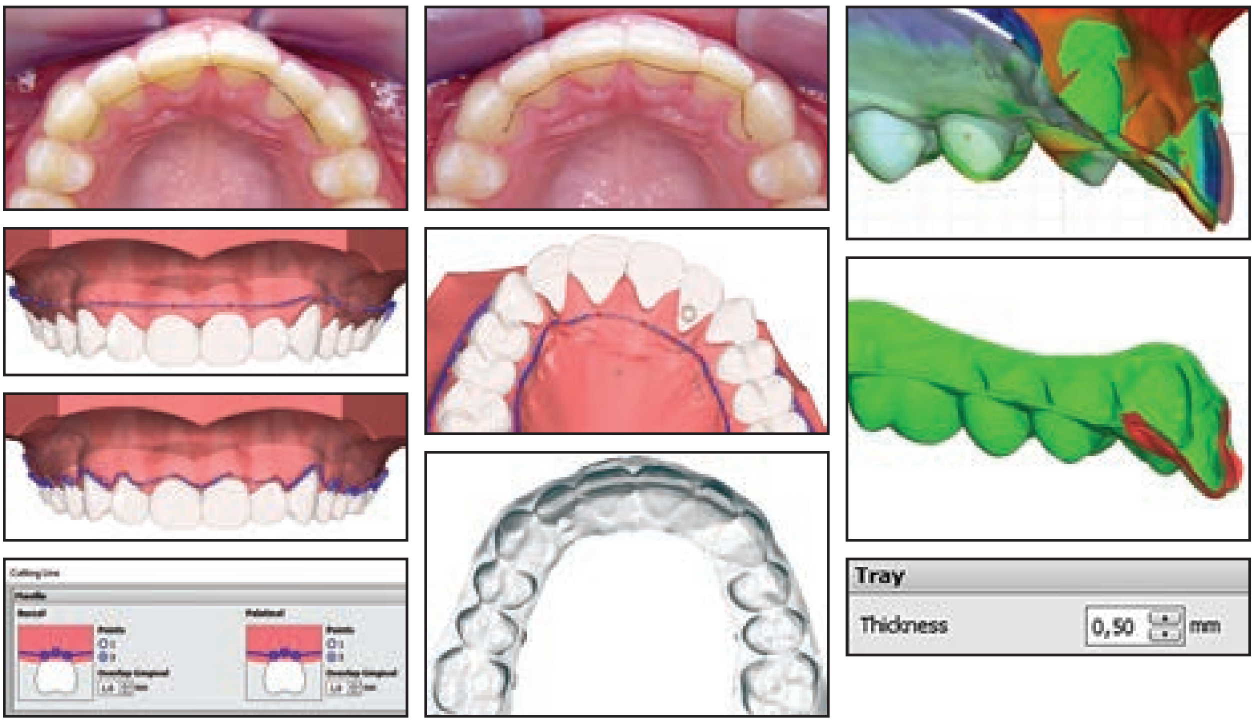

Fig. 1 Altering trimlines, individualizing thickness, and adding pressure points can optimize three-dimensional movements, as demonstrated in replacement case.

*Trademark of Graphy, Inc., Seoul, South Korea; www.itgraphy.com.

after relapse, a tube can be incorporated for insertion of a TMA** spring. Hooks for elastics can be integrated, and trim lines can be customized.[8] For extrusion, pressure columns can be used in place of attachments.[9]

Tera Harz TC-85 further expands the potential uses of direct-printed aligners. The material's most prominent feature is its shape memory: after exposure to high temperatures, the aligner can be deformed to easily snap over undercuts. When the aligner is kept in an oral environment (more than 30°C) for at least 22 hours a day, as typically prescribed, any deformation required for insertion or removal will self-correct.[10]

Studies have demonstrated that 3D-printed aligners can successfully treat mild crowding, with an accuracy that compares favorably to that of conventional aligners.[11,12] When used in conjunction with interproximal reduction, direct-printed aligners can also predictably and effectively correct moderate crowding (Fig. 3). Furthermore, their customizability makes these aligners ideal for unexpected complications or support during the finishing stages of difficult cases.[13]

