

## Effects of Polymeric Herbal Gel on Plaque and Gingivitis: A Randomized Controlled Clinical Trial.

### Abstract:

Dental diseases are recognized as major public health problem throughout the world. Numerous epidemiological studies showed that the diseases such as tooth decay and diseases of the periodontium are among the most common afflictions of mankind. Dental plaque plays a major role in the etiology of periodontal disease: and that there is a direct relationship between the presence of dental plaque and the development of gingivitis. Various synthetic chemical agents have been evaluated over the years with respect to their antimicrobial effect in oral cavity, however, all are associated with various side effects. Thus patients are going away of modern day medicines, and they prefer using herbal ayurvedic preparations which are efficient without causing any side effects. Hence the purpose of present study was to evaluate the effects of novel herbal polymeric gel on gingival inflammation clinically and microbiologically.

**Methods:** This was a split mouth clinical trial, designed for comparison of 3 treatment modalities, scaling, scaling plus novel herbal polymeric gel and only novel polymeric gel. Both sexes belonging to age group 18-55 years were included in the study. Plaque index, gingival index and gingival bleeding index were recorded at baseline, 7day, 14 day and 21st day. Microbiological assessment was done at baseline and 21st day.

Statistical analysis used: paired t test & ANOVA

**Results:** The results showed significant reduction in the clinical parameters within group. Between the groups, clinically there was more improvement in the group which received both scaling and topical application of herbal gel. There is significant reduction in microbial parameters from baseline to 21st day in a group which received both herbal gel and scaling.

**Conclusions:** Results confirmed that novel herbal polymeric gel is an effective agent for treating plaque induced gingivitis along with scaling, compared to only herbal gel application or scaling with least side effects. Further long term studies are needed to confirm effects of this gel on periodontal diseases.

**Key-words:** Neem, Tulasi, paan oil, gingivitis, polymeric herbal gel

**Key Message:** Herbal gel is useful in treating gingivitis when used along with scaling and root planning.

### Introduction:

Dental diseases are recognized as major public health problem throughout the world. Numerous epidemiological studies showed that the diseases such as tooth decay and diseases of the periodontium are among the most common afflictions of mankind.[1] Dental plaque plays a major role in the aetiology of periodontal disease.[1] and that there is a direct relationship between the presence of dental plaque and the development of gingivitis.[2] Various synthetic chemical agents have been evaluated over the years with respect to their antimicrobial effect in oral cavity, however, all are associated with various side effects.[3]

Present study included formulation of Bioadhesive dental gel containing Paan Oil (Piper betle L.), Tulsi Oil (Ocimum sanctum L.) and Neem extract (Azadirachta indica A. Juss.) A clinical and microbiological study was conducted to evaluate

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the efficacy of a herbal polymeric gel against Gingivitis and Dental plaque, with the objectives to evaluate the anti-inflammatory effects of novel herbal polymeric gel in the treatment of plaque induced gingivitis, to evaluate the effects of novel herbal polymeric gel on various clinical parameters such as plaque index, gingival index and gingival bleeding index, to compare the anti-inflammatory effects of novel herbal polymeric gel alone and along with scaling and to evaluate the adverse effects of novel herbal polymeric gel.

### Subjects and Methods:

This was a clinical trial, designed for comparison of 3 treatment modalities, scaling, scaling plus novel herbal polymeric gel and only novel polymeric gel. The trial was undertaken in Department of Periodontology, College of Dental Sciences, Davangere, Karnataka. Both sexes belonging to age group 18-55 years were included in the study. Prior to the participation in the study the patients were explained about the protocol and each participant included in the study signed a consent form.

**Inclusion Criteria:** Patient who were diagnosed as suffering from chronic plaque induced gingivitis. Patients of both sexes of 18-55 years were selected. Patients who had not received periodontal therapy for last 6 months. Patients who had not received antibiotic therapy for last 1 month.

