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By Dr. Priyal Billaiya, Dr. Vivek Amin & Dr. Mohammadi Begum

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Methodology: 12 patients between age group of 15 – 26 years with mild to moderate crowding based on Little"s irregularity index, in upper and lower arches which were bonded with Incognito™ Appliance System.

Results: The average rate of initial aligning and levelling for all patients is 0.0361mm/ day. When time taken for initial aligning and levelling in both the arches was compared, it was seen that time was more for maxilla than mandible but it was statistically insignificant.

Conclusion: Majority of patients reported, eating and having hot drinks aggravated pain while lying down, medication, sleep and having cool drinks relieved pain. 83.33 % of patients described the overall pain experience as mild.

Keywords: *incognito appliance system, ibraces, invisible, pain perception, VAS.*

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Dr. Priyal Billaiya [α], Dr. Vivek Amin [σ] & Dr. Mohammadi Begum [ρ]

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I. Introduction

As society and science advances, patients are seeking treatment not only for cure but also for enhanced esthetics.[1]Esthetics is one of the objectives in orthodontics in present era. The demand for esthetics in treatment has been the reason for change in bracket morphology and material. Lingual orthodontics is one of the best approaches for meeting demand of enhanced esthetics and quality treatment outcome. Incognito™ (3M Unitek) appliance system is an individually customized precision lingual bracket system with customized robot bent wires, individual precision bonding clear trays and software planned treatment outcome.[2-7] Since the bracket base is individualized as to the lingual surface of teeth in each patient, the bracket is closely bonded to the tooth with no resin base. Various case reports were published to highlight the versatility of the Incognito™ appliance in the treatment of malocclusions with varying severity.[8] However, there was no literature evidence about its efficacy during initial aligning and leveling stage of fixed Orthodontic treatment. This study tried filling the void and also listing out the patients levels of discomfort in the due course.[9,10]

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II. Aim

To assess the efficacy of customized lingual orthodontic system in terms of time taken during the stage stage I and pain perception by the patient during the same period. (Leveling and alignment) (Incognito™ 3M Unitek).

III. Objectives

1. To assess the time-efficacy in initial aligning and leveling using Conventional Labial(SS 0.022) appliance and Incognito appliance
2. To determine the patient's levels of discomfort if any in these stages using the above said appliances therefore.

IV. Methodology

Criteria for Patient Selection: 12 patients between age group 15 – 26 years were selected with mild to moderate crowding based on Little's Irregularity Index in maxilla and mandible. Patients who were willing to undergo orthodontic treatment with good oral hygiene having aesthetic concerns were selected from Yenepoya Dental College and other centers. Ethical clearance was obtained from Yenepoya University; Incognito appliance system certification was done.

a) Inclusion Criteria

- Subjects with/above 4 mm crowding in the anterior region.
- Subjects between ages 15-26 years.
- Subjects with class I molar occlusion.

b) Exclusion Criteria

- Subjects with compromised periodontal status.
- Uncooperative subjects.
- Subjects with previous fixed mechano-therapy orthodontic treatment

Steps Involved

Step I- Impression making of the patient: Maxillary and mandibular impressions of all subjects are made by

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using PVS Impression material. Dual Impression technique with two different consistency of putty materials: heavy body and light body. Heavy body impression material was kneaded properly; a homogenous mix was loaded on the plastic tray for primary impression. Light body putty material was loaded on the primary impression and final impression was made. Check the impression for details. (Fig: 1)

