Duration and Timing of Sensitivity Related to Bleaching

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ABSTRACT

Problem: Reports of sensitivity vary greatly from one study to another, probably because studies are small. Generally, only the percentage of subjects is reported.

Purpose: This study reports sensitivity using a large database. We investigated the source, duration, and timing of sensitivity during 14 days of active bleaching.

Materials and Methods: One hundred and seventy-two people recorded sensitivity from any of the five sources on a daily basis.

Results: No one withdrew from the study because of sensitivity. Forty-seven percent of participants experienced sensitivity. Seventy-seven percent had sensitivity of 3 or fewer days. Temperature sensitivity tended to occur later in the 14-day bleaching cycle, and hot and cold sensitivity tended to occur together.

Conclusions: There was great variability in sensitivity levels from person to person. Temperature sensitivity tended to occur later in the active phase of bleaching, whereas irritation of the tongue tended to occur earlier.

CLINICAL SIGNIFICANCE

The results from a large group of people are more likely to include a wide cross-section of the population sampled. This data provides practitioners with a better estimate of what their patients are likely to experience. It is estimated that, during 2 weeks of active bleaching, 77% of people will experience 3 or fewer days of sensitivity. On average, sensitivity is short-lived, thus making it is easy to underestimate the importance of discussing sensitivity with patients considering bleaching. However, for some, the duration of sensitivity is much greater and has a very negative impact on satisfaction.

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INTRODUCTION

Historically, reports of sensitivity from study to study have varied from 0 to 100% of participants.[1,2] The great majority of people are able to tolerate tooth whitening well. Yet sensitivity related to tooth whitening is a critical problem for some participants. Schulte and colleagues found sensitivity was severe enough to cause 14% of the participants to discontinue bleaching.[3] Haywood, in a review of nightguard vital bleaching, estimated that sensitivity was a problem for two out of three people.[4] Studies generally ask participants whether or not they experienced sensitivity at some point during the trial and report the result as a percentage of the total number of subjects. Many studies report a percentage of subjects that experienced sensitivity from a specific source. Haywood and colleagues[5] found that 52% of subjects experienced tooth sensitivity and 31% experienced gingival sensitivity.

Leonard and colleagues[6] investigated the preoperative factors that might be used to predict the likelihood that someone would experience sensitivity during whitening and found that bleaching more than once per day was associated with sensitivity. This article is sometimes cited as demonstrating that preoperative sensitivity is a predictor of sensitivity during bleaching. However, it was not one of the factors studied. Rather, it was an opinion offered by the authors in the Discussion section. Participants bleached for 42 days. Among the data presented was a graph showing the percentage of participants who experienced sensitivity on each of the 42 days. The graph seems to show a definite trend for more sensitivity during the first 14 days and reduced sensitivity levels afterward. The authors did not perform any statistical analysis to determine if there was a significant correlation between sensitivity level and the day of active treatment. Other studies have also noted a trend for sensitivity to occur early. In a study including 3 weeks of active treatment and a 1-week follow-up, Jorgensen and Carroll[7] noted the same trend. Again, the study did not examine the data specifically to determine if there was a significant association. Haywood and colleagues[5] reported that sensitivity occurred early in bleaching treatment. As no specific data were presented, no statistical test was reported to substantiate the claim, and the comment was made in the Discussion section; one must interpret this solely as an opinion of the authors rather than a conclusion based on study results.

This is an observational study using a database of daily sensitivity reports from 172 people who participated in a large clinical trial. The authors investigated the percentage of research participants who experienced sensitivity, the duration of their sensitivity, and the relative frequency of sensitivity from five common sources over 14 days of active bleaching. In addition, the data were examined to determine if there was a pattern of sensitivity during active bleaching. Specifically, the data were tested to determine whether there was a significant correlation between sensitivity and day of active bleaching, 1 through 14.

