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Effectiveness and Comfort Assessment of the Novel Intra-oral Bisecting Angle Bisector© and Paralleling RINN® Digital Imaging Receptor Holders in Low Palatal Height Patients

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ABSTRACT

This study was performed to assess the effectiveness and comfort of two intraoral imaging techniques using respective digital radiograph receptor devices/holder in obtaining digital intraoral images. A total of 60 patients undergoing anterior intraoral periapical radiographs were single-blindly recruited. The imaging procedure was performed by two calibrated researchers where the novel holder group (Bisector©) was prospectively compared to the conventional paralleling technique group, RINN® by performing thirty radiographic examinations, respectively. All patients were randomly segregated into different groups using block randomisation method. The effectiveness of both holders was quantified based on the repeat rate percentage and quality of the images. The comfort study was enumerated using the Horizontal Visual Analogue Scale 100mm (HVAS). The Mann Whitney test (alpha = 0.05) was applied to compare the repeat rate of different types of imaging receptor device. The repeat rate percentage for Bisector© and RINN® holder devices were 8.9% and 18.6%, respectively ($p < 0.05$). The median range of the "comfort data" according to RINN® and Bisector© was 16 mm to 56 mm and 14 mm to 57 mm, respectively. No patients scored more than 74 mm. The Bisector© holder exhibited lower percentage of repeat as compared to the RINN® holder. Both groups did not cause major discomfort (mild-moderate pain). The use of novel intraoral bisecting angle radiographic receptor holder is however recommended to optimise the repeat rate in low palatal height patients.

Keywords: *Bisecting angle; dental; digital image; radiography; repeat analysis*

INTRODUCTION

Intra-oral radiographs are pivotal as one of the diagnostic tools in order to propose dental treatment plans. Nowadays, direct digital radiograph has become more readily accessible in dental practice (Versteeg *et al.*, 1997). However, studies have shown that more errors and retakes occur in digital intra-oral radiography using receptors such as charge-coupled device (CCD) in comparison to conventional film (Versteeg *et al.*, 1998).

The common techniques that are widely practiced in intra-oral periapical (IOPA) radiographic imaging are divided into paralleling and bisecting angle techniques. Paralleling technique is the most accurate technique due to its common practicality and is frequently used for bitewing and periapical radiograph. This technique is also considered to be a gold standard in obtaining an IOPA image and should always be attempted prior to consideration of other techniques. On the other hand, bisecting angle technique is more technique sensitive where, if the bisecting angle is not appropriately measured, image geometry inaccuracy such as elongation and foreshortening may occur. According to Rushton and Horner (1994), the overall proportion of diagnostically unacceptable films that are produced from the bisecting angle technique is 44.5%, which is a remarkable indictment of this type of technique prior to treatments. This finding appears to be higher than the study by Mohd Yusof *et al.* (2017) that exhibited repeat rate of 15.1% to 34.4% for both digital bitewing and periapical images, respectively.

However, to provide for a more comprehensive diagnosis tailored to the needs and conditions of the patients, anatomical variations should always be considered. The anatomical variations such as low palatal vault and the presence of tori may present a challenge to the dental care providers in performing intra-oral radiographic examinations. Additionally, not all techniques are suitable to be used for each anatomical variation. In order to reduce the prevalence of non-diagnostic periapical radiographic images, film holders should be used (Rushton and Horner, 1994; Safi *et al.*, 2015). In the case of shallow palate, the acquisition of intra-oral radiographic imaging using paralleling technique may be difficult to perform although with the aid of the receptor holder. Furthermore, patients may experience certain degree of discomfort and therefore the diagnostic tools may subject them to various psychological states of mind such as fear and anxiety towards dentistry (Carter *et al.*, 2014). Thus, this study aims to determine the effectiveness and the comfort of the novel device (Bisector©) by comparing it with the gold standard holder (RINN®) in anterior teeth.

