# Effect of a multi-faceted intervention on gingival health among adults with systemic sclerosis

H.K. Yuen<sup>1</sup>, Y. Weng<sup>2</sup>, D. Bandyopadhyay<sup>2</sup>, S.G. Reed<sup>3</sup>, R.S. Leite<sup>4</sup>, R.M. Silver<sup>5</sup>

<sup>1</sup>Department of Occupational Therapy, School of Health Professions, University of Alabama at Birmingham, Birmingham, USA; <sup>2</sup>Division of Biostatistics and Epidemiology, Department of Medicine, <sup>3</sup>Department of Craniofacial Biology, <sup>4</sup>Division of Periodontics, College of Dental Medicine, and <sup>5</sup>Division of Rheumatology and Immunology, Department of Medicine, Medical University of South Carolina, Charleston, SC, USA.

This study was supported by the Scleroderma Foundation and the National Institutes of Health, National Center of Research Resources Grant Number P20 RR017696, South Carolina COBRE for Oral Health Research.

Hon K. Yuen, PhD, OTR/L, Professor, Yanqiu Weng, DDS, MS, Dipankar Bandyopadhyay, PhD Susan G. Reed, DDS, MPH, DrPH, Renata S. Leite, DDS, MS Richard M. Silver, MD, Professor

Please address correspondence and reprint requests to: Prof. Hon K. Yuen, Department of Occupational Therapy, School of Health Professions, University of Alabama at Birmingham, Birmingham, USA. E-mail: yuen@uab.edu

Received on January 23, 2011; accepted in revised form on March 9, 2011.

*Clin Exp Rheumatol 2011; 29 (Suppl. 65): S26-S32.* 

© Copyright CLINICAL AND EXPERIMENTAL RHEUMATOLOGY 2011.

**Key words:** oral health, assist devices, systemic sclerosis

Competing interests: none declared.

# ABSTRACT

**Objective.** To evaluate the effect of adaptive oral hygiene devices and orofacial exercise to improve gingival health among adults with systemic sclerosis (SSc).

Methods. Forty-eight patients with SSc were assigned randomly to the multifaceted oral health intervention or usual dental care control group. Participants in the intervention group received a rechargeable, powered Oral-B<sup>®</sup> oscillating-rotating-pulsating toothbrush and a Reach<sup>®</sup> Access<sup>™</sup> Flosser that has a toothbrush-like handle. For those with an oral aperture of less than 40 mm, orofacial exercises were taught. Participants in the control group were each given a manual toothbrush and dental floss. Participants in both groups received instructions and demonstration on the use of the devices, and were requested to perform the respective intervention twice a day for 6 months. Evaluations were at baseline, 3-, and 6months. The main outcome was gingival index (GI), an indicator of gingival inflammation.

**Results.** Both groups showed significant reduction in GI scores at 6 months (ps < 0.005). Reduction in GI scores of the intervention group at 6 months was 20.8% which is considered to be clinically significant. Compared to the control group, the intervention group showed a significant and larger reduction in GI score by 8% at 6 months (p=0.0007).

**Conclusion.** Results support the use of adaptive devices and orofacial exercise to improve gingival health in adults with SSc when compared to use of manual toothbrushing and finger-held flossing. Recommending and educating patients with SSc to use adaptive devices to clean the tooth surfaces looks promising for long-term oral health improvement.

# Introduction

In systemic sclerosis (SSc), defective vascularity and alterations of the microcirculation of the gingival tissues may lead to gingival inflammation (1, 2). Medical treatment of SSc and its complications require the use of systemic drugs such as immunosuppressants to control pulmonary and skin fibrosis, and calcium channel blockers to control Raynaud's phenomenon. These drugs are known to increase the risk of developing gingival hyperplasia (3). Sicca symptoms (including dry mouth) are common in SSc (about 60%), which are almost always due to salivary gland fibrosis (4-6). In addition, antihypertensives and antidepressants are associated with dry mouth as well (7). Dry mouth has been shown to promote the development of dental plaque and increase the risk of developing oral diseases (8-10), such as gingival inflammation, which is induced by dental plaque (11, 12). Compared to sex-matched healthy controls, a higher proportion of people with SSc exhibited more dental caries experience, periodontal disease, and gingivitis (13-15). Gingival bleeding was present in about 60% of patients with SSc (13). Despite the high risk of oral diseases in people with SSc, few research

programs, to date, have focused on improving the oral health of this particular population. Adaptive oral hygiene devices, such as powered toothbrushes and flossers with elongated and enlarged handles to accommodate microstomia, reduced manual dexterity, limited hand joint mobility and grip strength barriers in manipulating toothbrushes and dental floss, may help improve oral self-care (16).