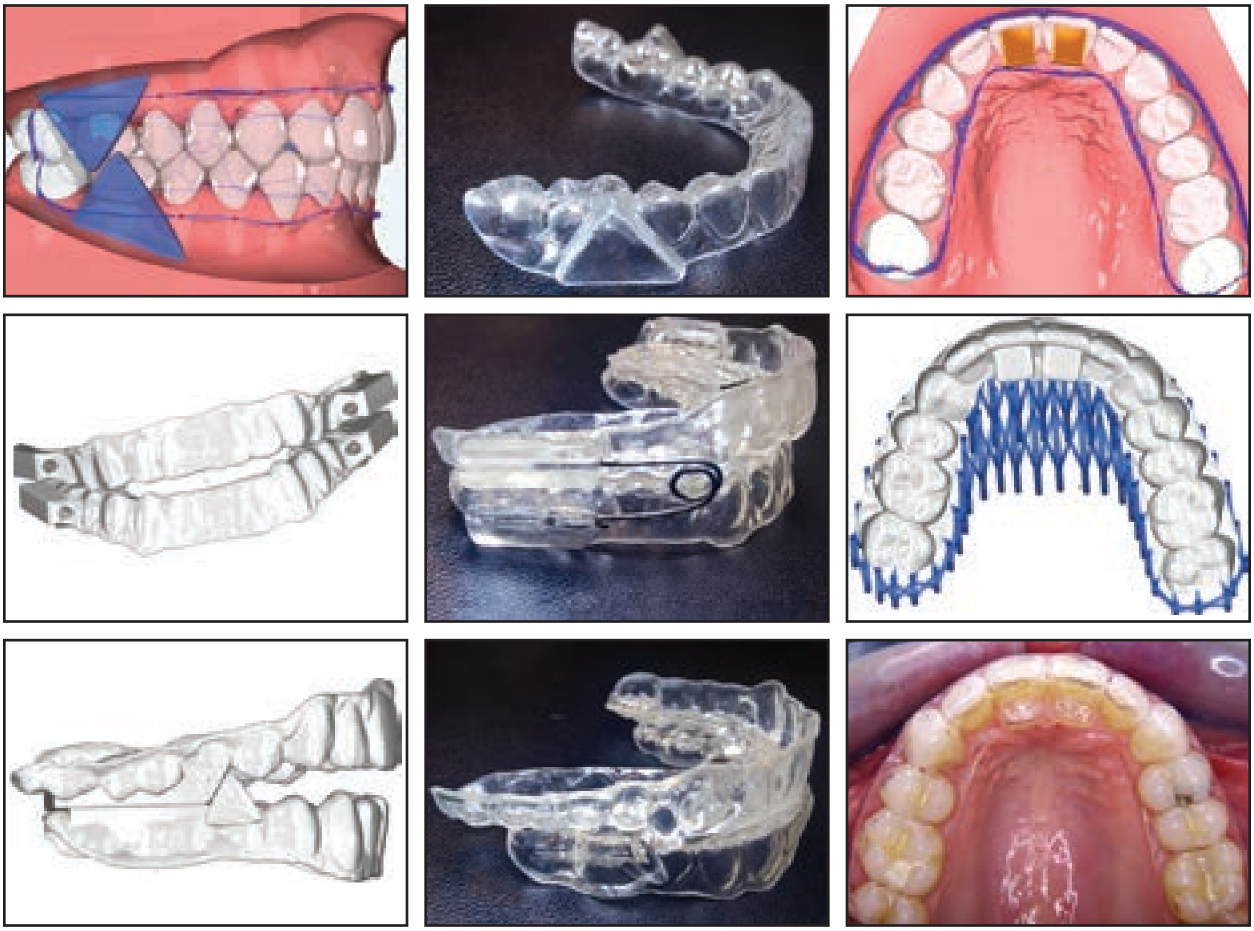

Fig. 2 Digital design, fabrication, and clinical use of 3D-printed aligners, demonstrating possibilities such as advancement wings, 3D-printed tubes for manually inserted TMA springs, and bite ramps.**

