Clinical assessment of efficiency and patient preference of diagnostic dental model acquisition for 3D printing via alginate impression and stone model scan vs. intraoral scan

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Clinical Assessment of efficiency and patient preference of diagnostic dental model acquisition for 3D printing via alginate impression and stone model scan vs. intraoral scan

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Abstract

Aims: Test three null hypotheses, that there were no differences in: 1. mean digital file acquisition times between the methods of desktop scanning of stone dental models and wax bite registrations, derived from alginate impressions (AI), and digital intraoral scanning (IS) of teeth and supporting structures, 2. subjects' preferences between alginate impressions plus wax bite registration and digital intraoral scan for diagnostic model acquisition, and 3. the clinical acceptability of diagnostic models between the two impression methods.

Methods: Subjects having initial orthodontic records (OR) and experienced clinical operators (CO) gave informed consent to participate. For each OR subject, CO subjects had steps for both methods identified via stop-start cues which were video-recorded. Times were determined by playback. OR subjects were surveyed about overall experience and comfort (0-100 Visual Analog Scale, VAS) and preferred method. Dental model quality was graded by CO subjects using a 9-point index. Paired t-tests compared times, VAS, and model quality scores between methods where $P<0.05$ defined significant differences. Mixed-effects model with post-hoc Tukey tests compared time differences between clinical operator and impression technique.

Results: For 30 OR subjects, IS vs AI methods had significantly shorter overall times (16:00±4:54 vs 26:51 ± 8:26 min:sec; $P<0.001$) and better but not significantly different VAS (overall: 78±18 vs 75±25, P=0.50; comfort: 76±19 vs 69±25, P=0.14). Preferences for IS, AI, and both methods were 57%, 37%, and 7%, respectively. Model quality scores were significantly higher for IS vs AI models (7±2 vs 6±2, P=0.01). The success rate for IS models was 90% vs 77% for AI models.

Conclusion: 1. The overall mean digital model acquisition times by IS was significantly shorter than by AI; 2. IS was the preferred method of diagnostic model acquisition versus AI but overall experience and comfort were not significantly different between impression techniques; 3. Digital models derived from IS had higher model quality scores and frequency of "clinically acceptable" models when compared to AI.

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Introduction:

The dental profession is currently undergoing a paradigm shift towards the digital age with increased utilization of technology in diagnosis, treatment planning, and delivery of treatment. Orthodontics in particular has seen a surge in recent years with the usage of intraoral scanners and 3-dimensional (3D) printing technologies.[1] Traditionally, diagnostic models derived from alginate impressions were used as the gold standard for treatment planning among orthodontists.[2] Alginate is a powder containing alginic acid, a compound derived from brown algae, which, when mixed with water, forms a viscous sol that can be used to capture an accurate impression of the intra-oral structures. Once removed from the mouth, the alginate impression can be filled with plaster powder mixed with water, which when set, forms a stone replica or model. The limitations of this method include physical space needed for storage of the stone models, risk of chipping or breakage of these models, and associated expenses for materials.[3]

With advances in 3D imaging technology, there has been a transition to digital models for convenient storage, improved file accessibility and availability for communication with other providers in real time, and elimination of model breakage.[3] As a result of these benefits, more orthodontic providers are incorporating digital models into their practices.[4] Currently there are three methods for creation of digital 3D models by desktop scanning of plaster models, direct scanning of intraoral structures, or indirect digitization with cone beam computed tomography (CBCT).[5] Digital intraoral scanners were initially introduced in the 1980s with the development of Chairside Economical Restoration of Esthetic Ceramics (CEREC) for restorative dentistry and the first in-office digital impression system capable of capturing full arch scanning became commercially available in 2008.[6] Intraoral scanning technology produces 3D representations of an object by gathering surface data points via a light projection from a handheld wand that is reflected back to the camera sensor from the object of interest.[6] Computer software processes this information to create point clouds which are then triangulated to create a 3D surface model in the form of a standard tessellation language (STL) file.[7] The accuracy of these STL files has been verified. That is, any advantages of digital models would be negated if the accuracy of 3D models was not comparable with that of the conventional approach of model acquisition using alginate impressions. Studies comparing the accuracy of full-arch digitization found that models were clinically acceptable for diagnosis, treatment planning, and fabrication of removable orthodontic appliances to an accuracy of 0.2mm.[4, 8] Furthermore, users need to accept that digital images are literally viewed on a 2D screen. However, from digital diagnostic models, it is possible to construct digital orthodontic treatment plan setups to help guide treatment options, better understand treatment limitations, quantify amounts of tooth movement, identify which teeth will not be moved or will need to resist movement forces (anchorage needs), and predict treatment results.[9] These benefits facilitate the delivery of treatment alternatives to patients to allow them easier understanding of proposed treatment.[10]

From digital models it is possible to plan and manufacture devices for interceptive and corrective orthodontics with fixed appliances and clear aligners.[11] Notable advantages to the utilization of computer-aided design and computer-aided manufacturing (CAD/CAM) software for appliance fabrication include durability and precision, allowing for digital models to be repaired or altered accurately prior to appliance fabrication.[12] By eliminating the intermediary step of conventional impression and stone model casting, potential errors are reduced by creating an accurate representation that is one step closer to the analogue being replicated.[13] Previous studies assessing the accuracy of direct CAD/CAM fabrication of orthodontic appliances from digital models has been found to be clinically acceptable to an accuracy of within 0.5mm.[14, 15] Additional benefits include improved infection control for patients and better occupational safety by reducing the chain of infection transmission made possible by traditional manufacturing techniques.[16] Fixed appliances can be digitally removed and retainers can be fabricated and immediately delivered following removal of fixed appliances in vivo , resulting in fewer appointments and shorter chairside time.[12] If a patient loses or damages an orthodontic appliance, then the same model can be used to produce replacement appliances. If any relapse is noted, it is feasible to correct teeth positions and produce appliances for realignment virtually.[11] While the accuracy of models and appliances derived from the two impression techniques described above have been verified, the clinical acceptability of these models has not been investigated. No study to date has aimed to assess how often a diagnostic model is of useful quality for means of treatment planning and appliance fabrication.

Patient preferences for clinical techniques can give important insight. That is, the most efficient chairside impression technique would not be applicable if it was uncomfortable, and patients were not accepting of it. There have been conflicting results on patient preference for type of impression technique. In a study by Grunheid et al.[4] it was concluded that 73% of patients preferred conventional impressions over intraoral scanning whereas Burhardt et al.[17] found that 51% of patients preferred digital impressions, 29% chose alginate impressions, and 20% had no preference.

Previous studies to evaluate the efficiency of diagnostic model acquisition between conventional and digital techniques have shown varying conclusions on the most efficient method. Sfondrini et al. assessed the diagnostic model acquisition efficiency and post processing times for sending stone models to a commercial lab for digitization and found that digital scanning had a mean total model acquisition time of 5:49 min:sec when compared to a mean time of 22:06 min:sec for conventional techniques and these differences were significant ($P<0.001$).[18] They concluded that digital scanning is more time efficient than traditional impression techniques.[18] In contrast, the same study above by Grunheid et al. found that total mean time for chairside procedures and processing tasks for conventional impressions and intraoral scans were not statistically significantly different with total times of 22:12 min:sec and 20:47 min:sec, respectively.[4] To our knowledge no study to date has compared the in-office time efficiency for digital model acquisition as a STL file, ready for treatment planning or appliance construction, between extraoral scanning of a stone model derived from an alginate impression and intraoral scanning.

The overall objective of the present study was to address the growing trends in orthodontics towards digital in-office 3D printing of orthodontic appliances with an emphasis on efficiency of digital workflow. Efficient digital workflow is based on the foundation of time-effective pre-treatment model acquisition. In a clinical practice setting, time spent per patient interaction has costs for both the patient and for office overhead. The benefits of in-office 3D printing of dental models for appliance construction (such as clear aligners) include quicker delivery of orthodontic treatment and more control by the orthodontist in treatment planning and delivery. The aim of this study was to compare the acquisition and processing times for digital diagnostic dental models, used for three-dimensional (3D) printing, acquired by two methods: 1) stone model of intraoral structures derived from alginate impression and scanned via desktop scanner, and 2) digital intraoral scan. Additionally, subjects' preferences between alginate impressions plus wax bite registration and digital intraoral scanning techniques were compared. The final aim was to assess for differences between the clinical acceptability of diagnostic models derived from alginate impressions and intraoral scanning using a simple grading rubric. The three null hypotheses tested were that there were no differences in: 1. mean digital file acquisition times between the methods of desktop scanning of stone models and wax bite registrations, derived from alginate impressions, and digital intraoral scanning of teeth and supporting structures, 2. subjects' preferences between alginate impressions plus wax bite registration and digital intraoral scan for diagnostic model acquisition, and 3. the clinical acceptability of diagnostic models between the methods of desktop scanning of stone models and wax bite registrations, derived from alginate impressions, and digital intraoral scanning of teeth and supporting structures.

Materials and Methods:

Subjects

The present pilot study was conducted at the Oregon Health & Science University (OHSU) School of Dentistry Orthodontics Department, Portland Oregon. Approval of the study protocol was obtained from the OHSU Institutional Review Board (Appendix A). Informed consent was obtained from all subjects or legal representatives of subjects. There were two types of subjects. One type were adolescent and adult subjects who planned to have comprehensive orthodontic treatment at the Oregon Health & Science University (OHSU) Graduate Orthodontics Clinic and who needed orthodontic records (OR subjects). The target accrual for OR subjects was a convenience sample of 30 adolescent and adult subjects, equal numbers of males and females. Potential OR subjects were identified after screening for orthodontic treatment and scheduling for a visit to make orthodontic records, which included having dental impressions made. Inclusion criteria for OR subjects in this study were fully erupted permanent dentition including at least one permanent molar in each quadrant and English-speaking subjects/parents or guardians. Individuals with temperature or pressure-sensitive teeth, limited mouth opening, temporomandibular disorders, mental or developmental disabilities, craniofacial anomalies, epilepsy, dental fear, or hyperactive gag reflex were excluded from the study.

