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Clinical Trial to Determine the Accuracy of Prefabricated Trays for Making Alginate Impressions

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CLINICAL TRIAL TO DETERMINE THE ACCURACY OF PREFABRICATED TRAYS FOR MAKING ALGINATE IMPRESSIONS

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ABSTRACT

AIM: The traditional tray of choice to make alginate impressions has been a metal tray. The aim of this study was to determine whether the use of plastic trays is clinically justified in making accurate alginate impressions for diagnostic casts. MATERIALS AND METHODS: Three trays, GC COE plastic, GC COE perforated metal, 3M ESPE directed flow impression trays have been considered in this study. The mean linear dimensions of their casts were compared with the mean linear dimensions of casts made from custom trays and PVS impression materials (Aquasil® monophase). A total of 84 casts were made on 7 subjects with three impressions per tray type per subject using randomization. Type IV silky-rock stone (Whip-mix Corporation, Louisville, KY) was used to pour all the impressions after disinfection. Each cast was identified using a unique 'XYZ' value. Blinding was done to avoid investigator bias. Using EPSON® 1680 scanner, all casts were imaged at 3200 dpi resolution and stored in psd format. Using Adobe® Photoshop 7, three data sets of measurements were generated as in M15-M2, M2-P12, and M15-P5. The points of reference were 3 pixel dots pre-selected in the background cast image and identified in new cast images per subject group. Data generated was analyzed using mixed model analysis of variance (alpha=0.05) with patient as a repeated effect and tray code as a fixed effect. RESULTS: There was no significant difference in the measurements M15-M2 (p=0.0882) and M2-P12 (P=0.3009).There was a statistically significant difference in the outcome measure M15-P5 (p=0.0009). In two data sets;

M15-M2 which could be considered ‘almost significant, the GC plastic trays and in the significant data set, M15-P5, the 3M ESPE directed flow impression trays and the GC plastic trays have made impressions closer in value to the custom tray and PVS impression materials. The metal trays have not performed as well in both outcome measures. The use of plastic trays seems justified in making accurate alginate impressions for diagnostic casts.

DEDICATION

To my parents, Smt D.Kamala, whose sacrifices and perseverance put all her three children in excellent careers, and Dr.D.N.Apparow, who is a rock solid support in my life. To my wife Pavani, without whose vision, my ‘American dream’ would have never taken flight.

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LIST OF ABBREVIATIONS

3M ESPE	3M ESPE directed flow impression trays
DPI	Dots per inch
PVS	Polyvinylsiloxane impression material
PSD	Photoshop format
PI	Principal Investigator
S.D	Standard Deviation
X	Times of magnification

CHAPTER 1

INTRODUCTION

The Glossary of Prosthodontic Terms states that a diagnostic cast is a "positive likeness of dental structures for the purpose of study and treatment planning."[1] Ideal diagnostic casts are accurate reproductions of both the hard and soft tissues of the dental arches.[1] Except for procedures done directly in the mouth, almost every restoration in prosthodontics depends upon an artificial stone cast for its dimensions, contours and clinical success.[2]

Uses of diagnostic casts

Diagnostic casts play a very important role in the dental treatment planning process. They help in the three dimensional visualization of the current dental situation of the patient. They are useful in understanding associated problems and provide a platform to build a rehabilitative, sequential treatment plan. The casts are a direct link between the patient's mouth and the prosthesis to be fabricated in the laboratory.[1] They aid in patient education, diagnosing malocclusion, determining the length of clinical crowns, need for any surgical intervention, custom tray fabrication, pre-extraction records for immediate dentures, fabrication of mouth guards, making implant surgical stents, provisional restorations,[3] provisional crown and bridge work and bleaching trays.

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Alginate Impression material

Diagnostic casts are usually made using alginate impression material, an irreversible hydrocolloid and one of the most commonly used impression materials in dentistry. [2, 4] Alginates depend on the hydration and gelation of a salt of alginic acid, such as sodium alginate, for the development of their elasticity and dimensional stability.[5] The success of this material is mostly due to its ease of manipulation, patient comfort and low cost, and it does not require elaborate equipment.[6,4]

Composition of alginate. Chief ingredients of alginate impression material include a soluble alginate, such as potassium, sodium or tri-ethanolamine alginate. When these are mixed with water, they react with calcium salt. A sol-gel reaction is initiated which becomes a viscous sol, producing calcium alginate.[3] Diatomaceous earth is included to control stiffness of the set gel. Trisodium phosphate, a retarder is used to increase the setting time. Calcium sulfate dihydrate is used as a reactor. Potassium titanium fluoride is added to ensure the stone poured into the impression forms a hard, dense cast surface.[6]

Reaction. When alginate powder is mixed with water, there is a simple reaction of soluble alginate with calcium sulfate resulting in the formation of calcium alginate gel. This reaction is very rapid and does not allow sufficient working time. A retarder, trisodium phosphate, a water soluble salt, is added to enable working time. As long as this salt is in supply during the reaction, the calcium ions do not react with potassium alginate to produce calcium alginate. The setting time is based on the amount of retarder added during the manufacturing process of the alginate powder. The water powder ratios and temperature of water used are critical in their effects of the setting time. The warmer the water, the less is the working time as the reaction is faster. The mixing proportions must be carefully used according to the manufacturer's instructions. The use of pre-weighed volume of powder mixed with previously determined amount of distilled water will give the mix the same consistency every time. Also, pre-weighed powder would be free from hydration or contamination which it would be if taken from a container.[4] Distilled water is recommended for use with all alginate mixes as it eliminates contamination with calcium and other minerals.[4] The mixing time for alginate is usually 1 minute. Hand mixing is the most commonly used method, but machine mixing is an option to reduce or eliminate mixing inconsistencies.

Properties. The detail reproduction of alginates is not nearly as high as those of elastomeric impression materials.[3, 7] The reproduction of finish lines of crown preparations with alginate is not accurate and thus cannot be used for fabrication of final prosthesis in fixed partial dentures.[10] The elastic recovery and tear strength are important in making impressions retain their negative likeness of the impressed surface. Dimensional stability of alginate is only for a short period of time. Alginate impressions lose water by evaporation and absorb water by imbibition which affects their dimensional stability.[2] Alginate tends to adhere to clean, relatively dry tooth surfaces. This tends to happen more when repeated impressions are made. To prevent this, a nondrying silicone applied to the surfaces of the teeth helps the release of the impression material.[4]

Alginates should not be exposed in air for a long period of time. For this reason, they need to be poured within 15 minutes of removing the impression from the patient's mouth to obtain accurate casts.[2, 8, 9, 10, 36] It is essential to gently remove excess liquid from the alginate surface by use of a gentle spray of air, especially in the depressions of teeth.[2] A vacuum mix should be used to pour stone for obtaining accurate casts. All casts should be separated from the impression within 45 minutes to an hour after being poured.

Elastomeric Impression materials.

There are four kinds of elastomeric impression materials available for making impressions. Polysulfides, condensation silicones, addition silicones and polyethers. These materials are available in different viscosities.

Composition of addition silicones. Addition silicones are made up of a base and a catalyst. The base is a low molecular weight polymer called polymethylhydrosiloxane with three to ten pendant hydrosilane groups per molecule. Base also contains filler. The catalyst is a dimethylsiloxane polymer with vinyl terminal groups and filler. There is a possibility of evolution of hydrogen gas as a by-product in the base-catalyst reaction. To prevent this, a hydrogen absorbent is incorporated. Platinum catalyst, a complex compound consisting of platinum and 1, 3 dimethyl-tetramethyl-disiloxane is added. When the base and catalyst are mixed together, a polymerization reaction is initiated and results in a polyvinylsiloxane impression material. The base and the catalyst are mixed in equal proportions; the silane and vinyl groups react together and form a cross-linked rubber called polyvinyl siloxane.

Properties. On setting there is a small amount of dimensional change with contraction due to cross-linking and rearrangement of bonds within polymer chains. The set impression also needs to elastically recover from undercuts to avoid distortion. Manufacturers give a range of elastic recovery of their products. The addition silicones are known to have the least amount of polymerization shrinkage among elastomers at 0.15 %.[3] The polyvinylsiloxane impression materials are highly accurate when used in clinical practice.[12] Since the pouring of the impressions gets delayed, it is absolutely critical for these impressions to remain dimensionally stable. PVS impressions have exhibited superior dimensional stability when compared with all other elastomers primarily because they do not release any by-products. On insertion of an impression tray with PVS material, about 6 minutes is required before removing the impression tray.[13]

Trays

The selection of proper size and shape of a tray is essential to make an accurate impression. Traditionally, the tray choice to make alginate impressions has been non-perforated metal trays and perforated metal trays.[9] A stock rim-lock nonperforated tray is recommended for impressions of partially edentulous patients.[4] Mitchell and Damele stated that the average deficiency recorded from impression distortion was greatest in a perforated tray.[14] Hartwell reported that there was no significant difference in the accuracy of perforated and nonperforated metal trays.[14] There is a need to understand the clinical performance of the plastic trays with scientific data and compare with metal trays. We considered two plastic trays and a perforated metal tray in this study.

GC COE plastic tray. These trays have become very popular in clinical practice. They come with a very simple design and are flexible and perforated. With an approximate thickness of 1.5mm, this tray is considered semi-rigid**.**[15] Most often these trays require rope-wax to be placed on their boundary to gain additional height and also not to impinge on the soft tissues before making an adequate impression. An adhesive must be employed before making impressions.