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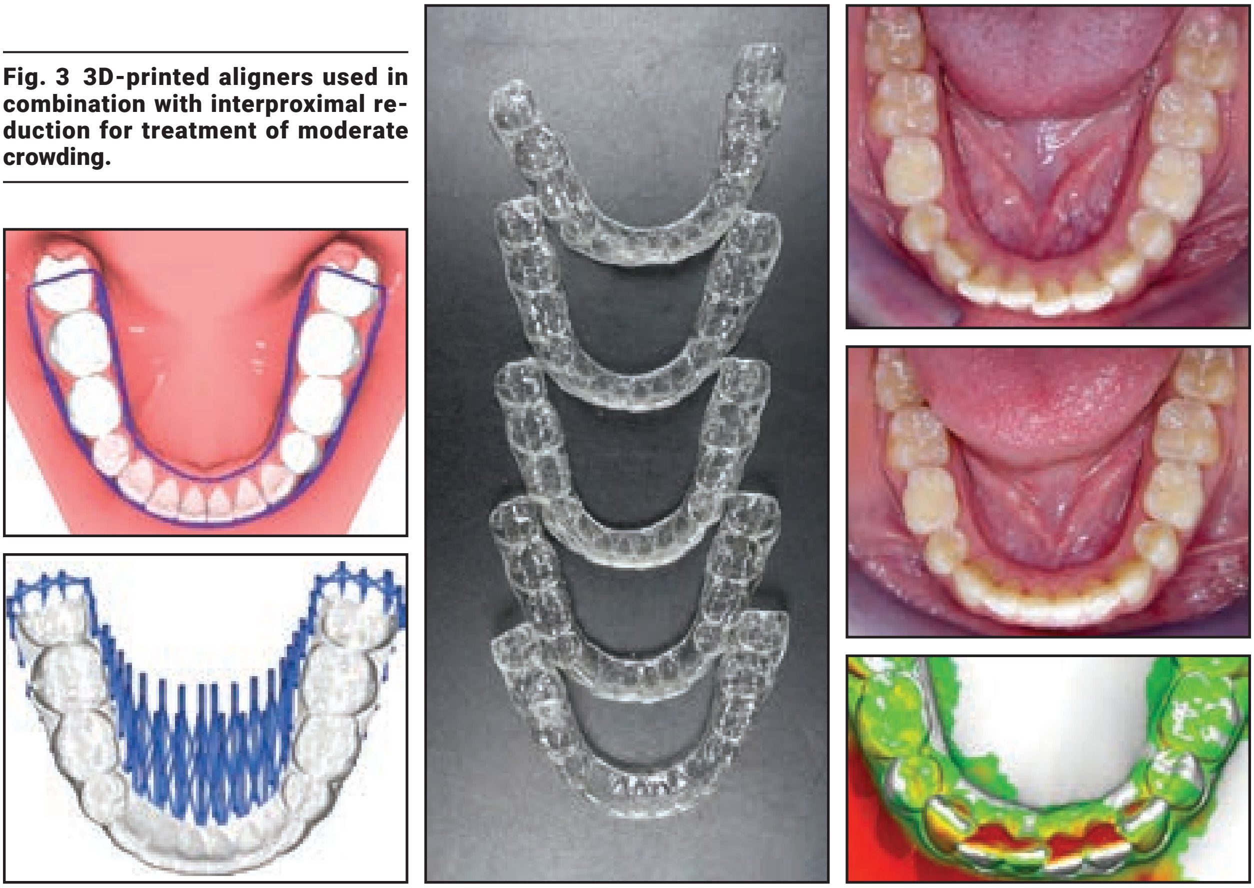

Fig. 3 3D-printed aligners used in combination with interproximal reduction for treatment of moderate crowding.

