Multi-Modal Digital Impressions For Palatal Defects

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Introduction

Head and neck cancer is the 8th most common cancer in the UK affecting males more than females (1). Treatment for head and neck cancer (HNC) may include surgery, chemotherapy, radiotherapy, or a combination of these modalities (2, 3). Treatment for HNC is coordinated via multi-disciplinary teams (MDT) including surgeons, clinical oncologists, pathologists, restorative dentists, radiologists, clinical specialist nurses, speech and language therapists, dieticians, etc. (4-6). As part of surgical intervention, patients may undergo partial or complete maxillectomies which can result in palatal defects; that may either be sealed with composite flaps or left open, thus leaving a palatal defect in the oral cavity (2). The non-surgically sealed defects can be sealed with an obturator prosthesis, sealing the oral passage from the nasal cavities, which aids with speech, swallowing, restores function, and aesthetics (7). Nevertheless, provision of an obturator can be complex as making impressions of the defects can be challenging, and uncomfortable for patients (8).

Patients who had received radiotherapy can also have post-operative radiation induced trismus with gradual loss of mouth opening (9-11). Normal mouth opening is defined as 40 mm of inter-incisal mouth opening measured from the upper left central incisor to the lower left central incisor tooth (or other teeth if the central incisors are not present). Making conventional impressions in patients with trismus can be difficult, and although intra-oral scanners (IOSs) show a high level of accuracy and reduction of trauma to the surgical site (12), the scanner head can be bulky and cannot always be used in such patients, making it challenging to capture the anatomy of the palatal defect. A study used DICOM files from Cone Beam Computed Tomography (CBCT) to take impressions of the palatal defects with promising results (13) . These methods can be utilised to take multi-modal impressions of patients with palatal defects where making conventional impressions may not be possible due to a history of trismus. Surface matching software can be utilised to create composite casts of patients’ palatal defects where it is not possible to take impressions using a single modality. The aim of this *in vitro* study was to explore limitations and benefits of digital tools (intra-oral scanning and cone beam computed tomography) to create composite digital casts to capture the anatomy of palatal defects in cases of simulated trismus and compare these composite casts to the gold-standard impressions. The objectives were:

1. To measure limitations of intra-oral scanning in capturing the maxillary dentition and palatal defect at a range of mouth openings simulating trismus, and
2. To measure the accuracy which constitute trueness and precision of 3D-printed composite models made by combining CBCT, IOS, and gypsum casts, compared to the gold standard (gypsum casts).

The null hypotheses were:

1. There would be a correlation between the amount of data captured of a palatal defect and maxillary dentition with an IOS at different mouth openings simulating trismus,
2. There would be no statistically significant differences in overall mean precision measurements between composite digital casts compared to the gold standard,
3. There would be no statistically significant differences in overall mean linear trueness measurements between composite digital casts compared to the gold standard.

Materials and Methods

Capturing Tooth and Soft Tissue Data by an Intra-Oral Scanner at Different Mouth Openings

A master model with a cleft palatal defect (**Error! Reference source not found.**) was mounted on a Dentatus semi-adjustable articulator against an opposing fully dentate model. The master model was scanned three times at eight inter-incisal mouth openings (5mm, 10mm, 15mm, 20mm, 25mm, 30mm, 35mm, and 40mm) using a 3M™ True Definition Intra-Oral Scanner (IOS). The master model was lightly and evenly coated with 3M™ High Resolution Scanning Spray (3M™ ESPE) as per the manufacturer's instructions prior to scanning. Additionally, the master model was scanned once unmounted using the same IOS, and this scan served as a reference scan. Each scan was exported as a stereolithography (STL) file. Each of the three scans at each inter-incisal opening was imported into Geomagic™ Control 2014 (Geomagic® Control, 3D Systems Inc, Darmstadt, Germany) and, following a best-fit iterative-closest point (ICP) alignment, all three were merged to create a composite file for each mouth opening. Amount of data capture was measured by superimposing each composite scan (5, 10, 15, 20, 25, 30, 35, and 40 mm) against the scan of the master model to measure data loss (loss of triangles/polygons captured) at each mouth opening compared to the master model. Data was measured as percentage coverage of each experimental cast at each mouth opening superimposed against the scan of the master model.

