Differences Between Conventionally and CAD/CAM Complete Removable Dental Prosthesis -

Subjective Analysis

BY

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THESIS

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<tr>
<td>AMD</td>
<td>Anatomical Measurement Device</td>
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<tr>
<td>CAD/CAM</td>
<td>Computer-Aided Design and Computer-Aided Manufacturing</td>
</tr>
<tr>
<td>HIPAA</td>
<td>Health Insurance Portability and Accountability Act</td>
</tr>
<tr>
<td>ICD</td>
<td>Informed Consent Document</td>
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<td>ICIDH</td>
<td>International Classification of Impairments, Disabilities, and Handicaps</td>
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<td>OHIP</td>
<td>Oral Health Impact Profile</td>
</tr>
<tr>
<td>OIDP</td>
<td>Oral Impact of Daily Performance</td>
</tr>
<tr>
<td>PDI</td>
<td>Prosthodontics Diagnostic Index</td>
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<tr>
<td>PHI</td>
<td>Protected Health Information</td>
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<tr>
<td>SAE</td>
<td>Serious Adverse Event</td>
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<td>SOP</td>
<td>Standard Operating Procedure</td>
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Removable Complete denture prostheses: a removable dental prosthesis that replaces the entire dentition and associated structures of the maxillae or mandible

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VIII
SUMMARY

The ever-growing population and increased lifespan of today’s society has caused an increased need for dental prosthesis. Dental professionals will need continual advancements in order to meet the rising need for full arch maxillary and mandibular prosthetic restorations. Since the introduction of polymethyl methacrylates in 1936, methods of denture fabrication have not progressed substantially for the past 70 years. The traditional process requires experienced prosthodontists or general dentists, skilled dental technicians, and numerous office visits requiring substantial time from both the dentist’s and patient’s perspective. This is in addition to the large amount of laboratory work needed to fabricate and process the denture to a final prosthetic component.

The age of computer and digital technology has brought about the introduction of Computer Aided Design and Computer Aided Manufacturing (CAD/CAM) fabricated dentures to overcome the disadvantages of conventional dentures. With computer aided design and manufacturing, a digital fabricated denture can be milled for a precision fit and maintain a digital record.

The purpose of this study is to examine any differences in conventionally fabricated dentures and CAD/CAM fabricated dentures based on patient perceptions. The areas to be assessed between conventional and CAD/CAM dentures are: denture fabrication process, extra-oral esthetics, intra-oral esthetics, patient phonetic satisfaction, patient functional satisfaction, and overall patient satisfaction.

Upon IRB was approval, 10 fully edentulous patients, who were in need of maxillary and mandibular removable complete dentures, were consented to participate in the study. Following
best practice procedures, one set of conventional complete dentures and one set of CAD-CAM
dentures were fabricated. At the completion of each prosthesis type, the subjects were
asked to complete a survey regarding their denture fabrication experiences. The subjects were
then randomly assigned to two different groups (A and B). Group A received the conventional
dentures and, after scheduled post-insertion follow-ups, wore the prostheses for 3 months.
After the three-month time period, the patients completed a second survey regarding their
post-insertion follow-ups, comfort, fit, and esthetics of the dentures-the clinician then retained
the conventional complete dentures and the CAD/CAM dentures was inserted and delivered to
the patient. The same post-insertion follow-ups and 3 months evaluation procedures were
performed and a second survey completed.

Group B followed the same protocol, but the CAD/CAM fabricated dentures were inserted
first, followed by the conventional denture.

All the findings were categorized and compared to determine any differences in patient
satisfaction with esthetics, phonetics, and function.

This is one of the first studies comparing patient perspectives with regards to CAD/CAM
and conventionally fabricated dentures and the results obtained are expected to serve as a basis
for clinical guidelines and as a foundation for future researchers in the fields of prosthodontics.

Due to the small number of participants, analysis for statistical significance was limited.
However, based on descriptive observations both types of prostheses had positive attributes
related to patient perceptions.
1. Introduction:

1.1 Review of the Literature:

Edentulism is a rising condition in the United States due to the increased average lifespan of the population. According to the American College of Prosthodontics, for the geriatric population, the ratio of edentulous individuals to non-edentulous is 2 to 1. There are about 23 million people that are completely edentulous and there are about 12 million people that are edentulous in one arch. Among these patients, only about 15 percent of the edentulous population has dentures made each year. Thus, more than 80% of the edentulous population is currently making due with potentially ill-fitting, worn dentures or without any type of prosthesis.

Millions of people depend on a removable prosthesis in order to maintain proper oral health and functioning. These prostheses however, come with potential challenges. Conventional complete denture wearers experience several problems on a daily basis, such as instability of their mandibular dentures, inability to comminute foods, decreased self-confidence, decreased quality of life, and decreased social contact and overall satisfaction. The question is, are there any new technologies today that can help millions of people obtain an improved removable prosthesis that can potentially overcome these problems.

The age of computer and digital technology has brought about the introduction of Computer Aided Design and Computer Aided Manufacturing (CAD/CAM) fabricated dentures. Scientific literature on CAD/CAM dentures deals with looking at the possibilities of CAD/CAM technologies and the role it will potentially play in the dental field. Earlier literature examined prototype systems for the fabrication of opposing complete dentures and helped aid the development in CAD/CAM denture fabrication. One of the biggest findings in earlier literature
was the possibility of fabricating a complete denture as one solid piece, using laser lithopgraphy. However, the process was deemed time consuming and cost prohibitive.\textsuperscript{20} The use of multi-axis milling units, has not only allowed for the manufacturing of dentures as one solid piece but also in a more time efficient manner. Other authors have indicated that CAD/CAM technologies are promising, but there are many areas in the overall CAD/CAM process that need further evaluation.\textsuperscript{11,19,20} These areas include the initial impression, computer software, denture material, and different denture milling units.\textsuperscript{20} Some feel further improvements are needed in the 3D design and subsequent 3D processing.\textsuperscript{19} The gap between intra-oral scanning, computer design, denture customization, and full 3D printing or milling is decreasing. However, as further improvements are needed, the conventional technique in denture fabrication is still critical.

“Published literature and current commercial manufacturing systems use a combination of manual and digital procedures for the clinical and laboratory stages of computer-aided denture fabrication.”\textsuperscript{4} It is important to be familiar with conventional impression techniques in order to optimize use of current CAD/CAM technologies.\textsuperscript{5} Capturing esthetic, phonetic, and muscle attachment information is still vital in the fabrication of CAD/CAM dentures. The conventional techniques used to gather this information are either scanned or taken into account in order to create virtual base forms, tooth placement, and eventually fabricate the prosthesis.\textsuperscript{11} Therefore, even with CAD/CAM dentures, the need for understanding conventional denture fabrication and assessment, is vital to incorporating this new technology into patient care.

The use of the CAD/CAM technology in the field of dentistry is promising; dental professionals should not wait to implement the use of this technology.\textsuperscript{19} Whether as an experienced clinician or a new dentist, it is important to be aware of the current technology in
order to offer patients the best dental care options. In daily practice, classic literature serves as the guideline for the fabrication of conventional dentures. “Classic literature on complete denture prosthodontics preceded modern concepts of evidence-based dentistry, resulting in a paucity of evidence-based discussion of many of the principles and techniques used in the fabrication of complete dentures.”4 This is important in the era of evidence-based dentistry, and should be kept in mind with the advent of computer based technologies. These technologies offer a chance to examine fundamental principles and to incorporate and improve denture fabrication via CAD/CAM technologies. However, at this time, there is a lack of scientific evidence to support and guide clinicians in the use of CAD/CAM denture fabrication. Therefore, there has never been a more important time to evaluate patient feedback in assessing CAD/CAM and conventional denture treatment options.

Patient perspective plays an important role in our practice since ultimately it is the patient’s quality of life that is affected by the prosthesis. In fact, “Edentulous patients’ main aim seems to be improving their Oral Health Related Quality of Life (OHRQoL).”26 The dental clinician needs to always keep in mind that each patient presents with a different self-image. “It seems that judgments about denture quality and satisfaction by clinician’s correlates quite poorly with the patients' own judgments, possibly because the patients concerns are more related to comfort, function, and esthetics, which are factors that are extremely difficult for the clinician to measure.”6 When patient’s concerns and self-image factors are not fully met then anxiety, insecurity, diminished self-esteem, and introversion can be typical psychosocial responses after denture therapy.6 To best avoid these possible negatives, it is important to gather data from the
patient perspective, to better assess fabrication processes, quality of life alterations, and ultimate satisfaction in denture therapy.

As CAD/CAM technology emerges in the area of completely removable prostheses, it is important to gather patient feedback associated with this new technology and how it attributes to a patient’s Quality of Life. “Oral Health Quality of Life (OHQoL) is the most used measure of patient perception, and is considered a more complete valuation of oral disease and its treatment than general measures of satisfaction.”34 It is important to not only understand the causes and possible physical outcomes of a disease but also the social impact a disease has on a patient’s ability to perform everyday activities. The measurement of social impact among specific patient populations can lead to the development of detailed dental care programs that focus on patients’ physical and mental needs. These measurements can also lead to improved preventive care or more comprehensive treatment protocols that promote positive behaviors and attitudes surrounding treatment.

“Several instruments in the form of questionnaires have been validated to measure the Oral Health Related Quality of Life (OHRQoL) in a scientific manner.”26 The most commonly used measure of OHRQoL is the Oral Health Impact Profile (OHIP). “The 49-item OHIP was developed on the basis of the 1980 World Health Organization’s International Classification of Impairments, Disabilities, and Handicaps (ICIDH).”34 The OHIP has been validated and demonstrates both high internal reliability as well as test reliability.31,32 The OHIP is comprised of statements grouped into different subsets or domains.7 “In accordance with the ICIDH, the OHIP-49 comprises seven subscales to evaluate impairment (functional limitation, physical pain, psychological discomfort), disability (physical, psychological, and social disability), and handicap resulting from dental
conditions.” The use of the OHIP domains allows for a standardized model to assess an individual’s health related quality of life as it relates to different treatment modalities.

