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Journal of Contemporary Orthodontics

Journal homepage: https://www.jco-ios.org/

Review Article

Shape memory resin for direct printed aligners: A scoping review

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ARTICLE INFO

Article history:
Received 13-04-2024
Accepted 02-07-2024
Available online 02-11-2024

Keywords:
3D printing
Direct printed aligner
Resin
Mechanical properties
Cytotoxicity
Accuracy

ABSTRACT

Aim: This review aims at analyzing the literature available regarding the properties of the novel Tera Harz resin introduced to manufacture direct printed aligners in terms of its mechanical characteristics, accuracy, and cytotoxicity.

Materials and Methods: Utilizing the databases of PubMed, Scopus, and the Cochrane Library, a search for publications published up until February 2024 was conducted by applying the search phrases ("3D printed" OR "three-dimensional printed") AND aligner AND (polymer* OR material* OR resin* OR technopolymer*).

Results: There were 620 records found in the first search. 220 studies were reviewed after duplicates were eliminated. A total of 196 complete texts were screened based on the title and abstract. 90 full-text papers had their eligibility evaluated. The qualitative synthesis contained 16 studies.

Conclusion: With its ideal characteristics, the new shape memory resin has the potential to be a viable replacement for thermoformed aligners, offering greater accuracy and force delivery. The gathered data is still only somewhat reliable and quantitatively scarce. It is necessary to do more research to assess the therapeutic efficacy of these new materials.

1. Introduction

In the past few years, the increased demands of esthetics and the innovation of aligners have caused an upheaval in the field of orthodontics and helped revolutionize this field. With the advantage of being invisible, their increasing popularity has led researchers to contribute more to aid in the development and further improve upon their shortcomings to ensure a seamless workflow. The history of aligners can be traced back to Kesling[1], who, in 1945, described a tooth positioner for the final artistic positioning of the teeth as well as an effective retaining device. Nahoum[2], in 1964 developed vacuum-formed “dental contour” thermoplastic appliances for dental use. He developed the concept of using successive appliances, with small incremental changes, to obtain major corrections that have formed the basis of the construction of the popular Essix appliance and Invisalign.

Direct-printed models have been in use for a long time in dentistry. Now, with the advancements in 3D printing technology, the focus has shifted to the direct printing of aligners, to reduce costs and improve accuracy. This technology has stemmed from the need to overcome the inherent errors that can occur during the various steps involved in the thermoforming process of aligner fabrication.

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https://doi.org/10.18231/j.jco.2024.062

