

Dental Caries Rates in Children with Down Syndrome

BY

AMARJOT SINGH

B.S., Carnegie Mellon University, 2008

D.D.S., Howard University College of Dentistry, 2012

THESIS

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Defense Committee:

Shahrbano Fadavi, Chair and Advisor, Pediatric Dentistry

Charles W. Le Hew, Pediatric Dentistry

Adriana Semprum-Clavier, Restorative Dentistry

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LIST OF ABBREVIATIONS

AAPD	American Academy of Pediatric Dentistry
DMFS	Decayed, Missing, or Filled Surfaces on Permanent Teeth
dmfs	Decayed, Missing, or Filled Surfaces on Primary Teeth
DMFT	Decayed, Missing, or Filled Teeth on Permanent Teeth
dmft	Decayed, Missing, or Filled Teeth on Primary Teeth
DS	Down Syndrome
IRB	Institutional Review Board

SUMMARY

The purpose of this study is to investigate dental caries rates for Down Syndrome (DS) children compared to healthy children (age 2-12 years) matched for age and gender. It is hypothesized that in a clinical sample conducted at University of Illinois at Chicago Postgraduate Pediatric Department, the caries rates for children with Down syndrome will be the same as the caries rates for non-Down Syndrome children matched for age and gender.

This is a retrospective, cross sectional, matched study that utilized chart review and abstraction. Charts from three years (2010-2013) were accessed. Each subject's number of decayed or filled permanent surfaces (DFS) and/or decayed or filled primary surfaces (dfs) was recorded.

DS patients expressed slightly higher caries rates compared to healthy patients in both primary and permanent teeth; however the difference was not statistically significant. When subgroups of DS and non-DS "caries free" subjects were compared, DS patients were slightly more likely to be caries free (17.1%) than non-Down Syndrome healthy patients (11.6%). However this difference was not statistically significant. This could be attributed to the rate of hypodontia and delayed eruption in DS population.

1. INTRODUCTION

1.1 Background

Down Syndrome (DS) is a genetic disorder in which a person has 47 chromosomes instead of the normal 46. In most cases, three copies of chromosome 21 are present, so the name “trisomy 21” has also been used to characterize this syndrome. DS has been labeled as the most common cause of genetic intellectual disability among humans¹⁵. DS affects approximately 1 in 800 live births and currently 350,000 individuals in the United States¹⁵. Males are slightly more affected by this syndrome than females and Hispanics are at higher risk than the rest of the population¹⁶. Increasing maternal age is a strong risk factor for having a child with DS. At 30 years of age, the risk ratio is 1:1000 and increases to 9:1000 by age 40^{1,17}.

DS varies in severity and presentation, but there are several symptoms that are seen in a majority of patients with Down Syndrome. Eighty percent of DS individuals have an intellectual quotient (IQ) between 25-50. Their height and weight levels at birth are typically below average, along with an associated growth delay^{1,18}. These individuals have immune system deficiencies, thereby leading to increased susceptibility to infections of the gastrointestinal, respiratory and urinary tracts^{1,19}. They are also at greater risk of developing leukemia, hypothyroidism, and congenital heart diseases^{1,18}. In addition, many individuals with DS have short stature, simian crease, and abnormal facies (small ears, eyes with a laterally directed upward slope, narrow palpebral fissures, and a short, broad nose).

1.2 Oral Manifestations of Down Syndrome Patients

There are many oral manifestations as well. Most notably, these include: macroglossia, delayed eruption, hypodontia, microdontia, bruxism, different proportions of salivary components, conoid teeth, enamel hypocalcification, fusion/generation, generalized spacing among teeth, mouth breathing resulting in dry mouth, fissured tongue and lips, high incidence of mucosal ulcers, candidiasis, acute necrotizing ulcerative gingivitis, imbalanced occlusal and soft tissue forces, open bite, impaired chewing, difficulty in self cleansing of teeth, and increased periodontal disease and gingivitis¹⁻⁸.

Midface hypoplasia is common, leading to a shortened palate antero-posteriorly. The small palate leads to enlargement of the tongue, which consequently increases pressure against the mandibular teeth. Midface hypoplasia also results in an open bite, which exacerbates the poor muscle tone in the tongue. This may cause an open-mouth posture and tongue protrusion. Mouth breathing is the result of frequent upper respiratory infections and narrow nasal passages. The skeletal and soft tissue changes together all lead to increased drooling, angular cheilitis, dry mouth, and fissured lower lips and tongue^{2,20,21}.

Previous studies have shown that patients with DS have decreased levels of dental caries compared to non-Down Syndrome children^{2,4,5,7}. Some of the aforementioned oral manifestations offer some protection from dental caries, such as generalized diastemas and delayed eruption. However, recent studies have exhibited that DS patients actually manifest

dental caries similarly to their healthy counterparts^{1,6,8}. Due to the inconclusive nature of the research further investigation is warranted.

1.3 Purpose of the Study

The purpose of this study is to investigate dental caries rates for Down Syndrome children compared to healthy children (age 2-12 years) matched for age and gender.

1.4 Hypotheses

1)

- Null Hypothesis: In this clinical sample, the caries rates for children with Down syndrome will be the same as the caries rates for non-Down Syndrome children matched for age and gender.
- Alternative Hypothesis: In this clinical sample, the caries rates for children with Down syndrome will be lower than the caries rates for non-Down Syndrome children matched for age and gender.

2)

- Null Hypothesis: In this clinical sample, children with Down syndrome will be as likely to be caries free as non-Down Syndrome children matched for age and gender.
- Alternative Hypothesis: In this clinical sample, children with Down syndrome are

more likely to be caries free than non-Down Syndrome children matched for age and gender.

2. LITERATURE REVIEW

2.1 Comparing Caries Rates Between DS Individuals and Healthy Individuals

There have been several reports of lower caries rates in DS patients. Researchers have offered many factors that may help explain this finding, including the buffering capacity of the saliva, delayed eruption, generalized diastemas, and bruxism, which would make the occlusal surface flat and smooth.¹ However, when DS patients intake an increased amount of carbohydrates in the presence of poor oral hygiene, the risk of dental caries may actually be higher than that of healthy children.²

Mathias (2011) performed a study of 69 DS patients between 13 months and 85 months of age and matched them with 69 healthy children for gender, age, and number of erupted teeth. By comparing both groups by number of teeth erupted, Mathias adequately accounted for delayed eruption and hypodontia experienced by DS patients. Decayed, Missing, or Filled Teeth (dmft) index, a saliva sample, and simplified oral hygiene index was obtained for each subject. The mean count of *S. mutans* was higher in DS patients compared to healthy patients. However, the difference in dmft index between the two groups was not statistically significant. After adjusting for the delayed eruption of DS patients, there was no statistical difference in dmft between DS and non-Down Syndrome children. In the logistic regression, DS children were at greater risk of developing caries with the high *S. mutans* counts. Additionally, the child's age was significantly correlated with dental caries, with a maximum prevalence seen between 13

months and 24 months.¹

In general, it is suggested that DS patients have inadequate oral hygiene. Therefore, it is critical for these patients to be involved in more controlled of preventive care programs.