MATERIALS AND METHODS

Study Design

Ethics approval was obtained from Universiti Teknologi MARA (UiTM) Research Ethics Committee under reference number 600-IRMI(5/1/6). This prospective comparison to a gold standard study consisted of 60 patients and two operators. Patients were recruited from the Comprehensive Care Clinic, Faculty of Dentistry, UiTM with equal distribution number of gender (N_{female} = 30, N_{male} = 30). Prior to effectiveness and comfort assessment, these patients were randomly divided into two groups of paralleling and bisecting angle techniques from XCP-DS® Digital Sensor Holder of Denstply RINN® and novel holder (Bisector©), respectively. The latter is a patent-pending modified intra-oral bisecting angle digital radiographic receptor holder that utilises a predetermined angle for anterior teeth imaging examination. Block randomisation method was used to assign these patients to a particular group until both groups achieved the minimal size to acquire statistically significant results with significant level of 5%. Allocation concealment was performed by opaque sealed

envelopes that were opened before taking radiographs. Sealed, opaque sequentially numbered envelopes (SNOSE) concealed randomisation of group allocation were used to prevent the clinician from (unconsciously or otherwise) influencing which patients were assigned to a given intervention group (Doig and Simpson, 2005).

Patient Selection

In order for the subjects to become eligible for this study, they must satisfy the inclusion and exclusion criteria outlined prior to the start of this study. The main inclusion criteria for the subjects included low palatal vault (less than 5 mm from the first molar cervical line). Normal and high palatal vaults (more than 5 mm from the first molar cervical line) were excluded from the study. All patients suitable for the study inclusion must be clinically justified for the anterior IOPA radiograph. The decision for radiographic examination was solely performed by an independent clinician who was blinded to the randomisation method. In addition, patients who were susceptible to severe gag reflex were excluded in this study as this could infer bias during comfort assessment evaluation. Special needs patients such as learning disabilities, sensory and cognitive impairments and patients who were undergoing endodontic treatment that required special endodontic imaging were also excluded from this study.

All patients were informed regarding the procedures and the expected research outcomes before radiographic examinations were carried out. Next, informed written consent was given to the patients. Prior to the intra-oral radiographic acquisition, a calibration was performed between both operators and a radiologist in terms of technical radiographic acquisitions and radiation protection measures. By doing so, the errors that are projected from the images will be exclusively considered as the faults from the intra-oral receptor device angulation.

Effectiveness Study

The images resulting from both groups were evaluated by the two calibrated researchers using two criteria which were repeat rate and quality of the images. Total number of examinations and repeat rate were documented. Quality of the image will be assessed according to geometric errors which are distortion, elongation and foreshortening. Distortion can be recognised by 'stretching out' of the image in a localised area of the radiograph. The elongation is related to the increase in vertical angulation of the X-ray beam. The foreshortening is related to the decrease in vertical angulation of the X-ray beam. The repeat rate was calculated according to the total number of repeat images and the total number of examinations.

Comfort Assessments

Patient's comfort was quantified by using the open source Horizontal Visual Analogue Scale (HVAS) 100 mm form that was provided to patients after every intra-oral procedure. HVAS was selected as instrument for this assessment as it is considered as an established method to assess subjective pain (Adamchic *et al.*, 2012). The scale is anchored by "no pain" (0 to 4 mm), "mild pain" (5 to 44 mm), "moderate pain" (45 to 74 mm) and "severe pain" (75 to 100 mm) (Gonçalves *et al.*, 2009). Verbal descriptions were provided to patients.

Data Collection

The images were collected and evaluated on EasyDent V4 viewer software version 4.1.4.5 (Vatech, Hwaseong, Korea). All digital radiographic examinations were automatically registered by the system and retrieved within the timeline. The system prohibited image deletion and did not allow for any image manipulation except modification of contrasts. The sensors used in this study were CMOS sensor (EzSensor, pixel size 35 μm VATECH Hwaseong, Korea) coupled to intraoral

machine (Satelec X-Mind AC/DC, Satelec ACTEON, Tuusula, Finland; 70kVp 8mA 230V ~ 50-60Hz) and X-ray tube (Toshiba DG-073B-DC). The sensor was compatible to both conventional and novel holder. The total numbers of repeat, total number of examinations, Horizontal Visual Analogue Score and the radiographic interpretations were recorded using Microsoft Excel 2010.