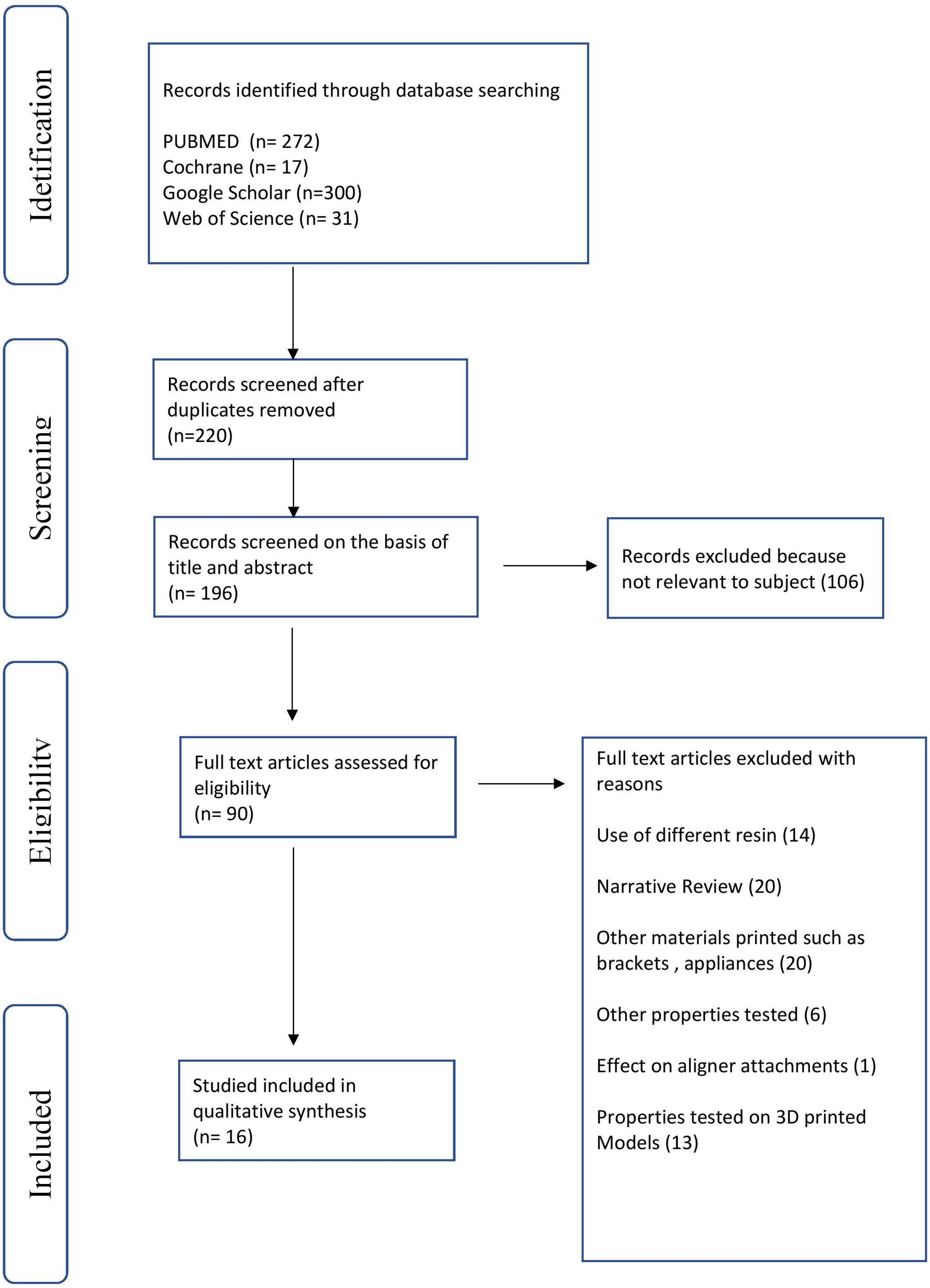

Figure 1: Flow diagram of the included studies according to the PRISMA

Table 1: Details of included studies

S. NO.	Authors	Year	Study design	Material used	Sample size	Properties tested	Limitations
1.	Esad Can et al[3]	2021	In vivo	Tera Harz TC-85DAW resin, Graphy	16	To investigate alterations in the mechanical properties of in-house three-dimensional printed orthodontic aligners after intraoral ageing.	Further investigation required in printing conditions, type of printer, and methods
2.	Spiros Zinelis et al[4]	2021	In vitro	Tera Harz TC-85DAW resin, Graphy	35	To compare the mechanical properties of orthodontic aligners among different commercially available 3D printing devices.	Time-dependent properties of materials in hand may be more indicative for their clinical efficacy
3.	Nickolas Koenig et al[5]	2022	In vitro	Tera Harz TC-85DAW resin, Graphy Zendura FLX Essix ACE	36	To evaluate and compare the dimensional accuracy between thermoformed and direct-printed aligners.	Scanning spray added significant error to the dimensions of the aligner's intaglio. The translucent nature of clear aligners presents a challenge for capturing their inner surface with an optical scanner Two different scanners were used to scan the samples The different thickness used for thermoforming material (0.75 mm) compared to the thickness used for the direct-printed aligners (0.50 mm) Small sample size
4.	Evan Hertan et al[6]	2022	In vitro	Tera Harz TC-85DAW resin, Graphy Polyethylene terephthalate glycol	6	To measure the forces delivered by direct-printed aligners (DPA) in the vertical dimension and compare the force profile with traditional thermoformed aligners (TFA) and to investigate the impact of non-engaged surface patterns to the properties of DPA and TFA.	Lack of PDL in the experimental teeth; thus, the force generated may be of higher magnitude Furthermore, when the aligner is compressed onto the teeth clinically, there may be over-compression followed by a release.

