

Results

Statistical Analysis

Numerical data were explored for normality by checking the distribution of data and using tests of normality (Kolmogorov-Smirnov and Shapiro-Wilk tests). Age, torque, surgival time as well as implant stability data showed normal (parametric) distribution while edema scale, satisfaction, pain scores, bone density as well as bone changes data showed non-parametric distribution. Data were presented as mean, standard deviation (SD), median and range values. For parametric data, Student's t-test was used to compare between mean ages in the two groups. Repeated measures ANOVA test was used to compare between the two groups as well as to study the changes by time within each group. Bonferroni's post-hoc test was used for pair-wise comparisons when ANOVA test is significant. For non-parametric data, Mann-Whitney U test was used to compare between the two groups. Wilcoxon-signed rank test was used to study the changes by time within each group. Friedman's test was used to study the changes in pain scores within each group. Dunn's test was used for pair-wise comparisons when Friedman's test is significant. Qualitative data were presented as frequencies and percentages. Chi-square and Fisher's Exact tests were used to compare between the two groups regarding qualitative data. The significance level was set at $P \leq 0.05$. Statistical analysis was performed with IBM SPSS Statistics for Windows, Version 23.0. Armonk, NY: IBM Corp.

Baseline characteristics

Study group showed statistically significantly higher prevalence of females than control group. There was no statistically significant difference between mean age values in the two groups. There was also no statistically significant difference between mean torque as well as surgical times in the two groups.

Table 1: Descriptive statistics and results of Fisher's Exact test and Student's t-test for comparisons between base line characteristics in the two groups

Base line characteristics	Study (n = 15)	Control (n = 16)	P-value
Gender [n, (%)]			
Male	1 (6.7%)	10 (62.5%)	0.001*
Female	14 (93.3%)	6 (37.5%)	
Age in years [Mean, SD]	42.1 (7.5)	40.3 (11.5)	0.609
Torque in N/cm [Mean, SD]	26.5 (15.6)	34.7 (18.1)	0.188
Surgical time in minutes [Mean, SD]	90.4 (24.4)	75.4 (14.6)	0.052

*: Significant at $P \leq 0.05$

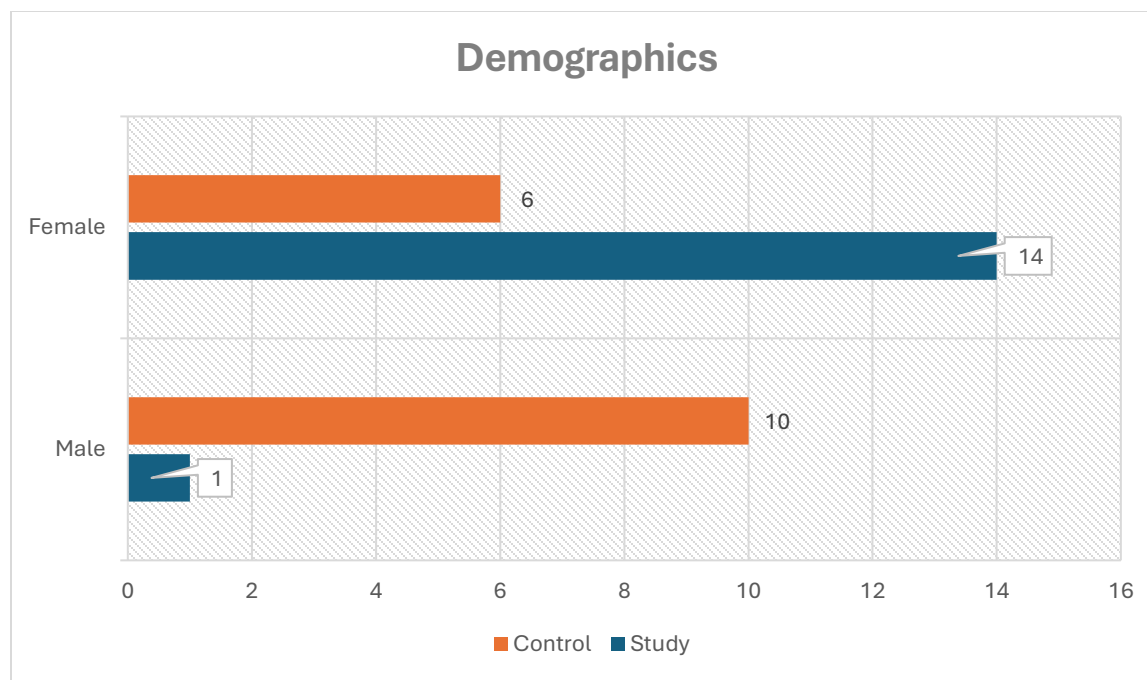


Figure 1: Bar chart showing Demographic distribution of two groups.

