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Time-Dependent Changes in the Mechanical Properties of Directly Printed Tera Harz TC-85 DAC (Direct Aligner Clear) After Manufacturing

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Abstract

Objectives: To investigate the time-dependent changes in flexural strength, tensile strength, and surface hardness of Tera Harz TC-85 DAC (Direct Aligner Clear) aligners after manufacturing.

Methods: The aligner specimens were fabricated using a 3D printer and tested for flexural strength, tensile strength, and surface hardness on days 1, 7, 14, 21, 30, and 60 after production. The flexural strength and tensile strength were tested by a universal testing machine, while the surface hardness was measured using a Shore type D durometer for the specimen surface hardness. Data were recorded and analyzed to determine changes in these mechanical properties for 60 days of room-temperature storage after manufacturing.

Results: Changes in the mechanical properties were observed over time. Compared to day 1, the mean tensile strength significantly decreased from day 7 to day 60 ($p < 0.05$), while the mean flexural strength significantly decreased from day 7 to day 30 ($p < 0.05$) with a significant increase in the mean flexural strength on day 60, compared to day 30 ($p < 0.05$). The mean surface hardness also significantly declined on day 21 ($p < 0.05$) with a gradual rise until day 60.

Conclusions: In general, the three mechanical properties of directly printed clear aligners decreased 7 days after manufacturing. However, these mechanical properties remained stable until day 60. Further studies are required to evaluate long-term stability of the aligners under various clinical conditions.

Keywords: 3D printing, clear aligner, flexural strength, tensile strength, surface hardness

Introduction

Up to the present, the demand for clear aligners in orthodontic tooth movement has been continuously increasing because they offer aesthetics, while still meeting the requirement of orthodontic treatment throughout the whole intervention. Additionally, use of clear aligners is not only effective in correcting malocclusions but also offers some advantages, such as shorter treatment times and less frequent dental visits, thus making the aligners ideal for patients who have time constraints. The aligner is highly aesthetic, enhances one's appearance, allows easy eating without interfering with chewing, and promotes good oral hygiene during the treatment. However, there are some limitations for clear aligners in correcting certain types of malocclusions.⁽¹⁾ Nowadays, thermoforming materials are usually used in producing clear aligners, which involves making a dental model as a mold.

Recently, a new resin material (Tera Harz TC-85) has been developed for production of clear aligners using direct printing. This material has the unique property of shape memory, which means its shape can be changed when exposed to heat but resumes its original form once the temperature decreases. This property helps to better control tooth movement and reduces pain and discomfort during insertion or removal of the aligners.⁽²⁾ A distinctive feature of clear aligner treatment is that all aligners are simultaneously manufactured at the beginning of the treatment and are worn in sequence.⁽³⁾ The TC-85 clear aligner is considered to be the first aligner to be directly printed using a three-dimensional (3D) printer. Moreover, it shows significantly better outcomes than the traditional thermoforming aligner materials.⁽⁴⁾ The TC-85 was developed to overcome some limitations of the thermoforming aligner materials currently available. The TC-85 material provides several benefits that include improvement of treatment effectiveness, patient comfort during wear, and a reduction in discomfort while inserting or removing the TC-85 aligner.

Additionally, the TC-85 material is durable, highly flexible, and easy to produce with minimal trimming. During the initial phase, TC-85 is stiff but it regains its original shape once placed in the mouth. Furthermore, the TC-85 allows a better control of tooth movement than thermoforming aligners and ensures its uniform thickness at every time point. The specific feature of treatment with clear aligners is the aligners are all produced at the same

time from the first to the last pairs at the beginning of orthodontic treatment, which are then worn in sequence.⁽³⁾ Clear aligners possess the property of maintaining their shape without many changes over time. Accordingly, it is necessary to study time-dependent changes of aligner specimens that are concomitantly produced, since time differences between their production and use could affect the mechanical properties of the TC-85 material. Therefore, the objective of this study was to investigate the flexural strength, tensile strength, and surface hardness of directly printed clear aligner specimens up to 60 days after production. The material used in this investigation was TC-85 DAC (Direct Aligner Clear), which was developed specifically for dental applications.

