Improving the Digital Sensor Positioning Device used in Bitewing Dental X-rays

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2 Supplemental Figures

14 References

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Abstract

Bitewing dental X-rays are a diagnostic tool used in the field of dentistry to be able to diagnose and treat cavities and other types of damage on the molars and premolars that are invisible to the naked eye. The current digital sensor positioning device used in dental offices is unsatisfactory, though there is a lack of published research on the topic, despite it being a well-known complication within the industry. This study aims to determine if the sensor positioning device may be improved upon from its current form. Specifically, it investigates whether a more reliable alignment procedure may be developed and if the piece can be redesigned to be more comfortable for the patient. In this context, alignment refers to the ability of the dental professional to place the sensor holder in such a position that the gaps between teeth are visible, providing the professional with a usable diagnostic tool to observe any type of damage. To test the hypothesis that the current standard could be improved, we designed and tested a novel device that served as a digital sensor positioning holder. The testing included comparing the diagnostic capabilities of X-rays taken with both devices, as well as a comfort rating given by enrolled patients. Responses were analyzed using a paired, two sample t-test for both diagnostic ability and comfort. The results showed a small, statistically significant improvement in comfort using the novel device, and a small improvement in diagnostic capability that was not statistically significant. These results suggest that the current standard can be improved, and that our novel device may yield statistically significant improvements as a diagnostic device with minor changes to its design.

Keywords: Bitewing, Dental X-rays, Misalignment, Digital Sensor, Digital Sensor Positioning Device, Interproximal Surface

Introduction

Background

The evidence linking poor oral health and worse health outcomes is well established and only continuing to grow. Poor oral health can cause a whole host of issues, including endocarditis, cardiovascular disease (though the connection is not fully understood), birth complications and pneumonia, among others. For this reason, maintaining high quality oral health is essential in supporting overall health. While some forms of damage to teeth and gums are visible to the naked eye, others require additional instruments that serve as diagnostic tools. One of the more important diagnostic tools used in dental offices are X-ray machines, which have been common practice since the mid-20th century, and which have moved from film to digital records over the last few decades. The change to digital records has necessitated digital manners of recording X-rays as well. The current method utilizes an X-ray machine with a digital sensor placed in the mouth to record the X-ray and immediately transmit it to a nearby computer.

Types of X-Rays

There are three main types of dental X-rays: bitewings, periapical, and occlusal. Bitewings are images taken of the wisdom teeth, molars, and premolars and are used to image the teeth at the very back of the mouth. Periapical X-rays are used to image the teeth at the front of the mouth, and

are helpful in detecting damage in the canines and incisors. Finally, occlusal X-rays are used to image the jaw and the roof and floor of the mouth. While there are improvements to be made surrounding the efficacy of all three types of X-rays, this study will focus solely on bitewing X-rays.

Industry's Current Standard

The current sensor holder that is an established standard in dental offices in the US is produced by Dentsply Sirona, and is seen in figure 1. The most important aspect of a bitewing X-ray is alignment. In this context, alignment refers to how well the sensor and the X-ray machine align in parallel with the gaps in the teeth being imaged. If they are well aligned, then the dental professional is provided with an image allowing them to view any damage that has occurred to the patient's enamel, the most exterior portion of the tooth, and may be able to detect cavities or other types of damage early. Detecting this damage in its early stages makes for better treatment, as a cavity, for example. When bitewing X-rays are misaligned, the gaps in teeth are no longer present as the teeth overlap in the radiograph and a dental professional can no longer be certain if there is damage.

The method that Dentsply Sirona's piece offers to dental professionals to aid in alignment is a small cutout near where the sensor attaches to the sensor holder (may want to reference the image again). While this cutout is better than no alignment aid, it is wholly insufficient. This process requires significant guesswork as the dental professional taking the X-rays must place the sensor at the correct angle and at the proper distance behind the teeth. Once the sensor is placed in the mouth, the cutout is no longer visible to the professional taking the image.

