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Title: CARIES PREVENTION IN ORTHODONTICS - HIGH-FLUORIDE VARNISH PERFORMANCE IN VIVO IN PREVENTING WHITE SPOTS LESIONS

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Abstract: Objective: To evaluate the efficacy of a fluoridated varnish in preventing white spot lesions in fixed orthodontics patients via a laser-induced fluorescence device, by determining any correlations between the degree of demineralization and length of observation period, arch sector, frequency of varnish application, and specific tooth site.
Methods: A split-mouth study was performed on 24 orthodontic patients, allocated randomly to two subgroups with differing frequencies of Duraphat varnish application. Repeated measures of the degree of demineralization were taken on the vestibular surface of 12 teeth (6 varnished and 6 unvarnished controls). Measurements were taken at 4 sites using a DIAGNOdent Pen 2190 laser, and then subjected to statistical analysis.
Results: Generalized linear model and coefficient model analysis showed a difference in the degree of demineralization between treated and untreated teeth, but this was not statistically significant in terms of time point, frequency of application or specific tooth site. However, when we analysed the position of the teeth, the varnished anterior teeth showed a statistically significant reduction in demineralization with respect to their unvarnished counterparts.
Conclusions: Periodic application of fluoride varnishes can offer some protection against white spot onset, but not to a statistically significant degree if patients have excellent oral hygiene control.

Title Page

CARIES PREVENTION IN ORTHODONTICS – HIGH-FLUORIDE VARNISH PERFORMANCE IN VIVO IN PREVENTING WHITE SPOTS LESIONS

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HIGHLIGHTS

- Fluoridated varnish can be used to prevent caries lesions, even in during orthodontic treatment
- The frequency of application does not change the trend of protection against caries
- If oral hygiene is excellent, fluridated varnish doesn’t significantly reduce the vestibular demineralization around brackets

CARIES PREVENTION IN ORTHODONTICS – HIGH-FLUORIDE VARNISH PERFORMANCE IN VIVO IN PREVENTING WHITE SPOTS LESIONS

ABSTRACT

Objective: To evaluate the efficacy of a fluoridated varnish in preventing white spot lesions in fixed orthodontics patients via a laser-induced fluorescence device, by determining any correlations between the degree of demineralization and length of observation period, arch sector, frequency of varnish application, and specific tooth site.

Methods: A split-mouth study was performed on 24 orthodontic patients, allocated randomly to two subgroups with differing frequencies of Duraphat varnish application. Repeated measures of the degree of demineralization were taken on the vestibular surface of 12 teeth (6 varnished and 6 unvarnished controls). Measurements were taken at 4 sites using a DIAGNOdent Pen 2190 laser, and then subjected to statistical analysis.

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Conclusions: Periodic application of fluoride varnishes can offer some protection against white spot onset, but not to a statistically significant degree if patients have excellent oral hygiene control.

INTRODUCTION

Enamel demineralization in the form of white spot lesions is a serious complication of orthodontic treatment[1]. White spot lesions are essentially areas of porous surface enamel induced by carious demineralization, and present as milky-white opaque spots on the smooth surface of the tooth.[2] White spots are more prevalent in fixed orthodontics patients than in those never fitted with brackets, and although they rarely progress to caries, they are unsightly and may cause aesthetic issues even years after the end of treatment.[3]

The prevalence of white spots in orthodontic treatment has been reported as 38% after 6 months and 46% after 12 months, as compared to the 11% seen in the control group.[4] The increased risk of developing white spot lesions during orthodontic treatment is due to an over-accumulation of plaque around the brackets,[5] which is partially attributable to the hindered access and reduced self-detersion capacity[6] that fixed orthodontics patients experience, as well as reduced patient compliance.

Patients, parents, orthodontists and general dentists alike have similar perceptions of white spots, and feel that the patients themselves are mainly to blame for their onset.[7] Indeed, white spots can be reduced or prevented by improving oral hygiene, lowering dietary carbohydrate intake, and applying topical fluoride. The safety of fluoride use has been amply demonstrated[8] and various means of topical application have been proposed. These comprise gels, mouthwashes and varnishes, but many such strategies require high patient compliance to be efficacious.

One method of topical fluoride application that does not rely heavily on patient compliance is fluoride varnish, which makes it particularly appealing in non-compliant patients and those who are not self-reliant. Studies[9-11] analysing the efficacy of one brand, Duraphat (Colgate-Palmolive Company, New York, NY), on the tooth surfaces adjacent to labial brackets have shown that it is able to lower the risk of decalcification at these sites by 48 to 50%. However, much of the research to date has mainly been conducted on extracted teeth or over limited periods in vivo, generally ranging from 1 to 3 months.

Nevertheless, one totally in vivo study with a longer follow up, of 6 months, conducted by Demito et al.,[12] showed a similar and significant reduction (50%) in white spot onset, but that it was not able to eliminate this risk completely. The authors concluded that the varnish should be reapplied every 12 weeks.

The purpose of the present study is to evaluate in vivo the efficacy of Duraphat in preventing white spot onset over a longer period, 12 months, in fixed orthodontics patients (upper and lower braces) with the aid of a laser fluorescence. In particular, we aimed to determine whether the degree of demineralization varies in function of:

1. The length of treatment (T0–T4, 12 months)
2. The location of the tooth (anterior, medial and posterior) at the four time points considered (3, 6, 9 and 12 months)
3. The frequency of Duraphat application (3-monthly and 6-monthly)
4. The specific tooth site (gingival, occlusal, mesial and distal).

MATERIALS AND METHODS

24 consecutive patients, all scheduled for fixed orthodontic treatment at a private dental clinic, were selected for this study. The sample as a whole consisted of 10 males and 14 females of mean age 14 years 1 month. Inclusion criteria were as follows: complete permanent dentition up to first molars, no vestibular caries or fillings, no hypocalcified teeth, no dental fluorosis, and no endocrine disorders (e.g., diabetes)

A split-mouth study was conducted, applying the varnish to quadrants 1 and 3, using quadrants 2 and 4 as untreated controls. Opposing quadrants were chosen to eliminate any bias resulting from handedness, which can affect the uniformity of brushing accuracy. The 6 varnished and the 6 control teeth were the central incisors, the canines, and the second premolars, i.e., teeth from each of the upper and lower anterior, medial, and posterior sectors.