Preventive programs have a positive impact on disease control and reduce the decay rates of those subjects involved in the programs. In a study by Castilho (2010), 85% of the subjects received dental care, while 15% did not. The largest number of decayed teeth were in children who were not involved in any preventive program. Castilho aimed to evaluate the effectiveness of the preventive program on dental caries incidence in individuals with DS. Twenty four individuals with DS were in the study. DMFS, DMFT, dmfs and dmft were obtained. The DMFT/DMFS and dmft/dmfs average for each group were obtained by dividing all affected teeth by the number of subjects tested. DMFS were used as a more refined alternative for the assessment of dental caries. Twelve months after the first exam, a subsequent examination was performed in the exact same manner to determine incidence of new carious lesions. Low caries rates were observed with a high percentage of caries free individuals. Castilho concluded that the DS subjects showed caries rates with low incidence of new lesions and stressed the importance of implementing preventive programs for these and all special needs patients.³

Asokan (2008) developed a descriptive, cross sectional study to determine caries prevalence in children with Down Syndrome in Chennai, India. Only children under 15 years of age were included in the study. The teeth were recorded as either decayed, filled with decay, filled with no decay, missing due to caries, missing for other reasons, fissure sealed, or

unerupted. The total number of decayed and/or sound teeth was calculated in both the primary and permanent dentitions. In addition, the percentage of caries free children was computed for each of these groups. This study showed a lower percentage (29.4%) of the DS children to be caries free, compared to previous studies. Although DMFT/S were not calculated in this study, the percentage of children with dental caries was found to be higher than in previous studies.⁸

Areias (2011) conducted a study to characterize the environmental and host factors associated with dental caries in DS children living in Portugal. This study was a sibling-matched, population-based, cross-sectional survey, using DS subjects between ages 6-18 years. DMFS index was recorded, as well as a questionnaire of socio-demographic questions. Bruxism was found in a significantly higher proportion of DS children (23%), compared to their healthy siblings (2%). A higher percentage of DS children visited a dentist before three years of age (77%) compared to their siblings (34%) ($p < .001$). A significantly higher percentage of DS children (78%) were within the caries free group versus their siblings (58%) ($p = 0.042$). Because the control group was siblings of the DS patients, factors such as diet and socioeconomic status have been reduced from confounding the study. The study was able to demonstrate children with DS having lower caries rates than their healthy siblings. The reduced caries prevalence may be due to parents taking the DS children to the dentist earlier, as well as higher bruxism prevalence and delayed tooth eruption.²

Bradley (2004) investigated oral health of Down Syndrome children in Ireland. The groups of children were divided by age. The caries rates for 5 year olds with DS had a mean dmft

of 0.2 compared to non-Down Syndrome children mean of 1.29. However, only 5 children were included in this age group. The caries rate for 8 year olds with DS was slightly higher in primary teeth (dmft=1.93) than non-Down Syndrome healthy (dmft=1.57). The caries rate for 12 year olds with DS was lower in permanent teeth (DMFT=0.83) than non-Down Syndrome (DMFT=1.16). The caries rate for 15 year olds with DS was lower in permanent teeth (DMFT=0.71) than non-Down Syndrome (DMFT=2.02). The authors concluded that dental services targeted towards DS patients may result in similar treatment outcomes compared to non-Down Syndrome patients.⁹

Cornejo (1996) investigated several oral health aspects of DS patients, including caries activity, gingival health condition, occlusal condition, dental anomalies, and microbiological differences. According to this study, caries rates differed based on whether the patient had a primary or permanent dentition. In every age group the dmft/dmfs indices were higher in the DS population compared to the non-Down Syndrome healthy population. Meanwhile, after the age of 10 years, DMFT/DMFS were higher in the non-Down Syndrome healthy population. Caries prevalence was actually higher in the age group of 3-6 and 7-9 years old in DS children. In the patients under age 7, 48% of the DS population and 66% of the control population were caries free. However, through 17 years of age, the ratio declined to 23.3% in DS subjects and 19.9% in control subjects. The authors concluded that the number of teeth affected by caries was very similar in both groups.¹⁰

Shyama (2000) investigated caries rates of DS patients compared to other children with

disabilities. Interestingly, DS children had the highest dental caries rates compared to the rest of the children with disabilities. The mean dmft of all children with disabilities was 5.4, with the highest mean dmft in Down Syndrome children and lowest in blind children. Similarly, the mean DMFT across all children with disabilities was 4.5, with the highest mean DMFT in DS children and lowest in blind children.¹¹

2.2 Salivary Components of DS Individuals

Saliva has multiple functions in the oral cavity. It prevents desiccation of the soft and hard tissues, enhances taste, facilitates chewing and swallowing, helps clear debris, and serves as a buffer. The buffering system aids in maintaining a higher (non acidic) oral pH. pH levels are lowest in infancy and then rise before adulthood.⁵

Previous studies have shown that salivary secretory IgA (sIgA), salivary pH, buffering capacity and flow rate have a critical role in oral mucosal defense. Dental caries is reportedly related to salivary antimicrobial factors, including lysozyme, peroxidase, and lactoferrin. Specifically, caries was correlated with sIgA and sIgG, such that lower incidence of caries was found in individuals with higher sIgA concentration. Salivary sIgA reduces the initial adherence of bacteria to saliva-coated teeth surfaces and neutralizes extracellular enzymes. Caries free patients have been reported to have higher levels of sIgA.⁴ Additionally, high *S. mutans* specific immunoglobulin levels in the serum were correlated with lower incidence of dental caries. The amount of *S. mutans* specific IgA/IgG are related to a reduction in caries.⁷

Cogulu (2005) compared caries prevalence and sIgA, salivary pH, buffering capacity and flow rate between DS and control groups. Seventy three children aged 7-12 years were included in the study. Caries rates were evaluated using DMFS/dmfs and saliva samples were collected. The DS group had a lower dfs index (1.02) than the healthy group (4.98), ($P < 0.05$). Similarly, the DS group had a lower DMFS index (0.92) than the healthy group (4.26), ($P < 0.05$). Salivary sIgA levels were significantly higher in the DS group than control group ($P = 0.022$). The correlation between sIgA and DMFS/dfs was significant ($P = 0.025$, $r = 0.041$). However, differences between caries and salivary pH, buffering capacity, and flow rate were not statistically significant ($P > 0.05$).⁴

Some researchers have indicated that DS patients have higher pH levels in the oral cavity and irregular salivary buffering capacity, which contributes to their lower caries incidence. This is a controversial finding as other researchers have found no such differences in saliva buffering capacity in DS individuals.⁵

Siqueria (2004) hypothesized that DS children have an alteration in secretory pathways of the salivary glands' ducts and/or acinar cells, due to differences in salivary electrolyte levels. The study found differences in sodium and potassium concentrations in DS children and attributed these differences to lower caries indices in these patients.¹²

Davidovich (2010) conducted a study to determine caries differences between DS children and healthy children by investigating oral mucosal pH and sialochemistry (concentration of salivary ions) between these groups. All children were first divided into four

different groups: Down Syndrome caries free (DS-CaF), Control caries free (C-CaF), Down Syndrome children with caries (DS-Ca), and Control children with caries (C-Ca). The following information was then recorded for each subject: Decayed, missing, or filled teeth (DMFT/dmft); oral mucosal pH measurements; and saliva analysis. The DS group had a significantly lower DMFT and dmft score compared to the healthy group. In the DS group, 56% of children were caries free, while in the control group, 22% were caries free. The calcium level in the DS-CaF group was significantly higher than in the C-Ca and C-CaF groups ($P=0.002$ and 0.01 , respectively). The DS-Ca group demonstrated significantly higher concentration of sodium and potassium levels than the DS-CaF group. The study found higher levels of chloride and calcium in the DS groups and higher concentrations of sodium and potassium were in the DS-Ca group. Interestingly, the study found significantly lower pH values in the DS children and specifically in the DS-Ca group. According to the study, DS subjects have a more acidic oral environment than healthy subjects, and thus, DS may manifest itself in the salivary glands, which may have a protective effect on dental caries.⁵

