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Influence of two caries-detecting devices on clinical decision-making/lesion depth for suspicious occlusal lesions: a National Dental PBRN randomized trial

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Abstract

Background—A suspicious occlusal caries lesion (SOCL) can be defined as a lesion with no cavitation and no radiographic radiolucency, but where caries is suspected. This study evaluated

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The authors declare no conflict of interest and that none have any business or financial interests in the corporations that manufacture or market the Spectra[®] or DIAGNodont[®] devices. The devices used in this study were purchased using grant funds.

Disclosure

None of the authors reported any disclosures.

whether using a device changed: (1) the percentage of SOCLs that were opened surgically; and (2) among those SOCLs that were opened, the proportion that had penetrated into dentin.

Methods—Eighty-two dentists participated. In phase 1 of the study, dentists identified approximately 20 SOCLs, obtained patient consent, and recorded information about the lesion, treatment(s), and depth, if opened. Dentists were then randomized into one of three groups: no device, DIAGNOdent[®], and Spectra[®]. In phase 2, dentists enrolled approximately 20 additional patients, and recorded the same phase 1 information, while using the assigned device to help make their treatment decisions. A mixed-model logistic regression was used to determine any differences after randomization in the proportion of lesions opened and, if opened, the proportion of lesions that penetrated into dentin.

Results—1500 SOCLs were enrolled in each phase. There was no statistically significant difference in the change in proportion of lesions receiving invasive treatment from phase 1 to phase 2 across the three groups ($p=0.33$) or in the change in proportion of percent of opened lesions that extended into dentin ($p=0.31$).

Conclusion—Caries detecting devices in the study did not change significantly dentists' decisions to intervene or the accuracy of the intervention decision in predicting lesion penetration into dentin.

Practical implications—The caries detecting devices tested may not improve dentists' clinical decision-making for SOCLs.

Keywords

practice-based research; questionable lesions; multi-center studies; clinical research; dental caries; Evidence-based dentistry; caries; dentin

INTRODUCTION

Suspicious occlusal caries lesions (SOCLs) can be characterized as initial caries lesions on occlusal surfaces of posterior permanent teeth that have no cavitation and no radiographic evidence of caries, but the presence of a carious lesion is suspected due to roughness, surface opacities, or staining. Such lesions may be difficult to detect^{1–5} and often present a diagnostic challenge because of the difficulty in determining if the lesion has penetrated into dentin^{3, 6–7}. Not surprisingly, the lack of clarity regarding the presence and activity of dentinal caries associated with SOCLs leads to uncertainty among dentists over how to manage these lesions. A previous study conducted by the National Dental Practice-Based Research Network (“network”), found the prevalence of these lesions was 34%, and that almost one-half of the lesions on which practitioners performed invasive procedures did not penetrate clinically into the dentin⁸.

Dentists' uncertainty about the management of SOCLs has been reflected in the introduction of, and, anecdotally, the rapid uptake of caries detection devices. Many dentists are turning to these devices hoping that they will provide more certainty, i.e., that they will accurately identify the SOCLs where caries is present and has penetrated into the dentin. The most-recent systematic review of these devices, in 2013, concluded that there is only limited

evidence supporting their use as adjuncts to clinical decision making⁹. A systematic review of the most popular device found that its specificity in the detection of enamel lesions was low, meaning that many enamel lesions were incorrectly classified as penetrating the dentin¹⁰. Inadequate specificity can lead to “false positives” and unnecessary surgical intervention, which has continued to concern those who evaluated its performance^{11–13}.

Previous studies of the performance of these devices were limited to assessing their performance (sensitivity, specificity, ROC analyses) *in vitro*, and less often, *in vivo* in an academic setting, i.e., not in a typical clinical practice setting. Outcomes obtained during their routine daily use by practicing dentists have never been explored. Thus, the utility of a diagnostic device to improve the accuracy with which dentists detect caries and assess its degree of penetration, is unknown. Furthermore, the extent to which the devices result in dentists making more-appropriate management decisions is equally unclear. Currently, two of the more-popular caries detecting devices are the DIAGNOdent® (laser fluorescence technology) and Spectra® (fluorescence technology that produces Doppler-like images). The purpose of this study was to evaluate whether using one of these devices changed: (1) the percentage of SOCLs that the dentist opened surgically; and (2) among those SOCLs that the dentist opened, the proportion that had penetrated into dentin.