MATERIALS AND METHODS

In a randomized, double-blind clinical trial, 172 people bleached their teeth for 14 days. Participants were instructed to use their assigned product 6 to 8 hours each night. Nine bleaching agents being studied as part of a product development project were tested. All used a 10% carbamide peroxide agent that contained various levels of potassium nitrate and sodium fluoride. The exact percentage of these additives was proprietary. A stent with reservoirs and scalloped just short of the gingival crest was fabricated for all participants. Color was evaluated at baseline, after 1 and 2 weeks of active bleaching, and 4 weeks after cessation of bleaching.

Each participant completed a daily log, in which he or she tracked his or her use of the whitening agent and the absence or presence of sensitivity from any of the five sources:

hot, cold, irritation of the gingiva, irritation of the tongue, or irritation of the throat. Logs were collected at evaluation appointments after 1 and 2 weeks of active treatment. Each category of sensitivity was tracked separately. Where sensitivity from more than one source occurred, each was recorded and counted. For example, if a participant experienced sensitivity to cold and gingival irritation on the same day, 2 days of sensitivity were recorded.

First, the data were examined to determine if all agents were effective whiteners, and they were (repeated measures analysis of variance [RM ANOVA] on ranks, Tukey post-hoc testing, $p < 0.05$). Next, the data were examined to determine if there was a significant difference in overall sensitivity level among the nine agents (ANOVA on ranks, $p = 0.33$). As there was not, the data were analyzed in the aggregate.

Descriptive statistics were performed, and because the data were not normally distributed, the 25th percentile, median, and 75th percentile were reported. To investigate the hypothesis of the study, a Pearson's product moment correlation procedure was performed to determine if there was a significant correlation between the day during the active bleaching phase, 1 through 14, and any of the five sources of sensitivity. As an additional observation, the data were recombined into two sources, hard tissue and soft tissue. As these data were found to be normally distributed, an RM ANOVA procedure was used.

TABLE 1. DISTRIBUTION OF OVERALL SENSITIVITY BY DAY.

Day	Number of Participants with No Sensitivity	Number of Participants with Sensitivity
1	163	18
2	165	32
3	165	41
4	157	42
5	163	39
6	163	38
7	166	35
8	162	38
9	164	44
10	169	40
11	167	36
12	163	47
13	159	40
14	159	35

For participants with sensitivity from multiple sources, each source was counted independently. For example, a participant who experienced both tooth and gingival sensitivity on the same day was included in the totals reported twice, rather than just once.

RESULTS

Ninety-one participants or 53% experienced no sensitivity from any source at any time, whereas 47% did experience sensitivity at some point. The distribution of the number of days of sensitivity among the participants was not normal. The median number of days that the participants experienced sensitivity was zero (25th percentile = 0.0, 75th percentile = 3.0). The mean (SD) number of days of sensitivity experienced by the group was 3.1 (5.3). The range was 0 to 28 days of sensitivity. Again, for participants who experienced tooth and gingival sensitivity on the same day, 2 days of sensitivity were recorded. Accordingly, even though bleaching was for 14 days only, an individual who experienced sensitivity from all five sources on each of the 14 days could record 70 days of sensitivity.

The distribution of overall sensitivity by day of active bleaching is shown in Table 1. As a group, these participants bleached their teeth 2,285 days or 95% of the maximum number of days possible. Of this total, 525 or 23% of all days