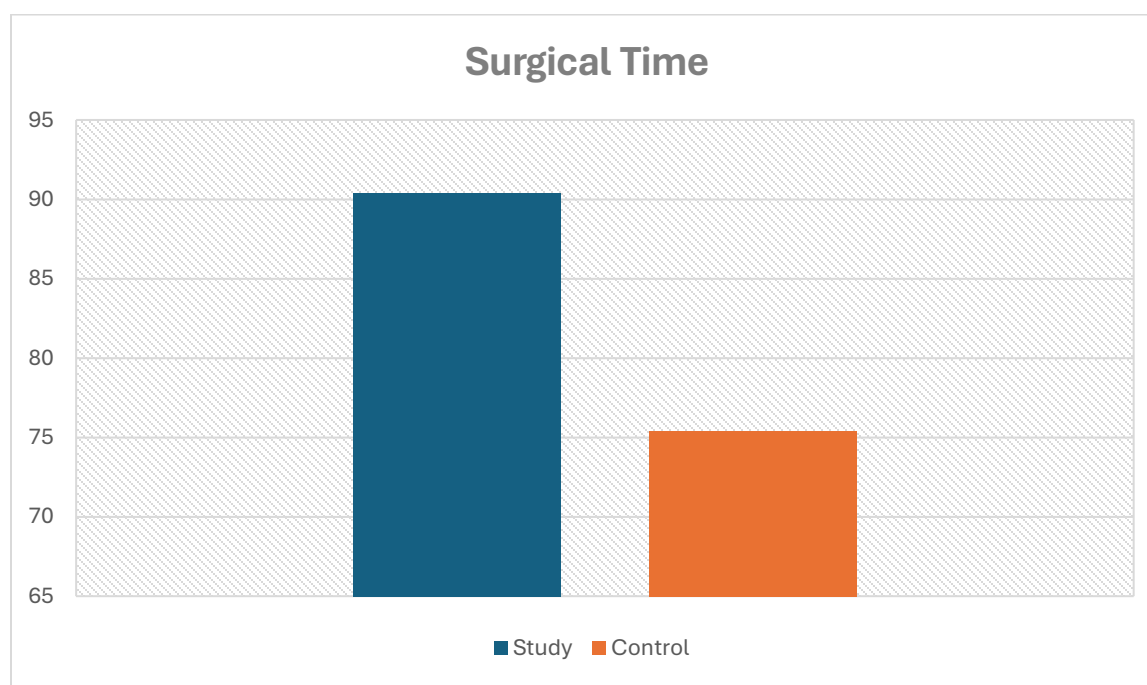


Figure 2: Bar chart showing Surgical Time of two groups.

I. Implant success.

There was no statistically significant difference between implant success in the two groups.

Table 2: Descriptive statistics and results of Fisher's Exact test for comparisons between implant success in the two groups

	Study (n = 15)	Control (n = 16)	P-value
Implant success [n, (%)]			
Success	15 (100%)	15 (93.8%)	1
Failure	0 (0%)	1 (6.2%)	

*: Significant at $P \leq 0.05$

II. Complications

There was no statistically significant difference between prevalence of Schneiderian membrane perforation and post-operative sinusitis in the two groups. None of the cases in the two groups showed intra-operative bleeding, epistaxis or peri-implantitis.

Table 3: Descriptive statistics and results of Fisher's Exact test for comparisons between presence of complications in the two groups

Complications [n, (%)]	Study (n = 15)	Control (n = 16)	<i>P</i> -value
<hr/>			
Schneiderian membrane perforation			
Present	1 (6.7%)	2 (12.5%)	1
Absent	14 (93.3%)	14 (87.5%)	
<hr/>			
Post-operative sinusitis			
Present	2 (13.3%)	2 (12.5%)	1
Absent	13 (86.7%)	14 (87.5%)	

*: Significant at $P \leq 0.05$

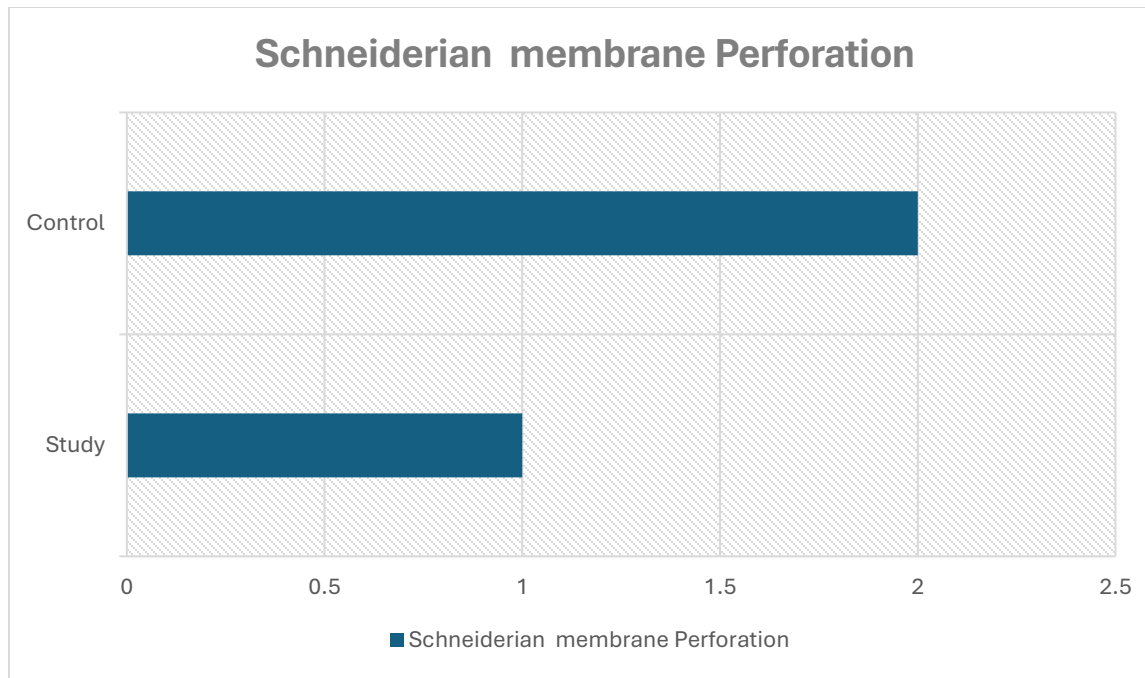


Figure 3: Bar chart showing Schneiderian Membrane perforation in both groups.