Results of a systematic review of 42 trials of non-disabled populations indicated that powered oscillating-rotating toothbrushes reduce plaque and gingivitis more than manual toothbrushes (17). Studies to compare the use of an adapted flosser to finger flossing indicated that the adapted flosser and finger flossing are equally effective in reducing plaque and gingival inflammation (18-22). However, participants preferred the adapted flosser over finger flossing (18, 22). Several authors concluded that the adapted flosser was significantly more effective in facilitating patient compliance and establishing long-term regular flossing habit (23, 24).

Risheim *et al.* (25) found that the use of a powered toothbrush for two weeks was more effective than the use of a manual brush for the same period of time in reducing plaque among patients with rheumatoid arthritis. However, a longer study duration and a more robust outcome measure such as gingival inflammation are needed to confirm the effectiveness of adaptive oral hygiene devices to improve gingival health in this and other connective tissue disorder populations.

The purpose of this study was to evaluate the effect of a multi-faceted oral health intervention for improving gingival health among adults with SSc. The selection of gingival health instead of dental plaque as the outcome is based on the fact that gingival inflammation is relatively not influenced by a single episode of self-performed oral hygiene (such as tooth brushing) (26). This study implemented a single-blinded, randomised controlled trial with two groups: (1) Multi-faceted oral health intervention group - adaptive oral hygiene devices, and orofacial exercise; and (2) Usual dental care control group - manual toothbrushing and dental flossing. It was hypothesized that adults with SSc receiving the multi-faceted oral health intervention would show a significant reduction in gingival inflammation when compared to the usual dental care control group at intervals of 3- and 6-month post baseline. This protocol was approved by the Institutional Review Board of the Medical University of South Carolina (MUSC) where the study was conducted.

# Methods

# Participants

Participants eligible for the study were adults (aged >18 years old) who ful-

filled the American College of Rheumatology preliminary classification criteria for SSc (27), and were diagnosed with SSc at least 1 year prior to study baseline evaluation. Exclusion criteria were localised scleroderma (e.g. morphea, linear scleroderma, and en coup de sabre), less than 10 natural teeth, an upper and/or lower full denture, requirement for antibiotic therapy prior to dental examination, use of a rechargeable, oscillating-rotating-pulsating or sonic powered toothbrush, or an adapted flossing device similar to Reach<sup>®</sup> Access<sup>™</sup> Flosser, performance of mouthstretching exercise on a regular (e.g. daily) basis, complaint of any major jaw joint problems (e.g. severe pain or dislocation), or currently receiving periodontal disease treatment.

#### Recruitment

One hundred and thirteen patients with scleroderma from the rheumatology clinic at MUSC facilitated by its local connective tissue disease database (CTDD) were invited to the study and if interested, contacted either in person or by phone. The CTDD contains medical information on the majority of patients with SSc who received consultation and/or treatment at the university rheumatology clinic beginning in 2001. Forty-eight eligible participants completed the baseline assessment with a recruitment rate of 42.5%. Reasons for patients not completing the baseline assessment included: not meeting the selection criteria, conflict with other medical needs, unable to take time off at work, fear of losing teeth, and unable to contact patients (after several attempts) to schedule an appointment. Based on a predetermined computer randomisation list, the 48 participants were randomly assigned to one of two study groups: the multi-faceted oral health intervention group (26 participants) or the usual dental care control group (22 participants).

#### Randomisation

Since the cutaneous form of SSc (limited *vs.* diffuse), and medical treatment regimens such as immunosuppressants and calcium channel blockers may have a different effect on gingival health, they were used as the strata for randomisation to ensure a balance of assignment for these two variables. Using these two variables as stratification factors, participants were subdivided into the four strata: limited form with medications, limited form without medications, diffuse form with medications, and diffuse form without medications. A block randomisation was used with a block size of seven and an allocation ratio of 4:3, which led to random assignment of 4 participants to the intervention group and 3 to the control group.

# Procedures

One to two days before the study appointment at the university research dental clinic, potential participants were contacted by phone and instructed not to perform any oral self-care procedures, nor to use chewing gum the evening and morning before the appointment. All participants who met the study criteria and chose to participate received a dental prophylaxis following the baseline mouth examination. The baseline evaluation included an assessment of gingival inflammation, and measurement of oral aperture, as well as completion of an oral health-related questionnaire including oral health behaviours and barriers to performing oral hygiene.

Participants in the multi-faceted oral health intervention group received a rechargeable, powered Oral-B® oscillating-rotating-pulsating toothbrush (no brushing time display) and a Reach® Access<sup>™</sup> Flosser. An Oral-B<sup>®</sup> Precision Clean<sup>™</sup> brush head was provided; this small brush head is supposed to help participants with microstomia reach the back teeth easier. For those with an oral aperture of less than 40 mm, orofacial (manual mouth-stretching and oral augmentation) exercises were taught, and handouts with pictures showing the exercises were given. The orofacial exercise protocol was adapted from Naylor et al. and Pizzo et al. (28, 29). Participants in the control group were each given a manual toothbrush (Oral-B® Complete Advantage Deep Clean toothbrush) and dental floss (Crest® glide shred guard floss).

