

De la conception numérique à l'utilisation clinique d'un dispositif orthodontique individualisé

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NANTES UNIVERSITÉ

UNITÉ DE FORMATION ET DE RECHERCHE D'ODONTOLOGIE

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De la conception numérique à l'utilisation clinique d'un dispositif orthodontique individualisé

THÈSE POUR LE DIPLÔME D'ÉTAT DE DOCTEUR EN CHIRURGIE DENTAIRE

Présentée et soutenue publiquement par

SALAMEH Georges

Le 26 octobre 2023 devant le jury ci-dessous

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Docteur de Nantes Université

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Introduction

Orthodontics has undergone a significant transformation in recent years due to the introduction of three-dimensional (3D) printing technology. This technological advancement has enabled various applications^(1–3), and the development of 3D-printed orthodontic devices in dental practices appears to be a promising avenue to explore.

Furthermore, the continuous advancement of design software tools has opened up opportunities for orthodontists to independently engage in the design and production of orthodontic devices within their own practices. This notable transformation promises various improvements in terms of organizational efficiency, logistical optimization, and possibly therapeutic effectiveness.

This article aims to explore the feasibility of a Class 2 correction device designed and 3D-printed through an in vitro study. The primary objective is to evaluate the structural integrity and mechanical properties of this device in a controlled laboratory setting^(4,5) to determine its suitability for potential use in clinical trials. A previous study⁽³⁾ has shown cases of debonding and breakage of such devices. Therefore, this article aims to explore the mechanical optimization of this type of device.

Materials and Methods

Phase 1

The objective of this initial phase was to evaluate the effectiveness of different designs for the base of bonded pieces concerning their adhesion to dental tissues to determine an appropriate interface between the tooth and the final device. For his device⁽³⁾, Thurzo had used a flat base design, and the device exhibited a high detachment rate (4/12); therefore, three designs were tested. The design of the bonded pieces was done using Fusion 360 (Autodesk, San Francisco, USA) and Meshmixer (Autodesk, San Francisco, USA). Thirty pieces were then manufactured using a Form 2 printer (Formlabs, Somerville, USA) with biocompatible Dental LT resin (Formlabs, Somerville, USA). The pieces were then evenly distributed among three groups designated Button, Striped, and Flat, based on their design (Figure 1).



Figure 1: The three designs used: Button, Striped, and Flat (from left to right).

These samples were bonded to teeth embedded in resin cylinders (Ultradent, South Jordan, USA) (Figure 2). To ensure uniformity between the groups, considering the nature of dental samples, dentin was chosen for bonding instead of enamel. Bonding was done using a self-etching primer (iBond Self-etch, Kulzer, Hanau, Germany), a universal adhesive (Scotchbond, 3M ESPE, Saint Paul, USA), and orthodontic adhesive (Transbond XT, 3M ESPE, Saint Paul, USA). In the case of the Button group, another adhesive (Orthoconnect flow, GC Corporation, Tokyo, Japan) was used to bond the printed piece to the button, which was itself attached to the tooth's surface. The same operator was responsible for sample preparation with acid and adhesive. Subsequently, the samples were randomly allocated to different groups for bonding with the 3D-printed pieces. Shear strength tests were performed using a bonding strength testing machine (Ultradent, South Jordan, USA). Each recorded value was measured in pounds, converted to kilograms, and subsequently used for statistical analysis to rank the different designs.



Figure 2: Test Sample for Phase 1, the piece is bonded to dentin.

Statistical Analysis

The statistical analysis procedure involved two successive tests. First, a Shapiro-Wilk test was conducted to assess the normality of the sample distribution. Then, a non-parametric Mann-Whitney test was performed to compare the different groups. In both tests, a significance level of 0.05 was used, and p-values lower than this threshold were considered statistically significant.

Phase 2

The main objective of the second phase of this study was to determine the theoretical rupture resistance of the entire dental device to compare it with existing literature. This comparison aimed to assess the device's suitability for a clinical trial. The device was designed as follows: it consisted of two bonded pieces (see phase 1) connected by a lever arm. The devices were designed using Fusion 360 software (Figure 3).



Figure 3: The Class 2 correction device, with the joint on the posterior part (Fusion 360)

The devices were then 3D-printed using the same biocompatible Dental LT resin. The attachment system chosen for the device was the Button base from step 1. Adjustments to the printed pieces with a polishing disc were made to remove the printing supports and ensure a precise fit of the arm inside the molar part of the joint. The arm's diameter was set at 3 mm, as thinner diameters resulted in flexibility, while thicker diameters were considered

uncomfortable for future patients. The length was fixed at 27 mm between the centers of the two buttons, simulating a high molar-canine distance.