III. Pain (VAS scores)

a. Comparison between the two groups

After one day, there was no statistically significant difference between the two groups (P -value = 0.114, Effect size = 0.576).

After two days, study group showed statistically significantly lower pain score than control group (P -value = 0.0121, Effect size = 1).

After three, four, five, six, seven, eight, nine as well as ten days, there was no statistically significant difference between the two groups (P -value = 0.236, Effect size = 0.428), (P -value = 0.146, Effect size = 0.537), (P -value = 0.170, Effect size = 0.505), (P -value = 0.340, Effect size = 0.346), (P -value = 0.188, Effect size = 0.474), (P -value = 0.826, Effect size = 0.078), (P -value = 0.780, Effect size = 0.085) and (P -value = 0.302, Effect size = 0.114), respectively.

b. Changes within each group

In study group, there was a statistically significant change in pain scores by time (P -value <0.001 , Effect size = 0.979). Pair-wise comparisons between time periods revealed that there was no statistically significant change in pain scores after two days. There was a statistically significant decrease in pain scores from two to three, three to four as well as four to five days followed by non-statistically significant change in pain scores from five to six days. From six to seven as well as seven to eight days, there was a statistically significant decrease in pain scores. From eight to nine as well as nine to 10 days, there was no statistically significant change in pain scores.

As regards control group, there was a statistically significant change in pain scores by time (P -value <0.001 , Effect size = 0.977). Pair-wise comparisons between time periods revealed that there was no statistically significant change in pain scores after two days followed by a statistically significant decrease in pain scores from two to three, three to four, four to five, five to six, six to seven as well as seven to eight days. There was no statistically significant change in pain scores from eight to nine as well as nine to 10 days.

Table 4: Descriptive statistics and results of Mann-Whitney U test for comparison between pain (VAS) scores in the two groups and Friedman's test for the changes within each group

Time	Study (n = 15)		Control (n = 16)		<i>P</i> -value	<i>Effect size (d)</i>
	Median (Range)	Mean (SD)	Median (Range)	Mean (SD)		
1 day	6.8 (0.5, 8.5) ^A	6.76 (1.89)	7.5 (0.5, 10) ^A	7.34 (2.33)	0.114	0.576
2 days	6.2 (0.5, 7.4) ^A	5.75 (1.67)	6.8 (0.5, 8.9) ^A	6.77 (1.94)	0.012*	1
3 days	5.4 (0.5, 5.9) ^B	4.64 (1.44)	5.4 (0.5, 8.2) ^B	5.34 (2.05)	0.236	0.428
4 days	3.7 (0.5, 5.2) ^C	3.73 (1.31)	4.5 (0.5, 7.1) ^C	4.51 (1.84)	0.146	0.537
5 days	2.1 (0, 5.2) ^D	2.66 (1.54)	3.7 (0, 6.5) ^D	3.68 (1.7)	0.170	0.505
6 days	1.8 (0, 3.7) ^D	2.07 (1.21)	2.35 (0, 4.3) ^E	2.44 (1.24)	0.340	0.346
7 days	0.5 (0, 2.4) ^E	1.07 (0.84)	1.8 (0, 2.8) ^F	1.56 (0.82)	0.188	0.474
8 days	0.2 (0, 1.2) ^F	0.5 (0.49)	0.4 (0, 1.2) ^G	0.47 (0.43)	0.826	0.078
9 days	0 (0, 0.6) ^F	0.17 (0.25)	0 (0, 0.5) ^G	0.11 (0.17)	0.780	0.085
10 days	0 (0, 0.2) ^F	0.01 (0.05)	0 (0, 0) ^G	0 (0)	0.302	0.114
<i>P</i> -value	<0.001*		<0.001*			
<i>Effect size (d)</i>	0.979		0.977			

*: Significant at $P \leq 0.05$, Different superscripts within the same column indicate statistically significant change by time

