

Clinical Evaluation of Chewable Probiotic Tablets as an Adjunct to Non-Surgical Periodontal Therapy in the Treatment of Periodontal Disease- A Pilot Project

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Key Words:

Probiotics, Periodontitis, Scaling & root planning, plaque index, bleeding index, clinical attachment level, probing depth, Non-surgical periodontal therapy.

Abstract:

Introduction: Probiotics have been recently investigated as a promising adjunctive treatment along with scaling and roots planning for treating periodontal disease owing to their antimicrobial and anti-inflammatory characteristics. The present study set out to determine how probiotics affected several clinical markers of periodontal health. Methods: 62 Subjects diagnosed with Periodontitis were subjectively allocated to examination and controlling clusters based on such exclusion and inclusion criteria. The test group participants were administered probiotic chewable tablets (2 billion CFU) for 7 days following scaling and root planing (non-surgically periodontal therapy) at baseline whereas the control group participants were only observed following scaling and root planning alone. Clinical periodontal parameters viz, oral hygiene index, bleeding index, periodontal pocket depth and clinical attachment loss were assessed at baseline, 30 days(1 month)and 90 days(3 months) follow-up. Results: Considering an intra-group P-value of less than 0.001, medical metrics significantly improved in both the experimental and control groups. Even though the test group's average variations were greater, intergroup interactions and analyses among the two groups showed no statistically significant variations ($P > 0.05$). Compared to the control group, the experimental(test) group had more obvious modifications to the disease condition. Conclusion: Probiotics may be beneficial as an adjunct to non-surgical periodontal rehabilitation in treating patients with periodontal disease.

1. Introduction

A change in the equilibrium of the oral biofilm leads to periodontitis, a chronic inflammatory condition that destroys the supporting dental network. *Porphyromonas gingivalis*, *Treponema denticola*, *Tannerella forsythus*, and *Aggregatibacter actinomycetem comitans* are the pathogenic bacteria that cause this condition. Scaling and root planning (SRP), the mainstay of non-surgical periodontal therapy, is a popular method of treating periodontitis [1]. In severe cases of periodontitis, however, SRP might not necessarily result in meaningful and durable clinical results. In order to better understand various supplementary therapies to SRP for enhancing periodontal health, Retamal-Valdes et al. (2021) undertook a research wherein it was concluded that the failure of SRP to produce a lasting shift in the oral microbiota that is required for maintaining periodontal health could be the cause of its poor efficacy in treating advanced cases of periodontitis. In order to increase the effectiveness of SRP, other treatments, such as systemically administered antimicrobials and probiotics, were proposed. [2]

Systematic antibiotics are frequently given to treat periodontal disease in order to eradicate pathogenic bacteria that were left behind following nonsurgical periodontal treatment. Although this course of treatment has the potential to produce desired outcomes and clinical enhancements, it may also cause a number of unfavourable adverse reactions, including diarrhoea, oral ulcers, and gastrointestinal discomfort. Antibiotic-resistant kinds of bacteria may also emerge as a result of the misuse of antibiotics. Thus, it is crucial to take into account other alternatives to antibiotics.

Probiotics are live microbes that are taken to re-establish microbial equilibrium, mostly in the gastrointestinal tract, and have no impact on the host. These are controlled as foodstuffs and nutritional supplements as well as being made of lactic acid bacteria, such as the *Lactobacillus* and *Bifidobacterium* organisms, along with the yeast *Saccharomyces boulardii*. These microscopic organisms provide a variety of beneficial impacts, including reducing the pH of the stomach and reducing the spreading and colonisation of harmful germs. [3]

Nancy Toedter Williams covers the subject of probiotics in her essay "Probiotics," which was

released in the American Journal of Health-System Pharmacy[4]. Probiotics are defined in detail throughout the paper, along with their kinds, legal standing, and positive benefits. The writer explores the possible therapeutic uses of probiotics while highlighting their significance for sustaining a healthy microbiological equilibrium in the human body, especially in the gastrointestinal tract. Williams also emphasises the difficulties of using probiotics, such as the lack of standardisation and the necessity of additional research to confirm their safety and effectiveness. [5]