# Multi-faceted intervention on gingival health / H.K. Yuen et al.

Participants were instructed to thoroughly brush their teeth for 2 minutes and to floss using the devices provided, as well as perform the orofacial exercise twice a day, if applicable, for 6 months. In addition, each participant received a 2-minute hourglass timer; and two tubes of fluoride toothpaste (Crest Pro-Health toothpaste). The timer was used to standardise the amount of time that participants in each group spent brushing their teeth. However, participants were not told not to use additional oral hygiene products such as mouthrinse. At the 3-month evaluation, the dental hygiene products and device parts were replenished.

#### Self-monitoring

Participants received monthly calendars to keep a record of their daily oral hygiene and were resupplied with these at the 3-month evaluation. On each day of the study follow-up, participants were requested to record whether they had brushed their teeth, flossed, and performed orofacial exercise (if applicable) by marking "yes" or "no" on the calendar. At the end of each month, participants mailed the completed calendar back to the research coordinator in a self-addressed, stamped envelope. Telephone reminders were made to those participants who had not returned their calendar.

#### Maintenance phase

The maintenance phase consisted of three telephone calls (about 15–20 mins each from the research coordinator) at 2-week, 2-month, and 5-month intervals post baseline. These monitoring phone calls served to encourage compliance and to answer any questions or issues that the participants had in relation to implementing the oral hygiene (and orofacial exercise) regimen.

# 3-month and 6-month post-training evaluations

At the end of the baseline visit, all participants were reminded to return to the research dental clinic at 3-month and 6-month for oral assessments. The research coordinator called participants one to two days before each evaluation to request that they refrain from oral hygiene practices as they did prior to the baseline evaluation. Each assessment was exactly the same as the baseline evaluation.

#### Blind assessment

Two calibrated dental hygienists (30) were designated as the oral health examiners and conducted the assessments at the baseline and each of the two subsequent evaluations. Efforts were made to have the same participant assessed by the same examiner at each evaluation. The oral examiners were blinded to the participants' group assignment. Participants were blinded to the other type of intervention available in the study. To avoid bias in the collection of the outcome measures, the oral examiners were instructed not to ask participants about any treatment-related issues of the study.

# Outcome measure

The Löe-Silness gingival index (GI) was used to estimate different degrees of inflammation in marginal gingiva (31). Gingival measures were made according to the GI. In this index, the gingival tissues surrounding each selected tooth are divided into four areas for scoring: mesial, distal, buccal, and lingual. Each area was scored for gingivitis on a 0-3 ordinal scale according to the following criteria: 0 = normal gingiva, 1 = mild inflammation - slight change in colour, slight oedema, and no bleeding on probing, 2 =moderate inflammation - redness, oedema, glazing, bleeding on probing, and 3 = severe inflammation - marked redness and oedema, ulceration, tendency to spontaneous bleeding. The GI scores were collected from a maximum of 28 teeth in each participant (third molars excluded).

Specific medical history including SSc disease sub classification, disease duration, medical co-morbidities and medications that are known to increase the risk of dental problems, or influence periodontal health or disease progression were obtained from patient medical records.

#### Data analysis

The main outcome was gingival inflammation using the change in GI scores, between any 2 of the 3 assessment times. The GI scores from the distal and mesial surfaces were pooled to form the interproximal scores. In addition to the composite GI scores for the whole mouth, changes in GI scores for specific surfaces were calculated in 12 sites based on the surface and tooth location. They were as follows: interproximal, buccal, and lingual surfaces of anterior (teeth 6-11 and 22-27) and posterior teeth (teeth 2-5, 12-15, 18-21, and 28-31) in the maxillary and mandibular arches.

Due to relatively small sample size, we used non-parametric statistics to test for (i) within-group comparisons: significant changes in GI scores between baseline and each post-baseline assessment point (i.e. 3 or 6 months), and between the two post-baseline assessment points, separately for the control and intervention groups, and (ii) betweengroup comparisons: improvement in GI change scores at each post-baseline assessment point (i.e. change scores from baseline to 3 months, 3 to 6 months, and baseline to 6 months) for the intervention group when compared to the control group. For within-group comparisons, we used the Wilcoxon signed rank test (two-sided at  $\alpha = 0.05$ ) and for between-group comparisons, we used the Wilcoxon rank sum test (one-sided at  $\alpha$  =0.025). Analysis of the subgroups was also conducted which is to compare participants in the intervention group (n=13) who received the powered toothbrush, adapted flosser, and orofacial exercise with the participants in the control group (n=15) having an oral aperture of less than 40 mm. All analyses were performed using SAS (version 9.1.3; SAS Institute; Cary, NC).

