

# **CHAPTER-4**

## **RESULT**

#### 4: RESULTS

A total of 111 participants were analyzed in the present study. This sample resulted after excluding those who were lost to follow-up, expired, changed treatment midway, or did not reported to follow up for any reason.

These patients were divided into two groups; Group A (monthly application) and Group B (Quarterly application) according to the frequency of fluoride application. These two groups were further subdivided according to the type of fluoride into V (varnish) and G (Gel). This resulted in 4 groups with 28 participants in **AV** (Monthly fluoride varnish), 27 participants in **BV** (Quarterly fluoride Varnish), 27 participants in **AG** (Monthly fluoride Gel), and 29 participants in **BG** (Quarterly fluoride Gel). (Figure 1)

##### 4.1: Baseline Demographic Results

The Mean  $\pm$  S.D for Age at baseline for 111 participants was  $49.11 \pm 11.36$  years with a range from 20-70 years. (Table 1)

**Table 1: Mean and standard deviation with lower and upper bound for Age in years, for the participants at baseline.**

AGE (in years)	Mean	Standard deviation	Lower bound	Upper bound
	49.11	11.36	20	70

36 (32.4 %) participants were in fourth decade of life, 28(25.2 %) were in fifth decade, 22(19.8 %) were from third decade, 21(18.9 %) in six decade and 4(3.6 %) were from second decade of life. (Figure-1)

### AGE GROUPS

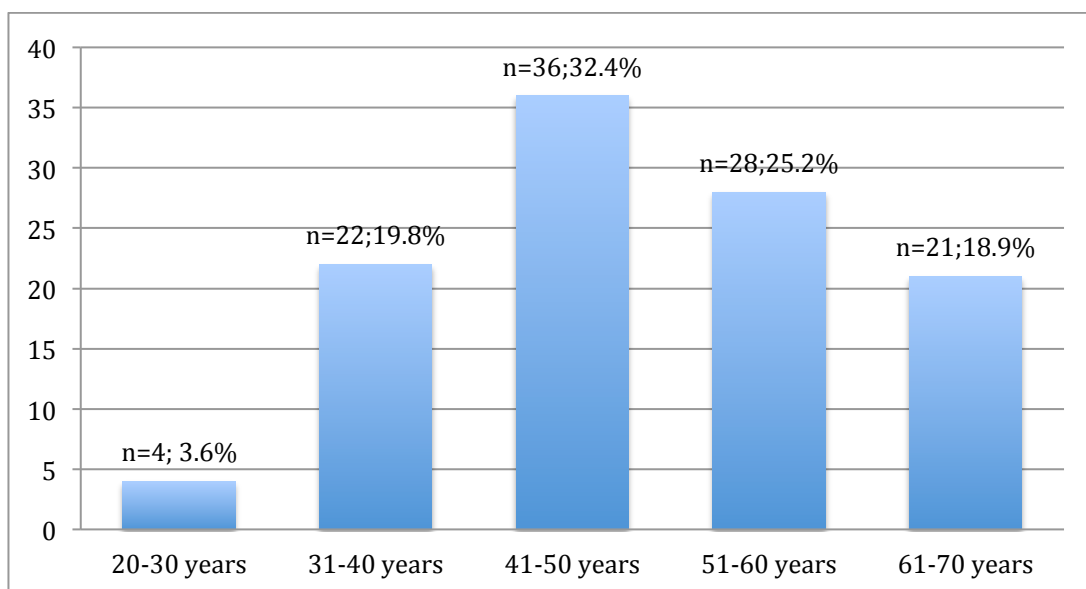


Figure 1: Frequency and percentage for Age groups of the participants at baseline.

Ninety-six participants were male which constituted 86.4% of the population. While fifteen females contributing to 13.6 % were present in the study. (Figure- 2)

### GENDER

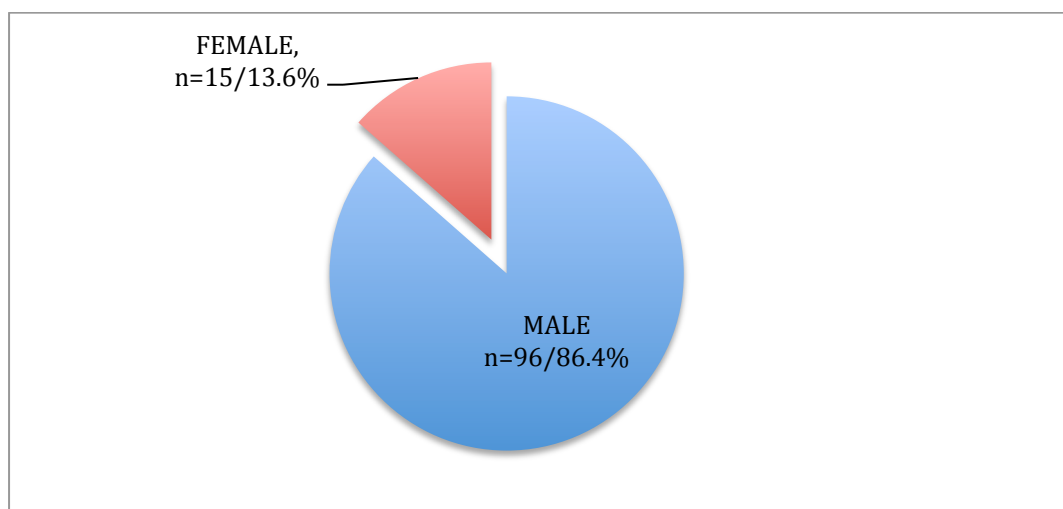
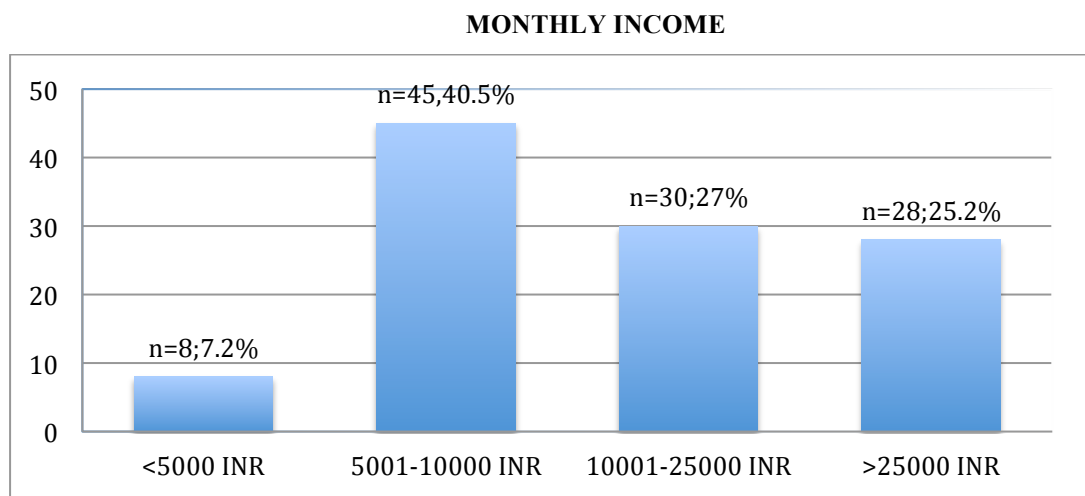
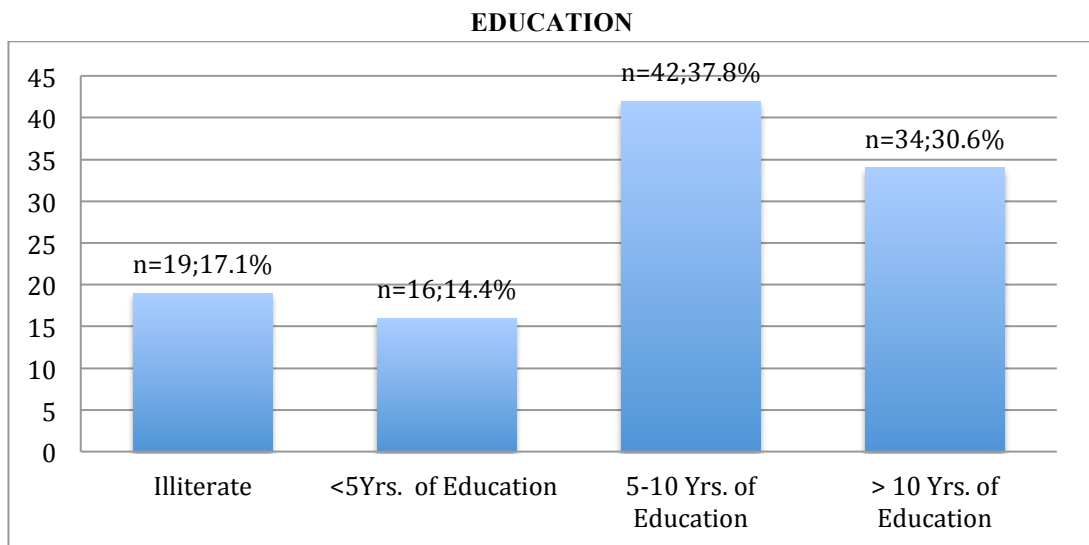


Figure 2: Gender distribution frequency and percentage at baseline among participants.

Monthly income for 45 (40.5%) participants ranged from five to ten thousand, 30 (27%) participants had income in the range of fifteen to twenty-five thousand, 28 (25.2%) earned more than twenty-five thousand and 8(7.2%) earned less than five thousand. Education for 42 (37.8%) participants was between five to ten years, 34(30.6) had an education of more than ten years, 19(17.1%) were illiterate and 16(14.4%) had an education of 5 years. (Figure 3,4)



**Figure-3: Frequency and percentage distribution for the monthly income of the participants at baseline.**



**Figure 4: Frequency and percentage distribution for years of education of the participants at baseline.**

No history of smoking was seen in 50 (45%) participants, 7(6.3%) participants smoked less than ten cigarettes/ bidi per day while 54 (48.6%) participants smoked more than ten cigarettes/ bidi per day. Tobacco consumption in 50 (45%) participants was nil, 30 (26.1 %) consumed more than five packets per day, 29 (26.1%) consumed more than 5 packets per day while 2 (1.8%) used tobacco occasionally. 80 (72%) participants did not consume alcohol, 21 (18.9%) consumed more than 250 ml of alcohol per day, 8 (7.2%) consumed less than 250 ml of alcohol per day while 2 (1.8%) consumed alcohol occasionally in moderation. (Table-2)

**Table 2: Baseline data for Smoking, Tobacco & Alcohol consumption, of the participants for frequency and percentage distribution.**

<b>Smoking (per day)</b>	<b>Percentage (%)</b>	<b>Frequency( n)</b>
No	45	50
≤ 10	6.3	7
>10	48.6	54
<b>Tobacco (per day)</b>	<b>Percentage (%)</b>	<b>Frequency( n)</b>
No	45	50
Occasional	1.8	2
≤ 5 Pouches	27	30
>5 Pouches	26.1	29
<b>Alcohol (Milliliters per day)</b>	<b>Percentage (%)</b>	<b>Frequency( n)</b>
No	72	80
Occasional	1.8	2
≤250	7.2	8
>250	18.9	21

Brushing was performed by 88 (79.2%) participants using a toothbrush with toothpaste, 22(19.8%) used either stick or finger for brushing, while 1(1%) did not

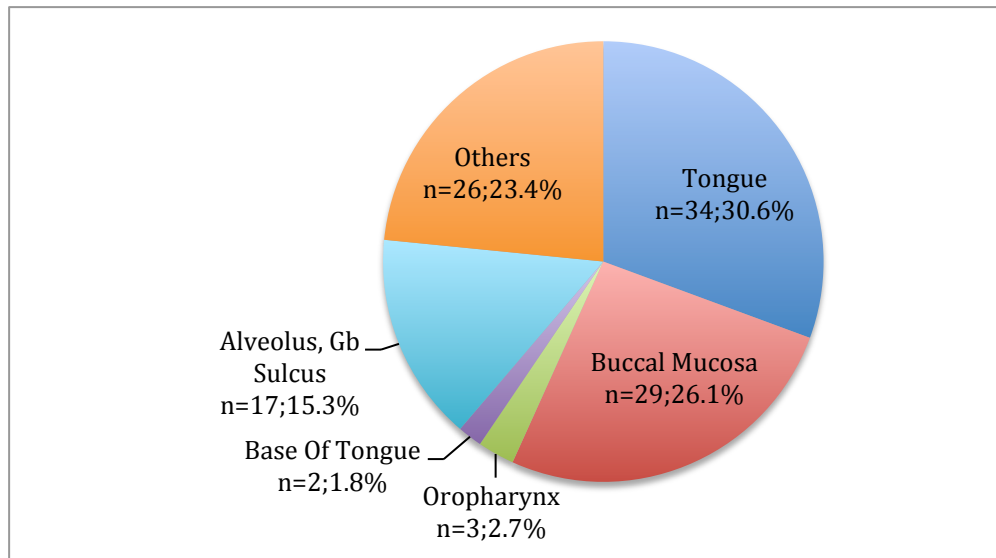
use any oral hygiene aid. 107(96.3%) participants brushed once daily, 3(2.7%) brushed twice daily and 1(1%) was not brushing (Table 3)

**Table 3: Baseline data for Brushing Aid and Brushing Frequency of the participants for frequency and percentage distribution.**

<b>Brushing Aids</b>	<b>Percentage (%)</b>	<b>Frequency (n)</b>
None	0.9	1
Stick/Finger	19.8	22
Brush	79.2	88
<b>Brushing Frequency</b>	<b>Percentage (%)</b>	<b>Frequency (n)</b>
None	0.9	1
Occasional	2.7	3
Once	96.3	107

Tongue carcinoma was seen in 34 (30.6%) participants, 29(26.1%) were diagnosed with carcinoma of buccal mucosa, 17(15.3%) had carcinoma alveolus and gingiva-buccal sulcus, 3 (2.7%) had carcinoma oropharynx and 2(1.8%) were diagnosed with carcinoma base of the tongue. While 26(23.4%) participants had other cancer which included carcinoma supraglottis, carcinoma pyriform with neck nodes, etc.

