

# hygienetown<sup>®</sup>

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## Research Results for

**Effects of the 30 Second Smile  
Power Toothbrush on Plaque Removal.  
A Clinical Practice Study**

# Introduction

This report contains the results of the Hygienetown 30-Second Smile Research Project, conducted between December, 2010 and June, 2011.

## Report Contents

This report is divided into six sections:

1. Introduction
2. Data Collection and Demographics
3. Individual Patient Results
4. Summary of Oral Hygiene Outcomes
5. Notes from Research RDHs
6. Research Protocol

The **Introduction** (this section) contains an overview of the report structure.

The **Data Collection and Demographics** section contains a description of the data collected and the demographics of the study subjects

The **Individual Patient Results** section contains the data for each test subject

The **Summary of Treatment Outcomes** section contains a summary of the clinical results for the 30-Second Smile Power Toothbrush.

The **Notes from Research RDHs** section contains written feedback from the research RDHs.

The **Research Protocol** section contains a copy of the research protocol as followed.

# Data Collection and Demographics

## **Research RDHs**

Interested dental hygienists were recruited from active Hygienetown Members. Interest was shown by four Townies who received the research protocol and six test toothbrushes. Three Townies completed data collection on a total of 12 patients using the 30-Second Smile Power Toothbrush. One of these hygienists recorded the before and after plaque scores incorrectly, so data from three patients is not included in this report. Complete data is available for nine patients. Data collection included baseline plaque scores using the O'Leary Plaque Index. Plaque scores were repeated approximately two weeks later, and in some cases further follow-up visits were scheduled. When possible, the research hygienists took before and after intraoral photographs.

## **Test Subjects**

Research dental hygienists selected patients in their practice who showed repeated high plaque levels after comprehensive oral hygiene instructions. Subjects ranged in age from children through adults.

# Individual Patient Results

## Hygienist Number One

Patient One - Baseline



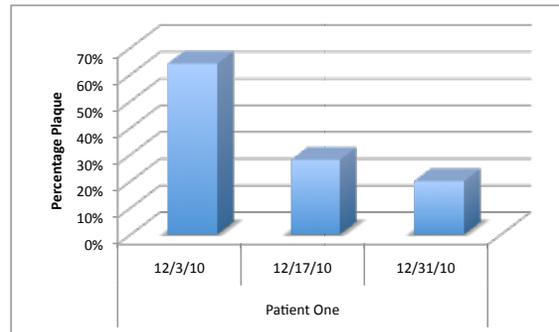
After 30-Second Smile



12/3/10      64% Plaque Score

12/17/10    28% Plaque Score

12/31/10    20% Plaque Score



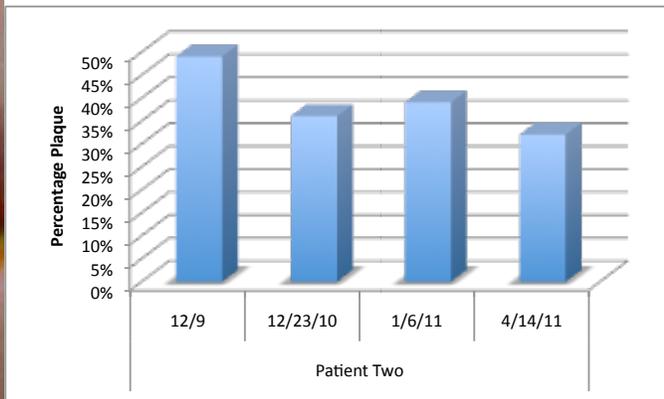
Patient Two, First Visit



Patient Two, Second Visit



Patient Two, Third Visit



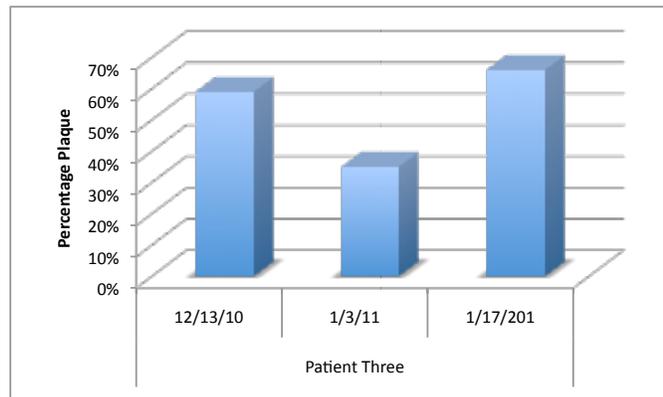
Patient Three, First Visit



Patient Three, Second Visit



Patient Three, Third Visit



Patient Four, First Visit



### Patient Four, Second Visit



### Patient Four, Fourth Visit



Fourth visit - patient stopped using the 30-Second Smile brush three weeks before and the plaque level increased to 50%. With this information, the patient realized how effective this brush really is and returned to using it.