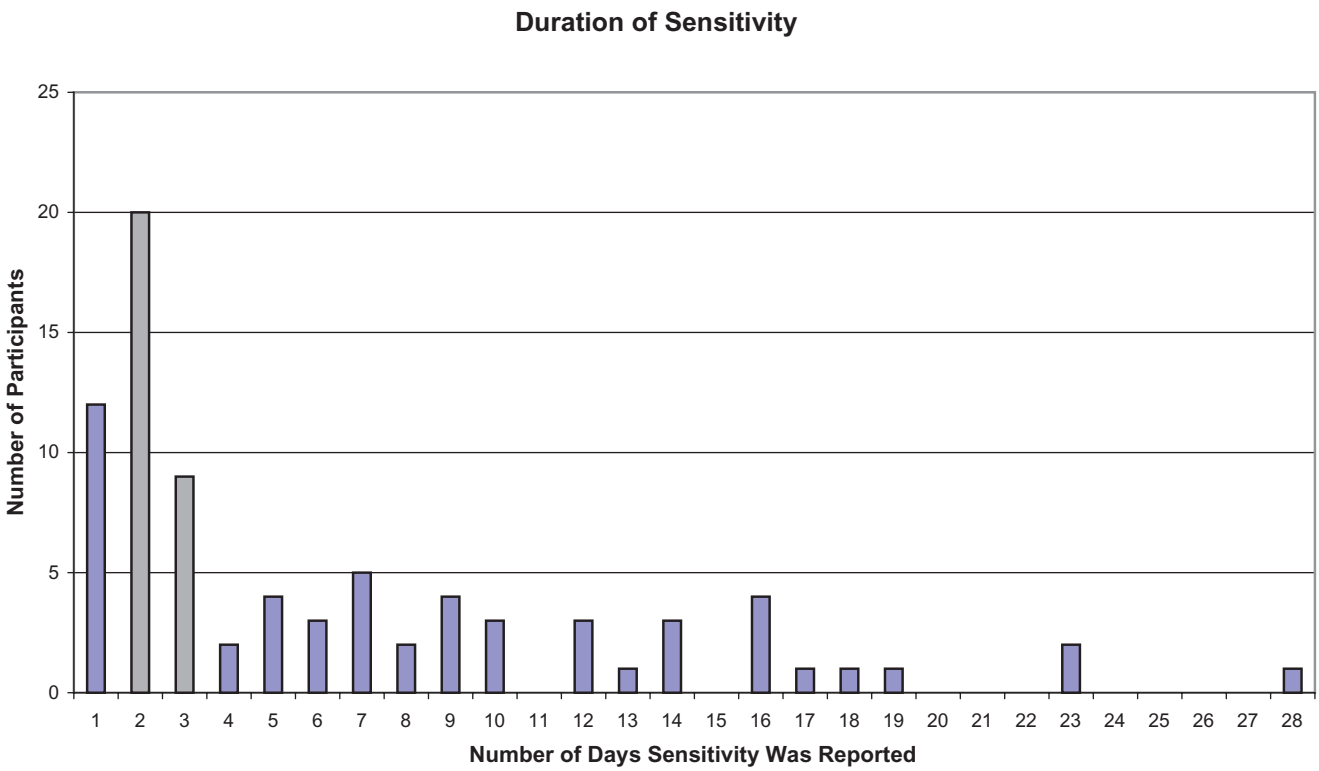

Figure 1. Duration of sensitivity.

the trays were used resulted in sensitivity. Seventy-seven percent or 132 participants reported 3 or fewer days of sensitivity. Considering only those participants who experienced sensitivity, the median number of days reported increased from 0 to 3 (25th percentile = 2.0, 75th percentile = 9.3). The mean number of days of sensitivity more than doubled to 6.5, and the SD was 6.2. The distribution of participants reporting sensitivity can be seen in Figure 1.

Thirty-eight participants (22%) reported soft tissue sensitivity only, 22 (13%) reported hard tissue sensitivity only, and 21 (12%) reported both. The distribution of sensitivity by category and day is listed in Table 2. There was a significant negative correlation between day and tongue sensitivity (Pearson's product moment correlation, $p < 0.03$). Tongue sensitivity was significantly more likely to occur earlier in the 14-day bleaching cycle. There were significant positive correlations between day and hot sensitivity, and day and cold sensitivity (Pearson's product moment correlation, $p < 0.023$ and $p < 0.0001$, respectively). Hot and cold sensitivity were significantly more likely to occur later in the 14-day bleaching cycle (Table 2).

Correlation testing also considered the possible significant correlations between the five sources of sensitivity investigated. There was a positive correlation between sensitivity from hot and sensitivity from cold (Table 3). Sensitivity from hot and cold were significantly more likely to occur together (Pearson's product moment correlation, $p < 0.0001$). There was a negative correlation between sensitivity from irritation of the tongue and from

TABLE 2. SENSITIVITY BY CATEGORY AND DAY.