**Exclusion Criteria:** Patients with known hypersensitivity to herbal formulations. Patients with systemic disease and smokers. Pregnant patients/Lactating mothers

### 45 quadrants from 15 patients are selected randomly:

- In each patients the quadrants were randomly assigned as follows
- Control site Scaling alone without Gel
- Experiment site A Scaling + Gel
- Experiment site B Gel alone

### Prior to scaling each selected site was subjected to assessment of the following clinical parameters:

Plaque index (Silness J. and Loe H., 1964), Gingival index (Loe H and Silness J., 1963), Gingival bleeding index (Ainamo and Bay, 1975) were recorded at baseline and after 7, 14 and 21st days of (twice daily) gel application. After recording the clinical parameters and collection of supra gingival plaque samples from each quadrants on baseline,

thorough scaling was done using ultrasonic scalers in control group, and experimental site A. Novel herbal polymeric gel and cotton applicator are given to each patients to apply approximately 1 gram of gel 3 twice daily, once in the morning after breakfast and then before going to bed, on experimental site A and B. The clinical parameters were assessed on day '0', 7th 14th and 21st day. Microbiological samples were collected on the '0' and 21st day only. During this study period patients were instructed to use only tooth brush without any tooth paste to clean their teeth.

### Microbiological analysis:

The supragingival plaque sample was collected from the tooth surface with the help of sterile cotton pellet or paper point on baseline and after 21st days of twice daily gel application. The samples were transferred to Thioglycollate broth transport media (2 ml) and sent to the laboratory on the same day of collection. The specimen was diluted in sterile phosphate buffered saline (1:100) and plated on to chocolate agar (general purpose medium), MacConkey agar (for coliforms) and Mitis salivarius agar (for s. mutans, s. mitis and s. salivarius). The first two media were incubated aerobically at 37°C overnight and MSA was incubated in 5%CO<sub>2</sub> (in candle jar) at 37°C for 48 hrs. The colony count was done by counting the number of colonies on each plate, multiplied by the dilution factor and expressed as CFU/ml. the organisms were identified by colony characters, gram staining and key biochemical reactions.

Novel herbal polymeric gel : Mucoadhesive biodegradable gel[4] is prepared by Head, Faculty of Pharmacy, B.B.D. National Institute of Technology & Management Lucknow, U.P. (INDIA) On baseline the clinical recording was done and microbial samples were collected from all the three sites. The gel is applied twice daily with the help of cotton bud for 21st days. Novel herbal polymeric gel and cotton applicator are given to each patient to apply approximately 1 gram of gel(3) twice daily, once in the morning after breakfast and then before going to bed, on experimental on experimental site A and B. The clinical parameters were assessed on day '0', 7th 14th and 21st day. Sterilized wooden spatulas were given along with gel to each patient to use the gel.

### Results:

A total number of 45 quadrants from 15 patients with Gingivitis were selected, using clinical parameters. The

quadrants were divided into Control group C treated by SRP alone; Experimental group A, which received SRP and novel herbal polymeric gel and Experimental group B received only novel herbal polymeric gel.

At selected sites the following clinical parameters were assessed at '0', 7th, 14th and 21st day and microbiological plaque sampling was done at baseline and 21st day.

The mean reduction of plaque index from '0'– 21st day was 0.63 (63%) for control group C, 0.66 (72%) for experimental group A and 0.59 (66%) for experimental group B. On comparison of reduction of plaque score between control group C and experimental group A and between control group C and experimental group B and experimental group A and experimental group B was not statistically significant from baseline to 21st day. [Table I]

The mean reduction of gingival bleeding index from '0'– 21st day was 24.6 (52%) for control group C, 41.4 (74%) for experimental group A and 33.2 (63%) for experimental group B. On comparison of reduction of plaque score between and between control group C and experimental group B and experimental group A and experimental group B was not statistically significant from baseline to 21st day. Reduction of plaque score between control group C and experimental group A showed statistically significant results with P value of <.05.[Table II]

The mean reduction of gingival index from '0'– 21st day was 0.72 (60%) for control group C, 0.93 (71%) for experimental group A and 0.77 (63%) for experimental group B. On comparison of reduction of plaque score between control group C and experimental group A and between control group C and experimental group B and experimental group A and experimental group B was not statistically significant from baseline to 21st day. [Table III]

Prevalence of various microorganisms at different intervals of study periods.[Table IV] Showed The Following Results, Streptococcus sanguis showed 50%, 27%, 17% reduction in GP A, GP B, and GP C respectively from baseline to 21st day which was statistically significant with P values of GP A <.001, GP B <.001 and GP C <.005, Streptococcus Mutans showed 53 %, 17% and 17% in reduction in GP A, GP B, and GP C respectively from baseline to 21st day which was statistically significant with P values of GP A <.05, GP B <.05 and GPC <.05.