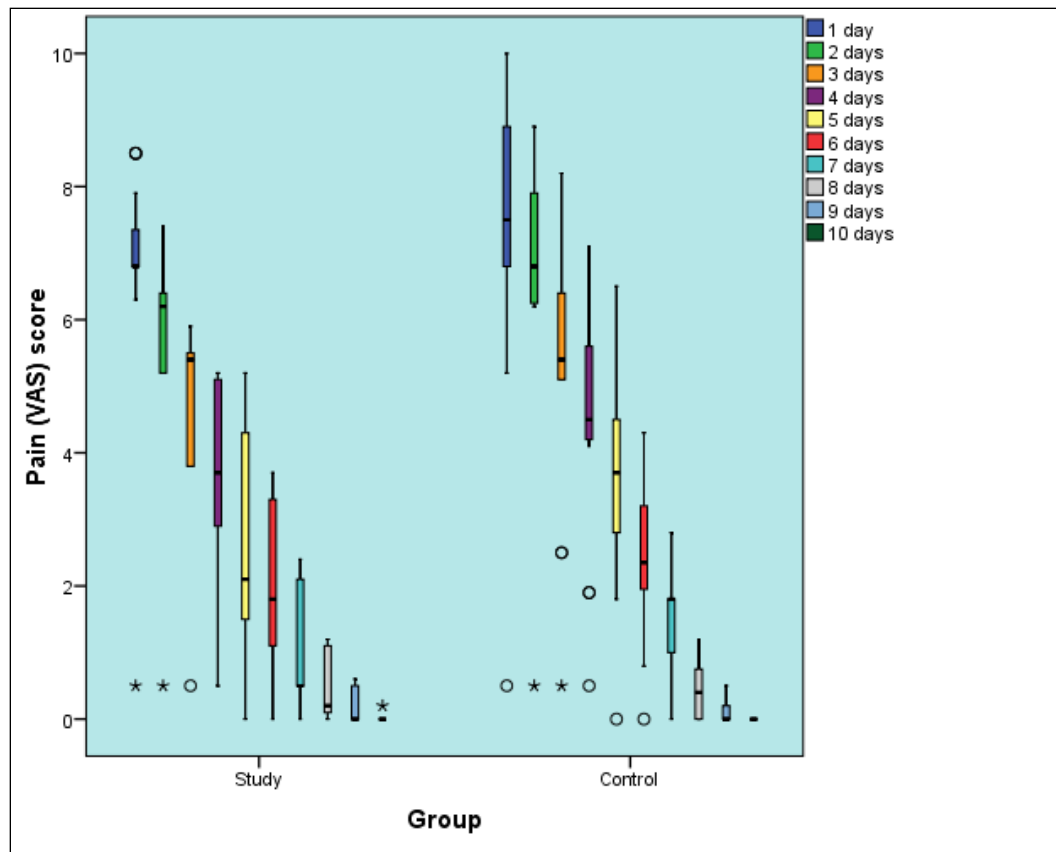


Figure 4: Box plot representing median and range values for pain scores in the two groups (Circles and stars represent outliers)

IV. Edema scale

As regards AC, AD as well as BE, the study group showed statistically significantly higher score than control group (P -value = 0.003, Effect size = 1.223), (P -value = 0.030, Effect size = 0.812) and (P -value = 0.005, Effect size = 1.156), respectively..

Table 5: Descriptive statistics and results of Mann-Whitney U test for comparison between edema scale in the two groups

Edema scale	Study (n = 15)		Control (n = 16)		<i>P</i> -value	<i>Effect size (d)</i>
	Median (Range)	Mean (SD)	Median (Range)	Mean (SD)		
AC	10 (5, 28)	12.4 (7.63)	5 (4, 13)	6.5 (2.76)	0.003*	1.223
AD	10 (5, 37)	14.6 (9.39)	9 (5, 15)	9.06 (3.53)	0.030*	0.812
BE	10 (5, 30)	14.27 (8.13)	5 (2, 15)	6.81 (3.51)	0.005*	1.156

*: Significant at $P \leq 0.05$

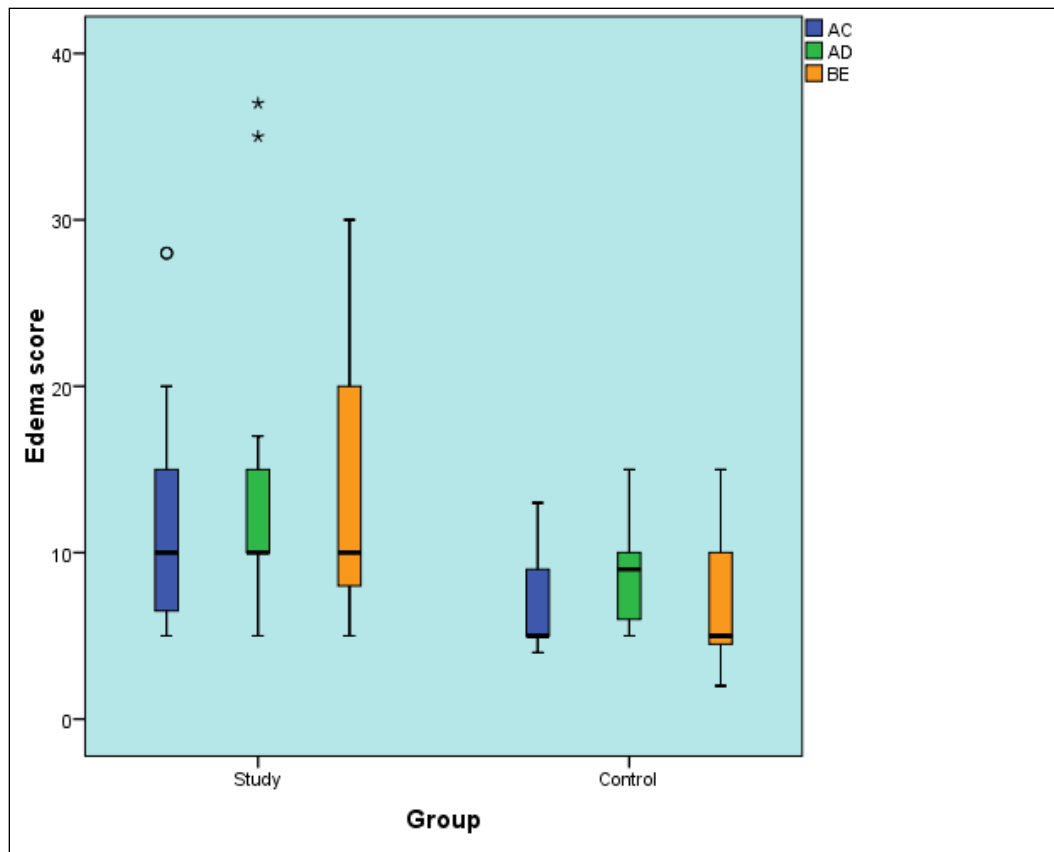


Figure 5: Box plot representing median and range values for edema scale scores in the two groups (Stars and circle represent outliers)

V. Severity of edema

Study group showed statistically significantly higher prevalence of moderate and severe edema than control group which showed higher prevalence of mild edema (P -value < 0.001 , Effect size = 0.673).

