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Conflict of Interest

Mr Michael Busby acts as a Denplan advisor and Prof Iain Chapple acts as an advisor to Oral Health Innovations, the license holder for DEPPA in the UK and Ireland.

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Abstract:

Aims: To explore the associations between periodontal status and patient reported outcomes (PROs) in a large cohort of patients based in non-specialist general dental practice.

Materials and methods: Analysis was conducted using data from 14,620 patients, in 233 non-specialist dental practices across the UK. As part of routine clinical care, data on periodontal probing depths (PPD), alveolar bone loss (ABL), bleeding on probing (BoP) as well as PROs (oral pain/discomfort, dietary restrictions and dental appearance) were recorded using an online database. The associations between periodontal status and PROs were investigated using logistic regression analysis, adjusting for confounders.

Results: We found a positive association between worse periodontal health and the prevalence of PROs. After adjustment for confounders, 13.8% of patients in the healthiest category (PPD <5mm, ABL <2mm, no BoP) reported pain/discomfort, compared to 20.7% of patients in the worst category (PPD >7mm, ABL >4mm). A similar trend was seen with reporting a restricted diet and unhappiness with appearance.

Conclusion: This study provides novel insights into the associations between periodontal status and PROs in a non-specialist, general dental practice, highlighting the benefits of prevention and management of periodontitis.

Clinical Relevance

Scientific rationale for study
To date, no studies have sought to investigate the relationship between patient reported outcomes in a non-specialist dental setting.

Principal findings
The probability of reporting pain or restrictions in diet or unhappiness with dental appearance increases with worsening periodontal status in a dose-dependent manner. Patients with alveolar bone loss but no deep periodontal pockets are less likely to report dental pain or restrictions in diet compared to patients with deep periodontal pockets.

Practical implications
This study highlights the impact of periodontitis on the well-being of patients and hints at the potential improvements in well-being that may be obtained by periodontal intervention.

Acknowledgements:

The authors would like to thank the patients and dentists contributing to the DEPPA database.

Introduction:

Patient reported outcomes (PROs) are defined as "any report of the status of a patient's health condition that comes directly from the patient, without interpretation of the patient's response by a clinician or anyone else'' (U. S. Department of Health and Human Services, 2009, U.S. Department of Health and Human Services). PROs are a way for the patient's perception of their disease or health to be incorporated into their clinical assessment and by doing so, ensuring that all dimensions of health are incorporated in the diagnosis and care for the patient (WHO, 2018).

The WHO defines oral health as a state of being free from diseases that "limit an individual's capacity in biting, chewing, smiling, speaking, and psychosocial wellbeing" (WHO, 2012). However, often the classification of oral health or oral disease is based on assessments carried out by the dental practitioner with little input from the patient. In the field of periodontology, disease status and treatment outcomes are measured using clinical measures such as periodontal probing depths (PPDs), clinical attachment loss (CAL), bleeding on probing (BOP) and radiographic bone loss. Clearly, these parameters may not be directly relevant to patients, who are thought not to be affected by their periodontal condition for many years before symptoms such as pain or tooth mobility present. Hence, periodontitis has widely been regarded as a "silent disease". However, this notion has recently been called into question, as several studies have suggested that periodontitis patients report worse oral health related quality of life (Buset et al., 2016).

The aim of the present study was to explore the associations between clinical and radiographic periodontal parameters and patient reported experience of oral pain, dietary restrictions and dental appearance in a large, non-specialist dental practice patient cohort.

Methods:

Patient population

This study used data of 14,620 dentate patients, collected as part of routine clinical care by 355 dentists in 233 non-specialist dental practices across the UK. The dentists were part of a dental payment plan scheme (Denplan), which enables them to charge their patients a fixed monthly fee that covers regular examinations and treatments (Busby et al., 2014a). Participating dental practices comply with a range of key performance/quality outcome measures, deemed consistent with "optimal" dental service provision (Busby et al., 2013). Beginning in 2013, dentists enrolled in the scheme have used an online tool, the Denplan PreViser Patient Assessment (DEPPA). The use of DEPPA is free to dentists who are Denplan Excel Certified, which is a voluntary quality assurance programme. Hence, the vast majority of DEPPA users are Denplan Excel Certified. The DEPPA system is used by participating dentists to record data on a patient's demographics, risk factors for oral diseases and clinical and radiographic findings. In addition, DEPPA also contains a short patient questionnaire that captures data on the patient's perceptions of their oral health and behaviours. For the present analyses, data of the first data entry for each patient were used, which may represent either an initial consultation for a patient new to the practice or a check-up appointment for a previously seen patient. These two types of appointment cannot be distinguished from the data available. While the DEPPA system uses these data to derive a number of scores as previously reported (Busby et al., 2013, Busby et al., 2014a., Busby et al., 2014b, Newton and Asimakopoulou, 2017, Sharma et al., 2016), only the raw data entered by clinicians were used for the analyses described in this paper.