In view of their capacity to support optimal microbial equilibrium and activity throughout the body, beneficial microorganisms have drawn interest as a possible adjuvant treatment for periodontal disease. Probiotics could be effective through a number of different processes, including stealing nutrients from dangerous bacteria, generating antimicrobial chemicals, and altering the immune system's response. In accordance with this justification, research was carried out to determine if probiotics are effective in controlling and preventing periodontal illness when used in conjunction with non-surgical periodontal therapy. [6]

1.1 Procedures and techniques

2. Material

After receiving clearance from the establishment's ethics review board (IRRB -02-04082022), the present research was carried out in the dental clinics at Jeddah, Saudi Arabia's Ibn-Sina National College for Medical Sciences. The research included 62 people in total, aged between 18 and 72 years, with a gender split of 21 men and 41 women. Patients were excluded if they had previous experiences of allergic reactions, systemic illnesses, maternity or infant feeding, cigarette smoking, parafunctional behaviours, inconsistent brushing practises, or frequent drug usage that would have an impact on the course of therapy. The research restricted itself to individuals who gave authorization in writing and were identified as having periodontal disease after undergoing a clinical periodontal assessment that involved measuring plaque and bleeding indicators and documenting periodontal charting.

These 62 patients received training in and strengthening of good oral hygiene practises after root

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planning and scaling. Then, at random from among them, they were allocated into a combination of an experimental group that included 32 patients or a group serving as a control with 30 patients. Following SRP, the experimental group was given chewable probiotic tablets (Berry Dophilus chewable, Now Foodstuffs Bloomingdale, IL 60108, USA) every day for 7 days, whereas the comparison (control) group was just observed at regular intervals. Both clusters were invited back for a follow-up periodontal assessment at 30 and 90 days, involving periodontal charting, plaque index and bleeding index.

A MS Excel spreadsheet was used for recording and analysing the information that was acquired at the initial state, one-month (30 days), and three-month (90 days) marks. The SPSSV22 programme was used to conduct statistical evaluations. The averages throughout each group as well as among the two groupings at various time points were compared using the technique of parametric testing. These percentage figures have been provided in order to evaluate and document the prevalence of periodontal disease. [7]

3. Results

The study consisted of 20 males (40%) and 40 females (60%) as seen in the demographic distribution (Table 1).

According to Tables 2A, 2B, 2C, and 2D, the experimental group demonstrated a substantial decrease in plaque and bleeding indexes, probing depths, and clinically loss of attachment from baseline across both 30 days and 90 days ($P < 0.001$). As illustrated by Tables 3A, 3B, 3C, and 3D, the control group identically demonstrated a substantial decline in these variables from the beginning to 30 days and 90 days ($P < 0.001$). As shown in Tables 4A, 4B, 4C, and 4D, there were certainly not any significant variations among the experiment as well as the control groups with regard to plaque index, bleeding index, probing depths, and loss of clinical attachment at various intervals of time ($P > 0.05$).

With regard to the status of periodontal disease, (Table 5), there was a substantial transformation in the extent of the disease at the test cluster with the number of generalized cases decreasing from 87.5% at baseline to 62.5% at 1 month to 53.13% at 3 months. On the other hand, the number of localized cases increased from

12.5% (baseline) to 37.5% (1 month) to 46.88% (3 months). Staging of the disease showed slight variations from baseline (21.88%) to 1 month (18.75%) to 3 months (31.25%) for stage I periodontitis; as well as for stage II with baseline (62.5%), 1 month (65.63%) and 3 months (59.38%); and stage III with baseline (15.63%), 1 month (18.75%) and 3 months (18.75%). Similarly, no significant changes were observed with Grading of the disease with grade A at baseline (9.38%), 1 month (6.25%) and 3 months (9.38%); grade B at baseline (81.25%), 1 month (81.25%) and 3 months (81.25%) as well as grade C at baseline (9.38%), 1 month (12.5%) and 3 months (9.38%) respectively. With regard to disease status, the stability improved from baseline (31.25%) to 1 month (50%) to 3 months (75%). However, there was a decrease in the unstable disease state from baseline (31.25%) to 1 month (28.13%) to 3 months (9.38%) as well as in remission state from baseline (37.5%) to 1 month (28.13%) to 3 months (15.63%) respectively.