Table 6: Descriptive statistics and results of Chi-square test for comparison between severity of edema in the two groups

Severity of edema	Study (n = 15)		Control (n = 16)		P-value	Effect size (v)
	n	%	n	%		
Mild	0	0	8	50		
Moderate	9	60	8	50	<0.001*	0.673
Severe	6	40	0	0		

*: Significant at $P \leq 0.05$

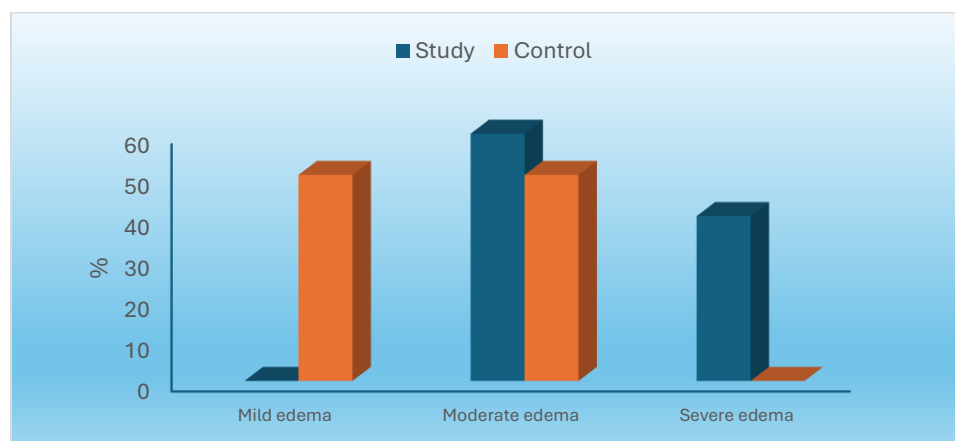


Figure 6: Bar chart representing severity of edema in the two groups.

VI. Implant stability assessment using Osstell (ISQ)

a. Comparison between the two groups

Whether immediately post-operative or at second stage, there was no statistically significant difference between ISQ scores in the two groups (P -value = 0.067, Effect size = 0.115) and (P -value = 0.176, Effect size = 0.064), respectively.

b. Changes within each group

In study group, there was a statistically significant increase in ISQ scores at second stage (P -value = 0.013, Effect size = 0.202).

In control group, there was no statistically significant change in ISQ scores at second stage (P -value = 0.128, Effect size = 0.081).

Table 7: Mean, standard deviation (SD) values and results of repeated measures ANOVA test for comparison between ISQ scores in the two groups and the changes within each group.

		Study (n = 15)		Control (n = 16)		P -value	Effect size (Partial Eta squared)
Time		Mean	SD	Mean	SD		
Immediate post-operative		69.8	9.8	75.4	5.8	0.067	0.115
Second stage		75.3	8.3	78.6	4.3	0.176	0.064
P -value		0.013*		0.128			
Effect size (Partial Eta squared)		0.202		0.081			

*: Significant at $P \leq 0.05$

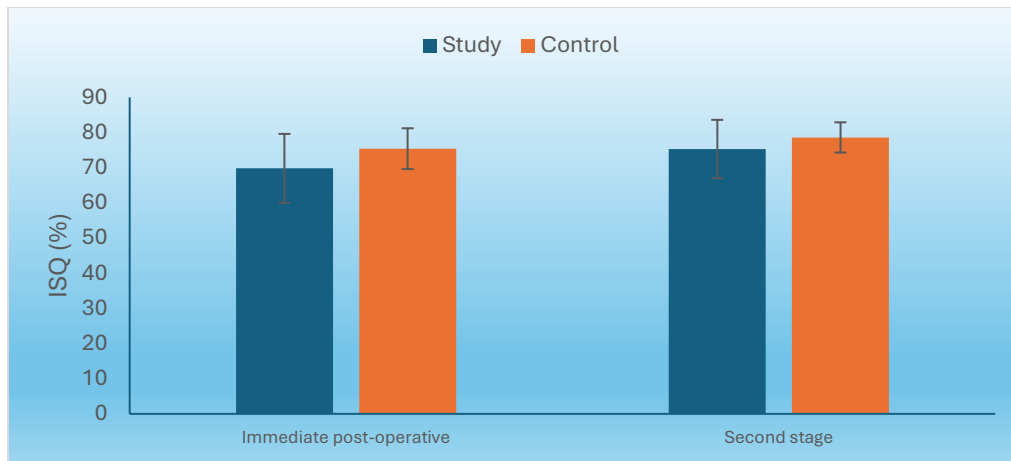


Figure 7: Bar chart representing mean and standard deviation values for ISQ scores in the two groups.

VII. Satisfaction (VAS scores)

There was no statistically significant difference between satisfaction scores in the two groups (P -value = 0.461, Effect size = 0.258).