3M ESPE directed flow impression tray. The company advertisement claims the following: Directed flow design that helps reduce flow defects and voids. A unique fleece strip precludes the need for an adhesive. The surrounding retentive lips help control the overflow of the material. A built-in reservoir helps prevent gagging. Designed based on anatomical studies and CAD/CAM technology. Indicated for initial and final impressions.

GC COE perforated metal trays. These are standard perforated metal trays. Rigid and easy to work with. No adhesive is required.

Custom trays. Most of the textbooks in restorative dentistry state that when elastomeric impression materials are used, a rigid custom tray must be constructed. It should be spaced enough to allow an equal thickness of impression material and with appropriate occlusal stops. Johnson and Craig have shown that addition silicones are very accurate impression materials. They determined that when addition silicone was used in a complete arch custom tray, most accurate impressions were obtained.[16, 17, 18, 19, 20] Elastomeric impression materials have been found to have highly accurate, superior elastic recovery, minimal permanent deformation and acceptable tear strength.[21] Custom trays are used to produce a more accurate representation of impressed areas. They produce accurate and clinically acceptable casts when used with PVS materials.[22] Casts made from custom trays and PVS impression material are significantly more accurate than those taken with stock trays, metal or plastic.[23, 24] However, stock trays are in popular use because of their ready availability and ease of use.[23] The disposable plastic stock trays are also being used in conjunction with high-viscosity impression materials.[25] The reason for this use is the ready availability of disposable plastic stock trays and to avoid the issues with infection control with metal trays.[13] The objective in making a custom tray is to provide a rigid tray with even thickness for the impression material and thus greater accuracy is achieved than that is provided by the stock plastic trays.[3,26]

Impressions made with plastic stock trays and PVS impression material resulted in consistently producing casts with greater dimensional changes than the custom trays made casts with PVS impressions.[27, 28, 29] A range of trays are at the clinician's disposal for daily clinical use, such as perforated metal, plastic stock, 3M ESPE plastic stock trays. Custom trays can be used for a range of indications as in making final impressions in fixed and removable, complete and partial denture frameworks, die fabrication and study casts. There are many variations in size and form within these basic materials used to fabricate impression trays. The choices available to the dentist today are innumerable.

Reproduction of oral detail. The possibility exists that the detail obtained with the PVS impression materials in vitro would be more accurate then when done in a clinical atmosphere due to the inherent hydrophobicity of PVS impression material.[6] But this makes a good argument to obtain clinical data for comparative analysis with these inherent difficulties associated, to present an accurate picture of the workings of the trays and impression materials in a clinical setting.

Data collection method

To measure horizontal distances a few employed tools have been a traveling microscope**,** [21, 30] 3-D digitizer, [31] vernier calipers**,** [14] and a gaertner microscope**.**[32] There appears to be no consensus in the literature on the measuring device that should be used to evaluate dental casts. Traditional methods have included using calipers or a measuring microscope and there is no agreement as to which device is best**.**[21, 27] There are several invitro studies done with intended reference points made on the casts/models for future identification and analysis.[14] Since we were undertaking a clinical trial, it was intended to select points on the casts that seemed repeatable as in cusp tips, wear facets etc.

The first method considered to analyze the casts was to use Keyence VHX–600 digital microscope (Osaka, Japan). This microscope allows magnification of a portion of the cast and measures the linear magnitude between two chosen points in the area of magnification. This is a very effective microscope**.**[33] At 5X, only a part of the cast was viewable. The possibility existed that though this area could be considered, a larger sized cast would probably not be viewable in the area required. Focus shifted to measuring the linear dimension of a single tooth, an incisor. The linear measurements from mesial to the distal aspects of a single tooth were obtained at 20X, and the standard deviation calculated. It ranged from 16μ to 44μ over three data sets. Given that a single tooth was considered and the high range of deviation obtained, this method was deemed unwarranted for this study.

Secondly, Proscan 2000 was considered. The amount of time required to scan a single cast was too long. Around 40 hours were estimated to be needed for a single cast. This is an excellent machine for volumetric analysis, but a linear measure tool was required to calculate the cast which wasn't available. The required time for scanning the casts was also not feasible.

Adobe® Photoshop 7 (Adobe Systems, Inc., San Jose, Calif.). Scanning a cast and linear measurement data collection[14, 15, 20] was chosen and a repeatable scanning model was developed. A simple grid was drawn on a transparency sheet and a cast was placed on it and imaged 20 times to analyze the standard deviation of the procedure. Adobe Photoshop® 7 software is used in research [34], for aesthetic analysis [35] etc. A cast was scanned 20 times at 24 bit color and 3200 dpi. The images were stored in psd format. Two points on the 1st molars, (tooth # 3 & 16) of each image were selected and using the measure tool the linear measurement was taken. After measuring all 20 images, the S.D was calculated to be 14µ (Table B-1). The subjective influence on the readings cannot be eliminated in total. More so because the reference points painted on the molars are 0.024mm in width. To be able to identify the same exact two points on a different image of another cast of the same patient is visually straining. All measurements will be made by the same investigator for consistency.[14] The eye-vision of the operator needs to be good. Attempts were made to try position the cast in the exact same position each time using the grid lines as a reference. It was observed that when the midline of the central incisors were made to intersect with two perpendicular lines on the grid, keeping in mind the relative position of the incisal edges to them, the rest of the cast seemed to follow a particular position which could be repeatable. At the resulted standard deviation, this method was considered credible enough to pursue the study.

Due to the visual strain on the investigator's eyes in following this method of analysis, it is advisable to limit the number of images worked on per hour. If images are constantly being analyzed, there is a possibility that the data generated may be biased.

In certain situations there might be a need to orient the screen in a different angle to enable image analysis for spot identification.

CHAPTER 2

OBJECTIVE AND NULL HYPOTHESIS

Objective

The objective of this study was to be able to identify the tray with the best clinical performance among; GC COE perforated metal, GC COE plastic and 3M ESPE directed flow impression trays, when compared with the clinical performance of custom trays. The first three tray groups were used to make alginate impressions and the custom trays, PVS impressions. The 'gold standard' in making alginate impressions has always been nonperforated metal trays. These have traditionally been used in the fabrication of not only the initial diagnostic impressions but also in the fabrication of partial denture frameworks in removable prosthodontics. The casts produced from the alginate tray impressions would be grouped by tray and subject-wise and compared with the casts produced from the PVS custom tray impressions, grouped similarly. These casts will be scanned to obtain psd images (photoshop format) and linear dimensional data in three sets of observations, M15-M2 (left 2^{nd} molar to right 2^{nd} molar), M2-P12 (right 2^{nd} molar to cross-arch left 1^{st} pre-molar), M15-P5 (left 2^{nd} molar to right cross-arch 1^{st} per-molar) will be generated for comparative analysis.

Null Hypothesis

No difference exists between the linear dimensional accuracy of casts made from alginate impression material using different tray types, namely, GC COE perforated metal, GC COE plastic stock and 3M ESPE directed flow impression plastic stock trays compared to casts made from custom trays and PVS impression materials.

CHAPTER 3

MATERIALS AND METHODS

On study approval from the Institutional Review Board at University of Alabama at Birmingham, the screening process was started for enrollment. Power analysis indicated the enrollment of seven subjects. Screening was based on the inclusion and exclusion criteria which were:

Inclusion criteria.

1. Subjects 21 years or older.
2. Subjects with teeth in the maxillary arch from second molar to second molar (# 2 to #15-minimum requirement).
3. Fixed bridge work is acceptable as long as they are cemented or screwed in permanent restorations (natural tooth or implant supported).
4. Subjects with maxillary arches within the available tray sizes. (Small, Medium, Large)

Exclusion criteria.

1. Subjects with bony exostoses or abnormal bony topographies in the maxillary arch.
2. Subjects with high gag reflex.
3. Undergone periodontal surgical rehabilitation within the last six months.
4. Provisional restorations in the maxillary arch.
5. Subject is unable to give informed consent.

6. Subjects with loose or mobile teeth in the maxillary arch.
7. Excessive plaque and calculus on the maxillary teeth.
8. Gross decay.

The tray types used in this study were:

1. Custom trays with PVS impression material. Considered the control group.
2. GC COE plastic trays with alginate impression material.
3. GC COE Perforated metal trays with alginate impression material.
4. 3M ESPE directed flow impression trays with alginate impression material.

Three impressions per tray group per subject were required to obtain an accurate average value of linear measurements in each cast group. Seven volunteers were screened, inform consented and enrolled into the study. An initial diagnostic impression was made and poured on the same day. The impression tray size was noted. A total of three impressions per tray group per subject were to be made making the total number of impressions and casts to 84.

Randomization

The appointment schedule and the sequence of impressions to be made were randomized to minimize the effect of variables (e.g., room temperature at the time of the day, humidity, etc from affecting any one tray set of impressions). Randomization was done using random card selection with A-G written on them and randomly picking them. First, the subjects' schedule was randomized and then the sequence of impressions to be made per subject per session was randomized (Tables 4-6).

