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ABSTRACT

Aim This study aimed to test the accuracy and precision of measurements of three-dimensional (3D) digital models from the pre-dentition period using a noncontact 3D measurement system (3D scanner) versus the gold standard method of direct measurements using a digital caliper on plaster models.

Materials and methods Ten pairs of plaster models were obtained from children during the pre-dentition period. Linear measurements were performed using both methods. Three operators were trained in the use of both methods for this study. Measurements were performed with a minimum 2-week interval between measurements in a randomly chosen order.

Results The mean difference between the measured values using the two methods was <0.2 mm for each measurement. There was no linearity in the measurements using pre-dentition digital models. An ANOVA Gage R&R analysis revealed that there was no significant operator difference (P < 0.307). The rate of variation of the 3D scanner over the total variation was 2.8%. The ICC was 0.982 (P < 0.001), suggesting excellent interoperator agreement.

Conclusion The results suggest that measurements of digital 3D pre-dentition models are highly accurate and precise, and also comparable to measurements using the gold standard method.

Keywords Morphometric analysis; Plaster models; Predentition period; Threedimensional digital models.

Introduction

With the growing interest in infant oral health, the involvement of dentists in neonatal care, and a national trend to treat decay and developing malocclusions at ever younger ages, knowledge about early orofacial development has become increasingly important [Ranly, 1998]. For instance, malocclusion is caused by a combined influence of genetic and environmental factors [Proffit et al., 2007]. Children who sleep lying with their face down during infancy were found to have a retracted [Kaihara et al., 1999], reduced arch width, increased arch length in the maxilla, larger overjet, and symmetrical and V-shaped forms [Kaihara et al., 1998]. These findings suggest that the early diagnosis of disorders affecting the palate and alveolar ridge during the pre-dentition period may not only prevent malocclusion, but also promote normal development of dental arches and jaw function.

Study model analysis is an essential component of the assessment of occlusion, diagnosis, treatment planning, and evaluation. Traditionally, diagnostic measurements have been obtained from plaster models as the gold standard. The most important determination in the evaluation of paediatric patients’ dental arches are linear measurements. However, in recent years, more accurate digital images of study models (digital models) have been obtained due to significant advances in the noncontact three-dimensional (3D) measurement systems [Abizadeh et al., 2012; Asquith et al., 2007; Bell et al., 2003; Bootvong et al., 2010; Dalstra and Melsen, 2009; Leifert et al., 2009; Quimby et al., 2004; Redlich et al., 2008; Santoro et al., 2003; Veenema et al., 2009; Zilberman et al., 2003]. Digital models have gained attention for their use in virtual model analysis and treatment simulation [Abizadeh et al., 2012; Asquith et al., 2007; Bell et al., 2003; Bootvong et al., 2010; Dalstra and Melsen, 2009; 2011; Leifert et al., 2009; Quimby et al., 2004; Redlich et al., 2008;
Santoro et al., 2003; Veenema et al., 2009; Zilberman et al., 2003]. Furthermore, digital models are easily accessible [Bootvong et al., 2010; Leifert et al., 2009; Quimby et al., 2004; Santoro et al., 2003; Veenema et al., 2009] and require minimal storage space [Abizadeh et al., 2012; Bell et al., 2003; Bootvong et al., 2010; Dalstra and Melsen, 2009; Leifert et al., 2009; Quimby et al., 2004; Redlich et al., 2008; Santoro et al., 2003; Zilberman et al., 2003].

To ensure that these new measurement modalities optimise diagnosis and treatment, it is essential to evaluate the accuracy and precision of any new type of 3D measurement system in comparison to the gold standard method, in this case caliper measurements on plaster models, prior to being introduced in clinical research. To aid dentists in deciding which measurements to be used, an analysis of measurements made by multiple operators using both methods on paediatric patients during the predentition period is necessary. According to previous reports, the differences between linear measurements obtained using calipers on plaster models and those obtained from digital models were <0.5 mm and were deemed clinically insignificant [Bell et al., 2003; Dalstra and Melsen, 2009; Leifert et al., 2009; Quimby et al., 2004; Redlich et al., 2008; Santoro et al., 2003; Veenema et al., 2009; Zilberman et al., 2003]. However, the accuracy and precision of 3D measurements using digital models from the pre-dentition period as a predictive model of malocclusion has not been tested.

This study aimed to test the accuracy and precision of 3D digital models from the pre-dentition period against direct measurements on plaster models.