Questionnaires are a subjective means of recording patient’s responses to concerns about their dental prosthesis and fabrication process. Using standardized questions based off of the OHIP produces valid and reliable data that the clinician can use to examine the oral health impact. Questionnaire responses may be recorded using different techniques such as the Likert and VAS scale. Both techniques have demonstrated a strong correlation with physiological markers. It is has been argued that the Likert scale is easier to use and simpler for study participants to fill out the survey. Overall, the results from a Likert scale may be easier to understand and score when compared to VAS scale. Some studies argue that the Likert scale is easier to interpret a minimal clinical difference. Observing a change in one to two points on a five to seven point Likert scale seems intuitively easier to grasp than a 10-20mm change on a VAS scale. Studies have shown that both the Likert and VAS scales show similar sensitivity to outcomes being measured. The current study used a 4 point Likert scale, in combination with questions derived from OHIP, in order to assess different attributes relative to a patient’s choice in selecting their final denture prosthesis.
1.2 Rationale:

The number of partially edentulous patients will continue to increase in the next 15 years to more than 200 million individuals.9 With such a dramatic increase, dental professionals will be challenged with the need to meet the growing demand of removal prostheses. Complete denture fabrication requires multiple appointments and includes material costs associated with impression material, stone casts, and wax. The increase in demand of dentures may potentially equate to increased time and money for the provider and in turn, the patient.

In addition to the possible increased costs of treatment to the patients, the prosthesis also has some limitations. Current complete dentures are mainly fabricated using polymethyl methacrylate (PMMA) which was first introduced in the 1930’s.23 Even though this has been the material of choice for over 80 years, there are a number of limitations associated with it. According to Bettencourt, these limitations include surface degradation, poor wear resistance, porous material, and microorganism colonization.3 In healthy individuals, it is reported that Candida albicans has a prevalence of 45-65% in the oral cavity.30 For individuals that wear dentures, the prevalence of Candida albicans is 60-100%.30 This increase of Candida can potentially lead to denture stomatitis. “Candida-associated denture stomatitis is a very common inflammatory process affecting about 60% of the subjects” that have Candida associated with their prosthesis.28 With the emergence of digital technologies, it is important to keep in mind not only the time and money benefits but also the potential for improvement in conventional material limitations.

The use of CAD/CAM technology for denture fabrication has many potential benefits. According to Kattadiyil, there are 6 distinct advantages of CAD/CAM fabricated dentures over the
conventionally fabricated counterpart. These include, “reduced number of clinical appointments, reduced treatment time, reduced fees without compromising quality, absence of polymerization shrinkage resulting in improved fit, easy fabrication of spare or replacement dentures from stored digital data, and reduced patient adaptation time for replacement dentures.”17,18

The CAD/CAM denture manufactures promote a 2-appointment complete denture fabrication technique. This allows for decreased chair time for both the patient and dentist. This 2-appointment design has potential benefits for both parties. It allows the dentist to provide care to more people with the additional chair time and potentially allows the dentist to decrease the cost associated with complete denture fabrication. It also allows the patient to have less overall appointments from start to finish. This means less total travel time, fewer lost work days, and a shorter treatment duration.

Digital records of each prosthesis is another large benefit to CAD/CAM dentures. If patients lose or break a denture, digital records allow for easy re-fabrication, without the patient being present. Even if the denture teeth have simply worn down over time, it is easy to have a new denture fabricated. Since the denture is a digital copy of the one they lost, it will be an exact copy and the patient needs less time to get adjusted to it.

Relative to the material, conventionally fabricated dentures using PMMA demonstrate a 7% volumetric shrinkage.21 The loss of acrylic monomer that causes this shrinkage also results in a porous material. This porous material accounts for many of the limitations noted previously and allows for the adhesion and inhabitation of Candida albicans on the dentures.30 CAD/CAM dentures are milled from a prepolymerized acrylic puck that results in a less porous denture
potentially making it more bio-hygienic. According to the CAD/CAM denture companies, this milling process also results in an improved fit, increased strength, increase wear resistance, and increased color stability due to the monolithic nature of denture.²

It is the dental community’s obligation to meet the needs of a growing edentulous population. Nothing is more clinically relevant than investigating different methods to meet this need and provide the best available options to patients. The potential for CAD/CAM dentures in serving the edentulous population and improve on the limitations of conventional dentures is a positive prospect and one that has not been thoroughly evaluated. The current study analyzed if CAD/CAM dentures can efficiently meet patients’ functional and esthetics needs. The outcomes from this project give us data on patient perspective on fabrication, function and esthetic outcomes of CAD/CAM dentures.
2. Objectives of Research:

The objectives of this research was to study the differences in conventionally fabricated dentures and CAD/CAM fabricated dentures in subjective patient perception as it relates to:

- denture fabrication process
- extra-oral esthetics
- intra-oral esthetics
- patient phonetic satisfaction
- denture choice within different classes of edentulism.
- patient functional satisfaction
2.1: HYPOTHESIS:

This study tested the following null hypotheses:

H0: There is no difference when comparing conventionally fabricated dentures and CAD/CAM fabricated dentures between patient related subjective perception of 1) Denture fabrication process, 2) Extra-oral esthetics, 3) Intra-oral esthetics, 4) Patient phonetic satisfaction, 5) Patient functional satisfaction, 6) Overall Satisfaction, 7) Denture choice within different classes of edentulism.
2.2 FEASIBILITY OF THE STUDY:

Prior to the start of the study, the anticipated number of subjects (20) for the study appeared to be feasible, considering that there was an adequate number of patients with treatment needs of complete maxillary and mandibular dentures at the University of Illinois at Chicago College of Dentistry. However, due to the low response rate to recruitment efforts, a total of 10 patients participated in the study. It should be noted that 1 patient dropped out of the study after the fabrication of both prosthesis. That specific participants information is included in the fabrication response tables but not the functional questions.

Conventional denture fabrication is a standard procedure done routinely in edentulous patients. CAD/CAM denture fabrication was based on the protocol proposed by the manufacturer. The new method for denture fabrication using CAD/CAM technology did not put the patient at risk for the purposes of this study and patients were monitored routinely.
3. Materials and Methods:

3.1 Experimental Design and Methods:

The study protocol (#2015-0699) was reviewed and approved by the Institutional Review Board of the University of Illinois at Chicago.

Subjects were recruited within the University of Illinois College of Dentistry. Recruitment flyers (attachment #2) were posted in the patient waiting area (patient lobby) outside the Prosthodontic Clinic - Restorative Department, room 361 - and the Urgent Care Clinic at the College of Dentistry located in 801 S. Paulina Street, Chicago, IL. Recruitment e-mails (attachment #3) were sent to all the residents, clinical associate and assistant professors, and students attending postdoctoral and pre-doctoral clinics. Recruitment messages (attachment #4) were sent through Axium software to all the clinical associate and assistant professors, students attending post-doctoral and pre-doctoral clinics and dental clinic managers.

The subjects who volunteered to participate were asked to contact the co-investigators via phone (attachment #5), for a screening appointment.

A total of 10 patients met the inclusion criteria and agreed to return for appointments and recall purposes. Because there is no specific effect size known to be equivalent to clinical significance, a calculation of power-driven sample size cannot be performed.

The study was carried out in the UIC College of Dentistry Postgraduate Prosthodontic Clinic.

Potential subjects were screened for participating in the study through a brief interview and intraoral examination by the co-investigators.

Subjects had to meet the Inclusion criteria (attachment 1) and not have any aspects
included in the exclusion criteria (attachment 1). Subjects were excluded if they were unable to understand the written informed consent, the verbal explanations given to them, and/or the questionnaires.

Each subject was provided with a brief handout describing the study and the nature of their participation (attachment 12). Patients were required to come to the study site 17 times over the following 8 months. Each of the visits took about 1-3 hours.

Following patient written consent (attachment #6), the investigators collected information regarding medical and dental history, demographics, current medications, and completed an oral soft and hard tissue examination (attachment #7).

Ten (10) patients were selected for the study and classified according to the American College of Prosthodontics classification for edentulous patient. One patient dropped out of the study after the fabrication of both sets of dentures and reasoning documented (attachment 11).

The subjects were randomly assigned to two different groups (X and Y), using random integer generator(www.random.org/integers/).

Following best practice procedures, one set of conventional dentures with bilaterally balanced lingualized occlusion was fabricated for subjects assigned to group X.

The conventional set of dentures was fabricated with the traditional 5-appointment process. The treatment sequence is similar to what has been preformed in previous studies.18

The first appointment, comprised of preliminary impressions using fast set alginate which were used to fabricate custom trays. In the second appointment, border molding of the custom trays was performed and final impressions of maxillary and mandibular arches completed using regular set polyvinyl siloxane. At the third appointment, occlusal rim adjustments, facebow
records, joint relation records and tooth selection process was completed. The fourth appointment comprised of anterior and posterior wax tooth try-in with Ivoclar SR Ortholingual teeth. Finally, the fifth appointment included denture adjustments and insertion of the final prosthesis. Dentures were smoothed and polished prior to delivery. A clinic remount was performed prior to the delivery of the final conventional dentures. The dentures were processed in Lucitone-199 via the compression technique and cured under a long cure protocol in accordance with the manufactures specifications: 9 hours in water bath at 163° ± 2°F (73°C ± 1°C). Follow by 1/2 hour in boiling water (Lucitone 199; Dentsply Intl). A patient satisfaction survey regarding the clinical fabrication appointments was filled out by each subject assigned to group “X” (attachment#8) following the prosthesis delivery appointment.

A second set of dentures was fabricated via the CAD/CAM technique according to the manufacture protocol and a second survey to test patient satisfaction during clinical fabrication appointments was filled out by each subject assigned to group X (attachment#8).

Groups “Y” followed the same protocol, but the CAD/CAM fabricated dentures were fabricated first, followed by the conventional dentures. Refer to section 3.2, phase 1 for fabrication appointment flowchart 1.

After each subject had both dentures fabricated and corresponding surveys completed, all the subjects were regrouped and randomized in groups A and B. The patients were blinded as to which denture they received first.