The tray groups were also randomized to a specific number:

GC COE perforated metal (DENTSPLY Caulk, Milford, DE): 1

3M ESPE Directed flow impression tray (3M ESPE, St Paul, MN: 2

GC COE plastic tray (DENTSPLY Caulk, Milford, DE): 3

Custom tray (DENTSPLY Caulk, Milford, DE): 4

Cast Identification

Per subject, a total of 13 impressions would be made including the initial diagnostic impression. These impressions needed to be identified during the impression making process, pouring of the impression. Most importantly, identification of the cast during blinding, a process that was needed to be done before the scanning of the casts. Hence a unique identification code was adopted not only to avoid subject linked identifiers on the cast, but also to ensure and maintain clarity throughout the experimentation process. The proper identification of each cast was tantamount in the successful completion of the impression making process as randomized. Hence, an XYZ value was adopted for the same.

XYZ thus represented the following:

X: The subject's assigned alphabet.

Y: The tray type and impression material being used.

Z: The sequence number of the impression. (First, second or third).

For example if a tray had the C21 value written, it meant that the impression was made on subject 'C', and the first of three 3M ESPE alginate impressions.

Description of a session

Per session, the following materials were required. All the impressions were made in the Maxillofacial Prosthetic clinic in the 3rd floor of the School of Dentistry.

Materials required for a session:

1- The four trays indicated in the randomized session.

2- Caulk Tray Adhesive for Custom trays. (DENTSPLY Caulk, Milford, DE).

3- Bosworth® TAC for Alginate trays (Bosworth Company, Smokie, IL).

4- Distilled Water stored at room temperature for the alginate impressions.

5- Bindi brushes for application of PVS and/or Alginate tray adhesive.

6- Two Cadco® specific bowls to mix alginate.

7- Two Dux® Dental metal spatulas.

8- Cadco® Alginator. (Cadco dental products).

9- Clean & Lube spray to clean the Cadco bowl after single use.

10- Four plastic bags with (XYZ) code for identification and storage of impression

11- Jeltrate® Plus dustless Regular set Alginate Impression material 25g pouches. (DENTSPLY Caulk, Milford, DE), Lot no: 071018.

12- Aquasil® Monophase medium bodied, regular set Impression material. (DENTSPLY Caulk, Lot no 080109).

13-Silky Rock ISO Type IV, Violet Die stone, 140g pouches (Lot no: 085020802).

14-Syringe to transport distilled water to the alginate bowl.

15-Biotrol disinfectant solution (Biotrol International, N Salt lake City, UT 85054)

16-Timer

Custom tray fabrication protocol

Custom trays were fabricated according to Stewart's protocol. With three custom trays per subject, a total of 21 custom trays were fabricated using SR Ivolen (Ivoclar Vivadent, Amherst, N.Y.) custom tray material. A spoon (supplied by the manufacturer) of polymer and 6ml of monomer were mixed together with a tongue blade. When the mix attained doughy stage, the material was mulled together with hands to gain a smooth consistency. At this point a small amount of material was placed aside to later make the handle. The material was placed over the initial diagnostic cast with the spacer on it and adapted covering the entire diagnostic cast and up to 2-3 mm beyond the gum line. A small handle was made and placed over the maxillary anterior region to enable easy positioning and retrievability of the tray during impression making process.

Alginate impression protocol

The indicated trays for the particular session were arranged on a table. According to the manufacturer's instructions, an adhesive layer was applied on the GC plastic trays at least 3 min before impression making. Manufacturer's instructions indicate that the GC metal and 3M ESPE directed flow impression trays do not need an adhesive. 3M ESPE directed flow impression tray comes with a strip of adhesive layer within the tray. Seating the subject in the dental chair, its position was adjusted to the elbow level of the dentist ensuring that the occlusal plane of the subject was parallel to the floor. Using a syringe, 57ml of distilled water was poured into the Cadco mixing bowl. A pouch of Jeltrate® plus dustless alginate was cut open with scissors and its contents completely emptied into the bowl. Using a metal spatula the alginate powder and liquid were mixed for 5s so as to enable total dissolution of alginate powder in the water. The low speed button on the alginator was then activated and the spatula held against the bowl to achieve a smooth mix for 30-35s. Using high speed button on the alginator, the mix was further spatulated for 20s to gain an even smoother mix. Alginate was then ready to be loaded into the tray. The entire mixing procedure was timed to be completed by 60s.

Loading the tray. The alginate impression material was loaded into the tray indicated for impression in that particular session. The tray was filled with adequate amount of material taken from the bowl with the spatula. Care is taken to avoid air entrapment. Total time required for loading the tray was 25-30s.

Seating the tray. Using the left index finger, [9] the left cheek of the patient was retracted to open and gain space for tray seating. Using the incisors as a guide the tray was rotated into position. When the tray was seated the tray was held with light pressure to prevent unseating. The investigator held the tray in position till the alginate material had set and gained enough strength to withstand tear at removal. 2min and 30s after seating the tray, the impression was removed with a snap and disinfected.

Disinfection and cast pour. On removal, the impression was rinsed in cool tap water for 5s to remove any debris or saliva. Excess water was shaken off. Biotrol disinfectant solution (Biotrol International) was sprayed on the impression. Wet towel was not used to prevent imbibition.The impression was then placed in a plastic bag with the specific identification code already written on it. Adhering to the protocol, the second impression in sequence was made within the next 7-8 minutes and after disinfection, the impression was placed in its coded plastic bag. The subject was asked to rinse and clean his/her mouth. The taste of the alginate used in this study seemed uncomfortable to the subjects and they preferred rinsing their mouth after every impression. This helped prevent the teeth from being dry so that the alginate couldn't stick to the teeth. Both the impressions made were taken into the adjoining prosthodontic lab for pouring with Silky-Rock (Whip-Mix Corp, Louisville, KY), an ISO type IV dental stone. It was essential to make sure that the impressions were removed of any excess liquid, so a gentle spray of air was employed to remove it. All the impressions were poured in the order they were made. 32ml of cold tap water was placed into the vacuum mixing bowl and a pouch of Silky-rock was opened and emptied into the bowl. Using the VPM2 Mixing machine, the bowl was engaged into the machine and mixing initiated to mix for 54s. The machine precluded the need for hand mixing. After 54s, the bowl was released from the machine. Using the stone vibrator in the slow mode, the mixed stone was slowly poured into the impression. The tray with the impression was placed in a slanting position with one corner touching the vibrator. Care was taken not to touch the impression but the tray on the vibrator to prevent distortion. A small amount of the stone is flowed through the impression, making sure that it painted the depressions first and then stone was slowly added in small increments to fill the impression. After pouring the impression, the tray was placed on its coded plastic bag for setting. They were not inverted. Placing the tray on the assigned coded bag enabled the cast's identification after tray removal. All the alginate impressions were poured within 15 minutes of making them. The casts were separated from the trays between 45 minutes to an hour. Each cast was trimmed of excess stone to a desired form. A base was not required to be made as the casts were to be scanned, placing them on their occlusal aspect. The specific XYZ code was written on the base of the cast and placed back in the plastic bag. After all the four casts of that specific session were trimmed, they were stored in a card-board box and placed in the 6th floor biomaterials laboratory in the UAB School of Dentistry.

PVS impression protocol

A thin layer of Caulk® Tray adhesive (DENTSPLY Caulk, Milford, DE) for custom trays was applied at least 30 minutes before impression making. The patient was comfortably seated in the dental chair which was then lowered to the investigator's chair position. The dental assistant was instructed to load the impression tray. When the assistant half-way filled the custom tray, the investigator used a small cotton roll to clean the bucal and lingual aspects of the subject's dentition. This was done to remove any moisture on the teeth. Air spray was used to dry the teeth just before making the impression. The dental assistant loaded the tray, filling it in the dentate region. With his left finger, the investigator retracted the patient's left lip and the custom tray with PVS impression material, slowly inserted and rotated using the central incisors as guidance. The impression material was slowly brought into contact with the teeth. The teeth were slowly immersed in the impression material and moved into position covering 2-3 mm apical to the gum-line. This step was done to avoid the entrapment of air. The tray was positioned using the subject's nose as the reference point. Five minutes from seating the tray, the impression was removed and disinfected adhering to the alginate protocol. All custom trays, PVS impressions were poured within 15-30 minutes of impression making.

Blinding

Dr.Deniz Cakir, Instructor, Dept of Prosthodontics & Biomaterials agreed to administer the blinding process. All the casts now had an XYZ value written on their bases. Using Excel software, Dr.Cakir generated a series of randomized numbers from1 to 84, each of these numbers being assigned to one of the XYZ values.

All the casts were taken out of their plastic bags and placed on a table (Fig 1), with each cast being placed on its respective coded plastic bag. Using opaque black tape, the XYZ value on the base of each cast was covered. This black tape was aggressively sealed using several pieces of regular cellophane tape. The tape and seal were then inspected by Dr Muna Anabtawi, Instructor, Dept of Prosthodontics. On approval, using a black permanent marker, Dr. Cakir assigned each of the randomized numbers on the palatal, buccal and the base area of each cast. The original ‘X’ value was re-written on the cast to ensure cast grouping by subject. For example, if the XYZ value was C21 and the assigned random number was 32, the blinded value written on the cast was C32.

Blinding was done subject wise. On assigning the blinded values to the casts in one subject group, Dr. Cakir randomly changed the positions of the casts on the plastic bags. With this, the original XYZ values on the plastic bags became irrelevant. Hence with the new randomized values on the casts, the investigator was blinded to the tray type, material and the sequence of impressions from which the casts were fabricated.