In comparison, in the control group, (Table 6) there was slight reduction in the extent of the disease with generalized being 80% at baseline to 73.33% at 1 month to remaining 73.33% at 3 months. However, there was a slight change in the localized cases from baseline (20%) to 1 month (26.67%) to 3 months (23.33%). Staging showed negligible variations from baseline (36.37%), 1 month (36.67%) and 3 months (33.33%) for stage I; significant variations from baseline (43.33%), 1 month (53.33%) and 3 months (50%) for stage II; and also for stage III with baseline (20%), 1 month (10%) and 3 months (13.33%). On the other hand, minimal or no variations were observed with grading of the disease with baseline (10%), 1 month (10%) and 3 months (10%) for grade A; baseline (76.67%), 1 month (80%) and 3 months (76.67%) for grade B; and baseline (13.33%), 1 month (10%) and 3 months (10%) for grade C respectively. [8]

On the contrary, significant changes were observed with regard to stable disease status with 26.67% (baseline) improving to 63.33% (1 month) and further to 70% (3 months). Similarly, unstable disease reduced from 30% (baseline) to 13.33% (1 month) to 10% (3 months) and remission state decreased from 43.33% (baseline) to 23.33% (1 month) to 16.67% (3 months). There was also 3.33% (1 patient) who returned to the state of periodontal health.

4. Discussion

Scaling and root planning (SRP) is the cornerstone of management of periodontitis. The treated diseased sites are susceptible to recolonization with plaque microorganisms comparable to those that were prevalent prior to medication; therefore, this kind of treatment does have its limitations. Numerous adjuvant treatments, such as treatment with antibiotics, antimicrobial photodynamic therapies, and probiotic therapies, have been suggested for tackling the aforementioned drawbacks.[9]

The Food and Agriculture Organisation (FAO) and the World Health Organisation (WHO) describe probiotics as living bacteria that, whenever given in sufficient proportions, promote the well-being of the recipient (Joint FAO/WHO Working Group, 2002). Probiotics may improve clinical variables, lower proinflammatory levels of cytokines, and strengthen the therapeutic impact of SRP, according to experiments looking into the consequences of treatment of periodontal disease with probiotics [10]. In addition, two meta-analyses suggest the application of probiotics as an adjuvant to the management of chronic periodontitis [11].

Different kinds of *Lactobacillus* have been the primary subject of previous investigations on the effects of probiotics on periodontal disorders. Nevertheless, the types of *Bifidobacterium* and the amount they produce may be related to periodontal wellness and therapy consequences in patients with periodontitis, according to a 2007 study by Hojo et al. Species of the *Bifidobacterium* genus may successfully cling to the subgingival biofilm and considerably lower the overall number of *Porphyromonas gingivalis* [12], according to similar *in vitro* research by Jasberg et al. (2016). Furthermore, a randomised, single-blind, *in vivo* study by Jothika et al. (2015) [13] demonstrated the efficacy of probiotic mouthwashes as adjuncts to oral hygiene in the treatment of *Streptococcus mutans*. In addition, a study by Shetty et al [14] also suggested beneficial effects of guided pocket recolonisation (GPR) with synbiotics along with scaling and root planning in periodontitis.

In our research, we gave the experimental group an assortment of 10 distinct probiotic strains for duration of 7 days following scaling and root planning. These strains included a blend of *Lactobacillus* and *Bifidobacterium* species in chewable forms. The

considerable changes in periodontal markers that were seen imply that these probiotics are useful in addressing periodontal disease.

The experimental group demonstrated greater average enhancements in every single parameter (plaque index, bleeding index, probing depths, and clinical attachment levels) compared to the control group, despite the fact that there were not any statistically significant variations in the periodontal characteristics among the two groups of patients at the 30 and 90-day follow-up appointments.

