Directly printed aligner therapy: A 12-month evaluation of application and effectiveness

Vanessa Knode,[a] Björn Ludwig,[b] Jean-Marc Retrouvey,[c,d] Nikolaos Pandis,[e] Jonas Q. Schmid,[f] Christina Erbe,[g] and Padhraig S. Fleming[h]

Mainz and Saar, Germany, and Houston, Tex, and Ho Chi Minh City, Vietnam, and Bern, Switzerland, and Dublin, Ireland

Introduction: Directly printed aligners (DPAs) are gaining in popularity, potentially streamlining manufacturing, decreasing environmental waste, and offering enhanced adaptation and tailoring. This transition has been facilitated by advances in materials, software, and production. Although DPAs may have enhanced versatility and application in the management of more complex malocclusions, there is little research evaluating their effectiveness. **Methods:** A total of 54 patients undergoing treatment with DPAs were evaluated for occlusal improvement, overall treatment duration, and adverse effects. Regression models were fit to evaluate the association between the need for refinement, final peer assessment rating (PAR) score, and independent variables, including the total number of aligners and treatment indications. **Results:** The mean number of aligners in the initial plan was 7.1 ± 2.9 and 5.1 ± 4.3 in maxillary and mandibular arches. Refinement was required in 40.8% (n = 20). The pretreatment PAR score of 17.01 ± 7.93 showed a significant improvement (86.6%), with a final PAR score of 2.25 ± 1.15. Minor complications were noted in 3 participants. The need for refinement was unrelated to the total number of aligners (odds ratio, 1.05; 95% confidence interval, 0.94-1.18; $P = 0.36$). There was weak evidence of an association between the final PAR score and the total number of aligners (odds ratio, −0.03; 95% confidence interval, −0.07 to 0.003, $P = 0.07$). **Conclusions:** On the basis of this preliminary retrospective evaluation, DPAs may be used to manage mild-moderate malocclusion, producing a significant reduction in PAR score. Nevertheless, additional prospective research is required to confirm these findings and compare the relative merits of DPAs to alternatives. (Am J Orthod Dentofacial Orthop 2025;167:73-9)

Traditional orthodontic aligners are derived from thermoformed plastics fabricated on sequentially physically printed models. Directly printed aligners (DPAs) obviating the need for intermediate steps, including the use of printed models, were introduced in 2021. DPAs offer several advantages, such as streamlining the manufacturing process and eliminating the requirement for 3-dimensional (3D)-printed models, thereby potentially reducing associated costs and reducing environmental waste. Moreover, enhanced precision and the potential for increased customization also exist.[1]

By obviating the need for additional steps, direct printing may lead to enhanced tooth-aligner adaptation with the potential for improved control of tooth movement.[1] On the basis of optical scanning techniques, absolute discrepancies with DPAs were comparable to those observed with Zendura FLX and lower relative to Essix ACE (Dentsply Sirona, Sarasota, Fla), but overall trueness was superior with the DPA material.[1] This advantage has also been applied to limit the usage of bonded attachments, which may streamline the process of aligner therapy, although evidence concerning the clinical effectiveness of this protocol is lacking. The goodness-of-fit may allow DPAs to avail of interproximal undercuts.[2] This could reduce the number of required

[a]Department of Orthodontics, University Medical Center of the Johannes Gutenberg, University of Mainz, Mainz, Germany.
[b]Department of Orthodontics, University of Homburg, Saar, Germany.
[c]Department of Orthodontics, Baylor College of Medicine, Houston, Tex.
[d]Faculty of Odontostomatology, Ho Chi Minh City University of Technology, Ho Chi Minh City, Vietnam.
[e]Department of Orthodontics and Dentofacial Orthopedics, Dental School, Medical Faculty, University of Bern, Bern, Switzerland.
[f]Department of Orthodontics, University of Münster, Münster, Germany.
[g]Department of Orthodontics, University Medical Center of the Johannes Gutenberg, University of Mainz, Mainz, Germany.
[h]Division of Public and Child Dental Health, Dublin Dental University Hospital, Trinity College Dublin, Dublin, Ireland
All authors have completed and submitted the ICMJE Form for Disclosure of Potential Conflicts of Interest, and none were reported.
Address correspondence to: Vanessa Knode, Department of Orthodontics, University Medical Center of the Johannes Gutenberg, University of Mainz, Mainz, Germany; e-mail, vanessa-knode@web.de.
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attachments with these systems, although evidence is required to prove their efficacy in this respect.