The patients were randomly assigned to two subgroups according to the frequency of Duraphat application: **Group 1**, comprising 13 patients (5 males and 8 females), to whom Duraphat was applied every 3 months, and **Group 2**, comprising 11 patients (5 males and 6 females), to whom Duraphat was applied every 6 months. Four to seven days before bonding, both groups were given a professional scale and polish, together with a hygiene motivation session. All patients were also provided with a hygiene kit that contained a medium-bristle toothbrush (Sunstar Gum, Chicago, IL).

Prior to bonding, the 24 subjects' teeth were cleaned via pumice stone and brush mounted on a low-velocity contra-angle handpiece, and the degree of enamel mineralization of all sample and control teeth was measured using a DIAGNOdent Pen 2190 (KaVo, Biberach an der Riß, Germany).

The DIAGNOdent Pen 2190 (Figure 1) contains a diode laser of wavelength 655 nm and power < 1 mW. It is able to detect small alterations in the tooth substance, invisible to the naked eye, up to a depth of 2 mm. According to the literature,[13-19] DIAGNOdent has great specificity and accuracy, comparable to that of visual-tactile examination and radiography (identifying 70%–80% of lesions), as compared to histology testing, provided that it is used on clean teeth (without tartar build-up) and in the absence of fluoridated substances. The DIAGNOdent Pen 2190 measures the fluorescence emitted by the tooth in response to irradiation of a certain wavelength; a reading of between 0 and

13 indicates healthy enamel, 14 and 20 initial demineralization, 21 and 29 considerable demineralization, and >30 dentinal caries.

The laser was calibrated for each patient as per the manufacturer's guidelines, and readings were taken at four labial sites on the enamel (gingival, occlusal, mesial and distal) as suggested by Banks and Richmond[20] (Figure 2). Initial values (T0) were recorded in the patients' dental records.

Following the initial readings, medical-grade steel brackets, self-ligating Damon Q (Ormco Corporation, Orange, CA), were bonded to the teeth by means of a light-cured composite. The dental arcades were then isolated, and the vestibular surfaces dried and treated. Duraphat (5% sodium fluoride) was applied to the vestibular enamel, around the brackets of teeth 11, 13, 15, 31, 33 and 35 using a microbrush (Figure 3). After roughly 5 minutes of hardening time had elapsed, the patient was instructed how to perform oral hygiene procedures and asked to refrain from eating or drinking for 4 hours, as the manufacturer recommends.

In follow-up visits, the degree of mineralization of the enamel was measured as follows: the vestibular surfaces of all teeth were cleaned using a brush mounted on a low-velocity contra-angle handpiece, and the residual varnish removed via an Air Polishing System (TPC Advanced Technology, City Of Industry, CA) to prevent it being read as a false positive. The fluorescence emitted at the four sites, each 1 mm from the bracket, was measured on all sample and control teeth using the DIAGNOdent pen 2190 (Figure 4), and then the Duraphat varnish was reapplied, as per the manufacturer's instructions, on the teeth in the first and third quadrants. Measurements were taken and fluoride varnish re-applied at 3, 6, 9 and 12 months from appliance fitting (T1, T2, T3 and T4, respectively) in **Group 1**, and at 6 and 12 months from bonding (T2 and T4, respectively) in **Group 2**. All patients were given a fresh hygiene kit (including toothbrush) every 3 months, and a professional scale and polish every 6 months.

All measurements furnished by the DIAGNOdent were recorded on a Microsoft Excel spreadsheet (Microsoft Corporation, Redmond, WA), and the significance of any differences was evaluated by the chi-square test at a significance level of $p<0.01$. General linear model was used, as the measurements displayed non-Gaussian distribution. Coefficient plots were also generated in order to illustrate the significance of each value with respect to the reference (Intercept).

RESULTS

The total number of measurements taken was 4704, 3120 in Group 1 (3-monthly Duraphat application) and 1584 in Group 2 (6-monthly Duraphat application). Table 1 shows the number of measurements taken and mean values for the degree of mineralization at T1–T4 in treated and untreated teeth, while Table 2 shows the mean readings taken at the 3 sectors (anterior, medial and posterior) in treated and untreated teeth, and Table 3 shows the average readings in sites treated or not every three months and every six months.

Figure 5 and Table 4 show the greater tendency towards demineralization in untreated versus treated teeth, although both linear and coefficient analysis showed that the difference was not significant at any of the four measurement time points (3, 6, 9 and 12 months).

Going on to verify whether the position of the tooth in function of the observation period can influence the degree of demineralization, we show that the differences between treated and untreated teeth are not statistically significant, except for at the anterior teeth. Specifically, at 9 months, the treated incisors showed a significantly lower degree of demineralization with respect to the unvarnished anterior teeth (Figures 6, 7 and 8, Tables 5, 6 and 7).

Considering the teeth treated at 6 and 12 months, there was no statistically significant difference when the product was applied twice or four times a year (Figure 9, Table 8).

Finally, at the 12-month time point, there were no statistically significant differences in the degree of demineralization between treated and untreated teeth at any of the four test sites (gingival, occlusal, mesial and distal) in function of the length of treatment, although our figures indicate that the gingival portion is slightly more susceptible to demineralization (Figure 10, Table 9).

DISCUSSION

The white spot lesions surrounding orthodontic brackets are a significant clinical problem during and after orthodontic treatment, influencing the aesthetical appearance of the teeth.

