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Research Article

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Clinical comparison of plain Chlorhexidine (0.2%) and Chlorhexidine (0.2%) in combination with Sodium Fluoride (0.05%) and Zinc Chloride (0.09%)

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ABSTRACT

Numerous mouthrinses are available commercially to control gingival & periodontal diseases. This study was aimed to compare the efficacy of 0.2% Chlorhexidine and 0.2% Chlorhexidine in combination with 0.05% NaF& 0.09% $ZnCl_2$. 50 subjects of both genders, aged between 18-32 years were selected for the study. They had undergone professional scaling, just before the trial of both mouthrinses. There was an experimental period of 2 months each & a washout period of 1 month in between the trials. They were examined clinically at each month from the baseline, till 2 months. The study results showed significant improvement in the plaque & gingival index scores at the end of 2 months, when compared with the baseline values. Comparative analysis between both the products showed statistically insignificant clinical results. Thus it is clear from the observed results that clinical effect of both the mouthrinses is almost same. The present study does not reveal any significant difference between both the products.

Key words: Mouthrinses, Chlorhexidine, Sodium Fluoride, Zinc Chloride, Plaque & Gingival Index

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INTRODUCTION

Chlorhexidine is available in different formulations. The most common available form of chlorhexidine in our country is 0.2% solution as a mouthrinse. Chlorhexidine has been included in mouthwashes not only at different concentrations, but also in different formulations. For example, chlorhexidine is available in combination with certain ingredients which are supposed to have added advantages (as claimed by the manufacturers) over the plain mouthwashes of chlorhexidine, but this is not supported by adequate research.

The aim of this study was to investigate the efficacy of chlorhexidine (0.2%) alone as compared to chlorhexidinegluconate (0.2%) in combination with NaF (0.05%) & $ZnCl_2$ (0.09%). Fluoride has a well-known effect on prevention of dental caries.[1], while Zn ions have an important role in masking halitosis.[2,3] & preventing formation of supragingival calculus.[4]

The objectives was to compare the efficacy of Chlorhexidinegluconate (0.2%) alone [Product A] as compared to Chlorhexidinegluconate (0.2%) in combination with NaF (0.05%) & $ZnCl_2$ (0.09%) [Product B] using the following clinical parameters:

1) Gingival Index (Loe&Silness) & 2) Plaque Index (Silness&Loe)
These indices were taken at the baseline (0 month) and then after every one month(1, 2, 3, 4, 5 months) of the study.

EXPERIMENTAL SECTION

Total 50 patients (irrespective of cast, creed & sex) aged between 18-32 yrs were selected for this study from the Outpatient Department of Periodontics. However 46 patients completed the study protocol, while 4 patients dropped out in between the study due to unexplained reasons.

Inclusion criteria
- Patients suffering from moderate gingivitis.
- Aged between 18-32 years.
- Atleast 24 permanent teeth with buccal& lingual scorable surfaces.
- Systemically healthy patients.

Exclusion criteria
- Allergic to chlorhexidine.
- With active periodontal disease.
- Pathologic conditions of the tongue, mucosa & gingiva.
- Patients using chlorhexidine or any other topical medication till 3 months, before the clinical trial.
- Patients with any fixed or removable prosthetic/orthodontic appliance.
- Smokers.
- Pregnant & lactating patients.

All the volunteers were given oral & written information about the products & purpose of study and they also signed the written consent forms.

Screening Examination
This study was randomized, controlled clinical trial& all the patients used both the mouthwashes at different time intervals.

In this study, there was an experimental period of 2 months each & a washout period of one month in between them. The patients were examined after every month of study period from the baseline level. All the patients had undergone professional tooth cleaning before starting the trial of both the mouthwashes.

After thorough examination, a brief case history was taken. All the selected patients exhibited signs of moderate gingivitis.

This was determined by taking:
Gingival Index….score 1.1-2, according to Loe & Silness.

Plaque Index….score 1.1-2, according to Silness & Loe.
All the patients were given professional scaling at the base line level (0 month) to remove plaque, stains & calculus.

Patients were instructed to brush their teeth twice a day with the help of dentifrice & toothbrush and were also told to rinse with 10 ml of 0.2% chlorhexidine solution *(Product A)* for 60 seconds, twice a day. (1:1 ratio i.e. equal amounts of mouthwash & water, in the morning & in the evening) Brushing should be done twice a day at least 30 minutes before using mouth rinse to avoid any possible pharmacological interactions.

They were refrained from eating/drinking for the next half an hour, after using the product. Rinsing with water was also not allowed during this duration. They were instructed not to use any other dental hygiene product during the study period.

After one month, the patients were re-examined & they were questioned about any unwanted side effect during rinsing with prescribed mouthwash. GI & PI were again taken at this time. They were allowed to continue their normal brushing and rinsing with 0.2% chlorhexidine mouth rinse as prescribed to them earlier.