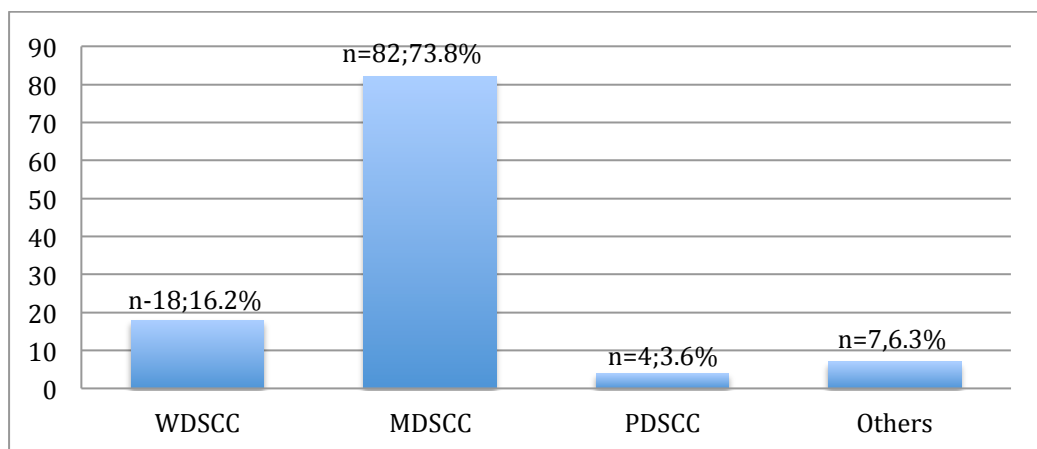
### SITE OF CANCER



**Figure 5: Frequency and percentage for cancer site distribution amongst participants at baseline.**

Histopathological diagnosis of Moderately differentiated squamous cell carcinoma was found in 82(73.8%) participants, 18(16.2%) had well-differentiated squamous cell carcinoma and 4(3.6%) had poorly differentiated squamous cell carcinoma. 7(6.3%) participants had diagnoses under other categories. This included Mucoepidermoid and Adenocystic carcinoma of the salivary gland. (Figure 6)

### HISTOPATHOLOGY



**Figure 6: Baseline data for Histopathology of the participants for frequency and percentage distribution.**

A radiation dose of up to 60 Gy. was received by 72(64.8%) participants, while 39(35.1%) received radiation above 66 Gy. 80(72%) participants received chemotherapy while 31(28%) did not receive chemotherapy as part of cancer treatment. (Table 4)

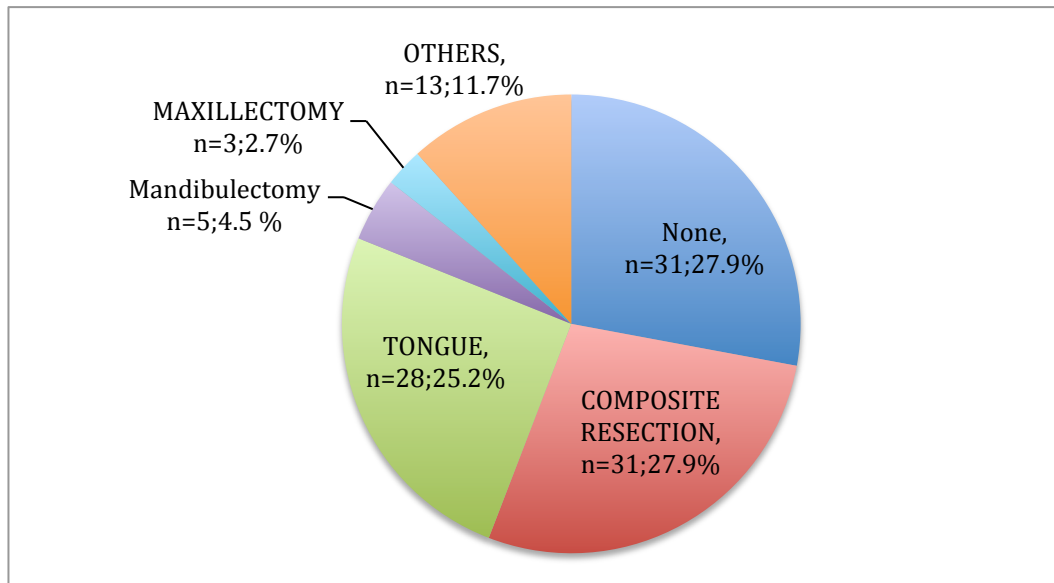
**Table 4: Frequency and percentage details of Radiation dose and Chemotherapy of the participants at baseline.**

<b>Radiation Dose</b>	<b>Percentage (%)</b>	<b>Frequency (n)</b>
60 Gy Or Less	64.8	72
66 Gy Or More	35.1	39
<b>Chemotherapy</b>	<b>Percentage (%)</b>	<b>Frequency (n)</b>
Yes	72	80
No	28	31

31(28%) participants did not received surgery as a part of cancer treatment. 31(28%) participants underwent composite resection, 28(25.2%) received tongue surgery, 5(4.5%) got Mandibulectomy, and 3(2.7%) participants had Maxillectomy. While 13(11.7%) participants received other surgery including Tonsils, Parotid glands, etc. (Figure7)



### SURGERY TYPE



**Figure 7: Baseline data for Type of surgery received amongst the participants depicting frequency and percentage distribution.**

Immediately after completion of radiotherapy 89(80%) participants had Grade II oral mucositis while 22(20%) had Grade III mucositis. For trismus 60(52.2%) participants had mouth opening in the range of 31-40 mm, 26(23.5%) participants in the range of 21-30mm, 22(19.8%) in the range of 11-20 mm, and 5(4.5) in range of less than 10 mm. 75.7% of participants had sufficient mouth opening of more than 20 mm, and 24.3% less than 20mm. The mean mouth opening with standard deviation in millimeters was  $30.33 \pm 9.68$  mm with a range from 5-40 mm was observed (Table 5,6)

**Table 5: Baseline data for Mucositis and Trismus for frequency and percentage.**

<b>Mucositis</b>	<b>Percentage (%)</b>	<b>Frequency (n)</b>
Grade 2 WHO	80	89
Grade 3 WHO	20	22
<b>Trismus</b>	<b>Percentage (%)</b>	<b>Frequency (n)</b>
<10 mm	4.5	5
11-20 mm	19.8	22
21-30 mm	23.5	26
31-40 mm	52.2	58

**Table 6: Mean and standard deviation with lower and upper bound values for trismus in millimeters at baseline.**

<b>Mouth opening in millimeters</b>	<b>Mean</b>	<b>Standard Deviation</b>	<b>Lower bound</b>	<b>Upper bound</b>
	30.33	9.68	5	40

#### **4.2: Dental treatment and cost for the supportive care protocol (SOCP)**

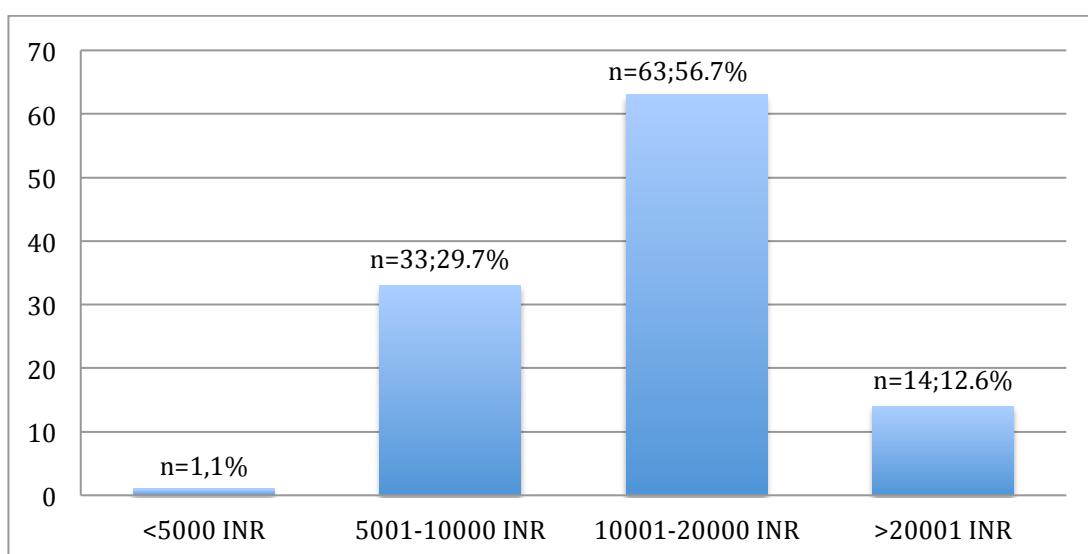
Overall 62(55.5%) participants did not receive any extractions, 38(34.2%) received extraction for less than five teeth and 11(9.9%) got more than five teeth extracted due to dental disease. Tooth restoration was performed on 72(64.8%) participants, 12(10.8%) received restoration between six to ten teeth, and 5(4.5%) received more than ten restorations. While 22(19.8%) participants did not receive any dental restoration for tooth decay. There was no need for Root canal treatment in 91(82%) participants, while 20 (18%) received root canal treatment for the carious exposed tooth. (Table 7)

**Table 7: Extraction, Restoration, and Root Canal Treatment-related dental burden of the participants with frequency and percentage distribution during the duration of the study.**

<b>Extraction</b>	<b>Percentage(%)</b>	<b>Frequency(n)</b>
NO	55.8	62
≤5 Teeth	34.2	38
>5-10 Teeth	9.9	11
<b>Restoration</b>	<b>Percentage(%)</b>	<b>Frequency(n)</b>
No	19.8	22
≤5 Teeth	64.8	72
6-10 Teeth	10.8	12
>10 Teeth	4.5	5
<b>Root Canal Treatment</b>	<b>Percentage(%)</b>	<b>Frequency(n)</b>
No	82	91
<2 Teeth	18	20

Money spent annually for the duration of the trial in SOCP for 63(56.7%) participants was in the range of ten to twenty thousand Indian rupees. 33(29.7%) participants spent in the range of five to ten thousand Indian rupees and 14(12.6%) participants spent more than twenty thousand rupees annually. While only 1(1%) participant's expenditure was less than five thousand. (Figure 8)

#### **ECONOMIC LOAD DUE TO SOCP**



**Figure 8: Frequency and percentage distribution of Annual economic load after enrolling in Supportive Oral Care Protocol calculated at first-year recall (SOCP).**

