Research

Efficacy of a Prototype Solution to Facilitate the Removal of Supragingival Dental Calculus: A proof of concept study

Miranda A. Drake, MSDH, RF; Scott A. Lunos, MS; Christine M. Blue, RDH, MS, DHSc

Abstract

Purpose: The purpose of this study was to determine whether the adjunctive use of an experimental calculus disruption solution (EXP-955), combined with the exclusive use of hand instruments, decreases the amount of time required to remove supragingival dental calculus deposits.

Methods: A single-site, randomized, split-mouth clinical trial was conducted to compare the time needed to remove supragingival dental calculus on deposits pretreated with an experimental calculus disruption solution vs. calculus deposits that were not pretreated. Quadrants were randomized to either the treatment or control group and the principal investigator (PI) was timed while using hand instruments to remove the calculus. At the end of each session, both the subjects and the PI completed a questionnaire assessing their perceptions regarding the various aspects of the appointment and the solution. Descriptive statistics were used to analyze the data. Recurring themes from the questionnaire were examined.

Results: Twenty-five healthy subjects, each having two quadrants matched for number of teeth and level of calculus deposits, completed the study (n=25). A statistically significant difference was found in in the supragingival calculus removal times between the control, (M=12.5 minutes; SD=6.0), and the treatment, (M=9.7; SD=4.6), quadrants; Mean difference (95% CI) = 2.8 (1.8-3.7), $p<0.0001$. Thematic analysis of the questionnaire responses showed that the perceptions of the principal investigator and subjects were positive towards the use of the solution with less pain being a common participant comment. The experimental calculus disruption solution was well tolerated by all subjects.

Conclusions: Results from this proof of concept study provide preliminary evidence that use of an experimental calculus disruption solution (EXP-955) reduced the time needed to remove supragingival calculus while using hand instrumentation.

Keywords: dental calculus, calculus disruption, calculus removal, hand instrumentation

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Introduction

Dental calculus is a contributing factor to periodontal disease, as it provides a nidus for biofilm attachment which can subsequently lead to inflammation.[1–3] The gold standard for calculus removal has been hand instrumentation with adjunct use of the ultrasonic scaler. This combination of techniques may be time consuming, fatiguing for the clinician, and uncomfortable for the patient.[1–5] Multiple factors may extenuate the removal of dental calculus, including but not limited to: tightness of gingival tissues, tooth positioning, depth of periodontal pocket, along with the amount, duration, and tenacity of the calculus deposits.[1]

Comfort is an essential component of patient centered care.[6] little is quantitatively known concerning the effects of instruments, technique and treatments on debridement (scaling). Dental anxiety has been associated with needles, the sound of drills, and the discomfort of hand instrumentation.[7,8] For some patients the very sight of dental instruments and/or sound of hand instrumentation creates anxiety.[7] Dental providers may use local anesthesia to increase patient comfort during scaling of deposit, however some patients may decline the use of local anesthesia due to the fear/anxiety of needles and/or the lingering numbness extending long past the appointment time.[9]

The amount of pressure required to remove heavy calculus deposits during hand instrumentation has been linked to patient discomfort, provider fatigue, and musculoskeletal

problems.[6,10–15] A wide variety of hand instrument designs including larger diameter and light weight handles have been developed to relieve operator fatigue and reduce muscle tension.[14-18] In addition to hand instruments, a wide range of ultrasonic scalers and dental handpieces have been designed with operator comfort and musculoskeletal health in mind. Instrumentation techniques, such as sequencing of quadrants, ergonomic postures, stretching, and breaks between patients have also been recommended as strategies to reduce musculoskeletal disorders.[19-25] Additionally, calculus disruption products have been developed in an effort to relieve muscle tension and minimize the effort needed to remove deposits.[1-5] Research indicates that no technique or product has been shown to be superior, and musculoskeletal disorders and provider fatigue remain a significant issue for dental hygienists.[26–29] In addition to provider fatigue, effective hand instrumentation may be time consuming, impacting overall productivity. Dental hygiene professionals devote a significant amount of patient appointment time to the removal of calculus deposits.[10,11,15,20] It has been suggested that one way to increase productivity is to increase the efficiency of deposit removal.[30]