After two months from the base line level, the patients were clinically examined & the same parameters (GI & PI) were noted. They were asked to discontinue the use of mouthwash for one month & were allowed to perform their routine tooth brushing method. They were instructed not to use any other chemical oral hygiene product during this period.

The patients were recalled after one month for the next examination. *There was a washout period of one month in between the study period.*

After one month i.e. 3 months after the baseline level they were re-examined & underwent complete oral prophylaxis at this level.
Patients were reinstructed to brush his/her teeth twice a day with the help of toothbrush & a dentifrice and were asked to rinse with 10 ml of undiluted 0.2% chlorhexidine solution combined with NaF 0.05% & $ZnCl_2$ 0.09% *(Product B)* for 60 seconds twice a day (1:1 ratio.. i.e. equal amounts of mouthwash & water) in the morning (about an hour after brushing) & in the evening. They were not allowed to eat/drink anything for next half an hour. Rinsing with water was also restricted during that period.

After one month the patients were re-examined & they were asked about any unwanted side effect during rinsing with prescribed mouthwash. GI & PI were again taken at this time. They were allowed to continue their normal brushing & also rinsing with prescribed mouthwash (Chlorhexidine 0.2%, NaF 0.05%, $ZnCl_2$ 0.09%) for the next one month.

After two months from the base line level, the patients were examined & the same parameters (GI & PI) were recorded again.

This completed the study protocol of 5 months. Patients were recalled & examined every month from the baseline level.

Statistical Analysis
Plaque Index (PI) & Gingival Index (GI) were taken as the clinical parameters for testing the efficacy of Product A& Product B.

Difference between both products was compared via a set of pair-wise comparisons.

In the present study, plaque & gingivitis reduction for both the *Products A& B* was compared with one-another.

Values of PI & GI were taken on baseline (0 month), 1 month, 2 month for both the products. Percentage reduction was calculated in PI & GI from 0-1 month, 1-2 month & 0-2 months. Thus the results of 3 phases of each index were obtained. These values (Percentage difference in PI & GI) were compared with one-another.

Mean percentage reduction, standard deviation & standard error mean were calculated.

All analysis, comparing differences between Product A & Product B were performed using *t-tests*. p-value, Degrees of freedom & Confidence Interval (CI) were also determined.

All tests were carried out by using a statistical software program. Two sided value of $p<0.05$ (corresponding value of $t>1.96$) were considered as statistically significant.

Study Trial-1			wash out period (2-3 months) routine brushing without the use of mouth rinse	**Study Trial-2**		
0 month,	1 month,	2 month,		3 month,	4 month,	5 month.
PRODUCT A				**PRODUCT B**		
Baseline (0 month)	1 month	2 month		Baseline (0 month)	1 month	2 month
1.Clinical Examination -Plaque Index -Gingival Index 2. Scaling 3. Oral Hygiene Instructions use of mouth rinse (Product A)	Clinical Examination -Plaque Index -Gingival Index	Clinical Examination -Plaque Index -Gingival Index		1.Clinical Examination -Plaque Index -Gingival Index 2. Scaling 3. Oral Hygiene Instructions, use of mouth rinse (Product B)	Clinical Examination -Plaque Index -Gingival Index	Clinical Examination -Plaque Index -Gingival Index

RESULTS

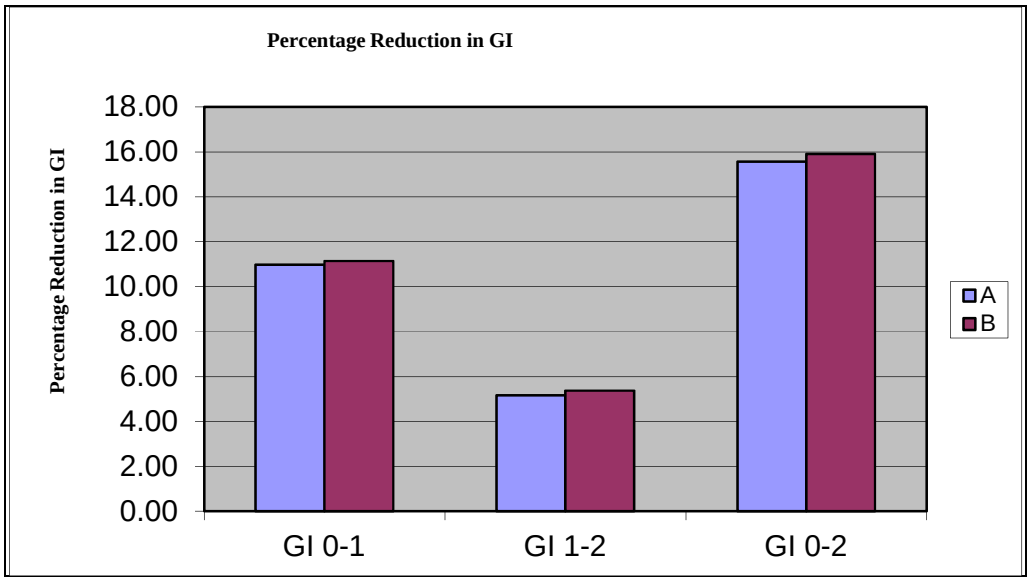
Out of 50 patients, who were selected for the study purpose, 46 patients were able to complete the study, 4 patients dropped out during the study protocol due to unknown reasons i.e. they were unable to report on some of the recalled visits.