Lee (2004) examined 28 DS children between ages 8-17 years old. Two healthy control patients were matched for each DS subject for age and gender. Caries was recorded for each patient using dfs and DMFS. Unstimulated saliva was collected through children spitting in a 15 mL tube. The average dfs index (6.84) for the DS group was much lower than the control group (34.81) ($P<0.05$), and the DMFS index (4.82) was lower in the DS children than healthy children (8.35) ($P<0.01$). Serotype g-s-IgA and serotype c-s-IgA for DS children were significantly higher

than those of the control group ($P < 0.05$). However, total IgA concentration was similar between both groups. When caries free groups in the DS and healthy children were compared, no statistical difference was noted. This study concluded stating that DS children have lower caries rates than healthy children, which may be attributed to their higher amounts of *S. mutans* specific IgA antibodies.⁷

Morinushi (1995) evaluated the status of dental caries in subjects having DS. The relationship between caries status and serum antibody titers against *S. mutans* and *S. mitis* was also investigated. Caries rates were determined by both DMFT and Original Caries Severity Score (OCSS). This was a scale devised by Inoue (1979) to indicate the severity of dental caries in a given subject. The relationship between IgM antibody titer to *S. mutans* and OCSS was significantly positively correlated ($p < .0001$). The findings suggested that there is a significant relationship between caries or plaque indices and IgM antibody titers to *S. mutans* in the primary dentition of DS patients.¹³

In summary, all four studies found differences in DS children's salivary components. Although still controversial, there is sufficient evidence indicating that DS may manifest itself in the salivary glands; DS children have different electrolyte salivary environments, higher sIgA levels and higher amounts of *S. mutans* specific IgA antibodies. The authors attribute these differences to overall lower caries indices in these children.

2.3 Methodology for Investigating Dental Caries in DS Patients

Most of the studies investigating caries rates in DS patients compared means of DMFS/dmfs or DMFT/dmft between healthy individuals and DS individuals. However, most of these past studies were poorly controlled and did not account for the fundamental physiological differences between these populations.⁶

Many DS patients have a few to many congenitally missing teeth. Most studies have not accounted for the differences in number of teeth when comparing rates. Without accounting for the number of teeth in each subject, the results are misleading. Since DS patients have fewer teeth, they will consequently have lower DMFT/DMFS compared to healthy patients.⁶

Fung (2005) expressed caries as a proportion per tooth, thereby reducing the confounding variable of congenitally missing teeth from analysis. The study was an observational, matched cross-sectional design to investigate caries rates between DS subjects and control subjects, matched for age. To account for missing teeth, whether due to trauma, caries, or congenital absence, all missing teeth were excluded from analyses. The DMFT index was changed to DFT, where untreated, decayed teeth (DT) and number of restored surfaces (FT) were recorded. To further account for hypodontia and delayed eruption, adjusted DFT was incorporated, such that: $\text{Adjusted DFT} = (\text{DT} + \text{FT}) / \text{Total number of teeth}$. This transfers caries rates to a percentage. Other variables investigated were oral hygiene, fluoride use, and bruxism. In the control group, the mean adjusted DFT score was 0.18, meaning 18 percent of teeth were affected by caries, while 27.4% had no caries. In the DS group, the mean adjusted DFT score was 0.1, meaning that 10 percent of teeth were affected by caries, while 59.9 percent had no caries. When the sample

was stratified by DS status, a significant result was found ($p < 0.001$). A multiple linear regression analysis was performed; DS status, age, language and dentist-administered fluoride treatment were found to have an association with adjusted DFT score. Although adjusted DFT score was significantly higher in the control group during bivariate analysis, once the multiple linear regression model was run, only age and professional fluoride application were statistically associated with differences in caries rates. Once all variables were accounted for, it was determined that DS subjects had an average of 5 percent fewer teeth affected by caries compared to healthy subjects, and this difference was not statistically significant ($p = 0.18$). Additionally, subjects who had regular fluoride treatments by a dentist had a lower mean adjusted DFT score than those who did not by 11 percent ($p = 0.01$). At the multivariate level, once caries was expressed as a percentage, caries rate differences between DS subjects and healthy subjects were not significant. The only factors that were associated with caries at the multivariate level were age and professional fluoride therapy.⁶

Fung stressed that the mean unadjusted DFT between DS patients and healthy patients was of borderline significance. However, once controlled for the number of teeth, there were no statistical differences in adjusted DFT between the groups. Following this, all future studies should control for the physiological differences in the DS population so as to not confound the results.

3. METHODS

3.1 Sample Selection

Inclusion criteria for the study sample were: 2 to 12 year old children, seen in the post graduate pediatric dentistry clinic at UIC College of Dentistry, after June 2010, and children who had at least one subsequent complete oral examination before July 2013. Additionally, inclusion criteria for the experimental group were children identified as having “Down Syndrome” in their medical history forms on Axium system of UIC electronic charts, while the control group required children having a completely unremarkable medical history form on Axium system of UIC electronic charts.

Exclusion criteria for both groups were patients treated exclusively in urgent care clinic and patients with incomplete DFS and/or dfs records on Axium charts. Exclusion criteria for the control group were having any medical alert on Axium system of UIC electronic charts.

Statistical power is the probability of getting a statistically significant result, assuming that the null hypothesis is false. Statistical power is proportional to the study’s sample size, significance criterion (alpha level), and effect size. Effect size is a measure of “biological significance”: it is the difference between the results predicted by the null hypothesis and the actual state of the population being tested²².

A power analysis can establish the probability that an experiment will produce a statistically significant result if a biological difference exists in the population. Conventions of 80 percent power to detect a true difference have been suggested in the literature (Cohen 1988, page 56; Peterman 1990)^{23,24}. Based on data from an aggregate of several sources^{1,3,4,6,7,8}, we predict that DS children will have a mean DMFT of 3 and non-DS children will have a mean

DMFT of 5. Assuming a standard deviation of 5 (as found in other sources^{1,3,4,6,7,8}), at a power of 0.8, this study would need 78 Down Syndrome subjects and 78 or more non-DS subjects to detect a statistical difference between the DS group and non-DS group.

In other words, the power analysis determined that a sample of 78 Down Syndrome patients would have an 80% chance of detecting a difference in number of decayed, missing, or filled surfaces in primary (dmfs) and/or permanent teeth (DMFS). A list of DS patients and healthy patients fulfilling the eligibility criteria was generated, using random selection from the electronic dental record system. The Principal Investigator (PI) obtained these patients' chart numbers and dates of birth on an excel spreadsheet. After inclusion and exclusion criteria were applied, the total number of participants was 82 DS subjects and 164 control subjects.

This study was approved by IRB of University of Illinois at Chicago (Protocol #2013-0767), Appendix A.