The other type of subjects were clinical operators (CO) that were identified and recruited from trained orthodontic dental assistants (DA) employed at OHSU School of Dentistry and graduate orthodontic students (OGS) currently enrolled at OHSU. Both DA and OGS routinely performed impressions for diagnostic treatment planning and were qualified to perform these tasks in a clinical setting. Inclusion criteria included previous experience with alginate impression and digital intraoral scanning techniques. Clinical operators were calibrated with each impression method per manufacturer's recommendations and trained to follow the study procedures. CO subjects declining participation in the study were excluded from consideration.

Study Design

Each OR subject enrolled in the study experienced two clinical methods: impression-making with digital intraoral scanning (Fig 1a) and alginate material (Fig 1b), commonly used to acquire 3D replicas of the teeth and intra-oral structures (Fig 1c). Times for these clinical methods were measured in conjunction with times for processes needed to create a digital STL file (Fig 1d) for orthodontic treatment planning. Following both impression procedures, subjects were given a survey with a series of 7 questions assessing comfort and personal preference, utilizing a visual analogue scale (VAS), multiple-choice, and free-form written responses. Clinical procedures were performed by subjects who were trained clinical operators (CO subjects) who also performed the subsequent digitization for STL file creation. Each orthodontic records subject (OR) was assigned randomly to a CO subject to undergo a maxillary and mandibular alginate impression, intraoral scan, and occlusal registration procedure during the same records appointment (Table 1). The order of impression procedures for each subject was assigned according to a randomized sequence generator prior to the initial records appointment. Therefore, half of the subjects were assigned to start with the conventional technique and the remaining half assigned to start with digital intraoral scanning.

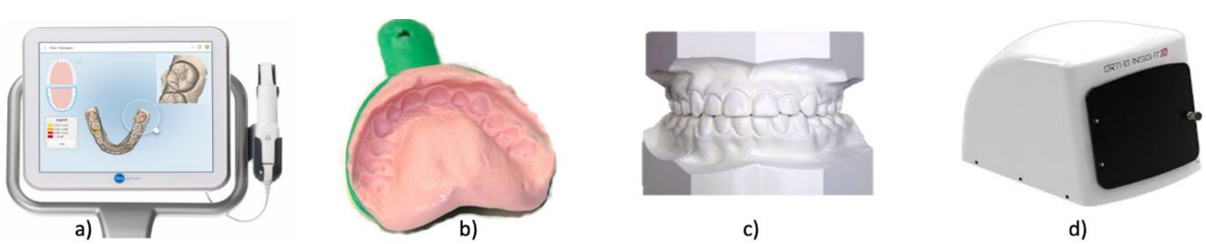


Fig 1. a) Intraoral scanner b) Alginate in plastic impression tray c) Stone model d) Desktop scanner

Table 1. Summary of the procedural steps at data collection visit.	
Impression tray size selection	
Wax occlusal registration	
Mandibular alginate impression Maxillary alginate impression Mandibular intraoral scan Maxillary intraoral scan Occlusal registration scan	Mandibular intraoral scan Maxillary intraoral scan Occlusal registration scan Mandibular alginate impression Maxillary alginate impression

For each study procedure type (Table 2): chairside, processing, and acquisition time requirements were video recorded using a laptop computer and event recording software (Webex, Cisco Systems Inc., San Jose, CA). CO subjects wore a portable microphone to facilitate audio recording in the clinical environment and verbally identified the start and end of each study procedure by naming the procedure and using the words "start" and "end," respectively. Time spent talking with the subject explaining procedures and setting time of plaster models were not included.

Table 2. Study procedures to be recorded for time measurements

Type	Stone model scan	Intraoral scan
Chairside	Tray selection Wax occlusal registration Alginate mixing Mandibular impression Maxillary impression Disinfection/Rinsing	Clinical information input to scanner software Mandibular arch scan Maxillary arch scan Bite registration scan
Processing	Plaster mixing Model pouring Rough trimming	Software digital impression processing Uploading files to server from scanner Downloading files from server to desktop computer
Acquisition	Mandibular model scan* Maxillary model scan* Models occluded scan* *to treatment planning software	Importing digital model files to treatment planning software

If a procedure was re-done because the clinical quality standards were not met (e.g. poor impression or poor scan) the procedure was repeated and the same recording protocol was followed.

Data Collection Visit:

Chairside Study Procedures

Alginate impressions were made with an irreversible hydrocolloid alginate material (Jeltrate Plus Fast Set, Dentsply Sirona, York, PA) in standard plastic impression trays (Fig. 1b). All impressions were checked by the same operator performing the impression procedure and once diagnostic validity was confirmed, the impressions were disinfected (CaviCide, Metrex, Orange, CA) and stored in a damp environment, according to manufacturer's instructions. A wax bite imprint (occlusal registration) was made for each subject to be used during desktop scanning procedures. To do so, a single layer sheet of wax of dimensions 3 x 5 x 1/16 inches was warmed with tap water and used to capture the imprint of subject's teeth in centric occlusion (Dental wax, Knorr Beeswax Products, Del Mar, CA).

Fig 2. Clinical Operator (CO) performing intraoral scanning of Orthodontic Records subject (OR)

Intraoral scanning (Figs 1a, 2) was performed according to manufacturer's instructions with an intraoral digital monochromatic scanner (Element Intraoral Scanner, iTero, San Jose, CA, Fig 2). Subjects were seated in an upright position and adequate moisture control was obtained by drying the teeth with an air-water syringe. The teeth were scanned starting with the mandibular occlusal surfaces followed by buccal and lingual surfaces, as recommended by the manufacturer. The same protocol was utilized for the maxillary arch. Second and third molars were included in the scan, when present. The bite registration was obtained by scanning the buccal surfaces from the subject's first molars to first premolars. At the end of each scan, any voids present were recaptured. Following completion of both impression methods, a survey (Appendix B) was administered to each OR subject assessing their perception of comfort and preference between both methods.

Processing Study Procedures

For stone model scans, following completion of chairside tasks, CO subjects mixed water and powdered orthodontic plaster together, added this mixture to each alginate impression, and allowed these to set for 30 minutes to create stone models (Figs 1b, 3) Following complete setting of the plaster mixture, impression trays and alginate were removed, and the inferior and superior bases of the stone models were trimmed to create flat surfaces, opposite the teeth and approximately parallel to the biting surfaces of the teeth. Plaster stone models were further trimmed around the dental arches and posteriorly with the wax occlusal bite registration between the maxillary and mandibular models.

Fig 3. Clinical Operator (CO) pouring up alginate impressions with orthodontic plaster stone.

For intraoral scans, following capture of the bite registration, scanner software digitally processed the 3D models and removed excess image information. Digital files were then ready for upload to cloud-based software (iTero, San Jose, CA). STL files were then downloaded as individual maxillary and mandibular files oriented in occlusion, to be imported into treatment planning software (Ortho Insight 3D, Chattanooga, TN).

Acquisition Study Procedures

For stone model scans, the trimmed models were scanned, separately and occluded together (biting position), and digitized using a desktop scanner (MotionView, Chattanooga, TN) to create a STL file (Fig 1d)

For intraoral scans, downloaded STL files were imported to treatment planning software using native import specifications for the intraoral scanner (Element Intraoral Scanner, iTero, San Jose, CA). Both maxillary and mandibular files were assigned to their respective arches for import. Digital model orientations in the X, Y, and Z axes were verified and STL mesh files were repaired during import, as recommended by the treatment planning software.

Clinical Acceptability Model Grading

To assess for the success rate and clinical acceptability of diagnostic models derived from alginate impressions and stone model scan versus intraoral scanning, a simple 5-step rubric was developed for this study to aid in a quick assessment of individual models. (Dental Model Diagnostic Quality Index, Appendix C) Models were graded on the presence or absence of defects on the clinical crowns, gingiva and vestibule, and occlusal relationship relative to subject's left and right intraoral photographs. Intraoral photographs were established as the baseline for occlusal relationship as this was the only available method for comparison of individual models to assess for occlusal accuracy. Digital models derived from IS and AI were compared using digital treatment planning software by CO subjects. That is, CO subjects were presented with the IS- and AI-derived digital models from all OR subjects in random order, to be graded using the following rubric. Five scores for each IS and AI model were averaged to create a mean value for both sets of models from each OR subject (total 60 models). For the occlusion assessment, the intraoral buccal photographs were presented via imaging management software (Dolphin Imaging, Chatsworth, CA) for comparison with digital models.

The model grading rubric consisted of three categories for assessment: dentition, base, and occlusion. For the dentition section, AI derived models were graded on the presence or absence of chips, cracks, distortions, fractures, and voids on the clinical crowns. IS derived models were assessed on the presence or absence of digital holes or voids on the clinical crowns. Both types of models were assessed for complete capture of the clinical crown to the point of the cemento-enamel junction (CEJ). A maximum score of 2 was awarded for clinical excellence for a model free from the aforementioned dentition defects. A score of 1 was awarded for clinical acceptability for a slight defect on the clinical crown that would not affect the accuracy of the model. A score of 0 was considered a "standard not met" where a large defect was present on the clinical crowns or incomplete capture of the crown to the level of the CEJ.

For the base category, both types of models were assessed for the extent of gingival and vestibular capture to a level of more than 5 mm past the CEJ (Excellent, 2 points), 0-5 mm past the CEJ (Clinically Acceptable, 1 point), and incomplete capture past the CEJ (Standard Not Met, 0 points). The gingiva and vestibule were also graded on the presence or absence of debris, positives, cracks, fractures, or voids. As described above, a score of 2 was awarded for a complete lack of defects, 1 point awarded for a slight defect not affecting accuracy, and 0 for a major defect affecting accuracy.

For the occlusion category, models were compared to the left and right buccal photographs of the same OR subject where a score of 1 denoted verification that the occlusion shown in the models matched the subjects' maximum intercuspation (MI) position represented in the photographs and a score of 0 denoted that the models failed to match the photographs. A maximum score for each category was 4 points for dentition, 4 points for base, and 1 point for occlusion, totaling an overall maximum quality score of 9 points for each model. CO evaluators were blinded to the OR subject ID and original CO who completed the impression techniques. Scores were tallied for each type of model and benchmark scores of less than 4 were deemed clinical failures, 5-8 clinically acceptable, and 9 clinically excellent.