### Patient Oral Hygiene History

40 year old male

SpinBrush

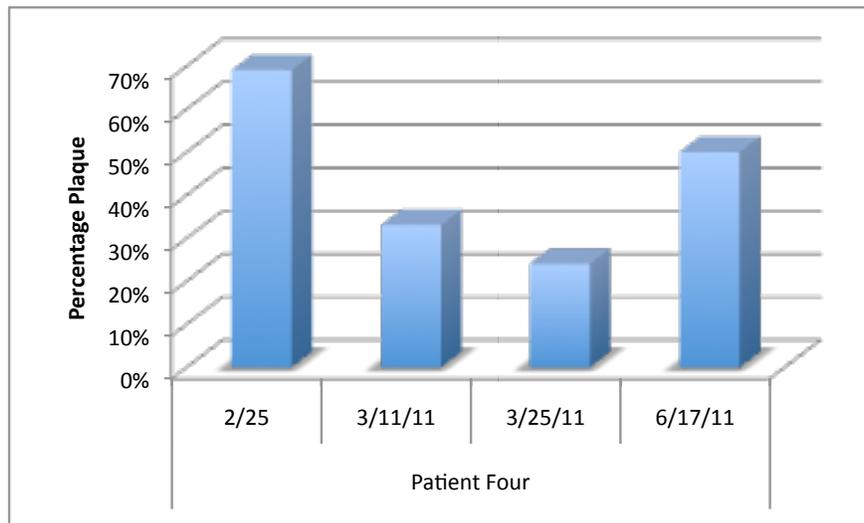
Colgate Toothpaste

No interproximal oral hygiene

Notes: Gagger who has difficulty with oral hygiene. He cannot thoroughly brush his teeth due to a severe gag reflex. He always present with heavy plaque and debris.

Patient Comments: Gag when the brush runs slow. Gel toothpaste is messy. Would like clearer information to install batteries into the brush, how to

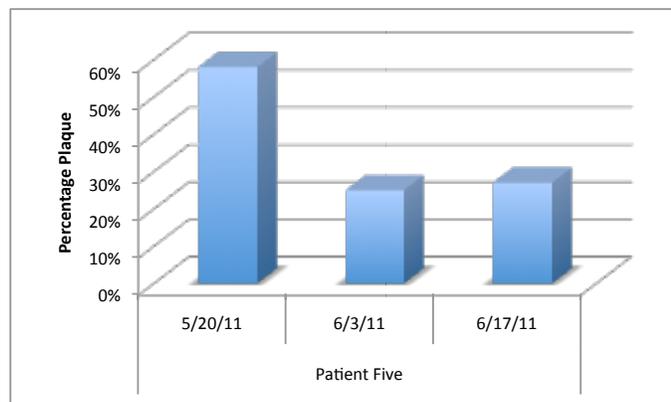
press toothpaste into brush and instructions for use. Really like the concept. Can clean insides of the teeth better.



