

**REVOLUTIONIZING ORAL CARE: CLINICAL VALIDATION OF A LIQUID  
TOOTHPASTE FOR PLAQUE AND GINGIVITIS MANAGEMENT****Dr. Gayatri Ganu<sup>1\*</sup>, Dr. Rajlaxmi Patil<sup>2</sup> and Dr. Dheeraj Nagore<sup>3</sup>**<sup>1</sup>Director, Mprex Healthcare Pvt. Ltd. Office Number 501, 514 Crossroads, Bhumkar Square, Wakad, Pune.<sup>2</sup>Consulting Dentist, Shree Samarth Multi-Specialty Hospital, 2nd Floor, Kate square building, Pimple Gurav. Pune, Maharashtra, India.<sup>3</sup>Assistant Professor, DY Patil Institute of Pharmaceutical Sciences & Research, Sant Tukaram Nagar, Pimpri, Pune 411018.**\*Corresponding Author: Dr. Gayatri Ganu**

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**ABSTRACT**

**Introduction:** Maintaining oral hygiene requires regular brushing and flossing to keep the mouth free from microbes. Factors like poor dental care, smoking, crash dieting, and acidic foods contribute to dental problems. Promptly addressing even minor issues is crucial. Many times, toothpaste and brushes may insufficient for effective oral care. The objective of the clinical trial was to assess the effectiveness of Zugu Oral Rinse Liquid Toothpaste as an alternative to traditional toothpaste in oral hygiene. **Materials & Methods:** A total of 60 subjects were enrolled based on inclusion and exclusion criteria. Gingivitis, plaque, and gingival bleeding were assessed using a modified gingival index, plaque index, and modified sulcular bleeding index, respectively. The visual teeth whiteness was assessed using the Vitapan Classic Shade Guide and visual carious teeth using ICDAS (International Caries Detection and Assessment System). The participant's oral hygiene satisfaction was also recorded. **Results:** The findings demonstrate that Zugu Oral Rinse Liquid Toothpaste resolves the patient's complaints such as lack of freshness & bad breath and Intermittent gum pain (90%). Significant reduction in plaque (24.91%), gingivitis (61.76%), gingival bleeding (44.08%), malodor (100%), and improvement in freshness (100%). The majority of subjects agree that Zugu Oral Rinse Liquid Toothpaste has the potential to replace traditional toothpaste and brushing. The product's tolerability remained excellent with no adverse events. **Conclusion:** Zugu Oral Rinse Liquid Toothpaste is a two-in-one toothpaste plus mouthwash combination. The product demonstrated effectiveness in resolving malodor, reducing plaque, gingivitis, and gingival bleeding, along with enhancing freshness alleviating intermittent pain, and enhancing teeth whiteness. Importantly, the formulation exhibited excellent safety, with no adverse events observed and consistent tolerability throughout the study. The subjects' high satisfaction rates and agreement on the potential of Zugu Oral Rinse Liquid Toothpaste as an alternative to regular toothpaste further emphasize its consumer appeal.

**KEYWORDS:** plaque, gingivitis, gingival bleeding, liquid toothpaste, malodor, freshness.**INTRODUCTION**

Oral hygiene is the practice of keeping your mouth clean and free of microbes and other problems through regular brushing and flossing. Maintaining good oral hygiene regularly is essential to prevent the development of dental diseases. Approximately 3.5 billion people worldwide are affected by oral diseases, with three out of four of those suffering from oral diseases living in middle-income countries, according to the WHO Global Oral Health Status Report for 2022. There are approximately 2 billion people globally suffering from caries of permanent teeth, and 514 million children suffering from primary tooth decay.<sup>[1]</sup> A poor dental hygiene regimen may also result in tooth decay,

infection, or loss. Several factors contribute to bad dental hygiene, including poor dental hygiene, smoking, chewing tobacco, being on a crash diet, and consuming strong acidic foods and beverages.<sup>[1,2]</sup> It is important to take care of dental problems such as dental caries, dental plaque, bad breath, gingivitis, gingival bleeding, tooth sensitivity, etc. even if they seem to be minor. Dental caries refers to the localized destruction of dental hard tissues caused by acidic by-products of bacterial fermentation of dietary carbohydrates.<sup>[3,4]</sup>

Plaque is formed when bacteria present in the mouth combine with food remnants and acid. A sticky film of bacteria is constantly produced on teeth and is known as

dental plaque. Plaque formation is primarily caused by poor oral hygiene and inadequate brushing. Plaque on the teeth may cause cavities, gingivitis, and periodontal disease.<sup>[4,5]</sup> Gingivitis is a serious dental condition. Periodontitis is the earliest stage of gum disease; it is an inflammation of the tissues surrounding and supporting the teeth, which is caused most commonly by poor dental hygiene. Various factors may contribute to gingivitis, including plaque, smoking, chewing tobacco, crooked or rotated teeth, metabolic diseases, stress, poor saliva production, etc.<sup>[6,7]</sup>