Data Analysis

The major finding was reported descriptively and comparison between two independent groups was analysed using the non-parametric test (Mann-Whitney U test). This test was applied to compare the repeat rate for the different types of imaging digital receptor devices. To prevent multicollinearity, each patient was subjected to only one-time intra-oral radiographic imaging procedure. Should the patient required imaging for both upper and lower anterior teeth, only one acquisition will be included in the study. The weighted Cohen's kappa and collected data from the HVAS was statistically analysed using RStudio (Version 0.99.893, RStudio, Boston, USA). The *ggplot2* function package was used to develop graphics in this analysis.

RESULTS

In our study, a total of 60 participants were randomly assigned into two groups and patients had undergone anterior periapical radiographic procedure by using novel and conventional holders, respectively. For each group, there was no subject's attrition leading to exclusion from this study. Data was collected within a four-month period.

The range of age within the sample was between 6 and 76 years old as shown in Table 1. Majority of the participants came from age group of 15 to 24 years old (14/60) and the overall age mean was 44.5 years old. The standard deviation was 24.49.

In effectiveness study, repeat rate was higher for conventional holder (18.6%) as compared to novel holder (8.9%) (Table 2). In perspective, the repeat of radiographic acquisition for conventional is approximately 2 out of 10 while novel is 1 out of 10. In addition, the repeat rate difference between both holders was statistically significant ($p < 0.05$). Ironically, the elongation ratio was higher in novel (1/6) as compared to the conventional holders (1/15). Both groups shared the same foreshortening ratio (1/30). However, the ratio difference was not statistically significant between both groups.

In comfort assessment, the pain was categorised into four types which were "no pain", "mild pain" and "moderate pain" according to the 100 mm HVAS as depicted in Fig. 1. More than half of the respondents scored "no pain" with scoring range of 0 to 4 mm (37 out of 60 respondents). Almost similar number of respondents scored "mild pain" (12 out of 60 respondents) and "moderate pain" (11 out of 60 respondents). The "mild pain" ranged between 5 to 44 mm followed by "moderate pain" that ranged between 45 to 74 mm. No respondent's scores were obtained for "severe pain" which ranged from 75 to 100 mm. The median for "no pain", "mild pain" and "moderate pain" were 0, 15 and 57, respectively.

Table 1 Baseline data of patient's age

Range of age (years)	Number of patients	Mean	SD
5–14	2	44.5	24.49
15–24	14		
25–34	9		
35–44	9		
45–54	11		
55–64	9		
65–74	5		
75–84	1		

Table 2 Repeat rate analysis

Holder	Repeat rate (%)	*p*-value
RINN®	18.6	0.0251
Bisector©	8.9	

Fig. 2 exhibited the distribution of HVAS scores according to its types of pain in both novel and conventional holders. In general, "no pain" scored the most for both conventional (19 out of 30) and novel holders (18 out of 30). However, in "mild pain", the conventional holder exhibited higher pain scores than the novel holder with median of 16 and 14, respectively. In contrast, the "moderate pain" scores were almost comparable in novel (median = 57) as compared to the conventional holder (median = 56).

Fig. 3 demonstrated the distribution of HVAS scores according to its types of pain in both conventional (Fig. 3a) and novel (Fig. 3b) holders for both females and males. Majority of the patients scored the pain as "no pain" for both female and male (12 females and 7 males). Nine out of 30 patients (6 females and 3 males) scored the pain as "mild pain". The highest pain score for conventional group was 63 mm and this was scored by a male patient. A female patient scored 50 mm. The pain score for female patients was comparatively less than