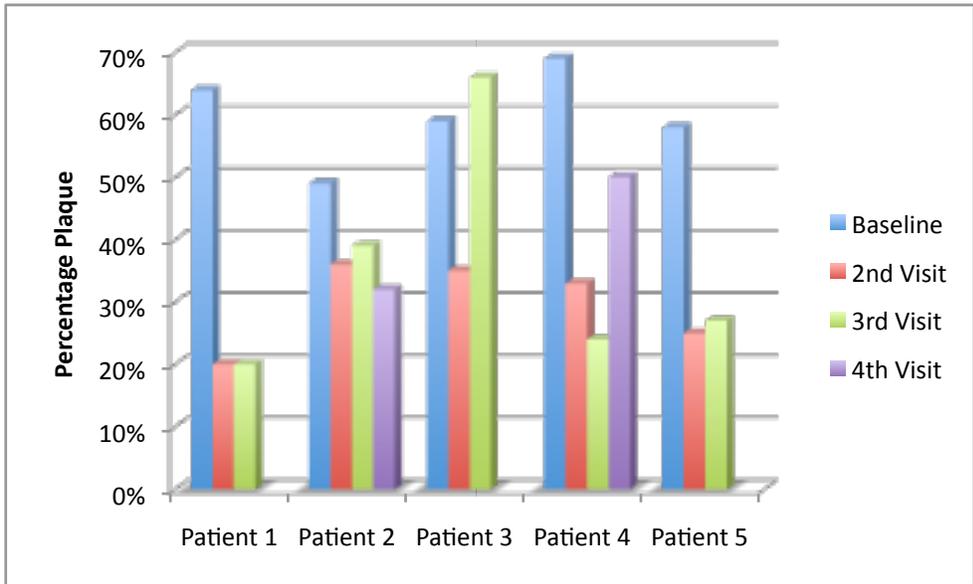
Patient Five, First Visit



Patient Five Second Visit



## Hygienist Number One - Summary of Patients



### Patient One

12/03/10 64%  
 12/17/10 28%  
 12/31/10 20%

### Greatest Reduction in Plaque Score

44%

### Patient Two

12/09/10 49%  
 12/23/10 36%  
 01/06/11 39%  
 04/14/11 32%

17%

Average plaque reduction when  
 using the 30 Second Smile  
 Brush: 32%

### Patient Three

12/13/10 59%  
 01/03/11 35%  
 01/17/11 66%

24%

### Patient Four

02/25/11 69%  
 03/11/11 33%  
 03/25/11 24%  
 06/17/11 50%

45%

### Patient Five

05/20/11 58%  
 06/03/11 25%  
 06/17/11 27%

31%

# Hygienist Number Two

## Patient JN - Age 15, male

Currently using a manual toothbrush, when he remembers, once a day for 30 seconds. Using Fluoridex gel. Not cleaning between his teeth.

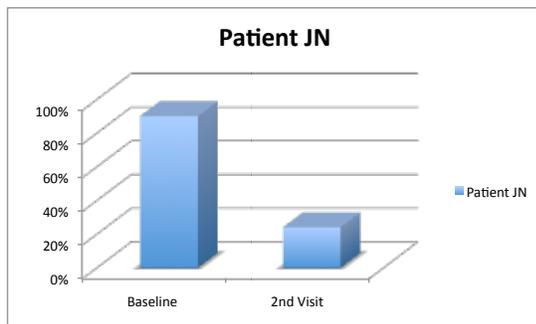
### NOTES:

Patient has a history of three month recare visits due to gingivitis, poor oral hygiene, and lack of motivation to improve. Patient agreed to use the 30-Second Smile brush because it only took 30 seconds to brush. His oral hygiene improved with use of the 30-Second Smile brush.



Before: 90% Plaque Score

After: 24% Plaque Score



12/13/10      90% Plaque Score

12/29/10      24% Plaque Score

**Patient AW - Age 18, male**

Currently using a manual toothbrush twice a day with a sulcular method. Using Pepsodyne toothpaste. Not cleaning between his teeth.

**NOTES:**

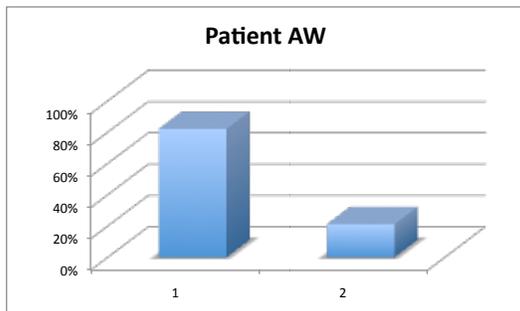
Patient did not like using the 30-Second Smile brush and quit after using it for one week. He was encouraged to continue using it and recommended he use the red brush head instead of the blue one. Patient continued using the brush for one more week of the trial and did not like using it. He did not feel the teeth were clean. He reported that he could not clean the maxillary teeth well along the gumline. He discontinued use after the study.



Before: 82% Plaque Score



After: 21% Plaque Score



12/2/10 82% Plaque Score

2/17/10 21% Plaque Score

**Patient GB - adult, male**

Currently undergoing four quadrants of scaling and root planing. He has multiple teeth with poor or guarded prognosis. He uses a manual toothbrush two to three times daily, using a sulcular brushing method and CloSYS toothpaste. He flosses with waxed floss and uses toothpicks between his teeth.

