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RESEARCH ARTICLE

CLINICAL STUDY ON BABYORGANO TOOTHPASTE: ORAL HEALTH SUPPORT FOR CHILDREN

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ABSTRACT

A single-arm, open-label clinical trial evaluated the efficacy and safety of BabyOrgano toothpaste in 34 children aged 1–7 years over 30 days. Participants used the toothpaste twice daily, with assessments at baseline, day 15, and day 30. Significant reductions were observed in plaque index (23.41% by day 15; 39.79% by day 30) and calculus index (9.40% and 21.57%, respectively). Teeth whiteness improved in 88.23% of participants, and pain sensation decreased, with 97% reporting no pain by day 30. ICDAS scores remained stable, indicating no new carious lesions. No adverse events occurred, and 67.65% preferred the Strawberry flavour. BabyOrgano toothpaste proved safe, well-tolerated, and effective in improving key oral health indicators in children.

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INTRODUCTION

Oral health is integral to general health and essential to well-being and quality of life (1). Using herbal toothpaste for children between 1 to 7 years old is increasingly important due to the challenges posed by modern diets rich in sugars. These diets can contribute to dental issues such as cavities and decay at an early age as well as It can lead to pain, discomfort, and difficulty in maintaining proper nutrition and oral hygiene, contributing to long-term health and developmental issues (2). Herbal toothpastes are beneficial as they often contain natural ingredients which help combat oral bacteria and reduce inflammation in the gums. Furthermore, herbal toothpastes are typically free from artificial colors, flavours, and harsh chemicals, making them gentler on sensitive young teeth and gums (3). Additionally, herbal toothpastes have been shown to offer comparable or superior protection against dental issues compared to conventional toothpastes. Given these benefits, using herbal toothpaste from an early age can promote good dental health and set a foundation for lifelong oral hygiene practices (4). In recent years, there has been growing interest in exploring natural and herbal products for oral health care. This approach aligns with the broader trend towards "green dentistry" and the use of naturally occurring active ingredients in healthcare. Herbal medicines offer the potential for health restoration with minimal harmful effects and maximum efficiency. The use of natural products in oral care represents a comprehensive approach, encompassing both promotive and preventive strategies for health maintenance (5). Natural herbs, used either exclusively or in combination, have shown promise in managing various oral health problems, including halitosis, bleeding gums, mouth ulcers, and dental caries (6). The rising interest in herbal oral care products is reflected in market trends. The "Global Herbal Dentifrices Market Research Report" indicates a significant increase in the sale of herbal dentifrices across various regions worldwide (7). This trend underscores the growing consumer preference for natural alternatives in dental care. The choice of dentifrice plays a crucial role in effective dental plaque removal and oral health maintenance (8). Herbal dentifrices have become a topic of debate in oral health care, driven by their increasing popularity in recent years (9). Natural ingredients such as Azadirachta indica (neem), sanguinarine, propolis, and miswak have been identified as primary components in herbal dentifrices, showing potential in plaque removal, halitosis prevention, and improving gingival health in children and adolescents (10-12). However, the efficacy of herbal dentifrices remains a subject of ongoing research and debate within the dental community. Some studies have reported significant benefits, while others

have found minimal differences compared to conventional products. For instance, Willershausen *et al*. observed a significant reduction in plaque and bleeding indices with the use of herbal dentifrices (13). In contrast, studies by some researchers demonstrated minimal reductions in plaque and gingival indices between groups using herbal and conventional dentifrices (14-17). More specific investigations into particular herbal ingredients have yielded varied results. Jagadish *et al*. conducted a study to determine the effect of *Triphala* on dental bio-films and concluded that *Triphala* had potent antioxidant and antimicrobial activity and inhibited the growth of Streptococcus mutans and gram-positive cocci involved in plaque formation when it was adsorbed on the tooth surface. (18). A systemic review on licorice extracts proves to be effective as an antimicrobial agent by reducing the count of Streptococcus mutans in children. Its action on biofilm limits the fall of pH thereby preventing acidic environment that increases the risk of dental caries (19). However, Saimbi *et al*. have reported that Neem extract had significant and higher antiplaque efficacy as compared to Ayurvedic tooth powder and commercial toothpastes (20). Another RCT by Patel *et al*., comparing the effects of commercially available herbal and non-herbal dentifrices on salivary bacterial counts in children aged 5-10 years, yielded inconclusive results (21). The inconsistency in these findings highlights the need for further rigorous clinical evaluation of herbal oral care products, particularly in pediatric populations. Children represent a vulnerable group in terms of oral health, with high rates of dental caries and unique challenges in maintaining oral hygiene. Moreover, establishing good oral health habits in childhood is crucial for lifelong dental health. The prevalence of oral diseases, their impact on overall health, and the potential benefits of natural ingredients, there is a clear need for comprehensive clinical trials evaluating the effectiveness of herbal dentifrices. This clinical study aims to address this gap by assessing the efficacy of BabyOrgano toothpaste in promoting dental health among children. Specifically, the study was to evaluate its impact on reducing dental caries, gingival inflammation, and plaque formation in pediatric populations.

