Accuracy and Reproducibility of Radiographic Images for Assessing Crestal Bone Height of Implants Using the Precision Implant X-ray Locator (PIXRL) Device

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Purpose: *Assessment of crestal bone levels around implants is essential to monitor success and health. This is best accomplished with intraoral radiographs exposed at 90 degrees to the long axis of the implant, but this can be challenging to achieve clinically. Radiographic paralleling devices produce orthogonal radiographs but traditionally have required access to the implant body for each exposure. This study was conducted to determine if use of the Precision Implant X-ray Locator (PIXRL), a radiographic paralleling device that indexes the implant at the time of surgical placement, can produce orthogonal radiographs of dental implants more accurately than traditional radiologic techniques for assessing crestal bone levels.* ***Materials and Methods:*** *Three dental implants were inserted in dry human skulls in supracrestal positions to simulate crestal bone loss (maxillary right first premolar [site 14], maxillary right central incisor [site 11], and mandibular left second premolar [site 35]). The implants were masked with a soft tissue moulage and restored with provisional restorations. Four dental assistants exposed six radiographs using their usual and customary technique and six using the PIXRL device for each implant. A single examiner measured crestal bone levels on the radiographs relative to the implant platform shoulder on the mesial and distal of each implant. Recorded measurements were compared to the known values. Statistical analysis was completed using a generalized linear regression model to analyze the differences, and post-hoc comparisons with pairwise adjustment were applied.* ***Results:*** *The images produced using the PIXRL device were more accurate overall compared to traditional techniques and were also more consistent. The greater degree of accuracy was statistically significant for all sites with the exception of the mesial measurements of the implant at site 11.* ***Conclusion:*** *This study demonstrates that the use of the PIXRL device can assist clinicians in obtaining more accurate orthogonal radiographs for assessing crestal bone height and would be a useful tool for researchers utilizing radiographic imaging of implants as a longitudinal measure of implant success and stability.* Int J Oral Maxillofac Implants 2017;32:830–836. doi: 10.11607/jomi.5683

Keywords: *bone height assessment, dental implants, intraoral radiographs, standardization, success criteria*

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Previously presented at the Academy of Osseointegration Annual Meeting, San Diego, California, February 19, 2016, as an oral presentation in the Clinical Innovations section.

Radiographic assessment of dental implants is a component of previously reported criteria for success, although different studies have had varying parameters defining success. It is known that routine assessment of crestal bone levels around a dental implant is essential to monitor success throughout the lifetime of the dental implant.[1] Intraoral radiographs are the diagnostic method of choice for obtaining the information required to accurately assess the status of crestal bone levels in the most minimally invasive fashion. The classic paper on osseointegration by Albrektsson et al clearly states that repeated and controlled individual radiographs provide the most useful information as to the state of osseointegration.[2] Albrektsson and Zarb further suggest that this does not necessarily guarantee correct clinical decision-making.[3]

The radiographic criteria for implant success has been well established: a mean annual bone loss of less than 0.2 mm after taking into account the changes that occur within the first year.[2–7] The assessment of such small changes requires meticulous radiographic technique that must be accurate and reproducible with good analytic technique.[8] In a study by Sonick et al, computed tomography (CT) radiographs were the most accurate images when compared to panoramic and intraoral periapical radiographs. The images had a mean distortion of 0.2, 3.0, and 1.9 mm, which correlates to an average distortion percentage of 1.8%, 23.5%, and 14% for CT, panoramic, and intraoral periapical radiographs, respectively.[9] Although more accurate on average, CT radiographs may be considered excessive for routine assessment due to an increase of radiation exposure to the patient. Therefore, a properly exposed and developed peri-apical film, or digital image, is the radiograph of choice. Serial radiographs should be made with the film or sensor positioned as parallel as possible to the implant and the x-ray beam at a right angle to the long axis of the implant in order to minimize distortion.[8] The ability to clinically produce consistently accurate radiographs is difficult due to positioning or angulation errors, individual patient anatomic factors preventing proper positioning of the film, and processing or measurement errors.[10–12]