Once white spots have arisen, conservative measures may be necessary. However, a recent systematic review of the literature[21] has revealed that there is little scientific evidence of the efficacy of enamel remineralization strategies applied after orthodontic treatment. In fact, although the remineralizing capacity of fluoride is widely accepted, its real-world efficacy is still debatable. Indeed, remineralization strategies involving gels, dentifrices and mouthwashes, for example, are reliant on patient compliance, and their success may be also be jeopardized by low fluoride concentration in the products themselves.[22] Although combining casein with fluoride in such products, to increase absorption of the latter, does appear to increase remineralization to a certain extent,[23] such a strategy is not able to eliminate white spot lesions completely. Hence, a preventative, rather than reparative, strategy seems to be a desirable option, something that orthodontists should bear in mind before commencing treatment.

Factors that influence the choice of preventative strategy include patient safety, efficacy, ease of use, and patient acceptance. Among the various means of topical application, flouride varnishes are simple to use and do not depend on patient cooperation.

Clinical trials that compared the efficacy of fluoridated products containing a high fluoride concentration (22600 ppm sodium fluoride) with respect to placebo varnishes containing no fluoride, involving the recruitment of over 2700 children, have provided evidence of their great capacity to inhibit caries formation in both permanent and deciduous teeth. Despite some variation in the percentages reported in these trials, they are at between 38% and 46%.[24] That being said, other studies have demonstrated that, although such products offer good protection, they cannot entirely prevent demineralization.[25]

Our assessment of the efficacy of Duraphat in preventing white spot onset in orthodontic patients over the course of 12 months showed that, despite an overall lack of statistical significance, teeth treated with this fluoride varnish do seem to present a lower degree of demineralization than untreated teeth (Figure 5). Statistical significance was, however, reached in the anterior teeth (Figure 6), thereby confirming reports by Divaris[26] that such a strategy is efficacious.

However, our findings differ from those yielded by the randomized clinical trial conducted by Stecksén-Blicks[25], who found a statistically significant reduction, but not elimination, of white spot onset in treated with respect to untreated teeth when the varnish was applied every 6 weeks. We, on the other hand, found no statistically significant difference between 3-monthly and 6-monthly application of fluoride varnish (Figure 9).

Our research does, however, confirm observations by Demito[12] that the gingival site is that most susceptible to demineralization, although not significantly so (Figure 10). Indeed, despite a trend in our results showing that the fluoride varnish in question offers substantial protection, this failed to reach either statistical (except in the anterior sector) or clinical significance, as DIAGNOdent readings remained below the caries threshold. In fact, the main factor influencing our results may have been the fact intensive hygiene monitoring our patients, only being recruited for one orthodontic study, were subjected to. It may be, therefore, that results would have differed had non-compliant patients been included or less attention been paid to oral hygiene. Furthermore, we used a split-mouth approach, and, in theory at least, fluoride ions released from the varnish, may have affected control areas of the dentition.

Nevertheless, it is likely that the application of fluoride in varnish form may be a valuable aid in protecting against enamel decalcification in situations without careful hygiene monitoring (non self-reliant patients, physical impediment to brushing, or a lack of adequate oral hygiene education), as previously reported by Arruda[27]. To determine to what extent topical fluoride varnishes can prevent caries formation during orthodontic treatment in such patients, however, more studies designed to reflect this particular situation are required.

CONCLUSIONS

• Periodic application of fluoride varnishes tends to protect against white spot onset, but not significantly so in patients with excellent oral hygiene control.

• The protection offered by this fluoride varnish is statistically significant in both the upper and lower anterior teeth (central incisors), but not in the medial or posterior sectors.

• No further protection is conferred by applying the product every 3 months with respect to every 6 months.

• Fluoride varnishes, together with other prevention strategies, may be a useful aid to enamel protection in non-compliant patients (disability or poor hygiene education).

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FIGURE LEGENDS

Figure 1. Calibrating the DIAGNOdent Pen 2190

Figure 2. Dividing the tooth surface to evaluate enamel demineralization, as proposed by Banks and Richmond[20]

Figure 3. Application of Duraphat fluoride varnish on the labial surface of tooth 11

Figure 4. Measuring the degree of mineralization at the occlusal site of tooth 11 using the DIAGNOdent pen

Figure 5. Coefficient plot: treated and untreated teeth at the 4 observation time-points

Figure 6. Coefficient plot: degree of demineralization of treated and untreated incisors over time

Figure 7. Coefficient plot: degree of demineralization of treated and untreated canines over time

Figure 8. Coefficient plot: degree of demineralization of treated and untreated second premolars over time

Figure 9. Coefficient plot: degree of demineralization in function of treatment frequency

Figure 10. Coefficient plot: degree of demineralization of treated and untreated teeth by sampling site at 12 months