**Materials and methods**

This retrospective study was conducted using plaster models (maxillary and mandibular) obtained from 10 Japanese full-term infants (mean age 4.4 months) weighing 2,500–3,500 g at birth. The Ethics Committee of Epidemiology, Hiroshima University approved the study protocol (No. 329).

**Measurements**

All experiments in this study compared the direct measurements of unmarked plaster models with the measurements of 3D digital models obtained from the same subject. Direct measurements were performed using a digital caliper (Digimatic Caliper: CD-15CPX; Mitutoyo, Kawasaki, Japan) with an accuracy of 0.01 mm. The digital models were obtained by scanning maxillary and mandibular plaster models using a noncontact 3D laser scanner (RexcanDS; Solutionix, Seoul, Korea). The measurement system of the RexcanDS is based on the principle of phase-shifting optical triangulation. The scanner provides noncontact high-accuracy inspection up to a cited resolution of 0.016 mm. RapidForm 2006 software (INUS Technology, Seoul, South Korea) was used to reconstruct the scanned image into a digital model (Fig. 1A). The linear measurements were performed using a function in the RapidForm 2006 software. The 13 measurement points, defined for our hypothesis while referencing Sillman’s study [Sillman, 1938], are shown in Figure 1B.

All measurements were performed under uniform conditions with at least a 2-week interval between measurements to avoid correlations between data resulting from repeated measurements.

**Data analysis**

The accuracy and precision of the 3D scanner compared to the caliper for the measurement of pre-dentition plaster models was evaluated based on the following four steps.

1. A typical measurement part (i.e., section) was chosen,
then the differences between the measurements obtained using a caliper (gold standard) and a 3D scanner were determined.

2. If there were no differences between the two methods, we determined whether equivalent results were also found in other sections using a bias and linearity study [AIAG, 2002; Bevilacqua et al., 2011].

3. The precision of the 3D scanner measurements was then verified using the Gage repeatability and reproducibility (R&R) method [AIAG, 2002; Bevilacqua et al., 2011].

4. The intraclass correlation coefficients were calculated to assess the reliability of measurements made by different operators.

Differences between the measured results using a caliper and a 3D scanner

The quantitative measurements were first verified for normality using the Shapiro-Wilk W test. A well-trained operator performed the caliper and 3D scan distance measurements between LoRB and LoLB. Differences in measurements using the two techniques were analysed by a paired t-test. If no significant differences were detected, a post hoc statistical power analysis was conducted to determine the sample size needed to attain a power of 80% to ensure that the insignificant difference was not because of a lack of detection power. A minimum sample size of 10 plaster pairs from different infants was calculated based on an acceptable difference between the mean and standard deviation (SD) of 0.2 mm and a power of 80% by a paired t-test. These acceptable differences were decided based on the results of our previous study using the same 3D scanner [Kaihara et al., 2014].

Bias and linearity of 3D measurements on pre-dentition digital models

Bias and linearity were tested to determine if it is possible to obtain the same measurement for any part. For calculating bias, the distances obtained on the 3D scanner were expressed relative to the mean of caliper measurements as a reference value (gold standard). If there was a significant difference between the two techniques, the impact of target size was evaluated (linearity). The number of parts with different sizes (n = 5), sample size (n = 1), operators (n = 1), and replicates (n = 10) were then determined based on the AIAG (2002) and ISO/TS16949 [Bevilacqua et al., 2011] guidelines. One operator trained using both techniques carried out 10 measurements using a pair of plaster models for five parts (UA-URB, URM-ULM, URB-ULB, LoRM-LoLM, LoRD-LoLD) (Fig. 1). First, each 3D scanner measurement was subtracted from the mean caliper reference value (single bias). Then we calculated the difference between the mean value of the 3D scanner measurements and the mean value of the caliper measurements (mean bias) for each part.

Repeatability and reproducibility of 3D measurements on pre-dentition digital models

Repeatability and reproducibility of 3D scanner measurements on pre-dentition digital models were analysed using an analysis of variance (ANOVA) Gage R&R analysis (two-way random effect model). The number of parts (n = 1; URC-ULC), sample size (n = 10), operators (n = 3), and replicates (n = 3) were determined based on the AIAG [2002] and ISO/TS16949 [Bevilacqua et al., 2011] guidelines. Each operator conducted the measurements independently in a randomly chosen order.

Calculation of intraclass correlation coefficient

The intraclass correlation coefficient (ICC) was computed using the results of the ANOVA test to assess the reliability of measurements made by different operators.