Patient comfort, provider fatigue, and productivity explain the interest in developing products to ease the removal of calculus.[3] SofScale™ (Dentsply Sirona; Charlotte, NC, USA), first became available in the mid 1990's as a pre-scaling gel for calculus removal. Active ingredients in this product include disodium EDTA and sodium laurel sulfate.[1] Reviews in the literature regarding the efficacy of this particular calculus softening gel have been mixed.[1–5,31] Wiggs et al., and Jabro et al. found that the product eased calculus removal and/or reduced calculus removal time.[2,31] In contrast, Miller et al., Maynor et al., Smith et al., and Nagy et al. found no significant difference in scaling time between the experimental and control sides and/or did not consider this adjunct to be beneficial for calculus removal.[1,3–5]

A new product has been developed to soften and loosen dental calculus. In vitro test results conducted on extracted teeth with visible calculus deposits, demonstrated a reduction in the time required to thoroughly remove deposits from the solution-treated vs. untreated teeth. Biological safety testing conducted on the prototype resulted in the solution being deemed safe for human use. The next step in the development process called for in-vivo testing in a clinical study. In developing the study design for the next stage of product development, it was decided to limit the testing to supragingival calculus, on a small number of subjects due to ease of assessing deposit removal on supragingival surfaces. If the findings from the proof of concept study document the usefulness of the prototype in reducing the amount of time needed for supragingival calculus removal, a subsequent study will be planned to test the product on subgingival deposits in a larger sample population. The purpose of this proof of concept study was to determine the efficacy of a calculus disruption solution (EXP-955; 3M Oral Care Solutions Division, St. Paul, MN) in facilitating the removal of supragingival calculus in-vivo, as measured by reduced examiner scaling time.

Methods

A single-site, randomized, split-mouth clinical trial was conducted to compare the time needed to remove supragingival dental calculus on deposits pretreated with an experimental calculus disrupting agent vs. calculus deposits that were not pretreated. Data for the necessary time to remove the supragingival calculus deposits were analyzed following the completion of all treatment quadrants in the study sample.

Sample population

Recruitment flyers advertising the study were placed throughout the University of Minnesota School of Dentistry. A total of 91 subjects were screened via telephone; and 64 met the criteria for the in-person screening. Inclusion criteria included being in good general health with no known allergies to commercial dental products; having at least 5 teeth in each study quadrant and the presence of supragingival calculus with a minimum rating of at least one, as determined by the Oral Calculus Index-Simplified (OCI-S) (Table I). Care was taken to select subjects having two quadrants matched for number of teeth and level of calculus deposits. Subjects who had a full mouth debridement, prophylaxis, and/or scaling and root-planing within the last year; those who required premedication prior to dental procedures; were pregnant, lactating, and/or lacking in the ability to provide consent, were excluded from the sample. Appointments were scheduled to treat eligible subjects within ten days of screening. Eligible participants received documentation to provide informed consent.

Table I. Oral Calculus Index-Simplified criteria (OCI-S)

Scores	Criteria
0	No Calculus Present
1	Supragingival calculus covering not more than third of the exposed tooth surface
2	Supragingival calculus covering more than one third but not more than two thirds of the exposed tooth surface
3	Supragingival calculus covering more than two thirds of the exposed tooth surface

Procedures

All study procedures followed good clinical practice (GCP) guidelines. Full approval from the Human Subjects Protection Program (Institutional Review Board) at the University of Minnesota was obtained. The principal investigator (PI), was an experienced, licensed dental hygienist and the clinical director for the University of Minnesota Dental Hygiene Program. It was not possible to blind the PI to the treatment quadrants because of the visual chemical reaction made by the experimental solution. Therefore, for the purposes of this proof of concept study, the PI served as both the examiner and the operator who performed all treatment procedures in the clinical trial. The term PI will be used for both examiner and operator roles in this manuscript. Training on the application of the solution was provided by the manufacturer prior to study initiation.

Subjects who met the inclusion criteria were scheduled to return for the treatment visit. General health status, medication usage and eligibility to continue in the study were reassessed. An oral soft tissue examination to determine the presence of any oral complaints or symptoms was made by the investigator-examiner. The PI then rated the supragingival calculus level using the OCI-S criteria. The subjects' quadrants were scored; only study quadrants with both the same number of teeth and equal amounts of calculus, based on the quadrant's OCI-S scores were selected. Block randomization was used to allocate subjects' quadrants to study groups using a split mouth design.