# Adherence rates

To analyse adherence rates, we calculate the monthly adherence rates across the 6-month study period as the ratio of the number of brushing and flossing sessions each month recorded in the participants' log to the number of sessions prescribed (*i.e.* number of days in that month). Brushing or flossing more than 2 times in a given day was treated as 2, which is the number of sessions requested. Forty participants (22 from

Intervention group

Control group

the intervention group) returned the monthly calendar. For the intervention group, the mean (SD) adherence rate on brushing was 90.8%±9.8% with 86.4% participants achieving 80% or higher adherence rate; and the mean (SD) adherence rate on flossing was 68.8%±29.6% with 72.7% participants achieving 50% or higher adherence rate. For the control group, the mean (SD) adherence rate on brushing was 82.2%±18.8% with 61.1% participants achieving 80% or higher adherence rate; and the mean (SD) adherence rate on flossing was 61.7%±32.7% with 66.7% participants achieving 50% or higher adherence rate. No significant differences in adherence rates were observed between the two groups. The selection of 80% for brushing adherence rate was based on the literature on health behaviour research that this cutoff is a common standard set for high adherence rate (32). In this study, 80% or greater adherent rate is equivalent to brushing teeth twice a day. Whereas for flossing behaviour, we selected the cutoff of 50% adherence rate, as 50% is equivalent to flossing once a day.

# Results

Descriptive statistics for the study sample are listed in Table I. Of the 48 participants enrolled, 6 participants (3 from each group) dropped out after completion of the baseline evaluation. As a result, there were 42 participants who completed the 3-month assessment - 23 in the intervention group and 19 in the control group. An additional 3 participants (1 from the intervention group) did not complete the 6-month assessment. Some of the known reasons for participants drop out included sickness, diagnosis of cancer, incarceration, complaint of sore throat after the dental cleaning in the intervention group; and hip replacement, deceased, military service, and unable to re-schedule the final visit before the termination of the study in the control group.

# Within-group comparisons

From baseline to 3 months, each group showed statistically significant differences (*i.e.* improvement) in their GI scores (*ps*<0.0005) (Table II). By spe-

	/ III (II= 10)	$(n_1=26)$	(n <sub>2</sub> =22)	
Characteristic <sup><sup>ψ</sup></sup>	Mean±SD (Range)	Mean±SD (Range)	Mean±SD (Range)	
Characteristic	or n. (%)	or $n_1(\%)$	or $n_2(\%)$	
	~ /	1 ( )	2 \ /	
Age (years)	50.7±13.0 (22-76)	51.9±14.3 (22-76)	49.2±11.4 (23-73)	
Disease duration (years) <sup>§</sup>	7.6±6.1 (1.0–24.7)	8.3±6.4 (1.5-24.7)	6.8±5.8 (1.0-17.8)	
Oral aperture at baseline (mm)	36.5±9.7 (10.0-56.7	) 36.2±11.0 (10.0-56.7)	36.8±8.0 (22.7-50.3)	
Diffuse cutaneous subset	20 (41.7%)	12 (46.2%)	8 (36.4%)	
Contractures (hand/wrist/elbow)	12 (25.0%)	8 (30.8%)	4 (18.2%)	
Tender/swollen hand joints	15 (31.2%)	9 (34.6%)	6 (27.3%)	
Gastroesophageal reflux disease	38 (79.2%)	22 (84.6%)	16 (72.7%)	
Sicca syndrome	14 (29.2%)	7 (26.9%)	7 (31.8%)	
Sjögren's syndrome	4 (10.4%)	3 (11.5%)	2 (9.1%)	
Salivary gland enlargement	1 (2.1%)	0 (0.0%)	1 (4.5%)	
Secretagogue	3 (0.06%)	1 (3.8%)	2 (9.1%)	
Calcium channel blocker	26 (54.2%)	12 (46.2%)	14 (63.3%)	
Immunosuppressant	11 (22.9%)	8 (30.8%)	3 (13.6%)	
Female	38 (79.2%)	21 (80.8%)	17 (77.3%)	
African American <sup>§</sup>	26 (54.2%)	13 (50.0%)	13 (59.1%)	
Married	22 (45.8%)	10 (38.5%)	12 (54.5%)	
Rural	27 (56.3%)	13 (50.0%)	14 (63.6%)	
Non-smoker (current)	46 (95.8%)	25 (96.2%)	21 (95.5%)	
Education (less than college)	27 (56.3%)	15 (57.7%)	12 (54.5%)	
Employment (FT and PT)	18 (37.5%)	8 (30.8%)	10 (45.5%)	
Not employed due to disability	14 (29.2%)	7 (26.9%)	7 (31.8%)	
Annual income (< \$20,000)	17 (35.4%)	10 (38.5%)	7 (31.8%)	
Annual income (≥ \$55,000)	17 (35.4%)	10 (38.5%)	7 (31.8%)	
No dental insurance	19 (39.6%)	11 (42.3%)	8 (36.4%)	
Private dental insurance	19 (39.6%)	7 (26.9%)	12 (54.5%)	
Number of teeth	24.3±4.0 (10-28)	25.3±2.8 (20-28)	23.1±5.0 (10-28)	
Number of missing teeth	3.7±4.0 (0-18)	2.7±2.8 (0-8)	4.9±5.0 (0-18)	
Dental visit (in past 12 months)	33 (68.8%)	19 (73.1%)	14 (63.6%)	
Brush teeth (at least twice a day)	31 (64.6%)	19 (73.1%)	12 (54.5%)	
Floss teeth (at least once a day)	25 (52.1%)	15 (57.7%)	10 (45.5%)	
Use an electric toothbrush	12 (25.0%)	7 (26.9%)	5 (22.7%)	
Use an oral irrigator	5 (10.4%)	3 (11.5%)	2 (9.1%)	
Use disposable floss picks	26 (54.2%)	14 (53.8%)	12 (54.5%)	
Have difficulty flossing back teet	h 26 (54.2%)	13 (50.0%)	13 (59.1%)	
Have difficulty using dental floss		14 (53.8%)	12 (54.5%)	
to floss teeth				