All personal identifiers are anonymised and collected in an encrypted format and the system is used as part of routine clinical care. The UK Data Commissioner has confirmed that collected data is non-

personalised. Ethical review was therefore not required for this analysis. As data were not recorded for research purposes, no formal calibration and no standardisation of clinical or radiographic procedures was performed.

Periodontal/exposure variables

As part of the clinical examination, dentists recorded the deepest periodontal probing depth (PPD) per sextant (<5mm, 5-7mm or >7mm), any bleeding on probing (BoP) in each sextant (yes/no) and the maximum radiographic alveolar bone loss (ABL) per sextant (<2mm, 2-4mm, >4mm) as measured from the cemento-enamel junction to the alveolar crest, from available radiographs. Third molars were excluded from the periodontal assessment.

Patient reported outcome variables

PROs were assessed on a 3-point Likert scale using questions on pain ("Are you experiencing any pain or discomfort in your mouth?" [Yes/Some/No]), dietary restriction ("Do your teeth allow you to eat an unrestricted diet?" [Yes/Mainly/No]) and appearance ("How do you feel about the appearance of your teeth?" [Happy/Some concerns/Unhappy]).

Other data

Data were collected on the following variables based on patients' self-report: age in years and sex (male/female); smoking status (ever/never smoker); diabetes status (yes/no); tooth grinding habits (yes/no) and frequency of sugar intake (less than 4 times/ 4 or more times in a typical day). Data on numbers of teeth with restorations and number of teeth needing restorations; patient's oral hygiene (adequate/inadequate); patient's dental attendance not as regularly as advised by the dentist (yes/no); presence of cervical tooth-wear as a measure of abrasion (yes/no) and salivary flow (adequate/inadequate) were collected, as judged by the clinician.

Statistical analysis

The following statistical analysis plan was defined *a priori*. To avoid sparse strata and facilitate interpretability, binary PRO variables were generated for pain (yes/some vs. no), dietary restriction (yes vs. mainly/no) and appearance (happy vs. some concerns/unhappy). In addition, we created binary outcome variables based on the number of positive PRO responses (at least one vs. none and more than one vs. one or none).

Based on the worst sextant score of PPD, BoP and ABL, patients were categorised into 8 different periodontal status (exposure) categories (Table 1).

Logistic regression analysis was used to investigate the associations between each PRO as the outcome variable and the various categories of periodontal parameters as independent variables. In multivariable analyses, adjustments were made for variables which might confound these associations. These included age, sex, smoking and diabetes status, number of teeth with restorations, number of teeth needing restorations, oral hygiene, dental attendance, abrasion, grinding habits and frequency of sugar intake. In addition, salivary flow was included as a covariate in the association between periodontal health status and dental pain and diet and but not for the association between periodontal health and appearance.

The adjusted probabilities and two-sided 95% CI of reporting various outcomes were calculated by periodontal status. We carried out a sensitivity analysis by investigating these associations in a sub-set of patients with no outstanding restorative needs.

To assess whether the reporting of oral pain, dietary restriction and unhappiness with appearance were clustered in a sub-group of patients, we investigated the correlation between reporting pain and restricted diet, reporting restricted diet and unhappiness with appearance and reporting unhappiness with appearance and pain using tetrachoric correlation coefficients.

Additional sensitivity analyses were conducted including comparisons of findings of the above associations between patients requiring no restorations and patients requiring at least one restoration. In addition, a sensitivity analysis was conducted omitting the variables “oral hygiene”, “dental attendance” and “salivary flow”.

Patients with missing data were not included in the analysis.