In order to ensure that the calculus in the control quadrant was not inadvertently compromised by the experimental solution, the control quadrant was always treated first. The start and end time to complete the removal of the supragingival dental calculus for each quadrant was recorded using an electric digital clock. In order to obtain a visual record of any gingival and hard tissue differences following treatment, photographs of both study quadrants were taken before and after completion of hand instrumentation. Prior to beginning treatment, all instruments were sharpened; sharpness was checked using a plastic test stick. The following instruments were used on each subject: 13/14 Gracey curette; 11/12 Gracey curette (Hu-Friedy Mfg. Co., LLC; Chicago, IL, USA); and, a Montana Jack™ scaler (Paradise Dental Technologies; Missoula, MT, USA).

Prior to initiating treatment, each subject was asked to review questions that would be asked at the completion of the procedures. Questions queried subjects' perceptions regarding the amount of time it took the PI to complete deposit removal, the amount of pressure used, and on taste/feeling of the experimental calculus disruption solution. Once the subject was familiar with the post-procedure questions, the PI recorded the starting time, and removed the supragingival calculus in the control quadrant with hand instruments, and recorded the end time. Next, the PI assembled the experimental calculus disruption solution dispenser, recorded the starting time, and then applied the solution to the supragingival dental calculus in the treatment quadrant. Once the solution was applied, the PI immediately began hand instrumentation in the treatment quadrant. The starting time for the removal of the supragingival dental calculus in the treatment quadrant included the time it took to place the solution. As this was a proof of concept study; dispenser assembly was not included in the time recorded, as the solution dispenser was not yet in its final form.

Upon completion of the scaling procedure, the subject's mouth was thoroughly rinsed with water. Standard assessment procedures, including a tactile evaluation with an 11/12 Explorer (Hu-Friedy Mfg. Co., LLC Chicago, IL USA), a visual evaluation with reflected light, and drying with the use of compressed air, were used to check for complete removal of supragingival dental calculus. Soft tissues were evaluated for changes in appearance and post-procedure photographs were taken. Each subject completed the patient questionnaire that they had viewed prior to treatment at the conclusion of the session. The PI completed the operator questionnaire at the conclusion of each session. The purpose of the questionnaire was to collect subjective feedback from the clinician regarding their perceptions of any differences in the amount of pressure used, the perceived amount of time spent to complete deposit removal, as well as to provide feedback on the solution's mechanics. Once the study procedures were completed, patients were offered an appointment to complete supra and subgingival deposit removal in all four quadrants.

Outcome measures and statistical analysis

The primary outcome measure was the time it took the examiner/operator to complete the supragingival scaling in each study quadrant. The secondary outcome measure was the subjective feedback from subjects and the PI. Descriptive statistics were used to summarize subject demographics and deposit removal times. A paired t-test was used to compare the mean removal times (minutes) between the control and the treatment quadrants and statistical significance was set at $p < 0.05$. The statistical software program SAS V9.3 (SAS Institute Inc., Cary, NC) was used for data analysis.

Results

Twenty-five subjects, seventeen males and eight females, met the inclusion criteria and consented to participate in the trial. Subjects were between 19 and 78 years of age, with a mean age of approximately 49.3 years (Table II). A statistically significant difference was found in the supragingival calculus removal times between the control, (M=12.5 minutes; SD=6.0) and the treatment, (M=9.7; SD=4.6) quadrants; Mean difference (95% CI) = 2.8 (1.8-3.7), $p<0.0001$. The total mean instrumentation time for the control and treatment groups is shown in Table III. Feedback from the operator and patient questionnaires indicated that the calculus disruption solution was well tolerated by all subjects. No adverse reactions were recorded on the gingival tissues.

One of the features of experimental calculus disruption solution was the ability to disintegrate the calculus without causing adverse events to the oral soft tissues. Post treatment feedback comments from the PI regarding calculus removal in the control quadrants included observations of the calculus flaking or popping off, becoming airborne, and landing in areas inside and outside of the mouth. Comments regarding the calculus deposits in the treatment quadrants included that the deposits seem to glide, or shed off the tooth and did not land outside of the mouth. Additional subjective feedback included that it was easier to use hand instruments in the treatment quadrant than in the control quadrant and that less pressure was needed in the treatment quadrant compared to the control quadrant. Regarding the interaction of the experimental solution with the calculus, use of the solution made it somewhat more difficult to visualize the calculus and the adjacent gingival tissues, requiring a greater reliance on tactile senses for deposit removal in the treatment quadrants. No adverse reactions were observed on either the tooth structures or gingival tissues in the treatment quadrants. Responses to the examiner questionnaire are shown in Table IV.