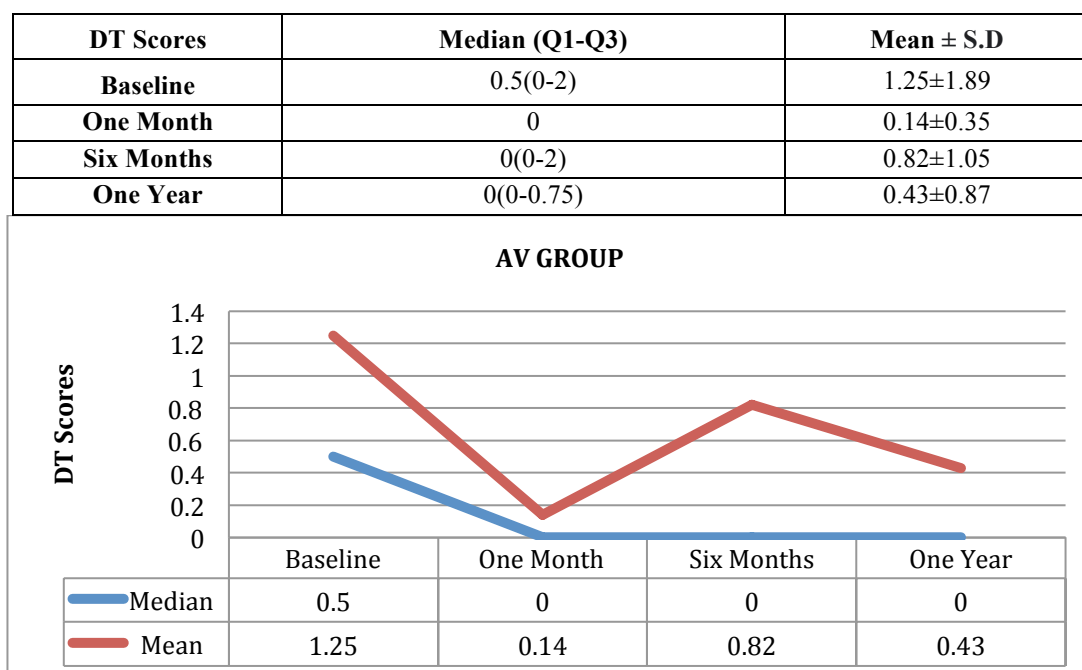
### 4.3: DMFT scores for intervention groups

#### 4.3.1: DT scores for intervention groups

##### 4.3.1.1: DT scores for Monthly Fluoride Varnish application group (AV)

The median DT scores and interquartile range for the Monthly fluoride varnish group (intervention AV) at baseline, one month, six months, and one year were 0.5(0-2), 0, 0(0-2), and 0(0-0.75) respectively. While the Mean  $\pm$  Standard deviation scores for the same parameters were 1.25 $\pm$ 1.89, 0.14 $\pm$ 0.35, 0.82 $\pm$ 1.055, and 0.43 $\pm$ 0.87 respectively. (Table 8, Figure 9)

**Table 8: Median, Interquartile Range (Q1-Q3) and Mean  $\pm$  standard deviation of DT scores for Monthly varnish application at baseline, one month, six months, and one year.**



**Figure 9: Median and Mean scores for DT scores of Monthly varnish application at baseline, one month, six months, and one year.**

Freidman nonparametric test was performed for the AV intervention group for within-group comparisons at four recall visits. Statistically significant results were observed.  $\{X^2(3, n=28) = 11.02, p=0.012.\}$

Post hoc analysis using Related samples Freidman two-way ANOVA by ranks with Bonferroni correction was performed to identify which time points in recalls were statistically significant. It was observed that after applying the adjusted P-value there was no significant difference between various time points. (Table 9)

**Table 9: Post hoc analysis for intragroup comparison for DT scores for monthly varnish application at baseline, one month, six months, and one year with adjusted p values. Significant at <0.05.**

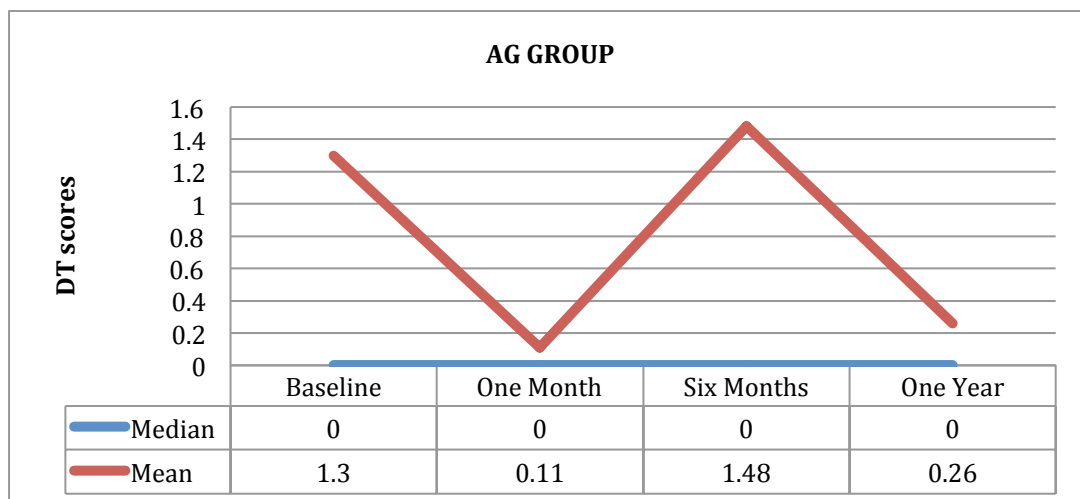
Intervention Groups	DT Scores at Assessment Visits					
	Baseline vs. one month	Baseline vs. six months	Baseline vs. one year	One month vs. six months	One month vs. one year	Six months vs. one year
AV	0.119	1	0.375	0.723	1	1

#### 4.3.1.2: DT scores for Monthly Fluoride Gel application group (AG)

The median DT scores and interquartile range for the Monthly fluoride gel group (intervention AG) at baseline, one month, six months, and one year were 0(0-1), 0, 0(0-2), 0 respectively. While the Mean  $\pm$  Standard deviation scores for the same parameters were 1.30 $\pm$ 2.232, 0.11 $\pm$ 0.32, 1.48 $\pm$ 1.76, and 0.26 $\pm$ 0.52 respectively. (Table 10, Figure 10)

**Table 10: Median, Interquartile range(Q1-Q3) and Mean± standard deviation of DT scores for Monthly gel application at baseline, one month, six months, and one year.**

DT Scores	Median (Q1-Q3)	Mean ± S.D
Baseline	0(0-1)	1.30±2.232
One Month	0.00	0.11±0.32
Six Months	0(0-2)	1.48±1.76
One Year	0.00	0.26±0.52



**Figure 10: Median and Mean scores for DT scores of Monthly gel application at baseline, one month, six months, and one year.**

Freidman nonparametric test was performed for the AV intervention group for within-group comparisons at four recall visits. Statistically significant results were observed.  $\{X^2(3, n=27)= 19.40, p=<0.001\}$ .

Related samples Freidman two-way ANOVA by ranks were performed as a post hoc analysis to observe which time points in recalls were significantly different. It was reported that median scores for one-month versus six-month recall were statistically significant with a p-value of 0.031. (Table 11)

**Table 11: Post hoc analysis for intra group comparison for DT scores for monthly gel application group at baseline, one month, six months, and one year with adjusted p values. Significant at <0.05.**

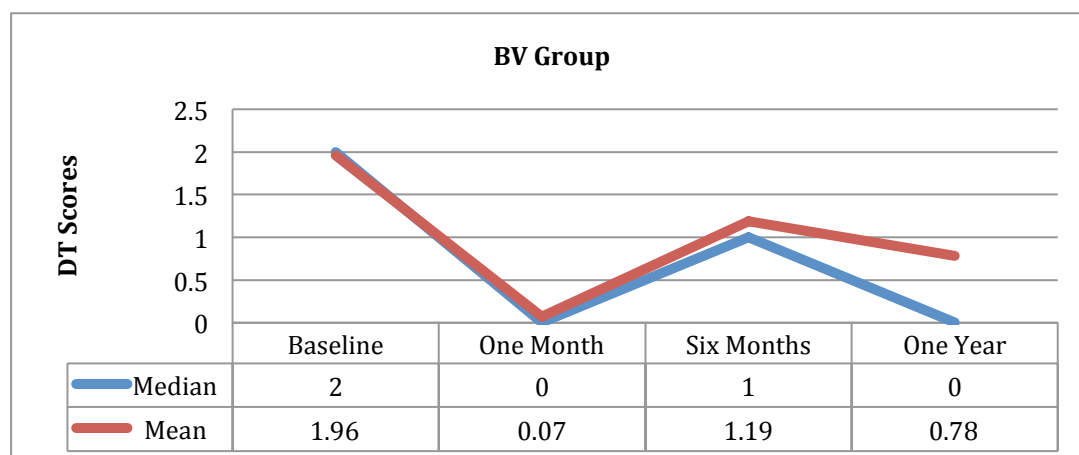
Intervention Groups	DT Scores at Assessment Visits					
	Baseline vs. one month	Baseline vs. six months	Baseline vs. one year	One month vs. six months	One month vs. one year	Six months vs. one year
AG	0.141	1	0.391	<b>0.031</b>	1	0.106

#### 4.3.1.3: DT scores for Quarterly Fluoride Varnish application group (BV)

The median DT scores and interquartile range for the Quarterly fluoride varnish group (intervention BV) at baseline, one month, six months, and one year were 2(0-2),0, 1(0-2), and 0(0-1) respectively. While the Mean  $\pm$  Standard deviation scores for the same parameters were 1.96 $\pm$ 2.40, 0.07 $\pm$ 0.26, 1.19 $\pm$ 1.44 and 0.78 $\pm$ 1.57 respectively. (Table 12, Figure 11)

**Table 12: Median, Interquartile range (Q1-Q3) and Mean $\pm$  standard deviation of DT scores for quarterly varnish application at baseline, one month, six months, and one year.**

DT Scores	Median (Q1-Q3)	Mean $\pm$ S.D
Baseline	2(0-2)	1.96 $\pm$ 2.40
One Month	0	0.07 $\pm$ 0.26
Six Months	1(0-2)	1.19 $\pm$ 1.44
One Year	0(0-1)	0.78 $\pm$ 1.57



**Figure 11: Median and Mean scores for DT scores of quarterly varnish application at baseline, one month, six months, and one year.**

Freidman nonparametric test was performed for the AV intervention group for within-group comparisons at four recall visits. Statistically significant results were observed.  $\{X^2(3, n=27)= 27.98, p=<0.001\}$ .

Related samples Freidman two-way ANOVA by ranks were performed as a post hoc analysis to observe which time points in recalls were significantly different. It was reported that median scores for baseline versus one-month recall and one-month versus six-month recall were statistically significant with a p-value of  $<0.001$  and  $0.013$  respectively. (Table 13)

**Table 13: Post hoc analysis for intra group comparison for DT scores for quarterly varnish application group at baseline, one month, six months, and one year with adjusted p values. Significant at  $<0.05$ .**

Intervention Groups	DT Scores at Assessment Visits					
	Baseline vs. one month	Baseline vs. six months	Baseline vs. one year	One month vs. six months	One month vs. one year	Six months vs. one year
BV	<b>&lt;0.001</b>	1	0.051	<b>0.013</b>	0.84	0.683

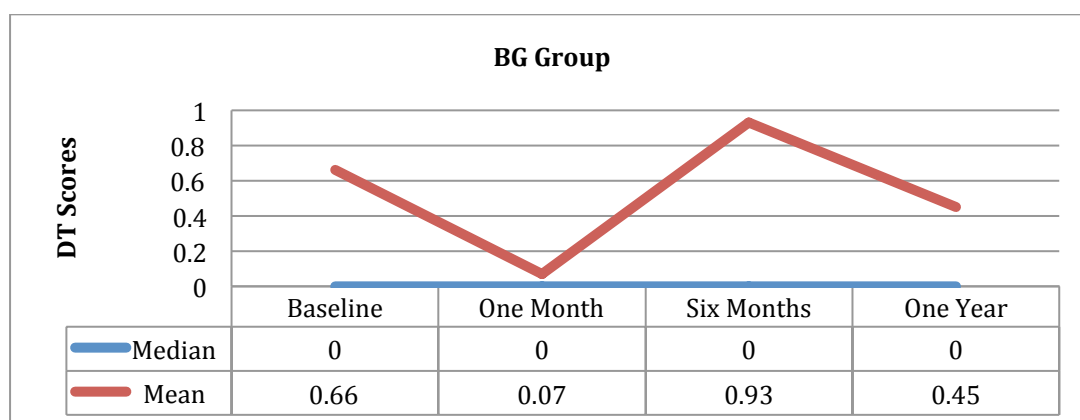
#### 4.3.1.4: DT scores for Quarterly Fluoride Gel application group (BG)

The median DT scores and interquartile range for the Quarterly fluoride gel group (intervention BG) at baseline, one month, six months, and one year were  $0(0-1.5)$ ,  $0(0-2)$ , and  $0(0-1)$  respectively. While the Mean  $\pm$  Standard deviation scores for the same parameters were  $0.66\pm 1.00$ ,  $0.07\pm 0.37$ ,  $0.93\pm 1.099$  and  $0.45\pm 0.63$  respectively. (Table 14, Figure 12)



**Table 14: Median, Interquartile range (Q1-Q3) and Mean± standard deviation of DT scores for quarterly gel application at baseline, one month, six months, and one year.**

DT Scores	Median (Q1-Q3)	Mean ± S.D
Baseline	0(0-1.5)	0.66±1.00
One Month	0	0.07±0.37
Six Months	0(0-2)	0.93±1.09
One Year	0(0-1)	0.45±0.63



**Figure 12: Median and Mean scores for DT scores of Quarterly gel application at baseline, one month, six months, and one year.**

Freidman nonparametric test was performed for the AV intervention group for within-group comparisons at four recall visits. Statistically significant results were observed.  $\{X^2(3, n=29)= 15.42, p=<0.001\}$ .