Results:

Sample characteristics

The final analytical sample consisted of 14,568 dentate patients, following the exclusion of 52 patients (0.003%) with missing data. The mean age of patients in this cohort was 55.5 years (SD 15.7, range 17-106), 6,280 (43%) were male, 830 (5.7%) reported being diagnosed with diabetes and 9,146 (63%) were never smokers. The mean number of teeth present, not including wisdom teeth, was 25 (SD 4, range 1-28). Of these, a mean of 11 (SD 5.7, range 0-28) were restored and 0.3 (SD 1, range 0-26) needed restorations. 696 (5%) did not attend the dentist as regularly as recommended, 6,469 (44%) had inadequate oral hygiene and 1,656 (11%) reported a high frequency of sugar intake (Table 1).

With regards to their periodontal parameters, 2,693 (18.5%) were in the healthiest group, 3,081 (21.2%) had BoP with no or limited periodontal tissue loss, with the remainder exhibiting various levels of periodontal tissue loss evidenced by PPD 5+mm and/or ABL 2+mm with or without bleeding on probing (Table 1).

Unadjusted prevalence of PROs

2.7% of patients reported experiencing oral pain or discomfort and 12.3% reported experiencing some oral pain or discomfort; 3.5% of patients reported a restricted diet and 7.8% reported a somewhat restricted diet; 2.7% of patients reported being unhappy with the appearance of their teeth and 23.5% had some concerns with the appearance of their teeth. In addition, 40% of the cohort reported at least one of these concerns and 11% reported more than one of these concerns (Table 1). Patients’ demographics, lifestyle factors and number of teeth with restorations, number of teeth needing restorations, oral hygiene, dental attendance, abrasion, grinding habits and frequency of sugar intake, were very similar regardless of whether they reported oral pain, diet restrictions or being unhappy with the appearance of their teeth (data not shown).

There were statistically significant correlations between the PROs with tetrachoric correlation coefficients being 0.3514 ($p<0.0001$), 0.3110 ($p<0.0001$) and 0.2940 ($p<0.0001$) for the correlations between reporting pain and restricted diet, restricted diet and unhappiness with appearance and unhappiness with appearance and pain, respectively.

Adjusted prevalence of PROs

Overall, the prevalence of all reported PROs tended to increase with worsening periodontal parameters (Tables 1&2, Figures 1-5).

Specifically, the adjusted prevalence estimates, i.e., predicted probabilities from multivariable logistic models, for pain ranged from 13.8% (95% CI 12.4-15.2%) in the periodontally healthiest group to 20.7% (95% CI 17.2-24.2%) in patients with the worst periodontal parameters (PPD >7mm and ABL >4mm, Table 2 and Figure 1). Similarly, the periodontally healthiest patients had a 10.8% (95% CI 9.5-12.0%) probability of reporting a restricted diet, compared to 19.2% (95% CI 15.9-22.5%) for patients with PPD >7mm and ABL >4mm (Table 2 and Figure 2). For appearance, 22.2% (95% CI 20.6-23.8%) of the periodontally healthiest patients compared to 34.3% (95% CI 30.3-38.4%) of patients with the worst periodontal parameters reported an impact (Table 2 and Figure 3).

In addition, a similar trend was found in the adjusted probability of any impact, with 35.6% (95% CI 33.7-37.4%) and 9.2% (95% CI 8.1-10.4%) of the periodontally healthiest patients compared to 52.4% (95% CI 48.2-56.7%) and 17.5% (95% CI 14.3-20.8%) of patients with the worst periodontal parameters reporting at least one or more than one impact, respectively (Table 2 and Figures 4, 5).

Results from sensitivity analysis

A similar trend to the whole-group analyses, in regard to all PROs, was observed in analyses restricted to the 11,744 (81%) patients not requiring any restorations at the time of assessment. Similarly, omission of oral hygiene, dental attendance and salivary flow from the model did not yield appreciably different results.

Discussion

In the present cross-sectional study of a large, general dental practice-based population, we found a dose-dependent association between worsening periodontal status and the probability of reporting pain or restrictions in diet or unhappiness with dental appearance.

The large sample studied here allows for some meaningful and interesting comparisons between categories of different periodontal parameters. For example, a large proportion of patients (44.2%) studied here had evidence of radiographic bone loss of 2+mm, but no periodontal pockets deeper than 4mm, with approximately 20% exhibiting no BoP. While several causes of alveolar bone loss other than periodontitis must be considered, the absence of deep periodontal pockets in the presence of alveolar bone loss is consistent with the periodontal parameters one would expect to see following successful periodontal therapy, or resolution of active disease. Hence, our results are at least consistent with a beneficial effect of successful periodontal therapy and maintenance on the patient reported outcomes evaluated here, in particular given the specifics of this population, i.e., patients enrolled in a quality-assured prevention-oriented capitation-based payment plan scheme.