Streptococcus salivarius showed 70 %, 22% and 21% in reduction in GP A, GP B, and GP C respectively from baseline to 21st day. Streptococcus mitis showed 63 %, 31% and 24% in reduction in GP A, GP B, and GP C respectively from baseline to 21st day .

**Plaque Index: Inter And Intra Group Comparison At Different Intervals of Time - Group A, B And C [Table -1]**

D = Difference from baseline P<0.001 Highly significant t = Paired t-test

GROUPS	0 DAY	7 DAY	D t P	14 DAY	D t P	21 DAY	D t P	%
A	0.92 ± 0.20	0.78 ± 0.13	0.14, 3.00, <0.01	0.47 ± 0.12	0.45 9.95 <0.001	0.25 ± 0.08	0.66 14.5 <0.001	72%
B	0.89 ± 0.32	0.70 ± 0.24	0.19 3.29 <0.01	0.51 ± 0.17	0.38 5.43 <0.001	0.29 ± 0.10	0.59 7.36 <0.001	66%
C	0.99 ± 0.23	0.80 ± 0.18	0.19 4.75 <0.001	0.50 ± 0.11	0.49 10.79 <0.001	0.36 ± 0.09	0.63 10.25 <0.001	63%
ANOVA F P			0.51 0.61		1.92 0.16		0.49 0.62	
DIFF BETWEEN GROUPS P-VALUES	A-B		0.71 NS		0.54 NS		0.65 NS	
	A-C		0.61 NS		0.69 NS		0.99 NS	
	B-C		0.98 NS		0.14 NS		0.71 S	

**Gingival Bleeding Index: Inter and Intra Group Comparison at Different Intervals of Time Group A, B And C [Table II]**

GROUPS	0 DAY	7 DAY	D t P	14 DAY	D t P	21 DAY	D t P	%
A	56.4 ± 19.1	45.0 ± 15.7	11.5 2.63 <0.05	29.4 ± 12.4	27.0 6.09 <0.001	15.0 ± 10.9	41.4 8.8 <0.001	74%
B	52.7 ± 17.9	44.7 ± 12.5	0.8 2.26 <0.05	30.8 ± 12.1	21.4 4.88 <0.001	19.5 ± 10.0	32.2 6.87 <0.001	63%
C	47.3 ± 16.4	39.9 ± 13.5	7.4 2.95 <0.05	33.3 ± 9.5	14.0 4.65 <0.001	22.7 ± 8.9	24.6 5.95 <0.001	52%
ANOVA F P			0.55 0.58 NS		2.53 0.09 NS		3.54 <0.05 S	
DIFF BETWEEN GROUPS P-VALUES	A-B		0.73 NS		0.70 NS		0.47 NS	
	A-C		0.57 NS		0.08 NS		<0.05, S	
	B-C		0.96 NS		0.32 NS		0.29 NS	

D = Difference from baseline P<0.001 Highly significant t = Paired t-test

Gingival Index: Inter and Intra Group Comparison At Different Intervals of Time Group A, B And C [Table III]

GROUPS	0 DAY	7 DAY	D t P	14 DAY	D t P	21 DAY	D t P	%
A	1.31± 0.36	1.03± 0.27	0.29 4.35, <0.001	0.70± 0.24	0.61 7.78 <0.001	0.38± 0.16	0.93 10.5 <0.001	71%
B	1.22± 0.37	1.01± 0.27	0.21 3.44 <0.01	0.68± 0.21	0.54 7.04 <0.001	0.45± 0.20	0.77 10.3 <0.001	63%
C	1.19± 0.19	0.97± 0.20	0.22 6.62 <0.001	0.74± 0.17	0.45 13.8 <0.001	0.47± 0.14	0.72 15.5 <0.001	60%
ANOVA F P			1.14 0.33 NS		1.38 0.26 NS		2.66 0.08 NS	
DIFF BETWEEN GROUPS P- VALUES	A-B		0.38 NS		0.74 NS		0.27 NS	
	A-C		0.40 NS		0.24 NS		0.07 NS	
	B-C		0.99 NS		0.62 NS		0.75 NS	