Unsatisfactory X-rays caused by improper alignment cause a few problems. The dentist is not able to accurately diagnose the patient if there are overlapping teeth in the image, as they are not able to see any cavities that may be on the interproximal surfaces. If a cavity goes untreated it can deteriorate and require a root canal or may even need to be extracted. Dental insurance only covers a certain amount of X-rays, which varies based on the patient's plan. Therefore if the X-ray taken is not useful as a diagnostic image, the dentist must either retake the image and not receive compensation or rely on the suboptimal image they already have.

Figure 1. Dentsply Sirona Rinn XCP-ORA Digital Sensor Positioning device: This is the standard positioning device used in dental offices. This is the device that we used to test our novel device against.

In addition to poor alignment and deficient X-rays, patients complain that the digital sensor holder is uncomfortable, and it is capable of cutting their gums or cheeks. This is especially true for patients with tori, a type of bone extrusion in the jaw.

While misalignment of bitewing dental X-rays remains a significant issue and is well known within the field of dentistry, there have been no studies published specifically examining this issue,

and dentistry overall tends to be an under-researched field.

Our solution

Attempting to create a proper alignment procedure was a difficult task, and numerous approaches were considered. At first we thought of attaching a floss-like point that could rest between the molar gaps and slide between the teeth through hole in the device, but we decided this was too uncertain as the piece would be flimsy and unstable. This would also require dental professionals to learn a new x-ray technique and method which our advisor does not want because that makes it harder to integrate into offices. Then, we considered using a similar concept but with the extended piece being a part of the 3-D printed design, but this piece was likely too slim to be printed and risked injuring the patient by poking their gums or cheek. And we worry it could snap off easily.

Our first design iteration (Figure 2) was the one that we used in testing. Here you can see the wedge that we placed on the device, so that it can be aligned between the patient's teeth more reliably than the current device. However, the wedge ended up being smaller than ideal, and the sensor arms were too close together to hold the sensor itself. We needed to break off an arm as seen in Figure 2, and secure the sensor with a rubber band.

If we were to test a second iteration of the device we would make the wedge protrude more from the surface, more pronounced, and we would make the arms wider apart in order to fit the sensor.

Figure 2. Novel positioning device: This is the device that we designed, 3D printed, and used for our testing trials.

Results

Data

Rating Comfort and Images

All ten enrollees in the study were tested with both the original (Figure 1) and new digital sensor positioning device and asked to rank their comfort on a scale of 1 to 5 (Table 1), with 1 being very uncomfortable, 3 being tolerable, and 5 being very comfortable. Each enrollee had 12 X-rays taken of their teeth, including six with each device. The 120 total X-ray images taken were ranked on a similar scale, 1 being unusable, 3 being barely diagnostic, and 5 being the ideal diagnostic image (Table 2).

	Old Comfort Rating	New Comfort Rating
Al	2	3
Am	2	2
B	2	3
J	3	3
N	2	3
W	2	2
C	3	3
M	3	2
T	2	3
S	1	3

Table 1. Comfort Ratings of Patients in Trials: Each patient enrolled rated the novel and current devices on a scale from 1 to 5, with 1 being the least comfortable and 5 being the most comfortable. Names have been shortened to the first letter(s) in order to maintain patient privacy.

The images were rated by Dr. Andrea Galina DDS, a dentist with more than 30 years of experience who served as our mentor throughout the project. We opted to have the images rated manually, as we deemed that the softwares available to interpret X-ray images are not as accurate as her trained eye. Dr. Galina rating the images also proved more convenient time-wise.