Figure 1

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Figure 2
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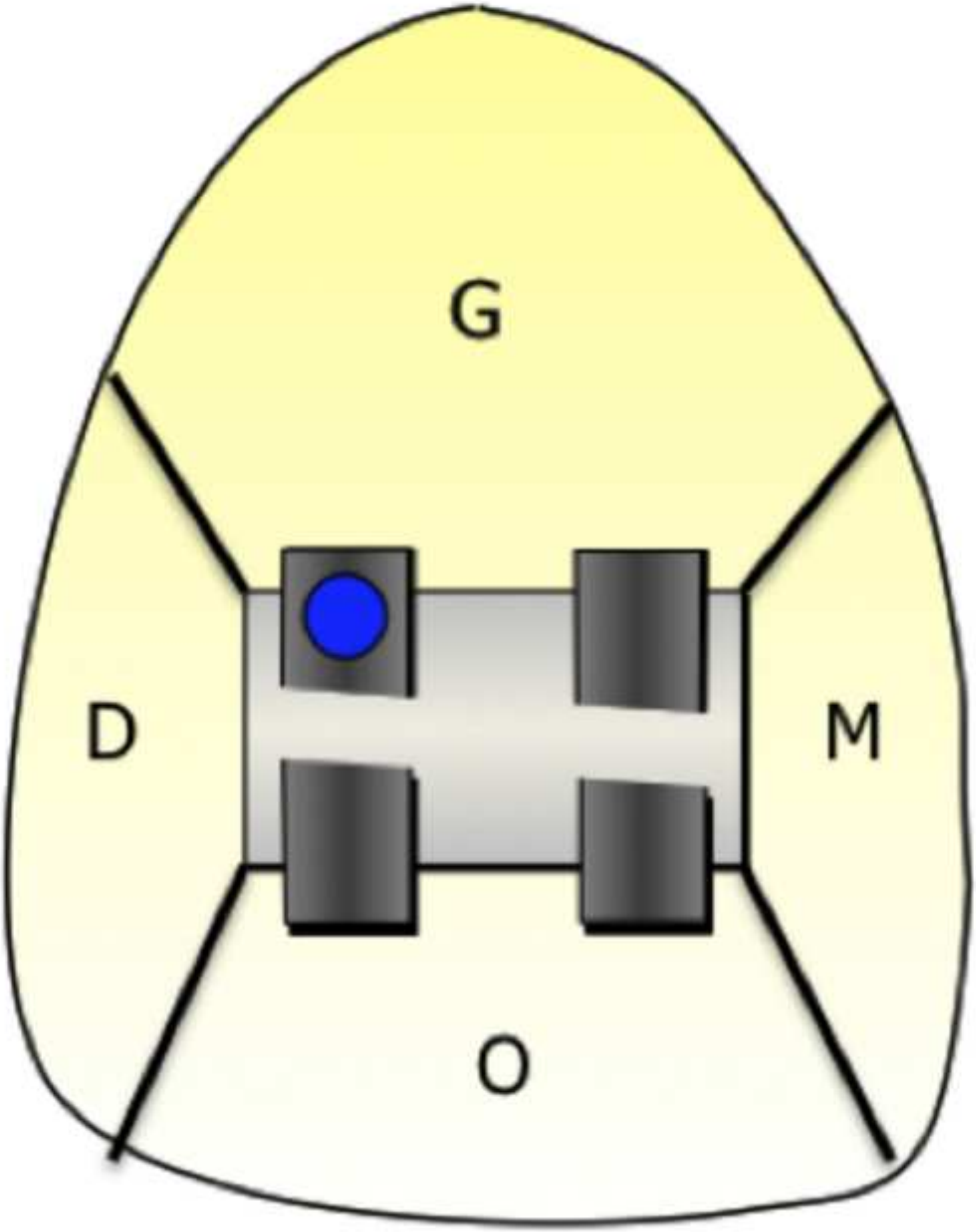

Figure 3
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Figure 4

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Figure 5

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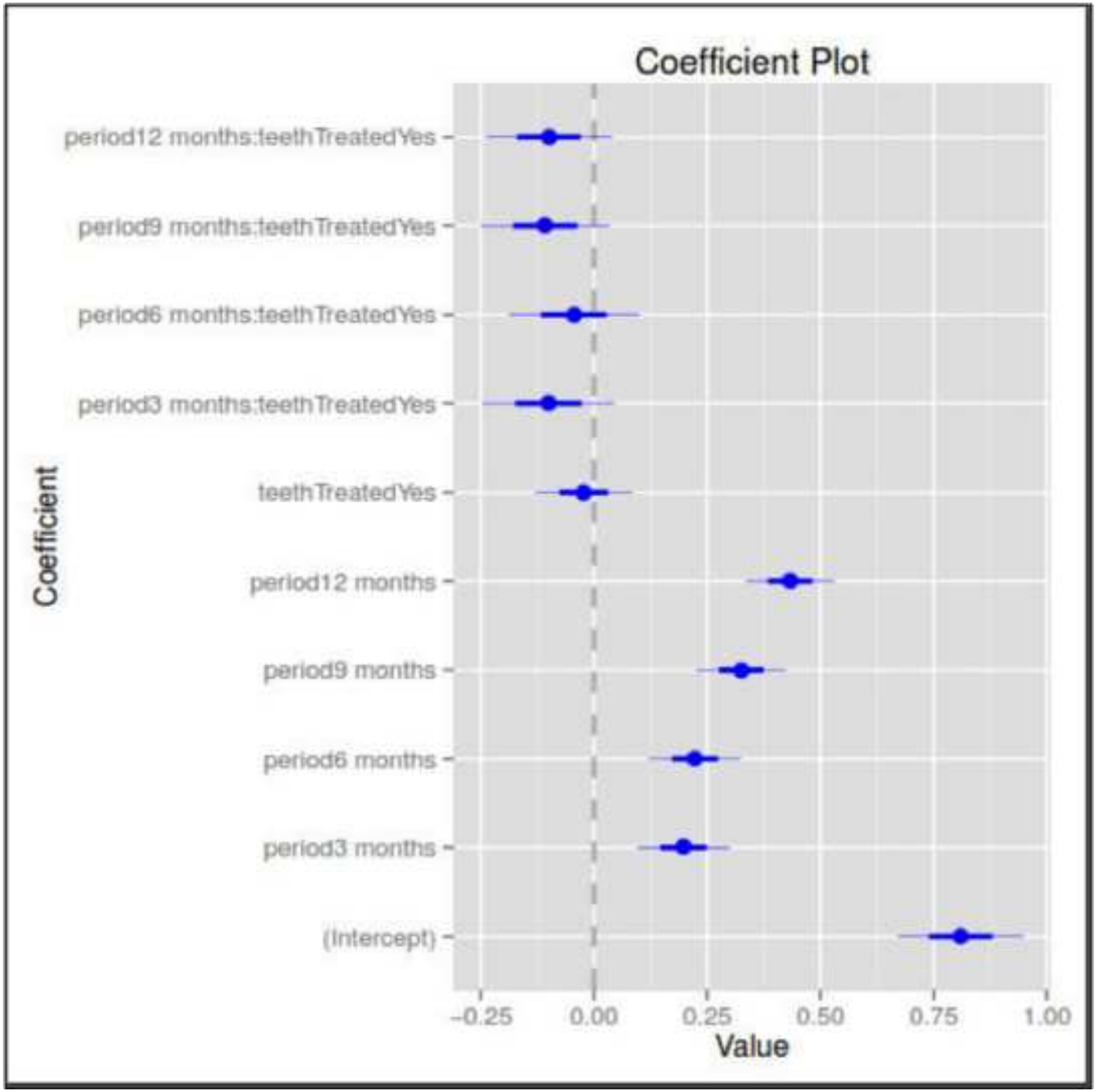