Day	Gums	Tongue	Throat	Hot	Cold
1	4	2	1	3	8
2	11	6	1	3	11
3	19	4	3	5	10
4	17	3	2	6	14
5	18	3	1	5	12
6	13	2	3	6	14
7	11	1	1	5	17
8	7	1	0	10	20
9	10	1	1	10	22
10	9	1	1	9	20
11	10	0	2	7	17
12	13	2	2	10	20
13	10	3	1	7	19
14	9	1	1	5	19
Total days of sensitivity (each source)	161	30	20	91	223
Percentage of total treatment days	7%	1.3%	0.09%	4%	9.8%

For participants with sensitivity from multiple sources, each source was counted independently. For example, a participant who experienced both tooth and gingival sensitivity on the same day was included in the totals reported twice, rather than just once.

cold (Table 3). These two were significantly more likely to occur at different times during the bleaching cycle (Pearson's product moment correlation, $p < 0.02$). Sensitivity from gums and throat irritation were positively correlated (Table 3). These two were significantly more likely to occur together (Pearson's product moment correlation, $p < 0.023$).

Further examination of the study results offered some interesting observations. The correlations between sensitivity from hot and cold, the correlation between gums and throat sensitivity, and the low occurrence of tongue and throat

TABLE 3. CORRELATION BETWEEN CATEGORIES OF SENSITIVITY AND DAY.

	Day	Gums	Tongue	Throat	Hot	Cold
Day						
Correlation coefficient		–0.234	–0.577	–0.173	0.599	0.853
p-Value		0.420	0.0308	0.555	0.0237	0.000107
Gums						
Correlation coefficient			0.445	0.602	–0.116	–0.280
p-Value			0.110	0.0228	0.692	0.332
Tongue						
Correlation coefficient				0.182	–0.524	–0.613
p-Value				0.534	0.0542	0.0199
Throat						
Correlation coefficient					–0.148	–0.339
p-Value					0.614	0.235
Hot						
Correlation coefficient						0.839
p-Value						0.000175
Cold						
Correlation coefficient						
p-Value						

TABLE 4. HARD VERSUS SOFT TISSUE SENSITIVITY.

Day	Number of Participants with Soft Tissue Sensitivity	Number of Participants with Hard Tissue Sensitivity
1	7	11
2	18	14
3	26	15
4	22	20
5	22	17
6	18	20
7	13	22
8	8	30
9	12	32
10	11	29
11	12	24
12	17	30
13	14	26
14	11	24

For participants with sensitivity from multiple sources, each source was counted independently. For example, a participant who experienced both tooth and gingival sensitivity on the same day was included in the totals reported twice, rather than just once.

sensitivity suggest that two categories, hard tissue sensitivity and soft tissue sensitivity, rather than five might be more descriptive. Accordingly, the hot and cold sensitivity were combined into a new category of hard tissue sensitivity, and the gums, tongue, and throat data were combined to create soft tissue sensitivity (Table 4). If reconsidered in these two new categories, the data were normally distributed. The mean (SD) number of participants experiencing soft tissue sensitivity on any given day during the bleaching cycle was 15.1 (5.6), and for hard tissue sensitivity it was 22.4 (6.6). Significantly, more participants experienced hard tissue sensitivity than soft tissue sensitivity (RM ANOVA, $p < 0.02$).

DISCUSSION

The present study offers an advantage relative to the previous studies cited in that it included a large number of participants. Generally, larger groups are more likely to include a broader cross-section of the population sampled. Larger groups also provide greater statistical power or the ability to find a significant association, if it exists.

None of the participants in this study experienced sensitivity severe enough to force them to withdraw from the study. The present study found that 47% of participants experienced sensitivity at some time. This is lower than the 67% reported by Haywood[4] in his review of sensitivity related to bleaching. Gingival sensitivity was experienced by 34% of the participants. This is very comparable to the Haywood study's[5] report of 31%. In that same study, tooth sensitivity was reported by 52% of the participants. The present study report of 25% appears to be substantially reduced from that level. Our results provide some evidence that bleaching products with additives of potassium nitrate and sodium fluoride are effective at reducing tooth sensitivity but not soft tissue irritation.