The value of PI & GI for both chlorhexidine formulations (Products A& B) at baseline (0 month), 1 month, 2 month is calculated. Then percentage reductions of both the products were calculated in PI & GI from 0-1 month, 1-2 month & 0-2 months. These values (Percentage difference in PI & GI) on each phase were compared with one-another.

Thus results of total 6 phases i.e. PI 0-1, PI 1-2, PI 0-2 and GI 0-1, GI 1-2, GI 0-2 were obtained.

The mean percentage reductions in PI of both the products are given below Product B showed little higher reduction in plaque scores as compared to Product A but the comparative results were statistically not significant ($p > 0.05$)

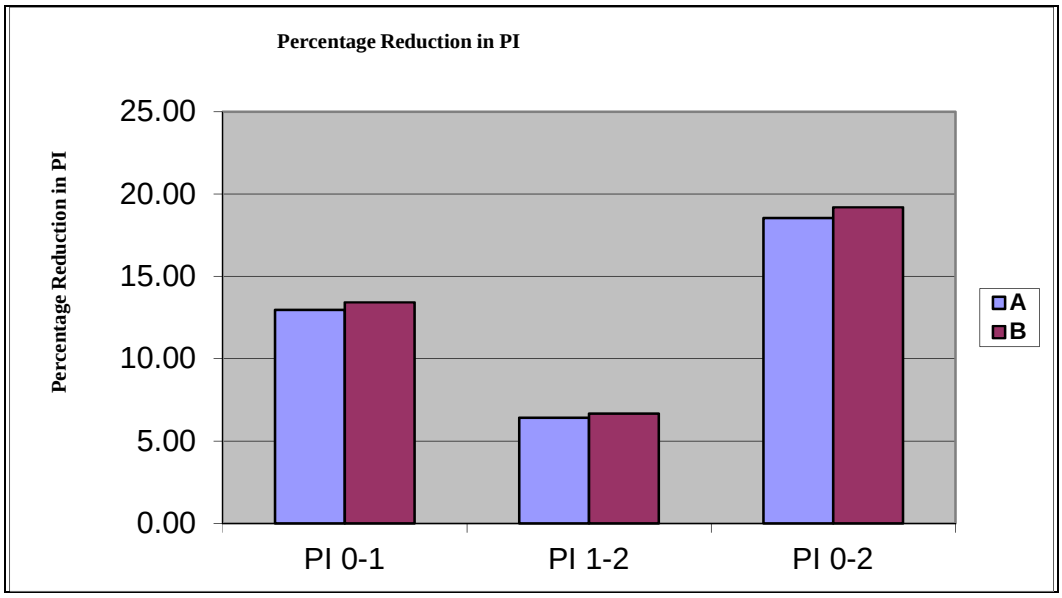
The mean percentage reductions in GI of both the products are given below:



Product B shows little higher reduction in gingival index scores in every phase of the study, as compared to Product A but the analysis showed that inter-comparative results were statistically insignificant (p>0.05)

Duration (Months)	Mean % reduction of Gingival Index	
	Product A	Product B
0-1	10.97	11.14
1-2	5.16	5.38
0-2	15.56	15.91

The mean percentage reductions in PI of both the products are given below:



Product B showed little higher reduction in plaque scores as compared to Product A but the comparative results were statistically not significant (p> 0.05)

Duration (Months)	Mean % reduction of Plaque Index	
	Product A	Product B
0-1	12.96	13.42
1-2	6.42	6.67
0-2	18.54	19.19

Clinical Parameters

Plaque Index

The mean percentage reduction in plaque scores from 0-1 month for product A was 12.96% as compared to product B, which was 13.42%. It is clear from above observation that average plaque reduction in product A was slightly less as compared to that of product B, but the difference was very small.

The mean percentage reduction from 1-2 months for product A was 6.42% & product B was 6.67%. Thus it is clear that more plaque reduction was seen from 0-1 month as compared to 1-2 months. It was due to the effect of oral prophylaxis & mouthwash (besides brushing) from 0-1 month while in the second phase plaque reduction was the effect of mouthwash (besides brushing) only.