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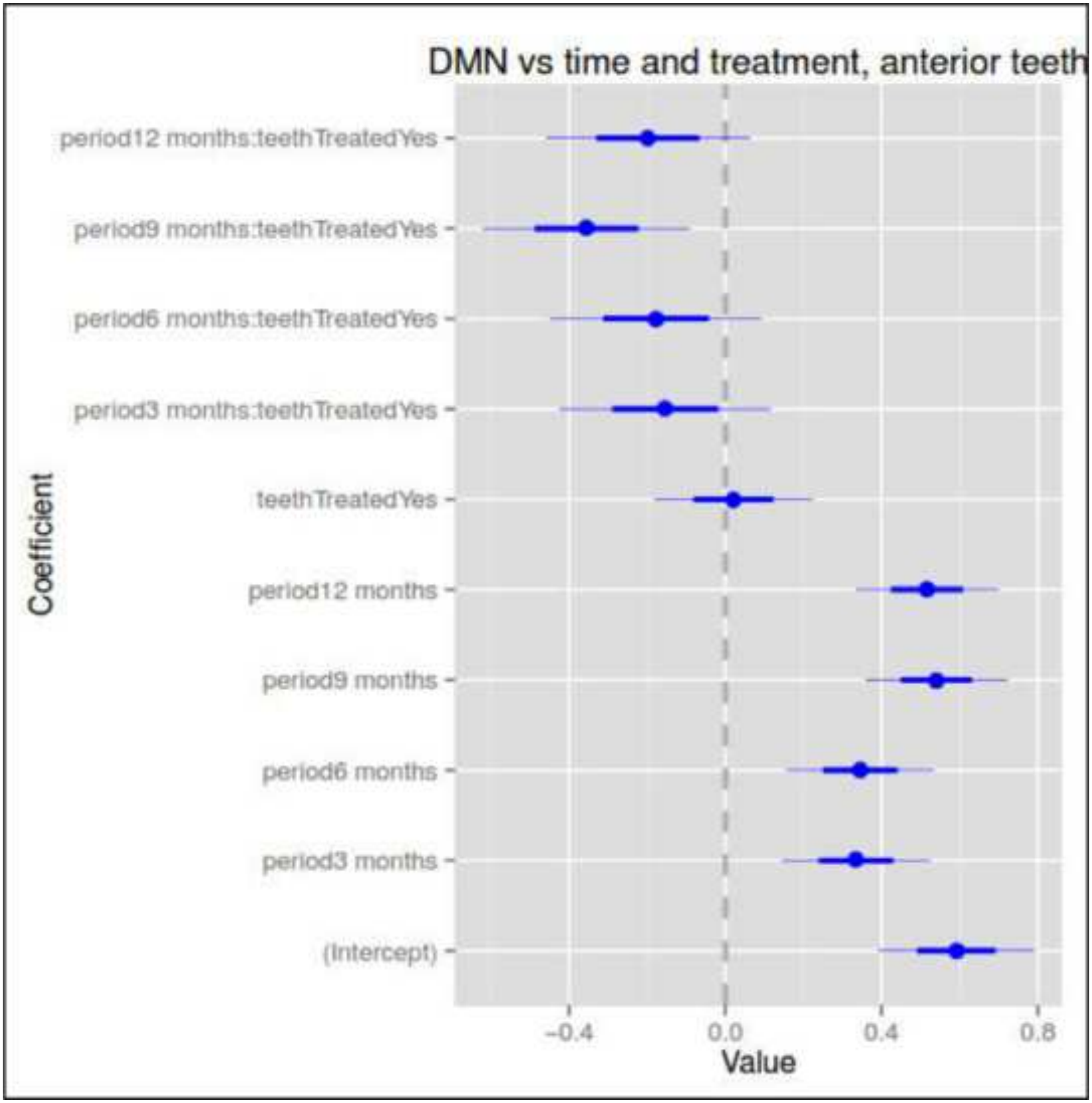

