

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. **Methods:** 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 paralleling technique group, RINN® by performing thirty radiographic examinations, respectively. All patients were randomly segregated into different groups using block randomization 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 Wilcoxon test ($\alpha = 0.05$) was applied to compare the comfort score of different types of imaging receptor device reported by the patients. **Results:** 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 conventional and novel intraoral radiographic receptor holder was 16 mm to 57 mm and 15 mm to 58 mm, respectively. No patients scored more than 74 mm. **Conclusion:** 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 optimize the repeat rate in low palatal height patients.

1. Introduction

To provide for a more comprehensive diagnosis tailors 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. In addition, 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.¹ 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.² 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.

2. Methods

Study design

This prospective comparison to a gold standard study consisted 60 patients and two operators. Patients were recruited from Comprehensive Care Clinic, Faculty of Dentistry, Universiti Teknologi MARA (UiTM) with equal distribution number of gender ($N_{\text{female}} = 30$, $N_{\text{male}} = 30$). 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 utilizes a predetermined angle for anterior teeth imaging examination. Block randomization 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%. Ethics

approval was obtained from UiTM Research Ethics Committee under reference number 600-IRMI (5/1/6).

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 - © 2009-2016 RStudio, Inc. Boston MA, USA. The *ggplot2* function package was used to develop graphics in this analysis.

3. Result

In effectiveness study, repeat rate was higher for conventional holder (18.6%) as compared to Bisector© 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 categorized into four types which were "no pain", "mild pain" and "moderate pain" according to the 100mm HVAS as depicted in Figure 1. More than half of the respondents scored "no pain" with scoring range of 0 to 4mm (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 44mm followed by "moderate pain" that ranged between 45 to 74mm. No respondent's scores were obtained for "severe pain" which ranged from 75 to 100mm. The median for "no pain", "mild pain" and "moderate pain" were 0, 15 and 57, respectively.

Table 2. Repeat rate analysis

Holder	Repeat Rate (%)	p-value
Conventional	18.6	0.0251
Bisector©	8.9	

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.³ 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 Bisector© holder. Horizontal Visual Analogue Scale (HVAS) was used in this study to assess the comfort assessment due to its ability to make the best method for the assessment of subjective pain.⁴ This instrument has been used for the measurement of intangible quantities such as pain, quality of life and anxiety.⁵

From the first part of our study to evaluate the effectiveness of the Bisector© 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 repeat, 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".⁶ As pain is very subjective, we further classified the pain as no pain, mild pain, moderate pain and severe pain.^{7,8} Clinical and experimental research indicates that pain is perceived differently and it is depending on a person's sex, race or ethnicity and age.^{11,12} In term of pain perception, women and men respond differently to pain.^{13,14} 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.⁸ 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. Upon unofficial interviews with some patients, it was revealed that most patients who complained of discomfort the size

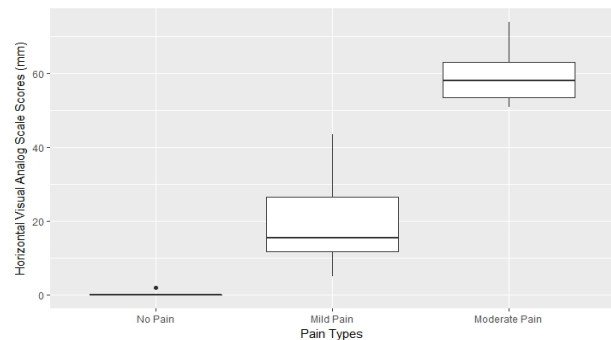
of the sensors contribute to the pain. We also found that the plastic barriers of the sensors caused the discomfort for the patients during the procedure. These findings correlated with the previous study which stated that the average HVAS score for patient discomfort in was significantly higher when plastic barriers are used compared to commercially-available hygienic sheath.⁸ Hence, it is recommended to include these factors while applying Bisector© 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 XCP-DS® Digital Sensor Holder of Denstply RINN® 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 Bisector© holder exhibited lower percentage of repeat as compared to the RINN® 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 utilized 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 Bisector© 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. Conventional holder requires parallelism of the tooth in order to obtain correct position and desirable image, so proper positioning is required.

Figure 1. Box plots of Horizontal Visual Analogue Scale (100mm) categorized by pain types.



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