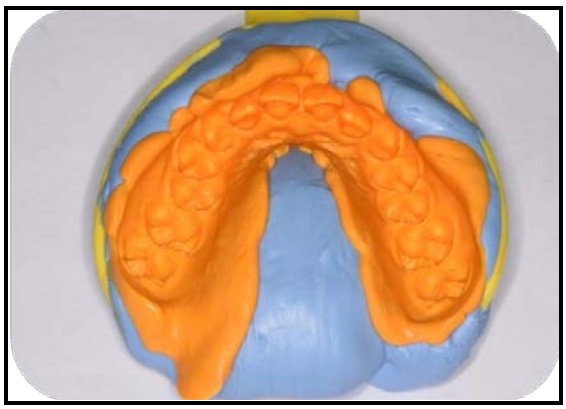


Figure 1: Heavy body PVS impression

Step II- Uploading prescription in TMP: Photographs and radiographs were uploaded in TMP portal. Prescription form was filled for the particular case. Patient details and bracket requirement form was filled and barcode for the patient was generated in 3M TMP software. A request for pick-up of impressions was made in TMP software. The impressions made were packed well and sent to the Incognito Lab (TOP Services, Bad Essen, Germany and Monrovia, CA, USA) through 3M, Monaco USA. Laboratory technicians check the impressions and pour cast. A high-resolution optical 3D scanner permits non-contact scanning of the plaster model or impressions. The scan produces a three-dimensional digital representation of the teeth consisting of many thousands of minute triangles (Standard Triangulation Language, STL surfaces). The surface resolution is at least 0.02 mm that can be documented and processed in the computer.[5] (Fig: 2)

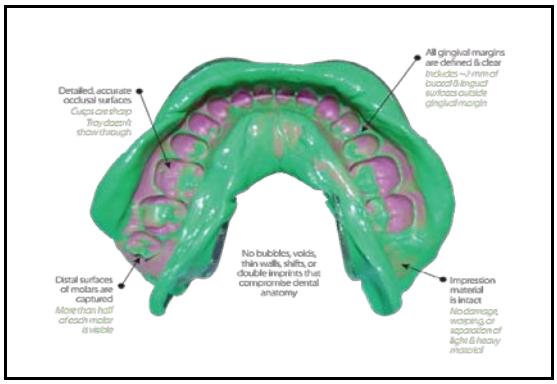


Figure 2: Check PVS Impression

Step III- Steps in making virtual model: The malocclusion digital model is uploaded in TMP software. The laboratory corrects the malocclusion by moving the teeth in the desired tooth positions. This was done all the three planes and treatment sequence was decided. Finally, a final treatment setup and uploaded in TMP for reviewing and approval of the practitioner. (Fig: 3-6)



Figure 3: TMP software

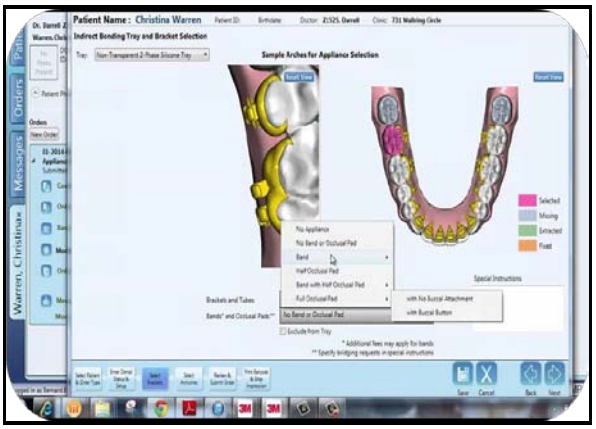


Figure 4: Selecting prescription of brackets on TMP software



Figure 5: Scanning of PVS impression

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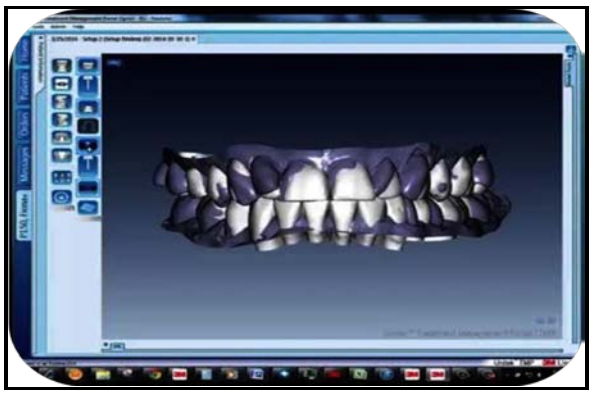


