



A Double-blind Randomised Clinical Trial Comparing the Acceptability of Two Commercially Available Pediatric Toothpastes in Children Aged 3-6

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Health

ABSTRACT:

Aim:

To compare the acceptability of two commercially available pediatric toothpastes based on taste, colour preference, parental satisfaction with oral care outcomes, likelihood of continued use, and overall satisfaction in children aged 3–6.

Methods:

This double-blind, randomised clinical trial was registered with the Clinical Trials Registry of India (CTRI) under registration number CTRI/2024/10/075062. 60 children aged 3–6, visiting the Department of Pedodontics and Preventive Dentistry, were randomly assigned to two groups: Group A (Green apple-flavoured toothpaste) and Group B (Strawberry mint-flavoured toothpaste). Data were collected using structured questionnaires administered to both parents and children. Statistical analyses were performed using SPSS version 21, with a significance level set at 5%.

Results:

A significantly higher percentage of children in Group A rated their toothpaste as more acceptable in taste (90%) compared to Group B (66.7%) ($p = 0.041$), indicating a greater preference for toothpaste among children in Group A. There was no significant difference in colour preference between the two groups ($p = 0.448$). Parental satisfaction was also higher in Group A, with 73.3% of parents being "very satisfied" compared to 50% in Group B ($p = 0.048$). Additionally, 53.3% of parents in Group A reported being "very likely" to continue using their toothpaste, compared to 23.3% in Group B ($p = 0.042$). Overall satisfaction was significantly higher in Group A compared to Group B ($p = 0.034$).

Conclusion:

The green apple-flavoured toothpaste was more favourably accepted than the strawberry mint-flavoured toothpaste in terms of taste, parental satisfaction, and likelihood of continued use. These findings highlight the significance of sensory and parental factors in selecting pediatric toothpaste, promoting adherence to oral hygiene practices and thereby enhancing oral health outcomes in children.



Introduction

Tooth brushing is a cornerstone of oral hygiene practices, particularly in children, as it significantly reduces the risk of dental caries and other oral diseases.¹ Toothpaste formulations tailored for children often emphasise taste, flavour, and safety to encourage compliance, as children's acceptance of oral care products is critical for establishing consistent hygiene habits.² Despite the availability of numerous toothpaste brands designed for children, there remains a lack of comprehensive comparative studies evaluating their acceptability and effectiveness from both parental and child perspectives.

Taste, colour, and overall satisfaction with toothpaste play significant roles in adherence to oral hygiene routines, especially among young children.^{3,4} The inappropriate selection of oral hygiene products can lead to reduced compliance, which negatively impacts oral health outcomes.^{5,6} While pediatric toothpaste formulations are widely available, limited studies are comparing their sensory acceptability and long-term adherence.

This study addresses a gap in the literature by comparing the sensory acceptability of two pediatric toothpaste formulations and their influence on adherence. Evaluating factors such as taste, colour, satisfaction, and the likelihood of continued use can provide valuable insights for dental professionals to guide parents in selecting the most suitable products for their children. Fostering positive oral hygiene habits during early childhood—a critical period for establishing lifelong health behaviours—is essential for improving oral health outcomes.⁷

The objective of this study was to compare the acceptability of two commercially available pediatric toothpastes in children aged 3–6 years based on their taste, colour preferences, parental satisfaction with oral care outcomes, and likelihood of continued use. Additionally, this study aimed to identify key factors influencing product adherence and to provide evidence-based recommendations for pediatric oral hygiene practices.

1. Materials and methods

This study was conducted in accordance with the principles outlined in the Declaration of Helsinki and was approved by the Institutional Ethics Committee of Chhattisgarh Dental College and Research Institute (Ethical Clearance Number: **CDCRI/DEAN/ETHICSCOMMITTEE/PEDO/PG 03/2024**). The trial was also registered with the Clinical Trials Registry of India (CTRI) under registration number **CTRI/2024/10/075062**. Written informed consent was obtained from all parents or guardians before the inclusion of their children in the study.