Material Properties

Force Delivery

Several studies have measured the forces exerted by direct-printed aligners. Customizing the thickness at different parts of the aligner tray has been found to better distribute the applied forces, thereby reducing side effects.[14,15] The flexibility and viscoelastic properties of TC-85, in particular, enable the aligners to apply continuous, light forces; in one study, the force levels produced by direct-printed aligners during extrusion were found to be significantly lower than those of thermoformed aligners.[9] Moreover, as Lee and colleagues reported, the material's shape memory and, hence, geometric stability at high temperatures appear to reduce the amount of force decay caused by repeated insertion and removal.[10] In a contrasting study, however, Sayahpour and colleagues found greater rigidity and more force decay with 3D-printed aligners than with vacuum-formed aligners.[16]

Wear and Aging

Tera Harz TC-85 is a urethane dimethacrylate-based photopolymer. At room temperature, aligners printed with TC-85DAC, the clear variant of this resin, are transparent and stiff, much like conventional thermoformed aligners. Photocurable resins such as TC-85D form 3D networks through radical polymerization, allowing them to revert to their original shapes after deformation, even if they are heated above the glass transition temperature. Therefore, unlike typical thermoplastic aligners, TC-85 aligners can remain at body temperature

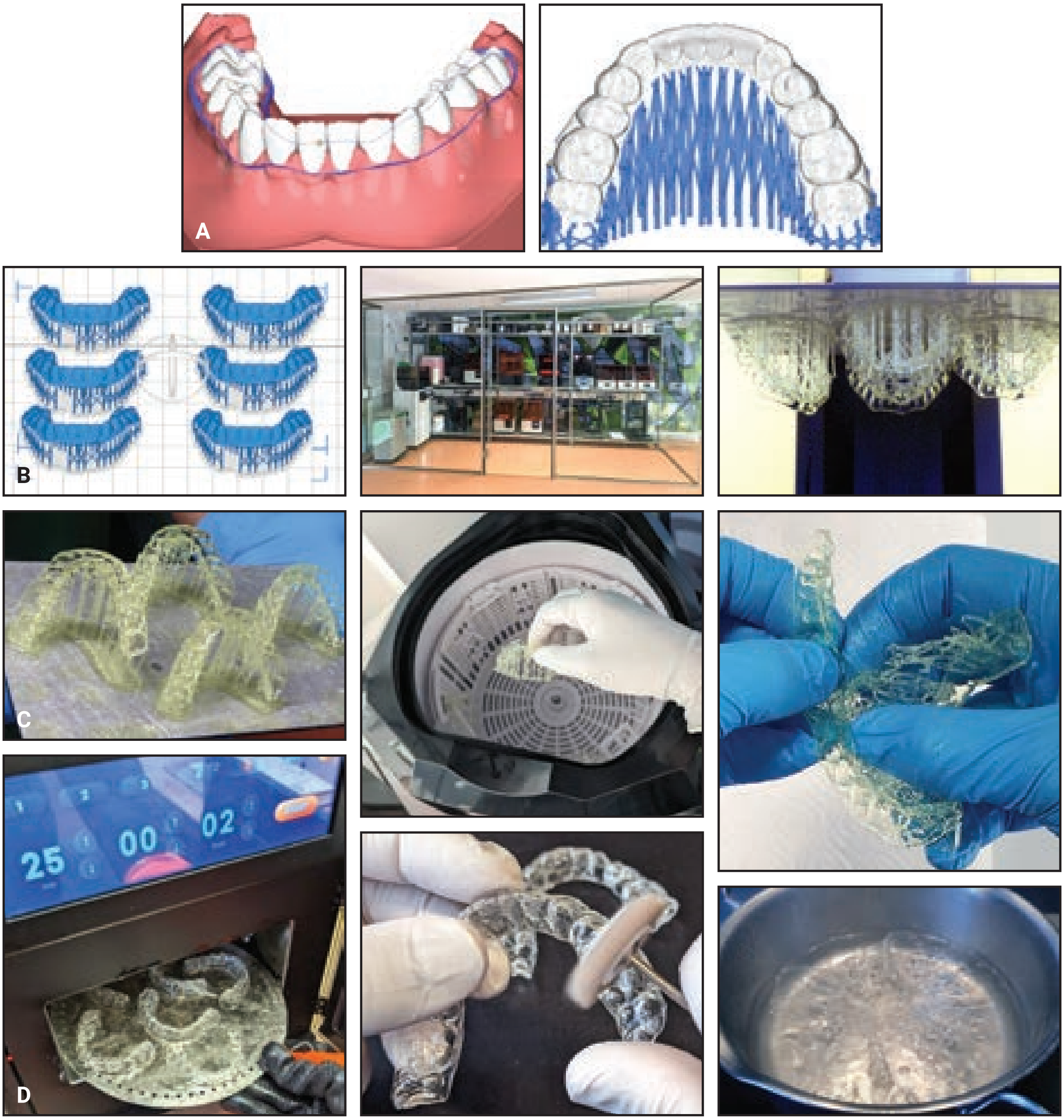

Fig. 4 Four major steps required for direct printing of aligners. A. Digital setup (left), staging (Table 1), and automatic generation of support structures (right). B. Aligner shells adjusted on virtual printing platform in slicer software (left) and printed on certified printers (center, right). C. Printed aligners (left) centrifuged (center), then supports removed by hand (right). D. Aligners light-cured in nitrogen atmosphere (left), followed by polishing (center) and ultrasonic cleaning (right).

TABLE 1
ALIGNER STAGING EXAMPLE: LIMITS OF TOOTH MOVEMENT FOR STEP 1 (MANDIBLE)

	Lower central incisors	Lower lateral incisors	Lower canines	Lower first premolars	Lower second premolars	Lower first molars
Strip mesial	0.30mm	0.30mm	0.50mm	0.50mm	0.50mm	0.50mm
Strip distal	0.30mm	0.30mm	0.50mm	0.50mm	0.50mm	0.50mm
Inclination (+/−)	2.00°	2.00°	2.00°	2.00°	2.00°	2.00°
Angulation (+/−)	2.00°	2.00°	2.00°	2.00°	2.00°	2.00°