MATERIAL AND METHODS

The rationale for this clinical study on BabyOrgano toothpaste stems from the urgent need to address the global burden of oral diseases in pediatric populations and explore effective, natural alternatives to conventional oral care products. Oral health is crucial for overall well being, yet dental caries remains a significant public health concern, affecting 60-90% of school-going children in developing countries. The high prevalence of oral diseases, coupled with the substantial economic burden of treatment, underscores the need for accessible and affordable preventive strategies. Conventional approaches to oral disease prevention, such as fluoride use and mechanical plaque control, face implementation challenges, particularly in rural and economically disadvantaged areas. These methods often require consistent application and professional oversight, which may not be feasible for all population. Additionally, while antimicrobial agents like chlorhexidine have shown efficacy, their long-term use is limited by side effects such as tooth staining and potential bacterial resistance. The limitations of current preventive strategies have sparked interest in alternative approaches, particularly those derived from natural sources. Herbal and plant-based oral care products have gained popularity due to their potential for minimal side effects, which are common in many over-the-counter products. By conducting this clinical trial on BabyOrgano toothpaste, we aim to address the gap in knowledge regarding the efficacy of herbal dentifrices in pediatric oral health. The study was to evaluate its ability to reduce dental caries, gingival inflammation, and plaque formation in children, potentially offering a safe, natural, and effective alternative to conventional toothpastes. Furthermore, this research aligns with the current trend towards natural and sustainable healthcare solutions, potentially offering a more acceptable option for parents concerned about the ingredients in conventional children's toothpaste.

Primary Objective: The primary objectives of the study were to assess the efficacy and safety of BabyOrgano toothpaste by evaluating its potential to reduce plaque and alleviate pain sensation.

Secondary Objectives: The secondary objectives of the study were to determine the effectiveness of BabyOrgano toothpaste in teeth whiteness, carious teeth, and calculus index (CI) and evaluating the safety of investigational product via assessment of compliance, tolerability and monitoring of adverse effect profile.

Study design: This was an open-label, single-arm clinical trial to assess the efficacy & safety BabyOrgano toothpaste to promote dental health in children. Treatment duration was of 30 days.

Study groups: This was an open-label, single-arm clinical trial study where 34 participants completed the study.

Allocation of participants in study groups: A total of 34 participants were screened, enrolled, and completed the study without any screen failures or dropouts. Participants used BabyOrgano Toothpaste A for the first 15 days, followed by BabyOrgano Toothpaste B for the subsequent 15 days.

Recruitment Plan: We intended to complete 30 participants at the end of the study. A total of 34 participants were screened, enrolled, and completed the study without any screen failures or dropouts. Data was collected between 21/11/2024 to 30/12/2024. The details are provided in CONSORT fig. 1. Participants providing written informed consent and who were ready to provide regular follow-ups till the completion of the study and meeting the inclusion and exclusion criteria were recruited in the study.

Inclusion Criteria: Male and female children aged 1 to 7 years (both inclusive), whose parents or guardians voluntarily provided written informed consent for their participation in the study and demonstrated the ability to understand and comply with the study procedures were enrolled in the study.

Exclusion Criteria: Participants were excluded from the study if they had known hypersensitivity to any ingredient in the tested toothpastes. Additional exclusion criteria included systemic disorders affecting salivary function or flow, regular use of medications that could alter salivary function or flow, or the need for antibiotic prophylaxis during dental treatments. Participants were also not enrolled if they were involved in another clinical study within the previous three months or had ongoing participation, lacked the intellectual or physical ability

to follow the study protocol, or had any other clinical condition that, in the investigator's judgment, rendered the participant unsuitable for the study.