	Image 1 (R1)	Image 2 (R2)	Image 3 (R3)	Image 4 (L1)	Image 5 (L2)	Image 6 (L3)
Al Old	3	5	4	5	4	3
Al New	5	5	3	1	1	5
Am Old	4	4	4	2	3	3
Am New	4	3	2	2	1	1
B Old	4	4	4	1	1	1
B New	4	5	5	5	4	4
J Old	5	5	5	5	4	2
J New	5	5	5	2	4	3
N Old	2	2	2	5	2	1
N New	5	1	5	5	5	5
W Old	4	4	3	2	4	4
W New	3	3	5	4	5	4
C Old	2	5	4	5	5	2
C New	4	5	5	4	5	5
M Old	5	5	2	5	4	1
M New	3	4	4	4	5	3
T Old	5	4	3	5	4	4
T New	5	3	4	4	3	5
S Old	5	3	1	5	5	1
S New	4	1	1	2	5	5

Table 2. Ranking of X-ray Image Diagnostic Quality: Dr. Galina rated each X-ray image on a scale from 1 to 5, with 1 being unusable as a diagnostic tool, and 5 being an exemplary bitewing X-ray.

Figure 3 is the graphs of the raw data, with the total number of each X-ray rated using the old device on the left and our new device on the right. As you can see, our device did tend to slightly outperform the old device, with the most notable finding being the higher percentage of 5s using our new device.

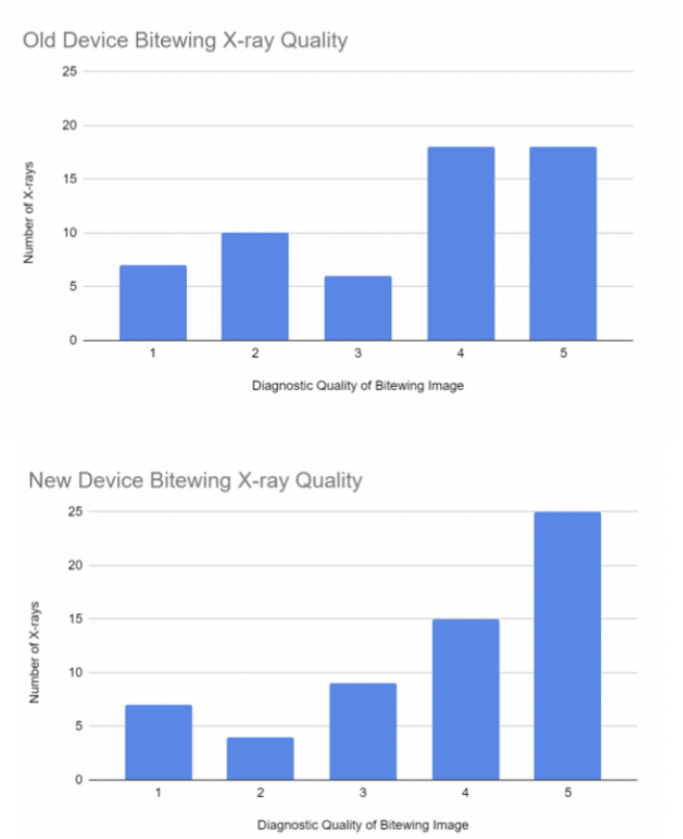

Figure 3. Bar Graphs of the Diagnostic Quality of the Bitewing Images: Old Device and New Device image rating.

In Figure 4 a radio graph displays the ratings, with our new device in red and the old device in blue. This visualization is an easy way to show that our device tended to be rated more comfortable than the old device, and can be seen on the next page.

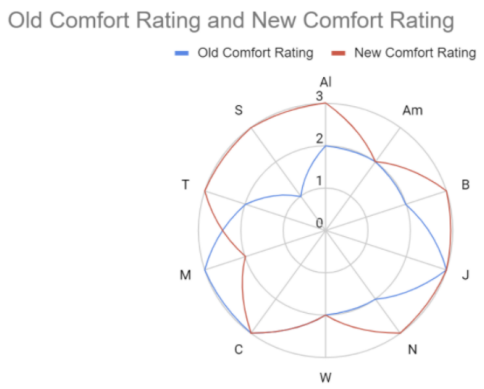

Figure 4. Radar Graph of the Comfort Rating of the Positioning devices: Old device (blue) vs. new device (red)