If the radiographs produced for assessment of crestal bone around dental implants could be controlled in a way to consistently produce orthogonal radiographic images, clinicians would be one step closer to having a consistent radiographic method of implant evaluation. However, the ability to consistently produce orthogonal radiographic images only accounts for the vertical angulation component, while the horizontal component has not been controlled. Depending on the anatomy of the alveolar ridge and orientation of adjacent dentition, orthogonal radiographs taken at the same site but at different horizontal angulations can appear very different due to superimposition of adjacent anatomy. This is known as parallax, an apparent displacement or difference in the apparent position of an object caused by an actual change of position of the point of observation.[13] The effect of parallax on an object is dependent on its buccal/lingual position, with a greater effect on buccally positioned objects associated with horizontal angulation changes and a greater effect on lingually positioned objects associated with vertical angulation changes. The use of a radiographic paralleling device, with control for both the vertical and horizontal angulation, would result in more precise serial standardized radiographs.

In the implant literature, almost all dental implant studies that utilize radiographs as a measure of health simply state that serial standardized radiographs were made and implant magnification effects were accounted for. However, this does not take into account the changes in marginal bone appearance as they relate to angulation errors. Little if any information is provided beyond this and it presents an issue if the examiners are interpreting radiographs that cannot be directly related one to the other.

Radiographic paralleling devices have been developed to produce orthogonal radiographs of dental implants, but to date they have required direct access to either the implant body or the abutment for fixation. This is not practical once the implant has been restored.[14–17] Studies have shown that removal and replacement of the prosthesis may result in marginal bone loss, which would confound the effects of other variables being studied.[18–20]

A novel radiographic paralleling device for evaluating implant component fit by facilitating serial standardized radiographs—the Precision Implant X-ray Locator (PIXRL)—has been developed and described.[21,22] The PIXRL device is used to index the implant at the time of surgical placement and does not require future access to the implant or abutment. The authors suggested that this device might be useful in the standardization of periapical radiographic images. The ability to consistently produce accurate radiographic images has great clinical relevance and would be a useful research tool for longitudinal implant evaluation, allowing increased accuracy of measurements. Therefore, the purpose of the present study was to determine if the PIXRL device can be used to produce orthogonal radiographs of dental implants more accurately than traditional radiologic techniques for assessing crestal bone levels, while also improving intra- and interoperator precision.

MATERIALS AND METHODS

Dry human skulls (Kilgore International) with root-form dental implants (NobelParallel Conical Connection RP, Nobel Biocare) placed at three sites (maxillary right first premolar [site 14], maxillary right central incisor [site 11], and mandibular left second premolar [site 35]) were used. The implants were restored with full-contour composite resin (Z100 Restorative, 3M) restorations with provisional metal abutments (Temporary Abutment Engaging Conical Connection RP, Nobel Biocare), and the implant site was masked using a surrogate soft tissue silicone-based gingival mask material (Gi-Mask, Coltene). The PIXRL paralleling devices were used as described by Lin et al[22] (Figs 1a to 1c). Access to the implant body was obtained by removing the provisional restoration. Next, the corresponding implant placement driver was fully seated into the implant body. This step essentially extended the long-axis of the implant. Tray adhesive (Caulk Tray Adhesive, Dentsply) was placed on the underside of the PIXRL