Study Methodology: This was an open-label, single-arm clinical trial conducted to assess the efficacy and safety of BabyOrgano toothpaste in promoting dental health in children. In this study, potential participants were screened based on inclusion and exclusion criteria, and 34 participants completed the study. Concomitant diseases/medication assessments were performed during screening. Clinical and physical examinations for investigational products were conducted from screening to the end of the study. The treatment plan involved using BabyOrgano toothpaste A for the initial 15 days, followed by BabyOrgano toothpaste B for the subsequent 15 days. Two different flavours were available for both Toothpaste A and B to improve and assess participants' preference towards the flavours. For each brushing session, a pea-sized amount of toothpaste was used. The child's teeth were gently brushed twice daily, once in the morning and once at night after meals, followed by rinsing with clean water. To minimize swallowing, the child was supervised during brushing and rinsing. Changes in plaque index score, pain sensation in response to tactile stimulus (Wong-Baker FACES pain rating scale), calculus index (CI) and dentist-reported visual teeth whiteness assessment scores were evaluated from baseline to the end of the study. Changes in caries status using The International Caries Detection and Assessment System (ICDAS) were evaluated at baseline and the end of the study. Treatment compliance and tolerability of the study intervention were assessed at visit 2 and visit 3. Adverse events (AEs) and serious adverse events (SAEs) were assessed throughout the study.

Product Study Profile

Composition along with the content details is expressed in the table 1 below.

Table 1. Active ingredients of BabyOrgano toothpaste

SN	Name of the Ingredient	Composition
1	*Triphala* extract	0.125 % w/w
2	Yastimadhu extract	0.125 % w/w
3	Khadir extract	0.125 % w/w
4	*Lodhra* extract	0.125 % w/w
5	Neem extract	0.25 % w/w
Other Ingredients		
1	Menthol	0.4 % w/w
2	Clove oil	0.2 % w/w
3	Calcium carbonate	30.00 % w/w
4	Hydrated silica	10.00 % w/w
5	Glycerine	5.00 % w/w
6	Sorbitol	35.00 % w/w
7	Coco glucoside	3 % w/w
8	Propylene glycol	1.00 % w/w
9	Sodium CMC	1.00 % w/w
10	Xanthan gum	1.50 % w/w
11	Sodium saccharine	0.50 % w/w
12	Sodium benzoate	0.50 % w/w
13	Perfume: Strawberry / Mango	0.5 % w/w
14	DM water	QS

Dosage and Duration of the Treatment: A pea-sized amount of toothpaste was being advised to use, gently brush participants teeth twice a day in the morning and at night after meals then rinse with clean water for 30 days. Parents were advised to supervise child's brushing and rinsing to minimize swallowing.

Study Visits/Follow-Ups

Following is the study visit schedule for the participants

- Screening Visit
- Baseline Visit (-7 to day 0) within 7 days from screening
- Follow-up Visit 1: Randomization (Day 1)
- Follow-up Visit 2: Day 15 ± 2 days
- Follow-up Visit 3: Day 30 ± 2 days (End of the study)

STUDY ASSESSMENT

Primary efficacy assessment: The primary efficacy assessment was done by evaluating changes Plaque score index from baseline to end of the study and assessment of changes in pain sensation in response to tactile stimulus (Wong-Baker FACES pain rating scale) from baseline to end of the study.

Secondary efficacy assessment: The secondary efficacy assessment was done by evaluating changes in calculus index from baseline to end of the study, assessment in changes in dentist-reported visual teeth whiteness and changes in caries status using The International Caries Detection and Assessment System (ICDAS) at baseline and end of the study.

Safety efficacy assessment: Safety in terms of adverse events, compliance and tolerability (for participants as per the discretion of the investigator) was also evaluated.

Statistical methods: Continuous variable i.e., age was summarized overall using summary statistics i.e. the number of observations, mean and standard deviation with 95% CI (among normal distribution) analyzed by student t-test and gender was analyzed using chi-square test. In this study, weight, height, BMI was represented in mean ± S.D.