Rotation (+/−)	2.00°	2.00°	2.00°	2.00°	2.00°	2.00°
Mesial (+/−)	0.20mm	0.20mm	0.20mm	0.20mm	0.20mm	0.20mm
Vestibular (+/−)	0.20mm	0.20mm	0.20mm	0.20mm	0.20mm	0.20mm
Occlusal (+)	0.10mm	0.10mm	0.10mm	0.10mm	0.10mm	0.10mm
Occlusal (−)	−0.10mm	−0.10mm	−0.10mm	−0.10mm	−0.10mm	−0.10mm

without losing force from deformation.

In fact, a study showed that aligners printed from TC-85 resin kept their mechanical properties for at least one week of intraoral use.[17] After a week of wear, however, surface roughness and porosity were found to increase,[18,19] potentially leading to more bacterial adhesion and biofilm formation in comparison with Invisalign*** aligners.

In addition to mechanical wear, chemical aging of direct-printed aligners has been investigated. No cytotoxic chemicals or estrogen mimics were detected after aligners fabricated with TC-85 were aged in water for two weeks.[20] In another study, no leaching of bisphenol A was detected, but the material was found to release urethane dimethacrylate.[21] The significant variability among samples suggested potential inconsistencies in the fabrication process.[21] To avoid this issue, strict protocols for aligner manufacturing should be followed.

Accuracy

Park and colleagues recently evaluated variations in aligner thickness caused by manufacturing differences, using micro-computed tomography and spectrophotometry to measure the gap width of thermoformed and 3D-printed aligners.[22] While changes in thickness were found in all aligners after printing and post-production—the thickness of 3D-printed aligners tended to increase and that of thermoformed aligners to decrease—the direct-printed aligners exhibited smaller gap widths, indicating a better fit.[22] Corroborating these results, Koenig and colleagues found that the trueness and precision of direct-printed aligners were superior to those of thermoformed aligners.[23]

Manufacturing Process

Production of 3D-printed aligners involves four basic steps (Fig. 4). First, the digital setup and staging are performed. Next, the aligner shells are adjusted using either a dedicated slicer program such as Chitubox† or the slicing capabilities of the design software, then fabricated with certified 3D printers. The printed aligners are cleaned in an alcohol-free process by spinning them in a dedicated centrifuge, and the supports are manually removed. Finally, the aligners are light-cured and ultrasonically cleaned. A detailed workflow is presented below.