METHODS

The results presented here were generated as part of a larger study conducted in dental practices affiliated with the network. The network is a consortium of dental practices and dental organizations, established to answer questions raised by dental practitioners in everyday clinical practice and to evaluate the effectiveness of strategies to prevent, manage and treat oral diseases and conditions^{14–15}. The network includes dental health care providers (general dentists, dental specialists, and hygienists).

Selection and recruitment process

Network practitioners were recruited by Regional Coordinators (RC) through letters and announcements sent to licensed practitioners from the six participating regions (Western, Midwest, Southwest, South Central, South Atlantic, and Northeast). To be eligible for this study, practitioners had to complete an Enrollment Questionnaire (EQ), attend an orientation session or watch a video of it, and complete their training in human subjects' protection. The EQ, which is publicly available at <http://nationaldentalpbrn.org/enrollment.php>, collects information about practitioner, practice, and patient characteristics. Once practitioners completed the requirements, the RC provided a training session with the practitioner and staff that included an overview of the study, steps to complete the necessary forms, and answered any questions they had related to the study. The network's applicable Institutional Review Boards approved the study; all participants provided informed consent after receiving a full explanation of the procedures.

Study Design

This 3-arm randomized clinical trial was divided into two phases. In phase 1, if a patient presented with a SOCL on a permanent molar, was 6 years of age or older, and consented (or

if a minor, assented, in conjunction with parental/guardian consent) to participate in the study, the practitioner completed data collection and patient characteristics forms. These forms included specific information about the patient and lesion. Lesion characteristics queried included luster (chalky or shiny), color (opaque, white spot, yellow/light brown, dark brown/black, or other), and roughness of the surface with the use of an explorer (did not use an explorer, yes roughness, or no roughness). Practitioners also documented the final treatment plan, which included monitoring, oral hygiene instruction, applying or prescribing fluoride, sealant (with no tooth structure altered), enameloplasty, preventive resin restoration, or full restoration. If practitioners indicated that the lesion was opened surgically, lesion depth and activity [no caries, inactive/arrested caries, active caries (E1), active caries (E2), active caries (D1), active caries (D2), active caries (D3)] were also recorded. Practitioners recorded risk factors of the patient, such as other caries, restorations in the previous three years, heavy plaque, high cariogenic diet, inadequate saliva flow, and infrequent/unpredictable recall intervals. The practitioners then categorized their patients as “low” or “elevated” caries risk. Additionally, practitioners were provided sample photographs of SOCL lesions as well as examples of stepwise removal of SOCL lesions to illustrate how to determine maximum penetration into enamel or dentin. Practices enrolled approximately 20 patients with lesions in phase 1.

For phase 2, practitioners were randomized into one of three treatment arms: no device, Spectra[®], or DIAGNOdent[®]. Practitioners enrolled approximately 20 patients with lesions (different patients than in phase 1) and collected the same information as in phase 1. If assigned to a device group, practitioners also recorded the device reading.

Practitioners were randomized by the Coordinating Center into one of three treatment arms using stratified permuted blocks of size 3. The randomization was stratified by region. This study was not masked. In the practitioner database the Coordinating Center provided the ordered list of random treatments (1–3) for each region (cohort). When the next randomization request was made, the practitioner was randomized into the next available slot. The randomization took place after the practitioners completed phase 1. Practitioners were not blinded and reported outcomes for the patients seen. Practitioners who were randomized into a device group, trained on the device using materials supplied by the manufacturer, and were free to consult with other users if they so desired. The only difference between the arms was the use of a device and the recording of the device reading. The Spectra[®] has a range of 0–5 with 2 or higher suggestive of dentinal caries¹⁶. The DIAGNOdent[®] has a range of 0–99 with 25 or higher indicating the possibility of dentinal caries¹⁷. Examples of the data collection forms are available at <http://nationaldentalpbrn.org/study-results/decision-aids-for-the-management-of-suspicious-occlusal-carries-lesions.php>. There were no methods or outcomes changes after the trial commencement.