Study Participants

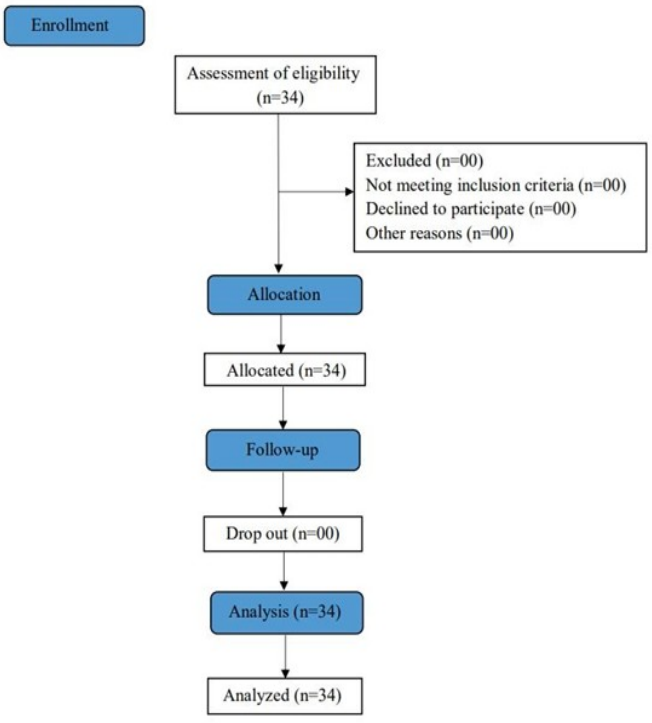

Figure 1. CONSORT diagram for the study

RESULT AND OBSERVATIONS

Assessment of demographics: A total of 34 male and female participants were enrolled in the study, and each participants successfully completed the study, as depicted in figure 1. of these,14 males and 20 females were considered evaluable for further analysis. The average age for males was 5.07 ± 2.09 years, while for females, it was 4.35 ± 2.13 years. The following Table 2 represents the demographic details. In gender distribution and age, there were comparatively higher number of females than males in the study groups.

Table 2: Demographic details

Demographic details				
Group	Male	Age (years)	Female	Age (years)
Test	14	5.07± 2.098	20	4.35±2.13

Age data is represented as Mean ± S.D. Male and female data is represented as number of participants.

Assessment of anthropometric parameters: The assessment of anthropometry refers to the measurement and analysis of the physical characteristics of the human body. Table 3 represents anthropometric measurements for study groups. The anthropometric screening showed that the average weight was 15.32 ± 4.22 kg. The average height was 98.64 ± 14.06 cm for males and 95.53 ± 12.21 cm for females, with an overall average of 96.81 ± 12.89 cm.

Table 3. Assessment of anthropometric parameters

Assessment of Anthropometric Parameters		
Screening		
Gender	Male	Female
Weight (kg)	15.36 ± 4.14	15.29 ± 4.37
Total weight (kg)	15.32 ± 4.22	
Height (cm)	98.64 ± 14.06	95.53 ± 12.21
Total height (cm)	96.81 ± 12.89	

Data is represented as Mean ± S.D.

Assessment of plaque index: The Plaque Index is a dental health scale used to measure the thickness of dental plaque on teeth, evaluating oral hygiene and the effectiveness of interventions such as brushing techniques or treatments. Scores range from 0 to 5, with 0 indicating no plaque, 1 indicating separate flecks of plaque at the tooth margin, 2 representing thin continuous bands covering up to one-third of the tooth surface, 3 for plaque covering one-third of the tooth, 4 for plaque covering up to half of the tooth, and 5 for plaque covering two-thirds of the tooth.

Higher scores indicate greater plaque accumulation and poorer oral hygiene, while lower scores reflect better oral hygiene. The plaque index demonstrated a marked, and gradual improvement, with a 23.41% reduction by day 15 and a further decline to 39.79% by day 30, both showing statistically significant changes, highlighting the effectiveness of the treatment over the study period. Table 4 shows the Plaque index score of the study participants.