**NOTES:**

Patient has high, uncontrolled blood pressure. The periodontal diagnosis is generalized active severe periodontitis. After using the 30 Second Smile brush four weeks, he reported that he did not feel the brush cleaned well along the gum line. He does like the concept of 30 seconds of brushing versus two minutes.



Before: 63% Plaque Score

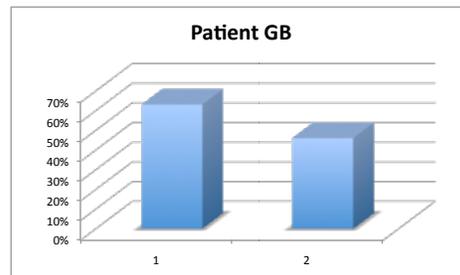


After: 46% Plaque Score



3/18/11      63% Plaque Score

4/15/11      46% Plaque Score



**Patient AH - Age 7, male**

Currently using an Oral-B CrossAction toothbrush twice daily. Brushes using a sulcular method, followed by parent oversight. He uses EZ Flossers or woven fluoride floss. He also uses CariFree Xylitots Wipes to clean his teeth.

**NOTES:**

Patient has mixed dentition with crowding in the lower anterior region. There was no parent intervention during the study. It took one week for the patient to adjust to the brush size and sensation. Patient reports that he likes how fast it was.