X-Rays

In Figures S1 and S2, we provide examples of the results, including the raw images and the corresponding rating. Patient B's images showed much better results with the new device. This is likely due to Patient B's strong gag reflex, which resulted in them handling the new, smaller device better (Figure S1). Patient J's images ranked about the same with both the new and old device. Our team and advisor believe that this is because they have a larger mouth that more easily accommodates the device and is able to be positioned correctly and not interfered with when the patient closed their mouth (Figure S2)

Statistical Computations

In order to compare the efficacy and comfort of our novel device with the current device, paired, one-tailed Student's t tests were completed with an alpha level of 0.05 and a beta level of 0.10 for each. The full results of the t-test comparing comfort can be seen in Table 3. The mean for the new device was 2.7 with a variance of 0.23, while the mean of the old device was 2.2 with a variance of 0.4. The calculated P value was 0.047, highlighted in the table, which is just below our alpha level of 0.05, indicating that we can be 95% confident that our new device is more comfortable than the current device. This result holds true despite the small sample size of only 10.

	Old Device Comfort	*New Device Comfort*
Mean	2.2	2.7
Variance	0.4	0.23333333
Observations	10	10
Pearson Correlation	-0.1454786	
Hypothesized Mean Difference	0	
df	9	
t Stat	-1.860521	
P(T<=t) one-tail	0.04786695	
t Critical one-tail	1.83311293	

Table 3. Paired one-tailed Student's t test for Comfort Rating: Comparing the comfort ratings of the old and new devices.

The results of the X-ray diagnostic capability t-test can be seen in Table 4. Our new device averaged a higher diagnostic ability rating, though it had more variance, and resulted in more extreme values than the current device. The mean for our new device was 3.783 with a variance of 0.574, while the mean for the old device was 3.5 with a variance of 0.438. The calculated P value was 0.211, highlighted in the table, which was greater than our alpha level of 0.05. Since our P value was greater than our alpha level we cannot be 95% confident that our device was a better diagnostic tool than the current standard. However, the P value also implies that we could be roughly 80% confident that our device is a better diagnostic tool.

	Old Device Efficacy	*New Device Efficacy*
Mean	3.5	3.78333333
Variance	0.4382716	0.57438272
Observations	10	10
Pearson Correlation	-0.1230305	
Hypothesized Mean Difference	0	
df	9	
t Stat	-0.8405959	
P(T<=t) one-tail	0.21117202	← Implies ~80% confidence
t Critical one-tail	1.83311293	

Table 4. Paired one-tailed Student's t test for X-Ray Image Rating: Comparing the quality ratings of the old and new devices.

Discussion

Conclusion

Overall, the results showed promise that our new device could improve upon the current device, both in terms of diagnostic capability and in patient comfort. While the difference between means was only statistically significant for the comfort ratings, the diagnostic ratings also showed that our device tended to improve performance, though it was not statistically significant. One of the major hurdles to creating a statistically significant difference was the small sample size of 10, as a small sample size requires a greater difference in means in order to yield statistically significant differences. It is important to note that the observed difference in means of diagnostic rating would become statistically significant should the difference be maintained using a larger sample.

Even without a statistically significant improvement in diagnostic accuracy, this study demonstrates that there are certainly aspects of the design of the current piece that may be enhanced to provide more reliable alignment when taking bitewing X-rays, and should prompt more research into this under-studied but important field.

Future Plans

Given that our design showed promise as an improved sensor holder that could align bitewing X-rays more easily while being more comfortable to the patient, the next steps involved actions necessary to eventually bring our device to market. First, we plan on visiting different dental offices in order to show our device to dentists besides our advisor, and have them use the device themselves so they can get a feel for it and understand how it works to improve alignment. During these visits, we'd also ask for any feedback that they are willing to give about the design, and potentially other ideas that they could offer that would further improve alignment and/or comfort. Finally, we plan to probe the level of interest in potentially purchasing our device and using it instead of the current standard should it be brought to market eventually.