Fig 1.The casts in the plastic bag laid out for blinding.

Scanning

The blinded casts were now ready to be scanned into photographic images. The scanner (Epson Expression1680) was connected to a desktop computer with the Adobe Photoshop® Elements software (Fig 3). This set up was required to store the images in the photoshop (psd) format for easy compatibility during data collection. The settings (Fig 2) of the scanning machine were as follows:

Mode: Professional. This enabled constant area selection of the scanning table per group.

Document source: Table

Scale: 100 %

Exposure type: Photo.

Image type: 24 bit color.

Resolution: 3200. For photographic settings, this was the best resolution at which the scanning was permissible. Any higher resolution was not possible for the scanner. The 3200 dpi resolution was detailed enough for image analysis during data collection.

Scanning a cast. We were interested in obtaining the linear dimensions of the cast, hence a two dimensional image was required. With the settings finalized, the casts were ready to be scanned. Within a subject's 12 casts, the effort was to be able to position each one of them individually in approximately the same X and Y axes. This not only enabled consistency in the area selected on the table for scanning per group, but also very importantly, enabled the approximate overlapping of the scanned images during image analysis for data collection. To achieve this goal, transparency sheets were used with two lines drawn perpendicularly to each other with a black marker. Only one sheet was used per subject group. The sheet was placed on the glass table to fit in the front end corner and sealed with cellophane tape. One of the blinded casts was randomly picked up and placed on the transparency sheet. The midline of the central incisors was made to coincide with the intersection of the lines on the sheet. The positioning was practiced a couple of times to ensure repeatability with the remaining casts in the group. With the cast in position, a metal scale (Westcott® stainless steel) was placed adjacent to the cast. The purpose of the scale was to scan the mm length. As Photoshop measurements would be read in pixels, the scale would give the length of a mm in pixels, the value of which would be a common divisor for the data collected. All the data collected, would eventually be converted to mm readings.

A preview scan was then run (Fig 4) and the area covering the cast and the mm part of the scale selected for scanning (Fig 5). Once the scanning was complete, the image was stored in Photoshop format (psd) and the blinded value assigned for the image file. This scanned image with the scale was used as the background and the referral image during data collection. All the images scanned were stored subject-wise, in an external hard-disk connected to the desktop. The images were later stored with the Supervising Investigator's official computer.

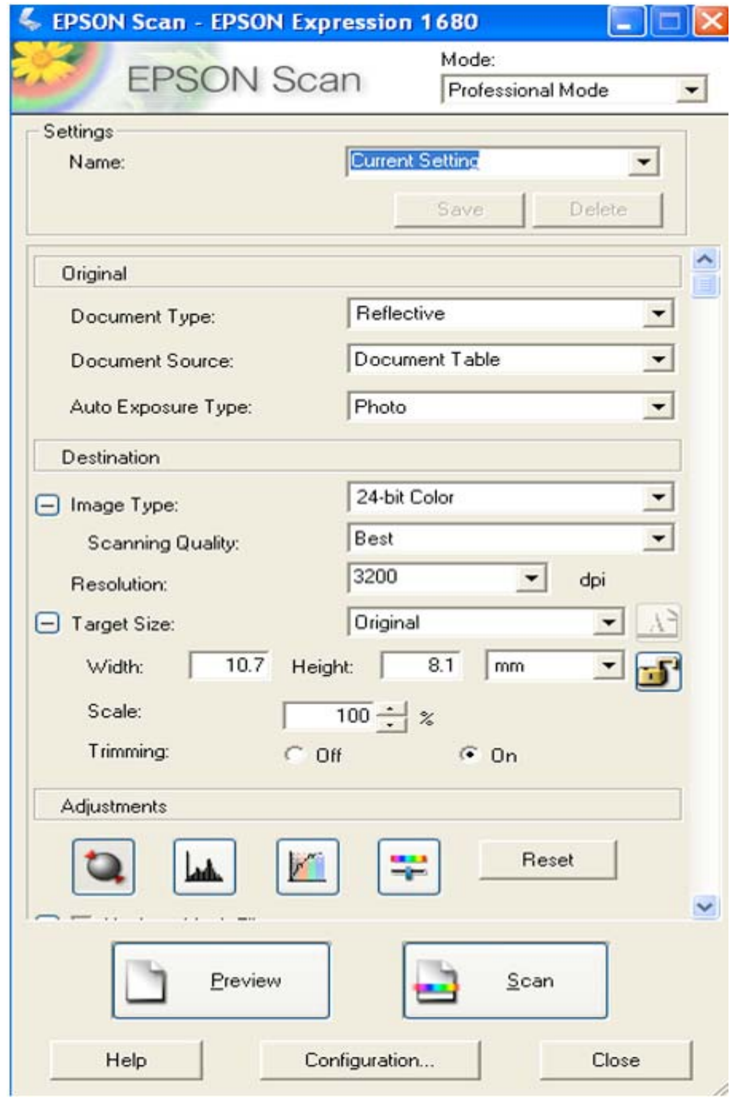

Figure 2. The settings for the scanning machine.

Figure 3. The scanning machine and the desktop with Adobe® Photoshop software.

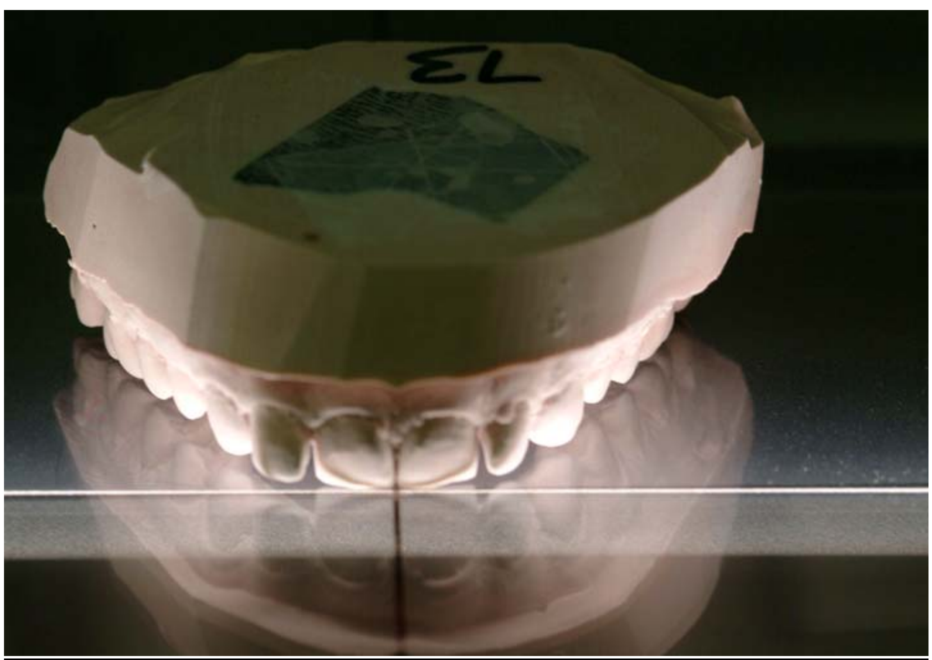

Figure 4. A blinded cast being scanned.

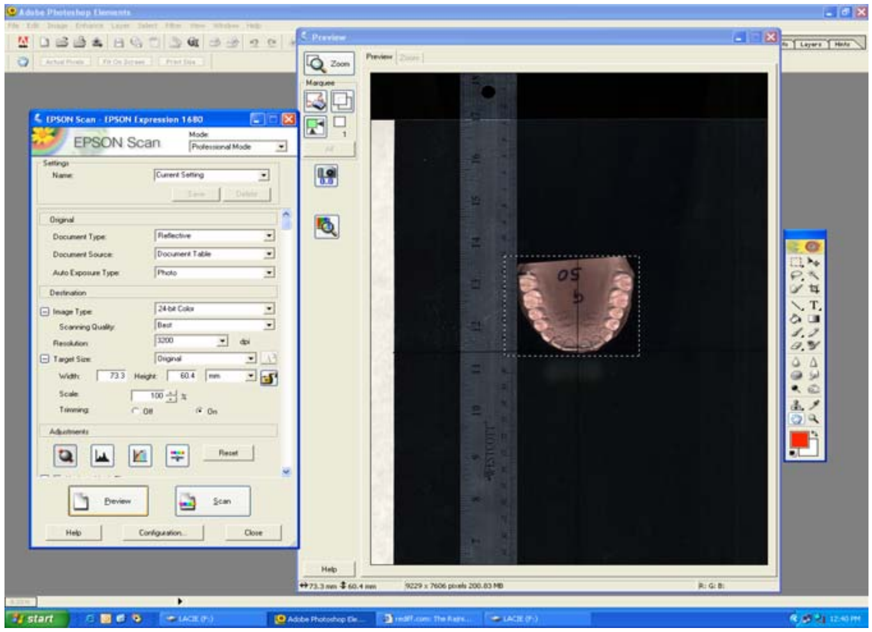

Fig 5. The selected area of scanning including the cast and the mm part of the scale.

Reading of casts

Adobe® Photoshop 7.0 was used for analyzing the images for data collection. The computer used was a Powerbook G4 with Adobe® Photoshop 7 software installed on it. The settings of Photoshop were arranged so that the scanned images could be read at the same resolution at which they were scanned. The screen resolution was set at 3200 pixels/inch. The rulers were converted to pixels. To enable easy opening of the images, each being around 140MB, the total available RAM of 647MB on the computer was dedicated to this software. Connecting the external hard-disk to this computer, the scanned image with the scale (background image) was opened.