Gingival bleeding refers to bleeding from the gums on any mild trauma. The condition is caused by plaque accumulation, tobacco consumption, vitamin deficiency, and stress. An infection of the gingiva or jawbone may lead to abscesses, periodontitis, mouth trenches, recurrent gingivitis, etc.<sup>[8]</sup> Tooth sensitivity is a discomfort or pain when certain substances or temperatures are encountered. It may be caused by brushing too hard or using a toothbrush with a hard bristle. It may also occur as a result of gum recession, cracked teeth, plaque build-up, and a diet high in acidic foods.<sup>[9,10]</sup>

By practicing good oral hygiene, such as brushing and flossing daily, dental problems can be prevented. In the treatment of various dental problems, antimicrobial agents can be embedded in personal care formulations such as toothpaste, mouthwashes, and oral mouthwashes. These help reduce the bacterial count, enhance the freshness, and maintain the pH of the mouth. Similarly, brushing and flossing are important for maintaining oral hygiene, but they are not very effective in the treatment of malodor. Therefore, after long-term use of conventional medicines, people tend to turn to alternative treatments such as herbal and Ayurveda therapies.<sup>[10,11]</sup>

Poor oral hygiene can significantly affect a person's professional, psychological, and social life. Oral health may affect the level of self-esteem which may further affect the mental health and Quality of life of an individual. Conventional oral care formulations consume more time, require routine care, and simultaneously use multiple products for oral care at a time which reduces the compliance of individuals. By assessing the need for strong alternatives in the management of oral hygiene and dental health, the innovative formulation of Zugu Oral Rinse Liquid Toothpaste is developed. Zugu provides convenience and saves precious time and effort for individuals with busy lifestyles by effectively cleansing the oral cavity, and eliminating harmful bacteria, plaque, and volatile sulfur compounds responsible for bad breath. This innovative approach eliminates the need for brushing and flossing, making it particularly appealing for those who struggle with manual dexterity or have difficulty adhering to a rigorous oral hygiene routine.

## MATERIALS AND METHODS

### Study Design

This was an open-label, single-arm clinical trial which included 60 subjects, both male and female, was conducted to evaluate the antiplaque and antigingivitis efficacy of Zugu Oral Rinse Liquid Toothpaste as an alternative to conventional toothpaste. The duration of the treatment was 30 days. Ethical approval was obtained from the Institutional Ethics Committee (IEC) of Lokmanya Medical Research Centre, Chinchwad. The clinical trial was registered with the Clinical Trial Registry-India (CTRI) with the registration number **CTRI/2023/08/056390 on August 10, 2023**. Clinical trial data was collected between Sep 2023 to Oct 2023.

**Investigational Product Composition:** Sodium Monofluoro Phosphate (0.05-0.1%), Sorbitol (19-20%), Calcium Carbonate (4-5%), Sodium Metasilicate (2-2.5%), Sodium Bicarbonate (1-1.5%), Zinc Citrate (0.5-1%), Sodium Lauryl Sulphate (0.35-0.5%), Potassium Nitrate (0.2-0.4%), Tetra Sodium Pyrophosphate (0.2-0.4%), Hydrogen Peroxide (0.05-0.1%), Arginine (0.1-0.15%), Mentha Piperita Herb Oil (0.1-0.2%) etc.

**The uniqueness of the product:** The product is a thick liquid to be swished in the mouth. It has unique particle technology making a cleansing process comparable to the brushing.

**Dosage and Duration of the Treatment:** Use 8 to 10 ml of Zugu Oral Rinse Liquid Toothpaste in the morning and evening, swish in mouth thoroughly for one minute, expel out and rinse mouth with water. The duration of the treatment was 30 days.

### Study Schedule

The duration of the study was 30 days. Screening visit (Within -7 days prior to Day 1); First visit - Baseline/ Enrollment Day (Day 1); Second visit- Evaluation Phase (Day 15  $\pm$  2 days); Third visit- End of the Study (Day 30  $\pm$  2 days).

### Inclusion Criteria

Subjects in the study, between the age range from 18 to 55 years (both inclusive) at the time of consent, included healthy males and non-pregnant/non-lactating females. Females of childbearing potential underwent a screening process, including a negative urine pregnancy test. Subjects in good general health, as determined by the Investigator based and medical history were included in the study. Individuals with clinically relevant mouth malodor detected by a Halimeter, as well as those with mild to moderate plaque (plaque index 2-4) and mild to moderate gingivitis (modified gingival index 0.1-0.3) were included in the study. Subjects willing to visit the study site without brushing their teeth in the morning for visit 1, visit 2, and visit 3, and to stay at the study center for 6 hours during these visits were included in the study. Additionally, subjects committed to abstaining from consuming anything except water after the meal of the

previous night before visiting the study site for were included in the study. Subjects able to understand & provide written informed consent and expressed willingness & ability to follow the study directions throughout their participation were considered for the inclusion in the study.