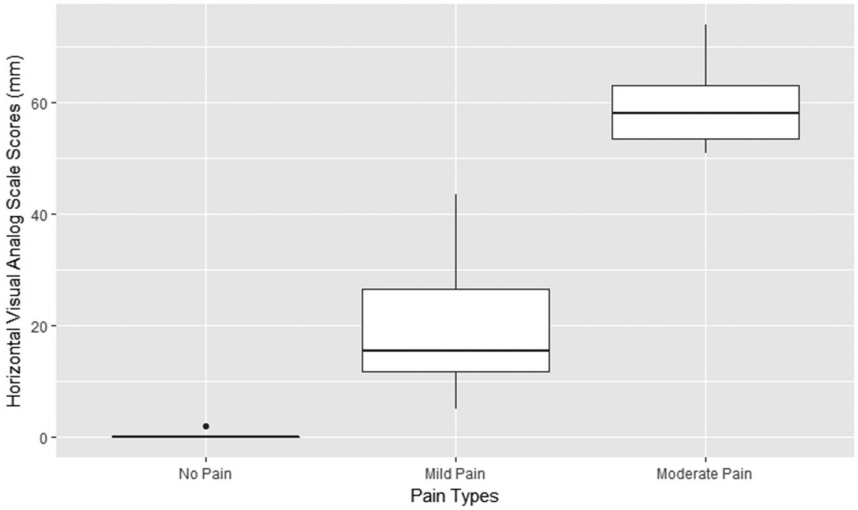

Fig. 1 Box plots of HVAS (100 mm) categorised by pain types.

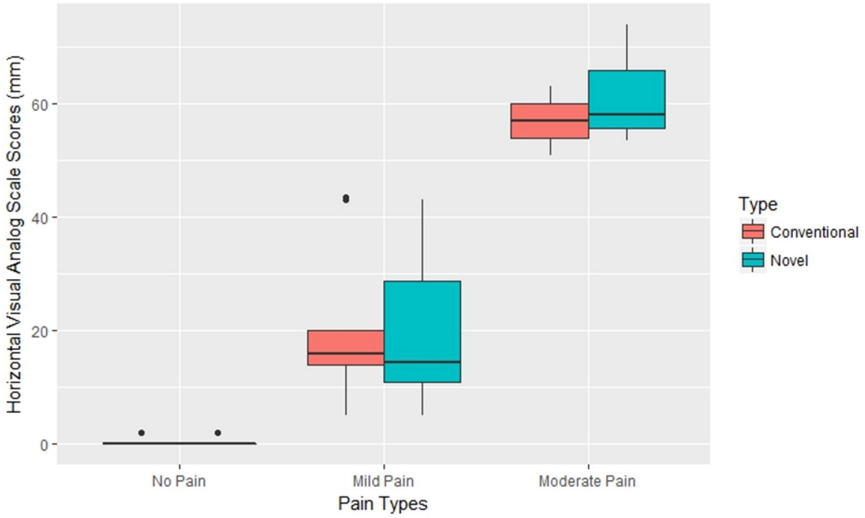

Fig. 2 Distribution of HVAS (100 mm) and types of pain between conventional holder (RINN®) and the novel holder (Bisector©).

male patients. Hence, referring to both Fig. 3(a) and 3(b), most patients stated that there was no pain felt during the procedure and the others scored the pain as "mild pain" and "moderate pain". No "severe pain" was scored for both holders and for both genders.

Using a weighted Cohen's kappa coefficient, the level of agreement was almost perfect, with the κ value ranging from 0.86 to 0.92. Calibration done with field experts also revealed an almost perfect level of agreement with a κ value of 0.90, except in determining the number of images repeated, which exhibited a moderate level of agreement with a κ value of 0.58. These reliability values were derived from CMOS-produced images (Fig. 4).

DISCUSSION

Based on the previous study that stated the moderate repeat rate (34.4%) of intraoral digital imaging, novel intraoral digital receptor device was invented (Mohd Yusof *et al.*, 2017). Bisecting angle technique was implemented in the design to make a tailor-made diagnostic approach for all patients especially for those with anatomically challenged such as shallow floor of the mouth, severe incisor overjet, low palatal vault and severe gag reflex.