Table 8: Descriptive statistics and results of Mann-Whitney U test for comparison between satisfaction (VAS scores) in the two groups

Study (n = 15)		Control (n = 16)		P -value	Effect size (d)
Median (Range)	Mean (SD)	Median (Range)	Mean (SD)		
9.8 (9.3, 10)	9.77 (0.2)	9.8 (9.3, 10)	9.71 (0.24)	0.461	0.258

*: Significant at $P \leq 0.05$

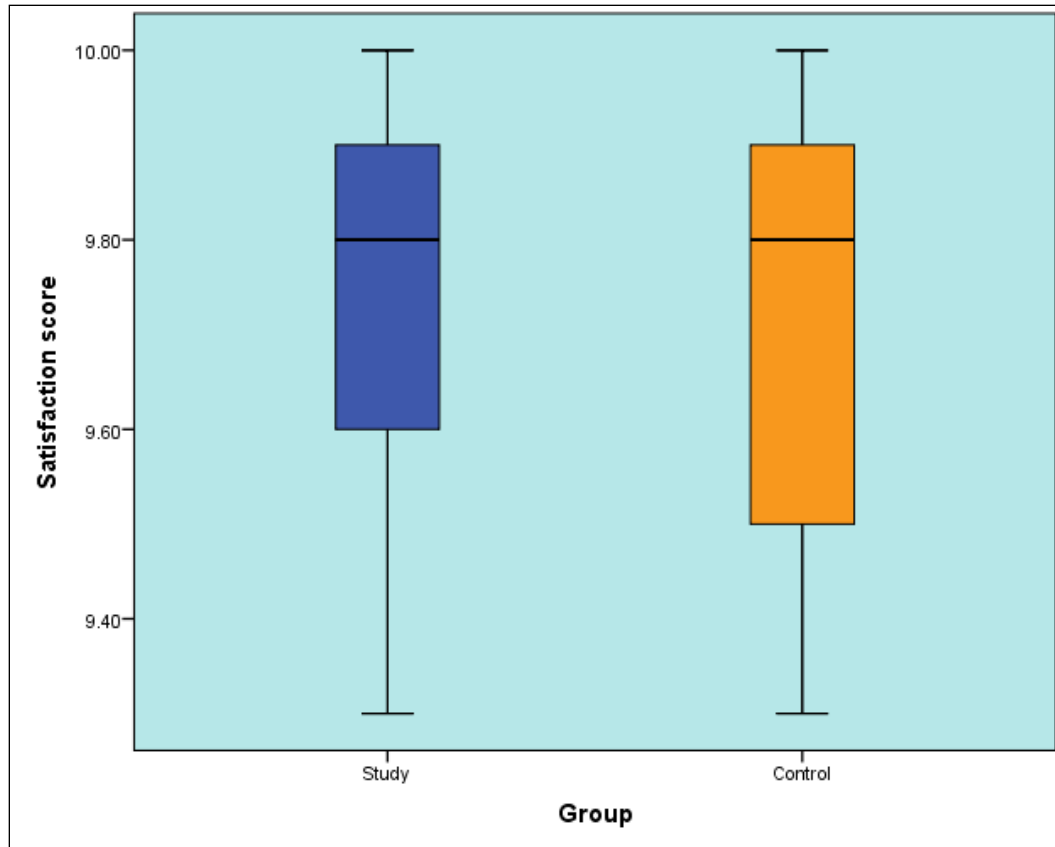


Figure 8: Box plot representing median and range values for satisfaction scores in the two groups.

VIII. Bone density (HU)

a. Comparison between the two groups

Whether pre-operative or after six months, there was no statistically significant difference between bone density measurements in the two groups (P -value = 0.110, Effect size = 0.691) and (P -value = 0.395, Effect size = 0.406), respectively.

b. Changes within each group

In both groups, there was a statistically significant decrease in bone density after six months (P -value = 0.001, Effect size = 3.704) and (P -value = 0.001, Effect size

= 3.255), respectively.

Table 9: Descriptive statistics and results of Mann-Whitney U test for comparison between bone density measurements (HU) in the two groups and Wilcoxon signed-rank test for the changes within each group.

Time	Study (n = 15)		Control (n = 16)		P-value	Effect size (d)
	Median (Range)	Mean (SD)	Median (Range)	Mean (SD)		
Pre-operative	426.2 (141.5, 613.5)	434.5 (148.5)	336.5 (168.2, 725.4)	355.8 (144.2)	0.110	0.691
6 months	306.8 (78.9, 607.1)	331.6 (146.6)	280.2 (22.8, 690.5)	291.6 (162.5)	0.395	0.406
P-value	0.001*		0.001*			
Effect size (d)	3.704		3.255			

*: Significant at $P \leq 0.05$

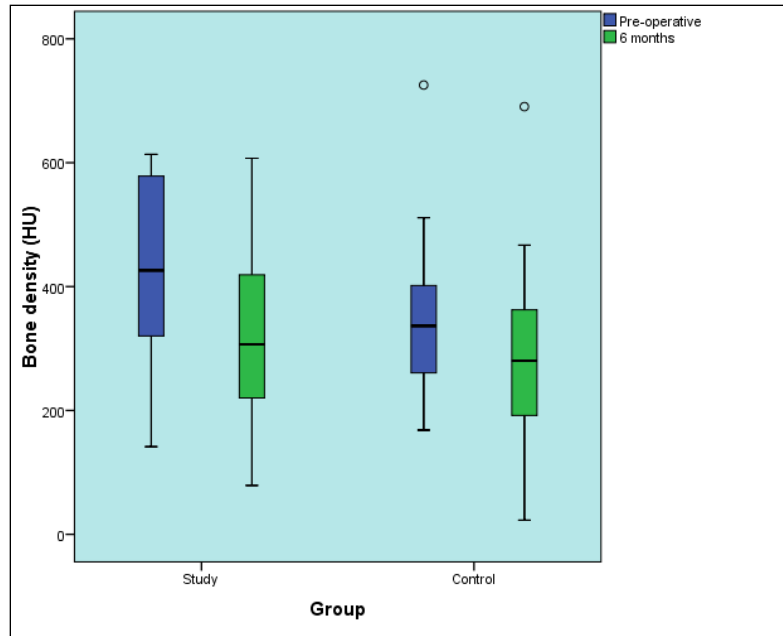


Figure 9: Box plot representing median and range values for bone density measurements in the two groups (Circles represent outliers)

IX. Vertical bone gain after six months (mm)

There was no statistically significant difference between vertical bone gain after six months in the two groups (P -value = 0.101, Effect size = 0.699).