Statistical Analyses

Times for chairside, processing, and acquisition study procedures were measured through review of video recordings by one investigator to identify each study procedure (Table 2), verifying that the "start" and "end" command match the video images of the procedure. Following identification of start and end procedures, time was recorded to the nearest second using the timing provided in the video recording and verified with a secondary stopwatch. If verbal commands did not coincide with the start and/or end of physical activities involved in the procedure, the video image timing was used and this was noted.

Means, medians, and standard deviations of times for procedure step (chairside, processing, and acquisition) and total times were calculated for both impression techniques (stone model scan, intraoral scan) by CO subjects individually and as a group (Appendix D). From the survey, VAS scores from each OR subject were measured on a 100 mm scale to the nearest millimeter with digital calipers and means and standard deviations calculated for "overall experience" (questions 1, 3) and "comfort with" (questions 2, 4) the two techniques (impressions and wax bite imprint, digital scan). Answers to the multiple-choice question (question 5) regarding preference for "impressions + wax bite" versus "digital scan of teeth" were summed for each choice and percentages of total number of responses were calculated. Reasons for choices and comments regarding likes versus dislikes (questions 6, 7) were compiled to assess for common responses that were grouped and counted. CO scores from the Dental Model Diagnostic Quality Index were averaged for individual IS and AI models from each OR subject. Overall IS and AI mean diagnostic model scores were then calculated and rounded to the nearest whole number. Frequencies for the clinical failure, acceptable, and excellent categories were also calculated for each method.

To determine the statistical differences in mean acquisition times between the two methods (stone model scanning and intraoral scanning) and CO subjects, a mixed-effects model with post hoc Tukey tests were used. Student's t tests were utilized to assess statistical differences between the two techniques in mean VAS scores for "overall experience" and "comfort," compiled overall, chairside, processing, and digitization mean acquisition times, and dental model quality scores. Percentage of subjects who preferred each impression method and percentages of models from the two methods in each of the 3 categories of dental model quality were compared. P values of less than 0.05 were considered significant for all statistical tests. Qualitative analysis of the written survey responses was conducted to assess for common responses.

Results

Subjects

32 OR subjects were screened for participation in the study with an enrollment of 30 subjects (10 males, 20 females; mean age 20.7 ± 9.5 years, Table 3). For COs, seven subjects were screened for participation in data acquisition, with an enrollment of six (two males, four females; mean age 32.3 ± 10.7 years). COs were divided into three groups based on self-reported comfort and experience for each impression technique. CO1 was a trained orthodontic assistant with 10 years of clinical experience, who reported increased comfort and experience with respect to performing intraoral scanning when compared to AI methods. CO2 was a trained orthodontic assistant with 30 years of clinical experience, who reported increased comfort and experience with respect to performing alginate impressions when compared to intraoral scanning. CO3 was a conglomeration of four first year orthodontic residents with self-reported minimal experience in both intraoral scanning and alginate impression methods. All COs were calibrated to manufacturer recommendations for intraoral scanning technique and order of scan.

Table 3. Enrolled OR and CO Subject Demographics

Subject Type	Male (Mean Age)	Female (Mean Age)	Total Enrolled (Overall Mean Age)
Orthodontic Records (OR)	10 (19.2 ± 10.3 years)	20 (21.5 ± 9.2 years)	30 (20.7 ± 9.5 years)
Clinical Operators (CO)	2 (25.0 ± 1.4 years)	4 (36.0 ± 11.6 years)	6 (32.3 ± 10.7 years)

Times for study procedures

The mean model acquisition time for the intraoral scanning technique (16:00 ± 4:34 min:sec) was significantly shorter (P<0.001) than for the alginate impression technique (26:51 ± 8:26 min:sec; Table 4). However, the mean chairside time for the alginate impression technique (6:12 ± 1:58 min:sec) was significantly shorter (P<0.001) than for the intraoral scanning technique (9:41 ± 2:41 min:sec). For processing times, the mean time for the intraoral scanning technique (3:26 ± 1:42 min:sec) was significantly shorter (P<0.001) than for the alginate impression technique (12:20 ± 6:26 min:sec). Steps for digitizing and importing files into treatment planning software were significantly shorter (P<0.001) for the intraoral scanning method (2:53 ± 2:00 min:sec) when compared to stone model scanning (8:18 ± 1:19 min:sec).

Table 4. Time comparisons for alginate impression (AI) and intra-oral scanning (IS) techniques

Time (minutes:seconds):	AI	IS	P-value
Model acquisition	26:51 ± 8:26	16:00 ± 4:34	**<0.001**
Chairside	6:12 ± 1:58	9:41 ± 2:41	**<0.001**
Processing	12:20 ± 6:26	3:26 ± 1:42	**<0.001**
Digitization	8:18 ± 1:19	2:53 ± 2:00	**<0.001**

When assessing for differences in model acquisition times for individual COs and each impression technique (Fig 4), for the intraoral scanning technique there was no significant difference between CO times (CO1: 14:49 ± 4:52 min:sec; CO2: 16:19 ± 3:32 min:sec; CO3: 16:52 ± 5:21 min:sec). For the alginate impression technique, mean time for CO2 (18:53 ± 1:50 min:sec) was significantly shorter ($P<0.05$) than for CO3 (27:38 ± 6:36 min:sec), and mean time for CO3 was significantly shorter ($P<0.05$) than for CO1 (34:03 ± 7:08 min:sec). Both CO1 and CO3 had significantly shorter model acquisition times for the IS when compared to the AI technique ($P<0.05$). CO2 had no difference in overall model acquisition times between IS and AI techniques.

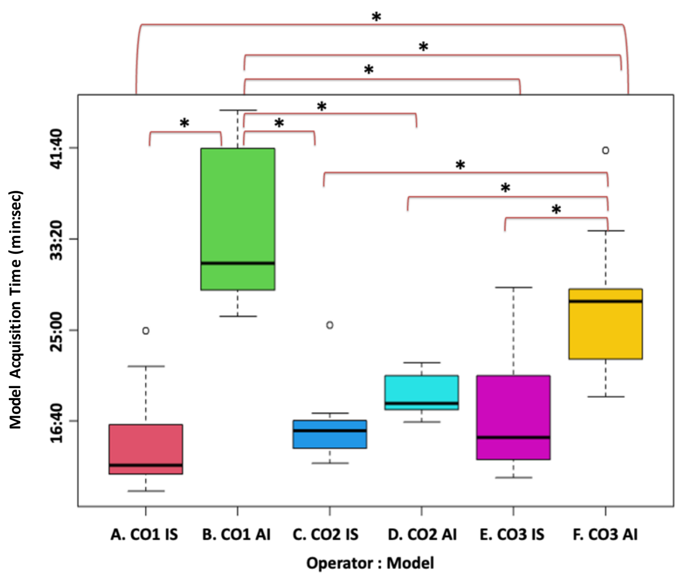


Fig 4. Boxplot of model acquisition time for each CO subject for each impression technique, where IS = intra-oral scanning, AS = alginate impression, and * indicates $P<0.05$ from mixed-effects model and post-hoc tests.

Comparing chairside times between techniques for CO subjects, CO1 had no significant difference in chairside times between IS (8:29 ± 1:33 min:sec) and AI (8:05 ± 1:32 min:sec) techniques (Fig 5), whereas CO2 (IS: 9:49 ± 2:38 min:sec, AI: 4:07 ± 0:29

min:sec) and CO3 (IS: 10:44 ± 3:11 min:sec, AI: 6:29 ± 0:47 min:sec) had significantly shorter (both P<0.001) chairside times for the AI compared to the IS technique (Fig 5). When comparing chairside times for the same technique between CO, for the intraoral scanning technique, there were no significant differences between CO times (CO1 8:29 ± 1:33 min:sec, CO2 9:49 ± 2:38 min:sec, CO3 10:44 ± 3:11 min:sec), while for the alginate impression technique, chairside time for CO2 (4:07 ± 0:29 min:sec) was significantly shorter (P<0.001) than for CO1 (8:05 ± 1:32 min:sec) and shorter than for CO3 (6:29 ± 0:47 min:sec) but not significantly (P=0.054) so (Fig 5).

Comparing processing times (Fig 6), CO1 and CO3 had significantly shorter (both P< 0.001) IS times (2:57 ± 1:17 and 3:24 ± 2:26 min:sec, respectively) than AI times (17:50 ± 6:31 and 12:18 ± 4:34 min:sec, respectively), whereas for CO2 the difference in processing times between IS (3:58 ± 1:03 min:sec) and AI (6:50 ± 1:29 min:sec) was not significant (P=0.390). When comparing between CO for each impression technique, there were no significant differences in processing times for IS between any of the CO and for AI, processing time for CO2 (6:50 ± 1:29 min:sec) was significantly shorter (P<0.001 and P=0.003, respectively) than for CO1 (17:50 ± 6:31 min:sec) and CO3 (12:18 ± 4:34 min:sec), and for CO3 was significantly shorter (P=0.003) than CO1 (Fig 6).

For digitization steps (Fig 7), all COs had significantly shorter times (P<0.001) for the IS technique (CO1 3:23 ± 3:17 min:sec, CO2 2:32 ± 1:09 min:sec, CO3 2:44 ± 0:38 min:sec) compared to the AI technique (CO1 8:08 ± 0:27 min:sec, CO2 7:56 ± 0:32 min:sec, CO3 8:51 ± 2:09 min:sec). When comparing between CO for each impression type, there were no significant differences in digitization times for IS or AI techniques between any of the CO.