Once we feel as though this project is feasible as a business venture, we would embark upon the regulatory pathway that is necessary for new devices to be brought to market. First, we would want to file a provisional patent application through the US Patent and Trademark Office so that we could establish intellectual property rights for our device. Given that there are no previous patents that deal with any methods to improve bitewing X-ray alignment, we feel confident that we could secure a patent for our design, and specifically for the wedge used to rest between teeth and ensure alignment. This would be our first step so that we could lock down our rights and prevent any competition from creating a similar device.

While we are going through the process of filing a provisional patent application and awaiting a response from the USPTO, we'd also begin to engage with the FDA. It's highly likely that our device would be considered a type I medical device

as a diagnostic instrument. While our device is a novel medical device, a de novo classification request would not be necessary, as our device is substantially equivalent to the Dentsply Sirona Rinn XCP-ORA sensor holder which would serve as the predicate device. The Dentsply Sirona device is already listed with the FDA, as it has been in the market for more than a decade, and is already classified as type I. Even though our device is used in the process of taking dental X-rays, which involves significant risk, the device itself is only the plastic piece used as a holder so the regulatory process is easier than expected.

The FDA also requires clinical trials to show that devices are safe and effective, a step which may be completed in future studies but was not conducted during this study as we had not secured full board IRB approval for a large-scale test. Any future studies done following IRB approval would likely be similar in nature to the testing completed in this study, but with a larger number of participants and a less subjective rating system. In addition, we would want a larger study to be completed with proper procedures, which includes withholding information from the participants to deter response bias.

Once the clinical trials and FDA classification requests were completed, we would move ahead with a 510(k) premarket notification. This notification is what allows the FDA to compare our device to an equivalent device, in our case the Dentsply Sirona device, in order to gain type I classification. This measure is also required in order to start selling our product, with the FDA notification allowing us to start marketing the medical device 90 days after the filing.

Should all the previous steps be completed, we would research how to go about manufacturing our device in a similar way to how the current device is made. This would entail finding a manufacturer that could take a provided mold and make our device using plastic that is safe for humans and that could be washed in an autoclave, the method of cleaning and sanitizing dental equipment.

Limitations

Finding Published Studies

While our results showed promise, there were some limitations to this study. The most glaring limitation was the lack of a more professional study.

IRB Process

Our process with the IRB at UVA proved to be more time consuming and difficult than anticipated. This resulted in approval from the radiation arm of the IRB, Human Investigations Involving Radiation Exposure, but not full board approval before we had to start collecting data. This meant that this study did not end up with 30 participants and did not adhere to the necessary standards that the IRB requires for approval. The sample size of 10 participants is much smaller than ideal, and may have skewed the results as such small sample sizes are liable to contain lots of variance. However, this effect is likely somewhat mitigated as our project involved paired data analysis, so it's likely that any bias introduced would have been maintained across devices.

Bias

Another issue with our data collection was the lack of blind results. By the nature of the device designs, it was impossible to keep the enrollees unaware of which device was which, which could have introduced some response bias in the patient comfort data. By the same token, the diagnostic X-rays were rated without the same blinding procedure, meaning that there is the possibility for some response bias to have occurred during the rating process.

Another problem that arose was the imprecise dimensions of the novel device. We reached out to Dentsply Sirona, the company that produces the current device, asking for dimensions to the current piece but did not receive any response. Since we did not receive a response, we had to

measure the current device's dimensions by hand, which led to improper measurements for some of the more precise aspects of the design. This affected our project most during testing, when we had to improvise as our sensor arms didn't hold the sensor tightly enough and had to be removed and replaced with rubber bands.

This action may have also skewed the comfort results, as the device was smaller and had fewer sharp points that could have contributed to discomfort in the imaging process.

The IRB process resulted in us only being able to test using our first iteration, which had some issues. Outside of the arms not being tight enough to hold the sensor, the wedge that we created on the main arm was not large enough to have as great of an impact as we had hoped. We updated the device in Fusion 360 to create a larger wedge and fix the arm size, but we were unable to print and test our improved design due to time constraints.