The plaque reduction from 0-2 months in case of product A was 18.54%, while in case of product B, it was 19.19%. The difference between the 2 products was negligible, although a little higher plaque reduction was seen in case of product B; it could be due to limitation & variation of sample size. The comparative analysis between the 2 products also shows statistically insignificant results.

Gingival Index
The mean percentage reduction in gingivitis from 0-1 month for product A was 10.97% as compared to product B, where it was 11.14%. It is clear from above observation is that mean gingivitis reduction in product A was slightly less as compared to that of product B, but the difference was very small.

The mean percentage reduction from 1-2 month for product A was 5.16% & product B was 5.38%. Thus it is clear that mean gingivitis reduction was more from 0-1 month as compared to 1-2 month. It was due to the effect of both oral prophylaxis, brushing & mouthwash from 0-1 month while in the second phase, plaque reduction was the only the effect of mouth rinse & brushing.

The mean percentage reduction in gingivitis from 0-2 months in case of product A was 15.56%, while in case of product B was 15.91%. The difference between the 2 products was negligible, although slightly higher reduction in gingivitis scores was seen in case of product B which could be due to limitation & variation of sample size. The comparative analysis between the two products also shows statistically insignificant results.

Analytical Review
This study shows chlorhexidine shows slightly better anti-plaque effect along with NaF & $ZnCl_2$ (Product B). Reduction in plaque scores in both the products (at every phase of study) was seen, but little more plaque reduction was found in case of Product B (as compared to product A). Comparison between both the products shows statistically insignificant results.

Reduction in gingival index of both the products was seen at every phase of study but little more gingivitis reduction was observed in case of Product B (as compared to Product A) though comparison in between both the products shows statistically insignificant results.

DISCUSSION

The role of dental plaque in the etiology of dental disease is well recognized with many excellent reviews. Plaque is known to be initiating factor in the development of gingivitis, when in contact with the gingival tissues.[5]Therefore, plaque control is the most important part of oral hygiene practice & thus prevents gingival & periodontal diseases.

Mechanical cleaning is the most widely used method of supragingival plaque control & is effective in areas, where access to the plaque deposit is possible.[6]Mechanical methods of plaque require time, motivation & mechanical dexterity.[7] This makes it difficult to effectively educate, train & encourage some patients to reduce plaque solely by mechanical means.[8]The use of chemical agents with anti-plaque & anti-gingivitis action as adjuncts to self-performed oral hygiene is based on the shortcomings of the mechanical methods.[9]

Until now chlorhexidine seems to be most effective among chemical plaque control agents. Several studies have shown that rinsing twice daily with chlorhexidine solution inhibits plaque formation & helps to prevent gingivitis & dental caries. Chlorhexidine has found many short to medium term uses in the control of oral flora & plaque accumulation, particularly when mechanical cleaning is difficult or inadequate.[10,11]

It should be noted that in present study, patients continued their normal tooth brushing habits. This is important because chemical agents like chlorhexidine formulations are always used as an adjunct to mechanical plaque control methods (can never be substitute of it). Many studies have shown that the use of a mouthwash associated with regular tooth cleaning was more beneficial than the utilization of mouth rinse alone.[12] It has also been suggested that the efficacy of chlorhexidine rinses may vary depending on whether or not these are used in conjunction with toothpaste.[13] So objective of this trial was to assess the adjunctive chemical plaque inhibitory action of mouthrinses, when used along with toothpaste.

Both chlorhexidine & fluoride may have valuable preventive roles in dental diseases & there is also evidence that in caries prevention they may act together to provide additional benefits. Therefore, sodium fluoride and chlorhexidine may be added together without any incompatibility.

Increased anti-plaque effect of Zn-chlorhexidine combination may be due to additional receptors for Zn ions not available to chlorhexidine. The superior plaque-inhibiting effect of this combination is explained by a synergistic

anti-microbial effect. The pH measurements also indicate the presence of available retention sites in dental plaque & in the oral cavity for both Zn & chlorhexidine, when used in combination. Thus this combination had several favorable clinical effects as compared with separate agents.

CONCLUSION

Significant reduction in plaque & gingivitis was observed in both the products (A & B) at every phase (0-1, 1-2, 0-2 months) of study. The comparative analysis between the 2 products also showed statistically insignificant results.

Thus it is clear from the observed results that the clinical effect of both the mouth rinses are almost same. The present study does not reveal any significant difference between both the products. The little difference between both the products may be due to small sample size. This may also be due to sampling error (collection of sample from different geographical areas may produce variable results)

As the findings were encouraging, it justifies the need of further studies with large sample size to evaluate more precise clinical effects of chlorhexidine alone, when compared to chlorhexidine along with Zn & F ions.

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