Participants in this trial, as a group, experienced sensitivity on 23% of the days spent bleaching. The authors have conducted other trials using the same study design. In a clinical trial[8] of a 3% hydrogen peroxide bleaching agent worn for 30 minutes three times daily and a placebo, the percentage of days that participants experienced sensitivity was 26 and 2%, respectively. The present results compare favorably to that study and another study involving a bleaching agent with desensitizing agents, Rembrandt Xtra Comfort (Den-Mat Corp., Santa Maria, CA, USA). Participants using that product reported that 27% of days resulted in sensitivity.[9] The present results do not compare favorably, however, to two other products with potassium nitrate and sodium fluoride additives. In clinical trials of Opalescence 10% PF[10] (Ultradent

Products, Inc., South Jordan, UT, USA) and Nite White Excel 2Z[9] (Discus Dental, Culver City, CA, USA), participants experienced sensitivity on 14 and 13% of the days spent bleaching, respectively.

The data demonstrate that sensitivity varies substantially from participant to participant. Accordingly, capturing the impact that sensitivity had on participants is difficult. Examining the percentage of participants who reported sensitivity at some point during the study versus the number of days of sensitivity reported provides views of the data that differ substantially. Considering only the percentage of participants reporting sensitivity, gingival irritation appears to be the most common problem. However, the highest number of days of sensitivity was because of tooth sensitivity from cold. Sensitivity from gingival irritation and tooth sensitivity to hot were second and third, respectively. Tongue and throat sensitivity resulted in relatively few days of sensitivity.

Similarly, examining the group as a whole provides a very different view than comparing the experiences of those who reported no sensitivity to those who did. More than half of the participants experienced no sensitivity and 77% experienced 3 or fewer days of sensitivity out of 14. Figure 1 depicts data for only the 47% of participants who experienced sensitivity. The data are skewed toward the left, meaning that it is not normally distributed. Accordingly, when trying to determine what happened to this group of participants "on average," reporting a mean of 6.5 days of sensitivity is not appropriate. Rather, the median more accurately describes what happened on average. Observers will better understand what happened "on average" by considering the fact that 50% of participants who reported sensitivity experienced only 3 days or less of sensitivity. Taken as a whole, it is clear from this data that sensitivity is not as important an issue for most participants as it is for a select subset of participants.

The present results appear to differ from those of other studies that report tooth sensitivity as occurring earlier in the bleaching cycle.[5–7] In one of these studies,[5] a statement was made in the Discussion section that sensitivity tended to occur earlier in the bleaching cycle. No data regarding the onset of sensitivity were presented and no report of statistical testing was presented, however. Rather, it was reported that 66% of subjects experienced tooth and/or gingival sensitivity at some time during the trial. The average duration of this sensitivity was 7.3 days, but the range was between 1 and 32 days. Accordingly, it is difficult to quantify exactly what was meant by "earlier." Further, in this study, participants were instructed to discontinue bleaching if sensitivity occurred. This approach was an appropriate means of safeguarding the safety of those who volunteered to participate in the trial. It may also be one that tended to reduce the degree to which sensitivity was a problem in the latter part of the bleaching cycle. During the latter portion of the bleaching cycle, participants may have altered their personal bleaching schedule until they found a pattern that was comfortable, thus reducing reports of sensitivity. The active bleaching phase for this study was 6 weeks. Relative to this longer study, the 2-week duration of bleaching in the present study may very well represent the earlier part of the bleaching cycle. Finally, the whitening agents in that study did not contain any products specifically included to reduce sensitivity. It is quite possible that these additives alter the pattern of sensitivity experienced by the participants.