Materials and Methods

Sample size calculation

The sample size was determined using G*Power 3.1. Based on power analysis, the initial requirement of 4 specimens per group was increased by 25% to 5 specimens to enhance statistical power.⁽⁴⁾ For three mechanical tests (tensile, flexural, and hardness) across 6-time intervals, a total of 90 specimens were fabricated and tested.

Specimen fabrication and post-processing

The specimens were directly printed by a 3D printer using TC-85 DAC (Graphy Inc., Seoul, Korea) and designed by the SketchUp 2017 program version 17.2.2555 (Trimble Inc., Sunnyvale, CA, USA). The fabrication and post-processing procedures were standardized as follows:

- Specimen fabrication: The specimens were fabricated using a high-speed LCD-based 3D printer (NBEE, UNIZ, San Diego, CA, USA) with UNIZ Dental software. The specimens were printed using with TC-85 DAC resin at a layer thickness of 100 μm , and a total fabrication time of approximately 12 minutes.
- Post-printing and cleaning step: After printing, the specimens were washed in 90% isopropyl alcohol for 5 minutes to remove residual uncured monomer from the surface. Excess resin was subsequently removed using a centrifugation process at 400 rpm for 6 minutes.
- Post-curing step: To ensure maximum polymer conversion and mechanical stability, the specimens were post-cured using a UV post-curing machine equipped with a nitrogen-generator (Tera Harz Cure, Graphy Inc., Seoul, Korea) for 20 minutes.

- **Finishing:** After post-curing, the support structures were removed, and the specimens were polished and finished to the final dimensions.

All specimens were stored in light-tight and airtight containers at room temperature until testing.

A total of 90 specimens in three different sizes were fabricated according to the International Organization for Standardization (ISO) for particular shapes and dimensions. The specimens used for testing the tensile strength were formed into a dumbbell shape with dimensions of 5 mm (narrow section width) x 30 mm (gauge length) x 2 mm (thickness) that followed the ISO 527 standard. The specimen dimensions used for testing the flexural test were 10x80x4 mm, according to ISO 178, while those used for testing the surface hardness were 12x12x6 mm that conformed to the American Society for Testing and Materials (ASTM) D2240 standard (Figure 1).

Tensile strength testing

The testing was performed in accordance with the ASTM D638 standard using a universal testing machine (Instron®, Norwood, MA, USA) at a crosshead speed of 5 mm/min and a gauge length of 30 mm (Figure 1). The specimens were secured between the upper and lower grips, and the upper grip applied a tensile load until specimen failure. Load and elongation were recorded continuously to generate a load–displacement curve (N/mm²).

Flexural strength testing

The testing was performed using a universal testing machine in accordance with the standard three-point bending methodology (ISO 178/ASTM D790). Each specimen was positioned on two supporting pins with a 40-mm space apart. The crosshead speed was maintained at 2 mm/min, and a centrally placed loading pin applied a downward force until a maximum midspan deflection of 20 mm was achieved (Figure 1). The apparatus continuously recorded the applied load and displacement that produced a load–displacement curve (megapascal; MPa).

Surface hardness testing

The surface hardness was assessed using a Shore durometer (Bareiss®, Bareiss North America Inc, Ontario, Canada). The durometer was adjusted so that the indenter tip was positioned 10 mm above the specimen surface before testing (Figure 1). Measurement commenced im-

mediately upon pressing the device onto the specimen, during which the display flashed to indicate data acquisition. An audible signal confirmed the completion of each measurement. Each specimen was tested at three different points, and the mean hardness value was calculated for analysis.

All three mechanical tests were performed on days 1, 7, 14, 21, 30, and 60 following specimen fabrication (n=5 for each time point and test), and all results were recorded on standardized data collection forms.