These results are in line with previous research on the association between periodontal disease and its treatment on oral health related quality of life. A recent systematic review summarising data from 14,087 patients in 37 studies, with sample sizes ranging from 21 to 3122 patients, found that patients with periodontal disease had poorer oral health related quality of life compared to periodontally healthy patients, and that the impact on quality of life was greater with increasing extent and severity of periodontal disease (Buset et al., 2016). All but one (Andersson et al., 2010) of the included 37 studies were based in hospital or specialist practices. The effect of treatment of periodontal disease on quality of life was reviewed by Shanbhag et al (2012), who reviewed 11 studies with sample sizes ranging from 32 to 183 patients, and concluded that periodontal treatment

can improve quality of life (Shanbhag et al., 2012). The authors reported an improvement in all domains of oral health related quality of life following periodontal therapy. All of the 11 trials (7 prospective case-series or uncontrolled studies, one controlled study and three RCTs with a total of 639 participants) reviewed in this article were conducted in hospital or specialist practices.

There are several important strengths of this study. Firstly, we were able to analyse data from a large, general practice based sample, resulting in precise estimates generalizable to a setting in which a large number of patients receive care. Secondly, we were able to adjust for several important potential confounders.

Several limitations of this study need to be considered. Firstly, the study used data from practices that were part of a dental payment capitation scheme. As a result, this study likely included patients with above average oral health motivation and compliance. For example, only 5% of patients were classed as irregular attenders (Table 1). Therefore, results may not be generalizable to the entire UK population. Secondly, as this is a pragmatic study using data collected as part of routine clinical care, some measurement error and misclassification may arise due to lack of calibration, use of different periodontal probes, use of routine radiographs. In this respect, assessment of oral hygiene, dental attendance and salivary flow may be particularly subjective. These were included in the statistical model as they are important confounders of the relationship between periodontitis and PROs studied here. However, a sensitivity analysis conducted, omitting these three variables from the model, resulted in findings that were not appreciably different. Thirdly, there is potential bias due to unmeasured and residual confounding. This is likely to be most relevant for common risk factors for caries and periodontal disease. For example, we had no data on some potential confounders, such as socio-economic status. However, the fact that this is a somewhat more homogeneous population in terms of oral health behaviours and socio-economic status reduces the risk of confounding relative to the general population. Our sensitivity analysis, limited to patients who needed no restorations, showed similar results.

In conclusion, our results demonstrate that in a large, non-specialist, general practice-based population, worse periodontal health as measured by increased probing depth, alveolar bone loss and bleeding on probing is associated with adverse patient reported outcomes including pain, dietary restriction and unhappiness with appearance in a dose-dependent fashion. Hence, prevention and successful management of periodontitis may have direct benefits on patient reported outcomes.

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Table 1: Demographics of the cohort. Data are unadjusted and are expressed mean (SD) unless otherwise stated

	Whole cohort (n=14,568)	**Cohort categorised by periodontal parameters**							
		I (PPD <5 mm, ABL < 2mm, BoP –) (n=2,693; 18.5%)	**II (PPD <5mm, ABL < 2mm, BoP +) (n=3,081; 21.2%)**	**III (PPD < 5mm, ABL 2-4mm, BoP –) (n=2,330; 18.0%)**	**IV (PPD < 5mm, ABL 2-4mm, BoP +) (n=2,898; 19.9%)**	**V (PPD 5-7mm, ABL 2-4mm, BoP +/-) (n=1,225; 8.6%)**	**VI (PPD < 5mm, ABL >4mm, BoP +/-) (n=911; 6.3%)**	**VII (PPD 5-7mm, ABL >4mm, BoP +/-) (n=868; 6.0%)**	**VIII (PPD >7mm; ABL >4mm, BoP +/-) (n=532; 3.7%)**
Age (years)	55 (16)	48 (16)	46 (16)	62 (12)	59 (13)	59 (13)	66 (11)	64 (11)	63 (12)
Male (%)	43	40	43	43	43	48	44	46	49
Diabetic (%)	5.7	3.8	3.4	5.5	6.3	6.6	9.1	9.6	11.5
Never smoker (%)	63	69	70	62	62	58	51	48	48
Teeth present*	25 (4)	26 (4)	26 (3)	25 (4)	25 (4)	25 (4)	23 (5)	23 (5)	23 (5)
Restored teeth	11 (6)	9 (6)	9 (6)	13 (5)	13 (5)	12 (5)	12 (5)	12 (5)	11 (5)
Teeth needing restoration	0.3 (1.0)	0.2 (0.9)	0.3 (1.1)	0.3 (0.7)	0.4 (1.0)	0.3 (1.0)	0.4 (1.1)	0.4 (1.1)	0.4 (1.1)
Frequency of dental visits less than recommended (%)	5	3	6	4	4	7	3	7	8
Improvement in oral hygiene needed (%)	44	18	54	27	58	52	58	56	64
High frequency of sugar intake (%)	11	12	14	10	10	11	11	10	14
Patient reported outcomes (%)									
Pain	15	14	15	14	15	17	14	18	21
Diet restrictions	11	11	9	10	11	13	13	16	20
Unhappiness with appearance	26	23	26	26	26	27	30	31	33
Any patient reported concerns	40	36	38	39	39	42	43	46	52
More than one patient reported concerns	11	9	10	10	11	12	11	15	18

