A clinical study evaluating the effect of 0.4% stannous fluoride gel in controlling plaque and gingivitis

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ABSTRACT

Background: Stannous fluoride is a broad-spectrum antimicrobial agent. It has been incorporated into dentifrice formulations and shown to be effective in the prevention and reduction of gingivitis [17, 18, 20], the aim of the study was to determine whether conventional tooth brushing and twice daily use of a brush on 0.4% stannous fluoride (SnF2) gel would be more effective for controlling plaque accumulation and gingivitis than conventional tooth brushing alone.

Materials and Methods: A randomized, six month, single examiner blind. Gingivitis study conducted according to the guide lines for evaluating chemotherapeutic products for the control of gingivitis. 0.4% stannous fluoride gel was tested against a commercially available negative control dentifrice (Crest Complete, KSA). The sample of the study included two groups, the first; control group (N=30) used tooth brushing with standard fluoride tooth paste(Crest Complete ,KSA),while the second; study group (N=30) used tooth brushing with the same tooth paste, supplemented with a 0.4% stannous fluoride gel used twice daily for the entire six month-study period. Clinical assessment involved plaque index(1) gingival index(2) and bleeding on probing index(3) were performed at base line, three and six months post-treatment.

Result: The stannous fluoride gel (SnF2) group had highly significant lower scores for plaque index (PL.I, $p< 0.01$), gingival index (GI, $p< 0.01$) and bleeding tendency at all examinations than did the control group. For the study group, mean baseline PL.I score was 1.83, at three months it was reduced to 0.84and after six months it was 0.54.For the GI. Mean baseline GI. was 1.60, at three months it was 0.82 and after six months it was reduced to 0.57.

Conclusion: It is concluded that the use of 0.4% SnF2 gel is an effective adjunct to mechanical tooth cleaning in decreasing plaque and gingivitis.

Key words: Stannous fluoride, plaque, gingivitis.

INTRODUCTION

The occurrence of gingivitis is wide spread in the population. [4] Studies have shown, the prevalence of gingivitis in adults was reported to exceed 75% and even to approach 100% in some populations.[5,6] Gingivitis can progress to more serious periodontal disease, leading to periodontal attachment loss , and ultimately, possible tooth loss. Data have recently shown that periodontal diseases may confer risk for cardiovascular disease and preterm low birth weight. [7, 8, 9]

Gingival inflammation can be controlled via mechanical plaque removal using a tooth brush and other oral hygiene aids. This mechanical plaque removal can be supplemented with chemical antigingivitis agents, one of the chemotherapeutic agents that has had antigingivitis activity reported in multiple clinical trials is a 0.4% stannous fluoride in gel and dentifrice form. [7, 10, 11]

The antigingivitis activity of stannous fluoride may be due to the inhibition of bacterial adhesion, growth, and carbohydrate metabolism.[12] In one in vitro study reported by Tseng and Wolff in 1991 [13] demonstrated that Stannous fluoride gel is as effective as chlorhexidine in inhibiting the growth of bacteria often found in dental plaque.

Another study reported by Svatun et al in 1977 [14] showed the plaque-inhibiting effect of a SnF2 solution was equivalent to that of chlorhexidine, when each was used twice daily. Tinanoff et al in 1976 [15] showed almost total inhibition of plaque and bacteria with a twice daily rinse of 0.1% SnF2, in a scanning electron microscopy study.Niderman[16] concluded that the use of SnF2 dentifrices results in greater gingivitis and plaque reduction compared with a conventional dentifrice. Due to conflicting research reported, it was decided to conduct this study over a period of six months. The aim of the study was to assess the antigingivitis efficacy of 0.4% stannous fluoride gel (alpha-dent, Hamlin avenue, Lincolnwood. USA) among subjects with plaque induced gingivitis.

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MATERIALS AND METHODS

Study design: A randomized, six months, single examiner blind, longitudinal, gingivitis study. Following baseline measurement all subjects received dental prophylaxis.

Subject population: Sixty subjects ranged in age from (**18-30)** years old, they were 35 women and 25 men, involving healthy dentate volunteers with no relevant medical or pharmaco-therapy histories. They were diagnosed as having plaque induced gingivitis, were with at least twenty teeth and no removable or fixed dental prosthesis or orthodontic appliance.The subjects were divided into two groups, matched with scores of plaque and gingivitis. The first, control group N=30 used tooth brushing with commercially available toothpaste (Crest Complete ,KSA).The second, study group N=30 used tooth brushing with the same tooth paste supplemented with 0.4% Stannous Fluoride gel(alpha-dent, Hamlin avenue, Lincolinwood. USA). All participants instructed to brush twice daily for 60 seconds for each product and the study group were applied the SnF2 gel on all teeth and brush thoroughly. The gel remained for 60 seconds then spited out, do not drink or eat for 30 minutes after brushing

Oral assessment : Plaque index (PL.I) [(1)] evaluations , gingival index (G.I) [(2)] and bleeding on probing index(BOP) [(3)] examination were performed for all subjects at base line (first visit) then at three and six months to assess efficacy of the test product.