A further theoretical advantage of DPAs relates to the potential to control and tailor material thickness and properties selectively once current software is optimized for their specific applications. Thermoformed appliances are also affected by blank material and dimensions,[3] as well as the size of the physical model. The thickness of thermoformed retainers and aligners is known to be site-specific, generally tapering significantly in the midlabial region of the mandibular incisors, for example.[3,4] The effect of selective thickening of DPAs has shown promise in titrating force levels and moments, although precise prediction of effects is complex.[5]

Research addressing the effectiveness of aligner therapy is building strong evidence to support their use to address a range of mild and potentially more complex malocclusions.[6-9] Limitations have also been highlighted with the observed effect of aligner therapy typically not reflecting simulated representations of force delivery[10,11] with the additional need for refinement and alternatives being commonplace.[12] Although the effectiveness of both conventional aligners and fixed appliances has been reported using recognized occlusal indexes such as the peer assessment rating (PAR),[6-8] a lack of clinical information remains concerning the efficacy of DPAs.[13-15]

An example of a DPA material is Tera Harz TC-85, an Aliphatic Vinyl Ester Urethane[16] material introduced by Graphy to overcome the current limitation of thermoforming sheet-type aligners. It is noteworthy that its manufacturing is particularly technique sensitive and a printable resin requiring more complex postprocessing steps involving nitrogen treatment to ensure full polymerization of the resin. This technique's sensitivity may predispose to potential adverse reactions if printing and postprocessing protocols are not carefully followed and controlled.[17]

Therefore, we aimed to evaluate the clinical effectiveness and efficiency of a DPA (Graphy; Graphy Inc, Seoul, South Korea) to correct moderate malocclusions and to evaluate the occurrence and nature of any complications associated with its use over 12 months.

MATERIAL AND METHODS

A retrospective evaluation of 54 consecutive patients treated by an experienced orthodontist (B.L.) with a proprietary direct printed-aligner system (Graphy) in a specialist orthodontic practice in Traben-Trarbach, Germany, was undertaken. Ethical approval for this 12-month evaluation was obtained from Landesärztekammer Rheinland-Pfalz Research Ethics Committee (reference No. 17634).

All aligner therapy was planned using OnyxCeph3 (Image Instruments GmbH, Chemnitz, Germany) software, with digital planning performed by 1 clinician (B.L.; Fig 1, *A-D*). Support structures to enable direct printing of aligners were autogenerated for each aligner using open-source software (Lychee Slicer; Mango 3D SAS, Mérignac, France). The DPAs were placed on the platform at a 45° angle. The tips of the supports were created with a length of 2 mm and a diameter of 0.4 mm. The objects were exported as stereolithography files to a Nbee 3D printer (Uniz Technology LLC, San Diego, Calif). Tera Harz TC-85 (Graphy Inc) was used to fabricate the DPAs. After printing, the DPAs were placed in a centrifuge (Tera Harz Spinner, Graphy Inc) for 6 minutes at 350 rpm to remove excess adhering material. The support structures were then manually removed. The DPAs were then light-cured for 20 minutes using Tera Resin Cure THC2 (Graphy Inc) under a 95% nitrogen atmosphere to achieve the desired shape memory properties and transparency. They were subsequently boiled in water for 1 minute to remove residual monomers. The surfaces of the DPAs were then smoothed with a polishing disk (Lisko; Erkodent Erich Kopp GmbH, Pfalzgrafenweiler, Germany) before being dried and provided to the patient in a paper box.

Aligners were prescribed for near full-time wear (22 h/d), with each aligner worn for 7 days (Fig 2, *A-D*). No more than 5 aligners were fabricated per batch with an in-person review before manufacturing further aligners. Good compliance was noted at the 5-week control intervals. After the completion of active treatment, final intraoral scans of the corrected malocclusions were obtained.