Related samples Freidman two-way ANOVA by ranks were performed as a post hoc analysis to observe which time points in recalls were significantly different. It was reported that median scores for one-month versus six-month recall were statistically significant with a p-value of 0.022. (Table -15)

**Table 15: Post hoc analysis for intragroup comparison for DT scores for quarterly gel application group at baseline, one month, six months, and one year with adjusted p values. Significant at <0.05.**

Intervention Groups	DT Scores at Assessment Visits					
	Baseline vs. one month	Baseline vs. six months	Baseline vs. one year	One month vs. six months	One month vs. one year	Six months vs. one year
BG	0.32	1	1	<b>0.022</b>	0.56	1

#### 4.3.1.5: Intergroup comparisons for AV, AG, BV & BG for DT scores

All four intervention groups i.e. AV, AG, BV & BG at four time recalls of baseline, one month, six months, and one year were analyzed for statistically significant differences in DT scores. Non-parametric Kruskal-Wallis H test was performed for inter-group comparisons. Baseline, one month, six months and one year test statistic value for Kruskal-Wallis H test were;  $H(3)= 7.26, p=0.064,$   $H(3)= 2.09, p=0.553,$   $H(3)= 2.03, p=0.566$  and  $H(3)= 1.75, p=0.624$  respectively. As the results were non-significant post hoc analysis was not conducted. (Table 16)

**Table 16: Kruskal-Wallis test for intergroup comparison for DT scores at baseline, one month, six months, and one year; based on the allocation of intervention.**

DT	BASELINE	ONE MONTH	SIX MONTHS	ONE YEAR
Chi-Square	7.263	2.095	2.030	1.758
P-value	0.064	0.553	0.566	0.624

#### **4.3.2: MT scores for intervention groups**

##### **4.3.2.1: MT scores for Monthly Fluoride Varnish application (AV).**

The median MT scores and interquartile range for the Monthly fluoride varnish group (intervention AV) at baseline, one month, six months, and one year were was 1(0-2). While the Mean  $\pm$  Standard deviation scores for the same parameters were 1.82 $\pm$  2.868.

##### **4.3.2.2: MT scores for Monthly Fluoride Gel application (AG).**

The median MT scores and interquartile range for the Monthly fluoride gel group (intervention AG) at baseline, one month, six months and one year were was 1(0-4). While the Mean  $\pm$  Standard deviation scores for the same parameters were 2.04 $\pm$  2.175.

##### **4.3.2.3: MT scores for Quarterly Fluoride Varnish application (BV).**

The median MT scores and interquartile range for the Quarterly fluoride varnish group (intervention BV) at baseline, one month, six months and one year were was 1(0-2). While the Mean  $\pm$  Standard deviation scores for the same parameters were 1.93 $\pm$  3.551.

##### **4.3.2.4: MT scores for Quarterly Fluoride Gel application (BG).**

The median MT scores and interquartile range for the Quarterly fluoride gel group (intervention BG) at baseline, one month, six months and one year were was 1(0-4). While the Mean  $\pm$  Standard deviation scores for the same parameters were 1.59 $\pm$  2.147.

**4.3.2.5: Inter and intra group comparisons for AV, AG, BV & BG for MT scores.**

Freidman test for intragroup comparison at baseline, one month, six months, and one year and Kruskal-Wallis test for intergroup comparison of AV, AG, BV, and BG was not performed, as there were no differences in the median MT scores.

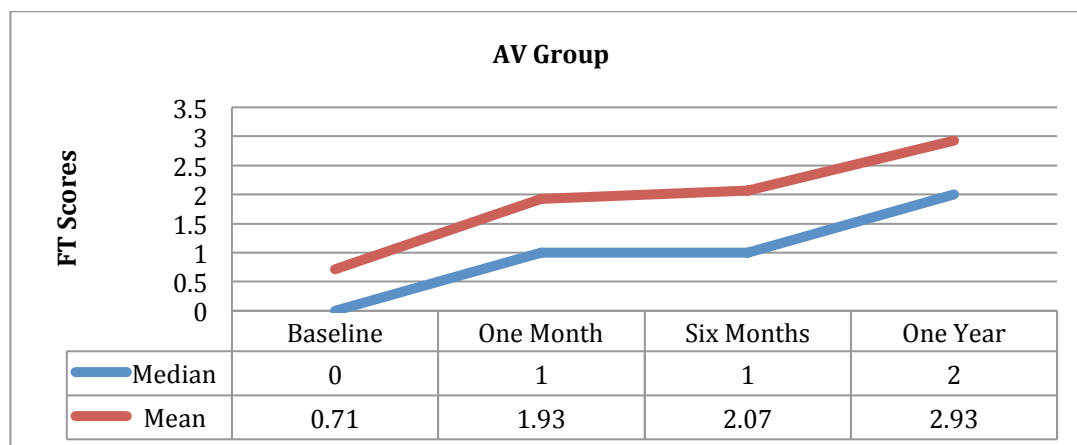
### 4.3.3: FT scores for intervention groups

#### 4.3.3.1: FT scores for Monthly Fluoride Varnish application (AV)

The median FT scores and interquartile range for the Monthly fluoride varnish group (intervention AV) at baseline, one month, six months, and one year were 0, 1(0-3), 1(0.25-3), and 2(1-5) respectively. While the Mean  $\pm$  Standard deviation scores for the same parameters were 0.71 $\pm$ 2.141, 1.93 $\pm$ 2.538, 2.07 $\pm$ 2.448, and 2.93 $\pm$ 2.993 respectively. (Table 17, Figure 13)

**Table 17: Median, Interquartile range (Q1-Q3) and Mean  $\pm$  standard deviation of FT scores for monthly varnish application at baseline, one month, six months, and one year.**

FT Scores	Median (Q1-Q3)	Mean $\pm$ S.D
<b>Baseline</b>	0	0.71 $\pm$ 2.141
<b>One Month</b>	1(0-3)	1.93 $\pm$ 2.538
<b>Six Months</b>	1(0.25-3)	2.07 $\pm$ 2.448
<b>One Year</b>	2(1-5)	2.93 $\pm$ 2.993



**Figure 13: Median and Mean scores for FT scores of Monthly varnish application at baseline, one month, six months, and one year.**

Freidman nonparametric test was performed for the AV intervention group for within-group comparisons at four recall visits. Statistically significant results were observed.  $\{X^2(3, n=28)= 49.18, p=<0.001\}$ .

Post hoc analysis using Related samples Freidman two-way ANOVA by ranks with Bonferroni correction was performed to identify which time points in recalls were statistically significant. Pair-wise comparison of recall visits at baseline, one month, six months, and one year were done. Baseline versus six months, baseline versus one year, and one-month versus one-year recall were statistically significant for FT scores with a p-value of 0.014, <0.001, and 0.019 respectively. (Table 18)

**Table 18: Post hoc analysis for intragroup comparison for FT scores for monthly varnish group at baseline, one month, six months, and one year with adjusted p values. Significant at < 0.05.**

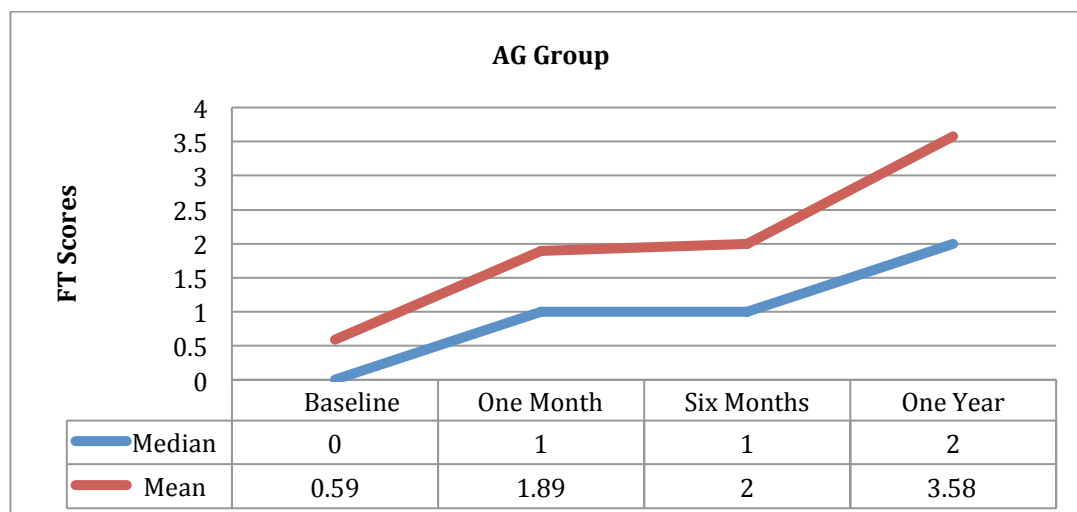
Intervention Groups	FT Scores at Assessment Visits					
	Baseline vs. one month	Baseline vs. six months	Baseline vs. one year	One month vs. six months	One month vs. one year	Six months vs. one year
AV	0.137	<b>0.014</b>	<b>&lt;0.001</b>	1	<b>0.019</b>	0.178

#### 4.3.3.2: FT scores Monthly for Fluoride Gel application (AG)

The median FT scores and interquartile range for the Monthly fluoride gel group (intervention AG) at baseline, one month, six months, and one year were 0, 1(0-3), 1(0-3), 2(0-6) respectively. While the Mean  $\pm$  Standard deviation scores for the same parameters were 0.59 $\pm$ 2.005, 1.89 $\pm$ 2.860, 2.00 $\pm$ 2.801, and 3.58 $\pm$ 3.580 respectively. (Table 19, Figure 14)

**Table 19: Median, Interquartile range (Q1-Q3) and Mean  $\pm$  standard deviation of FT scores monthly gel application at baseline, one month, six months, and one year.**

FT Scores	Median (Q1-Q3)	Mean $\pm$ S.D
Baseline	0	0.59 $\pm$ 2.005
One Month	1(0-3)	1.89 $\pm$ 2.860
Six Months	1(0-3)	2.00 $\pm$ 2.801
One Year	2(0-6)	3.58 $\pm$ 3.580



**Figure 14: Median and Mean scores for FT scores of Monthly gel application at baseline, one month, six months, and one year.**

Freidman nonparametric test was performed for the AV intervention group for within-group comparisons at four recall visits. Statistically significant results were observed.  $\{X^2(3, n=27)= 47.50, p=<0.001\}$ .