### Exclusion Criteria

Subjects with orthodontic bands, partial removable dentures, or tumors of the soft or hard tissues of the oral cavity were not included in the study. Subjects with plaque indices of 0, 1 and 5, advanced periodontal disease, history of drug-induced tooth discoloration were also excluded. Subjects requiring immediate restorative treatment for carious lesions, those undergoing ongoing antibiotic treatment, and those who had participated in any other dental clinical study within the last six months prior to the study entry were excluded from the study. Additionally, individuals who had undergone dental prophylaxis in the two weeks preceding baseline examinations, had allergies to oral care/personal care consumer products or their ingredients, were on prescription medicines that could interfere with the study outcome, or were pregnant/lactating were excluded. Subjects habitually consuming medicated sweets, chewing gum, breath fresheners, etc., containing antimicrobial agents, and those with diseases or a history potentially contributing to oral malodor (e.g., diabetes mellitus, bronchitis, tonsillitis, sinusitis, etc.) were not considered. Furthermore, individuals with habits of consuming alcohol, tobacco, and smoking cigarettes were also excluded from the study.

### METHODOLOGY

Assessments of physical, clinical, and dental examinations were done throughout the study. The evaluation of demographic details, concomitant diseases, and concomitant medication were assessed during screening.

Gingivitis reduction, plaque reduction, and gingival bleeding were assessed using a modified gingival index, plaque index, and modified sulcular bleeding index, respectively, visual teeth whiteness using the Vitapan Classic Shade Guide and visual carious teeth using ICDAS (International Caries Detection and Assessment System) at both screening and end of the study.

Assessment of malodor control using a halimeter, and freshness scores reported by subjects on a 5-point scale were done from screening to the end of the study. The potential of Zugu Oral Rinse Liquid Toothpaste as an alternative to toothpaste was evaluated on a 4-point Linkert scale by investigators and subjects at day 15 and end of the study. Additionally, subject satisfaction toward the study intervention was recorded daily through provided subject diaries, allowing for tooth brushing if dissatisfaction arose. Oral hygiene instructions were provided at the initial visit, describing do's and don'ts. The study also monitored treatment compliance and tolerability, adverse events, and serious adverse events from baseline to the study's completion (Figure 1).

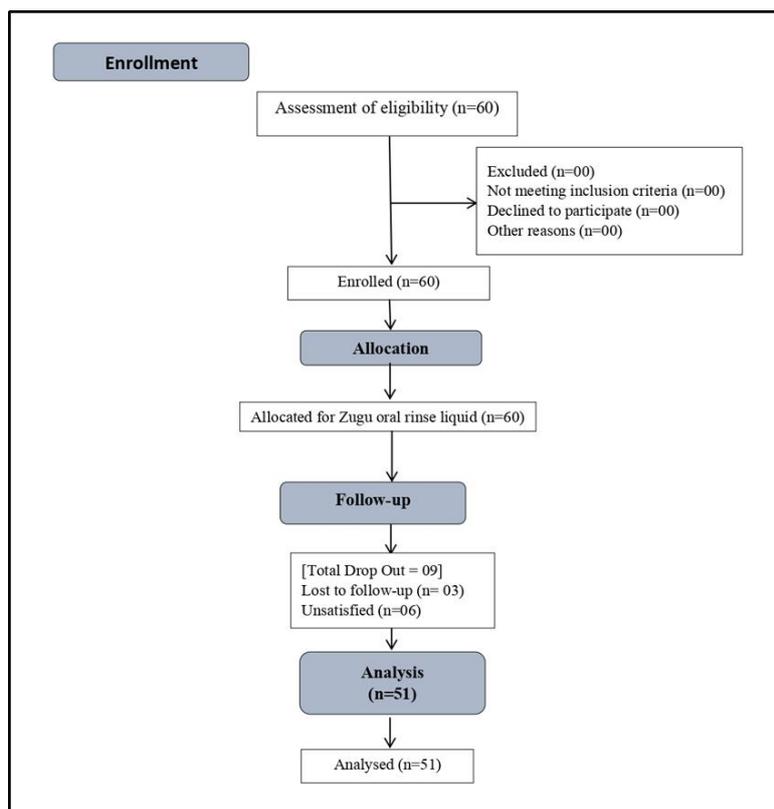


Figure 1: CONSORT diagram for the study.

### Statistical analysis

Statistical analysis has been done by using SPSS version 10.0. The primary and secondary endpoints were analyzed using a student t-test, Wilcoxon sign rank test, and one-way ANOVA. The p-values  $\leq 0.05$  were considered statistically significant.

## RESULT

### Demographic characteristics

In this study, a total of 60 male and female subjects were initially enrolled, with 51 completing the study. Nine

subjects dropped out: six discontinued participation due to dissatisfaction with Zugu Oral Rinse Liquid Toothpaste (three on day 15 and three on day 30), and an additional three were lost to follow-up during the day 30 visit as depicted in Figure 1.