2. Study Design

This was a double-blind, randomised clinical trial comparing the acceptability of two pediatric toothpaste formulations in children aged 3–6 years. The primary outcomes assessed were taste, colour preference, parental satisfaction, likelihood of continued use, and overall satisfaction.

3. Inclusion and Exclusion Criteria

Inclusion Criteria:

- Children between the ages of 3–6 years.
- Parents or guardians who provided written informed consent.
- Children with no medical conditions or known allergies.
- Children willing and able to cooperate during the trial.

Exclusion Criteria:

- History of antibiotic use within the past two weeks.
- Regular use of chemical mouth rinses or interdental cleaning aids.
- Presence of congenital anomalies or physical/mental disabilities.
- Known allergies or sensitivities to toothpaste ingredients.
- Regular use of medications or special healthcare needs.

Toothpaste Brands Used

Two commercially available toothpaste brands were selected for their child-friendly formulations.

- I. **Green Apple-flavoured toothpaste** (referred to as Toothpaste A). (Figure 1)
- II. **Strawberry Mint-flavoured toothpaste** (referred to as Toothpaste B). (Figure 1)

These toothpastes were chosen for their sensory appeal and child-focused formulations, which were designed to enhance compliance and acceptability.

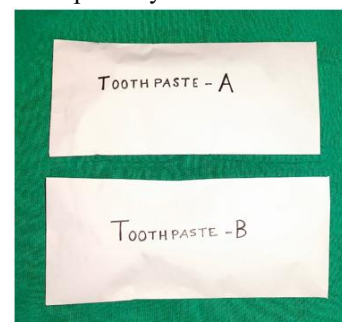


Figure 1. This figure depicts concealed toothpaste packages labelled as Toothpaste A & Toothpaste B



Toothpaste Allocation

Participants were randomly assigned to one of two groups:

- **Group A:** Assigned Toothpaste A.
- **Group B:** Assigned Toothpaste B.

Intervention Protocol

Each participant received an oral hygiene kit containing the assigned toothpaste and soft-bristled toothbrush. All toothbrushes were uniform to standardise the mechanical cleaning process.

Brushing Instructions:

Parents and participants were provided with brushing instructions through an educational video demonstrating the **Fones brushing technique**, which is suitable for young children. Participants were instructed to brush their teeth twice daily for three minutes over four weeks. They were also advised to avoid using other oral hygiene products, such as non-study toothpaste, dental floss, chewing gum, or mouth rinses, during the trial.

Data Collection

Pre-Trial Assessment

Baseline data were collected before the intervention, including participants' demographic information, oral health status, and prior oral hygiene habits.

During the Trial

Participants' compliance with the intervention was monitored, and any adverse events were recorded. Subjective feedback from children and their parents/guardians was collected using a structured questionnaire to evaluate the sensory properties of the toothpaste, including taste, texture, flavour, and overall satisfaction.

Post-Trial Assessment

At the end of the four-week trial, participants were reassessed to evaluate changes in their oral health status. Parents/guardians provided qualitative feedback on children's oral hygiene habits, preferences, and experiences with the assigned toothpaste. Data were collected using a post-trial questionnaire.

Questionnaires

Two versions of the questionnaire (in English and Hindi) were provided to accommodate the linguistic preferences of parents/guardians. The questionnaire gathered:

- **Sociodemographic data:** Age, gender, and parental education level.
- **Sensory attributes of the toothpaste:** Participants rated attributes such as colour, flavour, texture, and taste.
- **Acceptability feedback:** Parental opinions on satisfaction, compliance, and likelihood of continued use.