The data measurements were to be from:

Molar 1 to Molar 2 (#2 - #15) represented as M15-M2.

Molar 2 to cross-arch Premolar 1 (# 2 - # 12) represented by M2-P12.

Molar 1 to cross-arch Premolar 2 (# 15 - # 5) represented by M15-P5.

This system is highly subjective and operator reliability and repeatability is of essence. Each of these four teeth was analyzed carefully to be able to identify a small anatomical or wear feature. Two more images in the group were randomly opened in Photoshop and all the three images were analyzed to identify the same spots on all four teeth on all three images. Once repeatability of the feature was ensured, the background image was used to identify the spots. Using the pencil tool, a 3 pixel thick dot was placed on all the four identified spots on the teeth. Using the measure tool, the dot on one molar (M15) was selected and pressing the left mouse button, the tool was dragged to the contra-lateral molar (M2) and placed on the dot on that molar (Fig 6). The given distance in pixels was recorded. In similar fashion the measurements from M2-P12 & M15-P5 were also recorded. The next image was opened and using the move tool, the new image was selected and moved onto the background image. This opacity of the image was reduced to 50 % to enable easy overlap over the background image and approximate orientation in relation to the background image (Fig 7). Once that was achieved, the focus was placed on the selected teeth for measurements on this new image. With the capability to change the opacity on the new image, the exact position of the red dots on the teeth of the background image was compared with the new image. Using the measure tool and the opacity at 100%, the measurements were made accordingly for all the teeth (Fig 8). In this manner, measurements for all the cast images were done.

De-blinding

On completion of data collection, the measurement values were sent to Dr.Cakir who then gave the Investigator the assigned randomized numbers for the original casts. Using these numbers, de-blinding was done and values were grouped by subject and tray type. The data was submitted for statistical analysis.

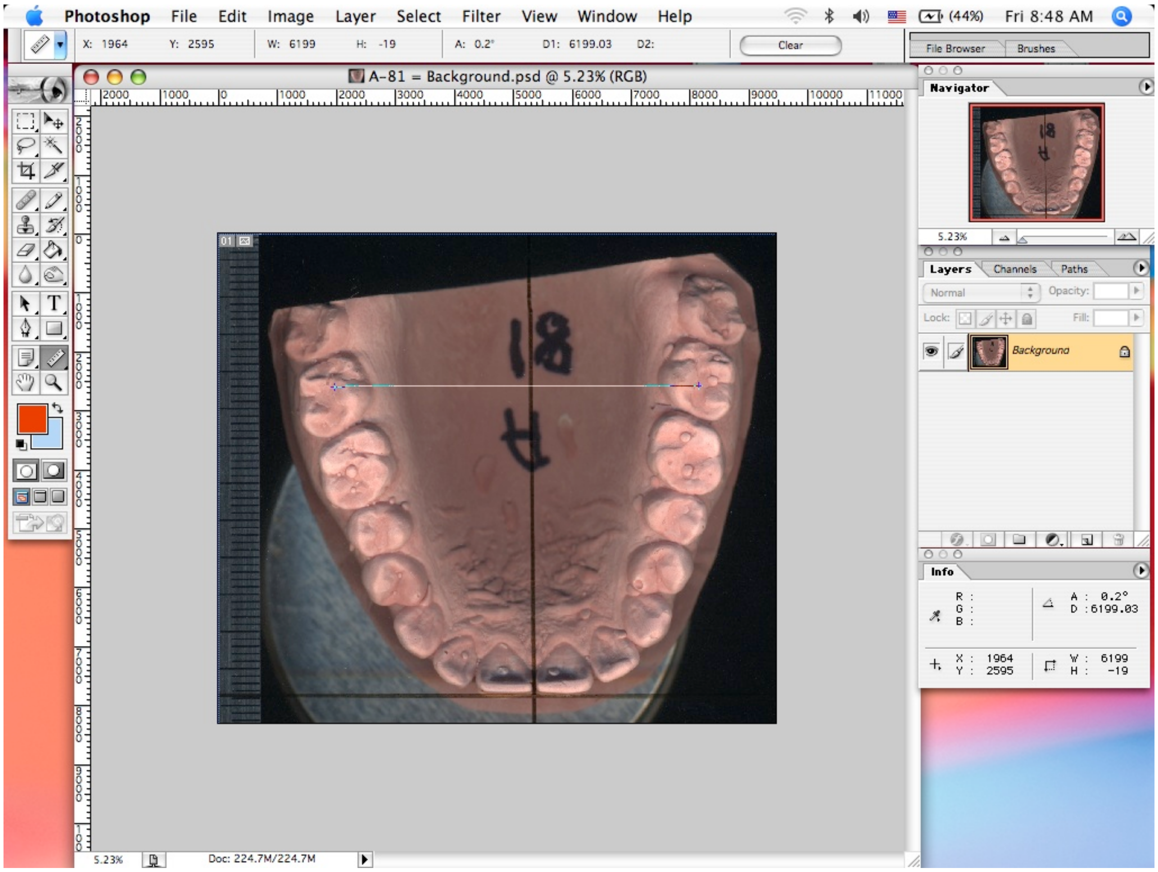

Figure 6. Measurement reading on the background image.

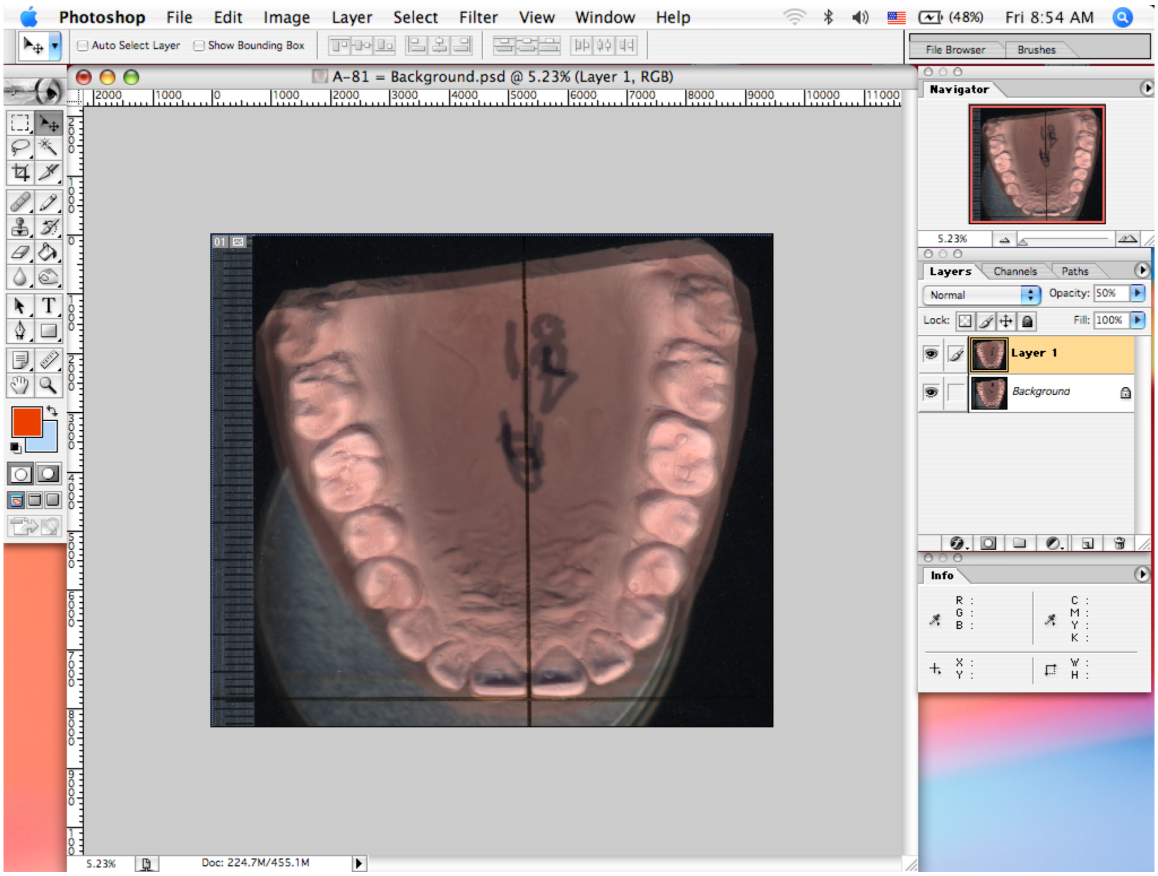

Figure 7.New cast image at 50% overlapped over the background image.