Data analyses were conducted by the application of the SPSS (version 15).Descriptive statistics and two ways analysis and t-test were performed.

RESULTS

Descriptive and statistics analysis were based on sixty participants who were present for all three examinations (baseline, 3 months, 6 months), the subject group was comprised of 35 women and 25 men. The average age of the subjects was 23.2 years.

Plaque Index results (PLI):

PLI results are reported in table (1) and figure (1).The mean baseline PLI score was 1.83 for the study group & 1.61 for the control group. Mean score at 3 months was reduced to 0.84 for the study group while it's 1.68 for control group. After 6 months, the study group mean of PLI was reduced to 0.54 but it was 1.69 for the control group.

By two ways analysis, a highly significant difference was noted when the study group was compared among the three visits (P< 0.01) while no significant difference occurs for the control group (table2).

t-test was applied to identify a comparison between study and control group, (table3) that showed a significant difference at baseline visit ,highly significant difference at three and six months visits.

Table (1): Mean and standard deviation of PL.I for both groups at the three visits

	Study group			Control group		
	Base line	After 3 months	after 6month	Base line	After 3 months	after 6month
Mean	1.83	0.841	0.54	1.61	1.681	1.697
SD	0.36	0.139	0.11	0.29	0.283	0.2316

Table (2) Comparison between different visits of the study and control groups

	F-test	P-value	Significant
Study group	24.7	0.000	HS**
Control group	0.85	0.430	NS*

**P>0.05 Non significant* ***P<0.01 High significant*

Table (3) Comparison between the PL.I in study and control groups.

	t-test	P-value	Significant
Base line	2.52	0.015	S*
After 3 months	14.58	0.000	HS**
After 6 months	24.68	0.000	HS**

**P<0.05 significant* ***P<0.01 High significant*

Gingival Index result (GI):
GI results are reported in table (4) and figure (2). The mean baseline GI score was 1.60 for the study group and 1.66 for the control group. The mean score at 3 months was reduced to 0.82 for the study group while it's 1.75 for control group. After 6 months, the study group mean of GI was reduced to 0.57 but it was 1.83 for the control group.
By two ways analysis, highly significant difference was noted when the study group was compared among the three visits (P< 0.01) while no significant difference was present in the control group, (table 5) t-test was applied to identify a comparison between study and control group, (table 6) showed no significant difference at baseline visit ,highly significant difference at three and six months visits.

Table (4) Mean & Standard deviation of GI of the two groups at the three visits

	Study group			Control group		
	Base line	After 3 months	after 6 months	Base line	After 3 months	after 6 months
Mean	1.602	0.824	0.573	1.669	1.753	1.83
SD	0.225	0.138	0.112	0.254	0.2623	0.32

Table (5) Comparison between different visits of the study and control group

	F-test	P-value	Significant
Control group	2.57	0.082	NS*
Study group	31.6	0.000	HS**

**P>0.05 Non significant* ***P<0.01 High significant*

Table (6) Comparison between the study and the control group

	t-test	P-value	Significant
Base line	1.09	0.28	NS*
After 3 months	17.18	0.000	HS**
After 6 months	20.28	0.000	HS**

**P>0.05 Non significant* ***P<0.01 High significant*

Bleeding On Probing (BOP):
Table (7) demonstrates two scores based on absence of BOP (0) and presence of BOP (1).The results showed that score (1) was recorded in (29.11%) of the study group and (29.2%) for the control group at base line. The difference is non significant (P> 0.05).
Table (7) also shows that in the second visit after three months, the study group exhibited score (1) in 16.2% while 30.9 % in the control group. Chi- square was applied to test the significance of BOP% of the study group with the control; the difference is significant (p< 0.05). In the third visit after six months, the percentage was in descending order in study group; 8.7% while it is 31.3% for the control group. The difference between the two groups is highly significant (p< 0.01).

Table (7) Comparison of Bleeding On Probing (BOP) between study group and control group
Expressed as %.