Sr. No.	Questionnaire Proforma
1.	Demographic information
2.	Which toothpaste brand did your child receive during the study? (Toothpaste A/ Toothpaste B)
Questions on a Child's Acceptability of Toothpaste	
1.	How would you rate the taste of the assigned toothpaste brand? (Pleasant/Unpleasant/Neutral)
2.	How would you rate the texture of the assigned toothpaste brand? (Smooth & Pleasant/Gritty & Unpleasant/Neutral)
.	Does the child like the colour of toothpaste? (Yes/No)
Questions on Parental Acceptability of Toothpaste	
1.	How satisfied are you with the assigned toothpaste brand for your child's oral care needs? (Very Satisfied/Satisfied/Neutral/Dissatisfied)
2.	Have you noticed any changes in your child's willingness to brush their teeth with the assigned toothpaste brand compared to their usual toothpaste? (Yes/Same/No)
3.	Does your child experience any discomfort (e.g. sensitivity, irritation) after using the assigned toothpaste brand? (Yes/No)
4.	How would you rate the effectiveness of the assigned toothpaste brand in cleaning your child's teeth?
5.	How would you rate the foaming action of the assigned toothpaste brand? (Very Good/Good/Fair/Poor)
6.	Did the foaming action of the assigned toothpaste brand affect your child's brushing experience in any way?
7.	Does this toothpaste leave your child's mouth feeling fresh and clean after brushing? (Yes/No)



8.	Have you noticed any improvement in your child's breath odour since using this toothpaste? (Yes/No)
9.	How likely are you to continue using the assigned toothpaste brand for your child after the study period? (Very Likely/Likely/Unsure/Unlikely/Very unlikely)
10.	Would you recommend the toothpaste your child currently uses to other parents based on its taste? (Yes/No)
11.	On a scale of 1-5, how would you rate your child's overall satisfaction with the assigned toothpaste brand?

Sample Size Calculation

The sample size for this clinical trial was calculated with a significance level (α) of 5%, power ($1-\beta$) of 80%, and a two-sided test using a formula appropriate for testing the null hypothesis with an outcome variable measured on a ratio scale.

The formula used for sample size calculation is as follows:

$$n = 2 \frac{S^2 (Z_1 + Z_2)^2}{(M_1 - M_2)^2}$$

The sample size calculation for this study was conducted using a **priori power analysis** with **G*Power version 3.0.1** (Franz Faul, Universität Kiel, Germany). The analysis used a two-tailed t-test to determine the difference between two independent means, with the following inputs: an effect size (d) of 0.75, a significance level (α) of 0.05, a power ($1-\beta$) of 80%, and an equal allocation ratio ($N_2/N_1 = 1$). The output indicated a non-centrality parameter (δ) of 2.885, a critical t-value of 2.0032, and a degree of freedom (df) of 56. The resulting required sample size was **29 participants per group**, for a total of **58 participants**. To ensure adequacy and account for potential dropouts, the sample size was rounded to **60 participants**, with **30 participants in each group**.

Randomization

A **simple random sampling technique** was used to ensure an unbiased distribution of participants into two groups. Participants were randomly assigned as follows:

- **Group A:** Received Toothpaste A.
- **Group B:** Received Toothpaste B.

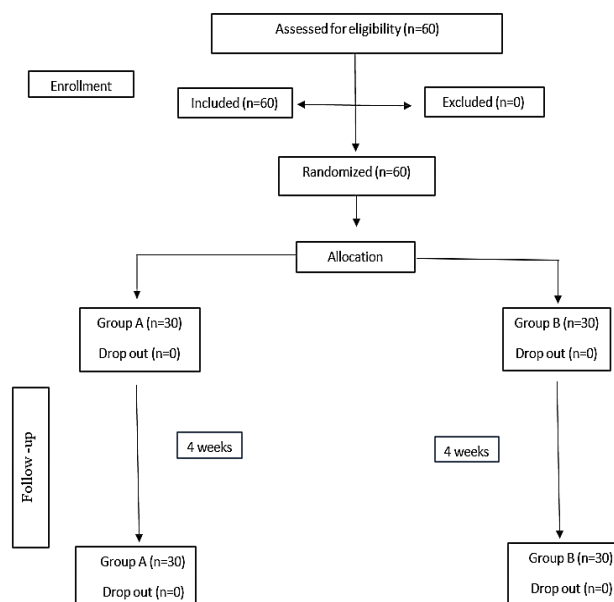
Participants were randomly allocated into two groups using a simple randomisation technique, maintaining an equal allocation ratio of 1:1. The randomisation process was