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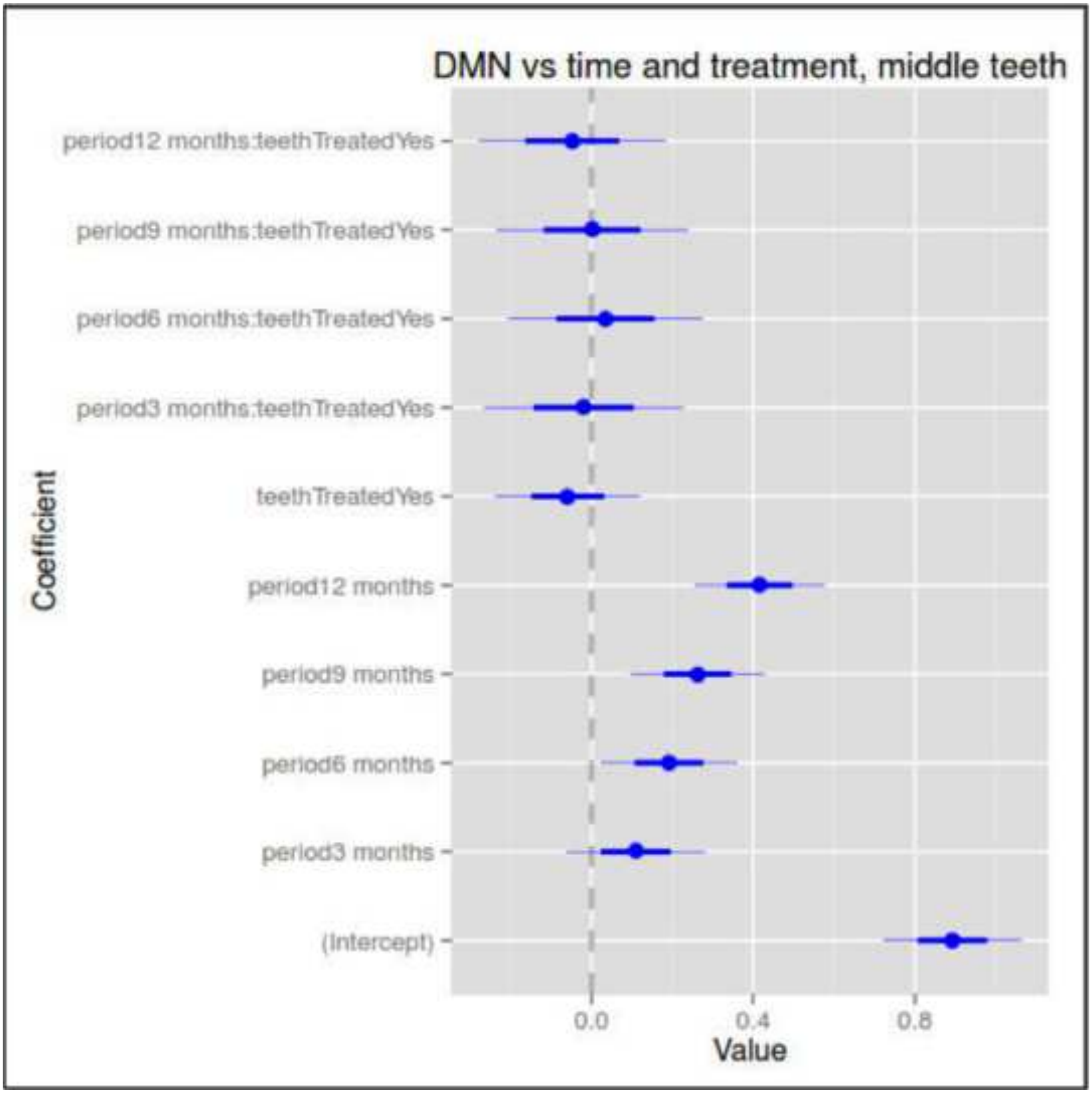

Figure 8

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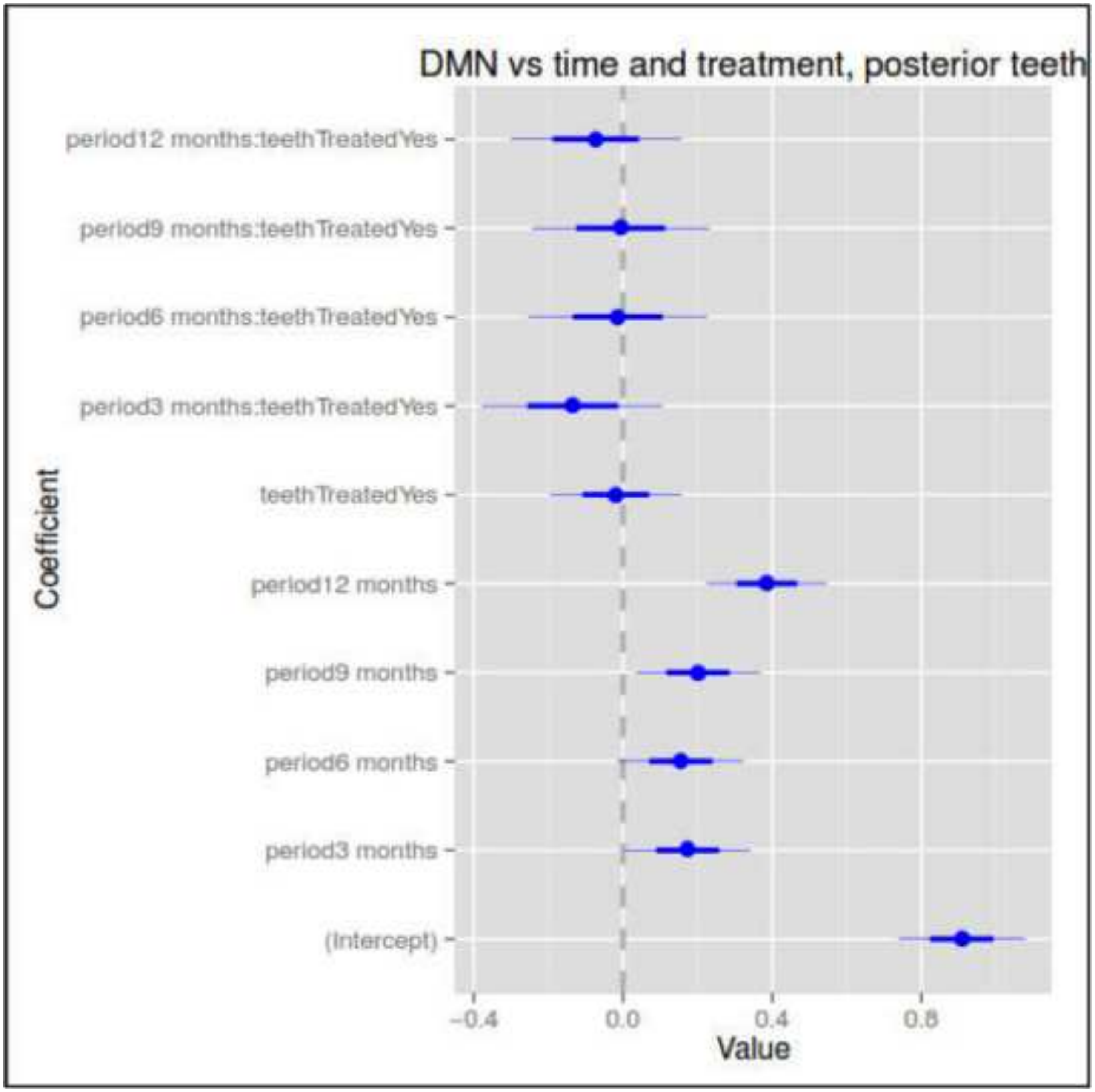