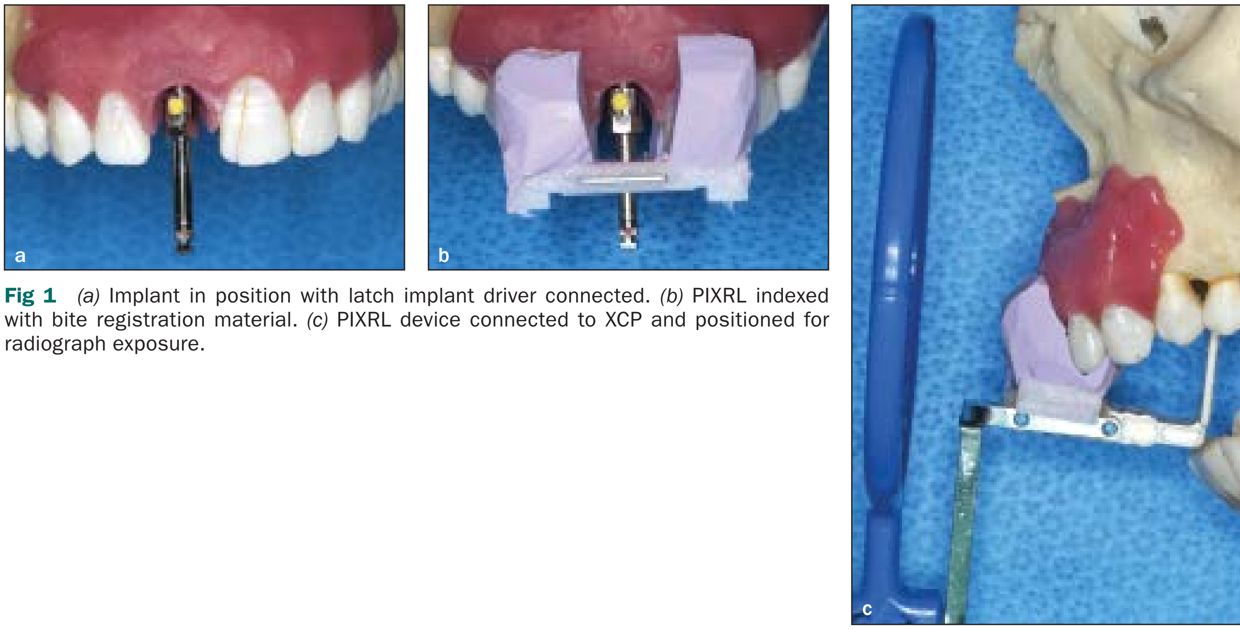

Fig 1 *(a)* Implant in position with latch implant driver connected. *(b)* PIXRL indexed with bite registration material. *(c)* PIXRL device connected to XCP and positioned for radiograph exposure.

device, and a vinyl polysiloxane bite registration material (Regisil VPS, Dentsply) was applied. The PIXRL jig was then connected to the shank of the implant placement driver through the hole in the center and was oriented to make an occlusal registration of the adjacent teeth. Once the registration material was set, the entire PIXRL jig was removed. The implant placement driver was then separated from the PIXRL jig and any excess registration material was also removed. The provisional restoration was replaced on the implant body. The appropriate radiographic film holder was then connected to the PIXRL device. At this point, the device was ready to be used.[22]

Four certified dental assistants who were well versed in making digital radiographs of implants were recruited from the Graduate Periodontics Clinic at the Oregon Health & Science University, School of Dentistry. With their preferred and usual radiographic technique, each of the four dental assistants made six digital radiographs of the skulls at each implant site utilizing a commercially available film holder and six additional images at each site utilizing the PIXRL device. The skulls were in a fixed position attached to the headrest of the dental chair simulating proper patient positioning. In total 144 images were produced, 72 using the traditional technique and 72 with the PIXRL device (Fig 2). The assistants were blinded to all images produced.