Post hoc analysis using Related samples Friedman two-way ANOVA by ranks with Bonferroni correction was performed to identify which time points in recalls were statistically significant. Pair-wise comparison of recall visits at baseline, one month, six months, and one year were done. Baseline versus six months, baseline versus one year, and one-month versus one-year recall were statistically significant for FT scores with a p-value of 0.019, <0.001, and 0.013 respectively. (Table 20)

**Table 20: Post hoc analysis for intragroup comparison for FT scores for monthly gel group at baseline, one month, six months, and one year with adjusted p values. Significant at < 0.05.**

Intervention Groups	FT Scores at Assessment Visits					
	Baseline vs. one month	Baseline vs. six months	Baseline vs. one year	One month vs. six months	One month vs. one year	Six months vs. one year
AG	0.109	<b>0.019</b>	<b>&lt;0.001</b>	1	<b>0.013</b>	0.081

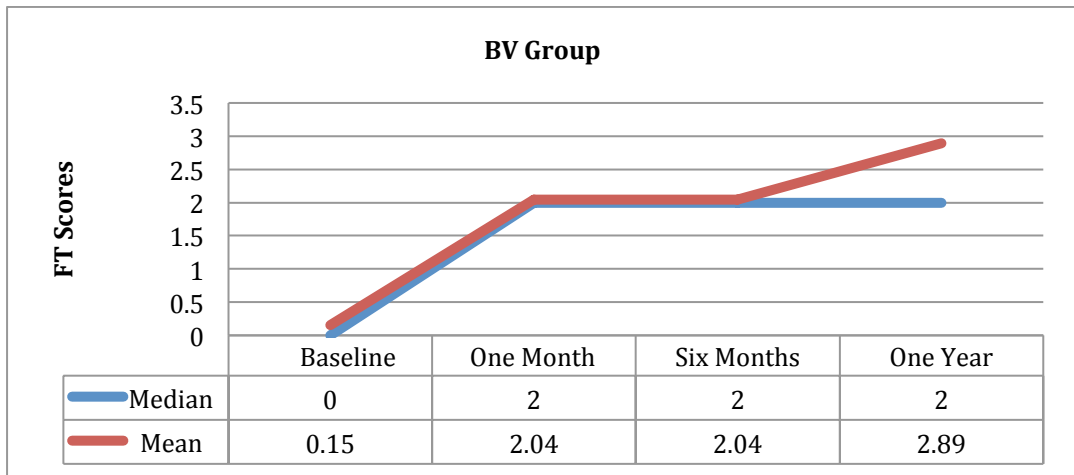
#### **4.3.3.3: FT scores for Quarterly Fluoride Varnish application (BV)**

The median FT scores and interquartile range for the Quarterly fluoride varnish group (intervention BV) at baseline, one month, six months, and one year were 0, 2(0-2), 2(1-2), and 2(1-4) respectively. While the Mean  $\pm$  Standard deviation scores for the same parameters were 0.15 $\pm$ 0.602, 2.04 $\pm$ 2.361, 2.04 $\pm$ 2.278, and 2.89 $\pm$ 2.423 respectively. (Table 21, Figure 15)



**Table 21: Median, Interquartile range (Q1-Q3) and Mean ± standard deviation of FT scores for quarterly varnish application at baseline, one month, six months, and one year.**

FT Scores	Median (Q1-Q3)	Mean ± S.D
<b>Baseline</b>	0	0.15±0.602
<b>One Month</b>	2(0-2)	2.04±2.361
<b>Six Months</b>	2(1-2)	2.04±2.278
<b>One Year</b>	2(1-4)	2.89±2.423



**Figure 15: Median and Mean scores for FT scores of Quarterly varnish application at baseline, one month, six months, and one year.**

Freidman nonparametric test was performed for the AV intervention group for within-group comparisons at four recall visits. Statistically significant results were observed.  $\{X^2(3, n=27)= 48.75, p=<0.001\}$ .

Post hoc analysis using Related samples Freidman two-way ANOVA by ranks with Bonferroni correction was performed to identify which time points in recalls were statistically significant. Pair-wise comparison of recall visits at baseline, one month, six months, and one year were done. Baseline versus one-month, Baseline versus six-month, and baseline versus one-year recall were statistically significant for FT scores with a p-value of 0.005, 0.003, and  $<0.001$  respectively. (Table 22)

**Table 22: Post hoc analysis for intragroup comparison for FT scores for quarterly varnish group at baseline, one month, six months, and one year with adjusted p values. Significant at < 0.05.**

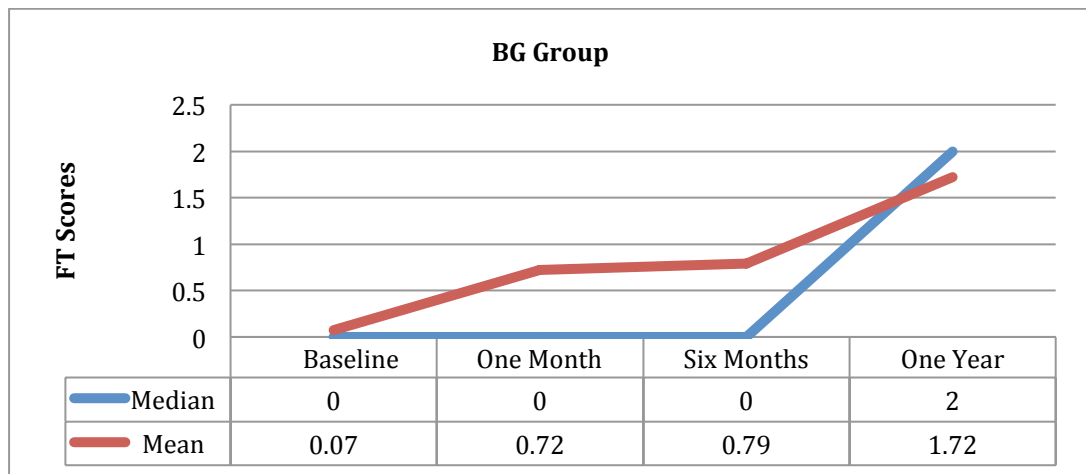
Intervention Groups	FT Scores at Assessment Visits					
	Baseline vs. one month	Baseline vs. six months	Baseline vs. one year	One month vs. six months	One month vs. one year	Six months vs. one year
BV	0.005	0.003	<0.001	1	0.122	0.184

#### 4.3.3.4: FT scores for Quarterly Fluoride Gel application (BG)

The median FT scores and interquartile range for quarterly fluoride gel group (intervention BG) at baseline, one month, six months, and one year were 0, 0(0-1.5), 0(0-2), and 2(0-2) respectively. While the Mean  $\pm$  Standard deviation scores for the same parameters were 0.07 $\pm$ 0.371, 0.72 $\pm$ 1.162, 0.79 $\pm$ 1.177, and 1.72 $\pm$ 1.509 respectively. (Table 23, Figure 16)

**Table 23: Median, Interquartile range (Q1-Q3) and Mean  $\pm$  standard deviation of FT scores for quarterly gel application at baseline, one month, six months, and one year.**

FT Scores	Median (Q1-Q3)	Mean $\pm$ S.D
Baseline	0	0.07 $\pm$ 0.371
One Month	0(0-1.5)	0.72 $\pm$ 1.162
Six Months	0(0-2)	0.79 $\pm$ 1.177
One Year	2(0-2)	1.72 $\pm$ 1.509



**Figure 16: Median and Mean scores for FT scores of Quarterly gel application at baseline, one month, six months, and one year.**

Friedman nonparametric test was performed for the AV intervention group for within-group comparisons at four recall visits. Statistically significant results were observed.  $\{X^2(3, n=29)= 46.11, p=<0.001\}$ .

Post hoc analysis using Related samples Friedman two-way ANOVA by ranks with Bonferroni correction was performed to identify which time points in recalls were statistically significant. Pair-wise comparison of recall visits at baseline, one month, six months, and one year were done. Baseline versus one year, one month versus one year, and six-month versus one-year recall were statistically significant for FT scores with a p-value of  $<0.001$ , 0.026, and 0.049 respectively. (Table 24)

**Table 24: Post hoc analysis for intragroup comparison for FT scores for quarterly gel group at baseline, one month, six months, and one year with adjusted p values. Significant at  $< 0.05$ .**

Intervention Groups	FT Scores at Assessment Visits					
	Baseline vs. one month	Baseline vs. six months	Baseline vs. one year	One month vs. six months	One month vs. one year	Six months vs. one year
<b>BG</b>	0.403	0.252	<b>&lt;0.001</b>	1	<b>0.026</b>	<b>0.049</b>

#### 4.3.3.5: Intergroup comparisons for AV, AG, BV & BG, and FT scores

All four intervention groups i.e. AV, AG, BV & BG at four time recalls of baseline, one month, six months, and one year were analyzed for statistically significant differences in DT scores. Non-parametric Kruskal-Wallis H test was performed for inter-group comparisons. Baseline, one month, six months and one year test statistic values for Kruskal-Wallis H test were  $H(3)= 2.99, p=0.393$ ,  $H(3)= 7.65, p=0.054$ ,  **$H(3)= 9.14, p=0.027$**  and  $H(3)= 4.02, p=0.259$  respectively. (Table 25)

**Table 25: Kruskal-Wallis test for intergroup comparison for FT scores at baseline, one month, six months, and one year; based on the allocation of intervention.**

DMFT	BASELINE	ONE MONTH	SIX MONTHS	ONE YEAR
Chi-Square	2.990	7.657	9.148	4.021
P-Value	0.393	0.054	<b>0.027</b>	0.259

As the six-month recall visit comparison was statistically significant for the difference in FT scores with a p-value of 0.027, post hoc for Kruskal-Wallis was done to see which pair had statistically significant. Bonferroni corrections were used to calculate the adjusted p-value. It was observed that the difference in FT scores for the quarterly Gel application group (BG) and quarterly varnish application group (BV) was statistically significant with BV having a higher FT score in comparison to BG at six-month recall visits. (Table 26)

**Table 26: Post hoc for Kruskal-Wallis showing the pair-wise comparison of AV, AG, BV, and BG groups based on the allocation of intervention for FT scores.**

Intervention Group Comparison	BG-AG	BG-AV	BG-BV	AG-AV	AG-BV	AV-BV
Adjusted P-Value	0.315	0.091	<b>0.038</b>	1	1	1

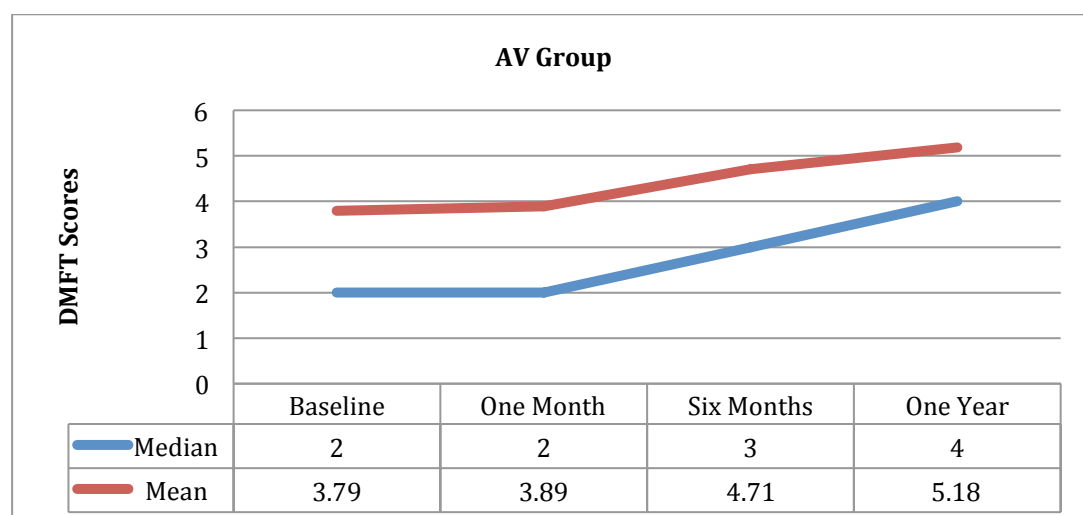
#### 4.3.4: DMFT total scores for intervention groups

##### 4.3.4.1: DMFT total scores for Monthly Fluoride Varnish application (AV)

The median scores and interquartile range for the Monthly fluoride varnish group (intervention AV) at baseline, one month, six months, and one year were 2(0.25-6), 2(1-6), 3(1-7.75) and 4(1-9) respectively. While the Mean  $\pm$  Standard deviation scores for the same parameters were 3.79  $\pm$  4.281, 3.89  $\pm$ 4.193,4.71 $\pm$  4.673, 5.18  $\pm$ 4.845 respectively. (Table 27, Figure 17)

**Table 27: Median, Interquartile range (Q1-Q3) and Mean  $\pm$  standard deviation of DMFT scores for monthly varnish application at baseline, one month, six months, and one year.**