In addition to demographic data, the following clinical information was obtained for each participant: (1) malocclusion type: Class I, Class II Division 1, Class II Division 2, or Class III; (2) indication for treatment: finishing, relapse, comprehensive treatment, or retention; (3) the use of attachments and auxiliaries (intermaxillary elastics or functional mandibular advancer); (4) the number of aligners in initial course, midcourse, if required, and final phases; (5) the need (yes/no) for refinement and associated reasons (lack of interproximal reduction, bite improvement, or lack of progress with alignment); and (6) the prevalence and nature of self-reported complications including aligner issues because of burning or reactions of soft tissues.

PAR score was evaluated using the digital models, and percentage improvement in PAR score was calculated. The measurements were conducted by a single operator. To evaluate the accuracy of the method, 20 of the 54 patients were randomly selected with PAR scores remeasured.

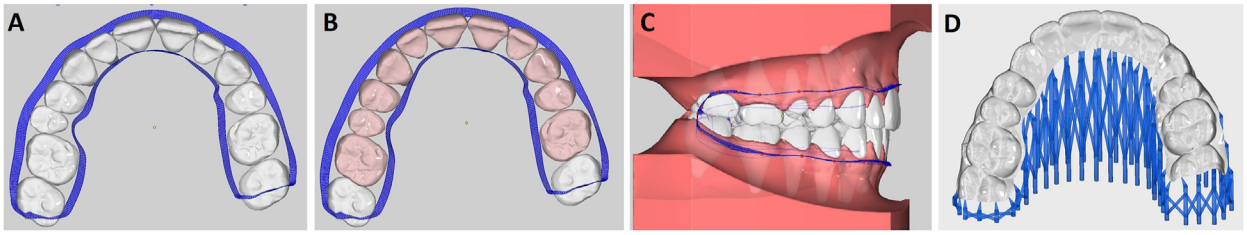

Fig 1. A-D, Digital planning of DPAs using OnyxCeph^3 software (Image Instruments GmbH, Chemnitz, Germany).

Fig 2. Progress of aligner therapy: **A**, initial stage without DPA; **B**, initial stage with DPA; **C**, midstage; **D**, final stage.

Statistical analysis

Descriptive statistics were calculated for the collected for the demographic and clinical characteristics of the sample. Univariable logistic regression was used to examine potential associations between the need for refinement, the number of aligners, and the indications for treatment. Linear regression was used to examine the association between the final PAR score and the number of aligners after adjusting for the initial PAR score. Confidence intervals (CIs) were calculated using nonparametric bootstrapping (500 iterations). All analyses were conducted in Stata (version 18; StataCorp, College Station, Tex).

The intraclass correlation coefficient (ICC) was calculated using a linear mixed model, with the PAR score as a random factor. The ICC represents the ratio of variability within the start PAR score (PAR 1) and final PAR score (PAR 2) to the total variability. ICC showed excellent reliability for all measured outcomes. For the PAR 1, the ICC was 0.997 (95% CI, 0.992-0.999).[18]

RESULTS

The sample included 54 participants (18 males and 36 females) aged 14-64 years, presenting with a range of malocclusion types: Class I (25/54; 46.3%), Class II/1 (16/54; 29.6%), Class II/II (7/54; 13.0%) and Class III (6/54; 11.1%). The indications for treatment included finishing (36/54; 66.7%), relapse management (13/54; 26%), and comprehensive treatment (5/54; 9.3%). Overall, the mean number of aligners in the initial plan was 12.2 ± 2.6, ranging from 2-28, with a mean of 7.1 ± 2.9 and 5.1 ± 4.3 in maxillary and mandibular arches, respectively.

No auxiliaries or attachments were used in most patients (36/54; 66.7%), with auxiliaries only in a

significant subset (17/54; 31.5%) and attachments used in a single case (1.9%). Furthermore, 20 patients (40.8%) required refinements, whereas 29 (59.2%) did not (Table I). The primary reasons for refinement were attributed to a need for interproximal reduction (7/20; 35%), interarch relationship issues (6/20; 30%), or a combination of these (1/20; 5%) with limited progress also being instrumental (6/20; 30%).