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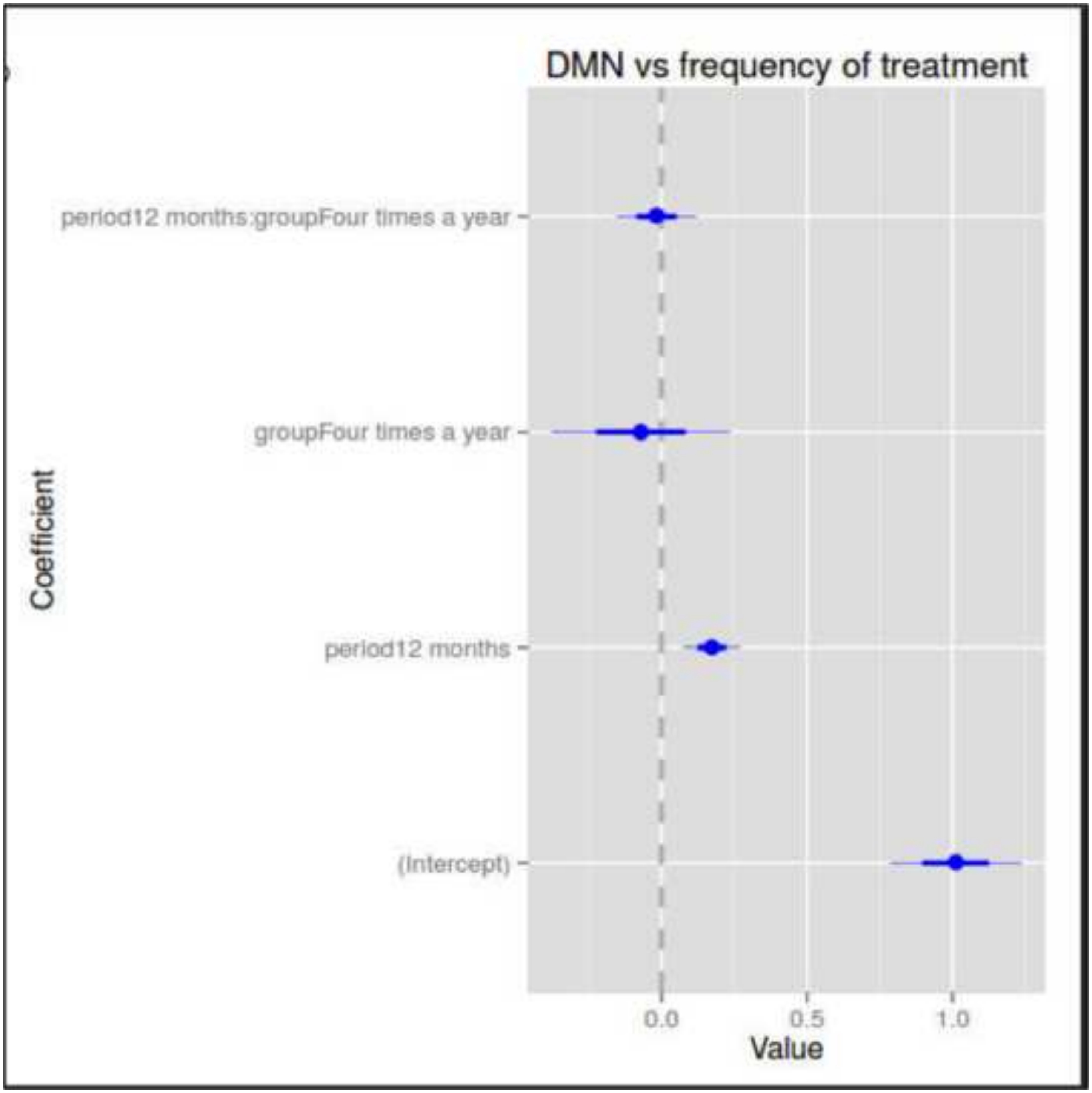