Table II. Participant demographics (n=25)

	n (%)
Gender	
Female	8 (32%)
Male	17 (68%)
Ethnicity	
White	15 (60%)
Black or African American	8 (32%)
Asian	1 (4%)
Unknown	1 (4%)

Table III. Summary of calculus removal time

Calculus removal time (minutes)	Control Quadrant	Treatment Quadrant
Mean (SD)	12.5 (6.0)	9.7 (4.6)
Median	12	9
Range	5-29	3-23

Subjects' views on the experimental solution were mixed. Some subjects stated they could tell a difference in the clinician's hand pressure and/or the amount of time it took to remove the calculus while others perceived no differences in pressure or time. A majority of the subjects (n = 24) stated that the experimental solution either tasted good, neutral, or had no taste. The majority of subjects (n = 24) also reported that there was no pain when the solution was applied. Subject responses are shown in Table V.

Discussion

The ability to soften calculus for easier removal by dental professionals has numerous potential benefits. The goal of this proof of concept study was to evaluate whether the use of an experimental calculus disruption solution (EXP-955), reduced the amount of time required to remove supragingival calculus using hand instrumentation. As the solution is proprietary, the PI is not at liberty to share the active ingredients responsible for the mechanism of action. Results of this study provide preliminary data that the experimental solution reduces the amount of time needed to remove supragingival calculus in vivo. Findings of this study replicate the in-vitro results on extracted teeth with visible calculus deposits. Currently, there is not a product in the marketplace comparable to the experimental solution, therefore comparisons cannot be made to other research findings.

Musculoskeletal health can be compromised throughout the career of a dental hygienist. Due to repetitive motions, static and uncommon positions, the neck, shoulders, back, hands and wrists of dental hygienists are common areas of reported pain, muscle imbalance, and injury.[32] These physical symptoms may also have mental and emotional effects on a dental hygienist.[33] In this study the PI perceived that the use of the solution reduced the intensity of lateral pressure required during hand scaling, which may in turn improve ergonomics and provider fatigue. The PI cited the benefits of using the solution specifically on those participants in which the tenacity of the deposit was lower.

A majority of the participants provided feedback that they perceived that the cleaning was less painful when the calculus disruption solution was used. This solution may contribute to patient comfort, as it may be

Table IV. Summary of operator (PI) responses

Question	Responses	Examiner Response
How difficult was it to scale the calculus in the **control** quadrant?	Easy	6
	Moderate	7
	Hard	12
How difficult was it to scale the calculus in the **treated** quadrant?	Easy	12
	Moderate	7
	Hard	6
Were you able to **transfer** the investigational product to the patient's mouth easily (without the product dripping)?	Yes	25
	No	0
How was the investigational product's **consistency/thickness**?	Too Thick	0
	Good Consistency	0
	Too Flowable	25
Were you able to **apply** the investigational product to the teeth easily?	Yes	25
	No	0
What is your overall satisfaction with the investigational product concept?	Good	24
	Bad	1
Did you feel that the investigational product helped you remove calculus on the treated quadrant more easily than on the control quadrant?	Yes	23
	No	2
Any comments or other likes/dislikes?	Calculus was very tenacious. Amount of pressure needed was similar to both quadrants. Had to put product on multiple times. Hand became tired	
	It's hard to see the gingiva	
	Some calculus came off without pressure	
	Seems to remove stain too	
	Hard to see with product. To see need to give multiple rinses on both quadrants due to bleeding. The product seemed to help remove deposit	
	Patient had sheet calculus that still seemed difficult	
	Could tell that the product helped soften deposit	
	I could tell in pressure but the calculus seemed just as hard to remove	

an option for patients who have conditions contraindicating the use of ultrasonic instrumentation in addition to patients who do not want local anesthesia used during scaling procedures. Anecdotally, the solution may be helpful in periodontal recall appointments with patients who have more recession and sensitivity. Use of the experimental solution is contraindicated with ultrasonic instrumentation, as the water rinses the solution away. More research is needed to determine the effectiveness of the solution with use of ultrasonic instrumentation.