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Table 1 continued

5.	Harris Pratsinis et al[7]	2022	In vitro	Tera Harz TC-85DAW resin, Graphy	20	To investigate the cytotoxicity and estrogenicity of a 3D-printed orthodontic aligner	In vitro study ; cannot take into account factors such as salivary enzymatic reactions, chewing forces, dietary chemical effects, thermal changes, or effects of oral microbiota. The frequent (7-10 days) renewal of aligners reinstitutes the source of elution in the oral cavity. that cannot be modeled in biocompatibility assays. in vitro assays underestimate the effect of environmental factors on the degradation potential of polymers.
6.	Se Yeon Lee et al[8]	2022	In vitro	Tera Harz TC-85DAW resin, Graphy	Not mentioned	To investigate the thermo- mechanical and viscoelastic properties	Not mentioned
7.	Despina Koletsi et al[9]	2022	In vivo	Tera Harz TC-85DAW resin, Graphy Polyurethane-based polymer	24	To assess the surface roughness of in-house 3D-printed orthodontic aligners compared to Invisalign appliances,	Uniformity of material properties of printed aligners fabricated through different 3D-printers has been questioned; this might also bear an impact on the surface characterisation of the materials. variabilities in the manufacturing technology, the printing process and apposition of resin layers, the resin layer depth, the depth of cure, the post-curing process are risk factors that may compromise accuracy of the fabrication process and consequently result in end-products of non-comparable surface properties

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Table 1 continued

8.	Se Yeon Park et al[10]	2023	In vitro	Tera Harz TC-85DAW resin, Graphy	40	To compare the thickness, gap width, and translucency of 3D-printed and thermoformed clear aligners using micro-computed tomography (micro-CT)	Differences in thickness and gap width when CAs are activated in various degrees of malocclusion have not been assessed. Further studies are required to evaluate physical properties and clinical performance for applications at 37°C temperature and at high relative humidity, in conditions similar to the oral cavity.
9.	James Grant et al[11]	2023	In vitro	Tera Harz TC-85DAW resin, Graphy	50	To measure the forces and moments exerted by direct printed aligners with varying facial and lingual aligner surface thicknesses, in all three planes of space, during lingual movement of a maxillary central incisor.	Study did not account for the natural space and elastic behavior of periodontal ligaments the study did not simulate the effects of masticatory occlusal forces or the impact of saliva on the performance of clear aligners.
10.	Abraham McKay et al[12]	2023	In vitro	Tera Harz TC-85DAW resin, Graphy ATMOS Zendura FLX	90. (30 ALIGNERS OF EACH TYPE) : ZENDURA, 3D PRINTED; ATMOS	To assess the possibility of extrusion of a maxillary central incisor with the use of buccal and lingual pressure columns in the absence of attachments, and to evaluate the forces and moments experienced by the teeth using both thermoformed and 3D-printed clear aligners.	Lack of simulated saliva, periodontal ligaments, and masticatory forces. This study investigated only single amount of tooth movement; the force systems produced by smaller or larger increments may differ.
11.	Andreas Willi et al[13]	2023	In vitro	Tera Harz TC-85DAW resin, Graphy	10	To quantitatively assess the degree of conversion and the water-leaching targeted compound from 3D-printed aligners.	

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Table 1 continued

12.	Mélanie Mattle et al[14]	2024	In vitro	Tera Harz TC-85DAW resin, Graphy	80 Forty dumbbell-shaped specimens and 40 resin aligners	to evaluate the mechanical properties of resin-made 3D-printed aligners and assess the effect of two different post-curing conditions.	A vast array of different resins are used today for this purpose, and the effect of tested parameters could differ substantially among different materials.
13.	Lukas Camenisch et al[15]	2024	In vitro	Tera Harz TC-85DAW resin, Graphy	20	To assess differences in the fundamental mechanical properties of resin-made three-dimensional (3D) printed orthodontic aligners according to the printing orientation.	Future research that includes structural and chemical characterization of 3D-printed components under various conditions and configurations (including different postcuring processes) may shed further light on this.
14.	Islam Atta et al[16]	2024	In vitro	Tera Harz TC-85DAW resin, Graphy CA Pro Zendura A Zendura FLX	72 (18 PER GROUP : CA® Pro (CP) Zendura ATM (ZA) Zendura FLXTM (ZF) Tera Harz TC- 851 (TC-85))	To conduct a physiochemical and mechanical material analysis on 3D printed shape-memory aligners in comparison to thermoformed aligners.	It did not account for the potential influence of oral aging conditions on the physiochemical and mechanical characteristics of the examined materials. The geometric configuration of the test specimens, being rectangular, is different from the actual shape of clinical aligners, Additional experimental studies and clinical trials are essential for a comprehensive assessment of the performance and long-term implications associated with clear aligners fabricated using shape memory polymers and 3D printing resin.
15.	Babak Sayahpour et al[17]	2024	In vivo	Tera Harz TC-85DAW resin, Graphy polyethylene glycol terephthalate polyurethane-based polymer	30 (10 per group)	To examine the impact of intraoral aging on the mechanical properties of directly printed aligners (DPA) compared to thermoformed aligners (TA).	