Figure 6: Virtual treatment setup on TMP

Step IV- steps in bracket manufacturing: After practitioner reviewed and approved the setup, Incognito appliance system was sent for manufacturing to the lab by CAD/CAM technology. Virtual construction of individualized bracket base (yellow). The pad surfaces are generously dimensioned to permit a positive lock. The thickness was 0.2–0.3 mm. The bracket body was manufactured specifically for the individual teeth with a CAD program used in mechanical engineering. The bracket slot runs parallel to the tooth surface. In the buccal region, the slot runs parallel to the tooth surface (Ribbon wise). However, the insertion direction of the archwire remains horizontal. The bracket bodies (red) were added as a complete library to the arches fitted with individualized bases (yellow). Whereas the second- and third-order positions were preset, the bracket body was placed optimally in the slot plane by shifting and turning. After positioning, the bracket bodies (green) are virtually fused with the bracket bases. In the Rapid Prototyping technique, the individualized lingual brackets were first made of wax. After casting, the brackets are tumbled and polished until they are smooth to ensure high patient comfort. They are then positioned on the original malocclusion model. Bonding tray of two-layer silicone with the new lingual brackets made of Degunorm M® or clear precision trays are made. (Fig. 7-11)

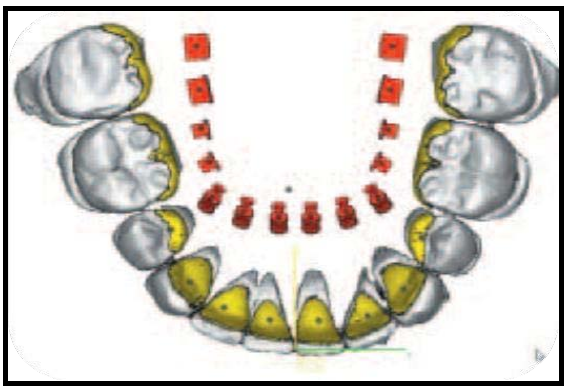


Figure 7: Bracket base (yellow) and bracket slot (red)

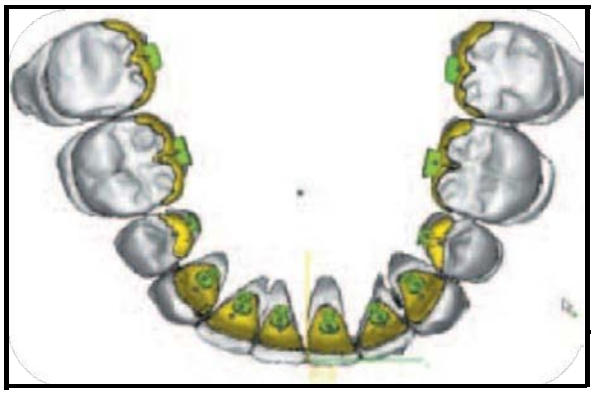


Figure 8: Bracket slot (green) attached to bracket base

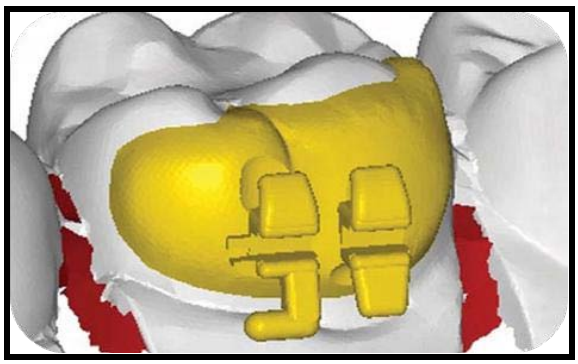


Figure 9: Final virtual model of the bracket



Figure 10: Incognito bonding kit

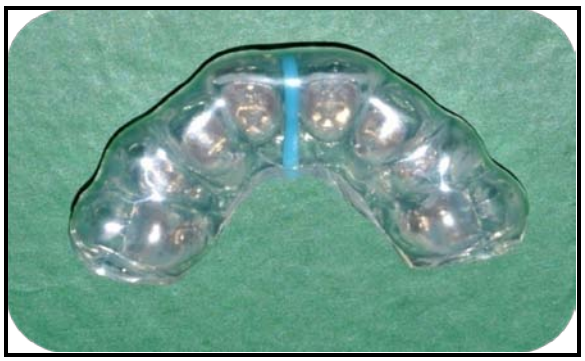


Figure 11: Occlusal view Bracket Placement Precision Tray

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Step V- Incognito kit: Finished brackets are sent to the clinician. (Figure: 12-15) Incognito kit included:- Impression, Cast, Bonding trays with brackets, Robotic bent wires, Bracket design.