Figure 10
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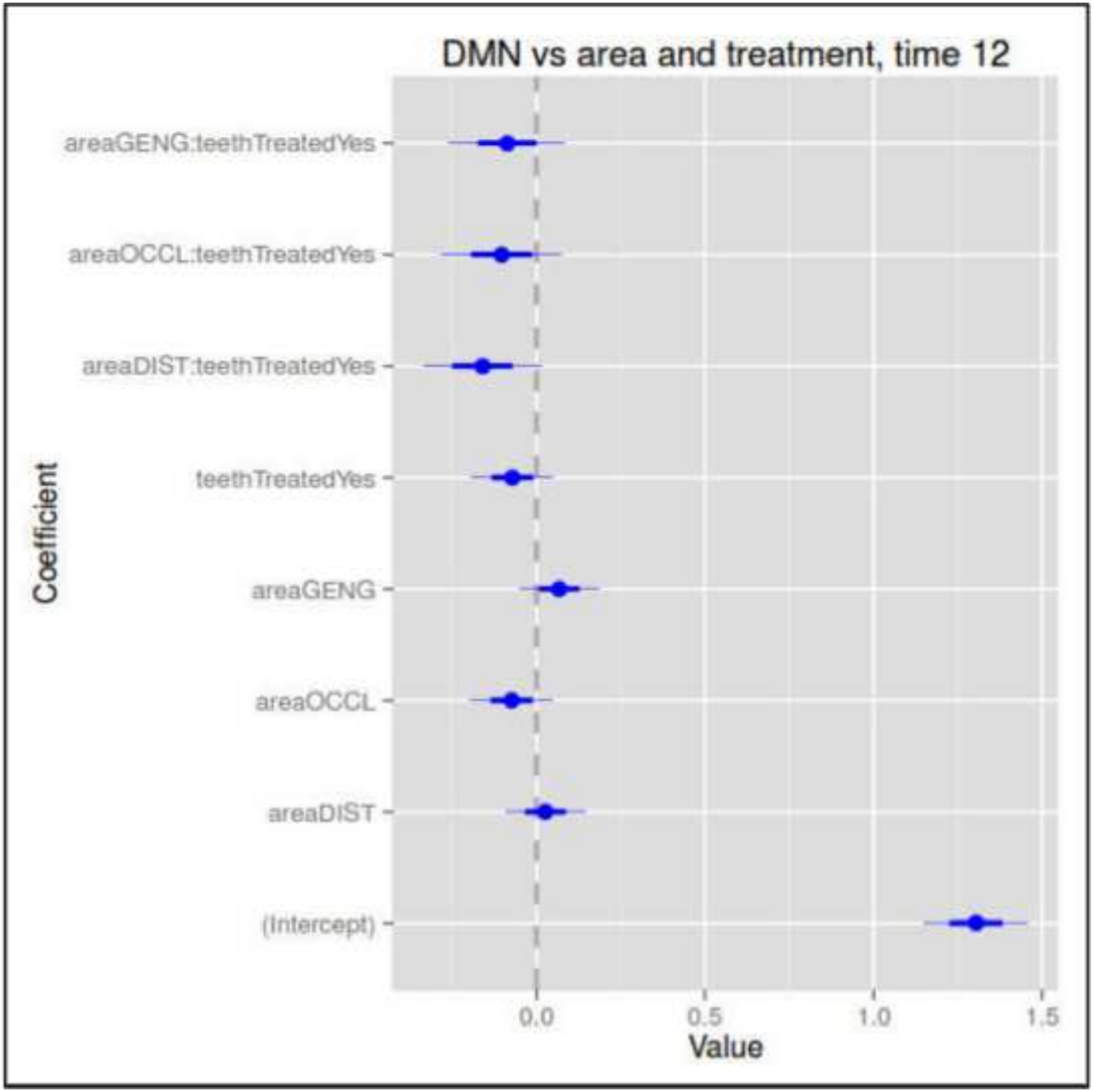

Table 1.

Total number of measurements and average demineralization readings over the observation period for treated and untreated teeth

Time point	N. of observations	Average	SD
T0 (pre-treatment)			
Treated teeth	576	2.11	0.93
Untreated teeth	576	2.19	0.97
T1 (3 months)			
Treated teeth	312	2.48	0.97
Untreated teeth	312	2.80	1.30
T2 (6 months)			
Treated teeth	576	2.83	1.92
Untreated teeth	576	2.92	1.70
T3 (9 months)			
Treated teeth	312	2.79	1.20
Untreated teeth	312	3.19	1.76
T4 (12 months)			
Treated teeth	576	3.33	1.97
Untreated teeth	576	3.91	2.12

SD indicates Standard deviation

Table 2

Table 2.
Number of measurements and average demineralization values for treated and untreated teeth across the three dental sectors

Sector	N. of observations	Average	SD
Anterior			
Treated teeth	784	2.28	1.28
Untreated teeth	784	2.76	1.80
Middle			
Treated teeth	784	2.90	1.64
Untreated teeth	784	3.08	1.67
Posterior			
Treated teeth	784	3.00	1.76
Untreated teeth	784	3.17	1.73

SD indicates Standard deviation

Table 3.
Number of measurements and average demineralization values for treated and untreated teeth by application frequency

Application frequency	N. of observations	Average	SD
3-monthly			
Treated teeth	1560	2.67	1.39
Untreated teeth	1560	2.94	1.65
6-monthly			
Treated teeth	792	2.83	1.96
Untreated teeth	792	3.12	1.91

SD indicates Standard deviation

Table 4

Table 4.
Correspondence between degree of demineralization, length of treatment, and treatment

	Chi-square	Df	Pr (+ χ^2)
Reference value	138.63	1	0.0000
Length of treatment	90.51	4	0.0000
Treated teeth	0.18	1	0.6710
Treated teeth / Length of treatment	3.49	4	0.4792

*p< 0.01

Table 5

Table 5.
Correspondence between degree of demineralization, treatment, and length of treatment in the anterior sector

	Chi-square	Df	Pr (+ χ^2)
Reference value	80.71	1	0.0000
Length of treatment	12.83	1	0.0003
Treated teeth	0.22	1	0.6420
Treated teeth / Length of treatment	0.007*	1	0-7978

*p< 0.01

Table 6

Table 6.
Correspondence between degree of demineralization, treatment, and length of treatment in the medial sector

	Chi-square	Df	Pr (+ χ^2)
Reference value	110.91	1	0.0000
Length of treatment	32.11	4	0.0000
Treated teeth	0.45	1	0.5042
Treated teeth / Length of treatment	0.61	4	0.9624

*p< 0.01

Table 7

Table 7.
Correspondence between degree of demineralization, treatment, and length of treatment in the posterior sector

	Chi-square	Df	Pr (+ χ^2)
Reference value	118.15	1	0.0000
Length of treatment	24.75	4	0.0001
Treated teeth	0.05	1	0.8268
Treated teeth / Length of treatment	1.98	4	0.7386

*p< 0.01

Table 8.
Correspondence between degree of demineralization and treatment application frequency

	Chi-square	Df	Pr (+ χ^2)
Reference value	35.40	1	0.0000
Application frequency/Length of treatment	43.57	4	0.0000
Treated teeth	0.04	1	0.8397
Treated teeth /Application frequency/Length of treatment	7.58	4	0.1083

*p< 0.01

Table 9.
Correspondence between degree of demineralization, treatment and sampling site

	Chi-square	Df	Pr (+ χ^2)
Reference value	288.68	1	0.0000
Sampling site	5.87	3	0.1181
Treated teeth	1.41	1	0.2346
Sampling site: Treated teeth	3.47	3	0.3246

*p< 0.01

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Angela Arreghini Angela Arreghini 23/04/2015