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Table 1 continued

16.	Sara Eslami et al[18]	2024	In vivo	Tera Harz TC-85DAW resin, Graphy polyurethane-based polymer	136. (34 ALIGNERS PER GROUP : DP-Clin consisted of DPAs retrieved after 1 week of intraoral ser- vice (DP-Clin), (2) Invisalign aligners after 1 week of in-traoral use (INV-Clin), (3) control for DP-Clin (DP-Ctr), and (4) control for INV-Clin (INV-Ctr).	To investigate the effects of 1 week of intraoral usage on the surface roughness parameters of directly printed aligners (DPAs) and commercially produced Invisalign aligners compared with their unused control counterparts using confocal laser scanning microscopy.	High rate of dropout in the DP-Clin group The in-house production lacks the standardization and efficiency of larger-scale outsourcing production methods.

The whole fabrication process is prone to many errors apart from other disadvantages like wastage of material, excessive costs, and time consumption. In addition, geometric inaccuracies are also induced during the thermoforming process.[19–21]

Other advantages include the ability for the orthodontist to have a completely digital workflow, reduce dependency on labs, reduce production costs, and enhance practice efficiency, overall patient experience, and satisfaction with better results: the ultimate aim of every orthodontist. 3D printing the aligner not only reduces time and effort, but also results in fewer geometric inaccuracies The accuracy, fit, and clinical feasibility of direct 3D printed clear aligners have been evaluated in several studies.[22,23]

Tera Harz is a 3D printable biocompatible material produced by the company Graphy, Korea, that was approved by the Korea Food and Drug Administration (KFDA) and the European Commission (EC). The mechanical properties and behavior of this cross-linked polymer are expected to be different compared with conventional thermoplastic materials composed of non-cross-linked polymers used for thermoforming.[24]

The unique property of this resin is its ability to display shape memory which enables it to perform better compared to others since lighter forces are applied to the dentition, owing to its flexibility and viscoelastic properties.[25]

2. Materials and Methods

2.1. Literature search

"What is the scientific evidence currently available on the mechanical properties, cytotoxicity, and accuracy of the new shape-memory resin for direct printed aligners?" served as the basis for the literature review. The experiments that addressed the characteristics of the recently developed shape memory resin material, TC -85, were the main focus of the search.

The following databases were used in the article search process: Pubmed, Cochrane Library, Google Scholar, and Web of Science. Publications with no language limitations through February 2024 were included in the literary search.

Studies with the following keywords were found: ("3D printed" OR "three-dimensional printed") AND aligner AND (polymer* OR material* OR resin* OR technopolymer*)

All titles identified from the literature were screened and selected by one author (R.S.) Duplicate studies were eliminated. The abstracts were examined, and full texts were obtained if additional data were needed to fulfill the eligibility criteria. When appropriate, studies were excluded for reasons. Conflicts were resolved by discussion with the second and third authors (A.K., V.M.)

2.2. Eligibility criteria

Owing to the topic's uniqueness, in-vitro investigations, case reports, and case series were also taken into consideration for the qualitative analysis. Conversely, poor-quality reviews, editorials, conference abstracts, and prospective research were not included. Every article received consideration till February 2024.

2.3. Data extraction

Following an initial screening of all relevant papers based on abstract and title, full texts of those articles were acquired. One author (R.S.) independently extracted the features of the included studies following a full-text examination. Figure 1 summarizes the flow chart used to choose the studies that were eligible for this review.