The radiographic images were exported from the digital dental radiograph software application (MiPACS Dental Enterprise Viewer, version 3.1.1404, Medicor Imaging) as tagged image file format (TIFF) files. The images were processed and then cropped to provide a direct view of the implant and adjacent bone (iPhoto, Apple) (Fig 3). A total of 288 vertical measurements were made using ImageJ (US National Institute of Mental Health) by one examiner (CG) blinded to how the radiograph was made and by which assistant. The examiner made the vertical measurements on the radiographic images at the mesial and distal of each implant from the implant platform to what the examiner perceived as the directly adjacent marginal bone height. The measurement tool was calibrated within ImageJ by making a horizontal measurement of the implant platform and setting that distance to the known diameter of the implant platform, provided by the implant manufacturer. This calibration was completed for each individual image. The diameter of the implant platform was chosen as the reference to calibrate each image due to the fact that the circular shape is consistent and not affected by the angulation of exposure. As a control, a standardized orthogonal photograph (Fig 4) was made at each implant site with the soft tissue moulage removed, and a calibrated measurement of the implant platform to adjacent marginal bone height was made using ImageJ, utilizing the same process previously mentioned for each radiographic image.

Averages and ranges of measurements with and without the device were collected. All analyses were done in SAS 9.3 (SAS Institute). Since the examiner measured each implant multiple times, a generalized linear regression model was used to analyze the differences (difference from true value and absolute difference from true value) between traditional and PIXRL. Post-hoc comparisons with Tukey pairwise adjustment were applied. $P < .05$ was considered statistically significant.

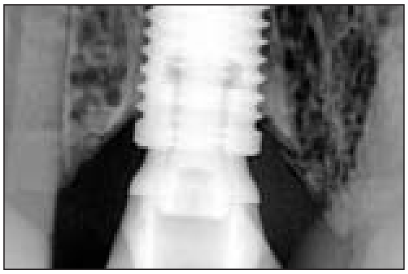

Fig 2 *(Left)* Example of image made of site 11 with the PIXRL device prior to cropping.

Fig 3 *(Center)* Cropped image from which measurements made, mesial and distal implant collar to most coronal bone site.

Fig 4 *(Right)* Control orthogonal photograph of site.

RESULTS

Examples of images produced and the range of measurements made from different assistants are shown in Figs 5 to 7. Use of the PIXRL device resulted in more consistent measurements when compared with the use of the traditional technique (Table 1). The magnitude of the standard deviations among the measurements when the PIXRL device was used compared to the traditional technique indicated a measure of imaging precision. When the traditional technique was used, the standard deviations ranged from ± 0.12 to ± 0.51 mm; when the PIXRL device was used, the standard deviations ranged from ± 0.03 to ± 0.07 mm.

The PIXRL device produced not only more consistent but also more accurate measurements. Therefore, use of the PIXRL device led to more precise radiographs when compared with the use of the traditional technique. Statistically significant differences ($P < .05$) were noted at all sites except for the mesial of site 11 ($P = .0571$) when comparing the absolute differences of the measurements from true values (Table 2).

The skill level and ability to make radiographs among the assistants using the traditional technique appeared to be similar; however, the range of images showed variation, especially with assistant no. 4, where the range appeared narrower (Figs 5c, 6c, 7c). When the PIXRL device was used, the previous degree of variation was not seen within each assistant (intraoperator) or between them (interoperator), as they were able to consistently produce highly accurate and precise radiographs.

DISCUSSION

A general standard of dental implant success as it relates to marginal bone loss is up to 1 mm within the first year and a maximum 0.2 mm per year thereafter.[2,3,7,8] The difficulties in standardization of radiographs unless direct access to the implant or abutment is available have been reported previously; however, repeated entry to the implant or abutment site has been shown to result in operator-induced marginal bone loss.[18–20] Also, the ability to remove a cemented restoration is unpredictable, as is the ability to re-cement without the potential for increasing the likelihood of operator-induced changes as a result of cement extrusion. Therefore, most clinicians and researchers are unable to get standardized, reproducible images. As a result, serial radiographs are usually poorly standardized and the interpretation made may be misleading.