Of the participants, 21 were male and 30 were female. The average age among male subjects was  $34.6 \pm 6.0$  years, while among female subjects, it was  $31.9 \pm 9.97$  years. The details are presented in [Table 1].

**Table 1: Demographic details.**

Parameters	No. of Subjects	Average $\pm$ S.D. in years
Male	21	$34.6 \pm 6.0$
Female	30	$31.9 \pm 9.97$
Total	51	-
Average $\pm$ S.D. in years	$33 \pm 8.6$	-
Anthropometric Parameters (n=51)		
Weight (Kg)		$61.94 \pm 9.34$
Height (cm)		$162.47 \pm 8.20$

### Assessment of anthropometric details and lifestyle habits

In the current study, subjects exhibited an initial body weight of  $61.94 \pm 9.34$  and a height of  $162.47 \pm 8.20$ . Furthermore, no lifestyle habits, including alcohol consumption and smoking, were reported by any of the participants [Table 1].

### Assessment of presenting complaint

In this investigation, 51 subjects were examined. Among them, 38 individuals initially presented with a complaint of halitosis (malodor) during the screening. Notably, this concern was entirely alleviated (100% resolution)

following the utilization of Zugu Oral Rinse Liquid Toothpaste. Similarly, 26 subjects reported a lack of freshness, and this issue was completely resolved (100%) with the use of Zugu Oral Rinse Liquid Toothpaste.

Conversely, bleeding gums, reported by 13 subjects, did not exhibit resolution after 30 days. Intermittent gingival pain was reported by 15 subjects at screening, and after 30 days of Zugu Oral Rinse Liquid Toothpaste usage, only one participant continued to experience this discomfort. Remarkably, the remaining 14 subjects reported relief from the intermittent pain in the gums [Table 2].

**Table 2: Assessment of Presenting Complaint.**

Presenting Complaint	No. of subjects	
	Screening	Day 30
Bad Breath	38	0
Bleeding Gums	13	13
Lack of Freshness	26	0
Intermittent pain in gums	15	1

### Assessment of vital signs

There was statistically significant change was observed in systolic blood pressure and body temperature. However, the change was clinically insignificant and both systolic BP and temperature were well within the normal range throughout the study. There was no clinically as well as statistically significant change observed in diastolic blood pressure, heart rate, or respiratory rate throughout the 30 days of Zugu Oral Rinse Liquid Toothpaste usage.

### Assessment of malodor score using halimeter

In the present study, malodor was assessed using a halimeter based on the following scale: 0- Very good; 1- Normal; 2- Not so good; 3- Bad; 4- Very bad breath.

On Day 1, the initial average malodor score at 0 hr (before swish) was 3.96. Following the use of Zugu Oral Rinse Liquid Toothpaste, a reduction in the average malodor score was observed: 2.69 at  $\frac{1}{2}$  hr after swishing, 3.00 after 1 hr, and 3.61 at 2 hr. However, the malodor score increased at 4 hr by 3.69 and further rose to 3.78 after 6 hr.

In contrast, on Day 30, a significant reduction in malodor score was evident due to daily usage of Zugu Oral Rinse Liquid Toothpaste. At 0 hr (before swish), the malodor score was 1.80, with subsequent reductions observed at  $\frac{1}{2}$  hr (0.02), 1 hr (0.94), and 2 hr (1.00). However, a slight increase occurred at 4 hr (by 1.02), and by 6 hr, it rose by 1.75. The reduction in malodor score observed in

the study was statistically highly significant. Notably, a substantial reduction was apparent within just 15 days,

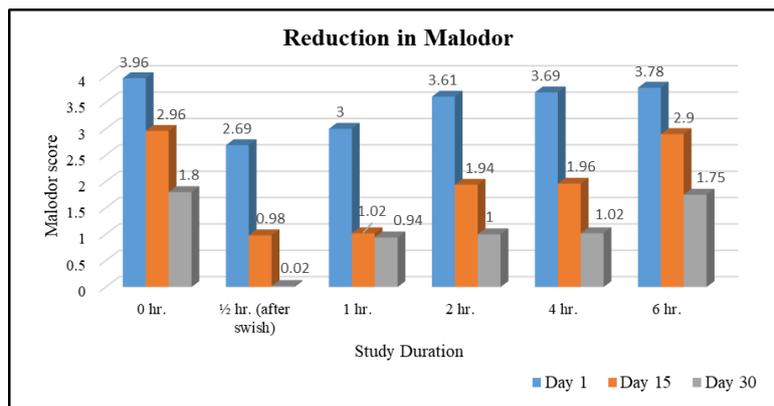
and this positive trend persisted until day 30, as detailed in [Table 3 and Figure 2].