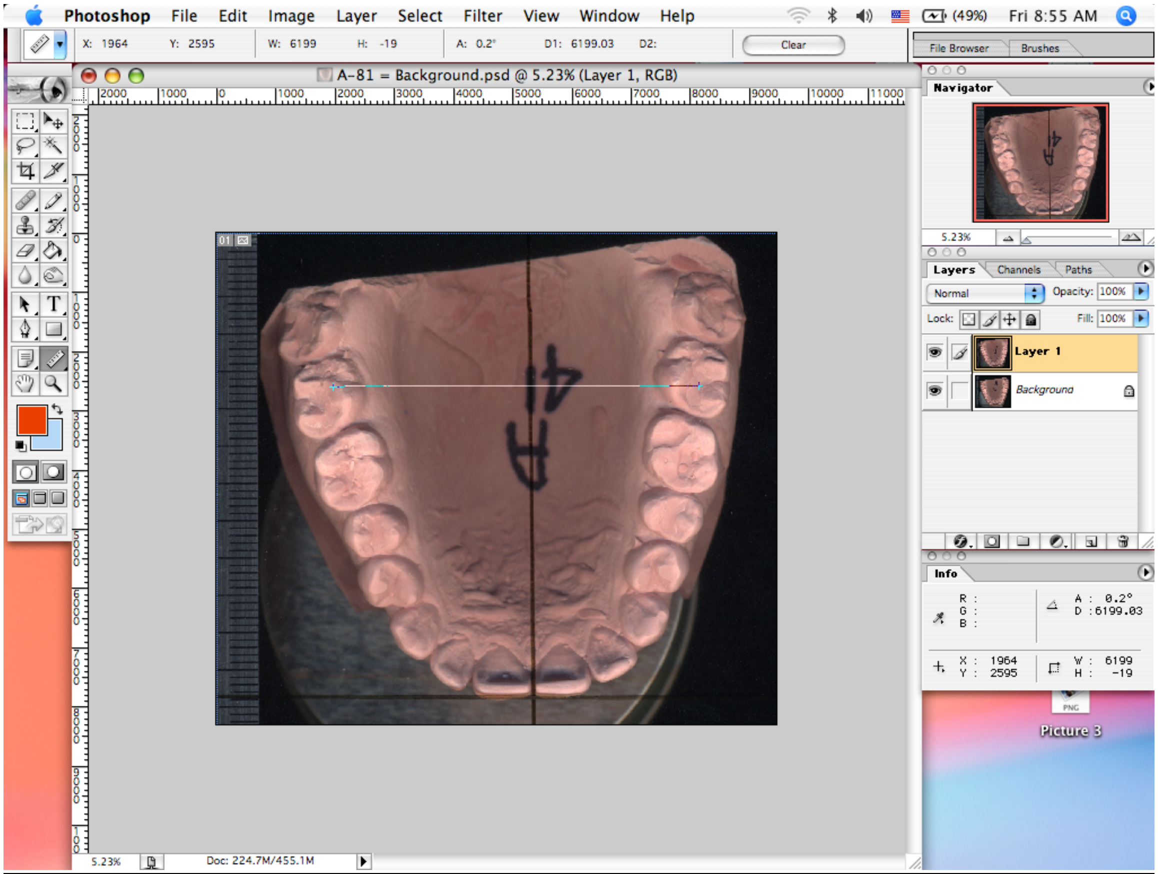

Figure 8. New cast image measurement reading at 100 %.

CHAPTER 4

RESULTS

Data was analyzed with 'patient' as a repeated effect and 'tray code' as a fixed effect using mixed model analysis of variance. The total observations used and read were 84. The outcome measures analyzed were M15-M2, M2-P12, and M15-P5. There was no significant difference in the outcome measure M15-M2 (p=0.0882) and M2-P12 (p=0.3009). There was, however, a significant difference in the outcome measure M15-P5 (p=0.0009). In this category, the tray groups GC plastic (p=0.0082), 3M ESPE (p=0.0015) and perforated metal (p=0.003) were significantly different from the custom tray group.

The custom tray measurements were numerically lower than the rest of the tray groups in all three sets of outcome measures. The perforated metal trays had the largest difference from the custom trays with their differences of least square means standing at M15-M2 (67µm), M2-P12 (39.6µm) and M15-P5 (102µm). The observation of 102µm in the third outcome measure (which was the statistically significant data set), was the only data point in the entire data set that matched the clinically significant difference of 90µm or more. The 3M ESPE trays were different from the custom trays at M15-M2 (55µm), M2-P12 (10µm) and M15-P5 (68µm). The GC plastic trays were the closest in accuracy with the gold standard, with its differences of least squares means at M15-M2 (43µm), M2-P12 (-4), M15-P5 (71µm).

Tray code	Tray Type	Estimate
1	PMetal	47.7691
2	3MESPE	47.7564
3	GCplastic	47.7444
4	Custom	47.7015

Table 1.Least squares means of all tray groups in the data set M15-M2.

Tray code	Tray Type	Estimate
1	PMetal	49.2351
2	3MESPE	49.206
3	GCplastic	49.1915
4	Custom	49.1955

Table 2.Least squares means of all tray groups in the data set M2-P12.

Tray code	Tray Type	Estimate
1	Pmetal	48.6976
2	3MESPE	48.6629
3	GCplastic	48.6661
4	Custom	48.595

Table 3.Least squares means of all tray groups in the data set M15-P5.

	M15-M2	M2-P12	M15-P5
Pmetal	0.06754	0.003961	0.1026
3MESPE	0.05486	0.01052	0.06789
GCplastic	0.04287	-0.00396	0.07113

Table 4. Differences of Least square means of all tray groups in all three data sets.

M15-M2 outcome measure (P=0.0882) has a statistical difference with the M15-P5 (P=0.0009), but which approaches a magnitude that appears to be close to significance to the set level of α =0.05. In such a situation where the sample size was 7, it probably requires a higher sample size to see a statistical significance in this group. For clinical inference purposes however, this data set cannot be totally ignored. With a higher sample size, the possibility of obtaining a significant data set exists. M15-M2 could be termed 'almost significant'.

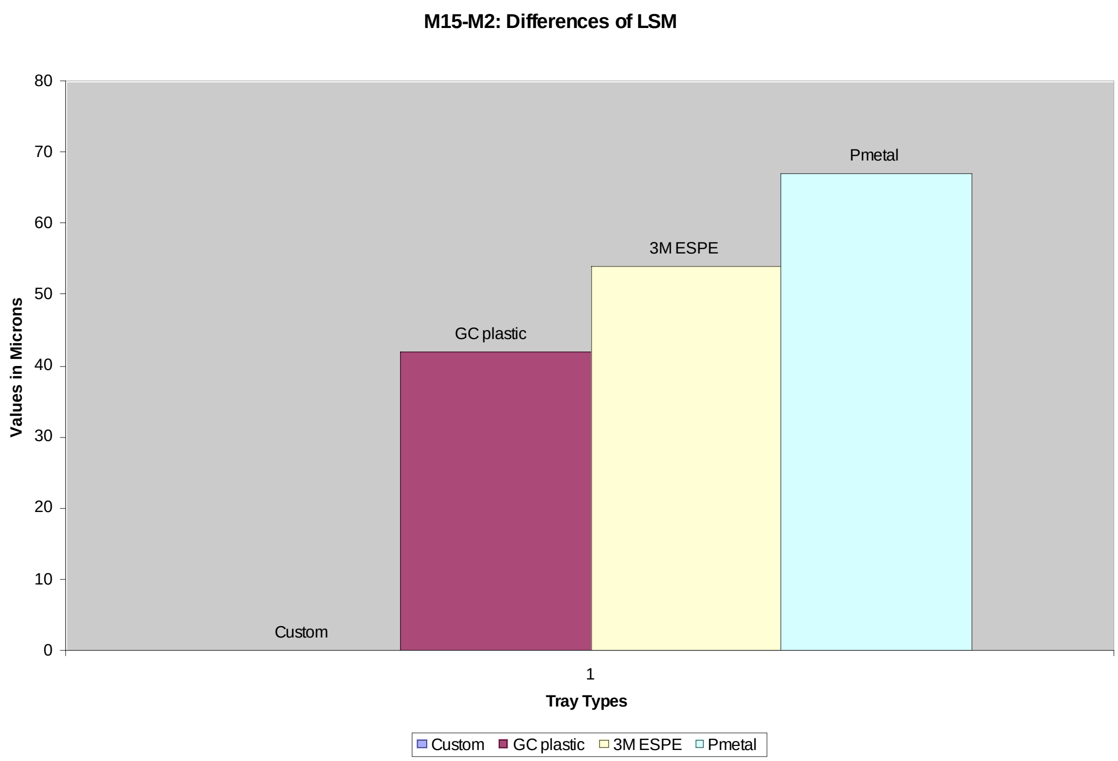

Figure 9. Differences of least squares means of M15-M2 data set. This graph shows that the GC COE plastic trays are closest in linear dimensions to the 'gold standard' closely followed by the 3M ESPE plastic trays. GC COE perforated metal is farthest away in linear dimensions. This is an 'almost significant' data set.