After two post-insertion appointments (24 hours and 1 week), both groups were instructed to wear the prostheses for 3 months. Extra follow-up appointments were documented (attachment 9).
After the 3 months, the patients in “group A” were asked to come to UIC College of Dentistry and at this time, the clinician retained the conventional complete dentures. The retained dentures were disinfected and kept in a properly labeled container in a zip lock plastic bag. The patients were asked to complete a survey regarding the denture comfort, fit, and esthetics (attachment 10) of the conventional denture as it related to the 3 months of wear. Following the survey, the CAD/CAM dentures were delivered. The same post-insertion follow-ups and 3 months of wear was completed. After the 3 months of CAD/CAM denture wear, the patients were asked to come back to the UIC College of Dentistry and complete a survey regarding the denture comfort, fit, and esthetics (attachment 10). This time however, the patients were asked to mark which denture they preferred: the first one or second one. Again, the patients were blinded to whether they had received the conventional or CAD/CAM denture first.

No wash period was given and the patients always had either the conventional or CAD/CAM fabricated denture.15

“Group B” followed the same protocol, but the CAD/CAM fabricated denture was inserted first, and the conventional denture after 3 months. Refer to section 3.3, phase 2 for functional wear flowchart 2.

At the end of the study, the patients were allowed to keep both the CAD/CAM and conventional fabricated dentures.

For the current study, due to the limited wear time of each denture, the handicap domain (6 questions) was not included in the questionnaire. Three of the original OHIP questions, such as, “have you had a toothache,” were not used as they did not pertain to removable prosthesis
being studied. Thus, the six domains used in the current study questionnaire involved questions concerning the functional limitation, the physical and psychological discomfort, the physical and psychological disability, and the social effect of denture wearing on the individual’s everyday life. This resulted in a questionnaire, with a total of 40 questions, that was completed by each patient. Patients responded to each question by marking one of four answers: never, sometimes, often always. All the findings were categorized and compared to study any differences in subjective responses to esthetics, phonetics, function and fabrication process.

Statistical software (SPSS v.20, Chicago, IL, USA) was used for descriptive and statistical analyses.

The responses to the questionnaire were categorized as follows: Never=0, Sometimes=1, Often=2, Always=3. A non-parametric test, Wilcoxon Signed Rank Test, was used for the analysis of the fabrication question responses.
3.2 Phase 1

Figure 1. Denture fabrication Flow Chart

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3.3 Phase 2  
(Groups “A” and “B” merge into the original group)  
Figure 2. Denture delivery and functional wear flow chart.
3.4 Scientific background:

There are very few published clinical studies that are similar to the current study. Significant advancements in CAD/CAM technology has been made since its inception, but currently few clinical trials or clinical reports are available in the scientific literature. With the growing advances in computer generated technology there is greater need for clinical data that analyzes the differences between CAD/CAM and conventionally fabricated dentures in regards to esthetics, phonetics, fabrication and patient functional satisfaction. As noted previously, there are potentially a number of advantages to CAD/CAM fabricated dentures. It is important to analyze whether these benefits lead to higher patient satisfaction or whether there are still areas that need to be improved in the CAD/CAM process. Some studies mention the theoretical implications of CAD/CAM technology and demonstrate the procedural steps in comparison to conventional dentures, but there is limited published data on patient satisfaction in relation to these different denture fabrication techniques.

There is an impending need for clinical trials on computer-aided dentures that can affect individual patient care, dental education, research and public health around the world.

The results of this study will lay the groundwork for future clinical studies and possible implications of CAD/CAM fabricated dentures.

This study aimed to provide clinical feedback on the fabrication, function, and esthetic nature of CAD/CAM dentures when compared to conventional dentures and fabrication process. After the patients wore both sets of dentures, they completed a questionnaire regarding the denture process and final result. The results of these responses were analyzed to compare CAD/CAM and conventional denture outcomes. The results obtained and described below
examine CAD/CAM technology and its ability to be implemented into future dental practices with reliable outcomes.
### 3.5 Significance of the Results

There are very few clinical studies published that analyze a patient’s satisfaction between CAD/CAM and conventionally fabricated dentures; therefore the results obtained in this study are extremely beneficial.\(^{18}\) CAD/CAM fabricated dentures have the potential to be an economical and efficient way to achieve a comfortable fitting removable prosthesis for the growing edentulous population. The digital storage capabilities and denture material property advantages are all appealing attributes of CAD/CAM dentures. However, the results of the patient questionnaires show evidence that further growth is needed in the CAD/CAM denture field, in order to make it a viable treatment modality for all edentulous patients. The feedback obtained is this study gives insight into current CAD/CAM denture technology and potentially identifies ways to improve this technology moving forward.
3.6 IRB Approval

Informed consent was obtained under a protocol (#2015-0699) reviewed and approved by the Institutional Review Board of the University of Illinois at Chicago for human participation in this study.
4. Results

4.1 Demographic Results

In total, 10 patients were selected for the study and classified according to the American College of Prosthodontics classification for an edentulous patient (Table II). One patient dropped out of the study after the fabrication of both sets of dentures. The PDI classification of the patients were as follows: 1 Class II, 6 class III, and 3 class IV.

The subjects comprised of 8 females and 2 males with an age range of 50 to 72 years. Nine of the subjects were African American and one subject was Caucasian. The patient who dropped after the fabrication protocol was an African American female. The total time experience with wearing a removable prosthesis ranged from less than a year to 25 years.
### Table I. Demographics

The following table summarizes the subject population at the time of recruitment and their final denture selection.

<table>
<thead>
<tr>
<th>SUBJECT</th>
<th>RACE</th>
<th>GENDER</th>
<th>AGE</th>
<th>YEARS OF WEARING DENTURES</th>
<th>DENTURE SELECTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Subject 1</td>
<td>AFRICAN AMERICAN</td>
<td>FEMALE</td>
<td>50</td>
<td>LESS THAN A YEAR</td>
<td>CONVENTIONAL</td>
</tr>
<tr>
<td>Subject 2</td>
<td>AFRICAN AMERICAN</td>
<td>FEMALE</td>
<td>56</td>
<td>4 YEARS</td>
<td>CONVENTIONAL</td>
</tr>
<tr>
<td>Subject 3</td>
<td>AFRICAN AMERICAN</td>
<td>FEMALE</td>
<td>60</td>
<td>12 YEARS</td>
<td>DIGITAL</td>
</tr>
<tr>
<td>Subject 4</td>
<td>AFRICAN AMERICAN</td>
<td>FEMALE</td>
<td>59</td>
<td>15 YEARS</td>
<td>DIGITAL</td>
</tr>
<tr>
<td>Subject 5</td>
<td>CAUCASIAN</td>
<td>FEMALE</td>
<td>64</td>
<td>15 YEARS</td>
<td>CONVENTIONAL</td>
</tr>
<tr>
<td>Subject 6</td>
<td>AFRICAN AMERICAN</td>
<td>FEMALE</td>
<td>72</td>
<td>25 YEARS</td>
<td>DIGITAL</td>
</tr>
<tr>
<td>Subject 7</td>
<td>AFRICAN AMERICAN</td>
<td>FEMALE</td>
<td>50</td>
<td>15+ years</td>
<td>CONVENTIONAL</td>
</tr>
<tr>
<td>Subject 8</td>
<td>AFRICAN AMERICAN</td>
<td>MALE</td>
<td>52</td>
<td>1 YEAR</td>
<td>CONVENTIONAL</td>
</tr>
<tr>
<td>Subject 9</td>
<td>AFRICAN AMERICAN</td>
<td>MALE</td>
<td>66</td>
<td>8 YEARS</td>
<td>CONVENTIONAL</td>
</tr>
<tr>
<td>Subject 10</td>
<td>AFRICAN AMERICAN</td>
<td>FEMALE</td>
<td>62</td>
<td>4 YEARS</td>
<td>DROP OUT</td>
</tr>
</tbody>
</table>
Table II. PDI Classification
The following table summarizes the PDI classification of the subject population at the time of recruitment and their final denture selection.

<table>
<thead>
<tr>
<th>SUBJECT</th>
<th>PDI CLASSIFICATION</th>
<th>DENTURE SELECTION</th>
<th>DENTURE SELECTED</th>
</tr>
</thead>
<tbody>
<tr>
<td>Subject 1</td>
<td>3</td>
<td>CONVENTIONAL</td>
<td>2nd</td>
</tr>
<tr>
<td>Subject 2</td>
<td>4</td>
<td>CONVENTIONAL</td>
<td>1st</td>
</tr>
<tr>
<td>Subject 3</td>
<td>3</td>
<td>DIGITAL</td>
<td>2nd</td>
</tr>
<tr>
<td>Subject 4</td>
<td>2</td>
<td>DIGITAL</td>
<td>2nd</td>
</tr>
<tr>
<td>Subject 5</td>
<td>4</td>
<td>CONVENTIONAL</td>
<td>2nd</td>
</tr>
<tr>
<td>Subject 6</td>
<td>4</td>
<td>DIGITAL</td>
<td>1st</td>
</tr>
<tr>
<td>Subject 7</td>
<td>3</td>
<td>CONVENTIONAL</td>
<td>2nd</td>
</tr>
<tr>
<td>Subject 8</td>
<td>3</td>
<td>CONVENTIONAL</td>
<td>1st</td>
</tr>
<tr>
<td>Subject 9</td>
<td>3</td>
<td>CONVENTIONAL</td>
<td>2nd</td>
</tr>
<tr>
<td>Subject 10</td>
<td>3</td>
<td>DROP OUT</td>
<td></td>
</tr>
</tbody>
</table>

Most of the patients had either a PDI classification of 3 or 4, with a single patient of PDI class 2. Thus, most of the patient’s responses and results are from those with multifaceted dental health issues and complex denture needs. From the limitations present in this study, there did not appear to be a correlation between PDI classification and which denture was selected by the patient.
4.2 Fabrication Survey Results

All of the graphs depict the responses from the individual subjects.

Fabrication Survey Questions

The following 3 graphs illustrate the responses from patients during different aspects of the fabrication of both the conventional and digital dentures.

Graph 1. Length of appointments

Did it feel that the appointments took a long time when making the denture?

[Graph showing the frequency of different appointment lengths for conventional and digital dentures]
Graph 2. Discomfort or pain during the fabrication process

Was there any discomfort during the making of the denture?