3.2 Research Design

This was a retrospective, cross sectional, matched study that utilized chart review and abstraction. Charts from three years (2010-2013) were accessed. Individual patient information at each new patient examination was originally entered into the electronic record by the assigned dental resident provider under the supervision of the attending pediatric dentistry faculty. The clinical charting module provided number of decayed or filled permanent surfaces (DFS) and decayed or filled primary surfaces (dfs).

Control subjects were matched to the experimental group by age and gender. The control group was medically healthy patients who were matched to the target group by gender and were

within 3 months of age (at the time of last appointment). A random number generator was used to randomly assign two non-DS control patients matched for age and gender to each DS patient.

The PI then used a data extraction form (see Appendix B) to record the following information for each patient: gender, age (at the time of recall appointment), medical status (DS or healthy), Decayed or Filled Surfaces on permanent teeth (DFS), decayed or filled surfaces on primary teeth (dfs), total number of permanent teeth, and total number of primary teeth. Teeth that were covered by crowns were recorded as 5 filled surfaces. Once all data extraction forms were filled out for each patient, the lists of healthy and DS patients were shredded and destroyed. The information from the data extraction form was then entered into the Statistical Package for the Social Sciences (SPSS) for analysis.

The adjusted DFS was calculated, using *DS* (number of surfaces with untreated decay) and *FS* (number of surfaces with restorations).

$$\text{Adjusted DFS} = (DS + FS) / \text{Total number of surfaces}.$$

This expressed caries as a percentage for each patient, which could theoretically range from 0-100%.

"Caries free" was defined as a patient that did not have a single decayed (*DS*) or filled surface (*FS*) in either the primary or permanent dentition. Using this definition, a subgroup among DS patients, and another subgroup among the non-DS patients were identified and compared. Each subgroup's caries free percentage was calculated in SPSS.

3.3 Statistical Analysis

Once the data were entered into SPSS, the variables were appropriately labeled and the data were cleaned. New variables were created, including the Adjusted DFS score and caries free indices. Independent t tests and chi square tests were performed to compare the caries rates

between patients with Down Syndrome and healthy patients ($p < 0.05$). Mann-Whitney U tests were run to confirm the results from the independent t-tests.

4. RESULTS

4.1 Descriptive Data

Demographic data for the sample are reported in Table I, which displays the subjects' health Status (DS or healthy), Gender, and Caries Free Status. There were twice as many non-Down Syndrome healthy subjects as DS subjects. There were 129 males and 117 females in this study. Few subjects were completely caries free. Most subjects had at least one surface with dental caries.

4.2 Analysis of Differences in Caries Rates Between Down Syndrome and Non-Down Healthy Subjects

An Independent t test was performed to compare the caries rates in primary teeth between patients with Down Syndrome and non-Down Syndrome healthy patients. Table II indicates percentage of decayed or filled surfaces on primary teeth between non-Down Syndrome healthy subjects and Down Syndrome patients. Levene's test for equality of variances was applied. The sample variances were not equal ($F=16.793$, $p<0.0001$).

DS patients had slightly higher caries rates in primary teeth (Adjusted DFS: 0.28, Std. Dev: 0.28) compared to non-Down Syndrome healthy primary teeth (Adjusted DFS: 0.25, Std. Dev: 0.20). However, the difference was not statistically significant ($P=.368$).

An Independent t test was performed to compare the caries rates in permanent teeth between patients with Down Syndrome and non-Down Syndrome healthy patients. Table III indicates percentage of decayed or filled surfaces on permanent teeth between non-Down

Syndrome healthy subjects and Down Syndrome patients. Levene's test showed that the sample variances were not equal ($F=6.278$, $p=.013$).

DS patients had slightly higher caries rates in permanent teeth (Adjusted DFS: 0.03, Std. Dev: 0.28) compared to non-Down Syndrome healthy patients (Adjusted DFS: 0.25, Std. Dev: 0.20). However, the difference was not statistically significant ($P=.192$).

Mann-Whitney U tests were performed to verify the findings because the data were not normally distributed. Again, the differences between Down Syndrome and non-Down Syndrome healthy subjects were not statistically significant for primary teeth ($U= 6525$, $Z= -.148$, $p = .883$) or permanent teeth ($U=1765$, $Z= -1.014$, $p=.311$).

4.3 Analysis of Differences in Caries Free Percentages Between Subgroups of Down Syndrome and Non-Down Syndrome Healthy Patients

Table IV displays the caries status of Down Syndrome and non-Down Syndrome patients in this study. There were 14 Down Syndrome subjects that were caries free and 19 non-Down Syndrome healthy subjects that were caries free. Therefore, Down Syndrome subjects were more likely to be caries free (17.1%) than healthy patients (11.6%). However, this result was also not statistically significant ($\chi^2= 1.417$, $p=.234$).

TABLE I

DEMOGRAPHIC DATA: HEALTH STATUS, GENDER, AND CARIES STATUS OF
SUBJECTS

Variable	Total	Percent
Case/Control	N=246	
Down Syndrome	82	33.3%
Non-Down Syndrome Healthy	164	66.7%
Total	246	100%
Gender	N=246	
Male	129	52.4%
Female	117	47.6%
Total	246	100%
Caries Free/Has caries	N=246	
Caries Free	33	13.4%
Has Caries	213	86.6%
Total	246	100%

TABLE II

COMPARISON OF DECAYED OR FILLED SURFACES ON PRIMARY TEETH BY
HEALTH STATUS

<u>Health status</u>	<u>N</u>	<u>Percentage of dfs</u>	<u>Mean</u>	<u>Std. Deviation</u>	<u>t value</u>	<u>95% Confidence Interval</u>		<u>Sig. (2-tailed)</u>
						Lower	Upper	
Down Syndrome	81	28.2%	.28	.28	t=0.903	-.0376	.1007	.368
non-Down Syndrome	163	25.1%	.25	.20				

TABLE III

COMPARISON OF DECAYED OR FILLED SURFACES ON PERMANENT TEETH BY
HEALTH STATUS

<u>Health status</u>	<u>N</u>	<u>Percentage of DFS</u>	<u>Mean</u>	<u>Std. Deviation</u>	<u>t value</u>	<u>95% Confidence Interval</u>		<u>Sig. (2- tailed)</u>
						Lower	Upper	
Down Syndrome	41	3.2%	.03	.06	t=1.322	-.0072	.0351	.192
non-Down Syndrome	95	1.8%	.01	.03				

TABLE IV

CARIES FREE SUBGROUPS BY HEALTH STATUS

	Caries Status				Total	Chi Square value	Significance
	Caries Free		Has caries				
	N	(%)	N	(%)			
Down Syndrome	14	(17.1%)	68	(82.9%)	82	$\chi^2= 1.417$	p=.234
non-Down Syndrome	19	(11.6%)	145	(88.4%)	164		
<u>Total</u>	33	(13.4%)	213	(86.6%)	246		

5. DISCUSSION

Dental caries rates in Down Syndrome patients are of critical importance to pediatric dentists and public health professionals. The purpose of this study was to assess and compare dental caries rates between Down Syndrome children and non-Down Syndrome healthy children matched for age and gender. The discussion will address four issues: 1.) significance of the study 2.) the results of this study versus previous studies 3.) limitations and strengths of the study and 4.) implications for future research.

