Precision Orthodontics: A Comparison of Custom vs Traditional Bracket Treatment Efficiency

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Proposed Investigational Testing

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Scope

LightForce Orthodontics' (LFO) investigational testing aims to target multiple investigations sites to examine treatment efficiency metrics using a completely digital and patient-specific bracket treatment system for the correction of malocclusions.

Hypothesis

A fully digital and custom treatment system will provide a more efficient treatment experience compared to standard bracket treatments within the associated orthodontist's experience.

Objective

Compare metrics of treatment efficiency from a traditional "one-size fits all" fixed appliance (FA) system to a fully digital and 3D printed FA system.

Proposed Testing

Significance

Standard orthodontic practices use injection molded stock (not custom; traditional) brackets based on pre-programmed prescriptions to treat all patients with a variety of malocclusions. As each patient's anatomy and malocclusion are unique, this one size fits all approach leads to multiple forms of inefficiencies within a treatment. LightForce Orthodontics offers a digital treatment planning platform and patient-specific 3D printed polycrystalline alumina brackets which combat these inefficiencies and provide a better treatment plan.

The proposed LFO technology receives a digital scan of the patient's anatomy into the treatment planning software where the teeth are digitally moved from their starting position to the desired finishing positions. Brackets are placed in locations which enable Andrews' Straight Wire Appliance (SWA) principles to obtain the final occlusion. Among others, SWA principles dictate that a

treatment is completed when the arch wire no longer has any bends to it. The software program then reconstructs the initial malocclusion with the brackets in the locations which provide the desired outcome. Thus, the orthodontist can begin a treatment knowing exactly where the teeth will end up.

Even with this digital system, a stock bracket would not be able to precisely move the teeth to the desired position. This is due to the aforementioned morphology difference between patients and the inability of a one size fits all bracket to accommodate. The differences between the stock bracket base structure and the tooth surface must be manually filled in with an inexact amount of bonding material yielding inexact positioning which may create unintended movement directions. While the LFO brackets have a similar facial profile to stock brackets, which facilitate standard methods of care, the bracket's base is contoured to match the patient's corresponding tooth morphology. This means that the exact angles of torque, tip, and angulation, which facilitate orthodontic movement, are built into each bracket creating a predictable solution.

In a current standard of care example, the torque of a stock bracket may not be enough to move a tooth into the appropriate finishing angle. In this case, the orthodontist must then bend the arch wire to a certain degree to compound this torque - also known as a third order orthodontic bend. The resulting force is then sufficient to move the tooth to the correct angle. This action may need to be applied to multiple teeth throughout treatment. When a wire bend occurs multiple weeks are added to the desired finishing appointment as the orthodontist must allow the tooth to move and then evaluate the change. Due to the LFO contoured base as well as the SWA principles employed in the LFO System planning process, there should be no need for wire bends during treatment.

Historically, stock brackets must also be placed directly onto the tooth. This can lead to imperfect positioning even by the most experienced orthodontists. This imperfect positioning can either be caused by human-error during placement or because the orthodontist can not anticipate the exact bracket placement that will lead to a perfect finishing occlusion. During treatment the orthodontist must debond the imperfectly placed bracket in favor of a new bracket placed with the same level of insufficient precision. Each replacement extends the finishing appointment date.

This practice of direct bonding could yield inaccurate placement of even perfectly positioned and contoured brackets created using a digital treatment program. To solve this issue, LFO created a 3D printed patient-specific indirect-bonding (IDB) system. Designed directly from the desired bracket placement on the teeth in malocclusion, like a digital mold, the IDB tray precisely matches the tooth anatomy and brackets. Once printed, the corresponding patient's brackets are placed in the IDB tray's bracket wells. The orthodontist can paste the bonding material onto the brackets, while remaining in their specific wells, then place the IDB trays in the patient's mouth and bond the brackets. Once the tray is removed the brackets remain on the teeth in the exact position they were designed for in the treatment planning system.