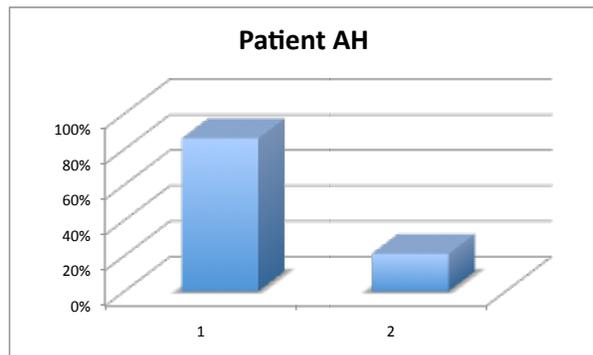
Before: 86% Plaque Score



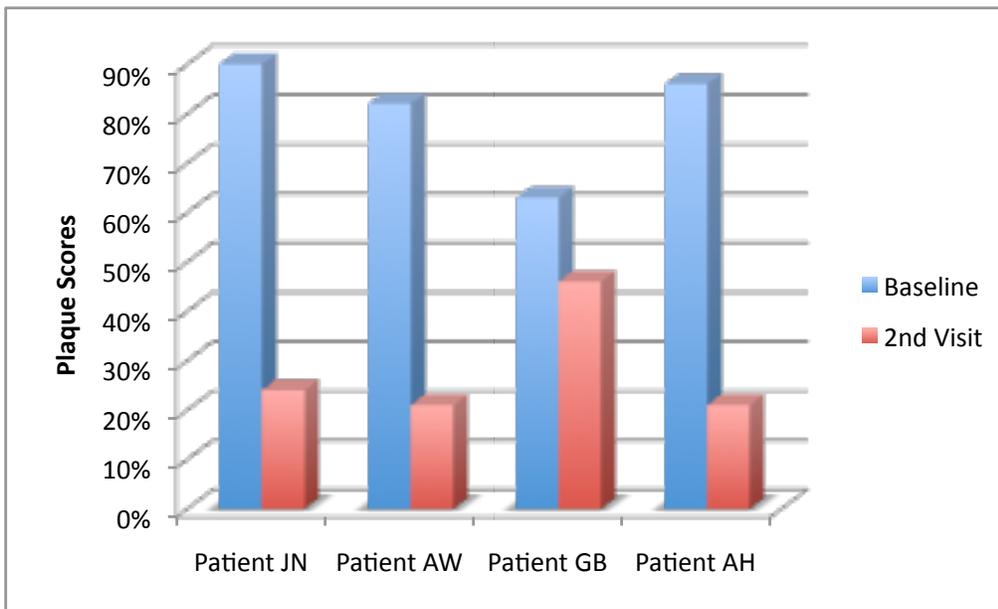
After: 21% Plaque Score

3/14/11      86% Plaque Score

5/2/11      21% Plaque Score



## Hygienist Number Two - Summary of Patients



### Patient JN

Baseline	90%
Second Visit	24%
Change	66%

### Patient AW

Baseline	82%
Second Visit	21%
Change	61%

Average plaque reduction when  
using the 30 Second Smile  
Brush: 51%

### Patient GB

Baseline	63%
Second Visit	46%
Change	17%

### Patient AH

Baseline	86%
Second Visit	21%
Change	65%

# Summary of Treatment Outcomes

## **Summary of nine patients**

The null hypothesis was disproved in this study. The null hypothesis stated that no changes in plaque scores would be seen with the use of the 30 Second Smile toothbrush. Results confirm that the majority of patients in this study showed lower plaque scores after two weeks or more of using the new brush. Others showed no difference and none showed increased plaque scores using the 30 Second Smile toothbrush.

The 30 Second Smile toothbrush provides better plaque removal when used instead of a manual toothbrush for those who are ineffective with daily plaque removal.

The average plaque reduction for Hygienist One's patients was 32%. The average plaque reduction for Hygienist Two's patients was 51%. Combining data from all nine patients from baseline to two weeks, the average reduction in plaque scores was clinically significant at 40%.

For patients who are not effectively removing plaque with a manual or power toothbrush, the 30 Second Smile brush promises to provide an effective alternative. The unique design and ability to reach all areas without depending on the manual dexterity of the user makes the 30 Second Smile ideal for those who need a new way to effectively clean their teeth.

# Notes from Research RDHs

The hygienists reported that some patients liked the brush because it was faster than two-minute brushing. Others did not like the brush and felt, despite plaque scores to the contrary, that the 30 Second Smile brush didn't remove plaque as well as their manual toothbrush.

There was a learning curve with the toothbrush. For some it took longer to get used to and for one at least, they never got used to the brush and stopped using it after the study. Others adapted quickly and enjoyed brushing with it. One stopped using the 30 Second Smile brush, only to discover at his next visit that his plaque score has increased considerably. With this information, he began using the 30 Second Smile brush again.

# Research Protocol

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## **Effects of the 30 Second Smile Power Toothbrush on Plaque Removal. A Clinical Practice Study**

## **Project Summary**

Toothbrushing times vary from 30 seconds to 60 seconds while professional recommendations remain three minutes for manual toothbrushing and two minutes for power toothbrushing. Such short toothbrushing times do not allow sufficient time to effectively remove all bacterial biofilm from all areas of the mouth. Research also shows that lingual surfaces are often missed or ignored when toothbrushing.

This pilot study is designed to evaluate a new power toothbrush design that allows the user to brush upper facial and lingual, lower facial and lingual and occlusal surfaces all at the same time. A 30 Second Smile power toothbrush is being given to patients who have been unsuccessful in achieving adequate oral hygiene after repeated attempts of providing conventional oral hygiene instructions. Using this technology, the 30 seconds most people now brush would provide more effective bacterial biofilm removal, reversal of gingivitis and whiter teeth.

## **Hypothesis:**

Null Hypothesis: No difference in plaque scores will be seen between current brushing technique and use of the 30 Second Smile Power Toothbrush. (A null hypothesis is used with the idea that the 30 Second Smile Power Toothbrush will be more effective and thus disprove the null hypothesis. To state a hypothesis that the 30 Second Smile Power Toothbrush is better requires an accurate estimate of how much better. This is the easier way to do it - thus proving the test brush is not just as good, but is in fact better than the standard manual brush or power toothbrush.)

## **Clinical Practice Pilot Study Methodology:**

### **RDH Researcher Must:**

1. Agree to select several patients for this study who fit study inclusion criteria
2. Have access to an intraoral camera
3. Follow the study protocol

4. E-mail data to [trisha@hygienetown.com](mailto:trisha@hygienetown.com)
5. Sign a Study Participation Form

### **Study Inclusion Criteria for Test Subjects:**

1. Patients must currently be unsuccessful using a manual or power toothbrush as evidenced by a high plaque score and gingivitis. The plaque score must be at least 35 percent.
2. Patients must have at least 20 teeth
3. Patients must sign the Consent Form prior to participation in the study

### **Baseline Data Collection:**

1. Ask patient how many hours since last toothbrushing.
2. Plaque scores recorded using the O'Leary Index
3. Intraoral photograph of the facial surfaces of the anterior teeth with disclosing solution.
4. Intraoral photograph of the lingual surfaces of the mandibular anterior teeth with disclosing solution. (Use photographic mirror to capture this image)
5. Summary of past oral hygiene instruction (form provided)
6. All data e-mailed to [trisha@hygienetown.com](mailto:trisha@hygienetown.com) or uploaded directly onto the secure Hygienetown Research page.
7. Final intraoral photo and data collection done on day 14.