Table 4: Assessment of Plaque Index

Parameter	Baseline	Day 15	P value	Day 30	P value
Plaque Index	2.28± 0.47	1.75 ± 0.45 (23.41 %)	< 0.001	1.37 ± 0.32 (39.79 %)	< 0.001

Data is represented as Mean ± S.D (percent change) The data was analyzed by using Student T test dependent means. Significant at p value

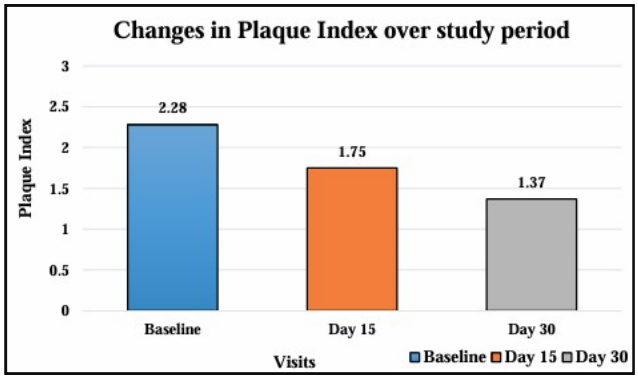

Figure 2. Assessment of changes in Plaque Index over study period

Assessment of dentist-reported visual carious teeth by using International Caries Detection and Assessment System: The International Caries Detection and Assessment System (ICDAS) is used to evaluate dentist-reported visual carious teeth, providing a comprehensive assessment of caries severity. Scores range from 0 to 6, with higher scores signify greater caries severity, while lower scores indicate healthier tooth surfaces. From baseline to day 30, 25 participants consistently had healthy tooth surfaces (score 0). Additionally, 3 participants exhibited slight enamel changes (score 1), one participant had visible enamel changes (score 2), two participants had enamel breakdown without visible dentine (score 3), another two participants had a dark shadow from dentine without enamel break (score 4), and 1 participant had a cavity exposing dentine (score 5). After 30 days of treatment, the ICDAS scores showed no significant change in the caries status of participants. The distribution of scores remained consistent from baseline to Day 30, with the same number of participants in each score category. This suggests that the tested toothpaste-maintained enamel health or did not progressed caries. Data is depicted in Table 5.

Table 5. Assessment of dentist-reported visual carious teeth using ICDAS score

ICDAS Score	Baseline	Day 30
0= Sound tooth surface	**25**	**25**
1= First visual change in enamel	**3**	**3**
2= Distinct visual change in enamel	**1**	**1**
3=Localized enamel breakdown due to caries with no visible dentine	**2**	**2**
4= Underlying dark shadow from dentine (with or without enamel breakdown)	**2**	**2**
5= Distinct cavity with visible dentine	**1**	**1**
6= Extensive distinct cavity with visible dentine	**0**	**0**

Data is represented as number of participants

Assessment of calculus by using calculus index (CI): The calculus index assesses the amount of dental calculus on tooth surfaces, with scores as follows: 0 (no calculus), 1 (supragingival calculus covering up to 1/3 of the exposed tooth surface), 2 (supragingival calculus covering more than 1/3 but not more than 2/3, or presence of subgingival flecks), and 3 (supragingival calculus covering more than 2/3 or a continuous heavy band of subgingival calculus). The CI score is calculated by dividing the total calculus score by the number of affected teeth. The interpretation of the CI score is as follows: 0.0– 0.6 (Good), 0.7–1.8 (Fair), and 1.9–3.0 (Poor). In a study as mentioned in Table 6 and Figure No. 3, the baseline CI score was 1.59 ±0.86, categorized as "Fair." At day 15, the CI score

slightly improved showing a 9.40% reduction in calculus, with a P value of (0.003), indicating statistical significance. By day 30, the CI score further decreased, representing a 21.57% reduction denoting high statistical significance.

Table 6. Assessment of calculus using the calculus index

Parameter	Baseline	Day 15	P value	Day 30	P value
Calculus Index	1.59 ± 0.86	1.44 ± 0.78 (9.40 %)	0.003	1.25 ± 0.71 (21.57 %)	< 0.001

Data is represented as Mean ± S.D (percent change).The data was analyzed for within group by using Wilcoxon Signed-Rank Test. Significant at p value <0.05.