Graph 3. Difficulty of any instructions given to patient during fabrication process

Were the instructions given by the dentist difficult to follow during the making of the denture?
Table III. Fabrication questions comparisons

<table>
<thead>
<tr>
<th></th>
<th>Q1 Digital - Q1 Conventional</th>
<th>Q2 Digital - Q2 Conventional</th>
<th>Q3 Digital - Q3 Conventional</th>
</tr>
</thead>
<tbody>
<tr>
<td>Z</td>
<td>-1.342^b</td>
<td>-2.000^b</td>
<td>.000^c</td>
</tr>
<tr>
<td>Asymp. Sig. (2-tailed)</td>
<td>.180</td>
<td>.046</td>
<td>1.000</td>
</tr>
</tbody>
</table>

a. Wilcoxon Signed Ranks Test
b. Based on negative ranks.
c. The sum of negative ranks equals the sum of positive ranks.

A Wilcoxon Signed Rank Test revealed a statistically significant difference in responding to Question 2 (Was there any discomfort during the making of the denture?), \( z = -2.00, p = 0.046 \). The median score of the response increased from conventional denture (Md=0.0) to digital (Md=1.0).

Thus, there seemed to be a statistical difference between the fabrication of the conventional and fabrication of the digital denture. Patient’s reported more discomfort with the fabrication of the digital denture.
4.3 Functional Results

The following 40 graphs illustrate the responses from patients related to different aspects of wearing both the conventional and digital dentures. The survey questions are divided into 6 domains, derived from the OHIP design. These domains (Functional Limitation, Physical Pain, Psychological Discomfort, Physical Disability, Psychological Disability, Social Disability) aimed to capture the impact that edentulism, and corresponding treatment modalities, have on an individual’s life.

4.3.1 Functional Limitation Questions
The following 9 graphs illustrate the responses from patients analyzing their functional capabilities with both the conventional and digital dentures.

Graph 4. Chewing capabilities

Have you had difficulty chewing any foods because of problems with your dentures?
**Graph 5. Pronunciation of words**

Have you had trouble pronouncing any words because of problems with your dentures?

<table>
<thead>
<tr>
<th></th>
<th>NEVER</th>
<th>SOMETIMES</th>
<th>OFTEN</th>
<th>ALWAYS</th>
</tr>
</thead>
<tbody>
<tr>
<td>CONVENTIONAL</td>
<td>2</td>
<td>3</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>DIGITAL</td>
<td>1</td>
<td>6</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

**Graph 6. Denture tooth appearance**

Have you noticed a denture tooth or teeth that doesn't look right?

<table>
<thead>
<tr>
<th></th>
<th>NEVER</th>
<th>SOMETIMES</th>
<th>OFTEN</th>
<th>ALWAYS</th>
</tr>
</thead>
<tbody>
<tr>
<td>CONVENTIONAL</td>
<td>9</td>
<td>1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>DIGITAL</td>
<td>1</td>
<td>3</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>
**Graph 7. Overall appearance**

Have you felt that your appearance has been affected because of problems with your dentures?

<table>
<thead>
<tr>
<th></th>
<th>NEVER</th>
<th>SOMETIMES</th>
<th>OFTEN</th>
<th>ALWAYS</th>
</tr>
</thead>
<tbody>
<tr>
<td>CONVENTIONAL</td>
<td>5</td>
<td>4</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>DIGITAL</td>
<td>3</td>
<td>2</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>

**Graph 8. Associations of stale and bad breath**

Have you felt that your breath has been stale because of problems with your dentures?

<table>
<thead>
<tr>
<th></th>
<th>NEVER</th>
<th>SOMETIMES</th>
<th>OFTEN</th>
<th>ALWAYS</th>
</tr>
</thead>
<tbody>
<tr>
<td>CONVENTIONAL</td>
<td>7</td>
<td>2</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>DIGITAL</td>
<td>6</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>
**Graph 9.** Ones sense of taste with prosthesis

Have you felt that your sense of taste has worsened because of problems with your dentures?

**Graph 10.** Food impaction in dentures

Have you had food catching in your dentures?
**Graph 11. Digestion effects**

Have you felt that your digestion has worsened because of problems with your dentures?

**Graph 12. Overall fit of the denture**

Have you felt that your dentures have not been fitting properly?
4.3.2 Physical Pain
The following 7 graphs illustrate the responses from patients analyzing their pain and discomfort directly related to either the conventional or digital dentures.

**Graph 13. Oral discomfort**

Have you had discomfort in your mouth associate with your dentures?
**Graph 14. Jaw soreness**

Have you had a sore jaw?

**Graph 15. Headaches associated with prosthesis**

Have you had headaches because of problems with your dentures?
**Graph 16. Gingival pain**

Have you had painful gums?

<table>
<thead>
<tr>
<th></th>
<th>NEVER</th>
<th>SOMETIMES</th>
<th>OFTEN</th>
<th>ALWAYS</th>
</tr>
</thead>
<tbody>
<tr>
<td>CONVENTIONAL</td>
<td>4</td>
<td>2</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>DIGITAL</td>
<td>0</td>
<td>2</td>
<td>3</td>
<td>0</td>
</tr>
</tbody>
</table>

**Graph 17. Discomfort during mastication of foods**

Have you found it uncomfortable to eat any foods because of problems with your dentures?

<table>
<thead>
<tr>
<th></th>
<th>NEVER</th>
<th>SOMETIMES</th>
<th>OFTEN</th>
<th>ALWAYS</th>
</tr>
</thead>
<tbody>
<tr>
<td>CONVENTIONAL</td>
<td>1</td>
<td>4</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>DIGITAL</td>
<td>1</td>
<td>2</td>
<td>1</td>
<td>0</td>
</tr>
</tbody>
</table>
Graph 18. Sore spots

Have you had sore spots in your mouth?

Graph 19. Overall denture comfort

Have you had uncomfortable dentures?
4.3.3 Psychological Discomfort
The following 5 graphs illustrate the responses from patients analyzing any psychological issues related to either the conventional or digital dentures.

**Graph 20. Self-conscious**

Have you been self-conscious because of your dentures?

**Graph 21. Feelings of misery**

Have dental problems made you miserable?
**Graph 22. Comfort related to overall appearance of dentures**

Have you felt uncomfortable about the appearance of your dentures?

<table>
<thead>
<tr>
<th></th>
<th>CONVENTIONAL</th>
<th>DIGITAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>NEVER</td>
<td>5</td>
<td>4</td>
</tr>
<tr>
<td>SOMETIMES</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>OFTEN</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>ALWAYS</td>
<td>1</td>
<td>2</td>
</tr>
</tbody>
</table>

**Graph 23. Tension due to dentures**

Have you felt tense because of problems with your dentures?

<table>
<thead>
<tr>
<th></th>
<th>CONVENTIONAL</th>
<th>DIGITAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>NEVER</td>
<td>5</td>
<td>4</td>
</tr>
<tr>
<td>SOMETIMES</td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td>OFTEN</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>ALWAYS</td>
<td>1</td>
<td>2</td>
</tr>
</tbody>
</table>
Graph 24. Feeling of worry

Have you been worried by dental problems?

<table>
<thead>
<tr>
<th></th>
<th>CONVENTIONAL</th>
<th>DIGITAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>NEVER</td>
<td>4</td>
<td>3</td>
</tr>
<tr>
<td>SOMETIMES</td>
<td>4</td>
<td>2</td>
</tr>
<tr>
<td>OFTEN</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>ALWAYS</td>
<td>1</td>
<td>3</td>
</tr>
</tbody>
</table>
4.3.4 Physical Disability
The following 8 graphs illustrate the responses from patients analyzing any physical disabilities directly related to either the conventional or digital dentures.

Graph 25. Speech issues

Graph 26. Misunderstood words
Graph 27. Gustation problems with dentures

Have you felt that there has been less flavor in your food because of problems with your dentures?

Graph 28. Avoidance of foods due to dentures

Have you had to avoid eating some foods because of problems with your dentures?
Graph 29. Unsatisfactory diet

Has your diet been unsatisfactory because of problems with your dentures?

Graph 30. Difficulty in eating

Have you been unable to eat with your dentures because of problems with them?
**Graph 31. Avoided smiling**

Have you avoided smiling because of problems with your dentures?

<table>
<thead>
<tr>
<th></th>
<th>CONVENTIONAL</th>
<th>DIGITAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>NEVER</td>
<td>6</td>
<td>5</td>
</tr>
<tr>
<td>SOMETIMES</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>OFTEN</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>ALWAYS</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

**Graph 32. Meal interruption**

Have you had to interrupt meals because of problems with your dentures?

<table>
<thead>
<tr>
<th></th>
<th>CONVENTIONAL</th>
<th>DIGITAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>NEVER</td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td>SOMETIMES</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>OFTEN</td>
<td>4</td>
<td>3</td>
</tr>
<tr>
<td>ALWAYS</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>
4.3.5 Psychological Disability
The following 6 graphs illustrate the responses from patients analyzing any psychological disabilities related to either the conventional or digital dentures.

Graph 33. Sleep interruption

Graph 34. Feeling upset
**Graph 35. Difficulty in relaxing**

Have you found it difficult to relax because of problems with your dentures?

**Graph 36. Feelings of depression**

Have you felt depressed because of problems with your dentures?
**Graph 37. Disturbances in concentration**

Has your concentration been affected because of problems with your dentures?

**Graph 38. Feelings of embarrassment**

Have you been a bit embarrassed because of problems with your dentures?
4.3.6 Social Disability
The following 5 graphs illustrate the responses from patients analyzing social disabilities related to either the conventional or digital dentures.

**Graph 39. Have not gone out socially**

Have you avoided going out because of problems with your dentures?

**Graph 40. Less tolerant of others**

Have you been less tolerant of your spouse or family because of problems with your dentures?
**Graph 41. Trouble interacting with others**

Have you had trouble getting on with other people because of problems with your dentures?

**Graph 42. Feelings of irritability**

Have you been a bit irritable with other people because of problems with your dentures?
Graph 43. Difficulty in day to day jobs

Have you had difficulty doing your usual jobs because of problems with your dentures?
4.4 Denture Selection

**Table IV. Denture Choice.** The following table summarizes which dentures the patient ultimately chose if they only were allowed to keep one of the dentures fabricated. This choice was made after the patient had an opportunity to wear each denture for a time period of three months.