The presented investigational testing aims to assess treatment efficiency metrics using the LightForce Orthodontic system on a variety of malocclusions across multiple sites compared to the investigator's past experience using traditional bracket systems.

Investigation Design & Participants

This multi-site investigation will evaluate treatment efficiency metrics of different orthodontists using the same LightForce Orthodontic digital treatment planning system and patient-specific brackets. Data collection will include treatment efficiency metrics, participant data such as (but not limited to) gender, age and medical history, and experiential data of standard bracket treatment efficiency metrics. Efficiency metrics may include:

- Treatment length
- Bonding/De-bonding appointment time length
- Length of time to achieve leveling and alignment
- Number of unscheduled appointment
- Number of debonded brackets
- Number of repositioned brackets

All patients that visit the investigation sites are evaluated during initial consultations for their particular medical needs and orthodontic treatment. If a patient is eligible for the investigation, they will be presented with the treatment plan, asked whether they would like to participate, and given a consent form to sign.

There are no specific recruitment materials for this study. However, each orthodontist is provided with a LightForce Orthodontics welcome kit before they enroll their first patient. This includes a typodont, a sample product package (box, brackets in trays and arch form) and patient brochures as pictured below. The patient brochures are not included as study recruitment material.

To run statistical analysis, at least 22 patients must participate at each investigation site to have a power of 90% at a 5% significance level. No patients will be withdrawn from the investigation unless the investigator or patient chooses to discontinue treatment. If there is a lack of compliance with the investigator's treatment plan and/or a developing health condition during treatment, the patient's data may be considered an outlier and not used in statistical analysis.

Inclusion Criteria

- All subjects must be healthy and between the ages of 10 and 65.
- Eruption of all permanent teeth excluding second and third molars
- Sufficient labial tooth surface for bonding
- No more than one tooth missing from a single arch quadrant
- No existing molar tubes or bands

Exclusion Criteria

- Presence of systemic diseases, cleft lip and palate, craniofacial anomalies, syndromes affecting bone or teeth, impacted teeth (excluding 3rd molars), and tumors of the parathyroid gland Presence of bridges or implants
- Cases requiring orthognathic surgery
- Significant periodontal disease
- Intake of drugs affecting tooth movement or bone formation (chronic use of Non-Steroidal Anti Inflammatory Drugs, bisphosphonates, levothyroxine, or teriparatide drug class) Pregnancy

Clinical Process

Orthodontic treatment process through out this investigation will follow standardized practices. Treatment data will be acquired throughout the following process:

- Facial photos and intra-oral scans will be taken of the patient's teeth
- Treatment will be planned using the LightForce Orthodontics' LF Pro treatment planning system
- LightForce Orthodontics will manufacture and ship the patient-specific brackets to the investigator
- Standard Orthodontic Treatment Progressions
    - Brackets will be bonded to patient’s teeth
    - Follow up appointments to change ligatures, move through standard wire progression, and/or replace brackets. The number of appointments can vary based on the patient’s treatment plan and progress.
    - Brackets are removed

Conflicts of Interest

The LightForce Orthodontic braces are commercially available in the United States. Every orthodontist in this study will pay LightForce Orthodontics for the LFO System as they would if they were available to purchase in Canada. As such there is no conflict of interest.

However, some investigators are a part of the LightForce Orthodontics' clinical executive board (CEB). If so a CEB Appendix is attached to their patient's consent form. To also combat any undue influence conflict of interests may have on this study, the investigators chosen are a mix of CEB and non-CEB members. This means any CEB member's data should not influence the overall study

results.

Statistical Analysis

Statistical tests (Student's t-test) will be run to make sure LightForce Orthodontics's Clinical Executive Board (CEB) member treatment group outcomes are not statistically different from non-CEB members within this study. If they are, the data collected from that investigation site will be removed.