Figure 12: Base of the Bracket Placement Precision Tray

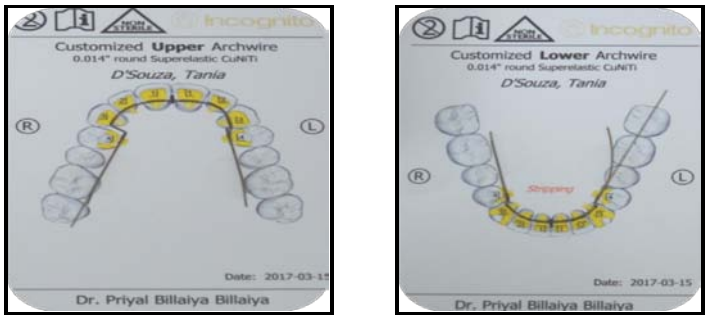


Figure 13: Upper and Lower Copper Nickel Titanium Wires

Step VI-Assessment of Patients: Patients with or above 4 mm of crowding in the maxillary and/or mandibular anterior region according to Little's irregularity index were selected for this study. A quantitative method of assessing mandibular anterior irregularity is proposed. The technique involves measurement from the mandibular and maxillary cast with a caliper (Calibrated to at least tenths of mm) held parallel to the occlusal plane. The linear displacement of the adjacent anatomic contact points of the mandibular and maxillary incisors is determined, the sum of the five measurements representing the Irregularity Index value of the case. Questionnaire using Visual analog system (VAS) is made to evaluate the pain experience during initial alignment phase. (Fig. 14)

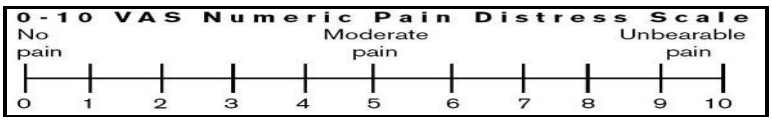


Figure 14: Visual Analogue Scale

Step VII- Measurement of Aligning and Levelling: Measurements were made on the initial pre-treatment (T1), obtained after aligning and levelling (T2) by using a fine-tip digital calliper. The rate of initial alignment and levelling of the anterior region was measured from the difference in the irregularity index at T1 and T2 using digital Vernier calliper, divided by the number of days between the 2 measurements.

Step VIII- Measurement of discomfort: Questionnaire using Visual analog system (VAS) is made to evaluate the pain experience during initial alignment phase.

c) Method of Study

Prospective Clinical Study, Sampling Technique: Purposive Sampling.

d) Statistical Analysis

Descriptive statistics using Paired and Independent sample 't' test Repeated measure ANOVA using SPSS for windows.

V. Results

A total of 12 arches within the age group 15 – 26 years, diagnosed with mild to moderate crowding according to Little's irregularity index, who required orthodontic correction for their malocclusion were enrolled for the study. Patients were bonded with Incognito appliance system.

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This study evaluated:

1. Efficacy of Incognito appliance system in initial alignment and leveling in terms of Time taken for the rate of initial alignment.
2. Evaluation of patient's discomfort.

The pain experience was assessed using a questionnaire using100mm VAS at three different intervals, at the end of 3weeks (T1), 2 months (T2) and 3 months (T3). Data was compared using t-test.
These were tabulated and compared.

a) Data analysis:

i. *Assessment of time bound efficacy of Incognito appliance*

There was a significant difference noted in time taken for leveling and alignment of maxilla and mandible using conventional labial appliance (SS 0.022 slot) and Incognito appliance.