managed by a staff member who was not involved in data collection or statistical analysis, ensuring impartiality.

Blinding

To minimise bias, a **double-blind study design** was implemented. Both participants and investigators were blinded to the toothpaste brand allocation. Toothpaste packages were sealed and labelled with codes (A or B) to conceal the identity of the brands.

The randomisation list and group allocation details were maintained by staff members responsible for the randomisation process. Neither the main investigator nor the statistician had access to the allocation sequence, ensuring blinding throughout the study.



Statistical Analysis

All statistical analyses were performed using **SPSS version 21** (SPSS Inc., Chicago, IL, USA). Descriptive statistics were used to summarise quantitative data, expressed as **means** and **standard deviations (SDs)**. The **Shapiro-Wilk test** was conducted to assess the normality of the data.

Intergroup Comparisons:

- **Qualitative parameters** were analysed using the **chi-square test**.
- **Quantitative parameters** were analysed using the **unpaired t-test**.

The confidence interval (CI) was set at **95%**, and the significance level (α) was established at **5%**. The study was designed to achieve a statistical power of **80%**, enabling the detection of significant differences between the two groups.



Results

Rating of the Taste of the Assigned Toothpaste Brand (Table 1)

The taste of the assigned toothpaste was rated significantly higher in **Group A (Pediflor Green Apple)** compared to **Group B (Kids Bunny Strawberry)**. In Group A, **90%** of participants found the taste pleasant, whereas only **66.7%** of participants in Group B rated it as pleasant. None of the participants in Group A rated the taste as unpleasant, while **10%** of participants in Group B rated it as unpleasant. Additionally, a higher percentage of participants in Group B (**23.3%**) rated the taste as neutral compared to Group A (**10%**).

The chi-square test value ($\chi^2 = 8.765$) indicated a statistically significant difference between the groups, with a **p-value of 0.041** ($p < 0.05$). These results suggest that the **Pediflor Green Apple toothpaste** was more favourably accepted in terms of taste.

Table 1: Rating of the taste of the assigned toothpaste brand

Taste	Group A (Pediflor Kidz Green Apple) N (%)	Group B (Kids Bunny Strawberry) N (%)	Chi-square test value	p-value, Significance
Pleasant	27 (90%)	20 (66.7%)	Chi = 8.765	p = 0.041*
Unpleasant	0 (0%)	3 (10%)		
Neutral	3 (10%)	7 (23.3%)		

Child Likes the Colour of Toothpaste (Table 2)

The colour of the toothpaste was liked by a similar proportion of participants in both groups. In **Group A (Pediflor Kidz Green Apple)**, **83.3%** of children liked the colour, compared to **90%** in **Group B (Kids Bunny Strawberry)**. The chi-square test value ($\chi^2 = 0.577$) indicated that the difference was not statistically significant ($p = 0.448$, $p > 0.05$).

These results suggest that both kinds of toothpaste were equally acceptable in terms of colour preference. That colour is not a decisive factor in the overall acceptability of either brand.