Fabrication of Composite Models Combining Cone-Beam Computed Tomography with Digitised Gypsum Casts or Intra-Oral Scanning

Five impressions of the master model were taken using 2 mm spaced special trays and using a three-consistency/two-step impression technique with heavy, medium, and light bodied polyvinyl-siloxane (PVS) following manufacturer's instructions. Impressions were cast in type IV gypsum according to the manufacturer's instructions. The 5 gypsum casts were scanned using a 3Shape™ R700™ laboratory scanner and were exported as STL files. The experimental protocols are shown on **Error! Reference source not found.**. The master model was scanned five times each using the following techniques: **Planmeca ProMax 3D Mid® Cone-Beam Computed Tomography** (CBCT-P) (field of view (FOV) of 80x80mm, 90 kilovolt (kV) x 2 milliampere (mA), and exposure time of 20 seconds). DICOM files were converted into STL files; **Accuitomo 170® Cone-Beam Computed Tomography** (CBCT-A) (FOV of 80x80mm size, 60 kV x 1 mA, and exposure time of 17.5 seconds). DICOM files were converted into STL files; **3M™ True Definition IOS Intra-oral Scanner (**IOS-T); **Planmeca PlanScan® IOS Intra-oral Scanner** (IOS-I). Data from the 5 scans were exported as STL files.

Data acquired from scanning of master model using the four digital techniques and the scanning of the gypsum casts were combined using Geomagic® Control 2014™ to create 30 composite files (5 each of: CBCT-P/IOS-T; CBCT-P/IOS-I; CBCT-P/Gypsum; CBCT-A/IOS-T; CBCT-A/IOS-I; CBCT-A/Gypsum). The 30 composite files were 3D-printed using an Objet 260® Connex1 (Stratasys®, San Francesco, USA) 3D-printer of 16-micron layer resolution using translucent composite resin (RGD720) with support resin (SUP705). The support resin was removed, and the models cleaned with Genie 400 jet wash machine (Gemini Cleaning Systems

Ltd) to remove support resin from the models. Each of the thirty 3D-printed composite models, five gypsum models, and the master model were scanned using a 3Shape™ R700™ laboratory scanner and exported as STL files. The trueness and precision of models produced from each of the techniques (6 digital and 1 conventional) were compared to scans of the master model.

Measuring Trueness and Precision of The Composite Models

The STL files from each of the 30 composite models and 5 gypsum models were imported into Geomagic Control 2014™. Each scan was digitally superimposed to the scan of the master model using an initial best-fit alignment based on an ICP algorithm using 300 iterative pairs of points, before a more precise fine-superimposition was performed using 1500 pairs of points. Trueness was determined using the 3D-Compare function we obtained a heat map representing 3D-deviations (µm) on the X, Y, and Z axes of the experimental datasets compared to the scan of the master reference model within ±3mm (**Error! Reference source not found.**a). Blue indicated negative deviations, red indicated positive deviations, green showed no deviations, and grey represented missing data.

The Target Point function was used to set a total of 180 points to analyse linear deviation. The target points were placed on the master reference model which allowed measuring the same locations across all superimpositions (**Error! Reference source not found.**b). Average linear deviations in the X, Y, and Z axes were measured across the 180 points for each of the superimpositions. Lower deviation values indicated higher trueness.

Precision of each of the techniques was measured using previously published methods which utilised best-fit alignment algorithm on Geomagic® Qualify 11 surface metrology software (Geomagic® Incorporated, North Carolina, USA)(14). Each individual model scan was digitally superimposed against each of its counterparts using Geomagic Control 2014™ using similar methodology described above. Differences between each technique was assessed by measuring average differences on the X, Y, and Z axes for each superimposition/technique. Differences between each superimposition were thus related to manufacturing and processing error for each technique as individual casts from each experimental arm and the control were produced in the same manner. The technique with the lowest mean measurement was the most precise.

Statistical Analyses

Data was tabulated into a spreadsheet and was classified per technique and mouth opening. Statistical analysis was done using Statistical Package for Social Science SPSS 27.0 (IBM Corp. Released 2020. IBM SPSS Statistics for Macintosh, Version 27.0. Armonk, NY: IBM Corp). Pearson Correlation Coefficient was used to assess the correlation between mouth opening (mm) and percentage (%) coverage between the master model and the composite models at each mouth opening (5mm, 10mm, 15mm, 20mm, 25mm, 30mm, 35mm, and 40mm). Trueness data for the composite casts was not normally distributed and is described in median (mm) and Inter-Quartile Range [IQR]. Kruskal-Wallis and post-hoc Wilcoxon rank-sum tests were used to measure differences in trueness between the 6 experimental groups and the control. The smallest median value indicated the technique of highest trueness. Precision data conformed to a normal distribution and therefore was computed using mean (mm) and

SD from the repeated superimpositions of each technique. The smallest mean value indicated the most precise technique. Univariate Analysis of the Variance (ANOVA) and post-hoc Bonferroni tests were used to assess differences in precision between the 6 experimental groups and the control. Statistical significance was inferred where $p<0.05$.