Statistical Methods

The primary analysis used mixed-model logistic regression to compare rates of invasive treatment and of lesion extension into dentin in phases 1 & 2 among the three study groups accounting for clustering of patients within dentists. Analysis of lesion extension into dentin included data for opened lesions only. Odds ratios for phase, study group and the two-factor

interaction were calculated. Analyses were conducted using SAS® Release 9.4 statistical software.

Power was estimated with adjustments for analysis of two outcome variables and for the effect of cluster randomization. The unit of randomization was the practitioner. Power estimates were based on effective sample sizes, accounting for the design effect, with values of intraclass correlation (ICC) ranging from 0.0 to 0.05.

Power was estimated for each of the two study outcomes: the proportion of all SOCL that are opened and the proportion of opened SOCL that are carious. The planned recruitment of 30 practitioners per group, each enrolling 20 patients during study phase 2, would yield a total sample size of 600 lesions per group for the first outcome. The expected rates of lesion opening were 50% for no device and 30–35% for the device groups. The planned sample size would provide approximately 92% power to detect a difference in rates of opening of lesions, assuming the most restrictive set of conditions considered (opening rates of 50% vs 35%, ICC = 0.05). Power would exceed 80% even if 10% of practitioners were to contribute no data.

Power for the second study outcome depends on the numbers of lesions that the dentists choose to open. Based on the planned total enrollment and that 50% of lesions in the no-device group and 35% of lesions in the device groups would be opened, the sample sizes for this outcome would be 300 lesions for the no-device group and 210 lesions in each device group. Assuming that 50% of opened lesions in the no-device group would be carious and that ICC = 0.05, estimated power would be 97%, 84% and 56% for 65%, 70% and 75% of opened lesions in the device group being carious, respectively. Appendix A shows the effect size observed during phase 2.

Sample size

Power to detect differences between each of the device groups and the no-device group was approximated based on two-sided testing with the Chi-square statistic, with adjustments for multiple comparisons and for the effect of clustering within practitioner. A Bonferroni-type adjustment was used to account for two comparisons: no device versus each of the device groups.

RESULTS

Flow diagram of Practitioners

The CONSORT flow diagram (Figure 1) illustrates the enrollment, allocation, follow-up, and analysis of the practitioners in this study. The study began practitioner recruitment in April 2015 and practitioners were given approximately 4–6 weeks to enroll 20 patients in each of the two phases and the study ended in January 2016.

Practitioner, Patient, Lesion, Diagnostic, and Treatment Characteristics

Characteristics of the 82 dentists who participated in both phases of the study are shown in Table 1. Almost 2/3s (62%) of the practitioners were male, most were Non-Hispanic White

(72%) and graduated from dental school more than 15 years ago. Practices were distributed across all US regions, varying from 10% in the Midwest, to 21 % in the South Central.

As shown in Table 2, the mean age of patients, overall, was 32.9 years and ranged from 32.4 in phase 1 to 31.7 in phase 2 no device arm, 33.7 in the Spectra[®] arm, and 34.8 in the DIAGNOdent[®] arm. Approximately half of the lesions were chalky (55% for phase 1, 55% phase 2-no device, 68% Spectra[®]; and 48% DIAGNOdent[®]) and dark brown/black in color (48% for phase 1, 42% phase 2-no device, 53% Spectra[®]; and 48% DIAGNOdent[®]). A majority of the lesions in all the groups had surface roughness, ranging from 64% for the phase 2 no device group to 69% in the phase 2 DIAGNOdent[®] group. Approximately 1/3 of the patients were classified by their dentist as elevated risk with 35% for the phase 1 group, 28% in the phase 2-no device group, 41% in the phase 2 Spectra[®] group; and 30% in the phase 2 DIAGNOdent[®] group. The mean (SD) Spectra[®] reading was 1.5 (0.5) and 28 (20.5) for the DIAGNOdent[®] arm.

Lesions Receiving Invasive Treatment

The three groups did not differ significantly from phase 1 to phase 2 in the percentage of lesions that were treated invasively (Table 3). The dentists who did not use a caries detecting device in phase 2 had a small increase in the percent of lesions opened, from 41% to 47%. Those using the Spectra[®] device had a smaller increase, while those using the DIAGNOdent[®] device had a larger increase. Similarly, there was no statistical difference among the three groups in the change in percent of opened lesions where caries had penetrated into the dentin between phases 1 & 2 (Table 3). The dentists who did not use a caries detection device in phase 2 had a small increase in lesions with caries into the dentin, 62% to 66%. Dentists using the Spectra[®] device had a somewhat larger increase, and dentists using the DIAGNOdent[®] device had a one percentage point decrease.