ABL: Alveolar bone loss ; Bleeding on Probing: BoP, either present (+) or absent (-) ; PPD: periodontal probing depth

*not including wisdom teeth

Table 2: Probabilities (and 95% CI) of reporting various outcomes by periodontal parameters. Adjusted for age, sex, smoking status, diabetic status, number of teeth with restorations, number of teeth needing restorations, oral hygiene, dental attendance, abrasion, grinding habits, frequency of sugar intake and salivary flow rate.

	Periodontal Parameters							
Adjusted probability (%) of reporting	**I (PPD < 5mm, ABL < 2mm, BoP –)**	**II (PPD < 5mm, ABL < 2mm, BoP +)**	**III (PPD < 5mm, ABL 2-4mm, BoP –)**	**IV (PPD < 5mm, ABL 2-4mm, BoP +)**	**V (PPD 5-7mm, ABL 2-4mm, BoP +/-)**	**VI (PPD < 5mm, ABL >4mm, BoP +/-)**	**VII (PPD 5-7mm, ABL >4mm, BoP +/-)**	**VIII (PPD >7mm; ABL >4mm, BoP +/-)**
Oral pain	13.8 (12.4-15.2)	13.9 (12.7-15.2)	14.9 (13.4-16.4)	15.0 (13.7-16.3)	17.3 (15.2- 19.3)	13.7 (11.5-16.0)	17.7 (15.1- 20.3)	20.7 (17.2- 24.2)
Restricted diet	10.8 (9.5- 12.0)	9.7 (8.5- 10.8)	9.5 (8.3-10.7)	11.2 (10.1-12.4)	12.5 (10.7- 14.3)	12.1 (10.0-14.2)	15.5 (13.1- 17.9)	19.2 (15.9- 22.5)
Unhappiness with appearance	22.2 (20.6- 23.8)	24.5 (23.0- 26.1)	26.6 (24.8- 28.4)	26.0 (24.4- 27.6)	27.3 (24.8-29.8)	31.7 (28.6-34.8)	32.5 (29.4- 35.6)	34.3 (30.3- 38.4)
Reporting any concerns	35.6 (33.7-37.4)	37.2 (35.5-39.0)	39.1 (37.1-41.4)	39.1 (37.3-40.9)	42.3 (39.6-45.0)	43.8 (40.5-47.1)	46.7 (43.4-50.0)	52.4 (48.2-56.7)
Reporting more than one concern	9.2 (8.1-10.4)	9.6 (8.5-10.7)	9.9 (8.7-11.2)	10.8 (9.6-11.9)	12.2 (10.4-14.0)	11.4 (9.3-13.5)	15.3 (12.8-17.7)	17.5 (14.3-20.8)

ABL: Alveolar bone loss ; Bleeding on Probing: BoP, either present (+) or absent (-) ; PPD: periodontal probing depth