<table>
<thead>
<tr>
<th>If you had to choose which denture would you like to keep?</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Conventional</td>
<td>6</td>
</tr>
<tr>
<td>Digital</td>
<td>3</td>
</tr>
</tbody>
</table>

Six of the 9 patients, who completed the study, chose the 2nd denture they wore as the denture they preferred. Each patient was randomly assigned to the order in which they would wear the prosthesis. From the limitations present in the current study, there did not appear to be a correlation between which denture the patient wore first and which denture the patient ultimately preferred. However, more patients did select the second denture that was worn, regardless of the fabrication technique.
4.5 Mean Functional Responses

The following table shows the mean percent responses in each of the OHIP domains, when comparing conventional versus CAD/CAM dentures. A person’s quality of life is composed of physical, cognitive, emotional and social aspects. Each question in the OHIP questionnaire gauges a patient’s reactions to different aspects of treatment and overall assesses areas that positively and negatively affect a patient’s OHQoL. The graph gives a side-by-side comparison of each of the 6 domains and the general trends in responses.

The highest number of “never” responses was from the psychological and social disability domains. The highest number of “always” responses was from the psychological discomfort domain.
Graph 44. Mean Percent Responses per Denture in Each Domain
4.6 Combined Means of Tallied Survey Responses

In order to get a closer look at the results, the six different domains for the OHIP questionnaire: functional limitation, physical pain, psychological discomfort, physical disability, psychological disability, and social disability, were analyzed individually based on the mean percentages. The conventional and CAD/CAM responses for each domain were separated respectively. The responses were added up and then divided into two categories: positive and negative. The “never” and “sometimes” responses were grouped into the positive category and the “often” and “always” responses were grouped into the negative category. Therefore, the overall mean responses for each domain were separated into positive and negative categories for both conventionally and CAD/CAM fabricated dentures. The percent difference in means in each domain was also noted. The first three domains of functional limitation, physical pain, and psychological discomfort resulted in a higher mean positive response for the conventional dentures. The last three domains of physical disability, psychological disability, and social disability resulted in a higher mean positive response for the CAD/CAM dentures. The categories with the biggest mean difference present were psychological discomfort and psychological disability.
Table V. Mean Percent Responses. The “never” and “sometimes” responses were grouped into the positive category and the “often” and “always” responses were grouped into the negative category. The mean percent difference was noted and marked in the row with the corresponding higher positive response.

<table>
<thead>
<tr>
<th>OHIP DOMAIN</th>
<th>DENTURE</th>
<th>POSITIVE</th>
<th>NEGATIVE</th>
<th>% Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>FUNCTIONAL LIMITATION</td>
<td>CONVENTIONAL</td>
<td>82%</td>
<td>18%</td>
<td>2%</td>
</tr>
<tr>
<td></td>
<td>DIGITAL</td>
<td>80%</td>
<td>20%</td>
<td></td>
</tr>
<tr>
<td>PHYSICAL PAIN</td>
<td>CONVENTIONAL</td>
<td>70%</td>
<td>30%</td>
<td>3%</td>
</tr>
<tr>
<td></td>
<td>DIGITAL</td>
<td>67%</td>
<td>33%</td>
<td></td>
</tr>
<tr>
<td>PSYCHOLOGICAL DISCOMFORT</td>
<td>CONVENTIONAL</td>
<td>80%</td>
<td>20%</td>
<td>9%</td>
</tr>
<tr>
<td></td>
<td>DIGITAL</td>
<td>71%</td>
<td>29%</td>
<td></td>
</tr>
<tr>
<td>PHYSICAL DISABILITY</td>
<td>CONVENTIONAL</td>
<td>79%</td>
<td>21%</td>
<td></td>
</tr>
<tr>
<td></td>
<td>DIGITAL</td>
<td>83%</td>
<td>17%</td>
<td>4%</td>
</tr>
<tr>
<td>PSYCHOLOGICAL DISABILITY</td>
<td>CONVENTIONAL</td>
<td>78%</td>
<td>22%</td>
<td></td>
</tr>
<tr>
<td></td>
<td>DIGITAL</td>
<td>86%</td>
<td>14%</td>
<td>8%</td>
</tr>
<tr>
<td>SOCIAL DISABILITY</td>
<td>CONVENTIONAL</td>
<td>84%</td>
<td>16%</td>
<td></td>
</tr>
<tr>
<td></td>
<td>DIGITAL</td>
<td>89%</td>
<td>11%</td>
<td>5%</td>
</tr>
</tbody>
</table>
5.0 Discussion

The current study aimed to provide clinical feedback on the fabrication process, function, and esthetic nature of CAD/CAM dentures when compared to conventional dentures. Within the limitations of the study, the hypothesis that there is no difference in patient satisfaction when comparing conventionally fabricated dentures and CAD/CAM fabricated dentures could be rejected. Within the limited nature of the study, the overall results of the study demonstrated a slightly higher acceptance of the conventionally fabricated dentures over the digitally fabricated counterparts. Due to the limited participants, the magnitude of difference between the groups was relatively narrow. Limited statistical analysis was performed, along with descriptive observations, based on the small sample size. The descriptive analysis of this study suggests specific areas for further investigation in CAD/CAM technology and process.

5.1 Demographic, PDI, Denture Selected Discussion

Tables 1 and 2 list the demographics and PDI classifications of the patients that participated in the study. Nine of the 10 patients that participated in the study had a PDI classification of either III or IV. In the current study, no observational difference was associated between PDI classification and the denture the patient preferred. A previous study that examined patient and provider preference between digital and conventionally fabricated dentures, demonstrated higher positive scores associated with digital dentures. However, in the previous study, all of the participants had a PDI classification of either I or II. As noted earlier, the current study had patient’s that mainly demonstrated a PDI classification of either III or IV. According to McGarry et al, PDI class III and class IV edentulous patients present with a wide array of complex anatomical and systemic issues. While organizing patients according to
their PDI classification is not a predictor of success, it can provide a basis for diagnosis and treatment planning. “The PDIs establish a more accurate diagnosis and the basis for the appropriate treatment procedures, resulting in the most successful patient care.”\textsuperscript{36} In the current study, the only class II patient chose the CAD/CAM fabricated denture. The class I and class II patients may lead to more positive outcomes with CAD/CAM fabricated dentures due their more predictable anatomical presentation. It is possible that the flexibility and customization, of the conventional method of fabricating dentures, allows for modifications designed to the uniqueness of more complex class III and class IV patients. Future studies are needed to include all of the PDI classifications in order to determine their effect, if any, on denture selection outcome.

A larger patient population is also needed to increase not only the ethnic diversity of the patient pool, but also the gender diversity. In the current study, 9 of the 10 patients were of African American descent and 8 of the 10 patients were female. A previous study that surveyed over 100 completely edentulous patients’ using OHIP-20, found no associations “with respect to sex, age group, global general health, avoiding certain food items, appetite, or the clinical variables retention of either denture, pain from the mandibular denture, or speech.”\textsuperscript{37} In contrast, a study by Singh et al., completed in India, found that females were more self-motivated and eager to complete denture treatment, when compared to males. The study, “clearly showed that females are more aware and concerned about their denture treatment to restore their lost esthetic, social wellbeing and function.”\textsuperscript{38} The male patients were more concerned about the function of the dentures. Studies performed by Singh et al and Taylor and Doku, found that overall, male patients were more satisfied with dentures than their female counterparts.\textsuperscript{38,39}
Considering that females have reported a lower level of satisfaction with their dentures in past studies, one must consider the possibility of obtaining different responses to certain survey questions in the current study if more male patients were included (or the proportion of M:F was different). Due to the limited number of participants in the current study, no conclusions can be made about a patient’s ethnicity or sex and their denture preference. All the same, it sheds light on the possibility that females and males have different levels of motivation, expectations and concerns that they are hoping to address with denture therapy. The study highlights the importance of considering each patient individually and tailor treatment to their specific needs.

It was noted that all the patients that chose the digital denture set had been wearing dentures for a minimum of 12 years with a range of 12-25 years. The patients that chose the conventional set had a range of less than a year to over 15 years of denture wearing experience. More participants are needed to observe any relationship between denture experience and the ultimate denture set chosen. Nevertheless, a patient’s prior experience to wearing dentures and more importantly, their satisfaction with their current denture, can play an important role in how dental professionals treatment plan. If a patient is very unsatisfied with their current dentures then a new set of dentures has the possibility of improving one’s oral health quality of life. In a study completed by Eric et al, “Dentures wearers perceived marked improvements in their functionality, aesthetics, stability, comfort and reported better overall satisfaction after poorly fitting dentures were replaced with new, better-fitting ones.”

Noted above, 6 of the 9 patients who completed the study, chose the 2nd denture they wore as the denture they would ultimately prefer to use. From the limitations present in the current study, no definitive extrapolations can be made regarding which denture they wore first
and which they ultimately preferred. More patients did select the second denture that was worn as the one they preferred. Future studies are needed to look at the possibility of the recency effect and if patients are inclined to select the most recent denture worn, merely due to familiarity. Since a patient was more familiar with the last denture they had, they may have chosen that one simply due to that fact they wouldn’t want to refamiliarize themselves with the first set of dentures.

5.2 Denture Fabrication Discussion

The main method of measurement in this study were surveys in which the patient responded to questions related to the individual denture fabrication process and overall function of the conventional and digital dentures. Patient’s responses to the survey questions were recorded using a Likert scale. As noted previously, observing a change in one to two points on a Likert scale seems intuitively easier to grasp than a 10-20mm change on a VAS scale.\textsuperscript{13} Observational conclusions can be drawn from the results of the tallied totals of the surveys.

The fabrication survey responses yielded relatively similar results except for question 2 that examined the discomfort during the making of the denture. As demonstrated in table 3, there was a statistical difference in discomfort felt between the fabrication of the conventional and fabrication of the digital denture. Patients recorded more discomfort during the fabrication of the digital denture. Most patients commented that the AMD (Anatomical Measurement Device) used to capture the vertical dimension, centric relation position, and lip support during the digital denture fabrication was awkward and uncomfortable. Patients verbally reported their discomfort and dislike of this specific step during the digital fabrication procedure. One patient
commented on subsequent appointments that the AMD, “hurt my mouth and that when I left after the appointment my mouth was sore and hurt in places.”

The AMD device itself was not very user friendly and was difficult to adjust the vertical dimension pin and lift support pin. A previous study that compared two digital fabrication techniques, noted that the pins of the click-on occlusal recording device easily fractures.41 In the current study, the lip support section of the AMD used a screw adjustment segment that easily broke or became stripped and the vertical dimension screw had to trimmed or grossly adjusted in order to fit into patient’s mouth. This led to increased appointment time and possible discomfort for the patient.