	1st visit		3 month		6 month	
	Study	Control	Study	Control	Study	Control
0	70.9%	70.8%	83.8	69.1%	91.3%	68.7%
1	29.11%	29.2%	16.2%	30.9%	8.7%	31.3%
Chi-square score (1)	0.02		6.258		15.38	
P-value	0.964		0.012		0.000	
Significant	NS P>0.05		S P<0.05		HS P<0.01	

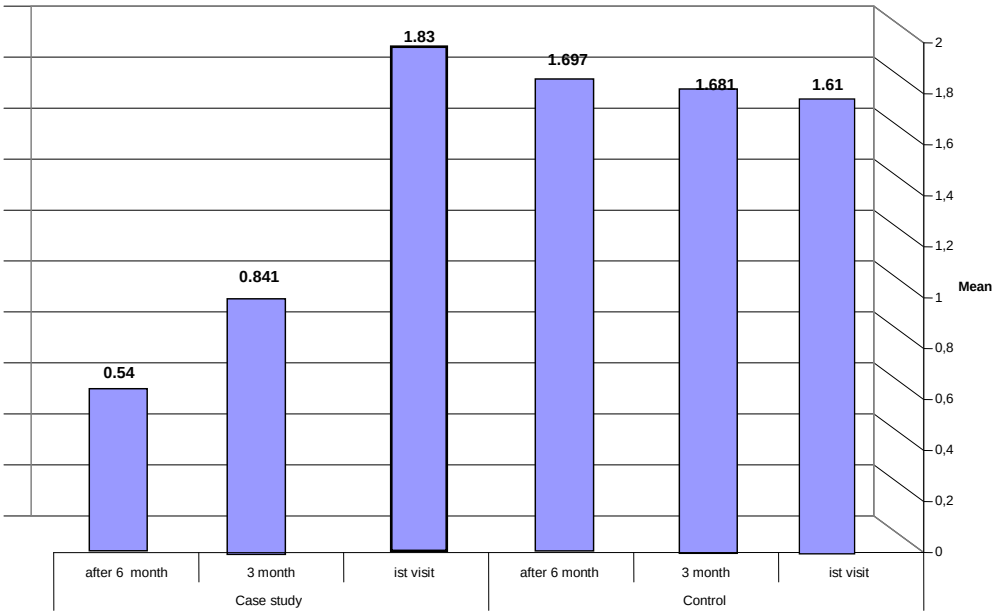

Figure (1) shows the mean plaque index for the study and control group at the three visits.

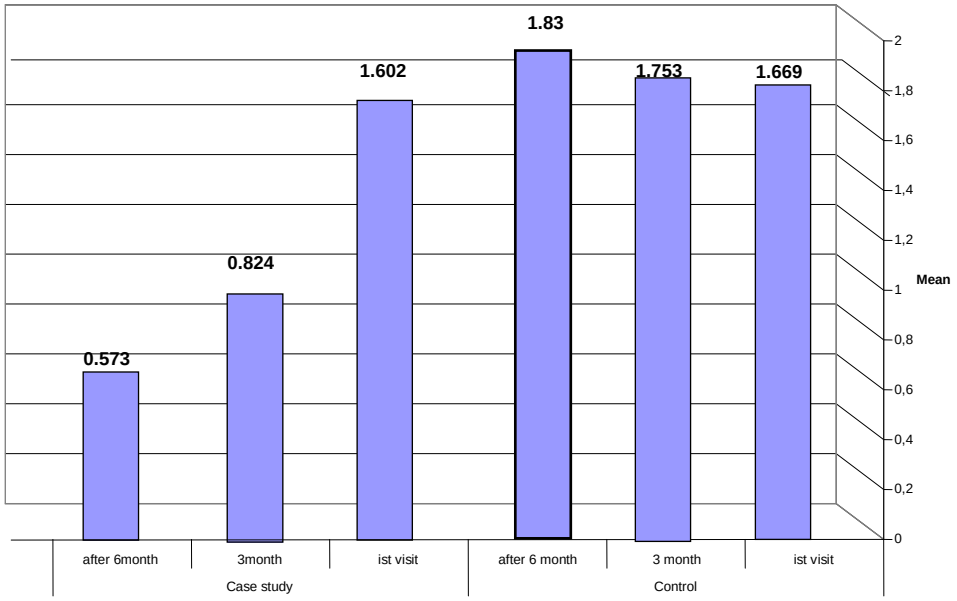

Figure (2) shows the mean gingival index for the study and control group at the three visits.

DISSCUSION

The single examiner blind study explored the antigingivitis efficacy of an experimental 0.4%SnF2 gel among subjects with plaque induced gingivitis. In this six months study, 0.4% Stannous fluoride gel resulted in statistically highly significant reduction (P< 0.01) in both PL.I and GI at both three and six months when compared to baseline reading. The most important finding in this study was that daily brushing with 0.4% SnF2 gel resulted in reduction in plaque formation, gingival inflammation and bleeding tendency when compared with standard fluoride tooth paste and these differences are statistically highly significant reduction in PLI and GI at both three and six months when compared to baseline, also highly significant differences in their comparison with the control group using t test. Inhibition of plaque by SnF2 gel has been demonstrated by previous short-term clinical and in vitro studies, and various mechanisms have been suggested:

1. Stannous fluoride causes an alteration of adhesive properties between enamel and bacteria and between bacteria themselves, resulting in less plaque accumulation [(12)]
2. An accumulation of tin within bacteria may alter their metabolism and other physiochemical characteristics. [(15)]
3. Stannous fluoride has been shown to have bactericidal and bacteriostatic properties which exceed those of sodium fluoride and of stannous chloride. This suggests that the effect is not caused by tin alone. [(12, 21-23)]

Data from the present study cannot be used to differentiate between these various potential mechanisms and indeed all may operate concurrently.Most of the oral health benefits of stannous fluoride result from its antibacterial efficacy, particularly against bacteria associated with dental caries, periodontal disease and oral malodor. The results of the study were in agreement with many studies (Niederman [(16)]; hoffman et al [(17)]; Steven and paul [(18)]; Madlena et al.[(19)]; Boyda and chunb [(20)]; Claydon N. et al [(24)] ;; Benjasupattananan S. et al [(25)]; Beiswanger BB. et al [(26)]. For BOP index, study group results significant reduction in score (1) after three months and highly significant reduction after six months, this in agreement with (Luis Archila et al [(5)]; mankodi et al [(27)]; Putte et al [(28)] ; Goliath et a,[(29)]) while the results disagree with Wolff et al [(30)] results, which indicated that 0.4%SnF2 is no more effective than a placebo in reducing gingivitis.

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دراسة سريرية لتقييم تأثير جل ٠,٤ % فلوريد القصدير في السيطرة على الصفائح الجرثومية والتهاب اللثة.

سوزان علي سلمان / بكالوريوس طب وجراحة الفم والاسنان/ ماجستير امراض وجراحة اللثة

اللقب العلمي : مدرس مساعد موقع العمل: كلية طب الاسنان /جامعة بغداد

الخلاصة : فلوريد القصدير هومضاد جرثومي واسع الطيف . تم مزجه مع مواد اخرى لتصنيع معاجين اسنان ولوحظ انه فعال في الوقاية والتقليل من التهابات اللثة.(٢٠,١٧,١٨). الهدف من الدراسة لتحديد فيما اذا كان تفريش الاسنان بطريقة تقليدية او الاستعمال اليومي لهلام او جل فلوريد القصدير سيكون اكثر تأثيرا في السيطرة على تراكم الصفائح الجرثوميةوالتهابات اللثـــة من الطريقـــة التقليدية في التفريش

المواد المستعملة وطريقة العمل: الدراسة شملت عينة عشوائية من المر**ضى** المصابين بالتهابات اللثة واستمرت لستة اشهر وتم توزيع لتقييم تأثيرمادة كيميائية علاجية في السيطرةعلى التهابات اللثة .٠,٤% من جل فلوريد القصدير تمت مقارنته مع معجون اسنان اعتيادي يحتوي على الفلورايد (Crest Complete ,KSA) . الدراسة تضمنت مجموعتين هي المجموعة الضابطة وتكونت من ثلاثين شخصا ، وهم اشخاص يستعملون معجون اسنان قياسي يحوي على الفلورايد (Crest Complete ,KSA) المجموعة الثانية : وهي المجموعة التجريبية وتكونت من ثلاثين شخصا يستعملون نفس معجون الاسنان القياسي اضافة الى التفريش بجل ٠,٤% فلوريد القصدير استعمال لمرتين في اليوم ولمدة ستة اشهر الفحص السريري شمل مؤشر الصفيحة الجرثومية(١) ومؤشرالتهابات اللثة (٢) ومؤشر النزف عند التسمير(٣) تم قياسه في الزيارة الاولى وبعد ثلاثة اشهر وبعد ستة اشهر.

النتائج: بالنسبة للاشخاص الذين استعملوا فلوريد القصدير النتائج اظهرت فرقا معنويا كبيرا لمؤشر الصفيحة الجرثومية ولمؤشر التهابات اللثة ولمؤشر النزف عند التسمير عند المقارنة مع المجموعة الضابطة. وكان متوسط الصفيحة الجرثومية في الزيارة الاولى (١,٨٣)وبعد ثلاثة اشهر اصبحت (٠,٨٤) وبعد ستة اشهر كانت (٠,٥٤) اما لمتوسط مؤشر التهابات اللثة فكان(١,٦٠) في الزيارة الاولى وبعد ثلاثة اشهر قل المتوسط ليصبح (٠,٨٢) وبعد ستة اشهر اصبحت (٠,٥٧)

الاستنتاج: ان استعمال ٠,٤% من جل فلوريد القصدير هو فعال وعامل مساعد للتفريش التقليدي الميكانيكي في تقليل تراكم الصفيحات الجرثومية والتهابات اللثة.

الكلمات الدليلة: فلوريد القصدير ، الصفائح الجرثومية ، التهابات اللثة.