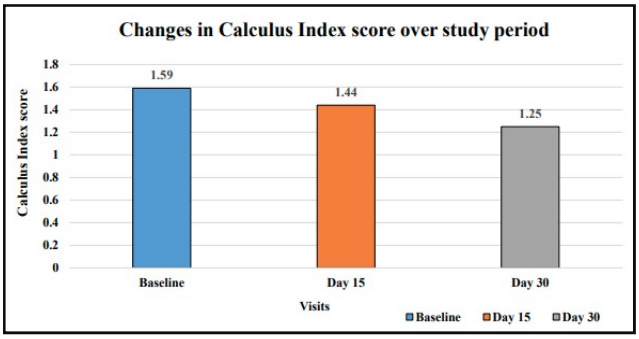

Figure 3. Assessment of changes in calculus index score over study period

Assessment of Visual Teeth Whiteness: The scale used to measure teeth whiteness by using the Vitapan Classic Shade Guide. The grade was assigned based on the following criteria to determine tooth color using the Vitapan Classic Shade Guide: A1 - A4 (reddish-brownish); B1 - B4 (reddish-yellowish); C1 - C4 (gray tones); D2 - D4 (reddish-gray). At screening, one participant was classified as A1, and three participants were in the B1 category. By Day 15, 55.88% of participants (19 subjects) demonstrated an improvement of one grade in teeth whiteness, with no participants achieving a two-grade improvement. By Day 30, 58.82% of participants (20 subjects) showed a one-grade improvement, and 29.41% (10 subjects) exhibited a two-grade improvement in teeth whiteness. These findings suggest progressive enhancement in teeth whiteness over the study period, with significant improvement observed by Day 30 (Table 7).

Table 7. Assessment of improvement in the teeth whiteness

Visit	Improvement by Grade 1	Improvement by Grade 2
Day 15	19 subjects (55.88%)	0 subjects
Day 30	20 subjects (58.82%)	10 subjects (29.41%)

Data is represented as number of participants (%).

Assessment of changes in pain sensation of Tactile stimulus by using WongBaker FACES pain rating scale: For the tactile stimulus, the dental probe was used. The Wong-Baker FACES pain rating scale is used to assess pain in children by having them choose from a series of faces ranging from a very happy face (score 0) indicating no pain to a very sad face (score 5) indicating severe pain.

According to the results presented in Table 8, the assessment of changes in pain sensation for 34 participants showed that at baseline, 29 participants reported no pain, two reported slight pain, and 3 reported moderate pain. By day 15, thirty-one participants reported no pain, three reported slight pain. By day 30, 33 participants reported no pain and only one reported slight pain. The results show that the majority of participants reported no pain even at baseline, with incremental improvement observed by Days 15 and 30. The reduction in the number of participants reporting slight and moderate pain suggests a potential role of the investigational product in alleviating minor pain perception over time.

Table 8. Assessment of changes in pain sensation on WBFS score using Tactile stimulus

WBFS Score	Baseline	Day 15	Day 30
0= No hurt	29	31	33
1=hurts a little more	02	03	01
2=hurts even more	03	00	00
3=hurts even more	00	00	00
4=hurts a whole lot	00	00	00
5=hurts worst	00	00	00

Data is represented as number of participants.

Assessment of compliance: The compliance rate was 99.56% at day 15 and improved slightly to 99.61% by Day 30. This consistently high compliance rate indicates that the children favored the toothpaste, demonstrating its acceptability and ease of use throughout the study period.

Assessment of tolerability: Tolerability was scored as following- where, 0- Poor Tolerability: Severe or serious adverse event(s) which necessitated stoppage of study; 1- Fair Tolerability: Moderate to severe adverse event(s) reported which subsided with or without investigational product and did not necessitate stoppage of investigational product; 2- Good Tolerability: Mild adverse events (s) reported which subsided with or without medication; 3- Excellent Tolerability. All participants reported excellent tolerability to the both toothpaste A and B.

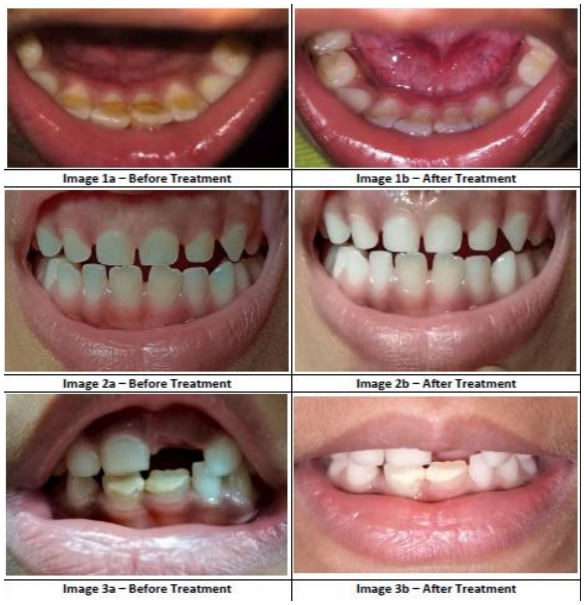

Figure 4. Before and After Images of Children's Teeth Showing Improvement in- i) Plaque: Image 1a &1b shows children's Teeth Showing Plaque reduction after treatment; ii) Teeth Whiteness: Image 2a &2b shows children's Teeth Whiteness improvement; iii) Calculus: Image 3a &3b shows children's Teeth Showing Calculus reduction after treatment

Assessment of Adverse events: Adverse events were documented through patients' self-reports or clinical examinations. Importantly, no adverse events were observed during the 30-days study intervention use.