In general, our study aimed to assess the comfort assessment and the effectiveness of the novel holder. HVAS was used in this

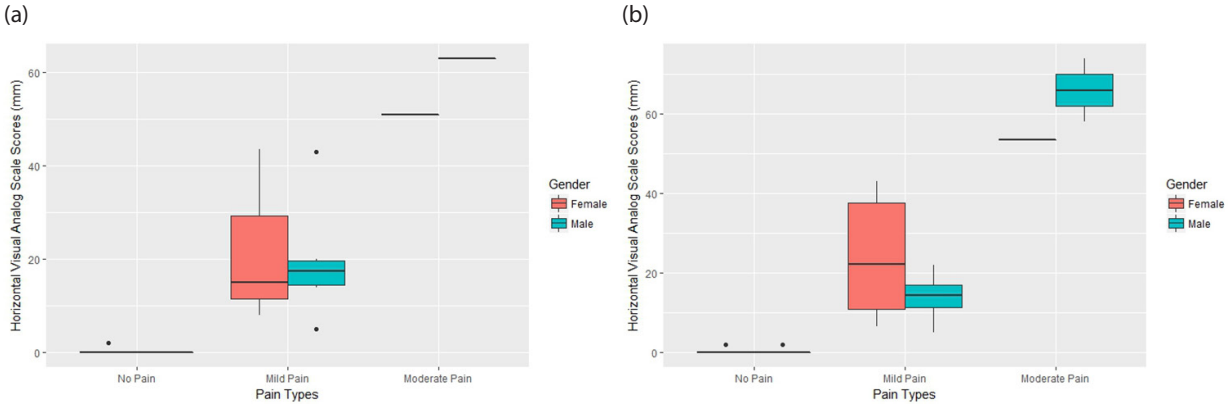

Fig. 3 Distribution of HVAS (100 mm) with pain types for conventional (a) and novel (b) holders by gender.

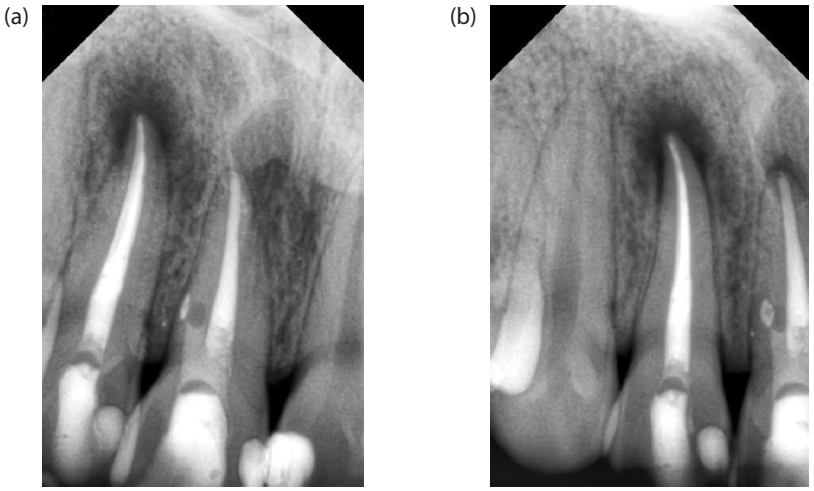

Fig. 4 CMOS-produced images for teeth 11 and 21 acceptable for diagnosis (a) and rejected (b).

study to assess the comfort assessment due to its ability to make the best method for the assessment of subjective pain (Adamchic *et al.*, 2012). This instrument has been used for the measurement of intangible quantities such as pain, quality of life and anxiety (Gonçalves *et al.*, 2009).

From the first part of our study to evaluate the effectiveness of the novel holder, it was ostensible that the repeat rate for conventional holder was higher as compared to novel holder. The significant difference between both groups indicates that the effectiveness, measured by the number of repeats, is remarkable. This finding is also managed to shed a light that the use of the novel holder is able to curb the radiograph repeat that has been synonymous with the use digital sensors among the operators.