The pretreatment PAR scores were moderate (17.01 ± 7.93), with a significant improvement (86.6%) generally observed during treatment. The final PAR score was 2.25 ± 1.15. Adverse effects or complications were rare, with none of these being serious. Three participants reported burning sensations, and 2 of them were unable to tolerate the aligners.

The requirement for refinement was not associated with either the total number of aligners used (odds ratio, 1.05; 95% CI, 0.94-1.18, $P = 0.36$) or the indication for treatment (Table II). On the basis of multiple linear regression, there was a weak association between the final PAR score and the total number of aligners (odds ratio, −0.03; 95% CI, −0.07 to 0.003; $P = 0.07$; Fig 3; Table III). As the number of aligners increased, the final PAR score worsened.

Table I. Demographic and clinical characteristics of the sample (n = 54)

Characteristics	*n (%)*
Gender	
Male	18 (33.33)
Female	36 (66.67)
Total	54 (100.00)
Incisor relationship	
Class I	25 (46.30)
Class II Division 1	16 (29.60)
Class II Division 2	7 (13.00)
Class III	6 (11.10)
Total	54 (100.00)
Indications	
Finishing	36 (66.67)
Relapse	8 (14.81)
Comprehensive	5 (9.26)
Retention	5 (9.26)
Total	54 (100.00)
Attachment/auxiliary	
None	36 (66.67)
Attachment	1 (1.85)
Auxiliary	17 (31.50)
Total	54 (100.00)
Patients having refinement	
Yes	20 (40.82)
No	29 (59.18)
Total[†]	49 (100.00)
Reasons for refinement	
IPR	7 (35.00)
Bite alignment	6 (30.00)
Limited progress	6 (30.00)
IPR and bite alignment	1 (5.00)
Total	20 (100.00)
Complications	
Burning sensation	3 (5.56)
Intolerance	2 (3.70)
None	49 (90.74)
Total	54 (100.00)
Tissue reaction	
Yes	2 (3.70)
No	52 (96.30)
Total	54 (100.00)

IPR, interproximal reduction.
[†]Five participants were given DPAs as removable retainers.

DISCUSSION

DPAs are a relatively new technique offering the possibility of addressing moderate malocclusions, and they show some promise in this study in managing mild-moderate malocclusion.[19] These aligners are created from simulation software that virtually corrects malocclusion incrementally. This procedure closely resembles that used for producing thermoformed aligners and is used to create the staging and rate of correction of specific tooth movements, including angulation and derotation. Upper limits of 0.3 mm for translation and 4° for inclination, angulation, and rotational change were preprogrammed in this study. The undercuts were not blocked to allow for aligner material flow and more precise force application. Small batches of aligners (up to 5) were produced to permit close in-person monitoring and to minimize the risk of loss of tracking.[12] Recent studies showed that TC-85 aligners exhibited some stress relaxation at an activation of 0.25 mm and performed better than thermoformed aligners in terms of force loss at an activation of 0.5 mm. This consistent force delivery may reduce complications and improve patient comfort compared with thermoformed aligners, which are prone to higher initial forces and associated side effects.[20,21] Future research should investigate these results through in vivo tests to confirm their clinical relevance. A recent study showed that attachments increase the efficiency of treatment by improving the force transmission and control of complex tooth movements.[22] In this study, attachments were considered an effective adjunct for only 1 patient, and effective treatment outcomes were achieved without using attachments, highlighting the high precision and adaptability of DPAs.[1] Thermoformed aligners require the use of attachments for certain tooth movements to enhance their effectiveness.[23] This is likely due to the inability to adapt hermetically to undercuts and their modulus of elasticity, which requires the use of attachments to achieve the desired force system.