We will assume the data will be normally distributed for this study. The primary outcome measures are impacted directly by the patient's age and by the treating orthodontists. Thus the outcome variables will be analyzed through analysis of covariance (ANCOVA) tests controlling for age and orthodontist. Multiple pair wise comparisons may be conducted (t-tests) to determine significant differences between groups. Bonferroni corrections may be conducted to prevent the introduction of Type 1 errors. Multivariate linear regressions may also be used to examine differences in the treatment groups. All statistical tests will be two-sided with a p-value of 0.05 for statistical significance. All statistical analyses will be conducted in a statical software such as SAS software (SAS Institute, Cary, NC).

Risk Assessment

There are no additional risks to participating in this study outside of the standard risks associated with orthodontic treatment. The study does not change the standard method of diagnosis and care for the treatment of malocclusion. The LFO bracket system has been approved by the FDA and is comparable to existing bracket systems. During the approval process, the device underwent standard orthodontic bracket performance tests compared to commercially available devices and biocompatibility tests. These reports can be made available upon request.

Each system is shipped with an instructions for use which contains the following precautions - there are no known adverse reactions or contraindications for this device:

- Due to the hardness of ceramic brackets, bonding brackets in occlusion should be avoided to prevent wearing of enamel surfaces during all phases of treatment.
- LightForce Orthodontic Brackets can withstand all normal torque requirements. However, care should be taken when making torquing activations. Large corrections with full size stainless steel wires may result in bracket failure and should be avoided.
- Instruct not to chew or bite hard substances such as hard candy, ice, or carrots. Careful and thorough patient instruction is key to avoiding appliance or enamel damage.
- LightForce Orthodontic Ceramic Brackets should be avoided in bonding to dental porcelain, restorative or compromised (i.e. large restorations, peg laterals, or pre-existing pathological conditions) enamel surfaces.
- Bonding to porcelain crowns or facings may cause chipping or breakage of the crown or facing during treatment or debonding.

- LightForce Orthodontic Ceramic Brackets are for single patient use only.

Data Monitoring and HIPAA Privacy Protections

All data taken during this study is apart of normal data acquisition for an orthodontic treatment. Each patient will be given a patient alias number. The LFO treatment representative will see identifying information regarding patients but will only record the patient's alias and relevant information for the study. The data collected will not directly link back to the participant's identity which minimizes the risk of a confidentiality breach. Experiential data will be acquired by LFO via communication with the orthodontist. All information is kept on password protected computers and servers. No paper print outs are kept in this study. The signed consent forms are scanned and sent back to LFO through secure emails. The orthodontist can then shred the forms. All personnel involved in this study as well as all members of LightForce Orthodontics are trained on Health Insurance Portability and Accountability Act (HIPAA) privacy rules. The investigators have all been trained on human subjects' research.

The LFO investigators will be responsible for process the data, ensuring the data is de-identified, and confidentiality is maintained. They will also be responsible for internal checks and project oversight. Data will be kept for a minimum of 4 years but up to 7 years after the study completion then destroyed.

Reportable Events

All reportable events will be documented by the treating orthodontist and relayed to the research team at LightForce Orthodontics within 72 hours. LFO will then inform all regulatory bodies deemed necessary within the said time frame.

This mandatory problem reporting includes cases in which the incident:

1. is related to a failure of the device or a deterioration in its effectiveness, or any inadequacy in its labelling or in its directions for use, and
2. has led to the death or a serious deterioration in the state of health of a patient, user or other person, or could do so were it to recur

Reports will be completed within timeframes set (10 or 30 days) within the Investigational Testing Guidance. If a participant feels the need to report any events, contact information is also provided in the consent forms.

Patient Assent/Consent

This investigation provides three types of informed consent forms. For patients under the age of 16 in Canada (18 in Quebec) a child's assent form must be signed as well as a parent/guardian's

consent for child's recruitment. A child may chose to not participate and not sign the assent form even if a parent or guardian has signed the recruitment consent. For patients over the age of 16 (18 in Quebec) a patient consent form is also provided.

All assent/consent forms are provided in English and French and maintained by LightForce Orthodontics. The investigator will scan the consent/assent form and send it to LFO after consent has been given. The investigator will provide the patient and/or guardian with a copy of their assent/consent form. The signed form will be kept in the Informed Consent folder at LightForce Orthodontics.