Visual assessment of dental improvements in children: The representative images below in Figure 4 depict the improvement in plaque, teeth whiteness, and calculus on children's teeth before and after the study period.

DISCUSSION

This was a single-arm, open-label pilot study; conducted among 34 pediatric participants to evaluate oral health outcomes. The primary endpoint, a reduction in the Plaque Index, showed a significant decrease of 23.41% by Day 15 and 39.79% by Day 30, highlighting the treatment's effectiveness in reducing plaque accumulation. There was a 21.57% reduction in the Calculus Index, progressive improvement in teeth whiteness (20 participants improved by Grade 1 and 10 by Grade 2 by Day 30), and stable dental caries status, as 25 participants maintained healthy tooth surfaces throughout the study. Pain levels, assessed using the Wong-Baker FACES scale using tactile stimulus, improved notably, with 33 participants reporting no pain by Day 30 compared to 29 at baseline. The intervention was well-tolerated, with no adverse effects reported, and the toothpaste A was preferred by the majority (67.65%). High compliance was also reported. These findings emphasize the efficacy and safety of the treatment in improving pediatric oral health, addressing both hygiene and comfort, with further studies recommended to validate these outcomes over longer periods. The present study demonstrated significant oral health improvements in 34 children over 30 days, supporting previous research on *Triphala*'s effectiveness in dentistry. Teeth whitening improved in 30 participants, which, although not directly attributed to *Triphala*, may be linked to its plaque-reducing effects. Dental caries remained stable, reinforcing *Triphala*'s protective role against enamel demineralization and caries, as observed in earlier studies. Pain reduction, with most participants reporting no pain by the study's end, supports *Triphala*'s anti-inflammatory and healing properties. These findings confirm the safety and efficacy of *Triphala* in improving oral health, consistent with literature (22).

Studies demonstrate that Neem effectively reduces plaque and bacterial growth, particularly targeting Streptococcus mutans, a primary contributor to dental caries. Its antimicrobial properties, as evidenced by a nearly 40% reduction in plaque over 30 days in the current study, highlight its role in preventing plaque formation. Neem's anti-inflammatory effects also alleviate gingival inflammation and discomfort, contributing to improved pain levels. Additionally, Neem supports teeth whitening and reduces calculus, further enhancing oral health. Its traditional use in Ayurvedic medicine for treating gingivitis and plaque is reinforced by its potential as a root canal irritant and in preventing periodontal diseases. Neem's inclusion in the current product provides a natural, effective solution with minimal side effects, improving oral hygiene and health. Neem effectively reduces plaque and bacterial growth, especially targeting Streptococcus mutans, a key cause of dental caries. The study's approximately 40% reduction in plaque over 30 days highlights its plaque-preventing properties. Its anti-inflammatory effects alleviate gingival discomfort, while also promoting teeth whitening and reducing calculus. Neem's traditional use in Ayurvedic medicine for gingivitis and plaque is supported by its potential in root canal irrigation and preventing periodontal diseases (23). *Yasthimadhu (Glycyrrhiza glabra)*, known for its antimicrobial, anti-inflammatory, and wound-healing properties, was a key ingredient in the study. Its active compounds, such as glycyrrhizin and flavonoids, effectively combat oral pathogens like S. mutans, reduce plaque, and alleviate gum inflammation. These findings align with the study results, where Yasthimadhu, combined with honey, significantly reduced plaque, gum irritation, and teething discomfort. The sweet taste of *Yasthimadhu* also improved compliance, making it a practical choice for pediatric dental care. This study reinforces the potential of *Yasthimadhu* as a natural, safe alternative to conventional dental products (24).
Lodhra (*Symplocos racemosa*), with its styptic, antibacterial, anti-inflammatory, and woundhealing properties, was also effective in treating dental conditions. The study's findings, which showed significant reductions in plaque and calculus, are consistent with *Lodhra*'s ability to combat oral bacteria through compounds like tannins and alkaloids (e.g., loturine and loturidine). Additionally, the observed improvements in teeth whiteness and pain relief support *Lodhra*'s role in strengthening gum tissue, preventing bleeding gums, and aiding in the healing of oral wounds. Both *Lodhra* and this study emphasize the effectiveness of natural solutions in improving oral health and comfort (25).