The x-rays, target implant, and film should be related consistently in three planes of space for serial radiographs, with the best image resulting from an orthogonal setup. Lin et al[21,22] described a radiographic positioning device that accomplished serial radiographs using a novel device that indexed the implant and adjacent dentition. Once the implant crown was placed, the paralleling device could still be used. The device was effective in highlighting component fit and was suggested to be useful for assessing bone level changes. In the present study, bone measurements were made that confirmed Lin's assumptions.

This study showed significant variation of the radio–graphs exposed by the four dental assistants when

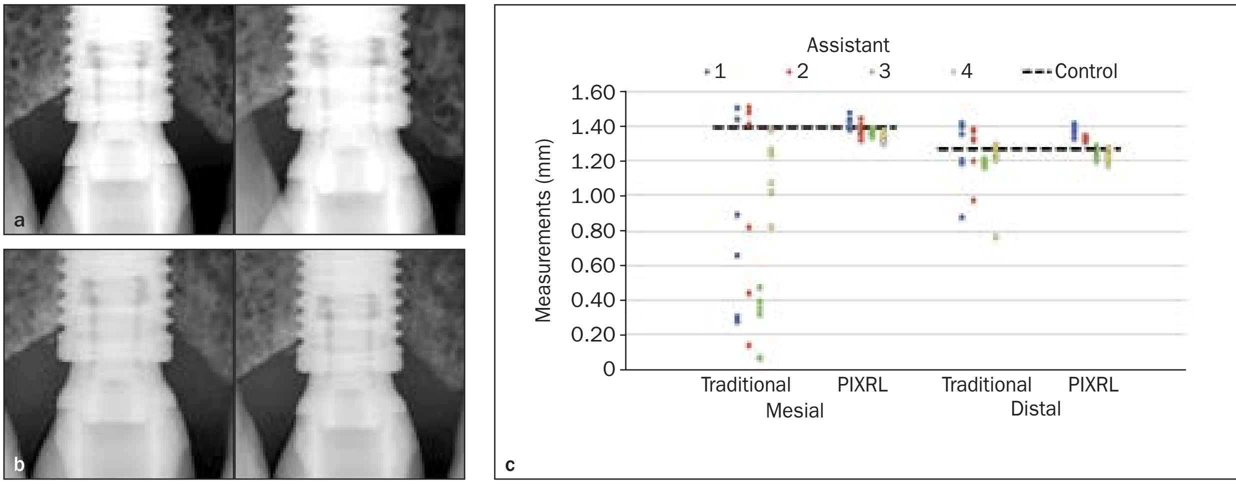

Fig 5 Examples of radiographs made for implant at site 14 *(a)* using traditional technique and *(b)* with paralleling device (PIXRL). *(c)* Graphic representation of range for assistants comparing traditional to PIXRL including control measurement.