DISCUSSION

Diagnosing caries is a process that involves three steps: detecting the lesion, determining the depth of the lesion and assessing the activity status of the lesion. This process provides the foundation for selecting the most-appropriate treatment for the lesion in the context of the patient's oral health situation. Numerous studies have shown that the accuracy of traditional methods of SOCL detection and penetration is less than perfect, in that some enamel lesions receive invasive treatment and some progressing dentinal lesions do not. As one means of improving accuracy of detection and diagnosis processes, the profession is exploring the use of detection devices. The studies using these caries detecting devices have been done in either *in vitro* or in *in vivo* studies that were not representative of typical clinical practice, and yielded varying results. Performing studies in practice settings can provide insights into the effectiveness and utility of these devices¹⁴ and possibly predict the outcomes in other general dental practices.

Prior to this current study, there was very sparse literature regarding the Spectra[®] device. Markowitz, et al¹⁸ conducted a study using the Spectra[®] device to determine the device's ability to assess early dental caries in sealed teeth and monitor sealed teeth for caries progression. The findings indicated a high sensitivity under clear sealant but lower

sensitivity for opaque sealants. Our study evaluated SOCLs with no evidence of sealant and no alteration of the tooth's surface.

An *in vivo* study that evaluated the effectiveness of DIAGNOdent® displayed a high sensitivity (88%) compared to visual (79%) and tactile (53%) methods¹⁹. The sensitivity for DIAGNOdent® in the current study was similar to that found in other studies^{20–22}.

Nevertheless, in this study there was no significant difference between practitioners using this device and practitioners using Spectra® or no device in change from phase 1 to phase 2 in either the proportion of lesions opened, or the proportion of opened lesions that extended into the dentin. It would seem that while these devices offer additional information for dentists to use in making treatment decisions, the information does not significantly alter those decisions. Either the information duplicates, parallels, or reinforces the information dentists bring to the decision process through oral examination and their own experience, or dentists are disregarding the information provided by the devices when it runs counter to dentists' findings and experience.

This study has limitations, as it investigated diagnosis and treatment as delivered in routine, "real world" clinical practice and, therefore, made no attempt to standardize or calibrate that diagnosis or treatment. Each practice was trained specifically for this study, so as to standardize the data collection process, but no effort was made to standardize diagnostic or treatment methods for SOCLs – in fact, such standardization would not be desirable because an objective of the study was to determine the distribution of the characteristics of these lesions given the diagnostic methods that dentists normally use in routine practice.

Two other factors, years since graduation from dental school and age of the patient, were also analyzed, although these were not part of the original aim of the study. Years since graduation from dental school (< 5 years, 5–15 years, and >15 years) was not associated with the decision to treat the lesions invasively ($p = 0.37$). Additionally, the percent of lesions with caries into dentin was also not associated with years since graduation ($p=0.25$). Patient age category (<19 years and >19 years) was significantly associated with the rate of invasive treatment ($p<0.0001$), with lower rates of invasive treatment among patients >19 years than in those <19 years of age overall (unadjusted rates 0.33 and 0.71, respectively). The difference in rates between age categories was somewhat larger during phase 1 of the study (0.29 vs 0.70) than during phase 2 (0.38 vs 0.73, interaction $p = 0.019$). However, age of the patient was not a predictor of lesions extending into dentin ($p=0.25$).

This study evaluated the use of caries detection devices designed to improve dentists' diagnostic decisions for SOCLs. As other studies have found, the percentage of SOCLs that has not penetrated into dentin that is nonetheless treated invasively, is unsettling. Many of these lesions will not progress, and operative treatment is unnecessary. Unfortunately, dentists' use of the caries detecting devices did not alter the rate at which such unnecessary treatment occurred. Greater efforts must be made to develop methods, mechanisms, and protocols designed to reduce inappropriate invasive treatment.

