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# Assessment of Efficacy (Time Taken during Stage I and Pain Perception) of Customizedlingual Orthodontic System

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#### 6 Abstract

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- 7 Introduction: To assess of the efficacy of customized lingual orthodontic system (Incognito
- 8 TM 3M Unitek), during initial aligning and Levelling based on time factor and also to assess
- <sup>9</sup> patient"s discomfort during initial aligning and Levelling.Methodology: 12 patients between
- <sup>10</sup> age group of 15 -26 years with mild to moderate crowding based on Little's irregularity index,
- <sup>11</sup> in upper and lower arches which were bonded with Incognito TM Appliance System.
- $_{12}$  Results: The average rate of initial aligning and levelling for all patients is  $0.0361 \mathrm{mm}/$  day.
- <sup>13</sup> When time taken for initial aligning and levelling in both the arches was compared, it was
- <sup>14</sup> seen that time was more for maxilla than mandible but it was statistically insignificant.
- <sup>15</sup> Conclusion: Majority of patients reported, eating and having hot drinks aggravated pain while
- <sup>16</sup> lying down, medication, sleep and having cool drinks relieved pain. 83.33

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18 Index terms— incognito appliance system, ibraces, invisible, pain perception, VAS

# <sup>19</sup> 1 Introduction

20 s society and science advances, patients are seeking treatment not only for cure but also for enhanced esthetics. 1 21 Esthetics is one of the objectives in orthodontics in present era. The demand for esthetics in treatment has been 22 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 TM (3M Unitek) appliance 23 system is an individually customized precision lingual bracket system with customized robot bent wires, individual 24 precision bonding clear trays and software planned treatment outcome. [2][3][4][5][6][7] Since the bracket base is 25 individualized as to the lingual surface of teeth in each patient, the bracket is closely bonded to the tooth with 26 no resin base. Various case reports were published to highlight the versatility of the Incognito TM appliance 27 in the treatment of malocclusions with varying severity. 8 However, there was no literature evidence about its 28 efficacy during initial aligning and leveling stage of fixed Orthodontic treatment. This study tried filling the void 29 and also listing out the patients levels of discomfort in the due course. 9,10 II. 30

# 31 **2** 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 TM 3M Unitek).

# <sup>34</sup> **3 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.

38 IV.

# 39 4 Methodology

40 Criteria for Patient Selection: 12 patients between age group 15 -26 years were selected with mild to moderate 41 crowding based on Little's Irregularity Index in maxilla and mandible. Patients who were willing to undergo

- 42 orthodontic treatment with good oral hygiene having aesthetic concerns were selected from Yenepoya Dental
- 43 College and other centers. Ethical clearance was obtained from Yenepoya University; Incognito appliance system
- 44 certification was done.

# 45 5 a) Inclusion Criteria

- <sup>46</sup> ? Subjects with/above 4 mm crowding in the anterior region. ? Subjects between ages 15-26 years.
- 47 ? Subjects with class I molar occlusion.

# <sup>48</sup> 6 b) Exclusion Criteria

- 49 ? Subjects with compromised periodontal status.
- 50 ? Uncooperative subjects.
- 51 ? Subjects with previous fixed mechano-therapy orthodontic treatment

# 52 7 Steps Involved

Step I-Impression making of the patient: Maxillary and mandibular impressions of all subjects are made by using
 PVS Impression material. Dual Impression technique with two different consistency of putty materials: heavy

54 PVS Impression material. Dual Impression technique with two different consistency of putty materials: heavy 55 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 kneaded property, a homogenous mix was loaded on the plastic tray for primary impression.

57 final impression was made. Check the impression for details. (Fig: ??)

# <sup>58</sup> 8 Figure 1: Heavy body PVS impression

59 Step II-Uploading prescription in TMP: Photographs and radiographs were uploaded in TMP portal. Prescription 60 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.

<sup>62</sup> 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

64 cast. A high-resolution optical 3D scanner permits noncontact 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: ??)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

71 reviewing and approval of the practitioner. (Fig: ??-6) Step VI-Assessment of Patients: Patients with or above 4

72 mm of crowding in the maxillary and/or mandibular anterior region according to Little's irregularity index were

<sup>73</sup> 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

<sup>77</sup> the Irregularity Index value of the case. Questionnaire using Visual analog system (VAS) is made to evaluate the

78 pain experience during initial alignment phase. (Fig. ??4)

# 79 9 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.

# <sup>86</sup> 10 c) Method of Study

87 Prospective Clinical Study, Sampling Technique: Purposive Sampling.

# 88 11 d) Statistical Analysis

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

90 windows.

91 V.

#### 92 12 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.

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.