***Registered trademark of Align Technology, Inc., San Jose, CA; www.aligntech.com.
†Chitu Systems, Commerce, CA; www.chitubox.com.

Software

The digital setup can be done with a variety of software platforms, including paid options such as NemoStudio,‡ Onyxceph,†† Deltaface,‡‡ 3Shape,§ Blue Sky Plan,§§ uLab,§§§ ArchForm,**** and Maestro 3D.§§§§ In addition, Graphy has released Direct Aligner Designer* (DAD), a free-to-use software platform that combines treatment planning with aligner design. Key features of this program include options for altering aligner thickness, customizing aligner margins for improved force delivery and retention, and adjusting resolution to enable the use of additional orthodontic devices with complex geometries. Aligners can also be engraved with patient names or tray numbers. The program includes an automatic block-out feature that fills in small gaps to ensure successful one-piece printing.

Once the shells are designed, the software automatically attaches supports for printing the aligners, significantly enhancing workflow efficiency and operational ease (Fig. 4A). (If a design platform without slicing capabilities is used, the aligner shells can be saved as STL files and imported into a program such as Chitubox, which will generate support structures.)

Printing and Post-Processing

With many 3D printers, six to eight aligners can be fabricated simultaneously over the course of 30-60 minutes (Fig. 4B). Because the materials are not immediately sturdy or biocompatible after printing, several post-processing stages are required, as with conventional aligner production. First, the aligners are centrifuged to remove residual resin, which takes about six minutes; many centrifuges can accommodate as many as eight aligners at once (Fig. 4C). Next, the support structures are removed either by hand or with nippers, which takes about a minute per aligner. The trays are then given an ultraviolet light-cure in a nitrogen atmosphere; Graphy's Tera Harz Cure* nitrogen generator will completely cure six to eight aligners in 17-25 minutes (Fig. 4D). Any remaining support parts are trimmed, and the aligners are polished, a process that takes only one or two minutes. Finally, the trays are washed in an ultrasonic bath of room-temperature water for two minutes, dried for 10 minutes, washed again in 100°C water for another minute, and dried for another 10 minutes (a total of about 25 minutes).

Effects of the Manufacturing Process

The particular 3D printers and post-production processes that are used may affect the mechanical properties of direct-printed aligners and, consequently, their clinical performance.[24] The mechanical properties of the trays do not appear to be altered by post-curing in a nitrogen atmosphere,[25] heat treatment,[25] or directional printing.[26] While ultraviolet-light-curing is crucial to ensure rigidity, an extended curing time has little effect on accuracy.[27]

The tendency of direct-printed aligners to increase in thickness after the manufacturing process may negatively affect their clinical utility.[22,28] No direct associations have been found between curing time or nitrogen-generator use and aligner thickness, but trays printed at a 60° inclination and then centrifuged did exhibit a local increase in thickness at the anterior teeth.[29]

Conclusion

Direct-printed aligners provide orthodontists with enough flexibility to maintain full control over the treatment workflow (Fig. 5). As evidence of clinical efficacy continues to emerge, in-house