Materials and Methods

Procedure

During testing, standard bitewing dental X-rays were taken at the Capital Trail Dental office in Henrico County, Virginia. Ten total patients were enrolled, including the two authors, but the rest of the patients' identities have been anonymized. Twelve total X-rays were taken per patient, including six X-rays using the novel device and six using the current device. Within each set of six X-rays using each device, three were first taken on the patient's right side of the mouth, then three were taken on the patient's left side of the mouth. The set of three X-rays began with the furthest back teeth to be imaged, and moved forward by one tooth length after each image two times, for a total of three X-rays per side. This was a protocol design choice in order to subject both devices to different sets of circumstances and to make sure that the devices would properly image both molars and premolars, as are typically imaged in bitewing X-rays. X-rays were taken first with the old device, then with the novel device. The novel device, due to poor dimensions, did not fit the digital sensor and had to have its top two sensor arms snapped off and replaced by elastic bands that helped to secure the sensor. All X-rays were taken by Dr. Andrea Galina DDS, and immediately printed out and stored. Immediately following the enrollee's X-ray imaging, they were asked to rate the comfort of both the new device and the current device on a scale from 1 to 5, with 1 being very uncomfortable and 5 being very comfortable. By the nature of the devices, it was impossible to have blind trials in which the patients did not know which device was which. After all patients had their images taken, the printed pictures were retrieved and rated by Andrea Galina on a scale from 1 to 5, with 1 being unusable, 3 being barely diagnosable, and 5 being an ideal bitewing image. The results of diagnostic ratings should have been blinded in order to deter any data skewing and bias but were not for this study.

Creation

The novel digital sensor positioning device was created on Autodesk Fusion 360 as a 3D design and then printed with standard ABV plastic that is safe to use in this context (within the patient's mouth).

End Matter

Author Contributions and Notes

Alexandra Galina and William RIppey designed the novel sensor holder device, performed research, analyzed data and authored this paper.

The authors declare no conflict of interest.

Acknowledgments

Dr. Andrea Galina supervised the project, took the x-rays with the standard device and our new device, and analyzed data. Dr. Tim Allen and Dr. Shannon Barker provided guidance and education. Dr. William Guildford 3D printed our device. Thank you to all of our patient volunteers.

Supplementary information

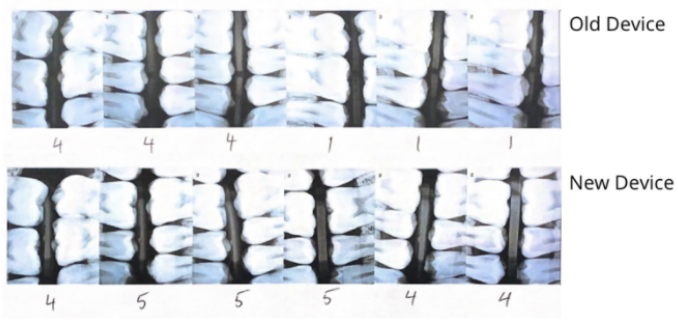

Figure S1. Patient B: X-Ray images taken with the old and new device and the ratings for each image.

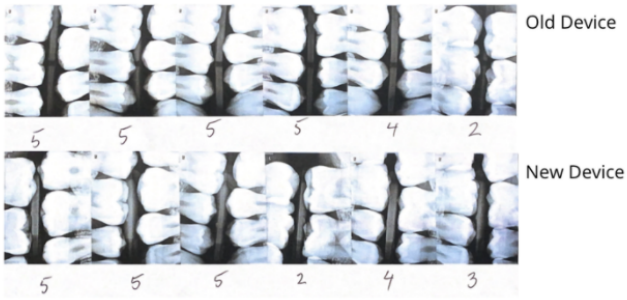

Figure S2. Patient J: X-Ray images taken with the old and new device and the rating of each image.

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