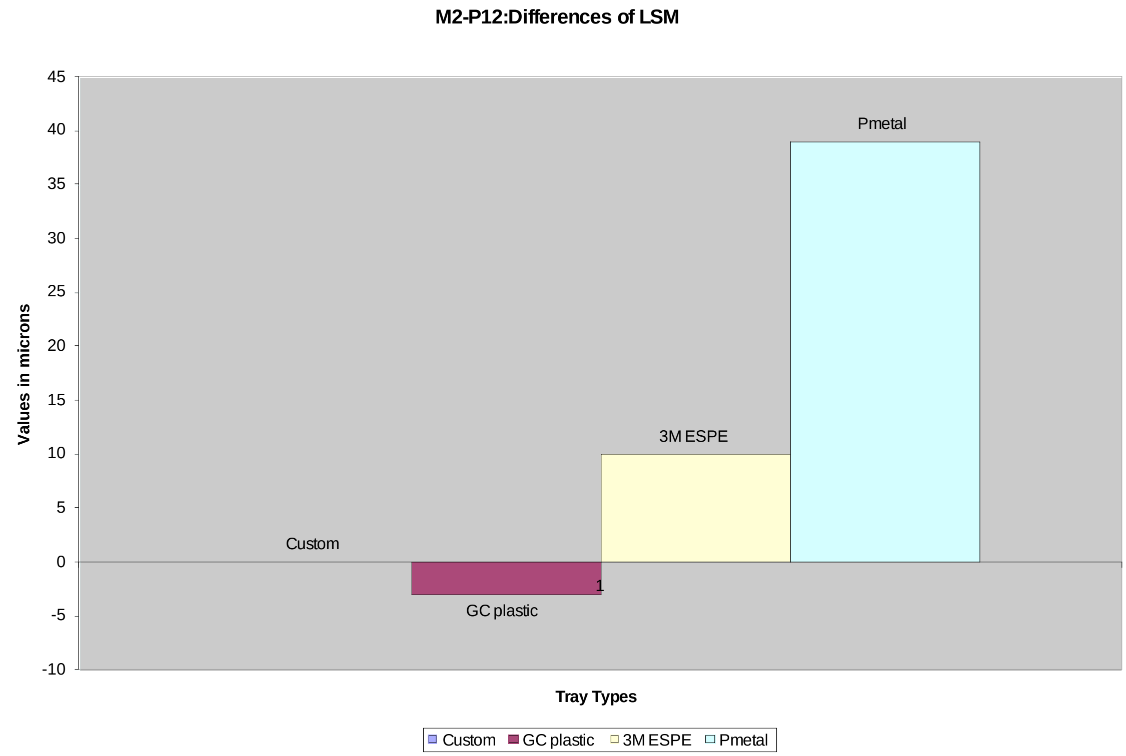

Figure 10. Differences of least squares means of M15-P12 data set. This graph shows that the GC COE plastic trays have the same value in linear dimensions to the 'gold standard' closely followed by the 3M ESPE plastic trays. GC COE perforated metal is farthest away in linear dimensions. This is a 'not significant' data set.

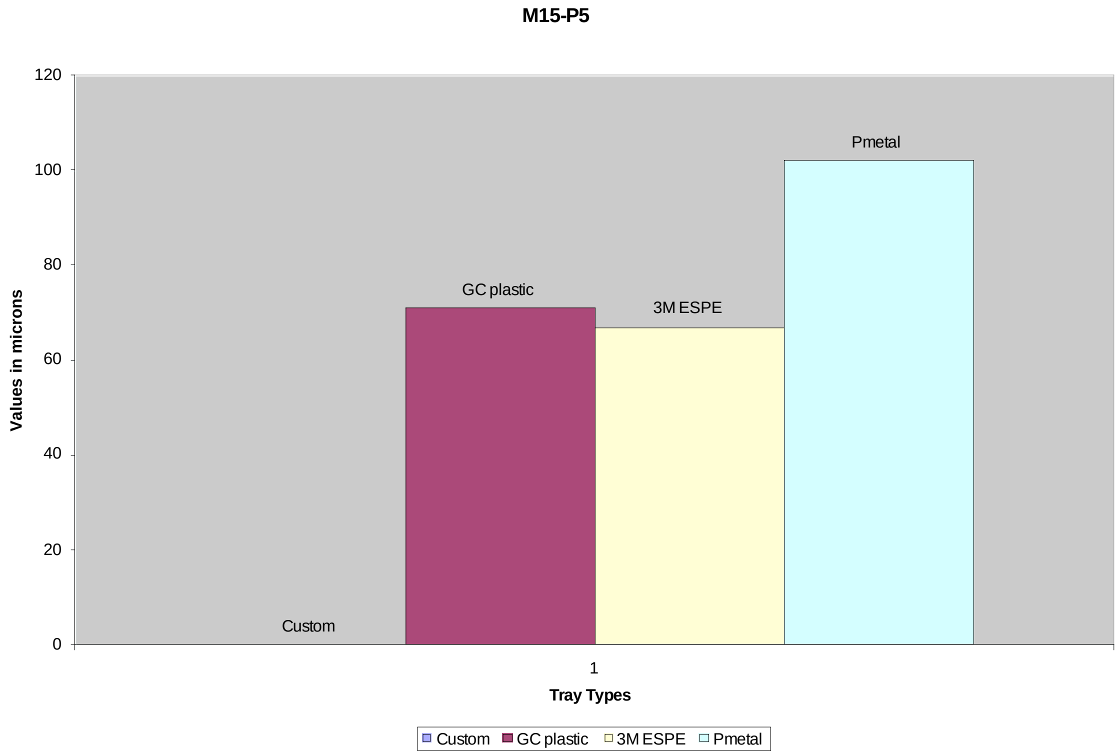

Figure 11. Differences of least squares means of M15-P5 data set. This graph shows that the 3M ESPE plastic trays are closest in linear dimensions to the 'gold standard' closely followed by the GC COE plastic trays. GC COE perforated metal is farthest away in linear dimensions. This is a 'significant' data set.

In the third outcome measure (M15-P5), we reject the null hypothesis and state that there is a significant difference among tray groups when compared with the custom tray impressions. We fail to reject the null hypothesis in the sets M15-M2 and M2-P12.

A retrospective observation worth mentioning is that within the tray randomization sequence, it was noted that in 3 patients, the metal trays were scheduled to be impressed thrice in their 1st session. Such a repeat schedule was not seen with any other tray group in any of the subjects in the entire random sequence.

CHAPTER 5

DISCUSSION

The outcome measure M2-P12 at P=0.3009 is not significant. M15-M2 is almost significant at p=0.0882. The statistically significant outcome measure is M15-P5 at P=0.0009.

The ‘gold standard’ which are the casts made from PVS and custom tray impressions has been numerically established with consistently lower values than the rest of the tray groups in all outcome measures. The GC plastic trays were the closest in value compared to the custom trays. In the statistically significant group (M15-P5), the GC plastic and the 3M ESPE trays were almost equal with a slight difference of 4µm. The perforated metal was clinically significant with differences of mean value at 102µm. GC COE perforated metal trays had not reached comparable values in any data set, statistically significant or otherwise.

The non-perforated metal trays have always been the standard of choice to make alginate impressions in removable partial denture prosthodontics.[4] They are also the first tray choice for making diagnostic casts.[9] The wide usage is mainly due to their rigidity, which is very helpful in confining the alginate material and making a properly extended impression.[9] Among the perforated and non-perforated metal trays, the latter is not recommended as they might not be able to perform as well as the solid trays and may result in incomplete, under extended impressions.[9] No distortion was found in either perforated or nonperforated trays when impressed with alginate impression material.[40] It is also advocated that the use of plastic trays should be avoided because of their flexibility which can lead to inaccurate impressions.[9]

Woodward et al (1985) showed that alginate impressions made in perforated trays were more accurate than those of rim-lock trays. Mendez in 1985 reported that perforated stock or custom trays produced more accurate horizontal dimensions than did non perforated trays**.** Vertical dimensions (depth of palatal vault) were produced most accurately by rim-lock non perforated trays followed by stock perforated and custom nonperforated trays.[3] The data generated in this study is from a clinical setting and it differs from the traditional opinion regarding metal trays. The performance of both the plastic trays was closest to the ‘gold standard’, especially in the statistically significant set, M15-M2 (P=0.0009). One study showed that the metal stock trays resisted deformation with the use of putty polyvinylsiloxane impression material and that the GC plastic exhibited dimensional changes which were attributed to their lack of rigidity.[13] Contrasting results are seen in our study with the same two trays but with alginate being used as the impression material. The non-perforated metal trays did not perform well compared to the ‘gold standard’. Clinically significant distortion was established to be any measure more than 90μm according to the movement of the periodontal ligament. Actually, the metal tray produced a data point that was clinically important at 102μ, which was clinically unacceptable as being more than 90μ. This standard is based on the periodontal ligament space and its range of movement between teeth, based on which we established that any measurement beyond 90μm would be considered a clinically unacceptable value.[37]

The 3M ESPE Directed flow impression trays performed on par with the GC plastic trays in the significant category. A slight difference in the M15-M2 category (P=0.0880) is seen between the trays.

The standard deviations per tray group within a subject were found to have been normal throughout the three outcome measures in all data sets. This can attest to the validity of the method of analysis employed in this study. It gives hope to the sequential steps used for data collection using Adobe® Photoshop 7, highly accurate software that researchers can consider for image analysis. It speaks about the investigator's repeatability of the points marked on the background image teeth and the consistency of accurately identifying the same spots in every other image analyzed in that group.

According to the literature, the tray spacer used in the fabrication of the tray did not have an effect on the accuracy of the impressions.[38] The casts being scanned in the inverted position seems to have been successful in controlling the Z variable, which needed to have been accounted for if they were scanned with casts on their bases. The attempt at positioning the casts in a subject group, in the same X-Y plane each time seems to have been considerably efficient with the use of a transparency sheet and two perpendicular lines intersecting with the cast's midline.

The strength of the study is definitely having had one investigator perform all the duties right from custom tray fabrication, randomization, patient enrollment, appointment scheduling, arranging sessions, impression making, cast pouring, scanning and data collection (except blinding). This kept an important variable constant.

