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COMPARATIVE EFFICACY OF HERBAL GEL ON ORAL HYGIENE AND MOUTH FRESHNESS: A DOUBLE-BLIND CONTROLLED STUDY

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ABSTRACT

Background: Halitosis or bad breath is an oral health condition characterized by unpleasant odours emanating consistently from the oral cavity. The origin of halitosis may be related both to systemic and oral conditions, but a large percentage of cases, about 85%, are generally related to an oral cause. The causes include certain foods, poor oral health, improper cleaning of dentures, dry mouth, tobacco products and medical conditions.[1] **Aim:** A Clinical study was conducted to evaluate the efficacy of Herbal Gel toothpastecomprising of Zinc Sulphate (*GandhakamleeyaYasada)*, Herbal extract and blend of essential oils for an oral malodour, Gingivitis Index(GI) and Plaque Index(PI)and Oral Hygiene Index evaluation study. **Material and Method:** A double blind, three-arm, randomized clinical study involving105 subjects (18-45 years) with complaints suggestive of plaque induced gingivitis,malodour and other set inclusion criteria;was conducted by randomly assigning the subjects to one of three study groups (35 each). **Result:** Results showed that test product Herbal Gel was 2 times and 4 timesstatistically significant in controlling oral malodourwhen tested against Control Gel and Control toothpaste respectively. Test product Herbal Gel was also found effective to reduce gingival index and plaque index and showedimprovement of oral hygiene index which was statistically significant v/s baseline and v/s control test products. Test product Herbal Gel was found to statistically significant in reducing oral malodour with single use, post 4 weeks of regular usage and even after 12 hours brushing post 4 weeks regular use. **Conclusion:** It can be concluded that test product Herbal Gel wasfound significantly effective in comparison to the marketed products on clinical parameters GI, PI, OHI-S and Oral Malodour.

KEYWORDS: *OralMalodour, Gingivitis, Plaque, Toothpaste, Herbal gel, Ayurvedic Zinc sulphate.*

INTRODUCTION

As the world is advancing day by day, more and more of emphasis is given on the personal care for grooming and beautification. The public domain is full of such personal care products. But due to the growing adverse effects from the use of chemicals raised the concern of the people, turning them to find the herbal based product. Herbal products are known for natural benefits texted in various literatures.

Oral cavity pathologies that can cause halitosis among others: dental cavities, periodontal disease, tongue coating, exposed tooth pulps, extractions/healing wounds, interdental food impaction, dentures kept atnight or not regularly cleaned, restorative crowns whichare not well adapted, cysts with fistula draining into the mouth, oral cancer and ulcerations. Most of these factorscause halitosis due to tissue breakdown, putrefaction of amino acids and decrease of saliva flow.[2]

Halitosis is defined as breath that is offensive to others,caused by a variety of reasons including but not limitedto periodontal disease, bacterial coating of the tongue, systemicdisorders, and different types of food. Halitosis is also knownas fetor oris or oral malodour or bad breath which has an influenceon the social interaction and confidence of the person.[3] Thehigh prevalence of moderate halitosis is seen among world'spopulation, whereas severe form of halitosis is restricted toless than 5% of the population.[4] Main contributing factors forhalitosis are local factors such as plaque, calculus, periodontaldisease, dental caries, xerostomia, coating on tongue, tobaccousage, and other infections of oral cavity, followed by fewsystemic factors such as diabetes, upper respiratory infections, and typeof food.[5]

In the ancient Indian traditional medicine system concept to stay healthy is described in various scriptures. From the use of products to seasonal impacts, on specific human based on "Prakriti, ailments; Acharya Charka has mentioned that human should use such specific herbs for

"Danta Dhavana" as a daily regime to maintain the oral hygiene including bad breath. Still today peopleare suffering from a lot of oral problems like malodour, gingivitis, plaque etc. and people are spending a lot on treating these problems once aggravated.