Table 10: Descriptive statistics and results of Mann-Whitney U test for comparison between vertical bone gain after six months (mm) in the two groups.

Study (n = 15)		Control (n = 16)		P -value	Effect size (d)
Median (Range)	Mean (SD)	Median (Range)	Mean (SD)		
8.66 (1.7, 9.56)	7.25 (2.719)	6.65 (2.45, 9.1)	6.5 (1.89)	0.101	0.699

*: Significant at $P \leq 0.05$

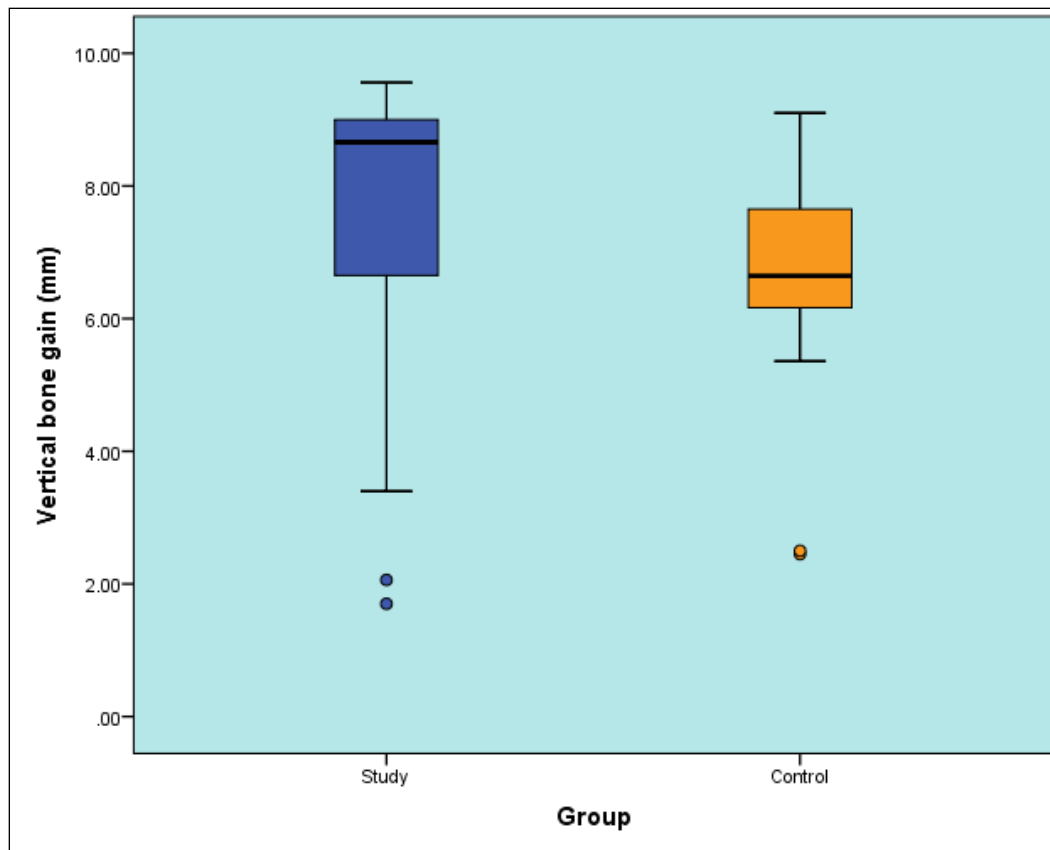


Figure 10: Box plot representing median and range values for vertical bone gain after six months in the two groups (Circles represent outliers)

X. Crestal bone changes (mm)

There was no statistically significant difference between the two groups (P -value = 0.303, Effect size = 0.376).

Table 11: Descriptive statistics and results of Mann-Whitney U test for comparison between crestal bone changes (mm) in the two groups

Study (n = 15)		Control (n = 16)		P-value	Effect size (d)
Median (Range)	Mean (SD)	Median (Range)	Mean (SD)		
-1.82 (-5.2, 4.33)	-1.66 (1.94)	-1.65 (-2.88, -0.7)	-1.68 (0.61)	0.303	0.376