Many 3-D digitizer and scanning systems are available but are very expensive and require additional training to operate the device and its related software.[39] It could be suggested that this model of analyzing the images could be looked into as an alternative to the expensive equipment usually required for image analysis and pursued accordingly.

Within the limitations of the study, the GC COE plastic and the 3M ESPE directed flow impression trays have been shown to be closer to custom tray and PVS impression casts than the GC COE perforated metal tray group. Since this experiment was carried out in a clinical setting, the results can be considered reflective of the clinical scenario.

Clinical observations

During impression making, the investigator felt that the 3M ESPE directed flow impression trays were difficult to use because of their sizes. It is prudent to mention that the subjects were generally not comfortable with the 3M ESPE trays. Almost universally, subjects complained of discomfort with these trays. The reason was that the 3M ESPE trays were felt to be slightly larger than the correspondingly sized GC COE trays, metal or plastic. However, the self-adhesive strip on the tray performed well as the adhesion of alginate to the tray was high. The custom trays had been fabricated in a manner not requiring any further trimming. The patient acceptability was high with these trays as it was with the GC COE plastic and GC COE perforated metal trays.

There is a possibly a reason which could explain the results obtained. The normal tendency of the right handed dentist when removing the impression from the patient's mouth is to remove it with a snap. This happens with a sudden force which is actually torqued towards the clinician's and the patient's right side. With this moment of force in play, distortion occurs from the anterior right part of the impression diagonally across to the posterior left part of the impression. This accounts for the M2-P12 reading being statistically not significant. The least distorted areas of the impression have produced statistically and clinically significant results.

Plastic trays being semi-rigid seemed to have the capability to flex and provide space for the impression to regain its elasticity during the torque occurring at removal, hence distorting the impression to the very minimum. Metal trays being totally rigid; confine the impression material in the tray, due to which the possibility of elastic recovery is minimal and the distortion in the impression gets incorporated, thus the casts produced seem to have linear measurement values numerically higher than any other tray group.

Metal tray analysis

Only metal trays were re-used with the other two being disposable trays. The possibility of residual micro-debris did not exist for the other two trays. That is one less variable for the plastic trays. The metal trays were thoroughly cleaned before sterilization and usage. The alginate impression material adhered strongly to the tray without an adhesive. It is possible that the repeated use of the trays and their repeated usage in the 1st sessions could probably have had an over-all effect on the data obtained. For these trays, all observations but one was within the clinically acceptable range. In general, we have been able to see a statistically significant outcome measure (M15-P5) and an almost significant outcome measure (M2-P12) where the GC COE plastic and the 3M ESPE trays have performed better than the GC COE perforated metal trays. These results were possible using a scanner (EPSON® 1680) and Adobe® Photoshop 7 software. The trays that were least expected to cross the finish line, come way on top. That was a very interesting, unexpected observation. We have been able to perform a range of duties with a minimum standard deviation which was amazing. The PI was concerned at the time of data collection whether the data by tray group would produce any comprehensible result. That it did proves the efficacy of the blinding technique. A better method needs to evolve to try orienting the casts on a scanner in an exact position. Even though the present method seemed to have worked, the operator variability could be high. The Adobe® Photoshop software has promise to be an alternative to high end magnification tools employed in research.

CHAPTER 6

CONCLUSIONS

The outcome measure M15-P5 showed that the casts produced were of significantly different in linear dimensions than the outcome measures M15-M2 and M2-P12. The performance of GC COE plastic trays and the 3M ESPE directed flow impression trays was better than that of the GC COE perforated metal trays. This conclusion is obtained by comparing the linear measurements of casts closest in value to the custom tray/PVS impression casts. Only linear measurements are analyzed in this study. Volumetric analysis should be performed to strengthen the conclusion.

CHAPTER 7

FUTURE DIRECTION OF RESEARCH.

All the observations, but one was in the range of clinical acceptability.

1. It would be interesting to test the accuracy of 3M ESPE trays which are indicated for final impressions in crown and bridge work.

2. To test the GC COE plastic stock trays with PVS material in a clinical situation and observe if the results contradict an earlier study that showed that plastic stock trays produce casts with greater dimensional changes than custom trays.[22]

3. To design a clinical model and analyze the casts using Proscan® for volumetric analysis and compare those results with this study results.

4. Substitution of PVS by an effective intra-oral scanner as the ‘gold standard’.

5. To involve a range of impression materials and different tray types to analyze their efficacy.

6. To compare the detail reproduction of PVS materials in vitro and in vivo situations.

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APPENDIX A

RANDOMIZED SCHEDULE TABLES

SESSION	X	TRAY&NUMBER	XYZ
1	F	GC Plastic	F31
		PMetal	F11
		GC Plastic	F32
		PMetal	F12
2	B	3M ESPE	B21
		PMetal	B11
		Custom	B41
		GC Plastic	B31
3	E	PMetal	E11
		PMetal	E12
		PMetal	E13
		Custom	E41
4	D	PMetal	D11
		3M ESPE	D21
		PMetal	D12
		PMetal	D13
5	C	Custom	C41
		PMetal	C11
		GC Plastic	C31
		PMetal	C12
6	E	3M ESPE	E21
		3M ESPE	E22
		GC Plastic	E31
		GC Plastic	E32
7	A	PMetal	A11
		GC Plastic	A31
		Custom	A41
		3M ESPE	A21

Table A-1.The sequence of 1-7 randomized sessions

SESSION	X	TRAY&NUMBER	XYZ
8	F	Custom	F41
		Custom	F42
		PMetal	F13
		3M ESPE	F21
9	D	GC Plastic	D31
		3M ESPE	D22
		Custom	D41
		GC Plastic	D32
10	G	PMetal	G11
		PMetal	G12
		GC Plastic	G31
		PMetal	G13
11	G	3M ESPE	G21
		GC Plastic	G32
		Custom	G41
		3M ESPE	G22
12	A	3M ESPE	A22
		3M ESPE	A23
		PMetal	A12
		Custom	A42
13	D	Custom	D42
		Custom	D43
		3M ESPE	D23
		GC Plastic	D33
14	F	GC Plastic	F33
		Custom	F43
		3M ESPE	F22
		3M ESPE	F23

Table A-2.*The sequence of 8-14 randomized sessions.*

SESSION	X	TRAY&NUMBER	XYZ
15	B	3M ESPE	B22
		Custom	B42
		GC Plastic	B32
		3M ESPE	B23
16	A	PMetal	A13
		Custom	A43
		GC Plastic	A32
		GC Plastic	A33
17	C	PMetal	C13
		3M ESPE	C21
		3M ESPE	C22
		Custom	C42
18	B	PMetal	B12
		GC Plastic	B33
		PMetal	B13
		Custom	B43
19	C	GC Plastic	C32
		Custom	C43
		GC Plastic	C33
		3M ESPE	C23
20	G	3M ESPE	G23
		Custom	G42
		GC Plastic	G33
		Custom	G43
21	E	Custom	E42
		3M ESPE	E23
		Custom	E43
		GC Plastic	E33

Table A-3.*The sequence of 15-21 randomized sessions.*

APPENDIX B

INITIAL PILOT TEST READINGS TABLE

	M14-M3
	46.04462
	46.04462
	46.04613
	46.02183
	46.02597
	46.03171
	46.02398
	46.04764
	46.04278
	46.02446
	46.01641
	46.03434
	46.02525
	46.03179
	46.03243
	46.05561
	46.03195
	46.01848
	46.04494
	46.07243
S.D	0.013912

Table B-1. Initial pilot test readings to determine the standard deviation of Adobe® Photoshop 7 method.

APPENDIX C

UAB INSTITUTIONAL REVIEW BOARD APPROVAL FORM

THE UNIVERSITY OF ALABAMA AT BIRMINGHAM

Institutional Review Board for Human Use

Form 4: IRB Approval Form
Identification and Certification of Research
Projects Involving Human Subjects

UAB's Institutional Review Boards for Human Use (IRBs) have an approved Federalwide Assurance with the Office for Human Research Protections (OHRP). The UAB IRBs are also in compliance with 21 CFR Parts 50 and 56 and ICH GCP Guidelines. The Assurance became effective on November 24, 2003 and expires on October 26, 2010. The Assurance number is FWA00005960.

Principal Investigator:	DAMODARA, ESWAR KERAN C.
Co-Investigator(s):	
Protocol Number:	**X080328009**
Protocol Title:	*Clinical trial to determine the accuracy of prefabricated trays for making Alginate Impressions*

The IRB reviewed and approved the above named project on 4/9/08. The review was conducted in accordance with UAB's Assurance of Compliance approved by the Department of Health and Human Services. This Project will be subject to Annual continuing review as provided in that Assurance.

This project received EXPEDITED review.

IRB Approval Date: 4-9-08

Date IRB Approval Issued: 4/9/08

Marilyn Doss

Marilyn Doss, M.A.
Vice Chair of the Institutional Review Board for Human Use (IRB)

Investigators please note:

The IRB approved consent form used in the study must contain the IRB approval date and expiration date.

IRB approval is given for one year unless otherwise noted. For projects subject to annual review research activities may not continue past the one year anniversary of the IRB approval date.

Any modifications in the study methodology, protocol and/or consent form must be submitted for review and approval to the IRB prior to implementation.

Adverse Events and/or unanticipated risks to subjects or others at UAB or other participating institutions must be reported promptly to the IRB.

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