In total, sixty teeth were obtained from the department of restorative dentistry for this test. These teeth were stored in water for 48 hours before bonding. Orthodontic buttons were then bonded to the teeth following this protocol: 37% orthophosphoric acid etching for 30 seconds, followed by a 15-second rinse and air drying. A universal adhesive (Scotchbond, 3M ESPE, Saint Paul, USA) and orthodontic resin (Transbond XT, 3M ESPE, Saint Paul, USA) were then used to place the buttons. The buttons were firmly applied to the teeth's surfaces, and any excess material was removed with a probe. Custom templates designed and printed for standardization purposes were used to maintain the teeth in a predetermined position relative to the bonded surface. Liquid resin was then poured into cylinders, surrounded by the templates, to set the installation. Once the templates were removed, the devices were bonded to the buttons using orthodontic resin containing a metal primer (Orthoconnect flow, GC Corporation, Tokyo, Japan) (Figure 4).



Figure 4: The sample preparation steps (from left to right): buttons are bonded to the teeth, the teeth are "clipped" onto the custom template using the buttons, the templates are placed on the supports, which are then filled with resin, and once it has set, the devices are bonded over the buttons.

The samples were then stored in water for 24 hours before testing. Thirty samples were available for the device bending test. The test was performed using a texture analyzer (Stable Micro System, Godalming, UK) equipped with a 500 kg cell. Each sample was positioned in the system, and the test speed was set at 0.6 mm/min, following ISO/TS 11405 recommendations (Figure 5). The load values obtained during the tests were recorded in kilograms (kg).



Figure 5: The fracture test, showing the bending of the arm until rupture occurs.

Results

Phase 1

The maximum load for the three groups and the results of the statistical analysis are presented in Figure 6. The normality of the Striped group's distribution was not confirmed by the Shapiro-Wilk test; thus, a non-parametric Mann-Whitney test was performed. The Button group ($20.91 \pm 5.71 \text{ kg}$) and the Striped group ($16.36 \pm -1.68 \text{ kg}$) showed a statistically significant difference compared to the Flat group ($6.23 \pm -2.84 \text{ kg}$), without being statistically different from each other.



Figure 6: Representation of the results of three groups. "***" indicates a statistical difference with a P-value < 0.0001, "ns" indicates non-significant.

Phase 2

Seven out of thirty samples exhibited tooth fractures before the device failure and were therefore excluded from the average calculation. The average load required for an incident to occur was 6.02 + 0.83 kg. The fracture locations are indicated in Figures 7 and 8.



Figure 7: The localization of fractures during the tests (from left to right): "Orthoconnect," "Canine + lever arm," "Button/tooth interface," "Anterior resin part."



Figure 8: Representation of the location of fractures during testing

Discussion

Advancements in digital design software and 3D printing technologies have offered orthodontists the opportunity to develop and produce orthodontic devices within the dental practice. Although bonding properties have been deemed clinically acceptable with 3D-printed Dental LT resin brackets⁽⁶⁾, the rupture resistance of resin-printed pieces is sparsely documented to our knowledge, except for Aretxabaleta's article⁽⁴⁾ in another highly specific application and Thurzo's article⁽³⁾. The latter article showed a detachment or rupture rate of 58% (7 out of 12 devices), occurring in 42% of its patients, which can be considered too high for incorporating this device into daily clinical practice. Therefore, the objective of this study was to provide approximations of the maximum load for this type of resin pieces, as such values are currently unavailable to our knowledge. Additionally, this study aimed to determine the optimal design of bonded pieces to achieve a better tooth/device interface because Thurzo had 4 detachments out of 12 devices with a flat base design and to establish if the bending resistance was compatible with occlusal forces, making the device theoretically suitable for a clinical trial.

The first in vitro step revealed no statistically significant difference between the Striped and Button groups. Despite this lack of significance, the button design was chosen due to its ability to achieve a tighter bond between the button and the tooth, resulting in a thinner layer of adhesive at the button-tooth interface. In the context of this specific application and design, a striated surface, when designed with a curvature, may be just as suitable for the tooth as a button. However, the subtlety lies in the fact that this device consists of two bonded pieces and a pivot. Therefore, bonding the first surface renders the second surface non-adaptable, as it will be bonded in a position determined by the rotation of the lever arm. With the button, adaptation can still occur within the adhesive bonding the button to the device's intrados. It also appears that enamel integrity after the removal of bonded printed pieces is unknown, and further investigations will be necessary.