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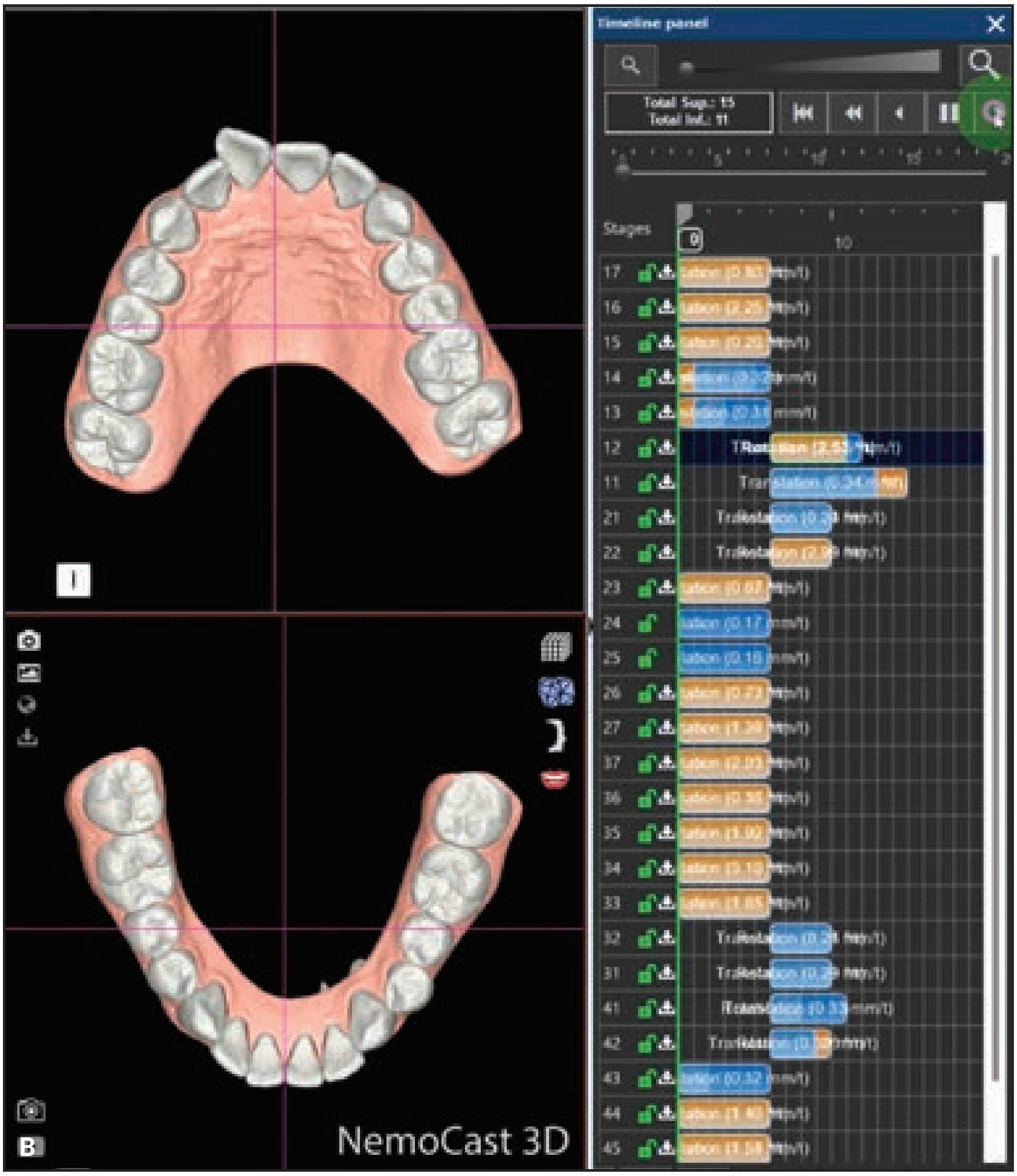
§§Registered trademark of Blue Sky Bio, Libertyville, IL; www.blueskyplan.com.
§§§ULab Systems, Memphis, TN; www.ulabsystems.com.
****ArchForm, Sunnyvale, CA; www.archform.com.
§§§§AGE Solutions, Pontedera, Italy; www.maestro3d.com.

Fig. 5 Sample case treated with combination of enamel reduction, slight expansion, and uprighting. A. Patient with Class I relationship and anterior crowding before treatment. B. Planning and staging performed in NemoStudio‡ software (continued on next page).