Statistical analysis

Data are expressed as mean±standard deviation (SD; n=5). Normality and homogeneity of variance were verified using Shapiro-Wilk and Levene's tests, respectively. Differences were analyzed by one-way ANOVA, followed by Tukey's or Games-Howell post-hoc tests depending on variance equality. Statistical significance was set at $p<0.05$.

Results

The tensile strength decreased from day 1 to day 21 and then slightly increased up to day 60 (Figure 2). The average tensile strength was reported at 16.32 N/mm² with the highest value of 21.93 N/mm² on day 1 and the lowest value of 13.324 N/mm² on day 30. The mean tensile strength value on day 1 was found to be significantly greater than on days 7, 14, 21, 30, and 60 ($p<0.05$).

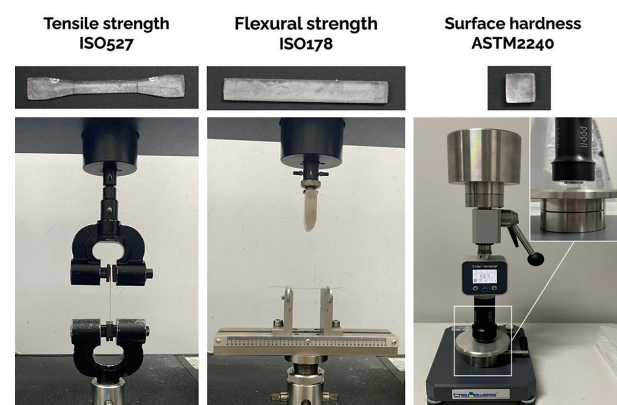


Figure 1: Three sizes of specimens were employed. (Left) Tensile strength specimens were formed into a dumbbell shape with dimensions of 5 mm (narrow section width) x 30 mm (gauge length) x 2 mm (thickness) (ISO 527 standard). (Middle) Dimensions of the flexural test specimens were 10x80x4 mm (ISO 178 standard). (Right) The dimensions of the surface hardness specimens were 12x12x6 mm (ASTM D2240 standard).

The flexural strength continuously decreased from day 1 to day 30, followed by an increase on day 60 (Figure 3) with the average flexural strength reported at 14.8987 MPa. The 1-day specimen showed the highest mean flexural strength at 22.632 MPa, whereas the lowest mean value at 11.242 MPa was observed on day 30. Accordingly, the mean flexural strength value on day 1 was found to be significantly greater than days 7, 14, 21, 30, and 60 ($p<0.05$).

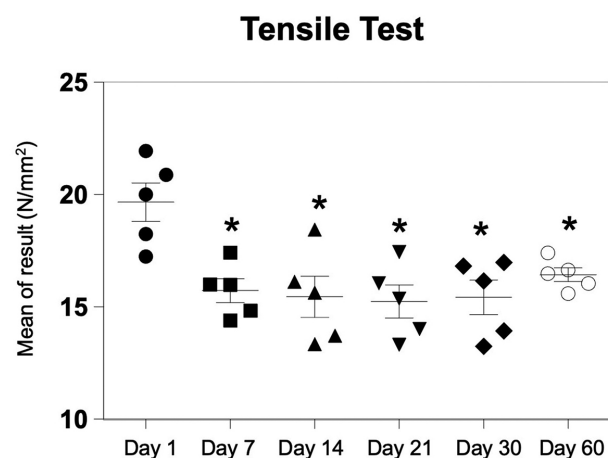


Figure 2: Dot plots illustrate the mean tensile strength values measured on days 1, 7, 14, 21, 30, and 60. Error bars represent the standard deviation ($n=5$). Statistical significance was set at $p<0.05$. *indicates a statistically significant difference compared with day 1, as determined by one-way ANOVA followed by post hoc analysis.