**Table 3: Assessment of malodor score using Halimeter.**

Malodor Score Average ± S.D (n=51)						
Duration	0 hr.	½ hr. (after swish)	1 hr.	2 hr.	4 hr.	6 hr.
Day 1	3.96±0.28	2.69±0.47*	3.00±0.28*	3.61±0.49*	3.69±0.47*	3.78±0.46*
Day 15	2.96±0.28	0.98±0.24*	1.02±0.14*	1.94±0.31*	1.96±0.28*	2.90±0.30
Day 30	1.80±0.45	0.02±0.14*	0.94±0.31*	1.00±0.20*	1.02±0.14*	1.75±0.44
P value	< 0.00001	< 0.00001	< 0.00001	< 0.00001	< 0.00001	< 0.00001

Between days (Screening, Day 15, day 30) comparison all data was analyzed by One-Way Repeated Measures ANOVA test. Within day (0 hr, ½ hr., 1 hr, 2hr, 4 hr) data was analyzed by Wilcoxon Signed-Rank Test while

0 hr and 6 hrs data was analyzed by student t test dependent. Significant at  $p < 0.05$ . \* represents high significance  $p < 0.001$ .



**Figure 2: Reduction in Malodor.**

**Assessment of freshness**

The freshness was assessed after 15 min, 30 min, 1 hr, and 2 hr of swish, and scoring was done according to the following-1- very poor freshness 2-poor freshness 3-Moderate freshness 4-Good freshness 5- Extreme freshness.

The results revealed a significant improvement in freshness scores, increasing from 2.78 on Day 1 to 4.96 on Day 30 after a 15-minute rinse. Similarly, following a 30-minute rinse, scores increased from 2.24 to 4.22 on

Day 30. However, a decrease in scores was observed after 1 hour on Day 1 to 1.39, indicating a decline in freshness. Yet, after 30 days of treatment, the score at 1 hour improved to 3.22, signifying an enhancement in freshness. At the 2-hour mark, the freshness score decreased to 1.14 on Day 1, but after 30 days of treatment, it was 3.04. The observed enhancement in freshness scores throughout the study was statistically significant, with noticeable improvements evident as early as 15 days, and this positive trend continued until Day 30 [Table 4 and Figure 3].

**Table 4: Assessment of freshness score.**

Freshness Score Average ± S.D (n=51)				
Duration	15 min (after swish)	30 min (after swish)	1 hr.	2 hr.
Day 1	2.78 ± 0.42	2.24 ± 0.43*	1.39 ± 0.49*	1.14 ± 0.35*
Day 15	3.90 ± 0.30	3.18 ± 0.39*	2.20 ± 0.40*	2.10 ± 0.50*
Day 30	4.96 ± 0.20	4.22 ± 0.42*	3.22 ± 0.42*	3.04 ± 0.56*

All the data was analyzed by Wilcoxon Signed-Rank Test and significant at  $p < 0.05$ . \*represents high significance  $p < 0.001$ .

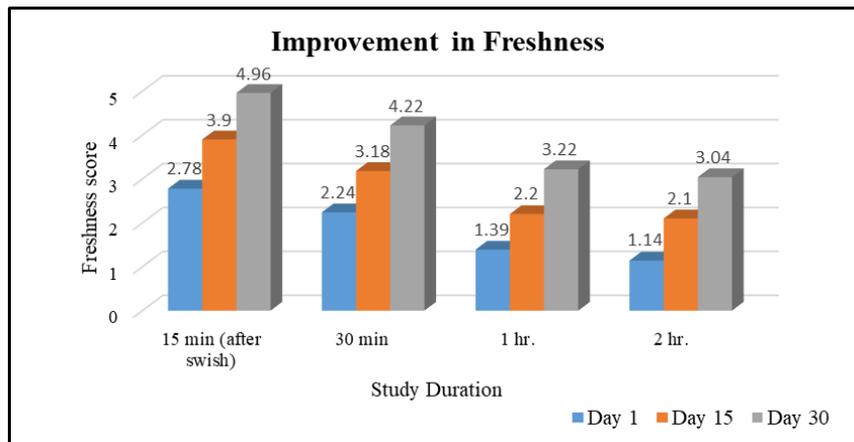


Figure 3: Improvement in Freshness.

**Assessment of dentist reported visual carious teeth**

The carious teeth of subjects were assessed by dentists according to the following scoring criteria: 0-Sound; 1-First visual change in enamel; 2- Distinct visual change in enamel; 3- Localised enamel breakdown due to caries with no visible dentine; 4- Underlying dark shadow from dentine (with or without enamel breakdown); 5-Distinct cavity with visible dentine; 6- Extensive distinct cavity with visible dentine.

In 51 study completer subjects, almost 27 subjects had Localized enamel breakdown due to caries with no visible dentine, while 21 subjects had Distinct visual change in enamel, and 3 subjects had First visual change in enamel. After using Zugu Oral Rinse Liquid Toothpaste for 30 days, there was no visual reduction in carious teeth observed in any subject.

**Assessment of visual teeth whitening**

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).

88.24% of the subjects showed reduction by Grade 1, while 5.88% of the population exhibited a reduction by

Grade 2. 1.96% of the subjects demonstrated a reduction Grade 3, and 3.92% of the subjects showed reduction by Grade 4 indicating increased teeth whitening.