Innovative treatment strategies are required for treating oral disorders linked to biofilm development as the frequency of resistant infections rises. In comparison with research that utilised antibiotics along with root planning and scaling for the therapy of chronic periodontitis [15-17], our research observed that the experimental group had comparable or even superior outcomes in probing pocket depth (PPD) and clinical attachment level (CAL) in deeper pockets after three months of therapies.

It is crucial to remember that the kind of bacteria used, the dose, regularity, and mode of application may all affect how beneficial probiotics are. Similarly, to the results seen in previous investigations using probiotics of the *Lactobacillus* and *Streptococcus* genera, this research's probiotic medical treatment, which included an assortment of *Bifidobacterium* and *Lactobacillus* strains, reduced PPD and increased attachment gain, albeit with a briefer period for administration (7 days). The effectiveness of probiotics varies depending on the strain; hence, the conclusions drawn from this research cannot be applied to every type of probiotic treatment.

The intention was to ensure initial colonisation (following SRP) by beneficial bacteria thereby preventing periodontal pathogenic flora from accumulating and causing disease. Most studies have used probiotics for a longer duration (30 days to 90 days) and found similar results as in our study in spite of short duration of 7 days' usage.

An interesting observation of the study is the changes with respect the periodontal disease status. Along the various time intervals, there were significant alterations in the extent of the disease, with a good percentage of cases progressing to localise towards the end of 3

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months from generalised state at baseline. Additionally, higher staging (II & III) and grading (B&C) shifted to lower levels and more number of cases became stable from unstable in both the test and control groups. However, the changes seemed more obvious in the probiotic administered group. Probiotics' capacity to control the microbiota of their environment is one way that they may benefit periodontal health.

The comparatively brief observational time and lack of contemporaneous evaluation of microbiologic characteristics and immunologic indicators were two drawbacks of this investigation. Long-term evaluations of these patients are crucial in order to ascertain if the beneficial benefits of probiotic treatment as an addition to SRP are sustained over time. In addition, this would correspondingly enable us to understand the microbial composition during the colonisation process.

5. Conclusion

The use of a blend of probiotics containing lactobacillus and Bifidobacterium strains in the form of chewable probiotic tablets, as an attachment to SRP compromises supplementary medical assistances during the therapy/medication of patients with periodontitis at various stages and grades and varying states of disease.

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TABLE 1 - DEMOGRAPHIC DATA:

		Number	Percentage
GENDER	MALES	21	33.87%
	FEMALES	41	66.13%
AGE GROUPS	18-20	4	6.45%
	21-30	20	32.26%
	31-40	21	33.87%
	41-50	11	17.74%
	51-60	5	8.06%
	>60	1	1.61%

TABLE 2 - Test group

2A - PLAQUE INDEX

Paired Samples Test

	Paired Differences					t	df	Sig. (2-tailed)
	Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
				Lower	Upper			
baseline – 1 month	25.67812	13.93646	2.46364	20.65349	30.70276	10.423	31	.000
baseline – 3 months	41.40000	19.69871	3.48227	34.29786	48.50214	11.889	31	.000
1 month – 3 months	15.72187	13.93887	2.46407	10.69638	20.74737	6.380	31	.000

2B - BLEEDING INDEX

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Paired Samples Test

	Paired Differences					t	df	Sig. (2-tailed)
	Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
				Lower	Upper			
baseline – 1 month	17.50312	18.21390	3.21979	10.93631	24.06994	5.436	31	.000
baseline – 3 months	24.64687	21.19732	3.74719	17.00443	32.28932	6.577	31	.000
1 month – 3 months	7.14375	8.18192	1.44637	4.19385	10.09365	4.939	31	.000

2C - PROBING DEPTH

Paired Samples Test

	Paired Differences					t	df	Sig. (2-tailed)
	Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
				Lower	Upper			
baseline – 1 month	.24219	.52865	.04673	.14972	.33465	5.183	127	.000
baseline – 3 months	.47656	.62701	.05542	.36689	.58623	8.599	127	.000
1 month – 3 months	.23438	.44340	.03919	.15682	.31193	5.980	127	.000