A Clinical study was conducted to evaluate the efficacy and safety of an oral care product (Gel Toothpaste) which herbal ingredients such as *Pippali (Piper longum), Marich (Piper nigrum), Sunthi (Zingiber officinale), Tumburu (Zanthoxylum alatum), Pudina satva, Gandhapura oil (oil of Gaultheria fragrantissima), Mentha piperata oil, Mentha Spicata oil, Takkola oil (oil of Illicium verum))* and *GandhakamleeyaYasada* (Zinc Sulphate) as active ingredients which are used from the ancient times in oral care and are said to be proven effective in combating oral malodour. Aim of this study was to evaluate the safety and efficacy of an oral care product, comparative reduction of oral malodour, plaque, gingivitis and improvement of Oral hygiene as compared to marketed oral care products.

The herbal dentifrice containingLavang, Tomar, Pippali, Kalimirch, Sunthi, Karpura which are known to reduce inflammation and maintain gum health in Ayurvedic text.

Lavang is known to cure gingivitis. Piper longum is ayurvedic rasayanas (Rejuvenators) which commonly used for antiaging and cell rejuvenation benefits in ayurveda.[6]

Tomar (Zanthoxylum armatum) present in ayurvedic toothpaste helps remove bad odor and has an antiseptic and antibacterial property. Tomar is one of the best remedies for toothache. Eugenol or clove oil has analgesic, antibacterial, antiviral, anti-inflammatory, and antioxidant properties. It has been used to relieve toothache, in periodontitis, as an anesthetic, and to treat bleeding gums. Karpura (Cinnamomum camphora) is another component in herbal toothpastes with antioxidant, antibacterial, and anti-inflammatory properties. The leaves of Pudina or Mint and possess several biological effects as antiseptic in oral preparations, antibacterial, antifungal, antiviral antioxidant effects.[7]

Two clinical studies independently support the efficacy of the test toothpaste with 0.2% zinc sulphate in reducing oral malodour after a single brushing, and after four weeks for 12 hours after brushing compared to a toothpaste without zinc ions.[8]

Zinc ions, which exhibit an inhibitory effect on VSCs and are incorporated into products for oral malodour prevention, employ the two mechanisms of direct binding with gaseous H_2S and antimicrobial activity.[9]

*Takkola oil and Clove oil in Ayurvedic freshness gel are mentioned for the treatment of halitosis,*Pudina (Peppermint) is mentioned in ayurveda for the Mukhasodhana (mouth Cleanser) andDurgandhinashak (Bad odour removal).[10]

Mints (*Mentha* spp.) are medicinal herbs that are valued worldwide in traditional medicines for their antimicrobial and antioxidant properties. They are also odor-masking agents, as menthol and menthyl acetate are responsible for a pungent and refreshing odor. Therefore, *Mentha* extracts are extensively used in oral hygiene products, mouth fresheners, toothpastes, and chewing gums.[11]

MATERIAL AND METHOD
Table 1: Product Details.

Groups	Details	Active Ingredients
Test Group – Herbal Gel	DaburGel	*Zinc Sulphate 0.25% (GandhakamliyaYasada) Herbal Extracts and essential Oils Excipients (Gel Base): q.s*
ControlGroup - Gel	Colgate Maxfresh	Sodium Fluoride in Gel base
Control Group -Toothpaste	Colgate Dental Cream	Sodium monofluorophosphate in Calcium carbonatebase

Study design and participant characteristics: A double blind, three-arm, randomized clinical study involving subjects with at least 20 natural teeth and with complaints suggestive of plaque induced gingivitis and malodour and other set inclusion criteria was conducted in the OPD of Inderprastha Dental College and Hospital, Sahibabad. After baseline assessments, subjects (n = 105) were randomly assigned to one of three study groups (35 each). The randomization was done by shuffling of OPD registration cards. The age range of participants was 18-45 years, with both genders matched.105 Volunteers received a pack containing of test product (considering 2 gm of amount to be used per application).

Inclusion Criteria
1. Those having sound general health.
2. Those having at least 20 natural teeth with no probing depths greater than 3 mm and a plaque index score of 1.50 or more at baseline.
3. All participants having a bad breath score of 2.0 or more at baseline.
4. Those having clinical evidence of a tendency to form plaque on teeth.
5. Those having plaque induced gingivitis.