**Assessment of plaque index**

Dentists assessed the Plaque Index of subjects based on the following scoring system: 0 - No plaque, 1 - Separate flecks of plaque at the margin of the tooth, 2 - Thin continuous bands of plaque covering 1/3 of the area of the tooth, 3 - Plaque covering 1/3 of the area of the tooth, 4 - Plaque covering 1/3 of the area of the tooth, and 5 - Plaque covering 2/3 of the area of the tooth.

As indicated in Figure 4, the average Plaque Index was  $2.93 \pm 0.34$  at screening and a statistically significant reduction was observed to  $2.20 \pm 0.32$  on Day 30. There was percentage reduction in plaque among all the 51 subjects, with 23.53% of subjects experienced a reduction of 10-20%, while a significant majority, constituting 56.86%, demonstrated a reduction in the range of 21-30%. Additionally, 19.61% of the subjects exhibited a reduction ranging from 31-40%. These findings emphasize the effectiveness of the intervention in reducing plaque levels.

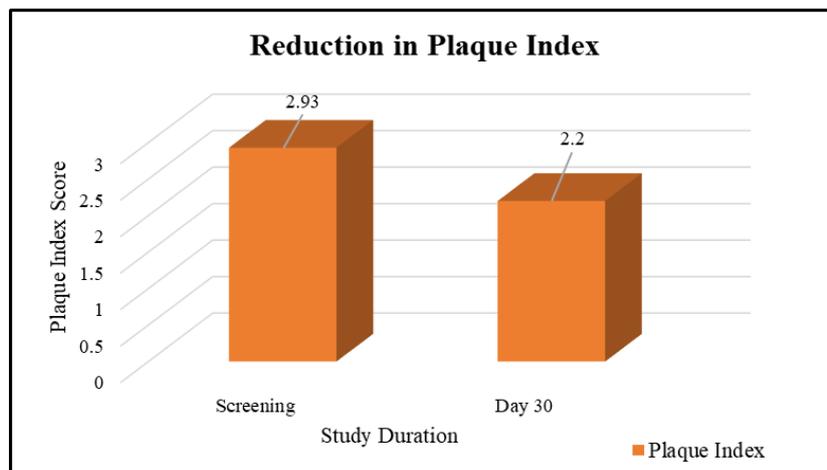


Figure 4: Reduction in plaque index.

### Assessment of gingivitis index

Dentists assessed the gingivitis index of subjects using the following scoring system: 0 - Normal gingiva; 1 - Mild inflammation – slight change in color and slight edema; 2 - Moderate inflammation – redness, edema, and glazing; 3 - Severe inflammation – marked redness and edema, ulceration, tendency to spontaneous bleeding. The degree of gingivitis was evaluated based on the following criteria: (0.1-1.0) Mild, (1.1-2.0) Moderate, (2.1-3.0) Severe.

In this study, out of the 51 subjects, only 14 individuals reported gingivitis at screening. The initial gingivitis score during the screening was 0.34, and after 30 days of using Zugu Oral Rinse Liquid Toothpaste, a statistically significant reduction was observed, with the score decreasing to 0.13. Despite this reduction, the observed degree of gingivitis remained consistently mild throughout the study, indicating that while there was improvement, the overall severity of gingivitis did not change.

### Assessment of gingival bleeding

The dentist assessed the Gingivitis Index of subjects using the following scoring system: 0 - No Bleeding, 1 - Isolated Bleeding, spots visible; 2 - Blood forms a confluent red line on the margin; 3 - Heavy or profuse bleeding.

Among the 51 subjects, only 14 reported gingival bleeding. Initially, the gingival bleeding score during screening was 0.93. After 30 days of using Zugu Oral Rinse Liquid Toothpaste, the score significantly decreased to 0.52, indicating a statistically significant reduction in observed gingival bleeding.

### Assessment of the potential of Zugu Oral Rinse Liquid Toothpaste as an alternative to toothpaste

The potential of Zugu Oral Rinse Liquid Toothpaste to serve as an alternative to regular toothpaste was evaluated by the subjects reported score based on a 4-point Likert scale: Strongly Disagree-0, Disagree-1, Neutral-2, Agree-3, and Strongly Agree-4.

After 15 days of the study intervention, the potential of Zugu Oral Rinse Liquid Toothpaste as an alternative to regular toothpaste was assessed. Approximately 28.07% of subjects disagreed, 22.81% agreed, and 26.32% were neutral. A comparison between day 15 and day 30 revealed a slight increase in the disagreement score to 29.41%, a slight increase in the agreement score to 23.53%, and a reduction in the neutral score to 25.49%. It also revealed that subjects strongly showing the disagreement was increased slightly [Table 5].