2D - CLINICAL ATTACHMENT LOSS

Paired Samples Test

	Paired Differences					t	df	Sig. (2-tailed)
	Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
				Lower	Upper			
baseline – 1 month	.31250	.67287	.05947	.19481	.43019	5.254	127	.000
baseline – 3 months	.60938	.80583	.07123	.46843	.75032	8.556	127	.000
1 month – 3 months	.29688	.53770	.04753	.20283	.39092	6.246	127	.000

TABLE 3 - Control group

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3A - PLAQUE INDEX

Paired Samples Test

	Paired Differences					t	df	Sig. (2-tailed)
	Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
				Lower	Upper			
baseline – 1 month	23.75833	13.61889	2.48646	18.67296	28.84371	9.555	29	.000
baseline – 3 months	36.47267	15.55442	2.83984	30.66455	42.28078	12.843	29	.000
1 month – 3 months	12.71433	10.65044	1.94449	8.73740	16.69127	6.539	29	.000

3B - BLEEDING INDEX

Paired Samples Test

	Paired Differences					t	df	Sig. (2-tailed)
	Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
				Lower	Upper			
baseline – 1 month	11.45833	16.09414	2.93837	5.44868	17.46798	3.900	29	.001
baseline – 3 months	15.74533	20.04919	3.66046	8.25884	23.23182	4.301	29	.000
1 month – 3 months	4.28700	5.78853	1.05684	2.12553	6.44847	4.056	29	.000

3C – PROBING DEPTH

Paired Samples Test

	Paired Differences					t	df	Sig. (2-tailed)
	Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
				Lower	Upper			
baseline – 1 month	.30000	.65594	.05988	.18143	.41857	5.010	119	.000
baseline – 3 months	.62500	.76765	.07008	.48624	.76376	8.919	119	.000
1 month – 3 months	.32500	.47034	.04294	.23998	.41002	7.569	119	.000

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3D – CLINICAL ATTACHMENT LOSS

Paired Samples Test

	Paired Differences					t	df	Sig. (2-tailed)
	Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
				Lower	Upper			
baseline – 1 month	.37500	.77852	.07107	.23428	.51572	5.277	119	.000
baseline – 3 months	.70000	.98390	.08982	.52215	.87785	7.794	119	.000
1 month – 3 months	.32500	.53707	.04903	.22792	.42208	6.629	119	.000

TABLE 4 - INTERGROUP COMPARISON – TEST v/s CONTROL GROUP

4A – PLAQUE INDEX

Paired Samples Statistics

	Mean	N	Std. Deviation	Std. Error Mean
BL-1MNTH	23.7583	30	13.61889	2.48646
	26.7733	30	13.46144	2.45771
BL-3MNTH	36.4727	30	15.55442	2.83984
	43.0433	30	19.04879	3.47782
1MNTH-3MNTH	12.7143	30	10.65044	1.94449
	16.2700	30	14.23733	2.59937

Paired Samples Test

	Paired Differences					t	df	Sig. (2-tailed)
	Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
				Lower	Upper			
baseline – 1 month	-3.01500	18.90851	3.45221	-10.07555	4.04555	-.873	29	.390
baseline – 3 months	-6.57067	22.56409	4.11962	-14.99624	1.85490	-1.595	29	.122
1 month – 3 months	-3.55567	16.31272	2.97828	-9.64694	2.53560	-1.194	29	.242

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4B – BLEEDING INDEX

Paired Samples Statistics

	Mean	N	Std. Deviation	Std. Error Mean
BL-1MNTH	11.4583	30	16.09414	2.93837
	17.1100	30	18.11651	3.30761
BL-3MNTH	15.7453	30	20.04919	3.66046
	24.0733	30	20.53685	3.74950
1MNTH-3MNTH	4.2870	30	5.78853	1.05684
	6.9633	30	8.07762	1.47476