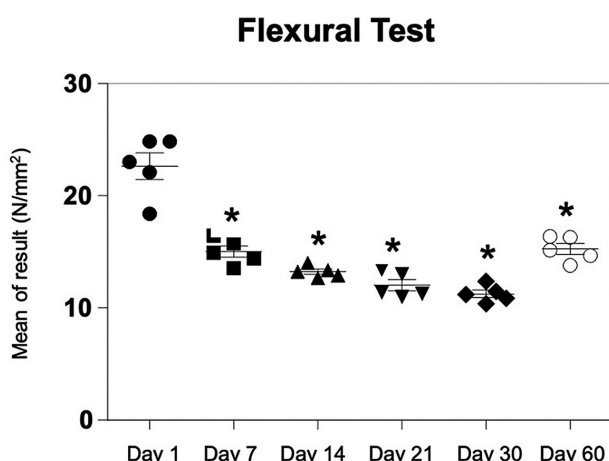


Figure 3: Dot plots illustrate the mean flexural strength values measured on days 1, 7, 14, 21, 30, and 60. Error bars represent the standard deviation ($n=5$). Statistical significance was set at $p<0.05$. *indicates a statistically significant difference compared with day 1, as determined by one-way ANOVA followed by post hoc analysis.

The average surface hardness value was reported at 67.405 with the mean highest value at 69.28 on day 1 and the mean lowest value at 65.41 on day 21 (Figure 4). Significant decreases in the mean surface hardness values of the specimen aligners were found on days 21, 30, and 60 compared to days 1, 7, and 14 ($p<0.05$; Figure 4).

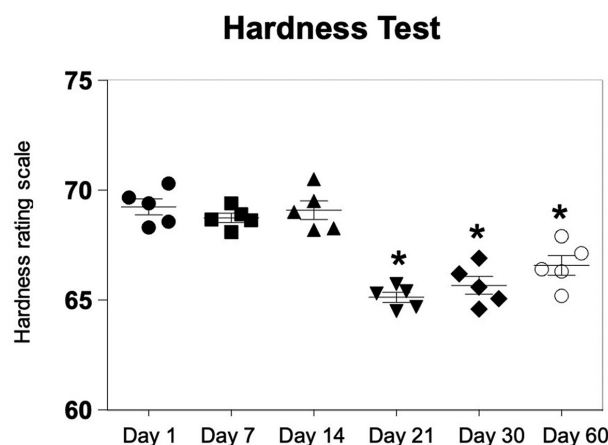


Figure 4: Dot plots illustrate the surface hardness values measured on days 1, 7, 14, 21, 30, and 60. Error bars represent the standard deviation ($n=5$). Statistical significance was set at $p<0.05$. *indicates a statistically significant difference compared with day 1, as determined by one-way ANOVA followed by post hoc analysis.

Discussion

The post-polymerization process in this study was monitored up to 60 days. The tensile strength demonstrated a decline until day 21, followed by a gradual recovery until day 60. The flexural strength decreased until day 30, after which it also increased on day 60. Similarly, the surface hardness declined on day 21 and rose slightly on day 60. These findings suggest that changes in the mechanical properties of directly 3D-printed aligners can be expected to decrease 7 days after manufacturing and remain stable until day 60. However, it is likely that these properties may continue to change beyond the observation period of this study. Moreover, it is important to note that external environmental factors, such as, temperature, humidity, storage conditions, and handling, can significantly influence the mechanical performance of clear aligners.^(6,7)