Statistical analysis

The statistical analyses were performed using IBM SPSS Statistics for Windows (version 20; SPSS, Inc., Tokyo, Japan) and R for windows (version 2.15.0; R Foundation for Statistical Computing, Vienna, Australia).

Statistical significance was set at P < 0.05.

Results

Differences between the results obtained using a caliper and a 3D scanner

The Shapiro–Wilks W test for normality indicated that the measurements were distributed normally (P = 0.245). Therefore, the measurements made on the digital models using the 3D scanner and those made with the caliper on plaster models were analysed with parametric tests (Table 1). First, a paired t-test revealed that there was no significant difference between the two methods (P = 0.65). The average difference was 0.025 ± 0.17 mm. A post hoc power analysis generated a power of 0.910, suggesting that the sample size was powerful enough to detect differences of 0.2 mm. Therefore, a difference between values measured by caliper and values measured by 3D scanner was not observed.

Bias and linearity of 3D measurements on pre-dentition digital models

Table 2 shows the mean bias between the distances measured using the 3D scanner and the calipers. The mean bias of two of the five sections obtained from the two measurement methods were statistically significant (P < 0.05, Student’s t-test). However, all of the five sections showed a difference of ≤0.2 mm (absolute value). Therefore, the differences between the mean
values were within the clinically acceptable range. An ANOVA indicated that the slope (linearity) and Y intercepts were not significantly different from zero (P = 0.955 and 0.958, respectively).

These data are clearly illustrated by a regression analysis between the 3D scanner bias and reference values that were the mean value of 10 measurements using calipers (Fig. 2). The five measurement pairs are ordered by size from small to large on the Y-axis. The 95% confidence interval (CI) in the upper and lower parts of the regression included the horizontal line that passed the origin (bias = 0), suggesting that the fitted straight line is statistically the same as the horizontal line. We therefore concluded that there is no linearity.

Repeatability and reproducibility of 3D measurements on digital models

There was no significant intraoperator variability for each replicate (P = 0.307) (Table 3). However, the variation of different patients (patient-to-patient) was statistically significant (P ≤ 0.000). As such, there was a significant interaction between operators and measurement points (P = 0.007).

Variance components of pre-dentition digital models were assessed using the Gage R&R report (Table 4).

The relations between these variability components

\[
\sigma^2_{\text{total variation}} = \sigma^2_{\text{total Gage R&R}} + \sigma^2_{\text{patient to patient}} \\
\sigma^2_{\text{total Gage R&R}} = \sigma^2_{\text{repeatability}} + \sigma^2_{\text{reproducibility}} \\
\sigma^2_{\text{reproducibility}} = \sigma^2_{\text{operator}} + \sigma^2_{\text{operator} \times \text{patient}}
\]

The contribution of each variability component (VarCompContrib) corresponded to the ratio of each component over the total variation for a sum equal to 1. According to the guidelines [AIAG, 2002; Bevilacqua et al., 2011], if VarCompContrib is >0.09 (9%), the measurement system is not acceptable. If 0.01 (1%) ≤ VarCompContrib ≤0.09 (9%), the measurement system is marginal. If VarCompContrib is <0.01 (1%), the measurement system is acceptable. In this study, VarCompContrib was 0.028 (2.8%). Therefore, the evaluation of our 3D scanner was marginal.

The %Study variation (%StudyVar) is equal to the SD of

![Fig. 2 Results of the bias and linearity study.](image)

### Table 1: Statistical analysis of the difference between the two methods.

<table>
<thead>
<tr>
<th>Difference of mean (mm)</th>
<th>SD (mm)</th>
<th>95% CI (mm)</th>
<th>Paired t-test</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Lower</td>
<td>Upper</td>
</tr>
<tr>
<td>-0.03</td>
<td>0.17</td>
<td>-0.10</td>
<td>0.15</td>
</tr>
</tbody>
</table>

### Table 2A: Results of the bias and linearity study.

<table>
<thead>
<tr>
<th>Parts</th>
<th>Reference value (mm)</th>
<th>Mean of bias (mm)</th>
<th>P value (t-test)</th>
</tr>
</thead>
<tbody>
<tr>
<td>UA-URB</td>
<td>9.83</td>
<td>-0.09</td>
<td>0.02</td>
</tr>
<tr>
<td>URB-ULB</td>
<td>18.40</td>
<td>0.15</td>
<td>0.12</td>
</tr>
<tr>
<td>LoRC-LoLC</td>
<td>24.13</td>
<td>0.00</td>
<td>0.96</td>
</tr>
<tr>
<td>LoRD-LoLD</td>
<td>27.29</td>
<td>-0.05</td>
<td>0.27</td>
</tr>
<tr>
<td>URM-ULM</td>
<td>31.85</td>
<td>-0.02</td>
<td>0.78</td>
</tr>
</tbody>
</table>