Table I. Characteristics of the participants at baseline.

All (n=48)

<sup>ξ</sup>n=42, due to missing data; <sup>§</sup>Only African Americans and Caucasians; FT: full time; PT: part time. <sup>ψ</sup>No significant difference in any of the above characteristics between the intervention and control groups.

cific tooth areas, statistically significant differences (i.e. improvement) were mainly on the surfaces of anterior teeth (both maxillary and mandibular). From 3-6 months, statistically significant differences (*i.e.* improvement, *p*=0.0001) were observed in the intervention group, especially on the interproximal and buccal surfaces of anterior teeth. Contrarily, statistically significant differences (*i.e.* regression, p=0.004) were observed in the control group, particularly on the interproximal and buccal surfaces of anterior teeth. For the whole study period (0-6 month), both groups showed statistically significant differences (*i.e.* improvement, ps<0.005) for GI scores. Statistically significant

differences (*i.e.* improvement) were recorded on all surfaces of the anterior teeth (ps < 0.03), and interproximal (p=0.026) and buccal (p=0.030) surfaces of the mandibular posterior teeth for the intervention group. For the control group, statistically significant differences (*i.e.* improvement) were recorded on the interproximal (p=0.017) and buccal (p=0.031) surfaces of the maxillary posterior teeth, and on the lingual (p=0.038) surface of mandibular posterior teeth.

#### Between-group comparisons

Compared to the control group, the intervention group did not show a statistically significant larger improvement

# Multi-faceted intervention on gingival health / H.K. Yuen et al.

of the GI scores at 3 months (Table II). From 3-6 months, the intervention group showed a significantly larger improvement in the GI scores than that of the control group (p < 0.0001). Specific surfaces of larger improvement included interproximal (ps<0.002) and buccal  $(ps \le 0.002)$  surfaces of anterior teeth in both arches. For the whole study period (0-6 months), the intervention group showed a statistically significant larger improvement in GI scores than that of the control group (p=0.0007) (Fig. 1). Specific surfaces of larger improvement included interproximal (ps<0.02) and buccal (p=0.018) surfaces of the anterior teeth, and buccal (p=0.01) surface of the mandibular posterior teeth.

# Subgroup analyses

Of the 28 participants with a mean oral aperture size of less than 40mm at baseline, 13 received orofacial exercise instruction. The mean (SD) age of these 28 participants was  $51.3\pm12.3$  years old, ranging from 23 to 76 years, with 78.6% of them being female, and 57.1%, African American. The mean (SD) disease duration based on the available date of diagnosis was  $8.6\pm7.1$  years, while 15 participants (53.6%) were diagnosed with limited cutaneous SSc.

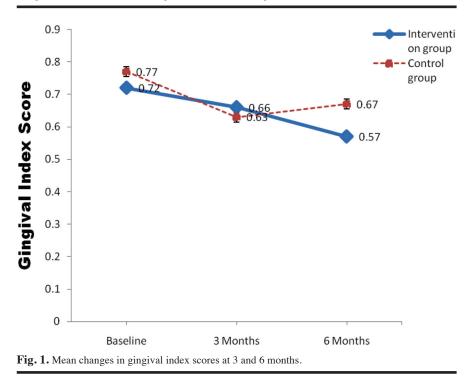
Results of the subgroup analysis between the multi-faceted intervention (in which participants with an oral aperture of less than 40 mm received the powered toothbrush, adapted flosser, and orofacial exercise) and the control group (in which participants' oral aperture was <40 mm) were consistent with those in the main analysis (Table II).

#### Discussion

Findings from the present study support our hypothesis that the multi-faceted oral health intervention (including the use of powered toothbrush and adapted flosser, and orofacial exercise) is superior to the usual dental care in improving gingival health at 6 months among adults with SSc. The multi-faceted intervention provided a significant advantage over the usual dental care by reducing gingivitis by 8% at 6 months, which is consistent with the findings from the Cochrane systematic review of randomised controlled trials com**Table II.** Change in the mean gingival index (GI) scores (whole mouth) of the intervention group when comparing to the control group.