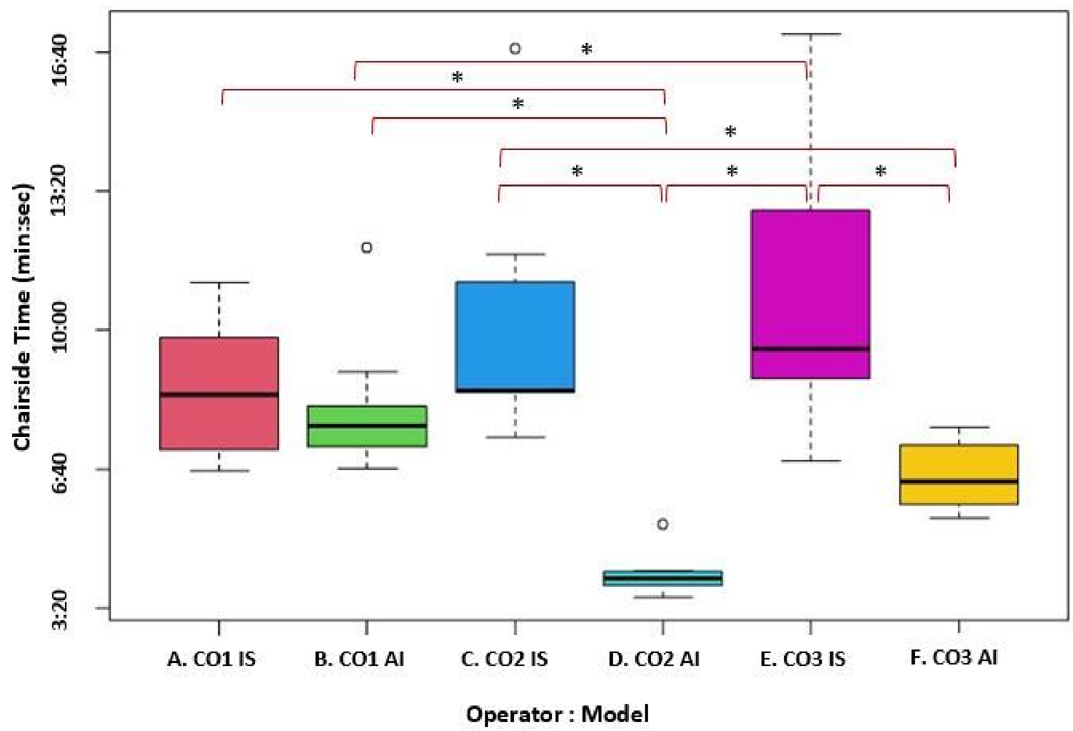


Fig 5. Boxplot of chairside step times for each CO subject for each impression technique, where IS = intra-oral scanning, AS = alginate impression, and ∗ indicates P<0.05 from mixed-effects model and post-hoc tests.

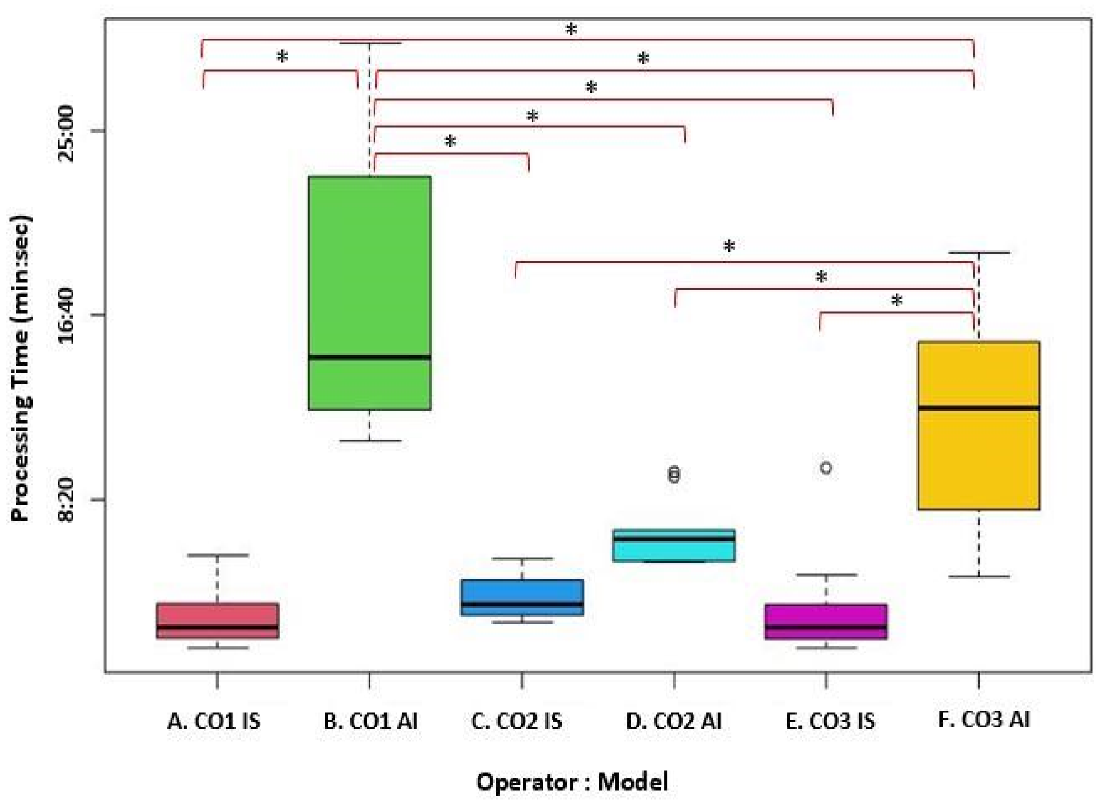


Fig 6. Boxplot of processing step times for each CO subject for each impression technique, where IS = intra-oral scanning, AS = alginate impression, and ∗ indicates P<0.05 from mixed-effects model and post-hoc tests.

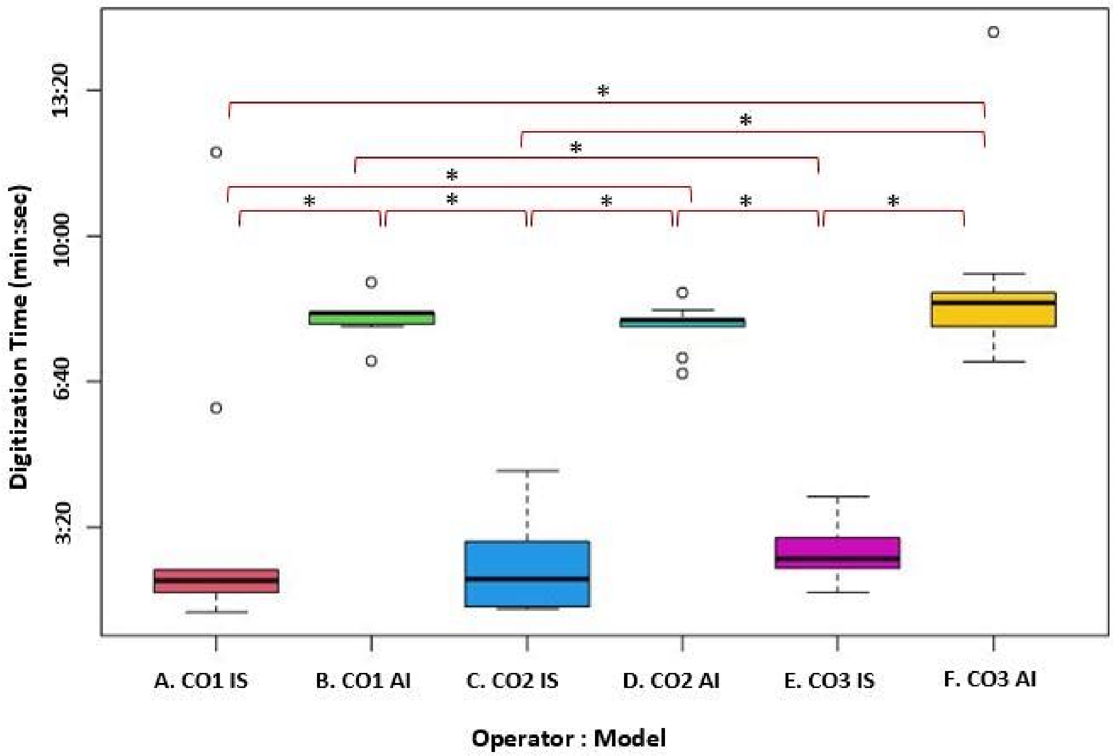


Fig 7. Boxplot of digitization step times for each CO subject for each impression technique, where IS = intra-oral scanning, AS = alginate impression, and * indicates P<0.05 from mixed-effects model and post-hoc tests.

Times for individual steps within procedure categories between CO are reported in Appendix D.

Subjects' survey outcomes

All 30 OR subjects responded to the 4 questions regarding VAS ratings of "overall experience" (questions 1, 3) and "comfort with" (questions 2, 4) the two techniques, the multiple-choice question (question 5) regarding technique preference and "why," plus provided responses for both "likes" and "dislikes" about each technique (questions 6, 7). When assessing OR subjects' preferences for impression technique (Table 5), 57%

preferred intraoral scanning, 37% preferred alginate impressions, and 7% had no preference. For overall subject experience and comfort, the mean VAS scores for alginate impressions were 75 ± 25 and 69 ± 25, respectively (Fig 8). Mean VAS scores for overall experience and comfort with intraoral scanning were 78 ± 18 and 76 ± 19 respectively. There were no significant differences between the overall experience (P=0.50) and comfort (P=0.14) for alginate impression and intraoral scanning techniques.