Like the present study, the Jorgensen study[7] included a whitening agent with a fluoride additive intended to reduce sensitivity. It also included a placebo group. This study reported only on tooth sensitivity and tracked levels of sensitivity using an ordinal scale, rather than the presence or absence of sensitivity each day. The pattern of the data suggests that sensitivity was

worst in the first week and declined after that. However, no statistical testing was done to determine a correlation between sensitivity and day during the bleaching cycle. Given the fluctuation in the number of participants reporting no, mild, moderate, or severe sensitivity, it is difficult to assess whether a significant pattern existed or not. Further, in the first week, 56% of participants using the placebo reported mild or moderate sensitivity. This is substantially higher than that experienced in the placebo-controlled clinical trials conducted by the authors.[8]

The Leonard study[6] published a graph of the percentage of subjects experiencing sensitivity for each of the 42 days of active bleaching in the study. The graph seems to show a clear pattern of increased sensitivity during the first 14 days. It is less clear whether sensitivity was worse during the first 7 days. Again, no statistical analysis was performed to investigate whether a significant correlation between these two factors existed. The authors reported the average (SD) duration of sensitivity as 6.7 (8.1) days, with a range of 1 to 39 days. A maximum of 42 days of bleaching was possible.

Tam[11] reported the onset of sensitivity in a small clinical trial involving three 10% carbamide peroxide products that did not contain any additives intended to reduce sensitivity. Because she found no significant difference in sensitivity levels for the three products, the aggregate results are presented. The average (SD) for the onset of sensitivity was 4.8 (4.1) days. She also reported an average (SD) duration of 5.0 (3.8) days.

Tongue and throat irritation represented a minor contribution to overall sensitivity. Further, sensitivity resulting from irritation of the tongue was significantly more likely to occur earlier in the bleaching phase. A possible explanation for this would be excessive loading of the tray during the early days of participation in the trial, and then, as the participant becomes more experienced, a reduction to a more appropriate amount of whitening agent.

In summary, given the differences in the types of outcome recorded, the way in which the data were reported, the duration of active bleaching, and the whitening materials used, comparison to other studies is difficult. It appears to the authors that, in terms of when sensitivity occurs during the bleaching cycle, our results are more similar than they are different from previous studies; there being little difference between sensitivity that occurs early in a 6-week study and later in a 2-week study. Unlike the other studies cited, this study specifically investigated whether or not reports of sensitivity from the five sources studied increased or decreased as the number of days of active bleaching increased. Specifically, statistical testing was conducted to determine if a significant correlation existed between these factors. Several statistically significant correlations were found: between day and tongue, there was a negative correlation; between day and hot and day and cold, there was a positive correlation; between throat and gums, there was a positive correlation; between tongue and cold, there was a negative correlation; and between cold and hot, there was a positive correlation.

CONCLUSION

Within the limits of the study, the following conclusions can be drawn:

1. Sensitivity varied greatly from person to person.
2. Sensitivity to hot and cold were significantly more likely to occur later in the 14-day bleaching cycle and to occur together.
3. Irritation of the tongue was significantly more likely to occur earlier in the bleaching cycle.

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COMMENTARY

DURATION AND TIMING OF SENSITIVITY RELATED TO BLEACHING

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The authors have provided further insight into the most common problem experienced by patients choosing nightguard vital bleaching to whiten their teeth; this problem is sensitivity of hard and/or soft tissue. This article points out that most previous investigations have not quantified the extent of sensitivity; rather they have reported on the percentage of patients who experienced sensitivity, with little information on how long and the source from which they experienced the sensitivity during the whitening treatment. By analyzing sensitivity reports from over 170 participants in a bleaching clinical trial, the authors provide data on the sources, length, and patterns of sensitivity. An important consideration is that all the 10% carbamide peroxide agents studied contained potassium nitrate and sodium fluoride, which are known to limit tooth sensitivity. The article offers the practitioner some key facts to use when discussing tooth whitening with their patients. Only about half of the patients should expect some type and degree of sensitivity. More 75% will likely have less than 4 days of sensitivity; furthermore, cold temperature causes the greatest number of days of sensitivity. For the patients who did report sensitivity, the median number of days of sensitivity was only 3. These results offer scientific data that confirms the anecdotal experience of dentists and patients that tooth whitening with 10% carbamide peroxide is well tolerated; only 22% of patients should expect to experience prolonged (more than 4 days) sensitivity during treatment.

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