### **Treatment Protocol:**

Twice daily use of the 30 Second Smile Power Toothbrush, brushing for 30 seconds each time. Brushing will be done without toothpaste for two weeks.

### **Instructions to patient:**

1. Patients are given a new 30 Second Smile Power Toothbrush and the DVD with brushing instructions
2. Patients are instructed to brush twice daily with the 30 Second Smile Power Toothbrush for 30 seconds each time.
3. Patients are instructed to use the ultra soft brush heads for the first 14 days.
4. Patients are scheduled to return at 14 days to measure bacterial biofilm scores with disclosing solution and have intraoral photographs taken of the anterior teeth.
5. Patients are asked to fill out a form about their experience with the 30 Second Smile Power Toothbrush.

### **Post Treatment Data Collection:**

1. Plaque scores are recorded according to the O'Leary Index. (form provided)
2. Intraoral photographs of the anterior teeth with disclosing solution are taken.
3. Intraoral photograph of the lingual surfaces of the mandibular anterior teeth with disclosing solution. (Use mouth mirror or photographic mirror to capture this image)
4. Comments from the hygienist researcher and the patient regarding the treatment protocol and the test toothbrush are collected and recorded into the electronic record.

### **Part II of the Study**

Subjects are asked to continue using the 30-Second Smile Power Toothbrush with the toothpaste of their choice. At this time, patients are instructed to switch to the standard soft brush heads for the remainder of the study. Subjects will be re-evaluated on or near day 30, following the above protocol.

### **Part III of the Study**

Subjects are asked to continue using the 30-Second Smile Power Toothbrush with the toothpaste of their choice. Subjects will be re-evaluated at their next regular dental hygiene visit.

## **Analysis of Results**

Data will be analyzed to determine differences in plaque scores from baseline to day 14 and to compare photographs from baseline to 30 days. A full report will be provided to the company. With adequate data, a scientific article will be written and submitted to an appropriate research journal. An article describing this research project will be published in Hygienetown Magazine.

# Research Study Consent Form

I, \_\_\_\_\_, voluntarily agree to

(patient's name)

participate in a Pilot Study Research Project. I understand and agree to use a new power toothbrush. I agree to give feedback on my experience with this new power toothbrush. My participation in this study requires no payment from me or to me.

Signed: \_\_\_\_\_

Date: \_\_\_\_\_

# Study Participation Form

I, \_\_\_\_\_, RDH agree to participate  
(hygienist's name)

in the Hygienetown Pilot Study Research Project. I agree to select five patients who fit the study inclusion criteria. I agree to follow the study protocol to the best of my ability and to collect and e-mail the data for which I am responsible. Study materials will be provided to my by the Hygienetown Research Center and the product manufacturer. I will keep my findings confidential, not sharing them with anyone other than the study monitor until advised to do so.