CONCLUSIONS

Our results indicate that the two caries detecting devices examined in this study did not significantly change dentists' decisions to intervene surgically or the proportion of lesions they opened that exhibited caries penetrating into dentin. The additional information provided by these devices does not improve SOCL treatment decisions.

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Appendix A

Effect sizes observed during phase 2. Mean differences, standardized differences and odds ratios

Invasive Treatment/Phase 2 Only						
contrast	Difference *	se	Effect Size	Odds Ratio	95%CI_L	95%CI_U
DIAGNOdent® vs No Device	-0.0179	0.3502	0.05	0.98	0.50	1.95
Spectra® vs No Device	0.0195	0.4107	0.05	1.02	0.46	2.28
DIAGNOdent® vs Spectra®	-0.0374	0.3750	0.10	0.96	0.46	2.01
Extension Into Dentin/Opened Lesions Only/Phase 2 Only						
contrast	Difference *	se	Effect Size	Odds Ratio	95%CI_L	95%CI_U
DIAGNOdent® vs No Device	-0.1029	0.3486	0.30	0.90	0.46	1.79
Spectra® vs No Device	-0.1187	0.3859	0.31	0.89	0.42	1.89
DIAGNOdent® vs Spectra®	0.0157	0.3401	0.05	1.02	0.52	1.98

* Differences between least-squares means

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Figure 1.
CONSORT Flow Diagram

Table 1Distribution of characteristics of practitioners participating in phases 1 and 2^{*}

Practitioner Characteristic	Number (%)
Gender	
Male	51 (62)
Female	31 (38)
Race	
Non-Hispanic White	58 (72)
Non-Hispanic Black	6 (7)
Other	17 (21)
Missing	1 (0)
Years since graduation	
<5	5 (6)
5–15	17 (21)
>15	60 (73)
Region	
Western	12 (14)
Midwest	8 (10)
Southwest	17 (21)
South Central	17 (21)
South Atlantic	14 (17)
Northeast	14 (17)

^{*} 84 practitioners were randomized, but two did not participate in phase 2 (n=82)

Table 2

Patient, lesion, diagnostic, and treatment characteristics* (column %)

	Phase 1 N=1500	Phase 2 No device N=525	Phase 2 Spectra® N=444	Phase 2 DIAGNOdent® N=531	Total N=3000
Patient's Age					
<19 years	427 (28)	164 (31)	128 (29)	122 (23)	841 (28)
>19 years	1073 (72)	361 (69)	316 (71)	409 (77)	2159 (72)
Mean age (SD)	32.4 (17.4)	31.7 (17.3)	33.7 (18.7)	34.8 (17.3)	32.9 (17.6)
Patient's Gender					
Male	617 (41)	228 (43)	207 (47)	228 (43)	1264 (42)
Female	883 (59)	297 (57)	237 (53)	297 (57)	1736 (58)
Patient's Race					
White	1053 (75)	360 (73)	319 (79)	345 (73)	2077 (75)
Black	233 (17)	102 (21)	47 (12)	77 (16)	459 (16)
Other	111 (8)	33 (6)	39 (9)	54 (11)	237 (9)
Patient's Ethnicity					
Hispanic	234 (16)	89 (18)	73 (17)	80 (16)	476 (17)
Not Hispanic	1203 (84)	413 (82)	348 (83)	411 (84)	2375 (83)
Any dental insurance					
Yes	1267 (87)	474 (92)	372 (87)	439 (85)	2552 (87)
No	193 (13)	42 (8)	56 (13)	76 (15)	367 (13)
Patient's Education[‡]					
Less than high school diploma	20 (2)	2 (1)	5 (1)	11 (3)	38 (2)
High school graduate	140 (13)	52 (14)	46 (15)	75 (18)	313 (15)
Some college	367 (34)	118 (33)	75 (24)	135 (33)	695 (32)
Bachelor's degree	339 (32)	119 (33)	116 (37)	119 (29)	693 (32)
Graduate Degree	195 (18)	69 (19)	69 (22)	66 (16)	399 (18)
Decline to answer	12 (1)	1 (0)	5 (1)	3 (1)	21 (1)
Location					