3. Results

The initial search identified 272 records for PUBMED, 7 for Cochrane Library, 300 for Google Scholar, and 31 for Web of Science.

620 records. After removing duplicates, 220 studies were screened. Based on the title and abstract, 196 full texts were screened. 90 Full-text articles were assessed for eligibility. Finally, 16 studies were identified according to the eligibility criteria to be included in the review.

The characteristics of the studies are presented in Table 1. Of the 17 included studies, 4 articles analyzed the in-vivo properties of 3D printed aligners with SMPs, while the rest were in vitro studies.

4. Discussion

New direct printed aligner technology has been created to address the issues with traditional thermoformed aligners in response to the growing acceptance and use of 3D printing technology in the manufacturing of models. These days, a variety of polymers are utilized to make aligners. Among them is TC-85 Tera Harz resin, which possesses a special shape memory characteristic.

Several studies have been carried out to assess various features after using an intraoral aligner for a week. After using the in-house 3D-printed aligners for a week, Can et al.[3] observed no changes in their mechanical properties. Nevertheless, a single kind of printer was used to create the aligners. This is insufficient to completely describe the entire spectrum of 3D printing techniques, including material jetting, extrusion, digital light processing, and stereolithography. Many other factors, such the type of printer, printing conditions, and methods to ensure print quality control, also need to be further investigated.

Using optical profilometry, Koletsi et al.[9] evaluated the surface roughness following a week of Invisalign use. The observed increase in roughness metrics following the testing of 3D-printed aligners while they were "in-service" suggests that the appliances' material integrity and inbred traits have been exposed to intraoral and real-world clinical settings.

Surface roughness characteristics of "in-house" manufactured aligners saw significant and severe modifications at all levels due to intraoral exposure and function. After one week of intraoral use, surface roughness is inevitably changed, which may facilitate plaque buildup and biofilm adhesion.[26] It is yet unknown how using these appliances during an orthodontic treatment course may affect clinical effectiveness and safety. Furthermore, it has been questioned if the material qualities of printed aligners made with various 3D printers are uniform; this could affect how the materials' surfaces are characterized.

Using confocal laser scanning microscopy, Eslami et al.[18] examined the impact of a week-long intraoral usage on the surface roughness of Invisalign and directly printed aligners (DPAs) in comparison to their unused control counterparts.

According to this research, after one week of intraoral use, DPAs' surface roughness and porosity increased, which may have increased bacterial adherence and biofilm formation in these aligners. One important aspect influencing the development of plaque, the adhesion of biofilms, the loss of transparency, and the discoloration of aligners is the surface roughness of the aligners.[26]

The study by Koenig et al.[5] showed that direct-printed aligners were more accurate than thermoformed aligners. The small sample size and the use of scanning spray, which significantly increased inaccuracy in the aligner's intaglio dimensions, were among the study's few shortcomings.

Se Yeon Park[10] used Micro CT to compare the thickness, gap width, and translucency of 3D-printed and thermoformed clear aligners. For 3D-printed CAs, the thickness increased during the fabrication process, and different thickness values were observed for each tooth type and location. However, this was an in vitro study, and only the thickness and gap width of passive-state CAs in a normal occlusion model were evaluated, not in various degrees of malocclusion.

Many studies have been conducted to assess the mechanical properties of these aligners.[4,8,15,16]

After comparing the mechanical characteristics of orthodontic aligners made with various commercially available 3D printing devices, Zinelis et al.[4] concluded that the mechanical characteristics of 3D-printed orthodontic aligners vary depending on the 3D printer used, which could lead to variations in their clinical efficacy. While both DLP and LCD cure the entire resin layer at once, these variations in mechanical qualities could be attributed to the various technologies utilized to flash light on the resin layer as a whole.

To assess their mechanical and viscoelastic properties in response to temperature, Se Yeon Lee et al.[8] used dynamic mechanical analysis (DMA) and static mechanical testing. Furthermore, an investigation was conducted into the shape memory feature of the photocurable resin (TC-85).

Lukas Camenisch et al[15] assessed the differences in the fundamental mechanical properties of resin-made three-dimensional (3D) printed orthodontic aligners according to the printing orientation. There were no discernible variations between the aligners or specimens produced in a vertical or horizontal orientation. The clinical implications of these results are that clinicians might consider 3D-printed aligners to be an isotropic material and, thus, a similar mechanical reaction might be anticipated intraorally under multidimensional activation.