	E		Subgroups with oral aperture <40 mm			
Time	Intervention**	Control**	Difference*	Intervention**	Control**	Difference*
0–3 months	0.05‡	0.14‡	-0.09	0.08‡	0.08‡	0.00
3-6 months	0.06‡	-0.05‡	$0.11^{+}$	0.06‡	-0.05	$0.10^{\dagger}$
0-6 months	0.12 <sup>‡</sup>	0.06‡	$0.07^{\dagger}$	0.16 <sup>‡</sup>	-0.02	$0.18^{\dagger}$

\*\*Sign rank test; \*Rank sum test; \*p<0.05, two-side test; \*p<0.025, one-side test.



paring powered and manual toothbrush use among non-disabled populations (33). Deery *et al.* (33) found powered toothbrushes were superior to manual brushes in reducing gingivitis by 6% in 1- to 3-month time intervals.

Within the intervention group, significant improvement in the GI scores across the 6-month study period was observed. The overall improvement in GI scores of the intervention group at 6 months was 20.8% which exceeds the recommended 15–20% from the American Dental Association to be clinically significant (34).

The lack of statistically significant improvement in GI scores when comparing the intervention and control group at 3 months may be explained by the learning curve effect of using the adaptive oral hygiene devices. Lazarescu (35) found it may take several weeks for someone to learn how to manipulate

a powered toothbrush efficaciously, and significant improvement in gingival health can be observed in18 weeks. For this particular SSc population, learning to use the oral hygiene devices proficiently may have taken longer compared to people without orofacial and manual dexterity problems. Between the 3- and 6-month evaluations, it seems participants were able to master how to use the adaptive devices well and incorporate them into their oral hygiene routine. As a result, we observed a statistically significant improvement in the GI score in the intervention group when compared to the control group. However, a more definitely conclusion could not be drawn unless we had collected at least one more data point beyond 6 months and these data showed the GI score in the control group returned to the baseline, and the GI score in the intervention group continued to improve. The statistically significant improvement in GI scores on the intervention group are mainly in the anterior teeth when compared to the control group, which may indicate that the addition of orofacial exercise may not have had a significant contribution to the improvement of the GI scores in the intervention group. Based on the findings in the literature (36), powered toothbrushes helped reduce gingival inflammation in lingual sites, however, this benefit was not observed in our intervention group. It may be because the participants did not place the powered toothbrush in such a way to clean the lingual surfaces of the anterior teeth. Cleaning the interproximal surface mainly confined to the anterior teeth, and very little improvement in the GI score was observed in the posterior teeth especially on the maxillary arch. Study participants did not seem to take full advantage of the adaptive devices to reach the posterior teeth (except the buccal surface on the mandibular arch) for cleaning.

Findings from the usual care control in the present study were consistent with the literature that a single oral hygiene instruction (toothbrushing and flossing), and professional oral prophylaxis provided at baseline had a small statistical significant positive effect on the reduction of gingival inflammation at 6-month follow-up (37). Typically, after a single oral hygiene instruction, there is a short-term improvement (within 3 months) in gingival health, which will then start to regress; and the condition of the gingival health eventually returns to that of the pre-instruction level a year later (38-40). In our study, the improvement in the GI score at 3 months was 18.2%, but at 6 months, the improvement reduced to 13% which is not clinically significant (34). The trajectory of the GI scores in the control group of the present study followed this classic clinical pattern. The frequency of oral hygiene was maintained but the time spent and quality of the cleaning may have diminished (38). Therefore, in order to maintain a longer term improvement in oral health, supervised (i.e. face-to-face), repeated reinforcement of oral hygiene instruction from

a dental health professional is essential (41).

Even though adaptive oral hygiene devices were shown to be efficient in reducing gingivitis at 6 months, not all participants were adherent to the study protocol. Data from the post-study telephone interview revealed that several participants in the intervention group raised some issues and concerns about the use of the adaptive oral hygiene devices. One participant complained the vibration of the powered toothbrush caused her to have a headache, another participant forgot to charge the toothbrush; therefore, she did not use it very often. A third participant complained the Reach<sup>®</sup> Access<sup>™</sup> Flosser caught between her teeth as a result she used floss picks instead.

The multi-faceted intervention offered the potential for reducing gingival inflammation (gingivitis) among adults with SSc in 6 months. Future studies with a longer-term follow-up are needed to evaluate whether the improvement will decrease extensive restorative and periodontal treatments and emergency dental care such as extractions, and fewer missed workdays due to dental problems such as toothaches, and reduce risk of having oral disease related systemic problems and/or aggravation of the existing systemic disease, as well as decrease oral health care costs.