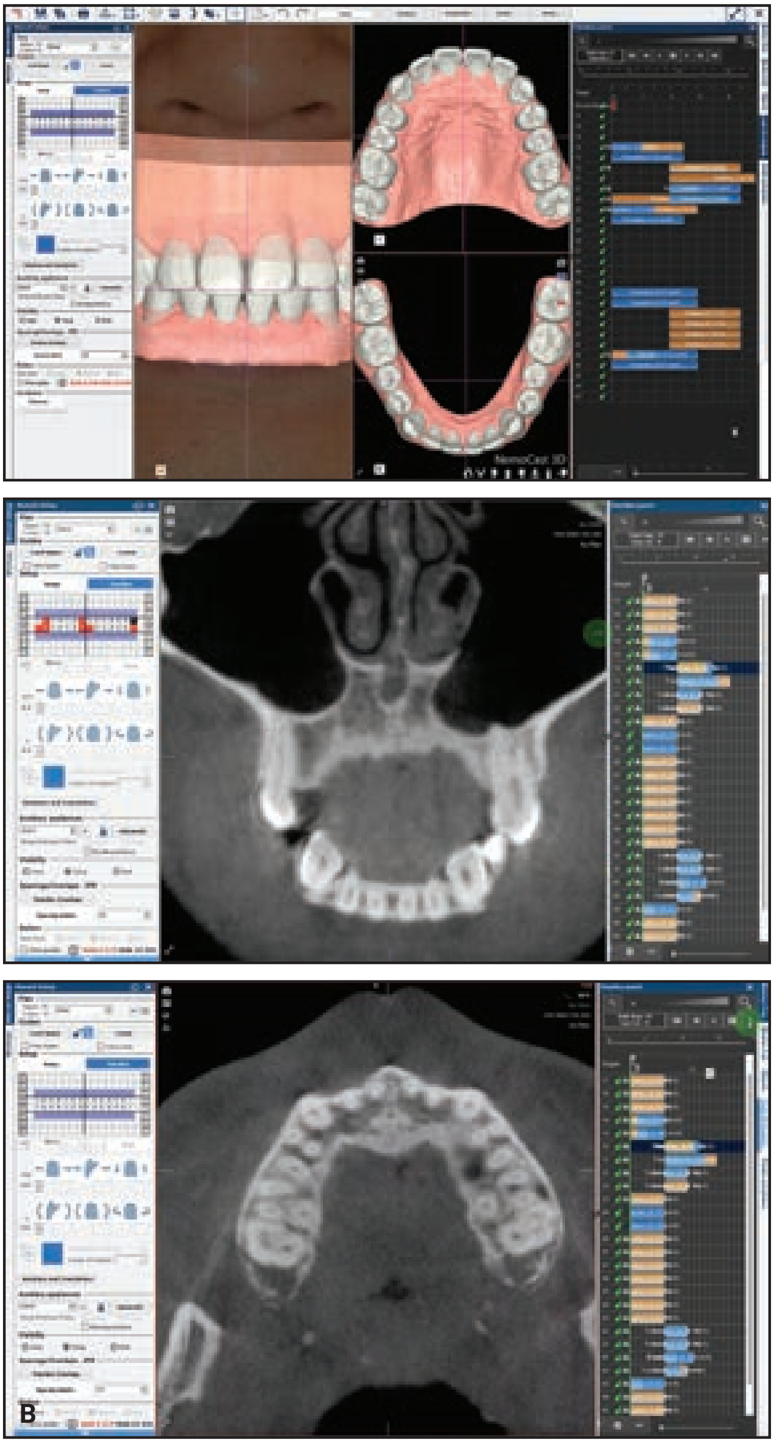


Fig. 5 (cont.) Sample case treated with combination of enamel reduction, slight expansion, and uprighting. B. Planning and staging performed in NemoStudio‡ software (continued on next page).

aligner fabrication will become increasingly widespread. Nevertheless, practitioners must carefully evaluate their aligner manufacturing processes and materials to ensure they can continue providing low-risk, effective treatment.

‡Registered trademark of Nemotec, Madrid, Spain; nemostudio. nemotec.com.

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Fig. 5 (cont.) Sample case treated with combination of enamel reduction, slight expansion, and uprighting. C. Progress of treatment with 17 sets of aligners. D. Final results after four months of treatment.

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