**Table 5: The potential of Zugu Oral Rinse Liquid Toothpaste as an alternative to Toothpaste.**

Score	Day 15 (n=57)	%	Day 30 (n=51)	%
Strongly disagree (0)	3	5.26	3	5.88
Disagree (1)	16	28.07	15	29.41
Neutral (2)	15	26.32	13	25.49
Agree (3)	13	22.81	12	23.53
Strongly Agree (4)	10	17.54	8	15.69

### Assessment of subject satisfaction score by using Dental Diary

The assessment of subjects' satisfaction with the morning and evening use of Zugu Oral Rinse Liquid Toothpaste was conducted through their entries in a dental diary, utilizing the following scale: 1-very satisfied, 2-satisfied, 3-neutral, 4-unsatisfied, and 5-very unsatisfied.

Regarding morning use on day 15, 61.40% of subjects expressed satisfaction, 21.05% were unsatisfied, and 10.53% were neutral. By day 30, satisfaction slightly increased to 70.59%, while dissatisfaction decreased to 13.73%, and 7.84% maintained a neutral stance.

Similarly, for evening use on day 15, 70.18% of subjects were satisfied, 12.28% were unsatisfied, and 15.79% were neutral. On day 30, satisfaction slightly decreased to 66.67%, dissatisfaction decreased to 11.76%, and 11.76% maintained a neutral stance. The dental diary entries provide valuable insights into subjects' satisfaction levels with Zugu Oral Rinse Liquid Toothpaste use, indicating trends over the study period [Table 6].

**Table 6: Assessment of subject satisfaction score by using Dental Diary.**

Score	Day 15 (n=57)				Day 30 (n=51)			
	Morning	%	Evening	%	Morning	%	Evening	%
1-Very satisfied	0	0.00	0	0	0	0	0	0
2-Satisfied	35	61.40	40	70.18	36	70.59	34	66.67
3-Neutral	6	10.53	9	15.79	4	7.84	6	11.76
4- Unsatisfied	12	21.05	7	12.28	7	13.73	6	11.76
5-Very unsatisfied	0	0.00	0	0.00	0	0.00	0	0.00

### Assessment of tolerability

Tolerability was scored as following- where, 0- Poor Tolerability: Severe 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: No adverse event reported. The tolerability of the investigational product remained consistently excellent in all subjects throughout the entire study duration.

### Assessment of adverse events and compliance

Adverse events were recorded through self-reporting by the subjects or the identification of clinical signs and symptoms during clinical examinations. Notably, there were no adverse events observed during the 30-day study intervention. Subjects demonstrated consistently outstanding treatment compliance throughout the study. The compliance rate was 92.06% up to day 15 and slightly increased to 92.83% up to day 30.

### DISCUSSION

The liquid toothpaste concept holds potential as this may add effectiveness, convenience, and novelty in oral care. Travel and Portability and usefulness in situations where there will be limited access to water. The Liquid toothpaste is the best oral care product for those who hustle and have time constraints for an elaborative oral care routine. This is best for people with medical conditions, disability, and who need special assistance for mobility. The product can be an alternative to brushing for people with sensitive gums and teeth. Liquid toothpaste may eliminate the need for brushing for use in public settings or for greater convenience. Zugu Oral Rinse Liquid Toothpaste provides holistic oral care as it is gentle on teeth, don't damage enamel yet cleanses well and provides mouth freshness.

In this study, we investigated the effectiveness of Zugu Oral Rinse Liquid Toothpaste in combating plaque, gingivitis, gingival bleeding, malodor, and carious teeth, as well as enhancing freshness serving as an alternative to conventional toothpaste.

None of the subjects reported alcohol consumption or smoking. Among 38 individuals with bad breath and 26 with a lack of freshness experienced complete resolution (100%) after using Zugu Oral Rinse Liquid Toothpaste. However, bleeding gums in 13 subjects did not show resolution after 30 days. Intermittent gum pain, reported by 15 subjects, significantly reduced, with only one subject experiencing the complaint after 30 days. No clinically significant changes were observed in vital signs after 30 days of Zugu Oral Rinse Liquid Toothpaste use.

The malodor score exhibited a significant decrease at various time intervals, with a noticeable reduction after just 15 days and a continued trend until day 30. Freshness scores also displayed significant improvement within 15 days, persisting until day 30. After using Zugu Oral Rinse Liquid Toothpaste for 30 days, no visual reduction in carious teeth was observed in any subject. The plaque exhibited a significant reduction of 24.91% compared to screening. This reduction included a 10-20% decrease in plaque for 12 subjects, a 21-30% reduction for 29 subjects, and a 31-40% decrease for 10 subjects. A significant reduction of 61.76% in gingivitis was observed compared to the screening. However, there was no substantial reduction in gingival bleeding after 30 days of using Zugu Oral Rinse Liquid Toothpaste.