5.1 Significance of the Study

It was hypothesized that DS children express dental caries similarly to the rest of the non-Down Syndrome healthy children, when matched for gender and age. This hypothesis was supported. In fact, contradicting previous studies, DS patients actually expressed slightly higher caries rates compared to non-Down Syndrome healthy patients, although this result was not statistically significant.

It was also hypothesized that an equal amount of DS children and non-Down Syndrome healthy children (identified as subgroups of “caries-free” populations) would be caries free. Consistent with previous studies, DS patients were slightly more likely to be caries free (17.1%) than non-Down Syndrome healthy patients (11.6%), however this difference was also not statistically significant.

The important point of this study is that the dental caries trend is similar in many populations including Down Syndrome individuals. This population was previously considered to be protected from dental caries due to their higher salivary pH and other dental/oral

manifestations^{4,5,7}. Many pediatric dentists work with Down Syndrome patients, so it is essential that these practitioners understand the importance of proper preventive care for this high risk population. Enrolling these patients in early preventive treatment modalities, particularly those in lower socioeconomic statuses, is of utmost importance.

5.2 Relevance to Previous Studies

This study both contradicted and supported previous research. Two recent studies properly accounted for the delayed eruption and hypodontia experienced by DS patients. Mathias (2011) compared DS subjects and non-Down Syndrome healthy subjects by the number of teeth erupted, thereby controlling for delayed eruption and hypodontia. In that study, after adjusting for the delayed eruption of DS patients, there was no statistical difference in dmft between DS and non-DS children¹. Fung (2005) accounted for hypodontia and delayed eruption by expressing caries as a percentage, such that: $\text{Adjusted DFT} = (\text{DT} + \text{FT}) / \text{Total number of teeth}$. Once all variables were accounted for, it was determined that DS subjects had an average of 5 percent fewer teeth affected by caries compared to non-Down Syndrome healthy subjects, and this difference was not statistically significant.⁶ The present study produced findings similar to both of these prior studies.

The present study also contradicted previous research that did not properly account for delayed eruption and congenitally missing teeth. Cogulu (2005) compared caries prevalence and sIgA, salivary pH, buffering capacity and flow rate between DS and control groups. The dfs index for the DS group was much lower than the control group and the DMFS index was also lower in the DS group than the control group.⁴ Lee (2004) examined caries in DS children using

dfs and DMFS. The average dfs index for the DS group was much lower than the control group, and the DMFS index was lower in the DS children than non-Down Syndrome healthy children.⁷

The present study directly contradicted the results of these two studies. These studies, along with many others comparing dental caries rates between DS patients and non-Down Syndrome healthy patients, failed to adjust for differences between the two populations. Since DS patients typically have fewer teeth, they would also generally have lower DFS/dfs. This study supported more recent research that controlled for these physiologic differences seen in the DS population.

5.3 Limitations and Strengths of the Study

This study has several limitations. It was conducted at only one site within the city of Chicago, which may not be representative of all children with and without Down Syndrome. The samples chosen almost exclusively came from a lower socioeconomic (SES) population. Lower SES populations generally have higher caries rates. This could have limited the generalizability of this study.¹⁴ Since this was a retrospective study, the ethnicity/race of the children was not consistently entered in the electronic dental record. Therefore, the subjects were not able to be identified by ethnicity.

Another limitation is the high number of clinicians that recorded DMFS/dmfs in this study. Each patient was evaluated by the resident/faculty assigned to him/her in the post-doctoral clinic of the Department of Pediatric Dentistry, so there may have been some variability in the treatment of dental caries in each patient. With six incoming residents each year, there have been a total of 18 residents that have planned treatment for the patients included in this

study. Due to the design of the study, inter-rater reliability was unable to be assessed. Still, the likelihood of bias is fairly low due to both groups being evaluated by the same clinicians.

There are also differences in the treatment of Down Syndrome and non-Down Syndrome healthy patients. DS patients are generally less cooperative than non-Down Syndrome healthy patients in the dental chair and have a higher incidence of atlanto-axial instability. Therefore, a higher percentage of DS patients are treated using general anesthesia. During general anesthesia appointments, treatment is generally more aggressive, where more teeth are crowned instead of simple fillings. This would increase the DFS/dfs values for these patients. Since DS patients have, on average, more general anesthesia appointments, it is likely that the caries rates would be inflated for this population. Therefore, it should be noted that despite the results of this study, it is possible that Down Syndrome patients may, in fact, have lower dental caries rates compared to non-Down Syndrome children.

A strength of this study was the relatively large sample. In many previous studies with Down Syndrome subjects, the samples were smaller. Additionally, two non-Down Syndrome healthy subjects (as opposed to one non-Down Syndrome subject) per Down Syndrome patient were included in this study. The larger sample led to greater statistical power than most studies have had. The sample size also satisfied the requirements from the power analysis, which required 78 DS subjects in order to detect a statistical difference in this sample. Finally, and most importantly, proper control for some of the physiological differences in the DS population, specifically delayed eruption and hypodontia, were accounted for in this study.

5.4 Implications for Future Research

The results of this study suggest that the previously held notion that DS patients have decreased dental caries rates may not be true. Additional studies should be performed on a wider patient population so that the results could be generalizable to a larger population. Using populations from different geographic groups and socioeconomic strata should be conducted. As it is unlikely that a national or world-wide sample could ever be achieved, a series of similar studies in multiple sites would allow for a more representative sample of the DS and healthy populations, thereby granting broader generalizability of the results.

Future studies should consider charting both DFS/dfs as well as DFT/dft. This way, researchers could potentially gain some consistency in the better measure for researching caries in these populations. Similarly, the presence of crowns in patients inflates the DFS/dfs values. Future research should control for these restorations by using DFT/dft. Additionally, a prospective study could immensely benefit the status of the literature.

6. CONCLUSIONS

- DS patients expressed slightly higher caries rates compared to healthy patients in both primary and permanent teeth; however the difference was not statistically significant.
- When subgroups of DS and non-DS “caries free” subjects were compared, DS patients were slightly more likely to be caries free (17.1%) than non-Down Syndrome healthy patients (11.6%). However this difference was not statistically significant. This could be attributed to the rate of hypodontia and delayed eruption in DS population.