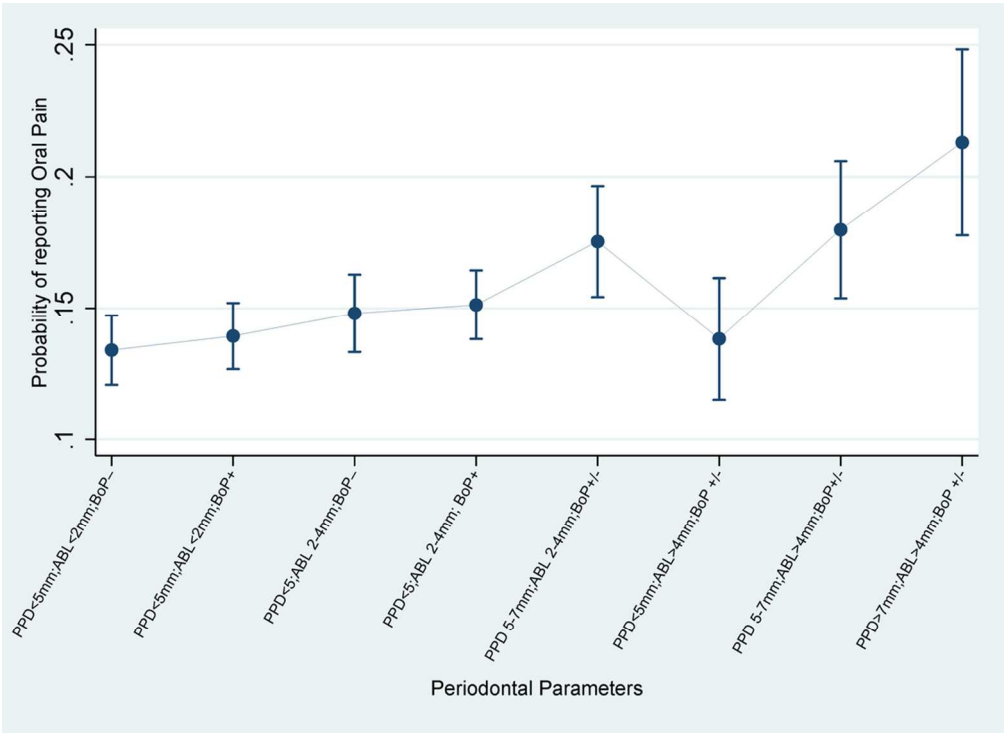

Figure 1) Probability of reporting oral pain Vs Periodontal parameters
ABL: Alveolar bone loss ; Bleeding on Probing: BoP, either present (+) or absent (-) ; PPD: periodontal probing depth

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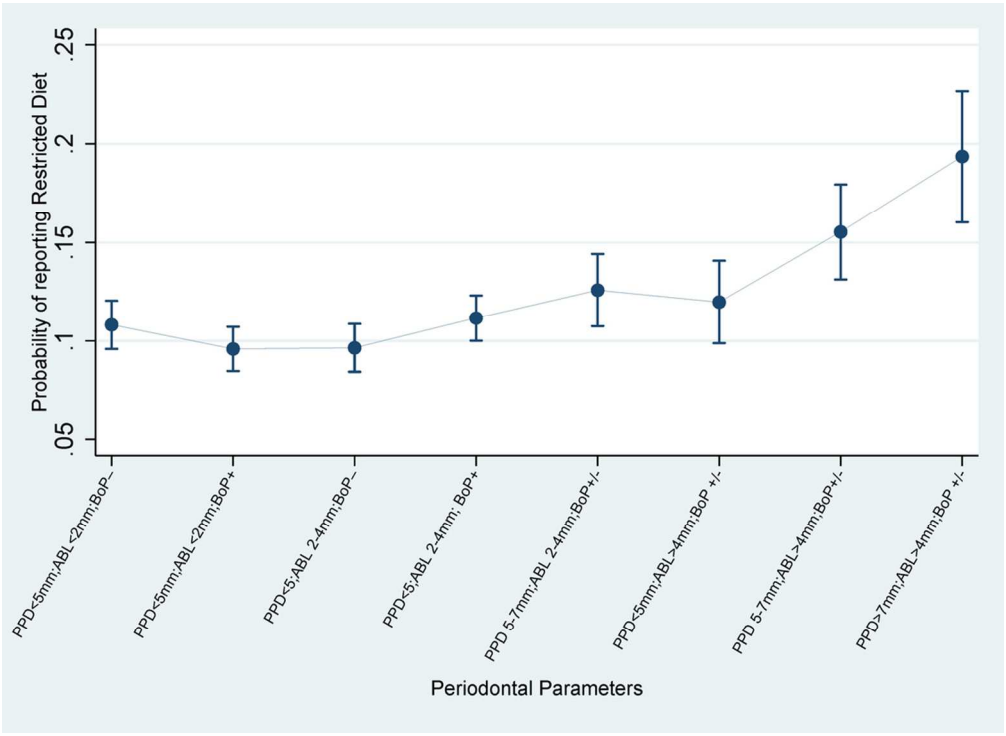