Table 5. Subject impression technique preference	
Impression Technique:	**Percentage (%)**
Intraoral scanning (IO)	57 %
Alginate Impression (AI)	37 %
Both	7%

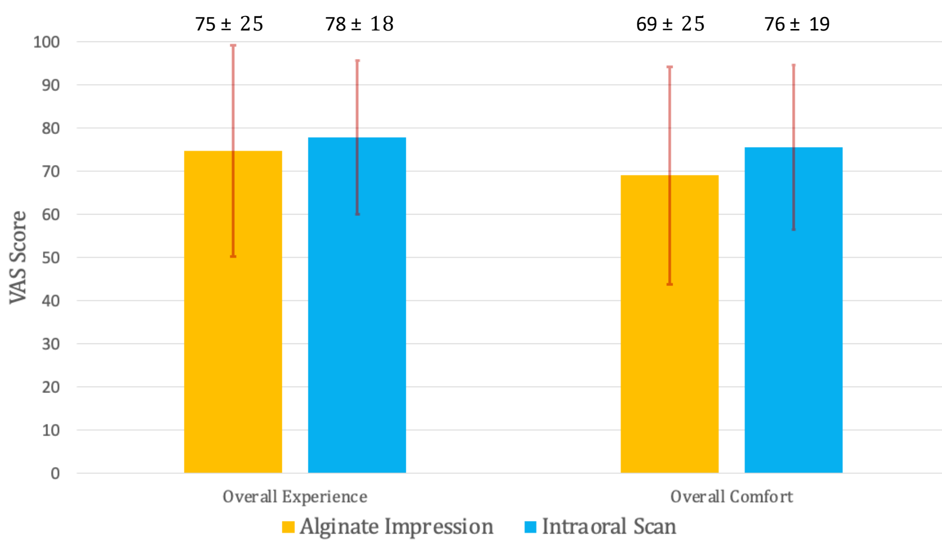
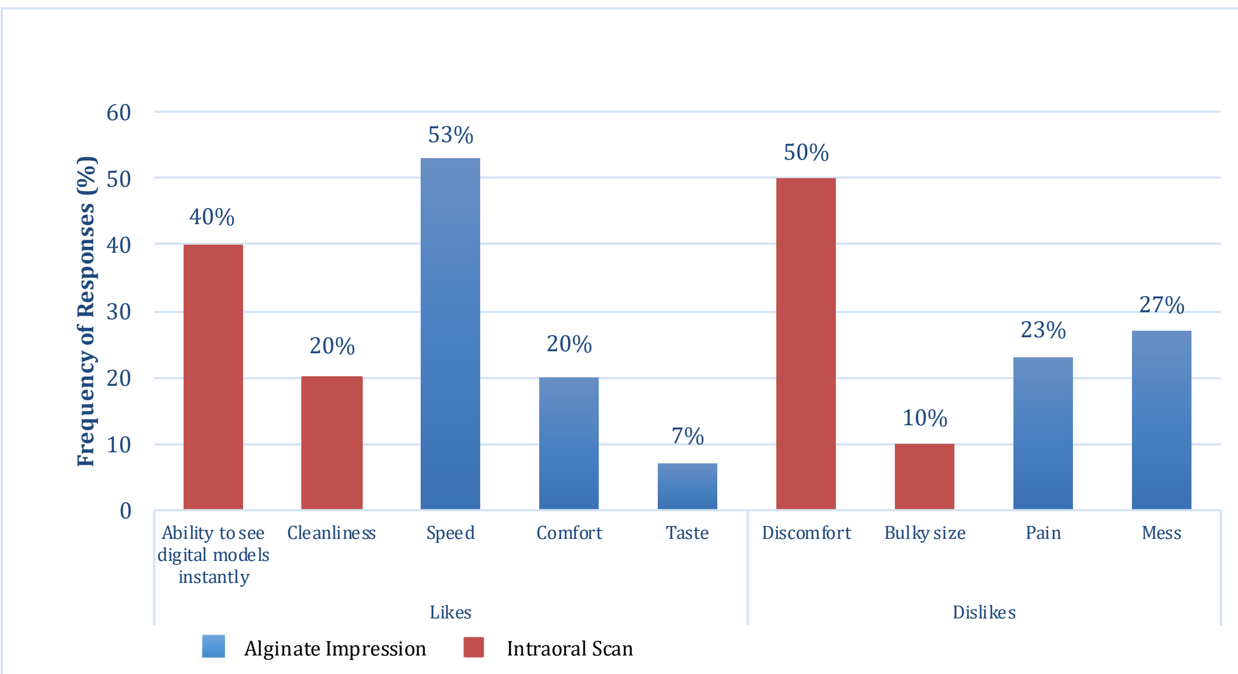


Fig 8. VAS scores from OR subjects' survey of overall experience and comfort between impression techniques

Frequencies of responses for likes and dislikes with respect to each impression technique were calculated (Fig 9) and showed 53% of subjects reported liking the "speed" of alginate impressions and 20% reported liking the "comfort." However, 27% and 23% of individuals reported disliking the "mess" and "pain" associated with alginate impressions, respectively. For intraoral scanning methods, 40% of subjects reported liking the "ability to see digital models instantly" and 20% reported liking the "cleanliness." On the other hand, 50% reported disliking the "discomfort" and stretching associated with the intraoral scanning technique and 10% reported that the intraoral scanner head had a bulky size.



Dental model diagnostic quality index scores

Five CO subjects participated in scoring the quality of the digital models. Models derived from alginate impressions had a mean diagnostic quality score of 6 ± 3 whereas models derived from intraoral scanning had a mean score of 7 ± 2 and the difference was significant (Table 6, P=0.013). Of the models attained via intraoral scanning, 20% were deemed of excellent diagnostic quality, 70% were of clinical acceptability, and 10% were clinical failures. For models derived from alginate impressions, 7% received an excellent score, 70% scored clinically acceptable, and 23% clinically failed. Overall intraoral scanning and alginate impressions had a success rate of 90% and 77%, respectively (Fig 10).

Table 6. Diagnostic Model Clinical Acceptability Scores		
Impression Technique:	**Score (Points)**	**P value**
Intraoral scanning (IO)	7 ± 2	0. 013
Alginate Impression (AI)	6 ± 3	

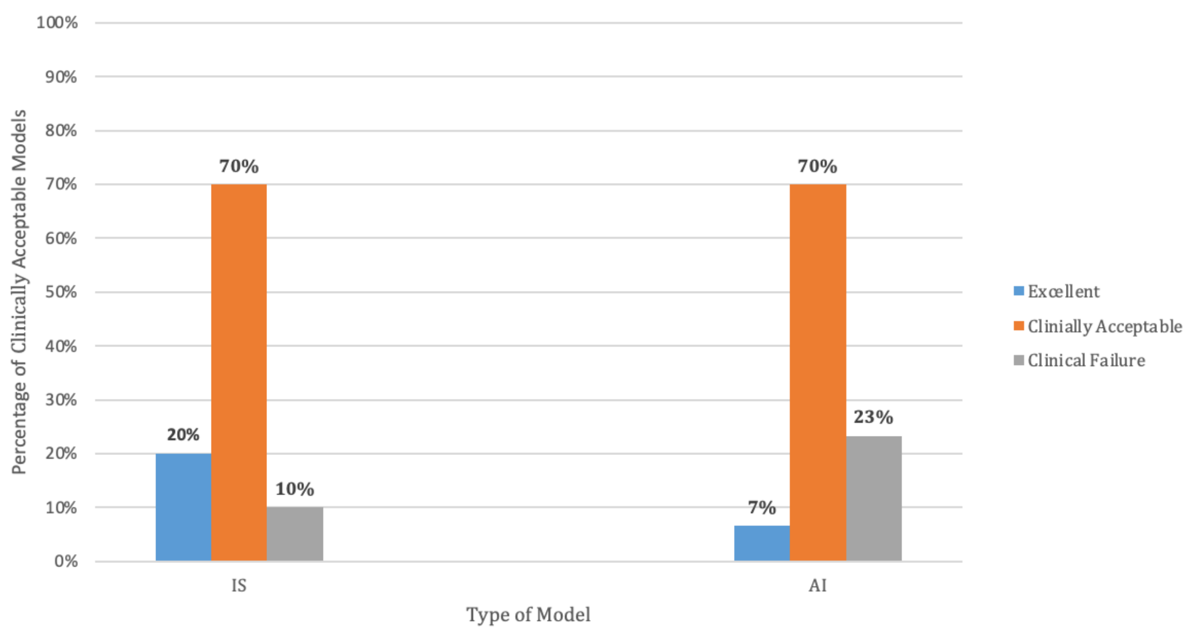


Fig 10. Frequency of diagnostic model quality index scores (Excellent 9, Clinically acceptable 5-8, Clinical Failure ≤4) for two impression techniques, where IS = intraoral scanning and AI = alginate impression.

Discussion

As the paradigm continues to shift to the "digital age" of dentistry, orthodontists are at a crossroads of when to "jump" into the adoption and integration of technology into their practices. Trends continue to change as cost of acquisition decreases and familiarity with new technology increases. Our study aimed to assess subject preference and clinical efficiency between conventional impression techniques compared to intraoral scanning techniques. To our knowledge, no previous study has compared the time for start-to-finish of impression acquisition to digital diagnostic model completion to a stage ready for treatment planning, in the same office by the same group of operators. Additionally, we aimed to gather insight into the trends between clinical operators who performed model acquisition tasks to assess if there were differences between individuals. Finally, we aimed to compare the clinical acceptability of models derived from alginate impressions that were subsequently digitized with a desktop scanner versus digital models captured directly from intraoral structures using an intraoral scanner.

Studies by Sfondrini et al.[18] and Grunheid et al.[4] compared the model acquisition times between alginate impressions to the point of sending to a commercial lab for digitization and direct intraoral scanning. There have been mixed conclusions on the most efficient method for model acquisition with Sfondrini et al. finding that overall times for intraoral scanning (5:49 ± 0:20 min:sec) were significantly shorter than alginate impression (22:06 ± 0:15 min:sec) techniques by an average of 16:07 min:sec ($P<0.0001$)[18] whereas Grunheid et al. concluded that there was no significant difference between the two methods.[4] In agreeance with Sfondrini et al., the current study found that intraoral scanning was significantly shorter by 10:51 min:sec when compared to alginate impressions, for overall diagnostic model acquisition. The discrepancies between studies may be explained by the fact that Grunheid et al. used a powder-based scanner that required additional time for powder application prior to scanning. As technology improves and the scanning speed increases, the time difference between both methods may grow, likely in favor of intra-oral scanning techniques. Since the introduction of the first commercially available full-arch scanning system in 2008, there has been in increase in available scanners on the market, resulting in more competition among manufacturers and a decrease in acquisition costs. There are continued maintenance costs for intraoral scanners that can range from monthly service fees to expendable scanner tips. The cost of ownership of an intraoral scanner following initial purchase is not insignificant and should be considered by the clinician when weighing the option of bringing the tool into their practice. Other disadvantages for the utilization of intraoral scanning for diagnostic model management include risk of data loss in the event of scanner or server failure and lack of cross-compatibility of scanner hardware and software between manufacturers. Commercially available scanners attempt to limit the user to propriety software for managing digital models, which raises the question: if one were to switch scanner manufacturers, would access to the previous database of digital models be possible?