6. Subjects with bad oral hygiene and halitosis (self-reported or clinically diagnose).
7. Subjects willing to follow 12 hr. overnight gap of brushing
8. Subjects willing to give voluntary informed consent and will be available for the entire duration of the study.

Exclusion Criteria
1. Those not fulfilling inclusion criteria.
2. Mouthwash or any other herbal or medicated toothpaste use in recent past.
3. Subjects having history of known sensitivity or oral mucosal tissue reaction to test toothpaste.
4. Subjects undergoing antibiotic or anti-inflammatory therapy or had undergone such therapy in the past 6 months.

5. Those having tobacco and alcohol abuse.
6. Any underlying uncontrolled medical illness including diabetes mellitus, hypertension, liver disease or history of alcoholism, HIV, hepatitis, or any other serious medical illness.
7. Those having untreated dental caries or having any orthodontic or prosthetic appliances
8. Subjects who are pregnant, lactating or nursing.
9. Subjects under continuous nutritional supplementation
10. Subjects undergoing radiotherapy, chemotherapy, and under long term medication.
11. Participation in any other clinical study or panel test or completion of clinical studies in the one month prior to the start of this study.

Table 2: Evaluation Time Points.
Timepoints were as follows –

Parameters	Visit 1 Baseline		Visit 2 4 weeks		Visit 3 6 weeks	
	Before	After*	Before	After*	Before#	After##
GI, PI, OHI Simplified	√	√	√	√	X	X
Organoleptic Measurement Score for Oral Malodor	√	√	√	√	√	√

*After 1 hr brushing, # after eating onion, ## after 1 hr bushing.
Day 0: Baseline examination; Examination of the Participants for GI, PI, OHI- Simplified, Winkel tongue coating index, Organoleptic Measurement Score for Oral Malodour.
4 Week: Examination of the Participants for GI, PI, OHI- Simplified, Organoleptic Measurement Score for Oral Malodour.

Clinical Methods
1. **Gingival index (GI):** (Loe H and Silness J 1963)
2. **Plaque index (PI):** (Silness J and Loe H 1964)
3. **Oral Hygiene Index- Simplified/ OHI-S:** (Greene J and Vermillion JR 1964)
4. **Oral Malodour - The organoleptic measurement**(Rosenberg M et al 1996)

Method for Organoleptic measurement to assess halitosis/ oral malodour: All the study participants were asked to avoid any kind of food and drinks 8 hours before the test. They were also asked to refrain from eating garlic or onions for 24 hours before malodour assessment. They were also asked to abstain from toothbrushing, using toothpaste, mouthwash, breath fresheners, and scented cosmetics, the morning of testing. On the day of examination in morning hours, participants were first assessed using the organoleptic method which was done by the principal investigator who was trained and calibrated. The organoleptic measurement of breath was taken at distances of 15 cm from the oral cavity. Severity grades were assigned as follows:

Six-point Organoleptic scale: to assess halitosis/ oral malodour: (Rosenberg M et al 1996)
0. No odor present.
1. Barely noticeable odor. Odor is of low intensity.

2. Slight to moderate odor. Odor is clearly noticeable and slightly unpleasant.
3. Moderate to high malodour. Clearly noticeable, unpleasant malodour of moderate intensity.
4. Strong malodour of high intensity.
5. Extremely foul odor.

Oral malodour, as perceived by the human nose, is the gold-standard halitosis test.[12,13,14]

The organoleptic method employing olfaction remains the gold-standard in detecting oral halitosis. The reason for this is the fact that in contrast to the Halimeter, which identifies only VSCs, the human nose can smell not only the VSCs but also the other organic compounds that come from exhalation and defining them as pleasant/unpleasant. Rosenberg and McCulloch have authored the most widely used organoleptic scoring system for ranking halitosis.[15,16] The organoleptic measurement depends on a trained examiner that has demonstrated reliability in smelling halitosis. Haas *et al*.[17] have demonstrated, under a blind evaluation, good levels of reproducibility of organoleptic oral malodour measurements.