Results:

Mouth Opening

Data for mouth opening showed that as mouth opening decreased, data captured by the 3M™ True Definition intra-oral scanner also decreased. **Error! Reference source not found.** shows the percentage coverage from each composite scan against the master model at each mouth opening. The results plateaued at 35 mm with only a slight increase in percentage coverage. At 40 mm, the percentage coverage of the scan decreased to the level of 25 mm mouth opening. Pearson Correlation Coefficient (*r*) was 0.93, showing a strong positive correlation between increased mouth opening and increased data capture ($p=0.0010$). Each composite scan was analysed individually against the master reference to evaluate the deficient areas at each mouth opening. At ≥20 mm inter-incisal opening, the intra-oral scanner was able to capture all the relevant data (tooth and palatal level) to aid in the fabrication of an obturator prosthesis. At 15 mm and below, there were limitations in capturing tooth and soft tissue data which would compromise use of IOS. Table 1 shows results of qualitative analysis capturing tooth and soft tissue data.

Trueness of The Composite Models:

Median and Inter-Quartile Ranges (IQR) are shown on Table 2. The composite models with highest trueness were, in order: Accuitomo CBCT (A) + True Definition IOS (T) > Planmeca CBCT (P) + True Definition IOS (T) > Accuitomo CBCT (A) + gypsum casts (G) > Planmeca CBCT (P) + gypsum casts (G) > Planmeca CBCT (P) + PlanScan IOS (I) > Accuitomo CBCT (A)+ PlanScan IOS (I) > And the gypsum casts had the lowest trueness (G). Kruskal-Wallis and post-hoc Wilcoxon rank-sum tests showed statistically significant differences between the six composite models compared to the gypsum models, indicating that all digital composite models had higher trueness compared to the gypsum models ($p<0.001$).

Precision of The Composite Models:

Mean and [Standard Deviation] measurements are shown on Table 3. The most precise composite models were, in order: Accuitomo CBCT (A) + True Definition IOS (T) > Planmeca CBCT (P)+ True Definition IOS (T) > Accuitomo CBCT (A)+ gypsum casts (G) > Planmeca CBCT (P)+ gypsum casts (G) > Accuitomo CBCT (A)+ PlanScan IOS (I) > Planmeca CBCT (P)+ PlanScan IOS (I) > And the least precise group were the gypsum casts (G). Univariate Analysis of Variance (ANOVA) and post-hoc Bonferroni tests indicated statistically significant difference between the six composite models compared to gypsum models ($p<0.001$) suggesting that the composite models were more precise compared to gypsum models.

Discussion

All null hypotheses were rejected. This study assessed the suitability of CBCT and IOS to fabricate models suitable for obturators for palatal defects patients. The results confirmed the limitations of intra-oral scanning in patients with reduced inter-incisal distance and suggest a fresh rethink on how to achieve accurate impression taking on this cohort of patients by potentially harnessing other digital techniques, such as CBCT scanning. The composite 3D-printed digital models can potentially be used clinically as the differences compared to the master reference model were within acceptable clinical values. Additionally, the composite models were more precise and had higher trueness than the gold-standard gypsum casts. To our knowledge, this *in vitro* study was the first to explore in detail the trueness and precision of combined digital techniques for model fabrication. Rehabilitation of patients with head and neck cancer or trismus requires a degree of innovation and creativity therefore, using composite models to deliver clinical care to patients could help deliver prosthesis for patients who would otherwise be unable to have impressions taken.

Medical imaging systems such as CBCT are being used as an alternative to conventional impressions to capture the anatomic detail of the maxillectomy defect and surrounding tissues in HNC patients. CBCT is capable of providing accurate radiographic and volumetric data which can be used in the construction of digital impressions (15); however, their accuracy in capturing the oral soft tissue and dentition is generally sub-optimal due to low contrast resolution yielded by the oral soft tissues, scattering radiation and beam-hardening artifacts caused by dental restorations (16). This limitation can be resolved by utilising digital scans from intra-oral scanners as they can provide scatter-free, high-resolution data of the oral soft and hard tissues and dental restorations.