### Table 2B: Results of the bias and linearity study.

<table>
<thead>
<tr>
<th>Coefficients</th>
<th>Estimate</th>
<th>SE</th>
<th>t value</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>(Intercept)</td>
<td>-0.0038</td>
<td>0.0730</td>
<td>-0.053</td>
<td>0.958</td>
</tr>
<tr>
<td>slope</td>
<td>0.0002</td>
<td>0.0031</td>
<td>0.057</td>
<td>0.955</td>
</tr>
</tbody>
</table>

SE = standard error; Reference value, mean of caliper measurements.
each component multiplied by the $6 \times$ SDs that enclose the central 99% of a normal distribution. If $%\text{Study Var} > 30\%$, the measurement system is unacceptable. If $10\% \leq %\text{Study Var} \leq 30\%$, the measurement system is marginal. If $%\text{Study Var} < 10\%$, the measurement system is acceptable [AIAG, 2002; Bevilacqua et al., 2011]. In this study, the $%\text{Study Var}$ of the total Gage R&R was 16.8% (1.490/8.860 × 100), meaning that the 3D scan measurements were marginal.

The number of distinct categories (NDC) designates the number of distinct groups within the processed data that the measurement system can discern. The measurement system is adequate if $\text{NDC} \geq 5$ [AIAG, 2002; Bevilacqua et al., 2011]. In this study, the $\text{NDC}$ was 8, and the 3D scanner could clearly distinguish the interpatient differences. This means that the 10 patients are different enough to be differentiated by the 3D scanner analysis.

Figure 3 shows the Gage R&R charts. The bar plot represents the components of variation, displaying bars for total Gage R&R, repeatability, reproducibility, and patient-to-patient variation (Fig. 3A). The vertical axis presents the ratio of the components of variance for VarCompContrib and StudyVar. In a reliable measurement system, patient-to-patient variability should account for most of the variability, as shown in this study. These data are consistent with the fact that there was no significant interoperator difference ($P = 0.307$) (Table 3) or operator plot analysis (Fig. 3B). The operator × patient interaction plot displays the average measurements by each operator for each patient (Fig. 3C). Each line connects the averages for a single operator. While the operator × patient interaction was found significant ($P = 0.007$) (Table 3), the VarCompContrib was low (0.9%) (Table 4), suggesting an overall small contribution to the total measurement variability.

**TABLE 4** The Gage R&R report for the ANOVA method (2-way random effect model).

<table>
<thead>
<tr>
<th>Source of Variability</th>
<th>Variance components</th>
<th>VarCompContrib</th>
<th>SD</th>
<th>Study variation (6 SD)</th>
<th>StudyVarContrib (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Gage R&amp;R</td>
<td>0.062</td>
<td>0.028</td>
<td>0.248</td>
<td>1.490</td>
<td>16.8</td>
</tr>
<tr>
<td>Repeatability</td>
<td>0.042</td>
<td>0.019</td>
<td>0.205</td>
<td>1.228</td>
<td>13.9</td>
</tr>
<tr>
<td>Reproducibility</td>
<td>0.020</td>
<td>0.009</td>
<td>0.141</td>
<td>0.844</td>
<td>9.5</td>
</tr>
<tr>
<td>Operator</td>
<td>0.001</td>
<td>0.000</td>
<td>0.029</td>
<td>0.176</td>
<td>2.0</td>
</tr>
<tr>
<td>Operator × Patient</td>
<td>0.019</td>
<td>0.009</td>
<td>0.138</td>
<td>0.826</td>
<td>0.1</td>
</tr>
<tr>
<td>Patient to Patient</td>
<td>2.119</td>
<td>0.972</td>
<td>1.456</td>
<td>8.734</td>
<td>98.6</td>
</tr>
<tr>
<td>Total Variation</td>
<td>2.181</td>
<td>1.000</td>
<td>1.477</td>
<td>8.860</td>
<td>100.0</td>
</tr>
</tbody>
</table>

SD = standard deviation; VarCompContrib = contribution of variance components; StudyVarContrib = contribution of study variation.