One of the largest advantages of the digital fabrication of dentures is being able to produce the final dentures in as short as 2 appointments. Many of the digital denture companies claim that it only takes 2 appointments for final denture delivery. A retrospective study concluded that the mean number of appointments needed for final delivery of the digital dentures was 2.39, not 2.29 One study noted that, “the lack of clinical trial placement procedures might be a disadvantage of using CAD/CAM dentures.”42 The current study included a trial set of digital dentures; therefore, the minimal amount of appointments a patient would have is 3. The minimal amount of appointments required for the final digital denture has appeal to both the patient and provider. However, in the current study the ‘total time’ needed for the final fabrication of the digital dentures was similar to that of the conventional dentures. In some cases, the total length of ‘time’ required for the fabrication of the digital dentures, from start to final delivery, was more than that of the conventional dentures.
This was due to the fact that once the final impressions and AMD was sent out to the digital lab, it took many weeks before the ‘trial’ digital dentures were sent back. Once the trial denture appointment was completed and returned to the lab, it took many more weeks for the final digital denture to be completed. It should be noted that 6 out of the 10 patients’ that completed the fabrication protocol, required more than one digital denture try-in appointment. Even though they used a different CAD/CAM system, a previous study noted similar problems during the fabrication process. The study noted that during the clinical try-in of the digital dentures, “the vertical dimension was insufficient after the preliminary recording of the maxillomandibular relation and needed correction.” Additional corrections involving esthetic problems, such as “shifted midlines, deviations from the inter-pupillary line or Camper plane, excessive lip support and in 1 patient the buccal corridor was excessively small.” Very similar problems were seen in the current study and are the reason many patient’s required more than one digital try-in appointment. This not only increased the number of appointments but also the total length of time required to fabricate the final prosthesis from start to finish.

A key component during the fabrication of the digital dentures was the computer-generated preview of the dentures, both during the trial phase and final prosthesis. Once the lab received either the final impressions or the trial denture, a digitally generated representation of the denture was emailed to the dentist/provider. Throughout the study, this specific step brought many aspects of the digitally fabricated denture process to light. The first of which is the overall communication with the digital design team. For each patient, changes to the digital preview of the denture were needed and the provider emailed the written explanation to the lab due to a lack of direct access to file modification. The provider receives an email saying the lab
received the request for modifications and then it would take anywhere from a day to a few days to receive the new updated preview. This process would continue until all the modifications were completed and the dentist/provider gave approval to move onto the next step of the process.

An aspect of the digital design process that was not recorded in the surveys, but was verbally commented on, was the patient’s ability to be involved in the design and fabrication of their dentures. Patient’s said they liked being able to see the denture set-up during the conventional wax try-in and voice their likes and dislikes. Tooth position or incisal length was easily manipulated during the appointment, so patients were able to visualize what the final shade and tooth set-up would be for their final prosthesis. Likewise, a previous study noted that one of the advantages of the conventional set of dentures was the ability to “personalize” each set of dentures, as opposed to the digital denture.\textsuperscript{18} It should be noted that the trial denture used in this study was a solid monolithic prosthesis, without the ability to move teeth position or change ‘gingival’ height while patient was in chair. The company used in the study has since developed a different trial denture where teeth movement is possible. Having said that, the different trial prosthesis does increase the time and cost to the provider and potentially the patient.

5.3 Denture Functional Discussion

One of the main areas the current study examined was the functional differences, if any, noted by the patients between the conventional and digital dentures. One of the strengths of the study was that the patients had a chance to wear each denture separately for 3 months. A previous study analyzed patient responses between conventional and CAD/CAM dentures after they wore each denture only a week.\textsuperscript{18} In the current study, each patient filled out a
corresponding 40 question survey related to different aspects of functional use and added any additional comments or observations they noted during the trial. Again, due to the limited number of participants, these descriptive comments are based on the answers recorded from the survey and both written and verbal annotations added by patients after each 3-month trial period. A larger study and more responses are needed to statistically describe the outcomes noted.

Despite the small patient population, certain trends were observed throughout the study. A higher number of patients reported noticing a denture tooth or teeth that did not look right when wearing the digital denture. Some patient’s commented that they liked having the ability to move the teeth during the fabrication of the conventional dentures and enjoyed being a part of the teeth setting process. Other patients said they did not like the esthetics of the digital dentures and that “they looked fake.” Conversely, one patient said she liked the look of the digital denture better but preferred the fit of the conventional denture. Having the ability to move the teeth during the digital trial denture would potentially involve the patient in the process and give the provider the ability to customize each set of dentures to the uniqueness of the patient, resulting in time efficiency and patient satisfaction.

Another characteristic of the digital denture is the milling of the final prosthesis out of a pre-polymerized acrylic puck. This results in a CAD/CAM denture that is fabricated with virtually no monomer, which results in a less porous prosthesis. Since, the “dentures are milled from a pre-polymerized acrylic resin puck, which is produced under high pressure and heat, polymerization shrinkage does not occur, porosity is decreased, and the adherence of Candida albicans to the denture base is decreased.” The lack of porosities leaves less surface area
available for bacteria and fungi to invade and cause unpleasant mouth odors. A study completed by Al-Fouzan found that CAD/CAM fabricated denture bases demonstrated less adhesion of *Candida albicans*, when compared to bases fabricated via conventional methods. In the current study, a higher number of patients reported that they felt their breath was stale or they had bad breath related to their conventional dentures. Some patients reported a noticeable difference between the conventional and digital dentures related to the smell both during and after wear.

With the homogenous acrylic puck, also comes the proposed benefit of strength of the denture. The digital monolithic denture has the potential to allow for thinner flanges and less bulk of acrylic material. One study reported that, “the virtual design process allows one to define the minimal thickness of the denture bases.” Two of the three patients, that ultimately chose the digital denture, commented that they liked the fact that the CAD/CAM denture felt thinner and less bulky. Nevertheless, a higher number of patients reported feeling that their digital denture did not fit properly, causing them to have painful gingiva, and was associated with more sore spots. Verbal remarks made from the patients may shed some light as to reason behind these reports.

When comparing the final flange thickness of the conventional denture to the digital denture, it was noted that in all but one case, the conventional denture had thicker flanges. Patients commented that although the digital denture felt thinner and smaller, the flanges themselves felt sharper. On post-op appointments, many patients commented that these ‘thinner’ flanges felt, “as if they dug more into their gums, especially when the denture moved around.” This may have been due to the fact that the conventional denture was border molded and processed to retain the same thickness in the flange achieved via the border molding. The
digitally fabricated denture may have been designed with a thinner flange or the flange may have been trimmed back after processing.

Another finding that was consistent with the digital dentures was the lack of coverage of the retromolar pad area for the mandibular dentures, despite the inclusion of the area in the final impression. Again, when comparing the conventional to the digital denture, the digital denture always had less retromolar pad coverage in both total material and material thickness. Two patients commented that they felt the mandibular digital denture was too loose and just never felt right in their mouth. They preferred the conventional mandibular denture because it stayed in place better and commented that the digital felt too flimsy. One of the 3 patients that indicated they preferred the digital dentures said she preferred the conventional mandibular denture over the digital mandibular because it was more retentive and she felt she could chew better with it. However, she reported that the maxillary digital denture felt thinner and did not feel as bulky, so this patient ultimately chose the digital denture set. A previous study did report that “the clinical variables chewing, comfort, fit of dentures, esthetics, and pain regarding the maxillary denture were significantly associated with satisfaction.”

Therefore, some patient’s may view the maxillary denture as their measure of comfort and satisfaction when analyzing the prostheses as a whole.

5.4 OHIP Domains Discussion

The OHIP is concerned with impairment and three functional status dimensions (social, psychological, and physical) which represent four of the seven quality of life dimensions. “All impacts in the OHIP are conceptualized as adverse outcomes, and therefore the instrument does not measure any positive aspects of oral health.” The 6 conceptual domains from OHIP used in
the current study are as follows: functional limitation (difficulty chewing), physical pain (sore jaw), psychological discomfort (self-consciousness), physical disability (changes to diet), psychological disability (reduced ability to concentrate), and social disability (avoiding social interactions). This conceptual model is based on the World Health Organizations classification in which the effects of diseases are categorized from internal symptoms, such as those found in functional limitations, to external symptoms, such as those affecting social roles and interactions.43

In looking at the survey questions after the patients had an opportunity to wear each set of dentures, certain trends appeared between the conventional and digital dentures. Again, patients responded to each question with: never, sometimes, often or always. When comparing these choices, the “never” and “sometimes” responses can be viewed as more positive and the often and always responses can be viewed of as more negative. Using this concept, the mean percentages of responses from each domain was calculated and graphed. As seen in graph 44, the highest number of never responses was from the psychological and social disability domains. Whereas, the highest number of always responses was from the psychological discomfort domain. Graph 44 is a great visual comparison of the different domains analyzed in OHIP and which domains the patients seemed to have more positive and negatives associations with.

In order to take a closer look at these trends, the overall mean responses for each domain were separated into positive and negative categories and the percent difference in means for each domain was also noted. The highest positive mean responses for the conventional dentures came first three domains of functional limitation, physical pain, and psychological discomfort. “Functional limitations are defined as restrictions in the functions customarily expected of the
body or its component organs or systems. Physical pain is the self-perceived feeling states or other symptoms.”47 The highest positive mean responses for the CAD/CAM dentures came from the last three domains of physical disability, psychological disability, and social disability. Interestingly, the last three domains reported a higher mean difference between the two dentures when compared to the first three domains. These last three categories looked at disability. “Disability looks at the limitations in or lack of ability to perform the activities of daily living. Current approaches encompass the domains of physical, psychological and social aspects when relating to this behavioral concept.”45,47 Therefore, one of the trends noted in the study was that conventional dentures had fewer negative impacts on patient’s functional limitations, physical pain, and psychological discomfort. In contrast, the CAD/CAM dentures had fewer negative impacts on patients physical, psychological, and social disabilities. More patient’s ultimately chose the conventional denture as the denture they would prefer to use. Relative to the limitations of the study, the domains of functional limitation, physical pain, and psychological discomfort appear to weigh more in determining which denture a patient was ultimately more satisfied with. In fact, the functional limitation and physical pain domains where the ones commented on the most by patients both written and verbally throughout the study.