Islam Atta et al.[16] compared the direct printed and thermoformed aligners and found that TC-85 demonstrates exceptional shape memory at oral temperature, improving adaptation, reducing force decay, and enabling, together with its higher flexibility, extensive tooth movement per step. Additionally, it maintains microhardness similar to thermoformed sheets, ensuring the durability and effectiveness of dental aligners. However, further studies are necessary to explore additional characteristics using full anatomical aligners and across diverse testing conditions. For a thorough evaluation of the effectiveness and long-term consequences related to clear aligners made with shape memory polymers and 3D printing resin, more experimental research and clinical trials are also necessary.

Mattle et al.[14] examined the mechanical characteristics of 3D-printed aligners made of resin and investigated the impact of different post-curing scenarios. They concluded that neither heat treatment nor post-curing in an N2 environment significantly changed the mechanical properties of 3D-printed resin aligners.

These aligners' cytotoxicity has also been evaluated. If any substances were released during the 14-day aging of 3D-printed aligners in water, Prastnis et al.'s[7] investigation found that they had no effect on the intracellular reactive oxygen species levels of human gingival fibroblasts and were not cytotoxic. Furthermore, an E-screen assay revealed that these potential eluates had no estrogenic effects. However because this was an in vitro study, it could not account for things like salivary enzymatic reactions, chewing pressures, dietary chemical impacts, temperature variations, or the effects of oral microbiota. Instead, it focused only on chemicals produced by the aligners' passive hydrolysis.

Since the continual insertion of new aligners in the oral cavity restores the source of elution in the oral cavity, the frequent (7–10 day) renewal of aligners introduces a variable that cannot be represented in biocompatibility studies.

A second set of research has been carried out to evaluate the force profile and force delivery quantity when utilizing these aligners. To compare the force profile of direct-printed aligners (DPA) with standard thermoformed aligners (TFA), Evan Hertan et al.[6] assessed the forces supplied by DPA in the vertical dimension. They concluded that the force profile provided by DPA was noticeably less than those shown by TFA.

James Grant et al.[11] examined the pressures and moments applied by direct printed aligners (DPAs) with varying lingual and facial aligner surface thicknesses during the lingual movement of the maxillary central incisor in all three spatial planes. Abraham McKay et al.[12] measured the stresses and moments felt by the teeth using thermoformed and 3D-printed transparent aligners. They also looked at the likelihood of a maxillary central incisor extruding in the absence of attachments using buccal and lingual pressure columns. They found that the force levels created during extrusion with transparent aligners with those 3D printed using TC-85 were significantly lower than those thermoformed using ATMOS or Zendura FLX.

However, being in vitro studies, they did not account for the natural space and elastic behavior of periodontal ligament. The study also did not simulate the effects of masticatory occlusal forces or the impact of saliva on the performance of clear aligners.

5. Conclusion

Advancement in orthodontic materials is influencing clinical practice. The search for efficient polymers and cost-effective techniques to reduce treatment time and patient compliance is making significant progress. It is expected that 3D printing technology will experience widespread use in everyday clinical practice in the near future

Several investigations have been performed to evaluate the various properties of this aligner material. However, the collected evidence remains quantitatively scarce and of limited reliability. The review of the literature reveals that the new Tera Harz resin has optimum properties that can enable it to be a promising alternative for thermoformed aligners, with better performance in terms of force delivery and more accuracy. However, most of the studies that have been conducted so far are in vitro and do not accurately simulate the intraoral environment.

There is also some clarity needed regarding the mechanical properties being dependent on the type of printer used and whether this has mechanical implications on the biomechanics of tooth movement in vivo as well.

The need of the hour is to further investigate the properties such as accuracy, cytotoxicity, and mechanical properties of this resin to assess the efficiency of these polymers compared to conventional orthodontic materials.

6. Source of Funding

None.

7. Conflict of Interest

None.

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Cite this article: Sobti R, Kanase A, Misra V. Shape memory resin for direct printed aligners: A scoping review. *J Contemp Orthod* 2024;8(4):404-414.