CITED LITERATURE

1. Mathias, M., Simionato, M., & Guare, R. (2011). Some factors associated with dental caries in the primary dentition of children with Down syndrome. *Eur J Paediatr Dent.*, 12(1), 37-42.
2. Areias, C., Sampaio-Maia, B., & Guimaraes, H. (2011). Caries in Portuguese children with Down syndrome. *Clinics (Sao Paulo)*, 66(7), 1183-1186.
3. Castilho, A., & Marta, S. (2010). Evaluation of the incidence of dental caries in patients with Down syndrome after their insertion in a preventive program. *Cien Saude Colet*, 2, 3249-3253.
4. Cogulu, D., Sabah, E., & Kutukculer, N. (2006). Evaluation of the relationship between caries indices and salivary secretory IgA, salivary pH, buffering capacity and flow rate in children with Down's syndrome. *Arch Oral Biol*, 51(1), 23-28.
5. Davidovich, E., Aframian, D., & Shapira, J. (2010). A comparison of the sialochemistry, oral pH, and oral health status of Down syndrome children to healthy children. *Int J Paediatr Dent.*, 20(4), 235-241.
6. Fung, K. (2005). A comparison of caries rates in non-institutionalized individuals with and without Down Syndrome. *Special Care in Dentistry* 25(6), 302-310.
7. Lee, S., Kwon, H., & Song, K. (2004). Dental caries and salivary immunoglobulin A in Down syndrome children. *J Paediatr Child Health.*, 40(9), 530-533.
8. Asokan, S., Muthu, M., & Sivakumar, N. (2008). Dental caries prevalence and treatment needs of Down syndrome children in Chennai, India. *Indian J Dent Res*, 19(3), 224-229.
9. Bradley, C., McAlister, T. (2004). The oral health of children with Down Syndrome in Ireland. *Spec Care Dentist* 24(2): 55-60
10. Cornejo, L.S., Zak, G.A., et. al (1996). Bucodental Health Condition in Patients with Down Syndrome of Cordoba City, Argentina. *Acta Odont. Latinamer.* Vol 9(2); 65-79.
11. Shyama, M., Al-Mutawa, S.A., Morris, R.E., & Sugathan T. (2001). Dental caries experience of disabled children and young adults in Kuwait. *Community Dent Health* 18(3); 181-6.
12. Siqueira WL, de Oliveira E, Mustacchi Z Micolae J. Electrolyte concentrations in saliva of children aged 6-10 years with Down Syndrome. *Oral Surg Oral Med Oral Pathol Oral Radiol Endod* 2004; 98:76-79.
13. Morinushi, T., Lopatin, D.E., Tanaka, H. (1995). The relationship between dental caries

- in the primary dentition and anti *S. mutans* serum antibodies in children with Down's Syndrome. *The Journal of Clinical Pediatric Dentistry*. Vol 19(4); 279-284.
14. American Academy of Pediatric Dentistry. Guideline on Caries-risk Assessment and Management for Infants, Children, and Adolescents. *Pediatric Dent* 2013; 35(6):123-130.
 15. Cohen WI, Nadel L, Madnick ME. Down Syndrome: Visions for the 21st Century. New York: Wiley-Liss; pp. 119-123, 232, 2002.
 16. Prevalence of Down Syndrome Among Children and Adolescents in 10 Regions of the United States. *Pediatrics* December 2009 (124:6);1565-1571.
 17. Johnstone SC, Barnard KM, Harrison VE. Recognizing and caring for the medically compromised child: 4. Children with other chronic medical conditions. *Dent Update* 1999; 26:21-6.
 18. Pinazo JDC, Vianna MIP, Lopes FL. Carie dentaria e placa bacteriana em crianças de 07 a 14 anos portadoras da síndrome de Down, matriculadas em instituições públicas e privadas do município de Salvador – Bahia. *Rev Fac Odontol da UFBA* 1998;17:15-24
 19. Rogers PT, Roizen NJ, Capone GT. Down Syndrome In: Capute AJ, Accardo PJ. Developmental disabilities in infancy and childhood. 2nd ed. Baltimore: Paul H Brookes; 1996. P 221-43
 20. Shore S, Lightfoot T, Ansell P, “Oral Disease in children with DS: causes and prevention”. *Community practitioner*. 2010;83:18-21.
 21. Roger RJ, Reeves RH. “Understanding the basis for DS phenotypes.” *PLoS Genet*. 2006;2:e50, doi:10.1371/journal.pgen.0020050.
 22. Thomas, L., Juanes, F. (1996). The importance of statistical power analysis: an example from Animal Behaviour. *Anim. Behav.*, 1996, 52, 856–859
 23. Peterman, R. M. 1990. Statistical power analysis can improve fisheries research and management. *Can. J. Fish. Aquat. Sci.*, 47, 2–15.
 24. Cohen, J. 1988. Statistical Power Analysis for the Behavioral Sciences. 2nd edn. Hillsdale, New Jersey: Lawrence Erlbaum.

APPENDIX A

UNIVERSITY OF ILLINOIS AT CHICAGO

Office for the Protection of Research Subjects (OPRS)
Office of the Vice Chancellor for Research (MC 672)
203 Administrative Office Building
1737 West Polk Street
Chicago, Illinois 60612-7227

Exemption Granted

August 12, 2013

Amarjot Singh, DDS
Pediatric Dentistry
801 S. Paulina
M/C 850
Chicago, IL 60612
Phone: (862) 228-4531 / Fax: (312) 413-8006

RE: **Research Protocol # 2013-0767**
“Prevalence of Dental Caries in Children with Down Syndrome”

Sponsors: None

Please note that this exemption determination does not include approval for Dr. Adriana Semprum-Clavier to conduct the research as her Investigator Training period expired on July 11, 201 and she has not completed HIPAA Research Training. After she has completed Investigator Continuing Education and HIPAA Research Training, please submit an Amendment adding her as a co-investigator.

Dear Dr. Singh:

Your Claim of Exemption was reviewed on August 11, 2013 and it was determined that your research protocol meets the criteria for exemption as defined in the U. S. Department of Health and Human Services Regulations for the Protection of Human Subjects [(45 CFR 46.101(b)]. You may now begin your research.

Exemption Period:	August 11, 2013 – August 11, 2015
Performance Site(s):	UIC
Subject Population:	De-identified medical records initially collected for clinical purposes from June 1, 2010 through July 1, 2013.
Number of Subjects:	250

The specific exemption category under 45 CFR 46.101(b) is:

(4) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

HIPAA Waiver:

The Board determined that this research meets the regulatory requirements for waiver of authorization as permitted at 45CFR164.512(i)(1)(i)(A). Specifically, that the use or disclosure of protected health information (PHI) meets the waiver criteria under 45CFR164.512(i)(2)(ii); the research involves no more

than a minimal risk to the privacy of the individuals; the research could not practicably be conducted without the waiver; and the research could not practicably be conducted without access to and use of the PHI.

You are reminded that investigators whose research involving human subjects is determined to be exempt from the federal regulations for the protection of human subjects still have responsibilities for the ethical conduct of the research under state law and UIC policy. Please be aware of the following UIC policies and responsibilities for investigators:

1. Amendments You are responsible for reporting any amendments to your research protocol that may affect the determination of the exemption and may result in your research no longer being eligible for the exemption that has been granted.
2. Record Keeping You are responsible for maintaining a copy all research related records in a secure location in the event future verification is necessary, at a minimum these documents include: the research protocol, the claim of exemption application, all questionnaires, survey instruments, interview questions and/or data collection instruments associated with this research protocol, recruiting or advertising materials, any consent forms or information sheets given to subjects, or any other pertinent documents.
3. Final Report When you have completed work on your research protocol, you should submit a final report to the Office for Protection of Research Subjects (OPRS).

Please be sure to:

→ Use your research protocol number (listed above) on any documents or correspondence with the IRB concerning your research protocol.

We wish you the best as you conduct your research. If you have any questions or need further help, please contact me at (312) 355-2908 or the OPRS office at (312) 996-1711. Please send any correspondence about this protocol to OPRS at 203 AOB, M/C 672.