Another interesting trend was looking at the total percent difference in each OHIP domain among the two prostheses. The domains with the biggest mean difference were psychological discomfort and psychological disability. “Until recently, the psycho-social consequences of oral conditions have received little attention, as they are rarely life threatening. Furthermore, the oral cavity has historically been dissociated from the rest of the body when considering general health status. However, recent research has highlighted that oral disorders have emotional and psycho-
This demonstrates that health care providers have to strive to continually focus on treating each person as an individual, both physically and psychologically, and not solely focus on the disease or treatment itself.

OHIP is one of the most widely used measures to assess patient’s Oral Health Related Quality of Life. “A major advantage of this measure is that the statements were derived from a representative patient group, and were not conceived by dental research workers. This increases the possibility of the measure tapping into social consequences of oral disorders considered important by patients, and is considered to be the most sophisticated measure of oral health.”44
6.0 Limitations

The nature of the study allowed incorporation of a number of limitations. The biggest limitation was the limited number of participants which resulted in a descriptive analysis with limited statistical analysis. The limited ethnic diversity of the sample subjects was not sufficient enough to extrapolate the results to other patient populations. There may have been inherent human errors during the fabrication of the dental prostheses. Flange thickness or retromolar pad coverage was not measured between both sets of dentures but was an interesting characteristic that warrants attention in future studies. Future studies are needed that incorporate a larger number of participants to statistically analyze the differences between the two sets of dentures and provide more strength and conclusions to the trends observed in the current study.
7.0 Conclusions

The aim of this study was to compare the CAD/CAM designed dentures versus traditionally fabricated dentures to assess their role in serving the edentulous population. Due to the limited number of participants, observational examination and limited statistical analysis of data was performed. Within the limitations of the study, based on the responses received from the surveys, some interesting trends were observed. More participants preferred the conventionally fabricated dentures over the digitally fabricated dentures. The digital denture fabrication process results in more discomfort when compared to conventional means of fabrication.

The conventional dentures had fewer negative impacts on patient’s functional limitations, physical pain, and psychological discomfort. In contrast, the CAD/CAM dentures had fewer negative impacts on patients physical, psychological, and social disabilities. More patient’s ultimately chose the conventional denture; therefore, relative to the limitations of the study, the domains of functional limitation, physical pain, and psychological discomfort weigh more in determining which denture a patient was ultimately more satisfied with. With the increasing longevity of the population, edentulism will continue to be a situation that needs to be addressed in the world. Now more than ever, it is important to analyze new technologies and assess their ability to treat patients and compare them to current means and methods.
CITED LITERATURE


31. Slade,G.D. and Spencer A.J., Development and evaluation of the Oral Health Impact Profile, Community Dental Health (1994) 11,3-11 Received 7 December 1992; accepted 5 April 1993


APPENDIX A

Patient #1 Written comments on fabrication of digital denture:

“hurt my mouth and that when I left after the appointment my mouth was sore and hurt in places.”

Patient #2 Verbal comments

Patient said they liked having the ability to move the teeth during the fabrication of the conventional dentures and enjoyed being a part of the teeth setting process. They felt the fabrication of the conventional denture was more of a team effort and they were part of the team.

Patient #3 Verbal comments

Commented on the digital denture, “they looked fake”

The patient said when they wore the (digital) denture other people commented on the fact they could tell she was wearing false teeth

Patient #4 Verbal Comments

Commented that she liked the look of the digital denture better but preferred the fit of the conventional denture.

Patient #5 Verbal Comments

Patient commented that the digital denture felt, “as if they dug more into their gums, especially when the denture moved around.”

The (digital) denture has thinner flanges than other denture and doesn’t feel as strong.
Subject’s ID#

Inclusion criteria of the subjects:

☐ Patients with complete edentulous maxilla and mandible

☐ No maxillo-facial deficiencies

☐ Patients with philosophical personalities

☐ No implants present in the maxillary or mandibular arch

☐ Patients 18 years and older

Exclusion criteria of the subjects:

☐ Any of the subjects who does not meet the above inclusion criteria

☐ Implants present in the mandibular or maxillary arch

☐ Patients with exacting, hysterical or indifferent personality

☐ Inability to understand both: the written informed consent paper and the verbal explanation

☐ Inability to understand English
APPENDIX B (continued)

Attachment #2

Recruitment Material for Subjects

IRB Protocol Number:

Drs. Manzotti, Coffey and Kendall are recruiting people to take part in a research study entitled:

“Differences Between Conventionally and CAD/CAM Fabricated Complete Removable Dental Prostheses”

We are looking for volunteers who are currently in need of complete dentures.

Your participation will involve:

17 visits at the University of Illinois at Chicago, College of Dentistry - Prosthodontic Dept. The estimated total time for your participation will be approximately 1-3 hours per visit.

17 visits are the only required appointments to complete the study.

If you would like to participate please call Drs. Manzotti, Coffey or Kendall at (312) 355-0631.

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RESEARCH SUBJECTS WANTED

This project seeks to investigate differences between conventionally and CAD/CAM fabricated complete dentures. The study will be in need of subjects who are edentulous, seeking denture fabrication and have the time necessary to participate in the study. Your assistance would be appreciated in recruiting this group.
We are looking to enroll subjects who are:

**Inclusion criteria:**
- Patients with complete edentulous maxilla and mandible
- No maxillo-facial deficiencies
- Patients with philosophical personalities
- No implants present in the maxillary or mandibular arch
- Patients 18 years and older
APPENDIX B (continued)

Exclusion criteria:

- Any of the subjects who does not meet the above inclusion criteria
- Implants present in the mandibular or maxillary arch
- Patients with exacting, hysterical or indifferent personality
- Inability to understand both: the written informed consent paper and the verbal explanation
- Inability to understand English

Participants will be asked to come to the UIC College of Dentistry 17 times over the 8 months: they will be asked to:

- Receive treatment for dentures - twice
- Complete a set of questionnaires
- Have a series of photographs taken from different angles
- Return 6 times for follow up evaluations
- Attend 17 visits which are the only required to complete the study.

If you have any patients that fit these criteria, I would appreciate it if you could provide them with a copy of my recruitment flyer found in each clinic front desk.

For details, please contact the principal investigator at (312) 355-0631 or manzotti@uic.edu if you have any questions.
Recruitment messages to clinicians

My name is Dr. Anna Manzotti and I work in the Department of Restorative Dentistry. I am writing you to ask you for your assistance with subject recruitment for my research study entitled “Differences Between Conventionally and CAD/CAM Fabricated Complete Removable Dental Prostheses” - IRB #2015: __________

In this study, we will investigate differences between conventionally and CAD/CAM fabricated complete dentures. We are looking for participants that meet the listed criteria and are ready for denture fabrication and have the time necessary to complete the study. Participants will be expected to attend 17 visits at the University of Illinois at Chicago, College of Dentistry - Prosthodontic Dept. The estimated total time for your participation will be approximately 1-3 hours per visit. 17 visits are the only required appointments to complete the study.

Your assistance would be appreciated in recruiting this group. To be eligible, these subjects must be meeting the following criteria:

**Inclusion criteria:**

- Patients with complete edentulous maxilla and mandible
- No maxillo-facial deficiencies
- Patients with philosophical personalities
- No implants present in the maxillary or mandibular arch
- Patients 18 years and older
APPENDIX B (continued)

**Exclusion criteria:**

- Any of the subjects who does not meet the above inclusion criteria
- Implants present in the mandibular or maxillary arch
- Patients with exacting, hysterical or indifferent personality
- Inability to understand both: the written informed consent paper and the verbal explanation
- Inability to understand English

If you have any patients that fit these criteria, I would appreciate it if you could provide them with a copy of my recruitment flyer. Please do not hesitate to contact me at (312) 355-0631 or manzotti@uic.edu if you have any questions.

Thank you for your time and any assistance that you can provide.

Sincerely,

Anna Manzotti DDS, MS, FACP.
APPENDIX B (continued)

Attachment #5

Phone Script

Study subjects interested in participating in the study will receive a phone call within 48 hours of expressed interest in order to ask them a few questions regarding their potential involvement and informed consent.

Principal Investigator/ Co-Investigator:
Hello, I am calling in response to your inquiry into the denture study.

Potential subject:
answers yes or no

Principal Investigator/ Co-Investigator:
(IF ANSWERS NO):
I apologize for the misunderstanding and I thank you for your time.
(IF ANSWERS YES):
We are investigating the differences between conventionally and CAD/CAM fabricated complete dentures.
Do you know what CAD/CAM means?

Potential subject:
answers yes or no

Principal Investigator/ Co-Investigator:
(IF ANSWERS NO):
CAD/CAM means computer-aided design and computer-aided manufacturing. CAD/CAM technology may improve the design and creation of dentures, decreasing clinical appointment number and length. These dentures are digitally designed and they are also called digital dentures.
(IF ANSWERS YES):
Perfect!

Principal Investigator/ Co-Investigator:
We are looking for participants that are ready for denture fabrication and have the time necessary to complete the study.
We would like you to come in to have a general screening appointment to determine if you qualify as a candidate for our study. If you qualify as a candidate for our study, you will be required to attend 17 visits at the University of Illinois at Chicago, College of Dentistry - Prosthodontic Dept. The estimated total time for your participation will be approximately 1-3 hours per visit. 17 visits are the only required appointments to complete the study.

If you would like to go ahead set up an appointment to come in, here is a list of available dates. The first screening appointment should take 15 minutes.

If you have any further questions, do not hesitate to call us at (312) 355-0631 or email us at manzotti@uic.edu. Thank you
APPENDIX B (continued)

Attachment #6

Subject’s ID#

University of Illinois at Chicago
Research Information and Consent for Participation in Biomedical Research

Differences Between Conventionally and CAD/CAM Fabricated Complete
Removable Dental Prostheses

You are being asked to participate in a research study. Researchers are required to provide a consent form such as this one to tell you about the research, to explain that taking part is voluntary, to describe the risks and benefits of participation, and to help you to make an informed decision. You should feel free to ask the researchers any questions you may have.