Given the relatively small numbers of participants in the sample, data analyses on subgroups participants with certain characteristics such as Sjögren's syndrome will not yield valid results. To determine the multi-faceted oral health intervention is more effective in patients with certain characteristics, it may require subject recruitment targeting at those characteristics as the inclusion criteria to get the needed numbers for achieving sufficient statistical power. Since people with connective tissue disorders were found to be less likely to visit a dental professional for preventive care when compared to that of the general population (42), rheumatologists have a role to encourage their patients to receive dental care on a regular basis, and may recommend them the use of appropriate adaptive oral hygiene devices to improve oral health.

#### Acknowledgements

The authors wish to thank the two dental hygienists: Pemra L. Hudson, RDH; Lisa M. Summerlin, MA, RDH for conducting the clinical mouth examination, and the project coordinator, Samantha Mahoney, for subject recruitment and data entry.

#### References

- 1. OZCELIK O, HAYTAC MC, ERGIN M, ANT-MEN B, SEYDAOGLU G: The immunohistochemical analysis of vascular endothelial growth factors A and C and microvessel density in gingival tissues of systemic sclerosis patients: their possible effects on gingival inflammation. *Oral Surg Oral Med Oral Pathol Oral Radiol Endod* 2008; 105: 481-5.
- SCARDINA GA, PIZZIGATTI ME, MESSINA P: Periodontal microcirculatory abnormalities in patients with systemic sclerosis. *J Periodontol* 2005; 76: 1991-5.
- SEYMOUR RA, HEASMAN PA: Drugs and the periodontium. J Clin Periodontol 1988; 15: 1-16.
- AVOUAC J, SORDET C, DEPINAY C et al.: Systemic sclerosis-associated Sjögren's syndrome and relationship to the limited cutaneous subtype: results of a prospective study of sicca syndrome in 133 consecutive patients. *Arthritis Rheum* 2006; 54: 2243-9.
- SWAMINATHAN S, GOLDBLATT F, DUGAR M, GORDON TP, ROBERTS-THOMSON PJ: Prevalence of sicca symptoms in a South Australian cohort with systemic sclerosis. *Intern Med J* 2008; 38: 897-903.
- SALLIOT C, MOUTHON L, ARDIZZONE M et al.: Sjögren's syndrome is associated with and not secondary to systemic sclerosis. *Rheumatology* (Oxford) 2007; 46: 321-6.
- SCULLY C: Drug effects on salivary glands: dry mouth. Oral Dis 2003; 9: 165-76.
- GUGGENHEIMER J, MOORE PA: Xerostomia: etiology, recognition and treatment. J Am Dent Assoc 2003; 134: 61-9; quiz 118-9.
- HASE JC, BIRKHED D: Salivary glucose clearance, dry mouth and pH changes in dental plaque in man. Arch Oral Biol 1988; 33: 875-80.
- SREEBNY LM, VALDINI A: Xerostomia. A neglected symptom. Arch Intern Med 1987; 147: 1333-7.
- 11. LOE H, THEILADE E, JENSEN SB: Experimental gingivitis in man. *J Periodontol* 1965; 36: 177-87.
- TROMBELLI L, TATAKIS DN, SCAPOLI C, BOTTEGA S, ORLANDINI E, TOSI M: Modulation of clinical expression of plaque-induced gingivitis. II. Identification of "highresponder" and "low-responder" subjects. *J Clin Periodontol* 2004; 31: 239-52.
- SCARDINA GA, MESSINA P: Systemic sclerosis: description and diagnostic role of the oral phenomena. *Gen Dent* 2004; 52: 42-7.
- WOOD RE, LEE P: Analysis of the oral manifestations of systemic sclerosis (scleroderma). Oral Surg Oral Med Oral Pathol 1988; 65: 172-8.
- 15. LEUNG WK, CHU CH, MOK MY, YEUNG KW,

#### Multi-faceted intervention on gingival health / H.K. Yuen et al.

NG SK: Periodontal Status of Adults With Systemic Sclerosis: Case-Control Study. J Periodontol 2011.