The literature acknowledges that scaling time has an effect on productivity; one could conclude that decreased scaling time may lead to increased efficiency and productivity in a dental practice.[10,11,15,20] Future studies testing the efficacy of the solution in subgingival deposit removal are needed as well as larger trial investigating the impact of the solution on provider fatigue and patient comfort.

This study had limitations. There are structural differences in supragingival and subgingival calculus, therefore this solution may not yield the same results with subgingival calculus removal. Further research will be needed to determine whether the solution can also reduce the time needed to remove subgingival deposits. Only one individual, the PI, used the solution for instrumentation and calculus removal. Future studies should be conducted with multiple examiners to elicit a greater range of opinions regarding its performance.

The PI and the subjects were not blinded to the treatment group, which could have introduced bias regarding the performance of the solution. Future research should blind both the examiner and the subject to increase internal validity. Ideally, the examiner scoring the calculus deposits, pre and post treatment, should be different than the clinician performing the calculus removal. Furthermore, someone other than the clinician performing the calculus removal should record the starting and ending times for the procedures. This would keep the investigator-operator blinded to the actual time spent on each quadrant. It is also important to note, while this was a sponsored study, the PI did not receive any emolument

Table V. Summary of patient responses (n=25)

Question	Response	n
Did the investigational product **hurt or burn** when applied to your teeth?	No Pain	24
	Mild Pain	1
	Moderate Pain	0
	Extreme Pain	0
1How did the investigational/ product **taste**?	No taste	5
	Good	6
	Neutral	13
	Bad	1
Was there any noticeable **aftertaste**?	No	15
	Yes good taste	1
	Yes neutral taste	9
	Yes, bad taste	0
Did you experience any **numbness** in your mouth during the procedure?	No	24
	Yes	1
Could you tell a difference in the **time** it took for the hygienist to remove the plaque on one side of your mouth over the other?	No	14
	Yes	11
	If Yes, which side took longer:	Right 6 Left 5
Could you tell a difference in the **amount of pressure** it took for the hygienist to remove the plaque on one side of your mouth over the other?	No	13
	Yes	12
	If Yes, which side used more pressure:	Right 6 Left 6
Additional comments/feedback:	Good chemical It went great, no problems I did not feel pain like in my regular cleaning, just slight pressure She was very fast for the procedure The product left my teeth feeling smooth The product was pleasant and it felt like it required less effort by the hygienist to remove plaque with it on. I didn't notice a time difference though. Tx side was easier, was freaking out if there was danger if I should swallow product. Rt side went definitely easier. Taste was cinnaminty mediciny. I kinda' liked it. The right side started with the same amount of pressure but it lightened up shortly after. The left side was more painful and the right side was more comfortable.	

and does not have any investment in the company or the solution.

Conclusion

Use of an experimental calculus disruption solution facilitated faster removal of supragingival calculus when compared to hand instrumentation alone. This conclusion is based on the significant reduction in calculus removal time between the control and treatment quadrants. The experimental calculus disruption solution was well tolerated by all subjects and appreciated by the investigator-examiner. Further research is needed to determine if the time reduction demonstrated in this trial is reproducible with a larger study population. If the performance of this experimental solution is validated to facilitate easier removal of supra- and subgingival calculus, this finding may be of fundamental importance with respect to reducing operator fatigue and improving the patient experience. In addition, as dental professionals seek ways to reduce the aerosols created when using sonic and ultrasonic scaling instruments, access to a product to ease the removal of calcified deposits with hand instruments may be an attractive alternative.

Disclosure

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Miranda A. Drake MSDH, RF is a clinical associate professor and interim division director, Division of Dental Hygiene, Department of Primary Dental Care; ***Scott A. Lunos, MS*** is a biostatistician in the Biostatistical Design and Analysis Center, Clinical and Translational Science Institute; ***Christine M. Blue DHSc*** is an associate professor, Department of Primary Dental Care, and the Assistant Dean for Faculty Development; all at the University of Minnesota, Minneapolis, MN, USA.

Corresponding author: Miranda A. Drake MSDH, RF; **mdrake@umn.edu**

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