Table 2: Child Likes the Colour of Toothpaste

Colour Preference	Group A (Pediflor Kidz Green Apple) N (%)	Group B (Kids Bunny Strawberry) N (%)	Chi-square test value	p-value, Significance
Yes	25 (83.3%)	27 (90%)	Chi = 0.577	p = 0.448 (NS)
No	5 (16.7%)	3 (10%)		

Satisfaction with the Assigned Toothpaste Brand for Oral Care Needs (Table 3)

Participants in **Group A (Pediflor Kidz Green Apple)** demonstrated higher satisfaction levels regarding the toothpaste's ability to meet oral care needs compared to **Group B (Kids Bunny Strawberry)**. In Group A, **73.3%** of participants reported being "very satisfied," whereas only **50%** of participants in Group B reported the same. Conversely, a larger proportion of participants in Group B (**46.7%**) reported being "satisfied," compared to **26.7%** in Group A.

Only **3.3%** of participants in Group B provided a neutral response, and no dissatisfaction was reported in either group. The chi-square test value ($\chi^2 = 3.961$) and p-value ($p = 0.048$, $p < 0.05$) indicated a statistically significant difference in satisfaction levels between the two groups. These results suggest that the **Pediflor Kidz Green Apple toothpaste** was perceived as more effective in meeting children's oral care needs compared to the Kids Bunny Strawberry toothpaste.

Table 3: Satisfaction with the Assigned Toothpaste Brand for Oral Care Needs

Satisfaction Level	Group A (Pediflor kidz Green apple) N (%)	Group B (Kids Bunny Strawberry) N (%)	Chi-square test value	p-value, Significance
Very Satisfied	22 (73.3%)	15 (50%)	Chi = 3.961	p = 0.048* (Significant)
Satisfied	8 (26.7%)	14 (46.7%)		
Neutral	0 (0%)	1 (3.3%)		
Dissatisfied	0 (0%)	0 (0%)		
Very Dissatisfied	0 (0%)	0 (0%)		

Likelihood of Continuing the Assigned Toothpaste Brand After the Study (Graph 1)

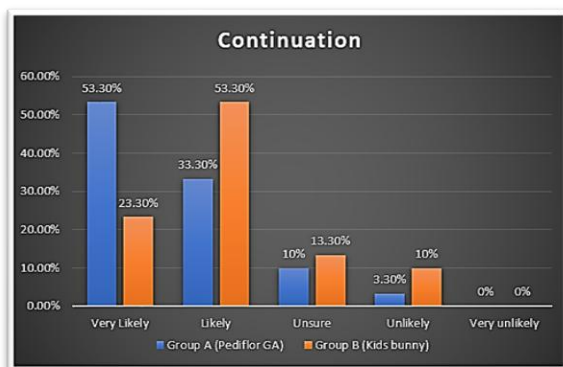
Participants in **Group A (Pediflor Kidz Green Apple)** were more likely to continue using the assigned toothpaste after the study period compared to **Group B (Kids Bunny Strawberry)**.

In Group A, **53.3%** of participants reported being "very likely" to continue, whereas only **23.3%** of participants in Group B reported the same. Conversely, a larger proportion of participants in Group B (**53.3%**) reported being "likely" to continue, compared to **33.3%** in Group A.

A smaller percentage of participants in both groups were unsure, unlikely, or very unlikely to continue using the toothpaste. The chi-square test value ($\chi^2 = 7.981$) and p-value ($p = 0.042$, $p < 0.05$) indicated a statistically significant



difference in the likelihood of continued use between the two groups. These findings reinforce that the **Pediflor Kidz Green Apple toothpaste** was more favorably received by participants, increasing its likelihood of continued use.



