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**Comparison of The Effectiveness of Autobrush® Versus Manual Regular Toothbrush
Among Adolescents with Fixed Orthodontic Appliances**

Study Design:

This study is a randomized crossover clinical trial designed to compare the effectiveness of a U-shaped automatic toothbrush (Autobrush®) versus a conventional manual toothbrush in reducing dental plaque among adolescents undergoing fixed orthodontic treatment.

Exposure Variables:

The primary exposure variable in this study is the type of toothbrush used by the participant:

- Group A: U-shaped toothbrush (Autobrush®)
- Group B: Manual regular toothbrush

Each participant will be exposed to both interventions during the study period due to the crossover design.

Outcome Variables:

The main outcome variable is the Full Mouth Plaque Score (FMPS). Plaque levels were recorded on six sites per tooth (three buccal and three lingual), both before and after brushing. The FMPS difference is calculated as:

FMPS difference = FMPS before brushing – FMPS after brushing

This difference is expressed as a percentage:

$(\text{Number of sites with plaque} / \text{Total number of sites examined}) \times 100$

Sample Size and Sampling Technique:

The total sample size is 40 participants, determined using G*Power software to achieve 80% power and a type I error rate of 5%, based on a similar previous study.

Sampling technique: Randomized allocation with crossover design.

Study Protocol:

- Before appointment, participants were instructed to refrain from all oral hygiene measures (e.g., brushing, chewing gum) for 12 hours. On the appointment time, at the clinic, participants are assigned randomly to a toothbrush group and given disclosing solution to visualize plaque.
- The FMPS was recorded before brushing. Then, participants brush under supervision with their assigned toothbrush group, either manual toothbrush using Bass technique for 2 minutes or using Autobrush® with side-to-side motion for 30 seconds. After brushing, FMPS is reassessed using

the same disclosing procedure. Following a washout period of at least 2 weeks, the participant repeats the procedure with the alternative toothbrush.

Statistical Analysis:

- Descriptive statistics: mean, SD, medians and IQR were calculated. Normality of the continuous variables was assessed using the Shapiro–Wilk test and visual inspection of Q-Q plots. Levene’s test was used to evaluate the homogeneity of variances across groups.

For within-group comparisons of plaque scores before and after brushing, paired t-tests were performed for both the U-shaped and regular toothbrush groups where assumptions of normality were satisfied. The paired t-test was also used to assess the effectiveness of brushing in the anterior and mandibular regions between toothbrush types.

In contrast, the Wilcoxon signed-rank test was applied for non-normally distributed comparisons. This included the analysis of brushing effectiveness between toothbrush types, as well as comparisons in the posterior and maxillary sections.

A p-value of < 0.05 was considered statistically significant. All statistical analyses were conducted using Stata software (version 16.1).