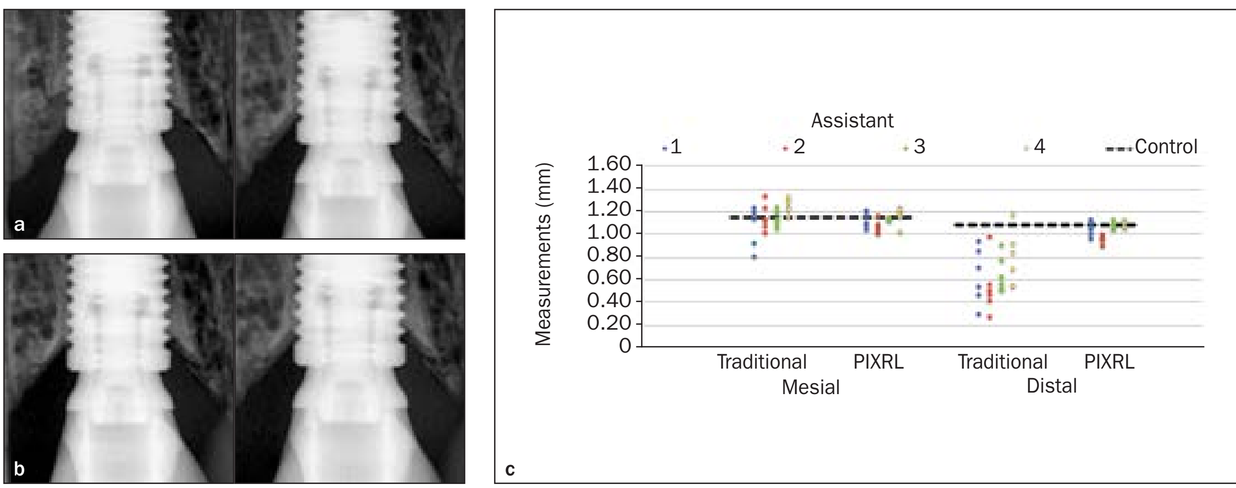

Fig 6 Examples of radiographs made for implant at site 11 *(a)* using traditional technique and *(b)* with paralleling device (PIXRL). *(c)* Graphic representation of range for assistants comparing traditional to PIXRL including control measurement.

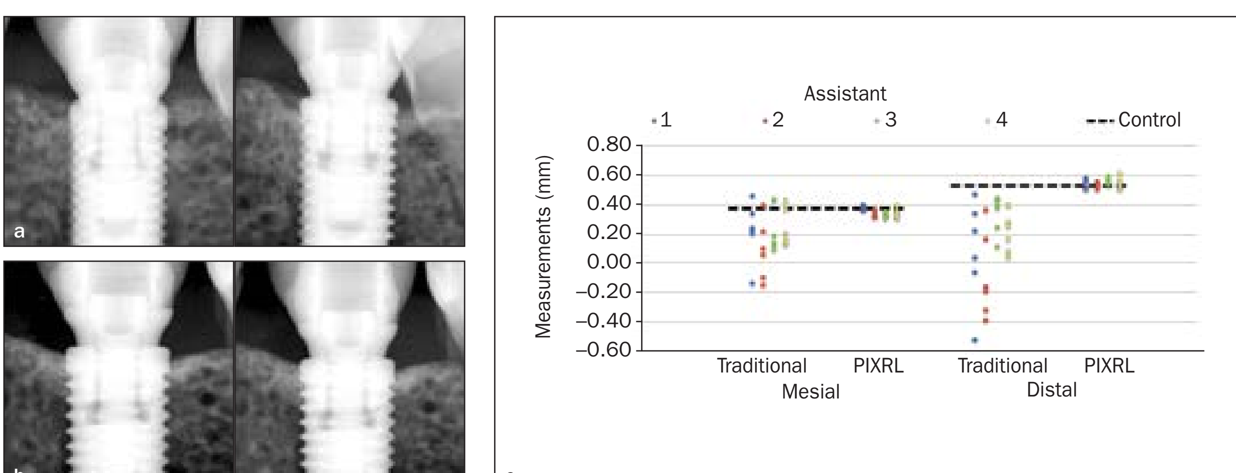

Fig 7 Examples of radiographs made for implant at site 35 *(a)* using traditional technique and *(b)* with paralleling device (PIXRL). *(c)* Graphic representation of range for assistants comparing traditional to PIXRL including control measurement.

Table 1 Mean Marginal Bone Measurements and True Value Measurements

Site	Mesial measurement (mm) Traditional (mean ± SD)	Mesial PIXRL (mean ± SD)	Mesial True value	Distal measurement (mm) Traditional (mean ± SD)	Distal PIXRL (mean ± SD)	Distal True value
14	0.81 ± 0.51	1.38 ± 0.05	1.39	1.22 ± 0.16	1.30 ± 0.07	1.27
11	1.16 ± 0.12	1.13 ± 0.07	1.15	0.65 ± 0.23	1.05 ± 0.07	1.08
35	0.20 ± 0.17	0.35 ± 0.03	0.37	0.14 ± 0.28	0.55 ± 0.03	0.53