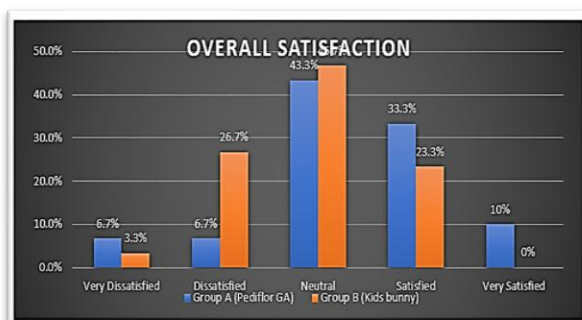
Graph 1: How likely are you to continue using the assigned toothpaste brand for your child after the study period? (p-value- 0.042)

Overall Satisfaction with the Assigned Toothpaste Brand (Graph 2)

Participants in **Group A (Pediflor Kidz Green Apple)** reported higher levels of overall satisfaction compared to those in **Group B (Kids Bunny Strawberry)**. In Group A, **33.3%** of participants were "satisfied," and **10%** were "very satisfied," whereas in Group B, only **23.3%** were "satisfied," and none reported being "very satisfied."

Dissatisfaction levels were higher in Group B, with **26.7%** of participants being "dissatisfied," compared to only **6.7%** in Group A. Neutral responses were relatively similar between the two groups, with **43.3%** in Group A and **46.7%** in Group B.

The chi-square test value ($\chi^2 = 7.578$) and p-value ($p = 0.034$, $p < 0.05$) indicated a statistically significant difference in overall satisfaction between the two groups. These results suggest that the **Pediflor Kidz Green Apple toothpaste** was perceived more positively overall compared to the Kids Bunny Strawberry toothpaste.



Graph 2: On a scale of 1-5, how would you rate your child's overall satisfaction with the assigned toothpaste brand? (p-value- 0.034)

4. Discussion

This study was conducted to compare the acceptability of two pediatric toothpaste brands, **Pediflor Kidz** and **Kids Bunny Strawberry**, in children aged 3–6 years. The comparison focused on taste, colour preference, parental satisfaction with oral care needs, likelihood of continued use, and overall satisfaction. The findings provide valuable insights into the sensory and practical factors influencing toothpaste acceptability, which are critical for promoting adherence to oral hygiene practices in young children.

Taste Preference

Taste is a key determinant of toothpaste acceptability among children, as it directly impacts their willingness to brush regularly.⁸ In this study, **66.7%** of participants rated the taste of Kids Bunny Strawberry as "pleasant," compared to **90%** for

Pediflor Kidz ($p = 0.041$). Importantly, none of the participants in the Pediflor Kidz group rated the taste as unpleasant, whereas **10%** of participants in the Kids Bunny Strawberry group did.

The higher preference for Pediflor Kidz may be attributed to its **sweet green apple flavour**, which is often perceived as enjoyable by children. In contrast, the **strawberry-mint flavour** of Kids Bunny Strawberry may present a more complex or acquired taste, less appealing to younger age groups. These findings align with previous research highlighting the importance of child-friendly flavour profiles in establishing consistent brushing habits.⁹ This suggests that Pediflor Kidz may be more effective in promoting regular oral hygiene behaviours among young children.

Colour Preference

Although less critical than taste, colour can influence a child's initial acceptance of toothpaste.¹⁰ In this study, both toothpastes were similarly accepted in terms of colour preference, with **83.3%** of Group A and **90%** of Group B participants liking the colour ($p = 0.448$). The lack of a statistically significant difference suggests that both toothpastes are visually appealing to children.

These results are consistent with the literature, which notes that bright and vibrant toothpaste colours are generally well-received by younger age groups.¹¹ However, given that colour preference did not differ significantly between the groups, its role in adherence appears secondary to factors such as taste and overall satisfaction.

Satisfaction with Oral Care Needs

Parental satisfaction is a crucial determinant of a



toothpaste's long-term use.¹² In this study, **73.3%** of parents in the Pediflor Kidz group reported being "very satisfied" with the toothpaste's ability to meet oral care needs, compared to **50%** in the Kids Bunny Strawberry group ($p = 0.048$).

The higher satisfaction levels in the Pediflor Kidz group may reflect the combined effect of its favourable taste, ease of use, and perceived effectiveness. These factors have been shown in previous research to enhance parental approval of pediatric oral care products.¹³ The absence of dissatisfaction in either group suggests that both brands meet baseline expectations for oral hygiene. However, Pediflor Kidz appears to exceed these expectations more effectively, contributing to greater satisfaction among parents.