Table II. Logistic regression analysis on the association between the need for refinement and the number of aligners in the initial course and treatment indication

Variables	*Odds ratio*	*95% CI*	P *value*
Refinement			
Initial No. of aligners (per unit)	1.05	0.94-1.18	0.36
Indications			
Finishing	Reference		
Relapse	1.06	0.22-5.18	0.94
Comprehensive treatment	7.08	0.71-70.19	0.10

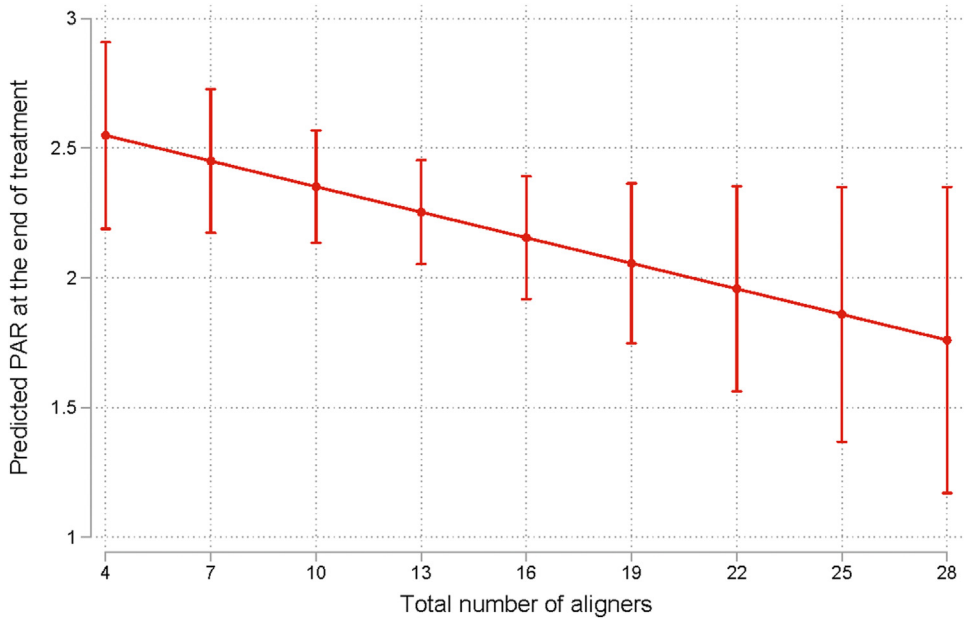

Fig 3. Association between number of aligners and PAR score.

Table III. Linear regression analysis on the association between the final PAR score (PAR 2) and the number of aligners in the initial course adjusted for PAR score at baseline (PAR 1)

PAR 2	*Coefficient*	*95% CI*	P *value*
Initial No. aligners (per unit)	−0.03	−0.07 to 0.003	0.07
PAR 1	0.12	0.094-0.1445	<0.001

Tera Harz TC-85 can be printed from any 3D resin printer, either using digital light processing or stereolithography.[14] This material has physical properties with significant differences in elastic modulus, ultimate tensile strength, and stress relaxation when compared with thermoformed materials in in vitro testing.[18] Moreover, DPAs appear to be more susceptible to moisture in a simulated oral environment, impairing delivery of force levels and impacting their ability to generate and maintain sufficient force levels for optimum and predictable tooth movement.[18,19] Claims regarding the presence and impact of superelastic behavior have also been made.[20] However, superelastic behavior exhibited by Tera Harz TC-85 has been demonstrated at higher temperatures, whereas high levels of stiffness were observed at intraoral temperatures with vulnerability to stress relaxation and significant force decay exposed over 7 days.[18,19] These unfavorable material properties may offset any potential benefit associated with enhanced goodness-of-fit of DPAs and may have contributed to their preferred applications in less complex scenarios (eg, during finishing and after a relapse), which is reflected in this study.

In a recent study involving rectangular sheets of Tera Harz TC-85, lower and more physiological flexural

strength and bending were observed with DPAs compared with 3 thermoformed materials (A Pro [Angel Align Technology Inc, China], Zendura A [Zendura Dental, Fremont, Calif], and Zendura FLX [Zendura Dental, Fremont, Calif]).[21] On the basis of differential scanning calorimetry, Atta et al[21] identified a glass transition temperature (T_g) of 42.3°C within the oral temperature range (30°C-45°C) with shape recovery of 86.1% after 10 minutes. Thermoformed materials exhibited recovery by as little as 1.5%-2.9% over this same period.[21] Using an alternative technique (dynamic mechanical analysis), a high glass transition temperature of up to 69.5°C has been shown with Tera Harz TC-85.[15] This discrepancy may relate to the evaluation of T_g at the midpoint of the second heating cycle in the study showing a more favorable behavior, whereas the midpoint during the cooling cycle was 97.5°C.[21] As such, further in vitro evaluations of the superelastic behavior as applied to its clinical relevance are required.