Pain is defined as "an unpleasant sensory and emotional experience associated with actual or potential tissue damage or describe in terms of such damage" (IASP, 1979). As pain is very subjective, we further classified the pain as no pain, mild pain, moderate pain and severe pain (Hawker *et al.*, 2011; Heller *et al.*, 2016). Clinical and experimental research indicates that pain is perceived differently, and it is depending on a person's sex, race or ethnicity and age (Oberle *et al.*, 1990; Wandner *et al.*, 2012). In term of pain perception, women and men respond differently to pain (Paller *et al.*, 2009; Lombana and Vidál, 2012). Correlative to our study, we observed that the pain perception in female patient was lower compared to male. Thus, it was indicated that there was gender bias in term of pain perception. Through another perspective, middle age group perceived more pain as compared to young adult group. This finding is parallel with a study that stated pain threshold increases with age (Lautenbacher *et al.*, 2017). In our current comfort study assessment, it was proven that during radiographic examination, there was no pain perceived by the patients and if there was any, it only confined from "mild" to "moderate pain" which was tolerable for the patient. The outliers were not due to systematic error such as technical error in data key-in but rather a random occurrence from the patient's perception of pain.

From our study, we identified new factors that can cause patient's discomfort which was the V-shaped of maxillary arch. Patient exhibited more pain as compared to those with normal shape of maxillary arch. From unofficial interviews with some patients, it was revealed that most patients who complained of discomfort the size of the sensors contributed to the pain. We also found that the plastic barriers of the sensors caused the discomfort for the patients during the procedure. These findings correlated with the previous study which stated that the average HVAS score for patient discomfort in was significantly higher when plastic barriers are used compared to commercially–available hygienic sheath (Wenzel *et al.*, 1999; Charuakkra *et al.*, 2017). Hence, it is recommended to include these factors while applying novel holder during the intra-oral radiographic acquisitions. The duration for the whole procedure was usually short and took around 10 to 20 seconds for a single examination. Thus, the no scores for "severe pain" from the respondents could be due to the patients that may have been able to withstand the short stint pain.

It is true that when conventional holder is correctly used, the produced image will not be distorted due to incorrect angulation. As this may hold true for patients with regular and high palatal vaults, it is not often the case for patients with low palatal vault. The paralleling angulation in this particular situation may be difficult especially for the placement of the solid state digital sensor. In addition, patients may experience great discomfort that could lead to dentophobia. Our current study showed that the novel holder exhibited lower percentage of repeat as compared to the conventional holder. However, both groups did not cause major discomfort (mild-moderate pain).

Bisecting angle technique is generally a technique-sensitive procedure and therefore requires a proper measurement between teeth and sensor. As this technique is susceptible to geometric error, the predetermined angle in the novel holder must be revisited. During this trial, the novel holder utilised only one angle and thus may limit its function on certain patients. It is important to note that the material used for the current prototype of the novel holder was Acrylonitrile Butadiene Styrene (ABS) material. Although this material was relatively cost effective for clinical testing, it was not as rigid as the conventional holder material. Therefore, the handling of the novel holder required extra care as compared to the conventional holder. In addition, the prototype may appear slightly bulkier and this may cause the discrepancy in getting the true comfort scale assessment scores. The less rigidity of the holder may affect the angle during positioning of holder inside the patient's oral space and this in turn may affect the radiographic images produced.

In term of practicality, the novel holder is more practical as the repeat rate is lesser than the conventional holder. This is also because the novel holder is relatively easy to be positioned as compared to conventional holder. As the bisecting angle technique is applied through the angulation of the novel intra-oral digital radiographic receptor device, this technique is more comfortable for the patient, relatively simple and quick (Azizah et *al.*, 2017). Conventional holder requires parallelism of the tooth in order to obtain correct position and desirable image, so proper positioning is required.

CONCLUSION

This study proved that there is statistically significant difference in repeat rate between both holders in term of effectiveness where novel intraoral holder exhibits lesser repeat as compared to the conventional holder. Both holders, however, provide equal comfort to the patients. Therefore, in addition to the comparable comfort scales between conventional and novel holders, the novel holder provides promising results to be used in intraoral imaging for a certain anatomically challenged individuals.

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