When comparing the average time for chairside procedures between intraoral scanning and alginate impressions, Sfondrini et al. found that the intraoral scanning technique was significantly shorter than the alginate impression technique by 1:43 min:sec,[18] whereas Grunheid et al. concluded that the alginate impression technique was significantly shorter than the intraoral scanning technique by 12:52 min:sec.[4] Similarly to Grunheid et al., the current study noted a shorter time for the alginate impression versus the intraoral scanning technique by 3:29 min:sec. An expectation of the AI method is to include complete capture of the maxillary palate. If the current study added a step to ensure complete scanning of the maxillary palate, this could have potentially added some time to the IS chairside procedures. For the processing procedures, in agreeance with previous authors, these were significantly shorter for intraoral scanning compared to alginate impression techniques. Differences between study protocols for tasks included in each step can be found between studies. Grunheid et al. included disinfection of impressions and wax bite under their processing steps, whereas the current study included this under chairside steps. Furthermore, both Grunheid et al. and Sfondrini et al. completed their processing steps at packing and submitting an order to a commercial lab for model digitization. In the present report, complete in-office digitization protocols for both impression techniques were utilized to assess for clinical efficiency. No other known study to date has measured a start-to-finish of digital model acquisition to the point of having models ready for treatment planning in an in-office setting.

Similarly, no other known previous study has assessed for differences between clinical operators in the time efficiency for model acquisition. CO1 had 10 years of orthodontic assisting experience with self-described more comfort using an intraoral scanner than alginate impressions. CO2 had 30 years of orthodontic assisting experience with self-described more experience and comfort with alginate impressions rather than intraoral scanning. Finally, CO3 was a conglomeration of new graduate orthodontic residents with minimal experience in both impression techniques. This study found that there are differences between the time efficiency of alginate impression and stone model scanning versus intraoral scanning between clinical operators. For CO1 and CO3, there were significant differences between the time for digital model acquisition with intraoral scanning being shorter than alginate impressions. Interestingly, for CO2, there were no differences in the time for digital model acquisition between the methods of intraoral scanning and alginate impressions. Future studies may be able to investigate clinical operator experience in a measurable way to assess for the impact on model acquisition times. The current study did not concretely measure CO experiences and comfort between the two impression techniques. However, it may be inferred that CO experiences may play a role in the time it takes to complete digital model acquisition between the two impression techniques studied.

The second aim measured in this study focused on the subjects' perspective of each impression technique. Previous reports had conflicting results on the preferred method of impression technique with Grunheid et al.[4] concluding that subjects preferred alginate impressions whereas Burhardt et al.[17] noted that intraoral impressions were the preferred method. In the current study, intraoral scanning was the preferred method with 57% of subjects reporting a choice for intraoral scanning to be used for their next dental models. The percentage of subjects preferring intraoral scanning was less than expected which may be due to the 50% of subjects reporting discomfort with intraoral scanning and 10% reporting disliking the size of the scanner head. Because 53% of subjects reported liking the speed of alginate impressions, this may have contributed to 37% of subjects preferring alginate impressions for their next set of dental models.

The final aim of assessing the diagnostic quality of models derived from each impression technique was developed using recommendations from the American Board of Orthodontics requirements for digital model submission and 3D printing.[19] The pilot rubric was designed to be a simple assessment that could be completed in a matter of minutes to give a snapshot of clinical acceptability of individual models (Appendix C). The accuracy of models derived from both alginate impressions and intraoral scanning has been previously validated,[4,5,13,18] but no study has aimed to view how often a model is produced that is of diagnostic quality to be used for diagnosis and treatment planning or appliance fabrication. Both impression techniques, on average, produced models of clinical acceptability at a rate of 70%, whereas intraoral scanning produced "excellent" models 20% of the time while alginate impressions produced models of "excellent" quality 7% of the time. Both impression techniques had clinical failures with a rate of 10% and 23% for intraoral scanning and alginate impressions, respectively. The overall success rate for intraoral scanning combined to be 90% whereas the success rate for alginate impressions totaled to 77%. Although there was significantly higher mean model quality score for intraoral scanning versus alginate impression techniques (7 ± 2, 6 ± 3, $P=0.013$), this difference was only 1 point on a possible total of 9 points, so may not be clinically that important because models from both alginate impression and intraoral scanning techniques had mean model scores that fell within the category of "clinically acceptable." The 10% failure rate for models from intraoral scanning was mostly associated with incomplete capture of clinical crowns of the most terminal tooth. This may be due to the "bulky size" reported by subjects in the survey and difficult access for field of view of the distal surface of the terminal tooth. With the failure rate of 23% of models from alginate impressions, the most common areas of point reduction came from deficiencies of the clinical crowns or incomplete capture of the gingiva and vestibule. Adding rope wax around the impression tray rims could potentially have helped prevent some of these deficiencies in the impression-making but potentially would have added some time to the AI chairside procedures. With stone models, the risk of crown chipping or fracture can produce models that are not worthy of clinical use for treatment planning and appliance fabrication. With models derived from intraoral scanning, this disadvantage is eliminated due to the ability to store models digitally without damage and allows the clinician to reproduce them through 3-dimensional printing with a resin model.

The present report focused on the clinical efficiency, patient preference, and clinical acceptability of digital models derived from intraoral scanning and alginate impressions. Due to the nature of being a pilot study, a convenience sample size was estimated from previous reports.[3,4,17,18] For the clinical efficiency and diagnostic model score aims, the enrolled sample size was sufficient to achieve statistical significance. For the overall experience and comfort VAS scores, a power analysis was performed and a recommended number of subjects needed to reach a power of 80% was 205 per IS and AI group. An uneven male:female distribution of enrolled subjects was noted and the effect of sex and age on measured outcomes was not investigated in the current study. The use of multiple clinical operators helped investigate the influence individual differences can have on the clinical efficiency of model acquisition but there was wide variation in the times reported between CO in this study. Individual clinical operator experiences were self-reported and not assessed in a measurable way. These differences in experiences and comfort between impression techniques may have influenced individual times that contributed to the significant differences between clinical operators. While this report showed that differences do exist between different individuals when it comes to model acquisition times, the results should be taken with caution due to the lack of quantitative reporting on previous experiences with both techniques.

Future studies could establish a way to measure operator preference and comfort between the two impression techniques to investigate how previous experiences influence model acquisition times. Additionally, the effect of sex and age on measured outcomes of subject preference and VAS scores for overall experience and comfort would be an area of interest to assess if there is an optimized impression technique for target age and sex groups. Furthermore, the effect of these parameters on the clinical efficiency and model quality scores could give insight into potential difficulties for each impression technique, that resulted in increased impression acquisition times or decreased model quality scores. As the current study found, the opinions and preferences for AI and IS techniques, does not completely favor one over the other, so there is room for further investigations to assess how reported likes and dislikes can be optimized to maximize clinical efficiency and patience acceptance.

Conclusions

This pilot study found that the three null hypotheses were refuted. That is:

1. The overall mean digital model acquisition time by intraoral scanning (IS) was significantly shorter than by alginate impressions (AI) and stone model scanning.
2. Intraoral scanning was the preferred method of diagnostic model acquisition versus alginate impressions but overall experience and comfort were not significantly different between impression techniques.

3. Models derived from intraoral scanning had higher model quality scores and frequency of “clinically acceptable” models when compared to models derived from alginate impressions.

Appendix A

OREGON HEALTH & SCIENCE UNIVERSITY
OHSU

IRB MEMO

Research Integrity Office
3181 SW Sam Jackson Park Road - L106RI
Portland, OR 97239-3098
(503)494-7887 irb@ohsu.edu

APPROVAL OF SUBMISSION

November 7, 2022

Dear Investigator:

On 11/7/2022, the IRB reviewed the following submission:

IRB ID:	STUDY00024002	MOD ID:	MOD00045737
Type of Review:	Modification / Update		
Title of Study:	Clinical assessment of efficiency and patient preference of diagnostic dental model acquisition for 3D printing via alginate impression and stone model scan versus intraoral scan		
Title of modification	Revised protocol and consent		
Principal Investigator:	Laura Iwasaki		
Funding:	None		
IND, IDE, or HDE:	None		
Documents Reviewed:	• Consent and Authorization Forms_CO subjects_v3_clean_LI_110422.pdf • Proposal		

The IRB granted final approval on 11/7/2022. The study requires you to submit a check-in before 2/7/2025.

Review Category: Expedited-Minor Modification

Copies of all approved documents are available in the study's **Final** Documents (far right column under the documents tab) list in the eIRB. Any additional documents that require an IRB signature (e.g. IIAs and IAAs) will be posted when signed. If this applies to your study, you will receive a notification when these additional signed documents are available.

Ongoing IRB submission requirements:

- Six to ten weeks before the eIRB system expiration date, submit a check-in.
- Any changes to the project must be submitted for IRB approval prior to implementation.

- Submit a check-in to close the study when your research is completed.

Guidelines for Study Conduct

In conducting this study, you are required to follow the guidelines in the document entitled, "Roles and Responsibilities in the Conduct of Research and Administration of Sponsored Projects," as well as all other applicable OHSU IRB Policies and Procedures.

Requirements under HIPAA

If your study involves the collection, use, or disclosure of Protected Health Information (PHI), you must comply with all applicable requirements under HIPAA. See the HIPAA and Research website and the Information Privacy and Security website for more information.

IRB Compliance

The OHSU IRB (FWA00000161; IRB00000471) complies with 45 CFR Part 46, 21 CFR Parts 50 and 56, and other federal and Oregon laws and regulations, as applicable, as well as ICH-GCP codes 3.1-3.4, which outline Responsibilities, Composition, Functions, and Operations, Procedures, and Records of the IRB.

Sincerely,

The OHSU IRB Office

Appendix B

Survey: Methods used to obtain dental model 1

Please take a few minutes to fill out this survey. Your responses are anonymous and will not affect your ability to receive orthodontic treatment. Thank you.

Mark your ratings with **X** on the scales below, where: 0=worst possible, 100=best possible.

1. Rate your overall experience of having impressions and a wax bite imprint made:

Worst **Best**

|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|

0 10 20 30 40 50 60 70 80 90 100

2. Rate your comfort with having impressions and a wax bite imprint made:

Worst **Best**

|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|

0 10 20 30 40 50 60 70 80 90 100

3. Rate your overall experience of having a digital scan of your teeth made:

Worst **Best**

|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|

0 10 20 30 40 50 60 70 80 90 100

4. Rate your comfort with having a digital scan of your teeth made:

Worst **Best**

|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|

0 10 20 30 40 50 60 70 80 90 100

5. For your next dental models, if you need these, which method would you prefer?

- ○ Impressions + wax bite
- ○ Digital scan of teeth

Why?