RESULTS
Study 1 – Overall Oral Hygiene
Table 3: PI, GI, OHI-S scores in study population (4 weeks regular usage).

PI, GI, OHI-S scores		Baseline		4 Weeks	
Clinical examinations	**Group**	**Mean**	**SD**	**Mean**	**SD**
Plaque Index	Test Gel	1.511	0.258	1.064	0.176
	Control Gel	1.547	0.265	1.416	0.243
	Control toothpaste	1.491	0.207	1.342	0.186
p-value		0.635		0.000	
Gingival Index	Test Gel	0.850	0.127	0.512	0.075
	Control Gel	0.837	0.116	0.627	0.087
	Control toothpaste	0.861	0.123	0.662	0.094
p-value		0.707		0.000	
OHI-S Index	Test Gel	2.69	0.354	1.902	0.226
	Control Gel	2.73	0.285	2.324	0.243
	Control toothpaste	2.72	0.240	2.372	0.209
p-value		0.814		0.000	

Table 4: PI, GI, OHI-S comparative scores Vs Control after 4 weeks usage.

Clinical Parameters	Group	% Change Post Usage Vs Baseline	Change from Baseline	Herbal Gel efficacy Vs Control Groups(Fold Change)
Plaque Index	Test Gel	29.58306	0.447	
	Control Gel	8.468003	0.131	3.4 X
	Control toothpaste	9.993293	0.149	3 X
Gingival Index	Test Gel	39.76471	0.338	
	Control Gel	25.08961	0.21	1.6 X
	Control toothpaste	23.11266	0.199	1.7 X
OHI-S Index	Test Gel	29.29368	0.788	
	Control Gel	14.87179	0.406	1.9X
	Control toothpaste	12.79412	0.348	2.3X

Comparison of GI and PI and OHI-S between Groups (Bonferroni Test) P Value <0.005; Statistically Significant.

Interpretation: The comparison of GI and PI scores between Test and control group showed statistically significant results (p <0.05) indicating the positive effect Testgel with herbs and essentials over a period of4 weeks. Bonferroni Test has been done to compare the groups.

Clinical Significance: The 4-week follow-up showed reduction in gingival index and plaque index and OHI-S which was statistically significant v/s baseline and v/s control test products. The Ayurvedic toothpaste with herbal extract helps in improving the gingival health as its usage significantly reduced GBI and PI scores.

Study 1A – Overall Oral Hygiene (single use efficacy)
Table 5: 1st Brushing Post Usage Comparison Vs Control in study populationfor Instant Freshness.

Instant Freshness (Up to 1 hr.)	0 Day Pre Usage		0 Day Post Usage			
Groups	**Mean**	**SD**	**Mean**	**SD**	**CFB***	**Fold Change**
Test Gel	4.85	0.429	3.65	0.838	1.2	
Control Gel	4.83	0.802	4.07	1.005	0.76	1.57
Control toothpaste	4.82	0.821	4.25	0.807	0.57	2.10

p Value <0.005, * CFB- Change from baseline
Comparison of malodour reduction between Groups (Bonferroni Test) P Value <0.005; Statistically Significant.

Table 6: Halitosis scores in study population after 4-week usage.

Summary of Malodour Reduction Vs Baseline					
Group	Time point	Baseline		4 weeks	
		Mean	SD	Mean	SD
Test Gel	Before Brush	4.85	0.429	2.2	0.632
	After Brush	3.65	0.838	0.84	0.507
Control Gel	Before Brush	4.83	0.802	3.59	0.741
	After Brush	4.07	1.005	2.96	0.739
Control toothpaste	Before Brush	4.82	0.821	4.18	0.787
	After Brush	4.25	0.807	3.85	0.598

p Value <0.005

Table 7: Pre- Usage Halitosis Comparison Vs Control in study population after 4-week usage* (12 hours freshness)

Pre-Usage Freshness	Baseline (Before brushing)		4 Weeks (Before brushing)		Comparison Vs Control	
Groups	Mean	SD	Mean	SD	CFB	Fold Change
Test Gel	4.85	0.429	2.2	0.632	2.65	
Control Gel	4.83	0.802	3.59	0.741	1.24	2.137097
Control toothpaste	4.82	0.821	4.18	0.787	0.64	4.140625

p Value <0.005, 12 overnight before brushing after 4-week usage.