Table 2 Absolute Differences from True Values

Site	Mesial measurement (mm) Traditional (mean ± SD)	Mesial PIXRL (mean ± SD)	Mesial *P* value	Distal measurement (mm) Traditional (mean ± SD)	Distal PIXRL (mean ± SD)	Distal *P* value
14	0.61 ± 0.47	0.04 ± 0.03	.0001	0.11 ± 0.12	0.06 ± 0.04	.0457
11	0.09 ± 0.08	0.05 ± 0.04	.0571	0.44 ± 0.21	0.06 ± 0.05	.0001
35	0.20 ± 0.15	0.03 ± 0.02	.0001	0.39 ± 0.28	0.03 ± 0.02	.0001

Statistical significance, $P < .05$.

they used the traditional method with a standard film holder. Interestingly, some of the radiographs made using the traditional method showed bone levels with crests at or coronal to the implant collar; these were clearly artifacts, as all implants were placed supracrestal (Figs 5a, 6a, 7a). These variations were seen among radiographs exposed by different assistants as well as by the same assistant. However, when the PIXRL device was used, the measurements were more accurate and precise, both individually and among the assistants. Using the PIXRL device resulted in more precise exposure of the radiographs regardless of who completed the exposure.

The need for accurate and precise radiographs cannot be overemphasized, not only from the perspective of data collection but also for a clinician's treatment, which relies on test methods. Results that are misinterpreted may lead to overtreatment or undertreatment. The only site that did not show a significant difference ($P < .05$) was the mesial of the maxillary central incisor, site 11 ($P = .0571$). It is likely that this site can be more precisely imaged due to direct access or visualization of the implant area. However, the distal of the site was significantly different with the traditional technique. This may be related to the curvature of the maxillary arch through this region and the effect of parallax.

In the studies by both Lin et al[21] and Begoña Ormaechea et al,[23] which evaluated component fit and radiography, the vertical angulation was critical; however, no variation was reported in regard to horizontal angulation. Significant variations in the height of the crestal bone levels between the midfacial and interproximal sites can create superimposition of bone levels if the horizontal angulation is not accurate and standardized. The use of the PIXRL device allows for consistently accurate positioning of the film or sensor by controlling both the vertical and horizontal aspects.

With respect to implant success, if serial radiographs are not correctly made, the notion that 0.2-mm changes can be identified is clearly incorrect and studies without meticulous detail to the radiographic technique are likely to yield misinformation. Additionally, early diagnosis and intervention of peri-implantitis is critical and may not be possible if a standardized radiographic technique is not used.

A limitation of this in vitro study is that a dehydrated skull was used as a model. Bone appearances vary with hydration and therefore in vivo results may be different. A future in vivo clinical study would be beneficial.

CONCLUSIONS

Within the limitations of this study, the null hypothesis was rejected, as the use of an implant-locating radiographic device gave more accurate and precise representations compared to traditional radiographic technique. Significant variations were seen among radiographs exposed by different assistants as well as by the same assistant when the traditional technique was used. However, when the PIXRL device was used, the measurements were more accurate and the range was much tighter, both individually and among the assistants, with an average of a 0.03 to 0.06 mm absolute difference from the true value, depending on the site. Using the PIXRL device resulted in more precise exposure of the radiographs regardless of who completed the exposure.

ACKNOWLEDGMENTS

The authors report no conflicts of interest related to this study.

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ERRATUM

In the May/June issue of JOMI, in the article "Placement of Zygomatic Implants into the Malar Prominence of the Maxillary Bone for Apical Fixation: A Clinical Report of 5 to 13 Years" (Int J Oral Maxillofac Implants 2017;32: 633–641. doi: 10.11607/jomi.5230) on page 638, Fig 4a was cropped incorrectly. The correct image is as follows:

a

b

We regret the error.