Figure 2) Probability of reporting restricted diet Vs Periodontal parameters
ABL: Alveolar bone loss ; Bleeding on Probing: BoP, either present (+) or absent (-) ; PPD: periodontal probing depth

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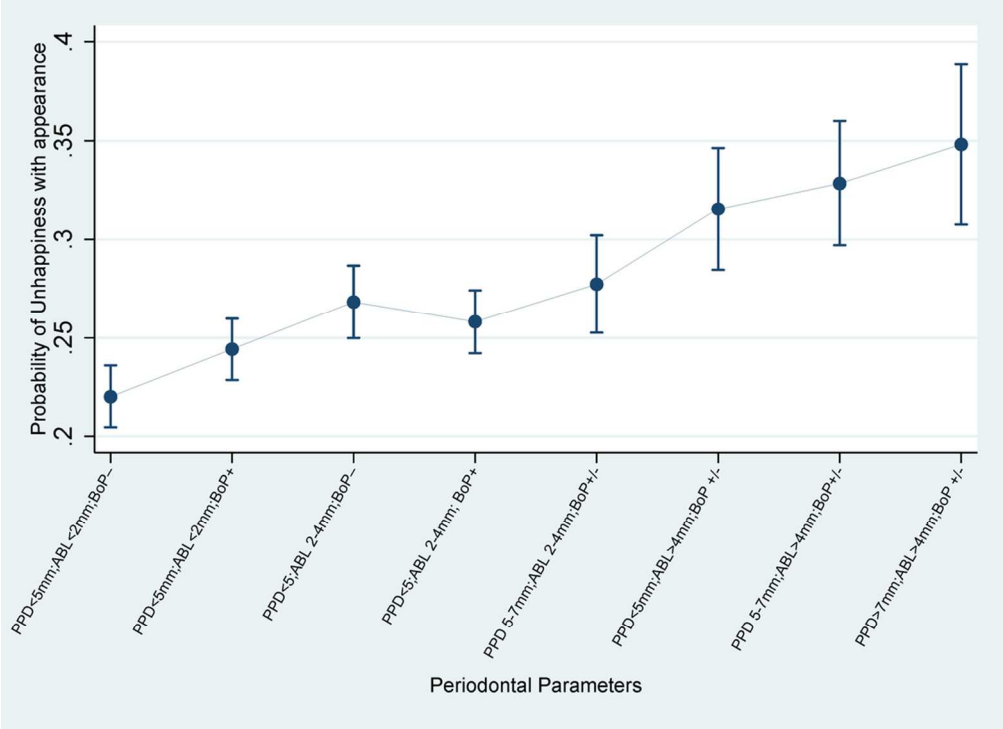

Figure 3) Probability of reporting unhappiness with appearance Vs Periodontal parameters
ABL: Alveolar bone loss ; Bleeding on Probing: BoP, either present (+) or absent (-) ; PPD: periodontal probing depth