Maxilla & Mandible: It took on an average 254.5 (SD=144.2744), 203.833 (SD=49.3372) days for initial leveling and alignment in maxilla and mandible with the reduction of irregularity index by 7.1317mm and 6.8433mm in the maxilla and mandible respectively. The difference was statistically significant with p value of 0.4346 using Incognito, whereas the labial appliance took on an average 179.8 (SD= 154.667), 184.0 (SD= 63.891) days for maxilla and mandible with the reduction in the irregularity index by 8.1380mm in the maxilla and 7.5792 mm in the mandible.

Males and females: The initial rate of alignment was more for male 0.0444(SD=0.0176) mm/day compared to female 0.0279 (SD=0.0063) mm/day. There was a statistical difference with p value of 0.2858

ii. *Assessment of patient's discomfort*

Using incognito appliance the overall pain perception was found to be more in specific region such as tongue (p< 0.01), whereas patients using labial appliances reported pain in the cheek mucosa (p< 0.01). However additionally the following details were reported with Incognito appliance:

- Highest pain during alignment was after initial archwire placement and second archwire placement.
- Difference in pain experienced at different time intervals with initial archwire was found to be significantly high (p 0.00001).
- 41.67% of patients reported pain as continuous steady constant, 58.33% as rhythmic periodic intermittent.
- 83.33% of patients have described the overall pain experience as mild, while 16.67% have described pain as discomforting.

VI. Discussion

Customized lingual appliance treatment has an obvious advantage over labial treatment. Despite of the advantage, lingual appliances have disadvantages as well. Lingual brackets are attached to irregular and inconsistent lingual surface of the tooth. Lingual side of the tooth has less crown height and inter-bracket distance. These factors make the lingual biomechanics differ from labial. Our study conducted statistically states that the average rate of initial aligning and leveling for all patients is 0.0361 mm/ day using Incognito appliance, whereas it is found to be 0.0288 mm/day using labial appliance. This customized system addresses 3 problems traditionally associated with the conventional lingual brackets: the brackets are more difficult to bond and tend to debond more often, finishing is more difficult, and the brackets cause speech problems or irritate the tongue in some patients. Several steps have been taken to address the problem of difficult bonding and frequent debonding. First, the bracket bases have been extended; this results in greater bond strengths. Overall, the brackets have a lower profile, which induces less leverage when biting on appliance components. The virtual production of the brackets on the computer almost completely eliminates errors in the actual production of the bracket bases. Since all the archwires are also produced with CAD/CAM technology, thus minimizing the potential source of errors associated with finishing process including inaccurate bracket positioning, improper archwire fabrication and inaccurate fit between brackets and archwires.[11-17]

As Incognito is a new concept, this study was carried out to assess the efficacy of Incognito in initial aligning and leveling. It was noted that the rate of initial alignment using lingual appliances is more when compared to that of labial appliances may be contributed due to the decreased inter bracket distance in lingual brackets and non-extraction therapy [18]. In this study we used questionnaire and visual analog scale (VAS) to investigate the perception of pain during chair side manipulation and the delayed type of pain with Incognito brackets. All patients reported decrease in pain while lying down and when on medication and 58 % had relief while having cool drinks. Majority of patients described the overall pain experience as mild and statistically highly significant. It was found that significantly greater discomfort was experienced during arch wire insertion and removal with the smart clip appliance.[19] Tecco S et al[20] found that patients with conventional brackets reported significantly more constant' pain than those treated with self-ligating brackets who complained of chewing/biting' pain. Correlating the above studies with our findings we can say that Incognito Appliance System have definitely improved the comfort level and pain experience of the patients. Pain during chair side manipulations was minimal with Incognito Appliance System, giving an edge over Smartclip brackets.

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VII. Conclusion

The custom bracket manufacturing like Incognito, provides new opportunities by solving the most frequently cited drawbacks of lingual appliances: Thus it can be concluded that, the advantage of customized brackets is not only the individualization of brackets but also highly comfortable for both the patient and the orthodontist.

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