The findings of this study align with previous research on Ayurvedic herbs in oral health. Studies on Khadir (*Acacia catechu*) highlight its antimicrobial efficacy against periodontal pathogens like Porphyromonas gingivalis and Aggregatibacter actinomycetemcomitans, reinforcing its role in oral hygiene. Similarly, research on *Yasthimadhu (Glycyrrhiza glabra)* and Nadihingu has demonstrated significant antibacterial, anti-inflammatory, and soothing effects, supporting their use in pediatric dental care (26). The synergistic action of these Ayurvedic components, particularly their combined antimicrobial, plaque-reducing, and anti-inflammatory properties, likely contributed to the improvements observed in plaque reduction, gum health, and overall oral hygiene in this study. This study's strength lies in the use of child-friendly assessment tools, such as the WongBaker FACES Pain Rating Scale, which ensured that pain evaluation was appropriate for young participants, enhancing the reliability of subjective outcomes. Additionally, the inclusion of validated indices like the International Caries Detection and Assessment System (ICDAS) adds scientific rigor, ensuring that oral health outcomes are systematically and accurately measured. However, certain limitations should be acknowledged. The single-arm design limits direct comparison with standard treatments or placebos, and the short study duration may not capture long-term effects. Additionally, the small sample size and limited age range restrict the generalizability of findings to a broader pediatric population.
Despite, this study provides valuable insights into the effectiveness of BabyOrgano toothpaste in reducing plaque, relieving pain, and improving teeth whiteness. As a natural, herbal alternative to conventional products, it offers a safe and child-friendly solution for pediatric oral care, with the added advantage of enhanced compliance due to its appealing taste. Future research should explore its long-term benefits, broader applications, and underlying mechanisms, potentially through randomized controlled trials with larger and more diverse

populations. In conclusion, this study reaffirms the potential of Ayurvedic herbal formulations in pediatric oral health, demonstrating their efficacy in maintaining oral hygiene and reducing discomfort. By leveraging the synergistic effects of multiple bioactive herbal components, BabyOrgano toothpaste presents a promising natural alternative for improving children's dental health.

CONCLUSION

In this clinically demonstrated study, 14 of participants were male, and 20 were females. The study recorded an overall average weight of 15.32 ± 4.22 kg and an average height of 96.81 ± 12.89 cm. This study demonstrated the effectiveness and safety of BabyOrgano toothpastes in improving various oral health parameters in children.

- A significant reduction of 23.41% in the plaque index was observed by day 15, and by day 30 the Plaque Index further reduced by 39.79% indicating the effectiveness of the intervention.
- The findings indicate a significant improvement in the Calculus Index over time, demonstrating the intervention's effectiveness in reducing dental calculus with sustained statistical significance.
- Dentist-reported ICDAS assessment confirmed that ICDAS scores remained stable from baseline to Day 30, indicating that the toothpaste helped maintain enamel health and prevented caries progression.
- Teeth whiteness assessment showed progressive improvement, with 19 participants exhibiting improvement by one grade Day 15, increasing to 20 participants by Day 30. Additionally, 10 participants achieved improvement in teeth whiteness by two grades at day 30.
- Pain sensation evaluation using the Wong-Baker FACES Scale indicated a notable reduction in discomfort. At baseline, 29 participants reported no pain (score 0), increasing to 33 participants by Day 30, highlighting significant pain relief.
- Product compliance was excellent, with compliance rates reaching 99.56% by Day 15 and 99.61% by Day 30.
- Importantly excellent tolerability was observed, with no adverse events reported during the study.
- By leveraging the synergistic effects of multiple bioactive herbal components in toothpaste, notable improvement in plaque index, teeth whiteness and calculus index, along with a slight reduction in pain sensation was observed. These findings support BabyOrgano toothpaste as a safe, well-tolerated, and effective herbal alternative for maintaining children's oral health.

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