Sincerely,

Charles W. Hoehne
Assistant Director
Office for the Protection of Research Subjects

cc: Indru C. Punwani, Pediatric Dentistry, M/C 850
Shahrbano Fadavi, Pediatric Dentistry, M/C 850
Privacy Officer, Health Information Management, M/C 772

UNIVERSITY OF ILLINOIS
AT CHICAGO

Office for the Protection of Research Subjects (OPRS)
Office of the Vice Chancellor for Research (MC 672)
203 Administrative Office Building
1737 West Polk Street
Chicago, Illinois 60612-7227

Exemption Granted UIC Amendment #1

April 8, 2014

Amarjot Singh, DDS
Pediatric Dentistry
801 S. Paulina
M/C 850
Chicago, IL 60612
Phone: (862) 228-4531 / Fax: (312) 413-8006

RE: Research Protocol # 2013-0767
“Prevalence of Dental Caries in Children with Down Syndrome”

Sponsors: None

Dear Dr. Singh:

The Amendment to your Claim of Exemption was reviewed on April 7, 2014 and it was determined that your amended research continues to meet the criteria for exemption. You may now implement the amendment.

Amendment: UIC Amendment #1 dated August 11, 2013 and initially submitted to OPRS on March 4, 2014 is an investigator-initiated amendment adding the following key research personnel: Adriana Semprum-Clavier

Amendment Approval Date: April 7, 2014
Exemption Period: April 7, 2014 – April 7, 2017

The specific exemption category under 45 CFR 46.101(b) is:

(4) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

Please note the Review History of this submission:

Receipt Date	Submission Type	Review Process	Review Date	Review Action
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03/04/2014	Amendment	Exempt	03/12/2014	Modifications Required
03/27/2014	Response to Modifications	Exempt	04/07/2014	Approved

You are reminded that investigators whose research involving human subjects is determined to be exempt from the federal regulations for the protection of human subjects still have responsibilities for the ethical conduct of the research under state law and UIC policy. Please be aware of the following UIC policies and responsibilities for investigators:

1. Amendments You are responsible for reporting any amendments to your research protocol that may affect the determination of the exemption and may result in your research no longer being eligible for the exemption that has been granted.
2. Record Keeping You are responsible for maintaining a copy all research related records in a secure location in the event future verification is necessary, at a minimum these documents include: the research protocol, the claim of exemption application, all questionnaires, survey instruments, interview questions and/or data collection instruments associated with this research protocol, recruiting or advertising materials, any consent forms or information sheets given to subjects, or any other pertinent documents.
3. Final Report When you have completed work on your research protocol, you should submit a final report to the Office for Protection of Research Subjects (OPRS).

Please be sure to:

→ Use your research protocol number (2013-0767) on any documents or correspondence with the IRB concerning your research protocol.

We wish you the best as you conduct your research. If you have any questions or need further help, please contact the OPRS office at (312) 996-1711 or me at (312) 355-2908. Please send any correspondence about this protocol to OPRS at 203 AOB, M/C 672.

Sincerely,

Charles W. Hoehne
Assistant Director
Office for the Protection of Research Subjects

cc: Marcio Da. Fonseca, Pediatric Dentistry, M/C 850
Shahrbano Fadavi, Pediatric Dentistry, M/C 850

UNIVERSITY OF ILLINOIS
AT CHICAGO

Office for the Protection of Research Subjects (OPRS)
Office of the Vice Chancellor for Research (MC 672)
203 Administrative Office Building
1737 West Polk Street
Chicago, Illinois 60612-7227

**Exemption Determination
Amendment to Research Protocol – Exempt Review
UIC Amendment # 2**

May 21, 2014

Amarjot Singh, DDS
Pediatric Dentistry
801 S. Paulina
M/C 850
Chicago, IL 60612
Phone: (862) 228-4531 / Fax: (312) 413-8006

**RE: Protocol # 2013-0767
“Dental Caries Rates in Children with Down Syndrome”**

Dear Dr. Singh:

The OPRS staff/members of Institutional Review Board (IRB) #2 have reviewed this amendment to your research, and have determined that your research protocol continues to meet the criteria for exemption as defined in the U. S. Department of Health and Human Services Regulations for the Protection of Human Subjects [(45 CFR 46.101(b))].

The specific exemption category under 45 CFR 46.101(b) is:

(4) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

You may now implement the amendment in your research.

Please note the following information about your approved amendment:

Exemption Period: May 19, 2014 – May 19, 2017

Amendment Approval Date: May 19, 2014

Amendment:

Summary: UIC Amendment #2 dated May 13, 2014 and submitted to OPRS on May 15, 2014 is an investigator-initiated amendment changing the research protocol title from "Prevalence of Dental Caries in Children with Down Syndrome" to "Dental Caries Rates in Children with Down Syndrome".

You are reminded that investigators whose research involving human subjects is determined to be exempt from the federal regulations for the protection of human subjects still have responsibilities for the ethical conduct of the research under state law and UIC policy. Please be aware of the following UIC policies and responsibilities for investigators:

1. Amendments You are responsible for reporting any amendments to your research protocol that may affect the determination of the exemption and may result in your research no longer being eligible for the exemption that has been granted.
2. Record Keeping You are responsible for maintaining a copy all research related records in a secure location in the event future verification is necessary, at a minimum these documents include: the research protocol, the claim of exemption application, all questionnaires, survey instruments, interview questions and/or data collection instruments associated with this research protocol, recruiting or advertising materials, any consent forms or information sheets given to subjects, or any other pertinent documents.
3. Final Report When you have completed work on your research protocol, you should submit a final report to the Office for Protection of Research Subjects (OPRS).

Please be sure to:

→ Use your research protocol number (2013-0767) on any documents or correspondence with the IRB concerning your research protocol.

We wish you the best as you conduct your research. If you have any questions or need further help, please contact me at (312) 355-2908 or the OPRS office at (312) 996-1711. Please send any correspondence about this protocol to OPRS at 203 AOB, M/C 672.

Sincerely,

Charles W. Hoehne, B.S., C.I.P.
Assistant Director
Office for the Protection of Research Subjects

cc: Marcio Da. Fonseca, Pediatric Dentistry, M/C 850
Shahrbano Fadavi, Pediatric Dentistry, M/C 850

APPENDIX B

DATA EXTRACTION SHEET (1/2)

Gender:

Age in months:

Date of last appointment:

Group (circle one): Down Syndrome or non-Down Syndrome healthy

number of primary teeth:

number of decayed surfaces on primary teeth:

number of filled surfaces on primary teeth:

number of permanent teeth:

number of decayed surfaces on permanent teeth:

number of filled surfaces on permanent teeth:

DATA EXTRACTION SHEET (2/2)

Record the number of decayed and filled teeth:

	2	3	A/4	B/5	C/6	D/7	E/8	F/9	G/10	H/11	I/12	J/13	14	15
D														
F														
	31	30	T/29	S/28	R/27	Q/26	P/25	O/24	N/23	M/22	L/21	K/20	19	18
D														
F														

VITAE

Amarjot (Amar) Singh, DDS

FORMAL EDUCATION

Certificate in Pediatric Dentistry June 2014
University of Illinois at Chicago
Chicago, IL

Master of Science in Oral Sciences (M.S.) June 2014
University of Illinois at Chicago
Chicago, IL

Doctor of Dental Surgery (D.D.S.) May 2012
Howard University College of Dentistry
Washington, D.C.