### 98 13 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:

### <sup>102</sup> 14 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.

# 110 15 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

# 113 16 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< 114 (0.01), whereas patients using label appliances reported pain in the cheek mucosa (p< (0.01)). However additionally 115 the following details were reported with Incognito appliance: ? Highest pain during alignment was after initial 116 archwire placement and second archwire placement. ? Difference in pain experienced at different time intervals 117 with initial archwire was found to be significantly high (p 0.00001). ? 41.67% of patients reported pain as 118 continuous steady constant, 58.33% as rhythmic periodic intermittent. ? 83.33% of patients have described the 119 overall pain experience as mild, while 16.67% have described pain as discomforting. 120 VI. 121

#### 122 17 Discussion

Customized lingual appliance treatment has an obvious advantage over labial treatment. Despite of the advantage, 123 lingual appliances have disadvantages as well. Lingual brackets are attached to irregular and inconsistent lingual 124 surface of the tooth. Lingual side of the tooth has less crown height and inter-bracket distance. These factors 125 make the lingual biomechanics differ from labial. Our study conducted statistically states that the average 126 rate of initial aligning and leveling for all patients is 0.0361 mm/ day using Incognito appliance, whereas it is 127 128 found to be 0.0288 mm/day using labial appliance. This customized system addresses 3 problems traditionally 129 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 130 patients. Several steps have been taken to address the problem of difficult bonding and frequent debonding. 131 First, the bracket bases have been extended; this results in greater bond strengths. Overall, the brackets have 132 a lower profile, which induces less leverage when biting on appliance components. The virtual production of 133 the brackets on the computer almost completely eliminates errors in the actual production of the bracket bases. 134 Since all the archwires are also produced with CAD/CAM technology, thus minimizing the potential source of 135 errors associated with finishing process including inaccurate bracket positioning, improper archieve fabrication 136 and inaccurate fit between brackets and archwires. [11][12][13][14][15][16][17] As Incognito is a new concept, this 137 study was carried out to assess the efficacy of Incognito in initial aligning and leveling. It was noted that the 138 rate of initial alignment using lingual appliances is more when compared to that of labial appliances may be 139 140 contributed due to the decreased inter bracket distance in lingual brackets and non-extraction therapy 18. In 141 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 142 while lying down and when on medication and 58 % had relief while having cool drinks. Majority of patients 143 described the overall pain experience as mild and statistically highly significant. It was found that significantly 144 greater discomfort was experienced during arch wire insertion and removal with the smart clip appliance. 19 145 Tecco S et al 20 found that patients with conventional brackets reported significantly more constant' pain than 146 those treated with self-ligating brackets who complained of chewing/biting' pain. Correlating the above studies 147

with our findings we can say that Incognito Appliance System have definitely improved the comfort level andpain experience of the patients. Pain during chair side manipulations was minimal with Incognito Appliance

pain experience of the patients. Pain during chairSystem, giving an edge over Smartclip brackets.

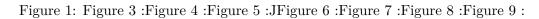
# <sup>151</sup> **18** VII.

### 152 19 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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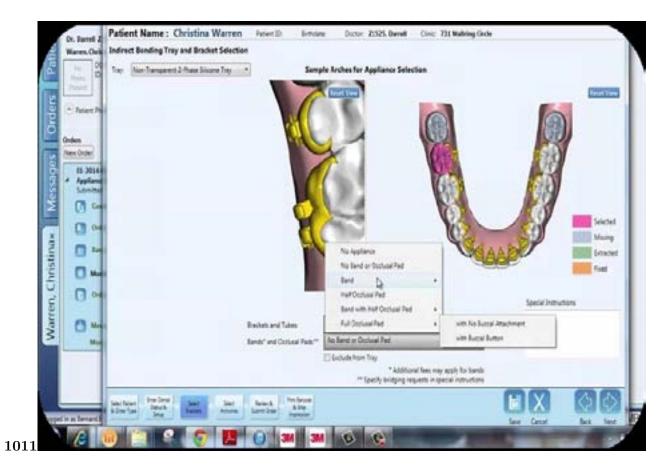


Figure 2: Figure 10 : Figure 11 :

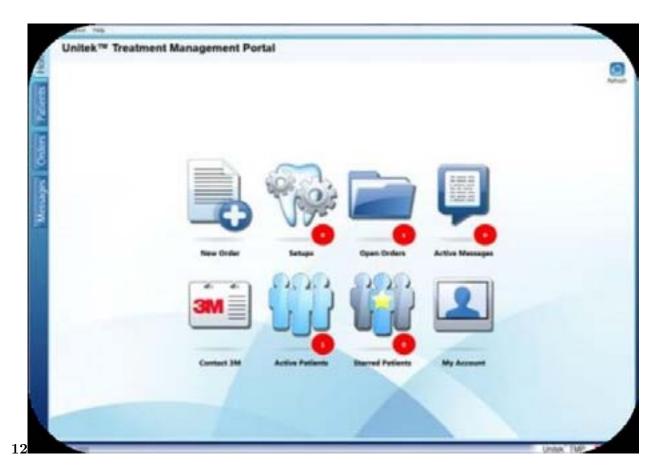


Figure 3: Figure 12 :

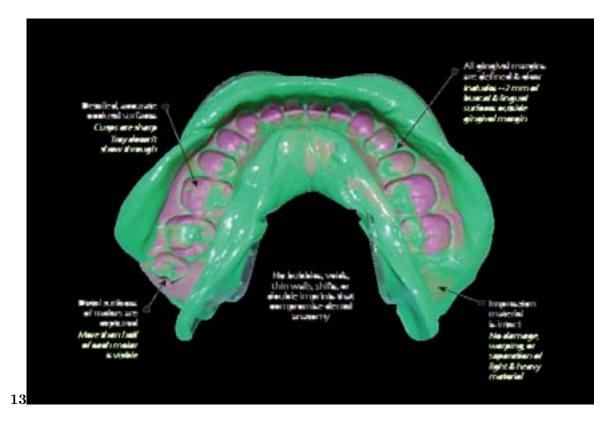


Figure 4: Figure 13 :

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