Signed: \_\_\_\_\_

Date: \_\_\_\_\_

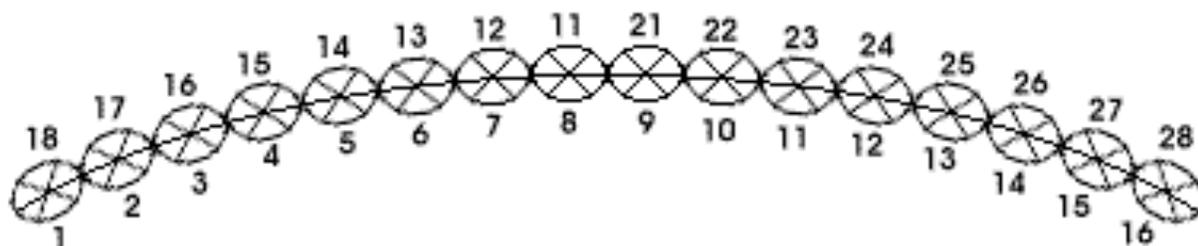
E-mail Address: \_\_\_\_\_

Mailing Address: \_\_\_\_\_

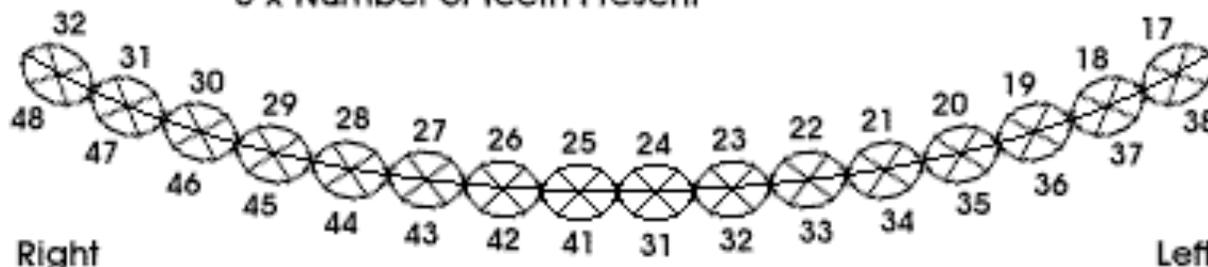
City: \_\_\_\_\_ State: \_\_\_\_\_ Zip: \_\_\_\_\_

# O'Leary Plaque Index

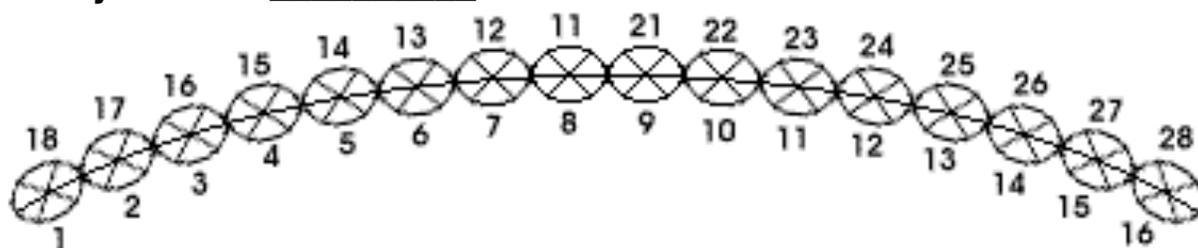
Baseline Date: \_\_\_\_\_



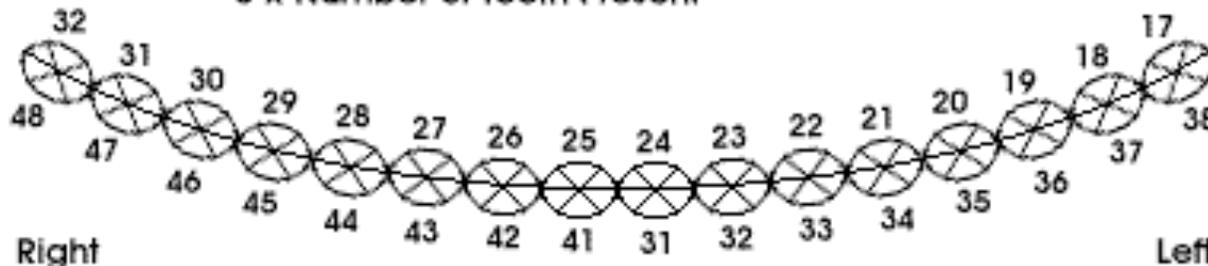
$$\frac{\text{Total Number Tooth Parts With Plaque}}{6 \times \text{Number of Teeth Present}} \times 100 = \text{_____} \%$$



14 Days - Date: \_\_\_\_\_

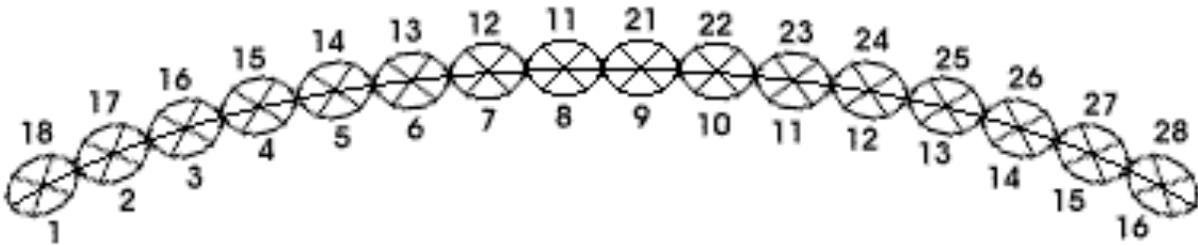


$$\frac{\text{Total Number Tooth Parts With Plaque}}{6 \times \text{Number of Teeth Present}} \times 100 = \text{_____} \%$$