Paired Samples Test

	Paired Differences					t	df	Sig. (2-tailed)
	Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
				Lower	Upper			
baseline – 1 month	5.65167	24.97562	4.55990	-14.97772	3.67438	-1.239	29	.225
baseline – 3 months	8.32800	30.75000	5.61416	-19.81024	3.15424	-1.483	29	.149
1 month – 3 months	2.67633	10.88745	1.98777	-6.74178	1.38911	-1.346	29	.189

4C – PROBING DEPTH

Paired Samples Statistics

	Mean	N	Std. Deviation	Std. Error Mean
BL-1MNTH	.3000	120	.65594	.05988
	.2417	120	.53446	.04879
BL-3MNTH	.6250	120	.76765	.07008

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1MNTH-3MNTH	.4833	120	.63489	.05796
	.3250	120	.47034	.04294
	.2417	120	.44901	.04099

Paired Samples Test

	Paired Differences					t	df	Sig. (2-tailed)
	Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
				Lower	Upper			
baseline – 1 month	.05833	.91022	.08309	-.10620	.22286	.702	119	.484
baseline – 3 months	.14167	1.03952	.09489	-.04623	.32957	1.493	119	.138
1 month – 3 months	.08333	.61608	.05624	-.02803	.19469	1.482	119	.141

4D – CLINICAL ATTACHMENT LOSS

Paired Samples Statistics

	Mean	N	Std. Deviation	Std. Error Mean
BL-1MNTH	.3750	120	.77852	.07107
	.2500	120	.56880	.05192
BL-3MNTH	.7000	120	.98390	.08982
	.5417	120	.72060	.06578
1MNTH-3MNTH	.3250	120	.53707	.04903
	.2917	120	.54071	.04936

Paired Samples Test

	Paired Differences					t	df	Sig. (2-tailed)
	Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
				Lower	Upper			
baseline – 1 month	.12500	.97500	.08901	-.05124	.30124	1.404	119	.163

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baseline – 3 months	.15833	1.22985	.11227	-.06397	.38064	1.410	119	.161
1 month – 3 months	.03333	.69733	.06366	-.09272	.15938	.524	119	.602

TABLE 5 – CHANGES IN DIAGNOSIS & DISEASE STATUS – TEST GROUP

		DIAGNOSIS					
EXTENT		BASELINE	%AGE	1MONTH	%AGE	3 MONTHS	%AGE
	GENERALISED	28	87.5%	20	62.5%	17	53.125%
	LOCALISED	4	12.5%	12	37.5%	15	46.875%
STAGE	1	7	21.875%	6	18.75%	7	31.25%
	2	20	62.5%	21	65.625%	19	59.375%
	3	5	15.625%	6	18.75%	6	18.75%
GRADE	A	3	9.375%	2	6.25%	3	9.375%
	B	26	81.25%	26	81.25%	26	81.25%
	C	3	9.375%	4	12.5%	3	9.375%
STATUS	STABLE	10	31.25%	16	50%	24	75%
	UNSTABLE	10	31.25%	7	21.875%	3	9.375%
	REMISSION	12	37.5%	9	28.125%	5	15.625%

TABLE 6– CHANGES IN DIAGNOSIS & DISEASE STATUS – CONTROL GROUP

		DIAGNOSIS					
EXTENT		BASELINE	%AGE	1MONTH	%AGE	3 MONTHS	%AGE
	GENERALISED	24	80%	22	73.33%	22	73.33%
	LOCALISED	6	20%	8	26.67%	7	23.33%
STAGE	1	11	36.67%	11	36.67%	10	33.33%
	2	13	43.33%	16	53.33%	15	50%
	3	6	20%	3	10%	4	13.33%
GRADE	A	3	10%	3	10%	3	10%

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	B	23	76.67%	24	80%	23	76.67%
	C	4	13.33%	3	10%	3	10%
STATUS	STABLE	8	26.67%	19	63.33%	21	70%
	UNSTABLE	9	30%	4	13.33%	3	10%
	REMISSION	13	43.33%	7	23.33%	5	16.67%

PERIODONTAL HEALTH – 1(3.33%)