	Phase 1 N=1500	Phase 2 No device N=525	Phase 2 Spectra® N=444	Phase 2 DIAGNOdent® N=531	Total N=3000
Molar	1143 (76)	414 (79)	316 (71)	402 (76)	2275 (76)
Premolar	355 (24)	111 (21)	128 (29)	129 (24)	723 (24)
Luster					
Chalky	823 (55)	288 (55)	302 (68)	254 (48)	1667 (56)
Shiny	676 (45)	237 (45)	142 (32)	277 (52)	1332 (44)
Color					
Yellow/light brown	603 (40)	225 (43)	174 (39)	208 (39)	1210 (40)
Dark brown/black	713 (48)	219 (42)	237 (53)	252 (48)	1421 (47)
Other	184 (12)	81 (15)	33 (7)	71 (13)	369 (12)
Surface roughness					
Yes	1027 (68)	334 (64)	301 (68)	368 (69)	2030 (68)
No	434 (29)	168 (32)	131 (30)	146 (28)	879 (29)
Did not use an explorer	39 (3)	23 (4)	12 (2)	17 (3)	91 (3)
Risk Factors^{***}					
Heavy plaque	261 (17)	102 (19)	64 (14)	99 (19)	526 (18)
Cariogenic diet	258 (17)	105 (20)	93 (21)	94 (18)	550 (18)
Infrequent recall	313 (21)	120 (23)	98 (22)	122 (23)	653 (22)
Xerostomia	28 (2)	9 (2)	8 (2)	13 (2)	58 (2)
None of the above	927 (62)	317 (60)	259 (58)	321 (61)	1824 (61)
Caries Risk Level					
Low	979 (65)	378 (72)	261 (59)	373 (70)	1991 (66)
Elevated	521 (35)	147 (28)	183 (41)	158 (30)	1009 (34)
Diagnostic Aids^{**}					
Dental explorer	1441 (96)	497 (95)	423 (95)	515 (97)	2876 (96)
Air drying	1415 (94)	522 (99)	431 (97)	497 (94)	2865 (96)
Magnification	999 (67)	107 (20)	303 (68)	325 (61)	2045 (68)
Radiographs	872 (58)	311 (59)	229 (52)	340 (64)	1752 (58)

	Phase 1 N=1500	Phase 2 No device N=525	Phase 2 Spectra® N=444	Phase 2 DIAGNOdent® N=531	Total N=3000
Invasive Treatment					
Non-invasive	885 (60)	277 (53)	226 (52)	276 (53)	1664 (56)
Invasive	603 (40)	246 (47)	213 (48)	248 (47)	1310 (44)
Lesion Depth, If Opened ***	N=566	N=227	N=207	N=221	N=1221
No Caries	20 (3)	6 (3)	6 (3)	4 (2)	36 (3)
Inactive Caries	41 (7)	11 (5)	13 (6)	10 (4)	75 (6)
Enamel	156 (28)	59 (26)	55 (27)	63 (29)	333 (27)
Dentin	349 (62)	151 (67)	133 (64)	144 (65)	777 (64)
Lesion Into Dentin ***					
Not dentin	217 (38)	76 (33)	74 (36)	77 (35)	444 (36)
Dentin	349 (62)	151 (67)	133 (64)	144 (65)	777 (64)
Device Reading					
Mean (SD)	NA	NA	1.6 (0.5)	28 (20.5)	NA

* Not all columns add up to the total N due to missing values. Percentages may not sum to 100 due to rounding

‡ For those >19 years of age

** Check all that apply; percentages are not additive

*** Opened, based on the question “When you treated the lesion, what did you find?”

Table 3

Percent (n) of lesions receiving Invasive^{*} treatment (n=1310)[†] and percent of lesions into dentin (n=1221)[‡] phases 1 and 2

Receiving invasive treatment	No Device	Spectra®	DIAGNOdent®	P-value
Phase 1	41 (204)	46 (214)	36 (185)	0.33
Phase 2	47 (246)	49 (213)	47 (248)	
Lesion into dentin				
Phase 1	62 (116)	58 (111)	66 (122)	0.31
Phase 2	66 (151)	64 (133)	65 (144)	

^{*}Invasive (sealant that alters tooth structure, enameloplasty, preventive resin restoration, full restoration)

[†]Not all columns add up to N due to missing values.

[‡]Not all columns add up to N due to missing values. 89 patients did not have depth recorded (1310–89=1221).