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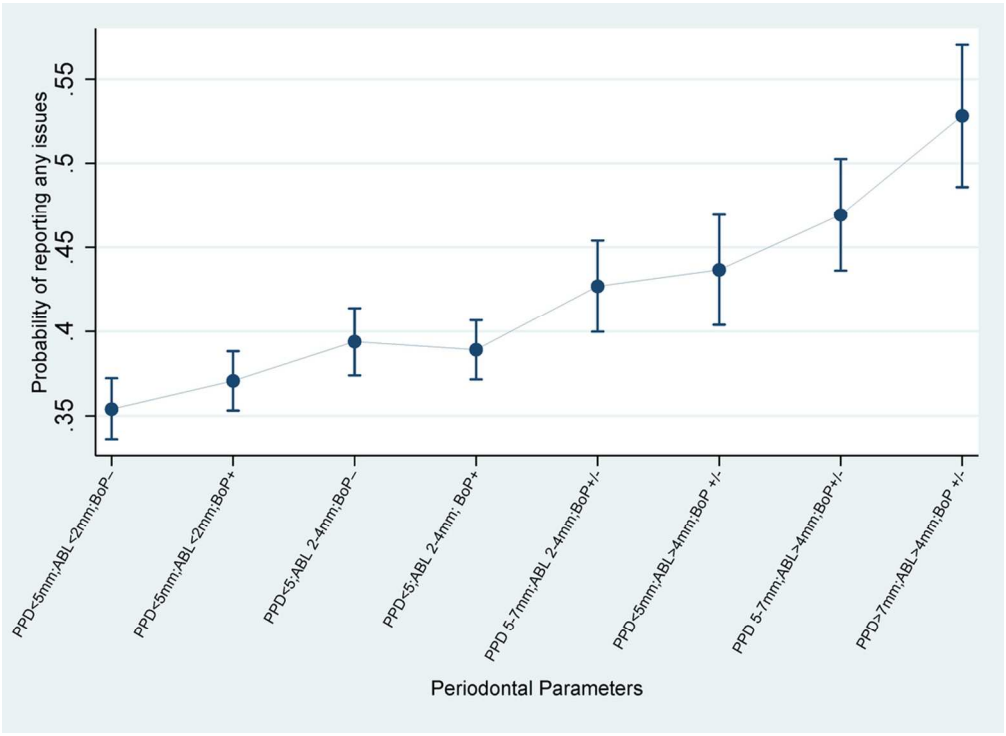

Figure 4) Probability of reporting oral pain or restricted diet or unhappiness with appearance Vs Periodontal parameters
ABL: Alveolar bone loss ; Bleeding on Probing: BoP, either present (+) or absent (-) ; PPD: periodontal probing depth

101x73mm (300 x 300 DPI)

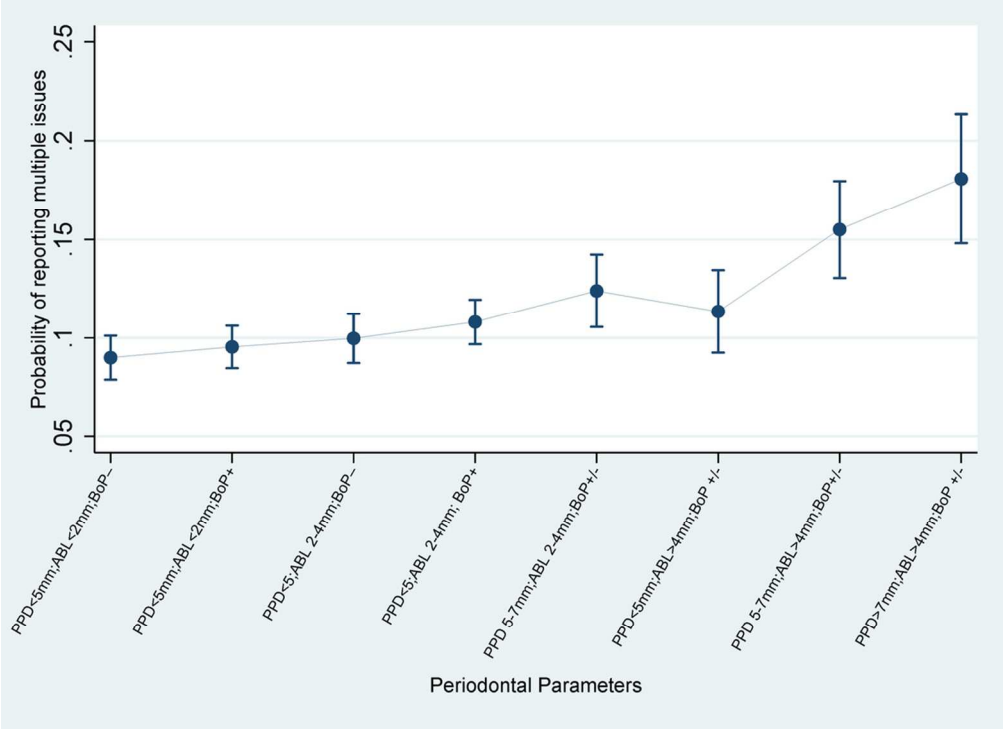

Figure 5) Probability of reporting more than one of oral pain or restricted diet or unhappiness with appearance Vs Periodontal parameters
ABL: Alveolar bone loss ; Bleeding on Probing: BoP, either present (+) or absent (-) ; PPD: periodontal probing depth

101x73mm (300 x 300 DPI)