- IACONO VJ, ALDREDGE WA, LUCKS H, SCHWARTZSTEIN S: Modern supragingival plaque control. *Int Dent J* 1998; 48: 290-7.
- ROBINSON PG, DEACON SA, DEERY C et al.: Manual versus powered toothbrushing for oral health. Cochrane Database Syst Rev 2005: CD002281.
- CARTER-HANSON C, GADBURY-AMYOT C, KILLOY W: Comparison of the plaque removal efficacy of a new flossing aid (Quik Floss) to finger flossing. *J Clin Periodontol* 1996; 23: 873-8.
- 19. KINANE DF, JENKINS WM, PATERSON AJ: Comparative efficacy of the standard flossing procedure and a new floss applicator in reducing interproximal bleeding: a short-term study. J Periodontol 1992; 63: 757-60.
- PUCHER J, JAYAPRAKASH P, AFTYKA T, SIG-MAN L, VAN SWOL R: Clinical evaluation of a new flossing device. *Quintessence Int* 1995; 26: 273-8.
- 21. SHIBLY O, CIANCIO SG, SHOSTAD S, MATH-ER M, BOARDMAN TJ: Clinical evaluation of an automatic flossing device vs. manual flossing. *J Clin Dent* 2001; 12: 63-6.
- 22. SPOLSKY VW, PERRY DA, MENG Z, KISSEL P: Evaluating the efficacy of a new flossing aid. *J Clin Periodontol* 1993; 20: 490-7.
- BROTHWELL DJ, JUTAI DK, HAWKINS RJ: An update of mechanical oral hygiene practices: evidence-based recommendations for disease prevention. *J Can Dent Assoc* 1998; 64: 295-306.
- KLEBER CJ, PUTT MS: Formation of flossing habit using a floss-holding device. J Dent Hyg 1990; 64: 140-3.
- 25. RISHEIM H, KJAERHEIM V, ARNEBERG P: Improvement of oral hygiene in patients with

rheumatoid arthritis. *Scand J Dent Res* 1992; 100: 172-5.

- 26. ROBINSON PG, DAMIEN WALMSLEY A, HEANUE M et al.: Quality of trials in a systematic review of powered toothbrushes: suggestions for future clinical trials. J Periodontol 2006; 77: 1944-53.
- 27. MASI AT: Preliminary criteria for the classification of systemic sclerosis (scleroderma). Subcommittee for scleroderma criteria of the American Rheumatism Association Diagnostic and Therapeutic Criteria Committee. *Arthritis Rheum* 1980; 23: 581-90.
- NAYLOR WP, DOUGLASS CW, MIX E: The nonsurgical treatment of microstomia in scleroderma: a pilot study. Oral Surg Oral Med Oral Pathol 1984; 57: 508-11.
- 29. PIZZO G, SCARDINA GA, MESSINA P: Effects of a nonsurgical exercise program on the decreased mouth opening in patients with systemic scleroderma. *Clin Oral Investig* 2003; 7: 175-8.
- HILL EG, SLATE EH, WIEGAND RE, GROSSI SG, SALINAS CF: Study design for calibration of clinical examiners measuring periodontal parameters. *J Periodontol* 2006; 77: 1129-41.
- LOE H, SILNESS J: Periodontal Disease in Pregnancy. I. Prevalence and Severity. Acta Odontol Scand 1963; 21: 533-51.
- 32. BORRELLI B, SEPINWALL D, ERNST D et al.: A new tool to assess treatment fidelity and evaluation of treatment fidelity across 10 years of health behavior research. J Consult Clin Psychol 2005; 73: 852-60.
- 33. DEERY C, HEANUE M, DEACON S et al.: The effectiveness of manual versus powered toothbrushes for dental health: a systematic review. J Dent 2004; 32: 197-211.
- 34. IMREY PB, CHILTON NW, PIHLSTROM BL *et al.*: Recommended revisions to American

Dental Association guidelines for acceptance of chemotherapeutic products for gingivitis control. Report of the Task Force on Design and Analysis in Dental and Oral Research to the Council on Therapeutics of the American Dental Association. *J Periodontal Res* 1994; 29: 299-304.

- 35. LAZARESCU D, BOCCANEALA S, ILLIESCU A, DE BOEVER JA: Efficacy of plaque removal and learning effect of a powered and a manual toothbrush. *J Clin Periodontol* 2003; 30: 726-31.
- 36. HAFFAJEE AD, THOMPSON M, TORRESYAP G, GUERRERO D, SOCRANSKY SS: Efficacy of manual and powered toothbrushes (I). Effect on clinical parameters. J Clin Periodontol 2001; 28: 937-46.
- 37. VAN DER WEIJDEN GA, HIOE KP: A systematic review of the effectiveness of self-performed mechanical plaque removal in adults with gingivitis using a manual toothbrush. J Clin Periodontol 2005; 32 (Suppl. 6): 214-28.
- GLAVIND L: Means and methods in oral hygiene instruction of adults. A review. *Tandlaegebladet* 1990; 94: 213-46.
- KIYAK HA: Recent advances in behavioral research in geriatric dentistry. *Gerodontol*ogy 1988; 7: 27-36.
- STEWART JE, WOLFE GR: The retention of newly-acquired brushing and flossing skills. *J Clin Periodontol* 1989; 16: 331-2.
- 41. MCGUIRE MK, SYDNEY SB, ZINK FJ, WEBER MB, FRITZ ME: Evaluation of an oral disease control program administered to a clinic population at a suburban dental school. *J Periodontol* 1980; 51: 607-13.
- 42. POKRAJAC-ZIROJEVIC V, SLACK-SMITH LM, BOOTH D: Arthritis and use of dental services: a population based study. *Aust Dent J* 2002; 47: 208-13.