Table 8: Post usage Comparison Vs Control in study population after 4-week usage*

Baseline Vs Post-Usage Freshness (After 1 hrs.)	Baseline		4 Weeks		Comparison Vs Control	
Groups	Mean	SD	Mean	SD	CFB*	Fold Change
Test Gel	4.85	0.429	0.84	0.507	4.01	
Control Gel	4.83	0.802	2.96	0.739	1.87	2.144385
Control toothpaste	4.82	0.821	3.85	0.598	0.97	4.134021

p Value <0.005, * CFB- Change from baseline, 1hrs after brushing after 4-week usage.

Interpretation: The comparison of malodour reduction between Test and control group showed statistically significant results (p <0.05) indicating the positive effect of gel with herbal extracts over a period of 4 weeks.

Clinical Significance: The 4-week follow-up showed malodour reduction in Test group was 2 times and 4 times better than control gel group and control toothpaste group respectively and which was statistically significant v/s both control test products.

Test product Herbal Gel was found to statistically significant in reducing oral malodour with single use, post 4 weeks of regular usage and even after 12 hours brushing post 4 weeks regular use.

Study 2 - Forced Malodour Study
Table 9: Malodour Scores in study population (after eating onion paste 2 g).

Group	Group	Mean	SD	CFB	Fold Change Reduction Vs Control
Test Gel	Before Brush	4.71	0.419	2.4	
	After 1 hr brushing	2.31	0.817		
Control Gel	Before Brush	4.87	0.789	0.96	2.5
	After 1 hr brushing	3.91	0.924		
Control toothpaste	Before Brush	4.91	0.843	0.56	4.3
	After 1 hr brushing	4.35	0.797		p Value <0.005

p Value <0.005, * CFB- Change from baseline

The aim of the study was to evaluate efficacy to reduce food malodour in subjects using test and control products regularly for 6 weeks.

After eating onion paste 2 g at visit 3 (at 6 weeks) and then brushing using test product in respective group; subjects showed malodour reduction in the sequence as; TEST HERBAL GEL, then CONTROL GEL and lastly in CONTROL TOOTHPASTE group. The difference is found to be highly statistically significant in malodour scores reduction in Test product HERBAL GEL, significant in CONTROL GEL and non-significant in CONTROL TOOTHPASTE groups.

Test product Herbal Gel> Control Gel> Control Toothpaste.

DISCUSSIONS

Even though people brush their teeth daily, the occurrence of malodour, gingivitis and plaque remains high in the population. These are much common problems, for which people frequently visiting dentists. Various herbs are mentioned in the classical Ayurvedic texts to curb the dental diseases.

The present study shows that the test product Herbal gel which is a concoction of herbal extracts, minerals like Zinc and essential oil blend has superior benefits in Improving Overall oral hygiene, malodour reduction, Gum health improvement and Plaque control post 4-weeks usage when compared to Marketed Ordinary Geland Marketed Toothpaste.

CONCLUSION

It can be concluded that test productHerbal Gelwas found statistically significant in comparison to the marketed product on clinical parameters GI PI, OHI-S and Oral Malodour and can be said as product of choice in the above discussed ailments treatment.Herbal Gel regular 4 weeks usage also resulted in reduction of plaque and gingival inflammation on established gingivitis. Herbal Gel was found to be statistically significant in reducing oral malodour with single use, post 4 weeks of regular usage and even after 12 hours brushing post 4 weeks regular use.

LIMITATIONS

Investigation of test gel product in elderly population with gingivitis, dry mouth and perio-breathcan be point of evaluation.

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