DMFT Scores	Median (Q1-Q3)	Mean $\pm$ S.D
Baseline	2(0.25-6)	3.79 $\pm$ 4.281
One Month	2(1-6)	3.89 $\pm$ 4.193
Six Months	3(1-7.75)	4.71 $\pm$ 4.673
One Year	4(1-9)	5.18 $\pm$ 4.854



**Figure 17: Median and Mean scores for DMFT scores of Monthly varnish application at baseline, one month, six months, and one year.**

Freidman nonparametric test was performed for the AV intervention group for within-group comparisons at four recall visits. Statistically significant results were observed { $X^2(3, n=28)= 41.54, p=<0.001$ }

Post hoc analysis using Related samples Freidman two-way ANOVA by ranks with Bonferroni correction was performed to identify which time points in recalls were statistically significant. It was observed that the difference in median scores for baseline versus six-month recall, baseline versus one-year recall, and one-month versus one-year recall values was statistically significant with p values of 0.043, 0.001, and 0.006 respectively. (Table 28)

**Table 28: Post hoc analysis for intragroup comparison for DMFT scores for monthly varnish group at baseline, one month, six months, and one year with adjusted p values. Significant at 0.05.**

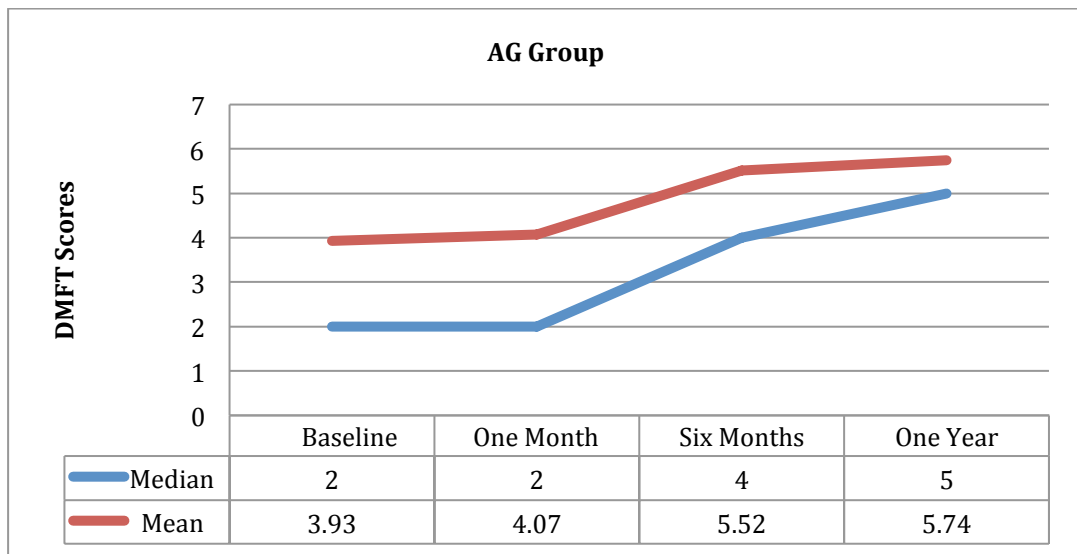
Intervention Groups	DMFT at Assessment Visits					
	Baseline vs. one month	Baseline vs. six months	Baseline vs. one year	One month vs. six months	One month vs. one year	Six months vs. one year
AV	1	<b>0.043</b>	<b>0.001</b>	0.178	<b>0.006</b>	1

#### **4.3.4.2: DMFT total scores for Monthly Fluoride Gel application (AG)**

The median scores and interquartile range for the Monthly fluoride Gel group (intervention AG) at baseline, one month, six months, and one year were 2(1-5), 2(1-5), 4(1-8) and 5(1-8) respectively. While the Mean  $\pm$  Standard deviation scores for the same parameters were 3.93 $\pm$ 4.287, 4.07 $\pm$ 4.305, 5.52 $\pm$ 4.902, and 5.74 $\pm$ 4.981 respectively. (Table 29, Figure 18)

**Table 29: Median, Interquartile range (Q1-Q3) and Mean ± standard deviation of DMFT scores for monthly gel application at baseline, one month, six months, and one year.**

DMFT Scores	Median (Q1-Q3)	Mean ± S.D
Baseline	2(1-5)	3.93±4.287
One Month	2(1-5)	4.07±4.305
Six Months	4(1-8)	5.52±4.902
One Year	5(1-8)	5.74±4.981



**Figure 18: Median and Mean scores for DMFT scores of Monthly gel application at baseline, one month, six months, and one year.**

When within group comparison was performed using Friedman non-parametric test, all four recall points reported a very highly significant difference for median scores  $\{X^2(3, n=27)= 46.82, p<0.001\}$ .

Related samples Friedman two-way ANOVA by ranks were performed as a post hoc analysis to observe which time points in recalls were significantly different. It was reported that median scores for baseline versus six-month recall, baseline versus one-year recall, one-month versus six-month recall, and one-month versus one-year recall values were statistically significant with a p-value of 0.004, <0.001, 0.031, and 0.002 respectively. (Table 30)

**Table 30: Post hoc analysis for intragroup comparison for DMFT scores for monthly gel group at baseline, one month, six months, and one year with adjusted p-value Significant at 0.05.**

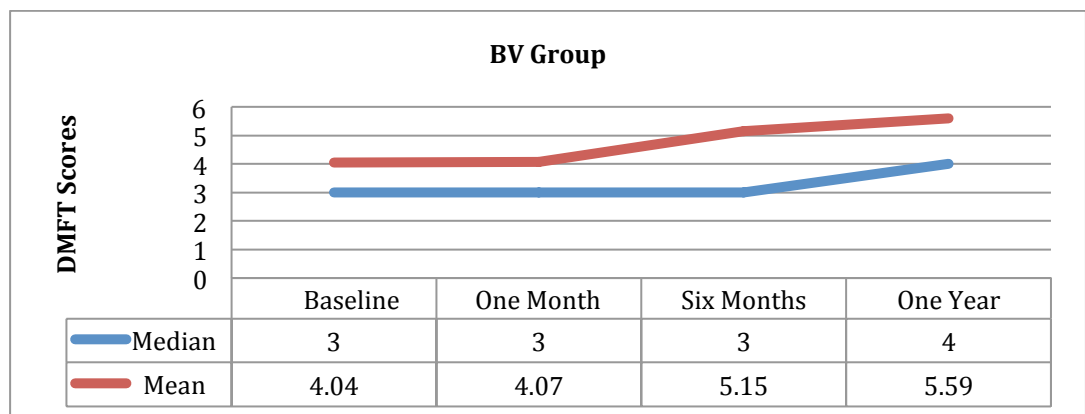
Intervention Groups	DMFT Assessment Visits					
	Baseline vs. one month	Baseline vs. six months	Baseline vs. one year	One month vs. six months	One month vs. one year	Six months vs. one year
AG	1	0.004	<0.001	0.031	0.002	1

#### 4.3.4.3: DMFT total scores for Quarterly Fluoride Varnish application (BV)

The median scores and interquartile range for the Quarterly fluoride varnish group (intervention BV) at baseline, one month, six months, and one year were 3(1-4), 3(1-4), 3(2-6), and 4(2-6) respectively. While the Mean  $\pm$  Standard deviation scores for the same parameters were 4.04 $\pm$ 5.474, 4.07 $\pm$ 5.449, 5.15 $\pm$ 5.586, and 5.59 $\pm$ 6.034 respectively. (Table 31, Figure 19)

**Table 31: Median, Interquartile range (Q1-Q3) and Mean  $\pm$  standard deviation of DMFT scores for quarterly varnish application at baseline, one month, six months, and one year.**

DMFT Scores	Median (Q1-Q3)	Mean $\pm$ S.D
Baseline	3(1-4)	4.04 $\pm$ 5.474
One Month	3(1-4)	4.07 $\pm$ 5.449
Six Months	3(2-6)	5.15 $\pm$ 5.586
One Year	4(2-6)	5.59 $\pm$ 6.034



**Figure 19: Median and Mean scores for DMFT scores of Quarterly varnish application at baseline, one month, six months, and one year.**



When within-group comparison was performed using Friedman nonparametric test, all four recall points reported a very highly significant difference for median scores  $\{X^2(3, n=27)= 46.50, p=<0.001\}$ .

Related samples Friedman two-way ANOVA by ranks were performed as a post hoc analysis to observe which time points in recalls were significantly different. It was reported that median scores for baseline versus six-month recall, baseline versus one-year recall, one month versus six-month recall, and one-month versus one-year recall values were statistically significant with a p-value of 0.027, <0.001, 0.037, and 0.001 respectively. (Table 32)

**Table 32: Post hoc analysis for intragroup comparison for DMFT scores for quarterly varnish group at baseline, one month, six months, and one year with adjusted p values. Significant at p< 0.05.**

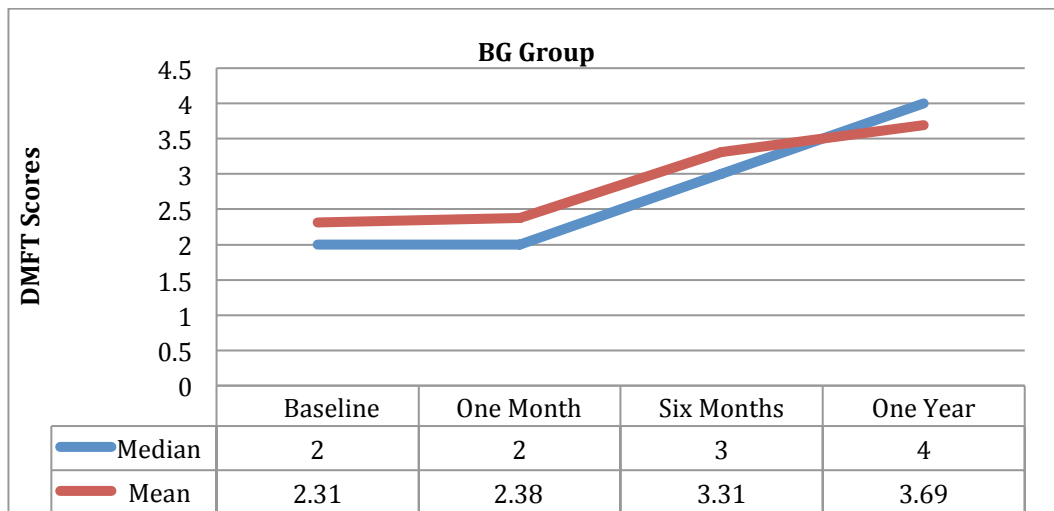
Intervention Groups	DMFT Assessment Visits					
	Baseline vs. one month	Baseline vs. six months	Baseline vs. one year	One month vs. six months	One month vs. one year	Six months vs. one year
BV	1	0.027	<0.001	0.037	0.001	1

#### 4.3.4.4: DMFT total scores for Quarterly Fluoride Gel application (BG)

The median scores and interquartile range for the Quarterly fluoride Gel group (intervention BG) at baseline, one month, six months, and one year were 2(0-4), 2(0-4), 3(1.5-4.5) and 4(2-5) respectively. While the Mean  $\pm$  Standard deviation scores for the same parameters were 2.31 $\pm$ 2.422, 2.38 $\pm$ 2.382, 3.31 $\pm$ 2.647, and 3.69 $\pm$ 2.661 respectively. (Table 33, Figure 20)

**Table 33: Median, Interquartile range (Q1-Q3) and Mean ± standard deviation of DMFT scores for quarterly gel application at baseline, one month, six months, and one year**

DMFT Scores	Median (Q1-Q3)	Mean ± S.D
Baseline	2(0-4)	2.31±2.422
One Month	2(0-4)	2.38±2.382
Six Months	3(1.5-4.5)	3.31±2.647
One Year	4(2-5)	3.69±2.661



**Figure 20: Median and Mean scores for DMFT scores of quarterly gel application at baseline, one month, six months, and one year.**

When within-group comparison was performed using Friedman nonparametric test, all four recall points reported a very highly significant difference for median scores  $\{X^2(3, n=29)= 46.39, p=<0.001\}$ .