Bachelor of Science (B.S.) May 2008
Carnegie Mellon University
Pittsburgh, PA

DENTAL EXPERIENCE

Residency:

University of Illinois at Chicago June 2014
Department of Pediatric Dentistry
Chicago, IL

- Two year training program specializing in pediatric dentistry
- Strong clinical experience performing all procedures on patients up to 18 years of age
- Weekly didactic seminars discussing current trends and research in pediatric dentistry
- Extensive clinical exposure to utilization of sedation and general anesthesia for management of behavior and special needs patients

Private Practice:

West Suburban Dentistry Jan-Sept 2013
Aurora, IL

- Moonlighted on Saturdays as an associate dentist treating children exclusively
- Treated all urgent care, recall, and operative patients

Externships:

Children's National Medical Center July 2011
Department of Pediatric Dentistry
Washington, D.C.

- Performed several procedures in operating room, including extractions

- and placing stainless steel crowns
- Performed new patient examinations and recall appointments for children of all ages and special needs patients
- Observed and assisted residents during all academic, clinical, and OR settings, including behavior management for non-cooperative patients

University of Illinois at Chicago

July 2011

Department of Pediatric Dentistry

Chicago, IL

- Observed residents during all academic, clinical, and OR settings
- Assisted residents in behavior management for non-cooperative patients

Montefiore Medical Center

July 2011

Department of Pediatric Dentistry

Bronx, NY

- Observed and assisted residents during all clinical appointments
- Assisted residents in behavior management for non-cooperative patients

Long Island Jewish Medical Center

May 2011

Department of Pediatric Dentistry

New Hyde Park, NY

- Observed residents during all academic, clinical, and OR settings
- Performed procedures including new patient exams, cleanings, and orthodontic recalls
- Assisted residents in behavior management for non-cooperative patients

Tufts University

May 2011

Department of Pediatric Dentistry

Boston, MA

- Observed residents during all academic, clinical, and OR settings
- Assisted residents in behavior management for non-cooperative patients

New York University

April 2011

Department of Pediatric Dentistry

New York, NY

- Shadowed residents and attendings during clinical appointments
- Observed residents during OR procedures

Allied Pediatric Dentistry

August 2010

Atlantic City, NJ

- Shadowed Pediatric Dentist, Dr. Sundeep Sekhon
- Assisted all treatments, including restorations, crowns, and sedations

University of Medicine and Dentistry of New Jersey
Newark, NJ

January 2010

- Shadowed for a brief period through several of the residency programs, including Pediatrics, Periodontics, and Endodontics

St. Joseph's Regional Medical Center
Paterson, NJ

August 2008

- Shadowed head of dental clinic and Oral Maxillofacial and Craniofacial Surgeon, Dr. Hillel Ephros, who performed a wide range of procedures in the operating room
- Observed routine extractions conducted by team of oral surgery residents

RESEARCH EXPERIENCE

Independent Research

July 2012-2014

University of Illinois at Chicago

Department of Pediatric Dentistry

- Researching caries rates in Down Syndrome patients with low socioeconomic status for Master's thesis in Oral Sciences

My Kids Dentist Research Poster Competition

May 2013

AAPD Conference

- Prepared research poster regarding caries rates in Down Syndrome patients
- Presented literature review to panel of judges

Research Assistant

Fall 2010- 2012

Howard University College of Dentistry

Department of Pediatric Dentistry

- Assisted Pediatric resident in data gathering and analysis for Master's thesis

LEADERSHIP ROLES

Class of 2012 Vice President

May 2011-June 2012

Howard University College of Dentistry

- Served as main liaison between Student Body and Administration
- Oversaw class Executive Board
- Class of 2012 Clinical Coordinator

Class of 2012 Executive Board

May 2009-June 2012

Howard University College of Dentistry

- Elected to serve as cabinet member
- Attended meetings and wrote legislature for governing body

Class of 2012 Fundraising Chair

May 2009-May 2010

Howard University College of Dentistry

- Raised over \$2,000 for class through the use of corporate sponsorship, alumni connections, and external initiatives

Tooth Fairy Treasurer, Member

January 2011-2012

Howard University College of Dentistry

- Executive board member for Tooth Fairy program
- Program aims at increasing patient education amongst child population
- Delivered presentations and helped raise money for events

COMMUNITY SERVICE

Big Brothers/Big Sisters of Chicago

November 2012-2014

Chicago, IL

- Facilitate instructional activities to provide safe and positive learning environment
- Positive male role model for underprivileged, troubled urban youth
- Maintain contact and worked to improve relationships between children and adults

Give Kids a Smile Day

February 2009-2012

Howard University College of Dentistry

- One of ten students to screen children at Harriet Tubman Elementary School, Washington, D.C.
- Participated in school-wide initiative to administer free dental care for all children in Washington, D.C. area
- Treatments ranged from fluoride therapy and sealants to extensive restorations and veneers

Tooth Fairy, Inaugural Member

January 2011- 2012

Howard University College of Dentistry

- One of ten students responsible for bringing national chapter of Tooth Fairy to Howard University
- Program aimed at disease prevention and oral health instructions for children

Special Olympics Volunteer

June 2010

Howard University College of Dentistry

- Provided dental screenings for Special Olympic athletes
- Aided the event by engaging contestants in separate games

Big Brothers/Big Sisters of Pittsburgh

January 2007-2008

Pittsburgh, PA

- Facilitated instructional activities to provide safe and positive learning environment
- Positive male role model for underprivileged, troubled urban youth
- Maintained contact and worked to improve relationships between children and adults
- Assisted program on week to week basis, including field trips and in-house projects

Oral Cancer Walk

March 2009-2012

Howard University College of Dentistry

- Two time participant of Howard University College of Dentistry's Annual Oral Cancer Walk
- Program seeks to raise awareness for oral cancer
- Performed free cancer screenings for general public of Washington D.C.

VOLUNTEER EXPERIENCES

Midwestern University Dental Student-Resident Liaison

July 2013

- Liaison for dental students of Midwestern University
- Delivered presentations and question-answer sessions to aid the transition for students considering residency

Carnegie Mellon University Student-Dentist Liaison

August 2008-2011

- Liaison for pre-dental society of Carnegie Mellon University
- Delivered presentations and question-answer sessions to aid the transition for students considering dentistry

Anatomy Tutor

August 2009

Howard University College of Dentistry

- Awarded position of Head Anatomy tutor for first year dental students based on prior exemplary performance
- Conducted tutoring sessions twice per week
- Prepared PowerPoint presentations for excellence in course work as well as NBDE Part I

SCHOLARSHIPS, AWARDS, AND HONORS

Omicron Kappa Upsilon National Honor Society, Pi Pi Chapter

Dr. I. Langston Manley Endowed Scholarship

Howard University College of Dentistry Dean's List

Howard University Dentistry Net Scholarship

Carnegie Mellon University Dean's List

Carnegie Mellon University Scholarship

PROFESSIONAL AFFILIATIONS

American Academy of Pediatric Dentistry (AAPD)

Illinois Society of Pediatric Dentistry (ISPD)
American Dental Association (ADA)
American Dental Education Association (ADEA)
Student National Dental Association (SNDA)
American Student Dental Association (ASDA)
National Dental Association (NDA)

LANGUAGES SPOKEN

English – Fluent
Spanish – Working proficiency
Punjabi – Working proficiency

LICENSES

Licensed Dentist: Illinois, New Jersey, Pennsylvania - Active
Controlled Substance - Active