**FIG. 3** Gage R&R charts with the ANOVA method. A Contribution of variance components.
Intraclass correlation coefficient
The ICC was 0.982 [P < 0.001; 95% CI, 0.956–0.996], suggesting excellent interobserver agreement.

Discussion
This study investigated the potential usefulness of a new noncontact 3D measurement system to measure paediatric dentition models of the predental period compared to the measurements of plaster models. The paired t-tests and bias and linearity studies found no clinically significant difference in accuracy between the direct measurement of plaster models with calipers and the measurement of digital models. These findings also suggest that noncontact 3D measurement system can be used to obtain the same measurements at any point.

Our previous study, which documented linear measurements of deciduous dentition, revealed average differences of <0.2 mm between using the same 3D scanner and caliper measurements. [Kaihara et al., 2014]. Previous studies, were deemed clinically significant, reported average differences between linear measurements of dental casts and 3D images: 0.27 [Bell et al., 2003], 0.62–0.19 mm [Asquith et al., 2007]; 0.16–0.49 mm [Santoro et al., 2003]; 0.15–0.61 mm [Quimby et al., 2004]; <0.5 mm [Leifert et al., 2009]. The present study shows equal or higher accuracy of the 3D measurement system during the predentition period, with bias within 0.2 mm, compared to the gold standard. The size of the section did not affect the measurement. It may be suitable for morphometric analysis of pre-dentition plasters in a clinical setting starting only a few months after birth.

Based on the results of the Gage R&R, most of the variability in 3D scanner measurements was observed due to part-to-part variability, which was very small compared with the clinically assumable interoperator and intraoperator effect. This analysis also showed a clear distinction of interpatient difference. Moreover, the low contribution of the operator × patient interaction variability (0.9%) and the high ICC (>90%) demonstrated that the operator is not expected to affect the quality of the measurements.

With respect to differences in variability between the two methods, previous reports have described higher [Dalstra and Melsen, 2009] or lower [Quimby et al., 2004; Zilberman et al., 2003] variability in 3D measurements compared to caliper measurements of postdentition plaster models. Nonetheless, all studies recognised the usefulness of the 3D scanner [Santoro et al., 2003; Quimby et al., 2004; Zilberman et al., 2003]. Bootvong et al. [2010] reported that ICCs were >0.70, and concluded that there was substantial-to-excellent agreement between assessments of tooth dimensions and arch relations from plaster and virtual
models. Quimby et al. [2004] reported that ICCs were ≥0.90 for all measurements. In our previous study on the measurement of deciduous dentition using the same 3D scanner, ICCs were typically >90% [Kaihara et al., 2014]. The ICC of this study (0.984) are in agreement with these reports, demonstrating the reliability of measurements with different operators and the potential usefulness of the 3D scanner during the pre-dentition period.

Although not clinically relevant, the variation in data sets may represent challenges in viewing control or landmark identification performed on a computer screen [Abizadeh et al., 2012; Asquith et al., 2007; Leifert et al., 2009; Zilberman et al., 2003]. This may be related to the result of the Gage R&R, which showed that the VarCompContrib and StudyVar values were larger for repeatability than for reproducibility. Despite the potential for improvement in these aspects, our results show that in terms of precision, the analysis of pre-dentition digital models is comparable to the gold standard method.

In addition to the challenge of identifying certain landmarks on a computer screen, this study highlights other areas for further investigation. For example, the reliability of measurements of angle, area, and volume should be examined. It will also be important to verify the 3D image analysis on growth changes from birth. Moreover, our results can help to verify the differences in growth patterns of the alveolar region and palate of the infants in a 3D view based on the malocclusion type of their family. Clarifying these remaining issues would confirm the reliability and potential usefulness of 3D measurements of dentition models and could lead to the adoption of this simple, convenient method in clinics and academic research centres.

The results suggest that the accuracy of analysing pre-dentition plaster models using a 3D scanner is comparable to that of the gold standard method employing plaster models and digital calipers. The 3D scanning system has many advantages over manual measurement methods. These results might lead to more widespread adoption of this technology for the morphometric analysis of pre-dentition models.

**Conclusion**

This study suggests that dentition analysis of pre-dentition digital models has high accuracy and precision, comparable to that of direct measurement of plaster models by digital calipers. This 3D system could be used in clinics and be adopted for analysing palates and alveolar ridges of children during the pre-dentition period.

**References**