*: Significant at $P \leq 0.05$

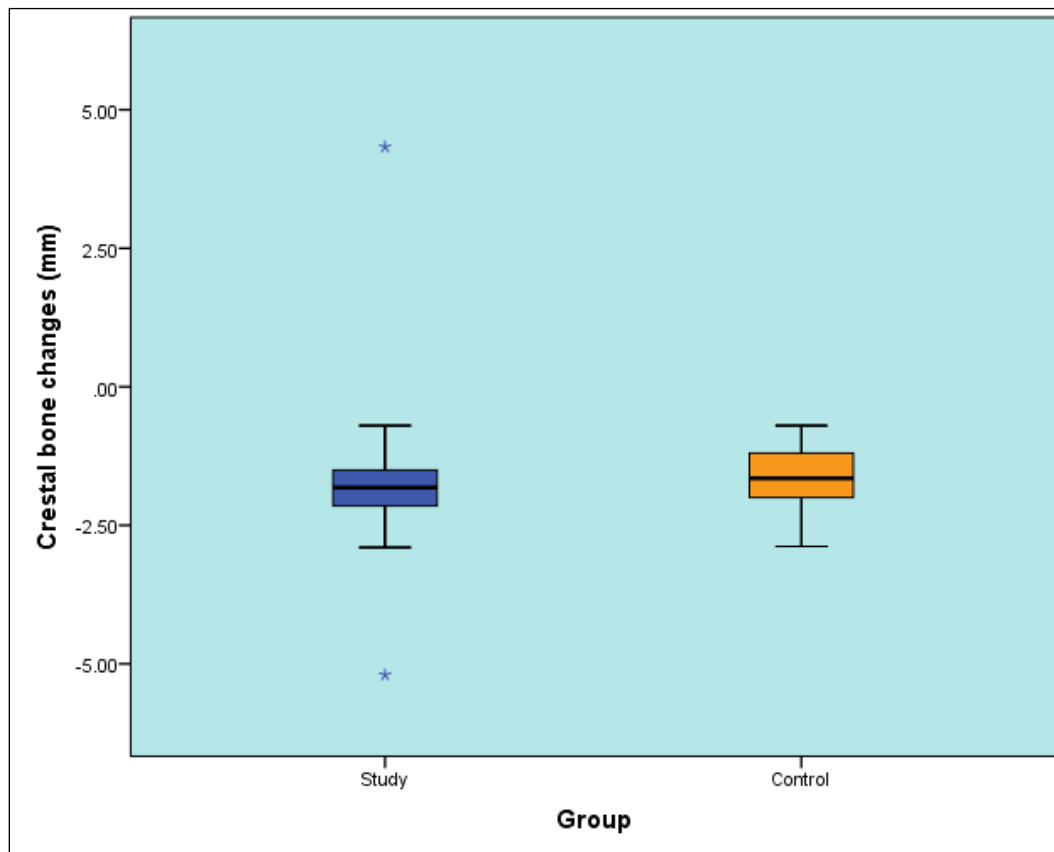


Figure 11: Box plot representing median and range values for crestal bone changes in the two groups (Stars represent outliers).

XII: Cost-Analysis

There was statistically significant difference between the two groups (The p-

value is $< .00001$, Effect size = 0.93). The cost of the study group is significantly higher than the control group.

Table 12: Descriptive statistics and results of Mann-Whitney U test for comparison between the cost of the two groups.

Study (n = 15)		Control (n = 16)		P-value	Effect size (d)
Median (Range)	Mean (SD)	Median (Range)	Mean (SD)		
5000 (2500 – 5000)	3833.33 (1291)	2000	2000 (0)	0.101	0.93

*: Significant at $P \leq 0.05$

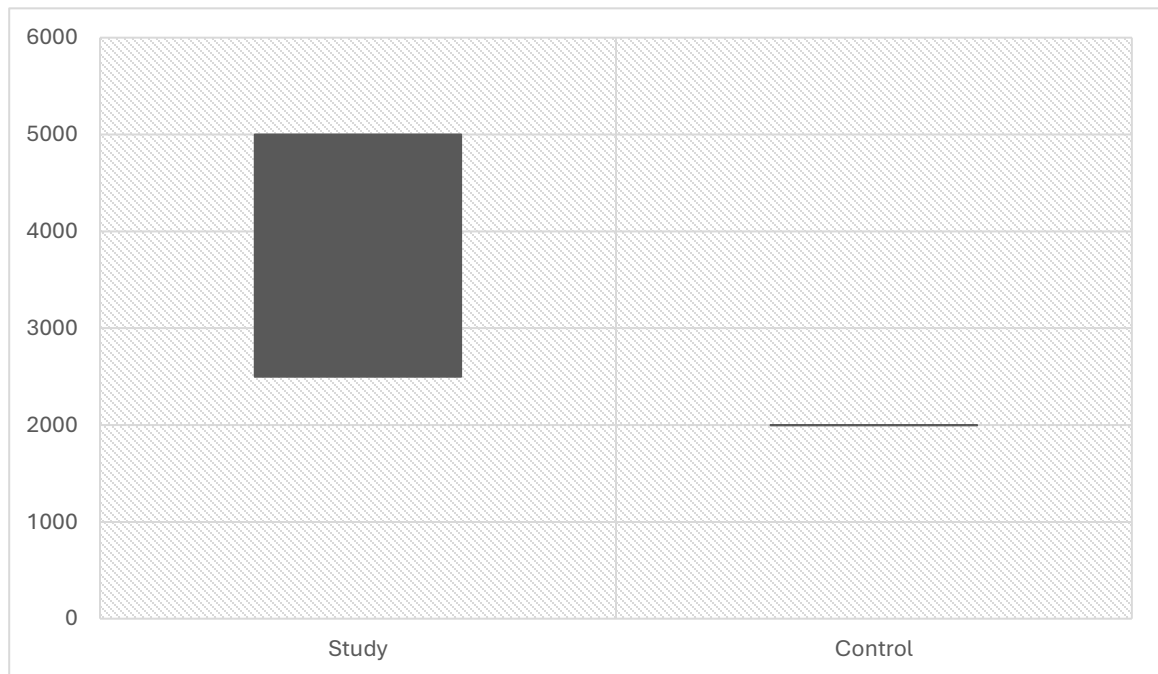


Figure 12: Box plot representing median and range values for cost in the two group.