Related samples Friedman two-way ANOVA by ranks were performed as a post hoc analysis to observe which time points in recalls were significantly different. It was reported that median scores for baseline versus six-month recall, baseline versus one-year recall, and one-month versus one-year recall values were statistically significant with a p-value of 0.036, <0.001, and 0.001 respectively. (Table 34)

**Table 34: Post hoc analysis for intragroup comparison for DMFT scores for quarterly gel group at baseline, one month, six months, and one year with adjusted p values. Significant at  $p < 0.05$ .**

Intervention Groups	DMFT Assessment Visits					
	Baseline vs. one month	Baseline vs. six months	Baseline vs. one year	One month vs. six months	One month vs. one year	Six months vs. one year
BG	1	0.036	<0.001	0.066	0.001	1

#### 4.3.4.5: Intergroup comparisons for AV, AG, BV & BG and DMFT total scores

All four intervention groups i.e. AV, AG, BV & BG at four-time recalls of baseline, one month, six months, and one year were analyzed for statistically significant differences. A nonparametric Kruskal-Wallis H test was performed for inter-group comparisons. Baseline, one month, six months and one year test statistic values for Kruskal-Wallis, H test were  $H(3) = 2.310$ ,  $p = 0.511$ ,  $H(3) = 2.588$ ,  $p = 0.460$ ,  $H(3) = 2.259$ ,  $p = 0.521$  and  $H(3) = 1.606$ ,  $p = 0.658$  respectively. As the results were non-significant post hoc analyses were not conducted. (Table 35)

**Table 35: Kruskal-Wallis test for intergroup comparison for DMFT scores at baseline, one month, six months, and one year; based on the allocation of intervention. P significant at  $< 0.05$ .**

DMFT	BASELINE	ONE MONTH	SIX MONTHS	ONE YEAR
Chi-Square	2.310	2.588	2.259	1.606
P-Value.	0.511	0.460	0.521	0.658

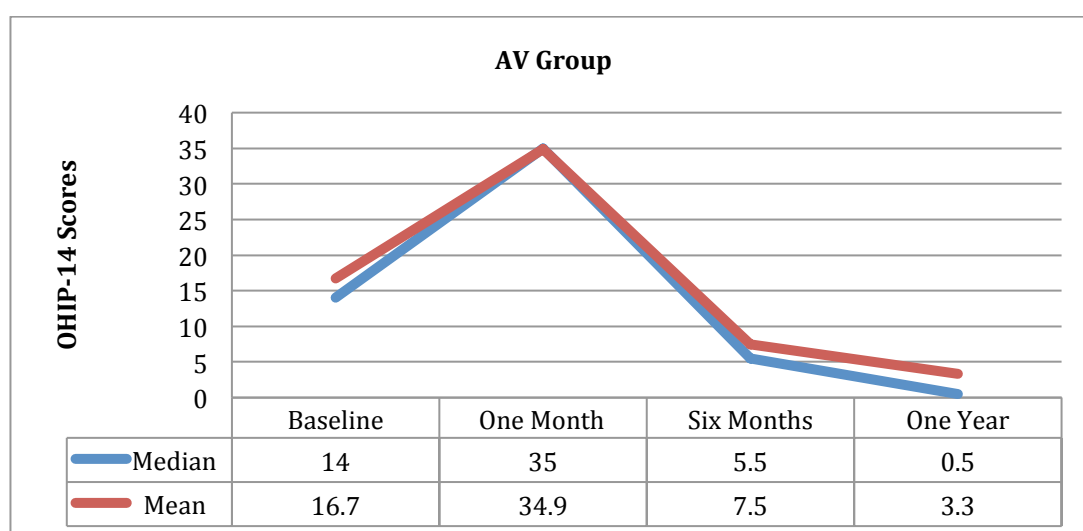
#### 4.4: OHIP-14 scores for intervention groups.

##### 4.4.1. OHIP-14 scores for Monthly Fluoride Varnish application (AV)

The median scores and interquartile range of total OHIP-14 scores for the Monthly fluoride varnish group (intervention AV) at baseline, one month, six months, and one year were 14(11-25.75), 35(28.25-40), 5.50(1-12.75) and 0.50(0-6) respectively. While the Mean  $\pm$  Standard deviation scores for the same parameters were 16.79 $\pm$ 10.27, 34.96 $\pm$ 7.92, 7.57 $\pm$ 7.88, and 3.36 $\pm$ 4.86 respectively. (Table 36, Figure 21)

**Table 36: Median, Interquartile range (Q1-Q3) and Mean  $\pm$  standard deviation of OHIP-14 Total scores at baseline, one month, six months, and one year for monthly varnish group.**

OHIP-14 Scores	Median (Q1-Q3)	Mean $\pm$ S.D
<b>Baseline</b>	14(11-25.75)	16.79 $\pm$ 10.27
<b>One Month</b>	35(28.25-40)	34.96 $\pm$ 7.92
<b>Six Months</b>	5.50(1-12.75)	7.57 $\pm$ 7.88
<b>One Year</b>	0.50(0-6)	3.36 $\pm$ 4.86



**Figure 21: Median and Mean scores for OHIP-14 scores of Monthly varnish application at baseline, one month, six months, and one year.**

Freidman nonparametric test was performed for the AV intervention group for within-group comparisons at four recall visits. Statistically significant results were observed  $\{X^2(3, n=28)= 78.70, p=<0.001\}$ .

Post hoc analysis using Related samples Freidman two-way ANOVA by ranks with Bonferroni correction was performed to identify which time points in recalls were statistically significant. It was observed that the difference in median OHIP-14 scores for baseline versus one month recall was statistically significant with a p-value of 0.006, while baseline versus one-year recall, one month versus six months one-month versus one-year recall values was statistically highly significant with a p-value of <0.001. (Table 37)

**Table 37: Post hoc analysis for intragroup comparison for OHIP Total scores at baseline, one month, six months, and one year for monthly varnish group, with adjusted p values. Significant at <0.05.**

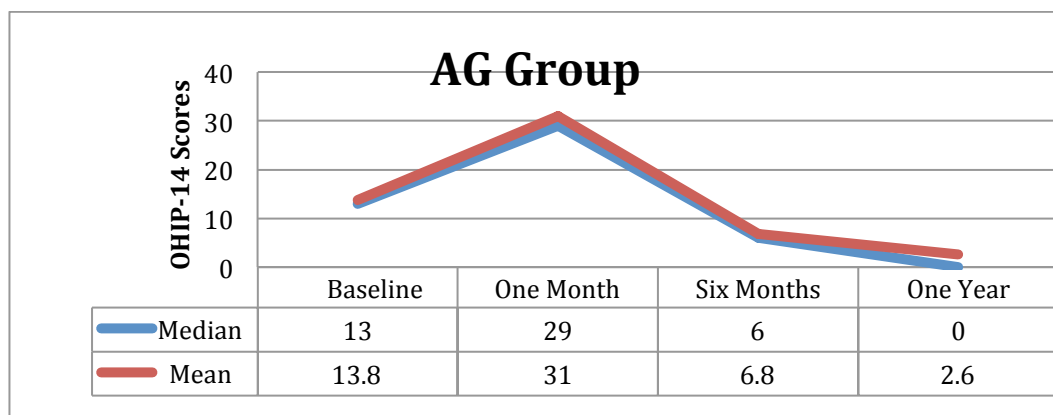
Intervention Groups	OHIP-14 Scores at various Assessment Visits					
	Baseline vs. one month	Baseline vs. six months	Baseline vs. one year	One month vs. six months	One month vs. one year	Six months vs. one year
AV	<b>0.006</b>	0.09	<b>&lt;0.001</b>	<b>&lt;0.001</b>	<b>&lt;0.001</b>	0.058

#### **4.4.2. OHIP-14 scores for Monthly Fluoride Gel application (AG)**

The median scores and interquartile range for the Monthly fluoride Gel group (intervention AG) at baseline, one month, six months and one year were 13(2-24), 29(26-36), 6(0-12) and 0(0-6) respectively. While the Mean  $\pm$  Standard deviation scores for the same parameters were 13.89 $\pm$ 12.11, 31 $\pm$ 7.80, 6.89 $\pm$ 6.45, and 2.63 $\pm$ 3.80 respectively. (Table 38, Figure 22)

**Table 38: Median, Interquartile range (Q1-Q3) and Mean ± standard deviation of OHIP-14 Total scores at baseline, one month, six months, and one year for monthly gel group.**

OHIP-14 Scores	Median (Q1-Q3)	Mean ± S.D
Baseline	13(2-24)	13.89±12.11
One Month	29(26-36)	31±7.80
Six Months	6(0-12)	6.89±6.45
One Year	0(0-6)	2.63±3.80



**Figure 22: Median and Mean scores for OHIP-14 scores of monthly gel application at baseline, one month, six months, and one year.**

When within-group comparison was performed using Friedman nonparametric test, all four recall points reported a very highly significant difference for median scores.  $\{X^2(3, n=27)= 69.60, p=<0.001\}$ .

Post hoc analysis using Related samples Friedman two-way ANOVA by ranks with Bonferroni correction was performed to identify which time points in recalls were statistically significant. It was observed that the difference in median OHIP-14 scores for baseline versus one month recall was statistically significant with a p-value of 0.001, while baseline versus one-year recall, one month versus six months, and one-month versus one-year recall values were statistically highly significant with a p-value of <0.001. (Table 39)

**Table 39: Post hoc analysis for intragroup comparison for OHIP Total scores at baseline, one month, six months, and one year for monthly gel group, with adjusted p values. Significant at <0.05.**

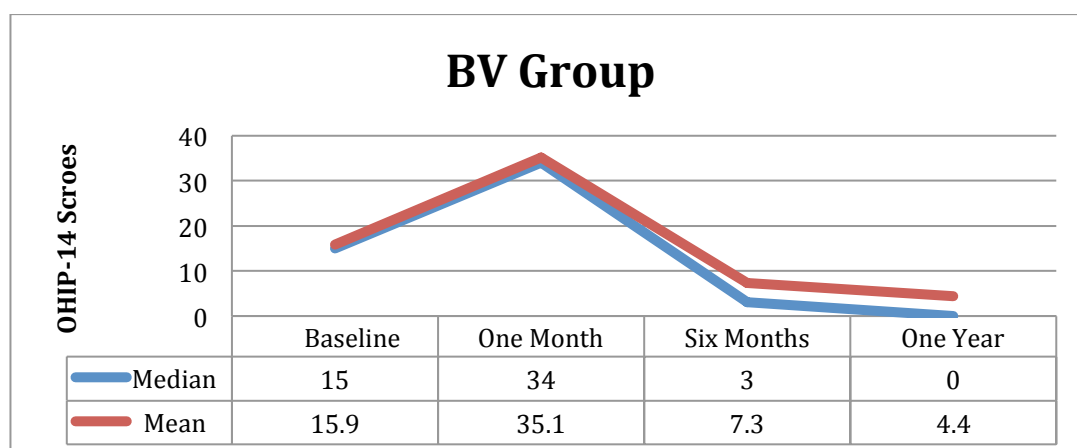
Intervention Groups	OHIP-14 Scores at various Assessment Visits					
	Baseline vs. one month	Baseline vs. six months	Baseline vs. one year	One month vs. six months	One month vs. one year	Six months vs. one year
AG	<b>0.001</b>	0.439	<b>&lt;0.001</b>	<b>&lt;0.001</b>	<b>&lt;0.001</b>	0.092

#### 4.4.3: OHIP-14 scores quarterly varnish group (BV)

The median scores and interquartile range for the Quarterly fluoride varnish group (intervention BV) at baseline, one month, six months, and one year were 15(10-24), 34(27-46), 3(0-14) and 0(0-7) respectively. While the Mean  $\pm$  Standard deviation scores for the same parameters were 15.96 $\pm$ 8.75, 35.19 $\pm$ 10.45, 7.33 $\pm$ 9.77, and 4.48 $\pm$ 7.78 respectively. (Table 40, Figure 23)

**Table 40: Median, Interquartile range (Q1-Q3) and Mean  $\pm$  standard deviation of OHIP-14 Total scores at baseline, one month, six months, and one year for quarterly varnish group.**

OHIP-14 Scores	Median (Q1-Q3)	Mean $\pm$ S.D
Baseline	15(10-24)	15.96 $\pm$ 8.75
One Month	34(27-46)	35.19 $\pm$ 10.45
Six Months	3(0-14)	7.33 $\pm$ 9.77
One Year	0(0-7)	4.48 $\pm$ 7.78



**Figure 23: Median and Mean scores for OHIP-14 scores of Quarterly varnish application at baseline, one month, six months, and one year.**

When within-group comparison was performed using Friedman nonparametric test, all four recall points reported a very highly significant difference for median scores.  $\{X^2(3, n=27)= 68.24, p=<0.001\}$ .