Intra-Oral Scanners have been reported as accurate and reliable to digitally record partially or completely edentulous arches with maxillectomy defects (17, 18). Although technique sensitive, once the scan was obtained there is no risk of distortion thus eliminating a multitude of errors and in return improving patient pathway and experience. Furthermore, previous studies have demonstrated that intra-oral scanning of single teeth, sextants and quadrants are more accurate than conventional impression techniques (19-22). On the other hand, different inferences exist in the literature for full-arch scans (23-29). The accuracy of intra-oral scanners tends to decrease as the area of scanned oral surface increases due to the device's image stitching process that may lead to propagation of errors and therefore a distortion of the real anatomy. IOSs and their technologies are constantly revised and updated, and improvements in accuracy are inevitable as manufacturers update hardware and improve the acquisition software.

The results of this study suggested that the use of intra-oral scanners may not be possible in patients with mouth opening <20 mm. It would thus be a sensible proposal to carry out an intra-oral scan of every patient about to undergo resective surgery for head and neck cancer. If the patient then develops trismus due to surgical resections or post-operative radiotherapy, a CBCT can be taken post-operatively. The CBCT can capture the soft tissue anatomy and defect, whereas the dentition can be captured using IOS. The CBCT and IOS can then be combined to create a composite model which can be utilised to deliver a prosthesis to these patients without the need for conventional impressions.

For convenience we used a single intra-oral scanner (3M True Definition, 3M, ESPE) to assess data capture at different mouth openings. Although the resolution and accuracy among different intraoral scanners can vary, 3M™ True Definition IOS has been extensively investigated in the literature and is considered amongst the best performing IOSs in terms of resolution, trueness, and precision (30-34). One advantage of using this scanner is its notably smaller tip size (254 x 16.2 x 14.4 mm) compared to other commercially available IOS. The results above demonstrate that if mouth opening is less than 20 mm, the use of an intra-oral scanner is not advocated due to the lack of clinical information captured. In such cases, composite models may be used to allow the construction of an obturator prostheses.

This study showed that the digital techniques were truer and more precise compared to the gypsum casts. Although gypsum casts are considered the gold standard in prosthodontics, they are labour-intensive and depend on operators' skills for precision. Impression materials' properties, handling, thickness, and polymerisation shrinkage as well as gypsum mixing, pouring and setting expansion can introduce errors in models including voids, drags, and lost detail (35). The trueness and precision of gypsum models depended on the impression materials' properties, type of tray, gypsum material's properties, and bubbles/drags which all contributed to the lower accuracy in this experiment. Conventional impressions were found to experience dimensional changes through thermal contraction from mouth to room temperature reaching 0.068-0.088mm posteriorly and 0.040-0.052mm anteriorly in clinical settings (35). Dental gypsum casts have been shown to exhibit a linear setting expansion of 0.14 – 0.35% after 120 hours (36).

Compared to the 3M™ True Definition IOS, the PlanScan® intraoral scanner showed inferior trueness and precision. This may be related to the different optical technologies utilised by each IOS to capture the surface morphology. True Definition uses active wavefront sampling technology, whilst PlanScan® uses laser triangulation. Our results agree with other studies. Mennito et al 2019 assessed the trueness and precision of full arch maxillary digital impressions of a human cadaver, and reported that the PlanScan® was significantly less accurate than other intra-oral scanners (37). Kim et al 2021 also reported greater accuracy of a 3M™ True Definition IOS compared to PlanScan® IOS (38).

In an in vivo study on 12 maxillectomy patients, (13) 3D-printed models made from CT scanners (Optima CT520Pro) and intra-oral scanning were reported to be as true and precise as gypsum models with no statistically significant difference in linear deviations between the digital and conventional models. The authors used the composite 3D-printed models to fabricate conventional cobalt chrome obturator prostheses and reported a good fit around the rest seats and minor connectors (13). This is an area we will investigate in the future.

The results of this *in vitro* study may differ from the clinical situation as the accuracy of models may be influenced by the presence of anatomical structures, saliva, limited space, and patient movement. Also, the surface optical properties, morphology and chemical composition of the master reference model used were different from the intra-oral situation. Moreover, the use of a CBCT scanner in a clinical situation may yield different results since soft tissues and teeth may scan differently compared to an in vitro experiment. The combination and manipulation of scans on Geomagic® Control 2014™ was straightforward in our study but the situation may be different in a clinical scenario where there are fewer areas in common between scans to allow superimposing the files. Furthermore, the benefits of using CBCT scanning as an impression technique clinically must be weighed against the risks of exposure to ionizing radiation.

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