The second in vitro step showed an average maximum load of 6.02 +/- 0.83 kg, which is considered comparable to average forces during chewing: 4 to 12 kg according to Reynolds⁽⁷⁾. Nevertheless, 17 out of 23 incidents, approximately 70%, occurred at the same point on the device and consisted of cohesive fracture within the resin in the anterior part, which appears to be a zone of weakness. A finite element analysis study could be conducted, similar to Thurzo's article, to enhance the design of the printed PowerArm⁽⁸⁾, to optimize the device's rupture resistance. The advantage of already having our load values as a function of deformation is that we can validate the mathematical model simulating the device before

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conducting simulations. Once this weak area is addressed, it would seem plausible to consider conducting clinical trials with this device.

During testing, seven tooth samples exhibited fractures. The cause of these fractures can be attributed to the poor quality of the samples, which had previously been used by students to create access cavities in endodontics. However, despite this issue, the sample size still provides a reasonable indication of the device's resistance to a certain range of forces. This issue could have been avoided by selecting higher-quality dental samples. In this particular type of test, specifically shear strength testing, the calculation and statistical analysis typically involve the use of shear strength values measured in megapascals (MPa). Shear strength value is calculated by dividing the applied load by the bonding area. The bonding areas were precisely known for the Flat and Striped groups because we designed these pieces ourselves. However, for the Button group, the bonding process involved injecting fluid composite into the resin piece, and then placing it on the button, inevitably causing the composite to spread around the button, increasing the bonding area in an immeasurable way. Therefore, to avoid bias, the analysis was performed using only the maximum load value obtained during the tests without converting it to stress.

It had been envisioned that a composite containing a metal primer would offer not only mechanical strength under the undercut of the button and the device but also a chemical component. However, this point would need to be studied more precisely in the future, especially regarding the need, if this protocol is retained, to use two different adhesives during bonding, with excesses more difficult to remove with the fluid composite.

Other alternative designs could be explored to improve the device. One potential design modification would be to incorporate curvature in the horizontal plane to align with the natural shape of the arch. Additionally, introducing slight curvature in the vertical plane above the gumline could also be beneficial to keep the device away from foods subject to occlusal forces. Furthermore, including a hook on the arm could serve to reduce the moment generated by placing elastics on the two bonded teeth.

Finally, it is important to note that in the study, the device was fixed to pre-existing buttons that were already bonded to the teeth. However, for greater clinical usability, another design could involve integrating the buttons within the device before bonding, at least for the molar part, thus replicating existing designs.

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Conclusion

The design and in-office 3D printing of orthodontic devices appear promising for the future. In our opinion, the development of design and production tools offers many advantages to orthodontists. Firstly, it allows practitioners to transform their ideas from conceptualization to reality. This potentially promotes greater treatment customization, as the devices used can be tailored to the ideal mechanics determined by the orthodontist, rather than the other way around. Design and in-office production also enhance the logistical independence of practitioners.

However, a precise understanding of the regulations to which orthodontic devices, printed resins, and medical devices at large are subject seems essential before integrating such a process into daily practice.

The results of this study indicate that resin-printed pieces exhibit rupture resistance characteristics consistent with forces observed in the oral cavity. Based on these biomechanical criteria and after reinforcing certain areas of weakness, it would seem plausible to consider conducting clinical trials with this device.

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Vu le Doyen,

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RESUME

L'orthodontie a été révolutionnée par l'impression 3D ces dernières années, ouvrant de nouvelles perspectives pour la conception et la fabrication d'appareils orthodontiques au cabinet. Cette avancée technologique propose d'améliorer l'efficacité organisationnelle et thérapeutique. Cet article évalue la faisabilité d'un dispositif de correction de classe 2 conçu et imprimé en 3D, avec une étude in vitro visant à mesurer sa résistance mécanique.

Dans la première phase, différentes conceptions de la base des pièces collées ont été testées pour mesurer l'adhésion aux tissus dentaires. La deuxième phase visait à déterminer la résistance théorique à la rupture du dispositif orthodontique, qui s'est avérée comparable aux forces moyennes de mastication. Cependant, des problèmes de fragilité ont été observés dans certaines zones du dispositif et devront être résolus. En conclusion, le design et l'impression 3D de dispositifs orthodontiques au cabinet semblent prometteurs, mais un savoir-faire technique et des connaissances règlementaires sont nécessaires pour garantir la sécurité et l'efficacité de ce type d'appareil.

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