Post hoc analysis using Related samples Friedman two-way ANOVA by ranks with Bonferroni correction was performed to identify which time points in recalls were statistically significant. It was observed that the difference in median OHIP-14 scores for baseline versus one month recall was statistically significant with a p-value of 0.004, while baseline versus one-year recall, one month versus six months, one month versus one-year recall values was statistically highly significant with a p-value of <0.001. (Table 41)

**Table 41: Post hoc analysis for intragroup comparison for OHIP Total scores at baseline, one month, six months, and one year for quarterly varnish group, with adjusted p values. Significant at <0.05.**

Intervention Groups	OHIP-14 Scores at various Assessment Visits					
	Baseline vs. one month	Baseline vs. six months	Baseline vs. one year	One month vs. six months	One month vs. one year	Six months vs. one year
BV	<b>0.004</b>	0.141	<b>&lt;0.001</b>	<b>&lt;0.001</b>	<b>&lt;0.001</b>	0.391

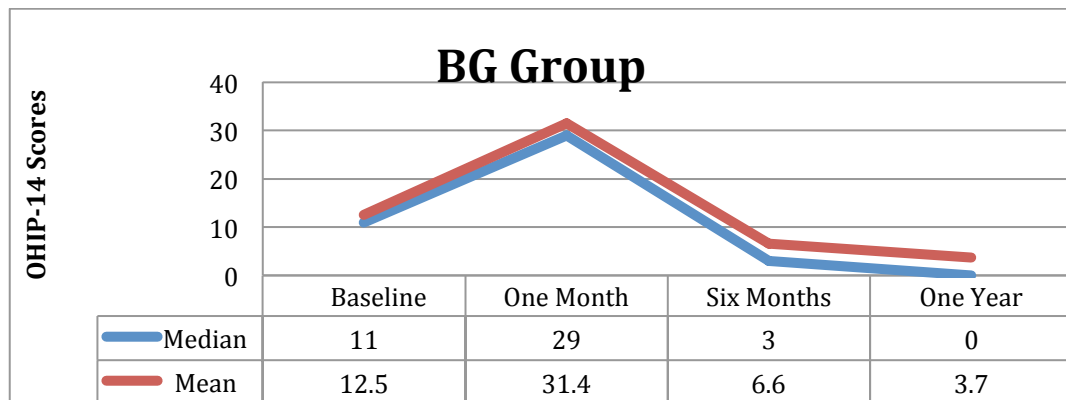
#### 4.4.4: OHIP-14 scores for Quarterly Fluoride Gel application (BG)

The median scores and interquartile range for the Quarterly fluoride Gel group (intervention BG) at baseline, one month, six months, and one year were 11(5-18.5), 29(23.50-40.04), 3(0-11) and 0(0-6.50) respectively. While the Mean  $\pm$  Standard deviation scores for the same parameters were 12.52 $\pm$ 9.92, 31.48 $\pm$ 9.82, 6.62 $\pm$ 8.71, and 3.72 $\pm$ 5.79 respectively. (Table 42, Figure 24)



**Table 42: Median, Interquartile range (Q1-Q3) and Mean ± standard deviation of OHIP-14 Total scores at baseline, one month, six months, and one year for quarterly gel group.**

OHIP-14 Scores	Median (Q1-Q3)	Mean ± S.D
Baseline	11(5-18.5)	12.52 ± 9.92
One Month	29(23.50-40.04)	31.48 ± 9.82
Six Months	3(0-11)	6.62 ± 8.71
One Year	0(0-6.50)	3.72 ± 5.79



**Figure 24: Median and Mean scores for OHIP-14 scores of Quarterly gel application at baseline, one month, six months, and one year.**

When within-group comparison was performed using Freidman nonparametric test, all four recall points reported a very highly significant difference for median scores.  $\{X^2(3, n=29)= 71.29, p=<0.001\}$ .

Post hoc analysis using Related samples Freidman two-way ANOVA by ranks with Bonferroni correction was performed to identify which time points in recalls were statistically significant. It was observed that the difference in median OHIP-14 scores for baseline versus one-year recall was statistically significant with a p-value of 0.002, while baseline versus one month, one month versus six months, and one month versus one-year recall values were statistically highly significant with a p-value of <0.001. (Table 43)

**Table 43: Post hoc analysis for intragroup comparison for OHIP-14 Total scores at baseline, one month, six months, and one year for quarterly varnish group, with adjusted p values. Significant at <0.05.**

Intervention Groups	OHIP-14 Scores at various Assessment Visits					
	Baseline vs. one month	Baseline vs. six months	Baseline vs. one year	One month vs. six months	One month vs. one year	Six months vs. one year
BG	<0.001	0.56	0.002	<0.001	<0.001	0.284

#### 4.4.5: Intergroup comparisons for AV, AG, BV & BG and OHIP-14 scores

All four intervention groups i.e. AV, AG, BV & BG at four-time recalls of baseline, one month, six months, and one year were analyzed for statistically significant differences. Non-parametric Kruskal-Wallis H test was performed for inter-group comparisons. Baseline, one month, six months and one year test statistic values for Kruskal-Wallis H test were  $H(3)= 3.56, p=0.313$ ,  $H(3)= 4.95, p=0.175$ ,  $H(3)= 1.499, p=0.682$  and  $H(3)= 0.12, p=0.989$  respectively. As the results were non-significant post hoc analyses were conducted. (Table 44)

**Table 44: Kruskal-Wallis test for intergroup comparison for OHIP-14 Total scores at baseline, one month, six months, and one year; based on the allocation of intervention.**

OHIP-14	BASELINE	ONE MONTH	SIX MONTHS	ONE YEAR
Chi-Square	3.563	4.958	1.499	0.120
P-value	0.313	0.175	0.682	0.989

#### 4.5: Correlation between OHIP-14 and DMFT scores at baseline for all four-intervention groups

Spearman's rank correlation test was performed to study the relation between OHIP-14 scores and DMFT scores for all four-intervention groups at baseline. The correlation coefficient was weakly positive for AV, AG, and BV and weakly negative for BG, while all were statistically non-significant. The test statistics for the group AV, AG, BV and BG were;  $Rho=0.03, p=0.876$ ;  $Rho=0.147, p=0.465$ ;  $Rho=0.024, p=0.905$  and  $Rho=-0.052, p=0.788$  respectively. (Table 45)

**Table 45: Spearman rank Correlation coefficient with a p-value for correlation of OHIP with DMFT, DT, MT, and FT scores at baseline as per allocation of intervention groups AV, AG, BV, and BG. Groups significant at P value <0.05.**

Dental Index	AV	AG	BV	BG
	rho/ p	rho / p	rho / p	rho/ p
<b>DMFT</b>	0.031/0.876	0.147/0.465	0.024/0.905	-0.052/0.788
<b>DT</b>	-0.066/0.739	0.107/0.595	0.258/0.193	0.257/0.178
<b>MT</b>	-0.008/0.968	0.041/0.839	-0.233/0.243	-0.164/0.396
<b>FT</b>	0.093/0.638	-0.025/0.902	-0.122/0.543	0.238/0.214

#### 4.6 Mouth opening and DMFT scores comparison

The mean  $\pm$  SD for DMFT scores for insufficient mouth opening and sufficient mouth opening were 3.85  $\pm$ 4.80 and 3.38  $\pm$ 4.06 respectively. An independent sample t-test was performed to compare differences in the mean of DMFT scores at baseline, between the insufficient mouth opening group and sufficient mouth opening group.

There was no statistically significant difference  $t(109)=0.501$ ,  $p=0.617$  between the two groups based on mouth opening. The Magnitude of difference between the mean (mean difference = 0.471, 95% CI (-1.392 to 2.334) was not statistically significant. The two groups did not differ in DMFT scores based on mouth opening for oral care. (Table 46)

**Table 46: Mean and standard deviation (SD), DF (Degree of freedom), Independent t-test value, P-value, Mean difference, Lower and upper bound for insufficient mouth opening (IMO) and sufficient mouth opening (SMO) groups based on Trismus at baseline for DMFT scores.**

<b>DMFT Scores</b>	<b>Mean</b>	<b>S.D</b>	<b>DF</b>	<b>t- Value</b>	<b>p- Value</b>	<b>Mean Difference</b>	<b>Lower bound</b>	<b>Upper bound</b>
<b>IMO</b>	3.85	4.801	109	0.501	0.617	0.471	-1.392	2.334
<b>SMO</b>	3.38	4.060						

#### 4.7 Mouth opening and total OHIP scores comparison

The mean  $\pm$  SD for OHIP-14 scores for insufficient mouth opening and sufficient mouth opening were  $20.67 \pm 9.54$  and  $12.87 \pm 9.89$  respectively. An independent sample t-test was performed to compare differences in the mean of OHIP-14 scores at baseline, between the insufficient mouth opening group and sufficient mouth opening group. There was a statistically highly significant difference,  $t(109)=3.59, p<0.001$  between the groups. The magnitude of difference in mean (mean difference = 7.79, 95% CI (3.49 to 12.10) was statistically significant. It was reported that insufficient mouth open had higher OHIP scores than the sufficient mouth-opening group. (Table 47)

**Table 47: Mean and standard deviation (SD), DF (Degree of freedom), independent t-test value, P-value, Mean difference, Lower and upper bound for insufficient mouth opening (IMO) and sufficient mouth opening (SMO) groups based on Trismus at baseline for OHIP-14 scores**

<b>OHIP-14 Scores</b>	<b>Mean</b>	<b>S.D</b>	<b>DF</b>	<b>t-Value</b>	<b>p-Value</b>	<b>Mean Difference</b>	<b>Lower bound</b>	<b>Upper bound</b>
<b>IMO</b>	20.67	9.543	109	3.592	<0.001	7.798	3.495	12.100
<b>SMO</b>	12.87	9.894						

#### 4.8 Secondary objective result SOCP validation

Supportive oral care protocol (SOCP) level of agreement 91% of the participants agreed, 8% of participants agreed with modification and 0.6% of participants disagreed on the 41 points of SOCP. A total of 99.4 % of participants accepted the final modified SOCP (Table 48).

**Table 48: Level of agreement amongst dental experts and medical experts on 41 items of SCOP. A(Agree), AM(Agree with modification, and DA(Do not agree).**

Decision	Dental experts, N (%)	Oncology experts, N (%)	Combined, N (%)
A	561 (91%)	225 (91.5%)	786 (91%)
AM	50 (8%)	21 (8.5%)	71 (8%)
DM	4 (0.6%)	0	4 (0.6%)
<b>Total Scores</b>	615	246	861

The inter-rater validity agreement was 0.9-1 amongst the fifteen dental experts while it was 1 for all the six-oncology experts. (Table 49,50)

**Table 49: Inter-rater validity agreement (IVC) amongst Medical Experts (ME) and their respective kappa measure.**

IVC	ME1	ME2	ME3	ME4	ME5	ME6
ME1		1	1	1	1	1
ME2			1	1	1	1
ME3				1	1	1
ME4					1	1
ME5						1

**Table 50: Inter-rater validity agreement (IVC) amongst Dental Experts (DE) and their respective kappa measure.**

<b>IVC</b>	<b>DE 1</b>	<b>DE 2</b>	<b>DE 3</b>	<b>DE 4</b>	<b>DE 5</b>	<b>DE 6</b>	<b>DE 7</b>	<b>DE 8</b>	<b>DE 9</b>	<b>DE 10</b>	<b>DE 11</b>	<b>DE 12</b>	<b>DE 13</b>	<b>DE 14</b>	<b>DE 15</b>
<b>DE1</b>	-	0.9	1	1	1	1	1	1	1	1	0.9	1	1	1	0.9
<b>DE2</b>			0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.9
<b>DE3</b>				0.9	1	1	1	1	1	1	0.9	1	1	1	1
<b>DE4</b>					0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.9
<b>DE5</b>						1	1	1	1	1	0.9	1	1	1	1
<b>DE6</b>							1	1	1	1	0.9	1	1	1	1
<b>DE7</b>								1	1	1	0.9	1	1	1	1
<b>DE8</b>									1	1	0.9	1	1	1	1
<b>DE9</b>										1	0.9	1	1	1	1
<b>DE10</b>											0.9	1	1	1	1
<b>DE11</b>												1	1	1	1
<b>DE12</b>													1	1	1
<b>DE13</b>														1	1
<b>DE14</b>															1