The results indicate that the majority of subjects agree that Zugu Oral Rinse Liquid Toothpaste has the potential to replace traditional toothpaste and brushing. Similarly, an assessment of the dental diary revealed that the subjects were satisfied with the use of Zugu Oral Rinse Liquid Toothpaste as of their regular brushing only within 15 days and continued till day 30. The tolerability of the investigational product remained consistently excellent throughout the study, with no adverse events observed. Subjects demonstrated outstanding treatment compliance. Additionally, it appears that oral hygiene instructions provided at the initial visit, describing do's and don'ts, had a significant positive effect on the reduction of plaque, gingivitis, malodor, and improvement in freshness.

Various clinical trials provide valuable insights into the efficacy of the individual ingredients used in Zugu Oral Rinse Liquid Toothpaste. Researchers found that the use of dentifrice with Sodium monofluorophosphate and sodium bicarbonate resulted in a stable fluoride ion concentration and relatively low tooth abrasion, which is safe for the tooth and effective for the removal of dental plaque. In the current study, a notable decrease in plaque index was observed following four weeks of use of the investigational product, indicating a statistically significant difference. This could be attributed to the presence of the same active ingredient in the investigational product.<sup>[12]</sup>

In three randomized controlled clinical studies, the efficacy and safety of a novel two-step dentifrice and gel system were assessed, focusing on oral health benefits. The research targeted short-term breath malodor (1 day), intermediate-length plaque control (3 weeks), and longer-term gingivitis effectiveness (11 weeks). A comparison was made with a regular toothpaste (control) containing sodium monofluorophosphate, used twice daily demonstrated significant reductions in breath malodor, plaque, and gingivitis in favor of the two-step system compared to the control.<sup>[13]</sup> Notably, the current study confirms these findings and emphasizes the convenience of Zugu Oral Rinse Liquid Toothpaste, a

single-step approach that delivers similar benefits to the two-step system, making it a more advantageous choice.

Another clinical study focused on the two-step sequence comprising adult patients with gingivitis and tooth stains, showed positive responses after just 1 week. By week 3, the two-step group showed significant reductions, in gingival bleeding (39%) and fewer stains (55%) compared to the control (containing sodium monofluorophosphate) toothpaste only. Remarkably, all two-step users experienced stain reductions and reductions in gingivitis.<sup>[14]</sup> Literature reveals that the enzymes glucosyltransferase and fructosyltransferase are incorporated in an active form into the pellicle; and by synthesizing glucan in situ from sucrose, can provide a surface for colonization by *Streptococcus mutans*. These enzymes can be inhibited by SLS and which subsequently retard the regrowth of plaque.<sup>[15]</sup> Similar findings were observed in the present study.

Research suggests that 1% zinc acetate solution had an excellent anti-volatile sulphur compound (VSC) effect throughout the test period of 3 hours.<sup>[16]</sup> Similarly, another trial reported zinc salt added into the palatal muco-adhesive tablet reduced malodor and VSC production.<sup>[17]</sup> Zinc chloride plus sodium chloride mouth rinse was shown to be more effective in reducing oral malodor than the mouth rinse containing no zinc chloride/no sodium chloride.<sup>[18]</sup> These results align with the current findings.

A meta-analysis reported that zinc-containing mouth rinses can be effective in the neutralization of odiferous sulfur compounds.<sup>[19]</sup> A recent study using two different mouth rinses, one containing 0.14% zinc lactate and the other containing 0.18% zinc pidol rinses reduced VSC at 1, 3, and 5-hour test intervals.<sup>[20]</sup> Zinc salts in oral hygiene products such as toothpaste and mouth rinse show good potential for reducing malodor.<sup>[21]</sup> It is observed that surfactants enhance the plaque-inhibitory role of zinc.<sup>[22]</sup> Similarly, present study outcomes also reduce malodor in subjects. Literature suggests that toothpaste containing high concentrations of sodium bicarbonate is more effective in removing intrinsic tooth stain.<sup>[23]</sup> In the present study, we also observed increased teeth whiteness. Notably, there was no observed change in carious teeth. Further studies are necessary to accurately depict subjects' satisfaction with Zugu Oral Rinse Liquid Toothpaste and to explore its potential as an alternative to regular toothpaste.

## CONCLUSION

The present study evaluating the effectiveness of Zugu Oral Rinse Liquid Toothpaste presents promising results, showcasing its two-in-one toothpaste plus mouthwash formulation as a potential game-changer in the oral care market.

The product demonstrated effectiveness in resolving malodor, reducing plaque, gingivitis and gingival

bleeding, along with enhancing freshness alleviating intermittent pain, and enhancing teeth whiteness. Importantly, the formulation exhibited excellent safety, with no adverse events observed and consistent tolerability throughout the study. The subjects' high satisfaction rates and agreement on the potential of Zugu Oral Rinse Liquid Toothpaste as an alternative to regular toothpaste further emphasize its consumer appeal. However, given the study's limitations, additional research in larger and diverse populations is warranted to comprehensively validate these findings and establish the broader market impact of this innovative oral care solution. Overall, the study suggests that Zugu Oral Rinse Liquid Toothpaste could potentially revolutionize the oral care industry with its innovative formulation and positive outcomes.

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