Our results align with a previous study by Mei *et al.*⁽⁶⁾ They reported that clear aligners exhibited significant reductions in flexural strength and hardness after days 7 and 10, respectively, while the tensile strength showed minor changes after day 21. Those results are

consistent with our findings that revealed progressive mechanical property degradation over time. Haruhisa *et al.*,⁽⁸⁾ referenced the ISO 20795-2 standards, which recommend that base polymers used in orthodontic appliances should have a flexural strength of at least 50 MPa and a flexural modulus of at least 1,300 MPa. However, our findings demonstrated flexural strength values that were below those thresholds, which were potentially due to differences in the materials and manufacturing processes, particularly the use of 3D printing technology that may impact mechanical performance. On the other hand, Siotou *et al.*,⁽⁹⁾ assessed Shore D hardness of aligner materials immediately after production and reported an average value of 61.71, which was slightly lower than the values obtained in our study using direct 3D printing methods. All of these discrepancies suggest that distinct fabrication processes play a critical role in determining material properties. Overall, our findings are consistent with those of a previous report⁽⁷⁾, in terms of the time-dependent changes in mechanical properties, thereby supporting the reliability of our results.

Changes in the mechanical properties of the printed specimens can be attributed to the continuation of the polymerization process even after completion of the curing stage. Photopolymerization can play a role in the process, in which monomers are cross-linked into polymer chains through light activation, which can alter the mechanical properties of the material.⁽¹⁰⁻¹²⁾ A previous study⁽¹³⁾, reported that the strength and dimensional accuracy of printed specimens may be influenced by the post-curing process, as each fabrication cycle may yield different material properties. Kim *et al.*,⁽⁶⁾ confirmed that the level of polymerization did not increase uniformly across the entire cross-section of the specimen, which raised further concerns regarding its effects on the mechanical strength of the material.

According to two studies by Jindal *et al.*,^(14,15) aligners fabricated using 3D printing technology were found to adequately meet the requirements of mechanical properties that make them effective appliances for facilitating tooth movement. In addition, aligners produced through this method can provide a highly accurate shape, which is a crucial factor in appropriately controlling the force and direction of tooth movement.⁽¹⁵⁾ The accuracy of the model used in aligner production is particularly important, as any dimensional inaccuracy may directly affect treatment

efficiency. Furthermore, the manufacturing and post-processing procedures involved in 3D printing require less time and complexity compared to a conventional aligner fabrication method. Therefore, 3D printing presents a clinically and technologically feasible alternative for aligner production.

During clinical use, clear aligners are subjected to complex mechanical forces, including localized stresses during tooth rotation, flexural forces during molar movement, and combined tensile and bending forces in patients with bruxism. TC-85 is a relatively new material for direct 3D-printed clear aligners. Previous research has demonstrated that the mechanical properties of in-house 3D-printed aligners were not significantly affected after one week of intraoral use.⁽¹⁶⁾ However, that study evaluated the appliances following clinical wear, reflecting material behavior under intraoral conditions. In contrast, the present study focused specifically on the assessment of mechanical properties before patient delivery, thereby investigating time-dependent changes occurring during the post-fabrication period rather than after clinical use.

In this study, the findings demonstrated time-dependent changes in mechanical properties, particularly within the first week after fabrication, whereas no further alterations were observed after day 21. However, in clinical practice, delivery of the appliance within one week may not be feasible, which could affect its mechanical properties at the time of patient delivery. Therefore, prolonged storage of the appliances prior to delivery to patients may potentially influence their material properties. This study provides preliminary data to support its clinical application.

A limitation of this study is the use of standardized test specimens, which do not fully replicate the complex morphology of clinical aligners. Consequently, caution should be exercised when extrapolating these mechanical results directly to clinical behavior, as aligner geometry significantly influences stress distribution and clinical efficacy. However, further investigations are warranted to evaluate long-term changes in the mechanical properties of aligners, in particular, a better understanding of the long-term stability and performance during extended storage is needed.

Conclusions

This study demonstrated that directly 3D-printed

TC-85 DAC aligners exhibited significant time-dependent changes in mechanical properties, likely due to ongoing post-polymerization. However, mechanical performance stabilized after day 21 and remained unchanged through day 60. Given the inherent complexity of 3D-printed materials under external loading, strict control of printing and post-processing parameters is essential to ensure consistent and reliable mechanical performance.

Acknowledgments

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Conflict of Interest

The authors declare no conflict of interest.

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