____

____

____

6. Please comment on having the impressions and wax bite registration made:

I liked:

I disliked:

7. Please comment on having the digital scan of your teeth made:

I liked:

I disliked:

Thank you for completing this survey!

Appendix C

MS Thesis Project – Dental Model Diagnostic Quality Index

Subject ID:
Model ID:

Component	Excellent +2	Clinically Acceptable +1	Standard Not Met 0
Dentition:			
1) Stone Model	1) No chips, cracks, distortion, fractures, or bubbles; debris-free	1) Bubble, void, or chip that does not affect accuracy	1) Chip or fracture on clinical crown, bubble/positive affecting accuracy of cast/stone positives affecting occlusion
2) Intraoral Scan	2) No digital holes/voids present	2) Slight digital hole/void not affecting accuracy	2) Digital hole/void affecting accuracy
3) Both	3) Complete capture of clinical crowns to CEJ		3) Incomplete capture of clinical crowns to CEJ
Base:	1) Complete capture of Mx/Md gingiva and vestibule	1) Partial capture of gingiva and vestibule beyond CEJ	1) Incomplete capture beyond CEJ, part of clinical crown not captured.
	a) >5mm at incisor or canine	a) 0-5 mm at incisor	
	2) Gingiva and vestibule free of debris, positives, cracks, fractures, or voids	2) Slight debris, positive, or void in gingiva or vestibule not affecting accuracy	2) Major debris, positive, or void extending from vestibule or gingiva to clinical crown
Occlusion		Occlusion verified and matches original patient in MI	Incomplete seating of occlusion, not matching patient's original MI

Diagnostic Quality Index

9 points = Excellent
5 - 8 points = Clinically Acceptable
0-4 points = Clinical Failure
Standard Not Met = Clinical Failure

Total Diagnostic Model Score

Appendix D

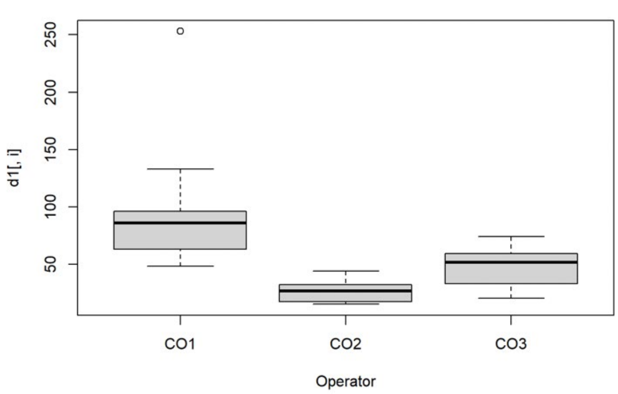
Operator	AI	IS	⁎ P-value (< .05)
CO1	A. 34:03 ± 7:08	B. 14:49 ± 4:52	a-bf, b-cdef
CO2	C. 18:53 ± 1:50	D. 16:19 ± 3:32	c-f, d-f
CO3	E. 27:38 ± 6:36	F. 16:52 ± 5:21	e-f

Overall time (min:sec) comparisons for Alginate Impression (AI) and Intraoral Scanning (IS) techniques between individual Clinical Operators (CO). (⁎ indicates P<0.05)

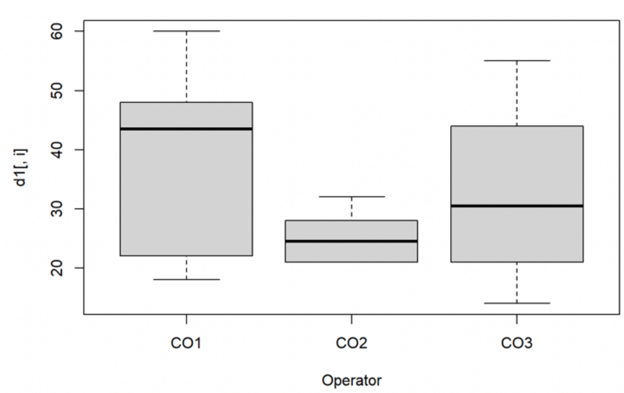
Model Acquisition Step	Intraoral Scanning			Alginate Impression		
Operator	CO1 (N=10)	CO2 (N=10)	CO3 (N=10)	CO1 (N=10)	CO2 (N=10)	CO3 (N=10)
Chairside	8:29 ± 1:33	9:49 ± 2:38	10:44 ± 3:11	8:05 ± 1:32	4:07 ± 0:29	6:29 ± 0:47
Processing	2:57 ± 1:17	3:58 ± 1:03	3:24 ± 2:26	17:50 ± 6:31	6:50 ± 1:29	12:18 ± 4:34
Digitization	3:23 ± 3:17	2:32 ± 1:09	2:44 ± 0:38	8:08 ± 0:27	7:56 ± 0:32	8:51 ± 2:09

Time comparisons (min:sec) at each step for individual Clinical Operator (CO) and each impression technique

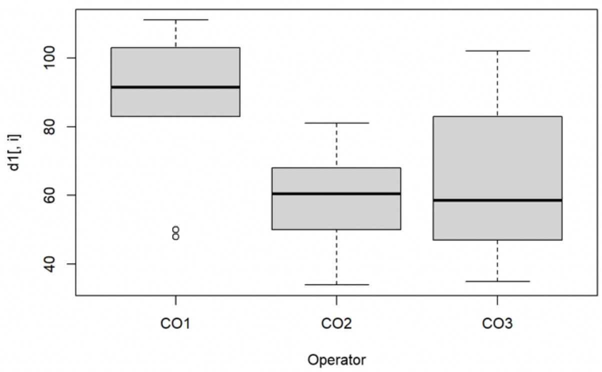
Chairside Steps:



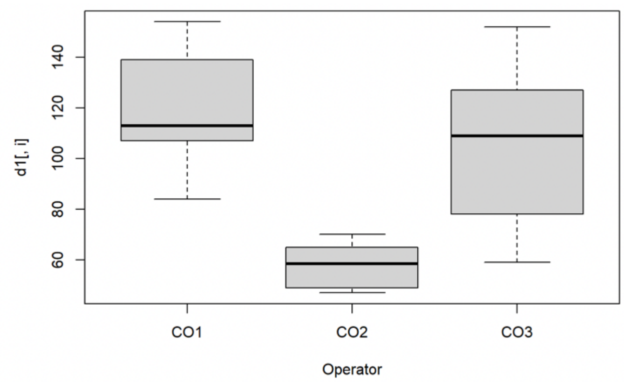
Tray selection times (seconds) for CO groups



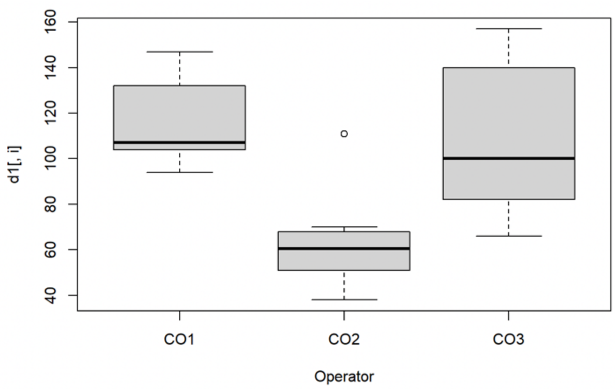
Wax occlusal registration times (seconds) for CO groups



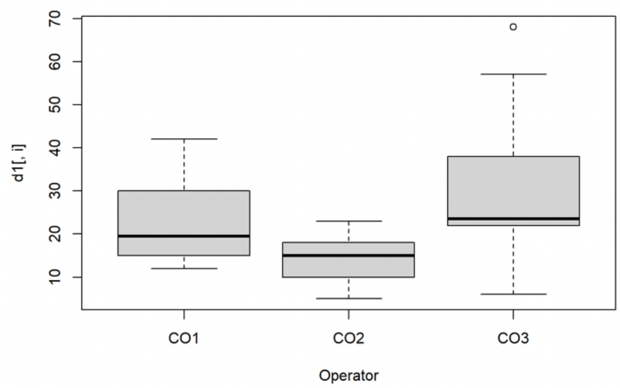
Alginate mixing times (seconds) for CO groups



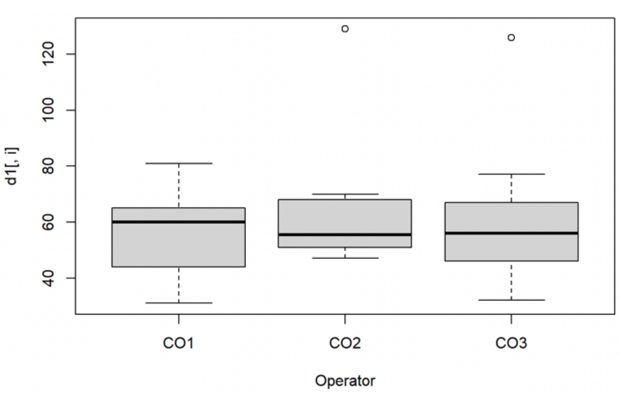
Mandibular impression times (seconds) for CO groups



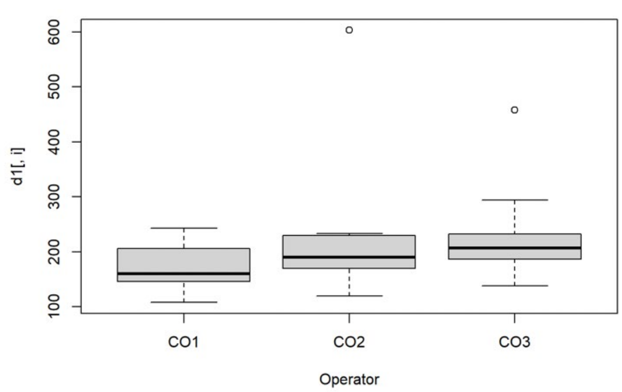
Maxillary impression times (seconds) for CO groups