Likelihood of Continued Use

The likelihood of continued use is a critical measure of toothpaste acceptability and long-term adherence.¹⁴ In this study, **53.3%** of participants in the Pediflor Kidz group reported being "very likely" to continue using the toothpaste, compared to only **23.3%** in the Kids Bunny Strawberry group ($p = 0.042$).

This finding underscores the importance of taste and parental satisfaction in influencing adherence. Previous studies have highlighted that children's preferences, when combined with favourable parental perceptions, play a significant role in the selection and continued use of oral hygiene products.^{15,16} Pediflor Kidz's higher likelihood of continued use suggests it is more successful at meeting both sensory and practical expectations, making it a preferred choice for long-term oral care.

Overall Satisfaction

Overall satisfaction ratings further emphasised the superiority of Pediflor Kidz. In Group A, **33.3%** of participants were "satisfied," and **10%** were "very satisfied," compared to **23.3%** and **0%**, respectively, in Group B. Dissatisfaction levels were notably higher in the Kids Bunny Strawberry group (**26.7%**) compared to the Pediflor Kidz group (**6.7%**). Neutral responses were relatively similar between the groups, with **43.3%** in Group A and **46.7%** in Group B.

The chi-square analysis ($p = 0.034$) indicated a statistically significant difference in overall satisfaction between the two groups. These findings suggest that Pediflor Kidz not only meets functional expectations but also exceeds sensory and subjective expectations more effectively than Kids Bunny Strawberry.

Limitations and Future Directions

Despite its strengths, this study has several limitations. The use of convenience sampling may restrict the generalizability of the findings to a broader population. Additionally, the **four-week study duration**, while sufficient for assessing acceptability, may not adequately capture long-term adherence or clinical outcomes.

Future studies should address these limitations by including a larger and more diverse sample size to improve generalizability. Extending the study period would allow for the evaluation of the long-term impact of toothpaste preferences on oral health outcomes. Moreover, future research could explore additional factors, such as **fluoride content, abrasive properties**, and their influence on both acceptability and clinical efficacy. Investigating these parameters would provide a more comprehensive understanding of the role of pediatric toothpaste in oral health care.

Implications for Pediatric Oral Care

The findings of this study have significant implications for pediatric oral care. First, they highlight the importance of sensory factors, such as **taste** and **texture**, in influencing toothpaste acceptability among children.¹⁷ Toothpaste brands that align with children's sensory preferences are more likely to be accepted, promoting regular brushing and improving oral health outcomes.

Second, the study underscores the critical role of **parental perceptions** in determining product adherence. Educating parents about selecting toothpaste based on both **sensory appeal** and **functional effectiveness** could enhance compliance and oral hygiene practices in children.¹⁸ By addressing both child and parent preferences, dental practitioners can make more informed recommendations for pediatric oral hygiene products.

5. Conclusion

This study demonstrated that **Pediflor Kidz Green Apple** was more favourably accepted than **Kids Bunny Strawberry** among children aged 3–6 years, particularly in terms of **taste**, **parental satisfaction**, and the **likelihood of continued use**. These findings highlight the importance of considering **sensory preferences** and **functional effectiveness** when recommending oral hygiene products for children.

By prioritising toothpaste brands that align with children's preferences and parental expectations, dental practitioners can promote better oral hygiene behaviours and improve oral health outcomes in pediatric populations.



Other Consideration

Registration

The trial was registered with the Clinical Trials Registry of India (CTRI) under the registration number **CTRI/2024/10/075062**.

Funding: Not applicable.

Ethics Approval: Not applicable.

Data availability: All data generated or analyzed during this study are included in this published manuscript.

Conflicts of Interest: The authors declare no conflict of interest.

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