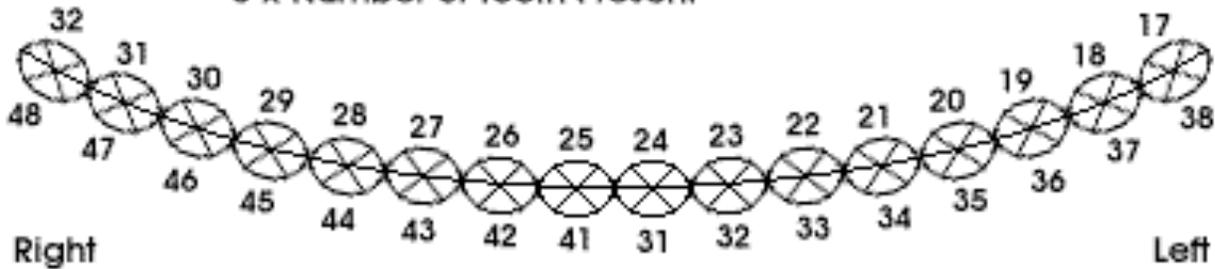


# O'Leary Plaque Index

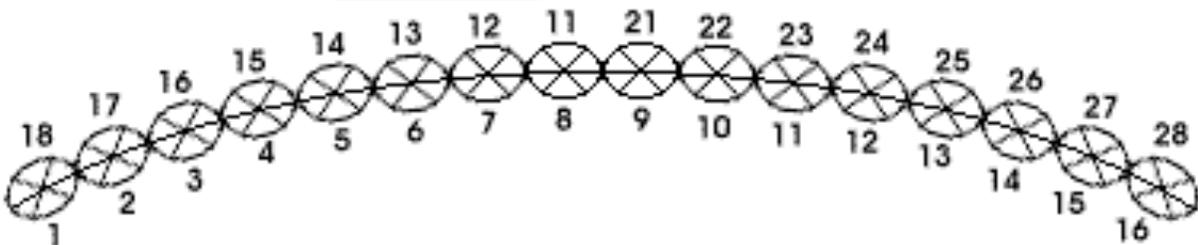
30 Days - Date: \_\_\_\_\_



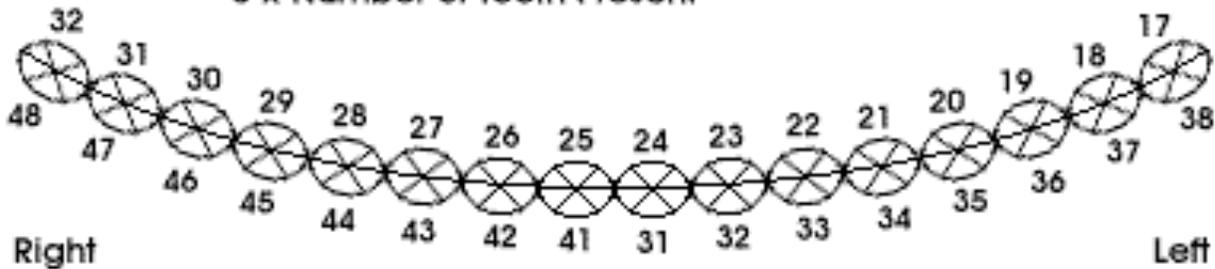
$$\frac{\text{Total Number Tooth Parts With Plaque}}{6 \times \text{Number of Teeth Present}} \times 100 = \text{_____} \%$$



Next DH Visit Date: \_\_\_\_\_



$$\frac{\text{Total Number Tooth Parts With Plaque}}{6 \times \text{Number of Teeth Present}} \times 100 = \text{_____} \%$$



# Past Oral Hygiene Instructions Form

Patient's Name: \_\_\_\_\_

\_\_\_\_\_ Years patient has received dental hygiene care at current practice

Current Toothbrush:

\_\_\_\_\_

Current Toothbrushing Method:

\_\_\_\_\_

Current Toothpaste:

\_\_\_\_\_

Current Interproximal Tools:

\_\_\_\_\_

NOTES:

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_