D = Difference from baseline P= Pvalue t = Paired t-test  
Microbiological Profile in Various Treatment Groups. Inter and Intra Group Comparison of Group A, B And C. [Table IV]

Microorganisms	Treatment groups	0' day	21th day	Difference p	% Reduction
STREPTOCOCCUS SANGUIS	C (Scaling)	156.0± 82.6	130.0± 64.6	26.0 <0.05, S	17
	A (Scaling)+ GEL)	230.7± 118.5	128.0± 87.8	102.7 <0.001	50
	B (GEL)	204.7± 63.0	150.0± 48.7	54.7 <0.001	27
	A-B	-	-	<0.01, S	
	A-C	-	-	<0.01, S	
	B-C	-	-	<0.05, S	
STREPTOCOCCUS MUTANS	C (Scaling)	43.6± 22.6	36.0± 18.5	7.6 <0.05, S	17
	A (Scaling)+ GEL)	120.8± 64.5	57.5± 41.7	63.3 <0.05, S	53
	B (GEL)	59.0± 32.1	49.0± 27.5	10.0 <0.05, S	17
	A-B	-	-	<0.01, S	
	A-C	-	-	<0.01, S	
	B-C	-	-	<0.66, NS	
STREPTOCOCCUS SALIVARIUS	C (Scaling))	136.3± 41.9	107.5± 49.2	28.8	21
	A (Scaling)+ GEL)	155.0± 56.1	46.7± 76.6	108.3	70
	B (GEL)	113.3± 58.5	88.3± 37.6	25.0	21
STREPTOCOCCUS MITIS	C (Scaling))	85.0± 49.5	65.0± 49.5	20.0	24
	A (Scaling)+ GEL)	100.0± 0.0	37.5± 53.0	62.5	63
	B (GEL)	39.3± 61.2	27.3± 45.6	12.0	31

Discussion:

The beginning of the periodontal disease occurs through accumulation of a thin film of bacteria on the surface of the teeth called plaque. Novel approaches were tried to deliver the drugs in different ways in treating such human ailments. Many antimicrobial agents were tried as mouth rinses, gels and mouthwashes to control oral infections with poor to moderate degrees of success.

The deployment of natural substances in dentistry is just starting and research in the field endeavors to analyze the chemical properties and the workings of these compounds.[5] Since the use of antibacterial agents may be restricted by side effects[6] great importance is given to natural alternatives for the prevention or decrease of microorganism adhesion to tooth surface and to cure oral diseases.

Loe H[7]and Bakdash B[8] stated that mechanical plaque reduction with assorted devices remains the primary and most widely accepted means of controlling supragingival plaque and maintaining gingival health. Christen D Wu, Savitt E.D,[9] reported that in conjunction with mechanical methods, oral hygiene products containing chemotherapeutic agents with a variety of antimicrobial mechanism have been desirable and beneficial.

Poch[10] stated that the combination of therapies with different mechanisms of action often results in functional synergism, i.e. when the efficacy of a combination of agents (eg. drugs) is equivalent to or greater than the sum of the individual efficacies. This holds true for the ingredients present in the herbal gel used in our study, which individually have shown their effects on oral microorganisms and gingival diseases.

Novel herbal polymeric gel is new product, with active ingredients like neem 5% (Azadirachta indica), Tulsi (Ocimum Sanctum) and Paan oil (Piper betle) clinically its efficiency is evaluated on different grades of gingivitis in the Subharti Dental College, Meerut.[11] It is been used as a topical gel on different grades of gingivitis, but its effects on oral micro organisms has not been experienced.

In the present study, an attempt has been made to evaluate the effectiveness of novel herbal polymeric gel in the treatment of plaque induced gingivitis and aerobic microorganisms associated with it. A clinical study was designed which

included[12] patients and 45 quadrants treated for 3 weeks. The study period of 3 weeks follows the recommendations of Chillon and Fleiss JL 12 to undertake trials regarding gingival inflammation with a study period longer than 2 weeks.

This study establishes the use of novel herbal polymeric gel in treating gingivitis by inhibiting the plaque growth as claimed by the traditional medicine. Gel formulated with a mucoadhesive polymer can significantly reduce the duration of the therapy in treating the oral infections and controlling the microbes responsible for the gingivitis. Present study provided more insights on the beneficial effects of novel herbal polymeric gel on gingivitis and dental plaque.

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