It is also noteworthy that although aligner change at 7 days is now commonplace, there remains uncertainty regarding the blanket prescription of 7-day changes.[22] A recent prospective study using thermoformed aligners demonstrated a 12% reduction in predictability associated with 7-day when compared with 14-day protocols.[22] The decline in mechanical properties and susceptibility over time to increased surface porosity associated with DPAs may be problematic.[23] In addition to the impairment of mechanical properties, porosities may predispose to increased bacterial adhesion, colonization, and biofilm formation with DPAs. Further refinement and associated clinical research are needed as increased porosity may also contribute to adverse soft tissue reactions, although few side effects were observed in this study. Three different patients reported moderate burning sensations, and 2 of these patients also experienced minor tissue reactions. This low amount of side effects likely reflect the strict adherence to the manufacturer's postprocessing guidelines as inadequate and partial cure of the resin are well-documented risks both in relation to thermoformed aligners and orthodontic retainers.[24] Inadequate or incomplete curing of the resin could pose an increased risk of side effects. Further studies are needed to improve the understanding of side effects. In vitro research involving Tera Harz TC-85 has highlighted the remaining eluents of urethane dimethacrylate, although samples were found to be free of bisphenol-A.[25] Although this study involved an experienced user of the system, strict adherence to recommended protocols, particularly with in-office fabrication of DPAs, remains of paramount importance.[26]

The use of thermoformed aligners has increased exponentially in recent years, although they are generally ~~r~~egarded as inferior to fixed appliances among specialist providers.[27] This impression may relate to a perceived inability to produce a moment-to-force ratio to predictably manage significant rotations, translation, and buccolingual torque. Because of their recent homologation, clinical research regarding the clinical efficacy of DPAs is lacking. This preliminary study demonstrates that the DPAs are efficient in correcting simple to moderate malocclusion within a reasonable timeframe. It is important to note, however, that the present evaluation was retrospective and confined to a single experienced operator. Moreover, a single software system (Onyxceph) was used. Further prospective research, ideally involving comparison with conventional thermoformed materials, would be beneficial to further clarify the relative merits of this novel approach.

The PAR index was used as it is a widely accepted index for the assessments of malocclusions and their correction regardless of the method used. DPA are orthodontic devices aimed at predictably correcting malocclusions, and the PAR index offers the capacity to objectively quantify the potential reduction in malocclusion. It has been shown to be reproducible and highly accurate. In this study, we did not use a control group as the objective was not to compare the efficacy of the DPA over thermoformed aligners but rather to determine the amount of reduction in the PAR index over time using DPAs.

Further prospective studies comparing the efficacy of printed aligners over thermoformed or even fixed orthodontic appliances would be a welcome addition. This retrospective study was designed to demonstrate the ability of direct aligners to reduce the PAR index significantly.

CONCLUSIONS

On the basis of this preliminary retrospective evaluation involving a single, experienced operator, DPAs may have a role in managing moderate malocclusions based on the PAR score reduction obtained. The need for refinement was unrelated to the total number of aligners used, whereas there was a weak negative association between the final PAR score and the number of aligners. Additional prospective research is needed to draw more meaningful conclusions and to compare the relative merits of DPAs to alternative appliances.

AUTHOR CREDIT STATEMENT

Vanessa Knode contributed to methodology and formal analysis; Björn Ludwig contributed to conceptualization, methodology, and formal analysis; Jean-Marc Retrouvey contributed to conceptualization and methodology; Nikolaos Pandis contributed to methodology and formal analysis; Jonas Q. Schmid contributed to

methodology and formal analysis; Christina Erbe contributed to conceptualization, and Padhraig Fleming contributed to methodology, formal analysis, and original draft preparation.

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