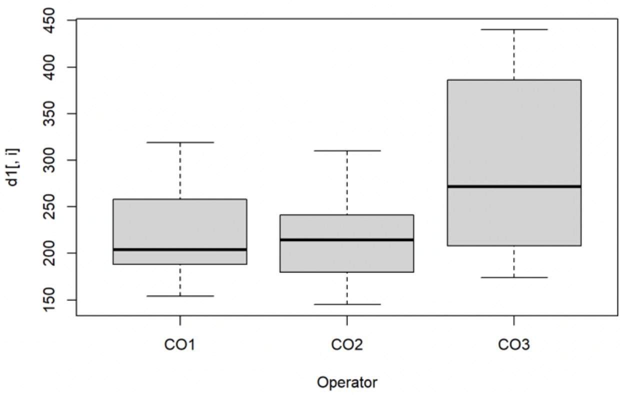
Disinfection times (seconds) for CO groups



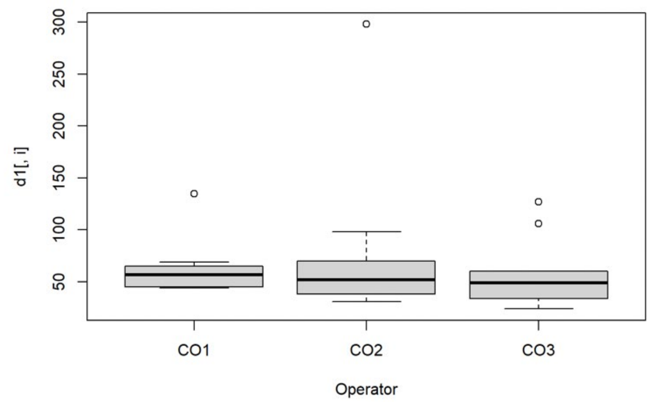
Information input times (seconds) for CO groups



Mandibular scan times (seconds) for CO groups

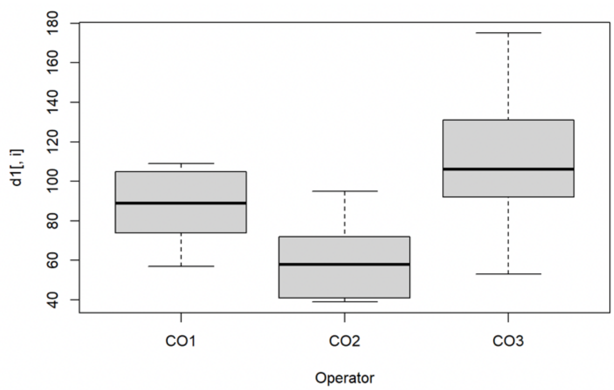


Maxillary scan times (seconds) for CO groups

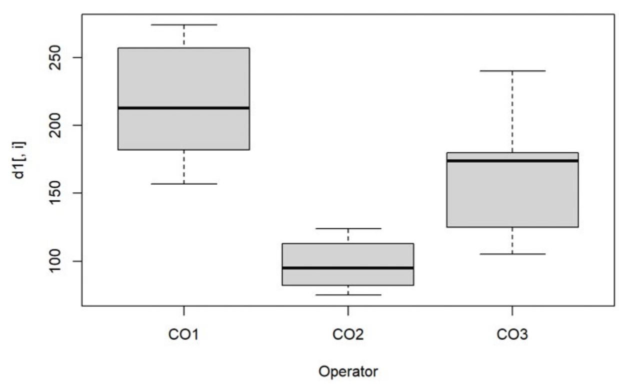


Bite registration scan times (seconds) for CO groups

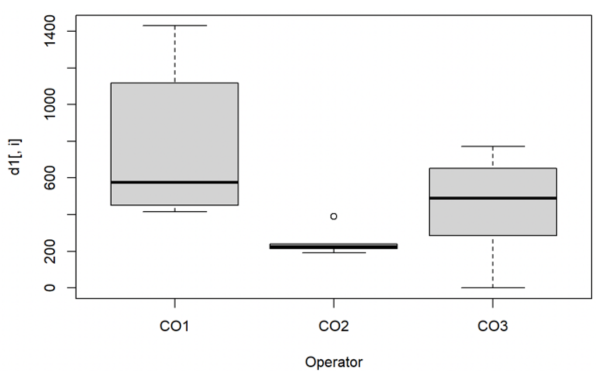
Processing Steps:



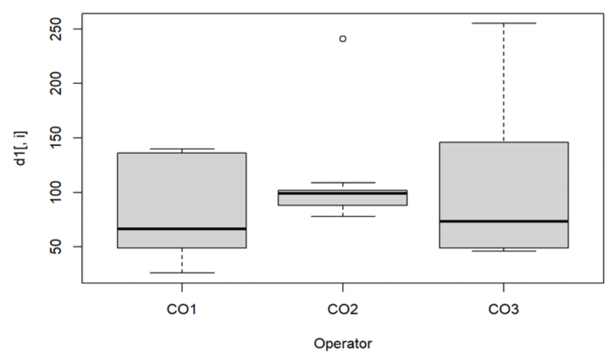
Plaster mixing times (seconds) for CO groups



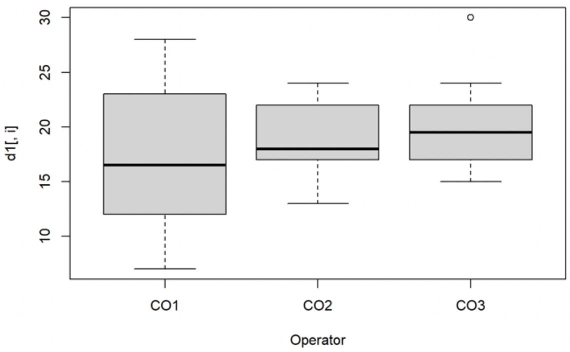
Model pouring times (seconds) for CO groups



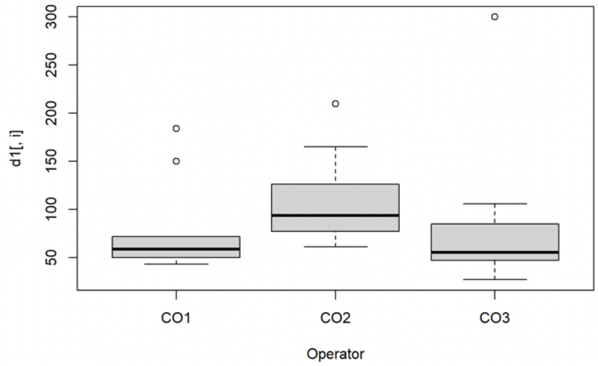
Model trimming times (seconds) for CO groups



Software processing times (seconds) for CO groups

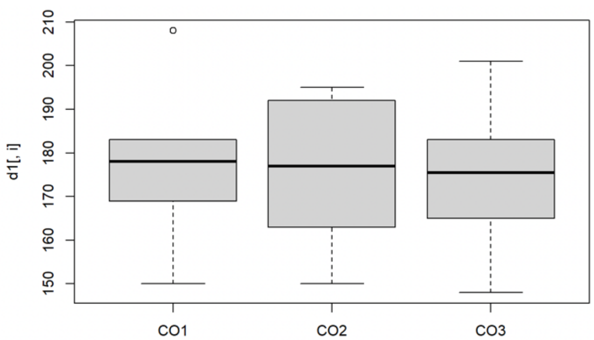


IO Upload times (seconds) for CO groups

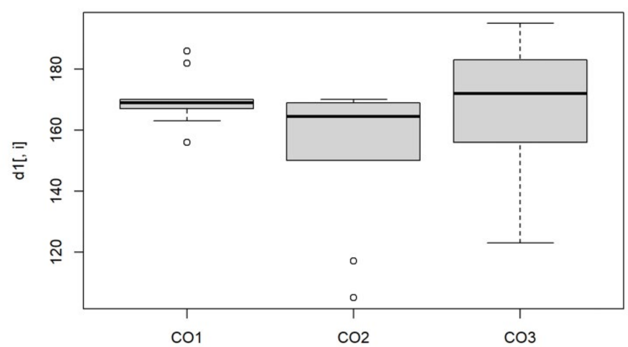


IO Download times (seconds) for CO groups

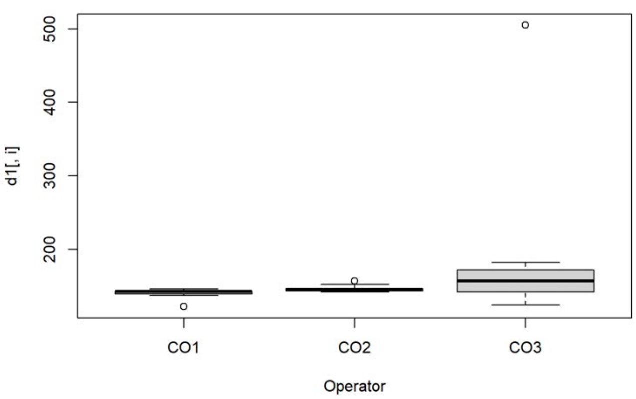
Digitization Steps:



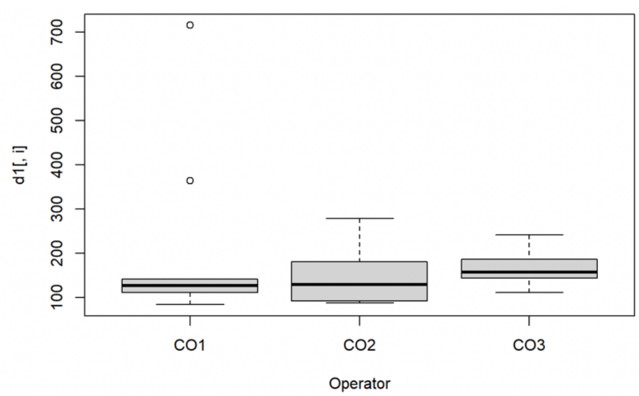
Mandibular stone model scan times (seconds) for CO groups



Maxillary stone model scan times (seconds) for CO groups



Stone models in occlusion scan times (seconds) for CO groups



IO Model import times (seconds) for CO groups

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