Principal Investigator Name and Title: Anna Manzotti DDS, MS, FACP
Department and Institution: Restorative Department -UIC College of Dentistry
Address and Contact Information: 801 S. Paulina Ave, Chicago IL 60612
Email: manzotti@uic.edu
Phone: (312) 996-9223
Emergency Contact Name and Information: Anna Manzotti (312) 996-9223
Your health care provider may be an investigator on this research protocol, and as an investigator, is interested in both your clinical welfare and in the conduct of this study. Before entering this study or at any time during the research, you may ask for a second opinion about your care from a clinician who is not associated with this project. You are not obligated to participate in any research project offered by your clinician. Your participation in this research study is voluntary and you do not have to participate. The decision to not participate will not affect your clinical care now or in the future.

**Why am I being asked?**

You are being asked to be a subject in a research study about differences between conventional and digital fabricated dentures. You have been asked to participate in the research because, throughout the screening process, you have been identified as having met the following inclusion criteria:

- Complete edentulous maxilla and mandible
- No maxillo-facial deficiencies
- Philosophical personality
- No implants present in the maxillary or mandibular arch
- 18 years and older

Your participation in this research is voluntary. Your decision whether or not to participate will not affect your current or future dealings with the University of Illinois at Chicago. **If you decide to participate, you are free to withdraw at any time without affecting that relationship.**

Approximately 10 subjects may be involved in this research at UIC.

**What is the purpose of this research?**

This research is being done to better understand if there are differences between conventional and digital fabricated dentures. The study will focus on:

- denture fabrication process
- esthetics
- phonetics
- function
- overall satisfaction.
APPENDIX B(continued)

The study is being done to test if there are objective and subjective statistical differences in CAD/CAM fabricated dentures and conventional dentures. The number of partially edentulous patients will continue to increase in the next 15 years to more than 200 million individuals. With such a dramatic increase, there will be a growing demand of removal prosthesis. Digital fabricated dentures are a fairly new technology, which represents the future of removable prosthodontics. Despite the last few years’ large-scale market expansion, the digital fabricated dentures are still not as common as conventional fabricated dentures. This phenomenon may be due to the lack of scientific literature, which focuses on the comparison of these two different ways of fabricating dentures. With this study we want to investigate this new technology as an alternative means to provide removable therapy to the ever-growing edentulous population.

**What procedures are involved?**

This research will be performed at the Prosthodontic Clinic (3rd floor – room 361) in the Restorative Department at UIC College of Dentistry – 801 S. Paulina Street, Chicago IL. You will need to come to the study site 17 times over the next 8 months. Each of those visits will take about 1-3 hours.

The study procedures are:

- **1st Appointment:** Screening.
  
  The screening process will include the following:
  
  a) Description of the study and nature of your participation
  b) Review of all inclusion and exclusion criteria
  c) Patient provided with brief handout describing the study and nature of their participations

- **2nd Appointment:**
  It will include the informed consent and privacy policy signatures and the following data collection:
  
  a) Medical and dental history
  b) Demographics
  c) Current/concomitant medication
  d) Oral soft and hard tissues examination

Your anatomy will be classified according to the American College of Prosthodontics. At this point you will be assigned by chance to group “X” or group “Y”; this process will determine the sequence of your appointments.
The 1st and 2nd appointment will take very little of your time: 15 minutes each.

If you will be assigned to group “X”, this will be your schedule:

- 3rd Appointment: Initial impressions will be made.
- 4th Appointment: Border molding of custom tray will be performed.
- 5th Appointment: Final impression will be made.
- 6th Appointment: Joint relation record will be assessed.
- 7th Appointment: Anterior and posterior tooth try-in will be done.
- 8th Appointment: Insertion of conventional fabricated dentures will be checked. You will be asked to fill in a survey regarding the clinical fabrication appointments.
  *Appointments 4 and 5 may be combined if time allows

The appointments from the 3rd to the 8th are the standard appointments required to fabricate a conventional denture; they may be 1 or 2 weeks apart and they will last approximately one hour each.

- 9th Appointment: Final Impressions and joint relation record will be made.
- 10th Appointment: Dentures try-in will be done.
- 11th Appointment: Insertion of digital fabricated dentures will be checked. You will be asked to fill in a survey regarding the clinical fabrication appointments.

The appointments from the 9th to the 11th are the standard appointments required to fabricate a digital denture; they may take 1 or 2 weeks total. The 9th will be a long appointment and it will take up to three hours. The 10th and the 11th will take about one hour. Appointments 9, 10, and 11 are standard of care appointments for fabricating a digital denture set; however, these three are additional appointments that are not normally associated with conventional denture fabrication but are required for the purpose of the study.

If you will be assigned to group “Y”, your sequence will be slightly different: Appointments 9th, 10th and 11th will be completed prior to the 3rd appointment.

At this time, during your last appointment of this session, intra-oral and extra-oral digital images will be taken with both sets of dentures (20 minutes). One set of dentures, which could be either of the two sets fabricated, will be delivered to you. You will not know which set is.
• 12th Appointment: 24 hours follow-up: we will check your dentures for sore spots (20 minutes).
• 13th Appointment: 1 week follow-up (20 minutes).

After 3 months you will be asked to come back to the College for your 14th appointment. If you need to see us before that, you can call anytime.

• 14th Appointment: You will be asked to fill in a survey regarding comfort, fit and esthetics of the dentures you have been using in the past 3 months. The clinician will retain your dentures and the other set will be delivered to you. You will go home only with the newly delivered dentures (20 minutes).
• 15th Appointment: 24 hours follow-up: we will check your new dentures for sore spots (20 minutes).
• 16th Appointment: 1 week follow-up (20 minutes).

After 3 months you will be asked to come back to the College for your 17th appointment. If you need to see us before that time you can call anytime.

• 17th Appointment: You will be asked to fill in a survey regarding comfort, fit and esthetics of the dentures you have been using in the past 3 months. The clinician will return to you your first set of dentures and you will keep both sets. You will go home with two sets of dentures. You will be able to wear the sets as you like, but you will not be able to use one denture of one set with one of the other. We will mark them in order to make sure you will use them correctly (20 minutes).

The appointments underlined and the underlined sentences are research related procedures. Both denture sets are standard of care; specifically, conventionally fabricated dentures are part of routine care at UIC College of Dentistry and digital dentures are provided to you for research purposes only.

**What are the potential risks and discomforts?**

There may be risks from the study that are not known at this time. There are no advantages or benefits from this study. The clinical procedures of this study may cause you discomfort or they may be painful.
APPENDIX B (continued)

The likely risks and discomforts expected in this study are:

- You may be asked to come for extra appointments if any procedure requires more time.
- Small cuts and abrasions on your gums and cheeks during the fabrication process of each set of dentures.
- Sore spots after the delivery of each set of dentures.
- Loss of confidentiality
- Photographs may be stolen from investigators or exposed to outsiders
- Photographs may be identifiable by people not associated with study

If cuts, abrasions or sore spots will occur, they will promptly treated adjusting the prosthesis or instructions will be given to you in order to assure a fast recovery.

The less likely risks and discomforts expected in this study are:

- Your facial appearance may slightly change due to the two different dentures.
  If you cannot accept the esthetic changes due to your dentures, you may quit the study at any time and the preferred set of dentures will be given to you.

- Your chewing function may be different when you will be asked to switch the dentures.
  If you cannot accept the functional changes due to your dentures, you may quit the study at any time and the preferred set of dentures will be given to you.

- Your speech may change when you will be asked to switch the dentures.
  If you cannot accept the changes in your speech due to your dentures, you may quit the study at any time and the preferred set of dentures will be given to you.

Rare but serious risks include

- The clinicians may drop the dentures and they could chip or fracture.
  If this will happen a new set of dentures will be made for you at no cost.

**Will I be told about new information that may affect my decision to participate?**

During the course of the study, you will be informed of any significant new research findings (either good or bad), such as changes in the risks or benefits resulting from participation in the research or new alternatives to participation, that might cause you to change your mind about
continuing in the study. If new information is provided to you, your consent to continue participating in this study may be re-obtained.

Are there benefits to taking part in the research?

You do not directly benefit from participation in the research. It is hoped that knowledge gained from this research may benefit others edentulous patients in the future.

What other options are there?

You have the option to not participate in this study. If you decide not to enter this study, there is other care available to you, such as conventional denture fabrication at the College of Dentistry or either conventional or digital fabricated dentures in private practices. The study principal investigator will discuss these with you. You do not have to be in this study to be treated for edentulism.

What about privacy and confidentiality?

The people who will know that you are a research subject are members of the research team, and if appropriate, your physicians and nurses. No information about you, or provided by you, during the research, will be disclosed to others without your written permission, except if necessary to protect your rights or welfare (for example, if you are injured and need emergency care or when the UIC Office for the Protection of Research Subjects monitors the research or consent process) or if required by law.

Study information which identifies you and the consent form signed by you will be looked at and/or copied for examining the research
- UIC Office for the Protection of Research Subjects, State of Illinois Auditors
- Study investigators.

A possible risk of the research is that your participation in the research or information about you and your health might become known to individuals outside the research. Your identity will be coded. Each photograph will be stored in a JPEG format on a computer with a locked pass-code. Each photograph will be assigned a 2 digits code ranging from 1 to 20, followed by letters to differentiate the pictures. The key file containing your name and assigned
code will be stored in a different computer with a locked pass-code, which will be accessible only by the PI. Further data will be collected in the form of surveys with the same numerical coded identity.

When the results of the research are published or discussed in conferences, no information will be included that would reveal your identity. The same measures will be taken as described previously. Furthermore, if full face pictures will be used, your eyes will be blocked to ensure anonymity.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. law. This web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

**Will health information about you be created, used or shared with others during this study?**

State and federal laws, including the Health Insurance Portability and Accountability Act (HIPAA), require researchers to protect your health information. This section of this form describes how researchers, with your authorization (permission), may use and release (disclose or share) your protected health information in this research study. By signing this form you are authorizing Manzotti Anna, Coffey Christopher, Kendall Krystle and their research team to create, get, use, store, and share protected health information that identifies you for the purposes of this research.

The health information includes all information created and/or collected during the research as described within this consent form and/or any health information in your medical record that is needed for the research and that specifically includes:

- Name
- Address
- Telephone number
- Medical record number
- Age
- Race
- Gender
- Years of wearing dentures
- Results of physical exams: Prosthodontic Diagnostic Index Classification
• Results of surveys
• Photographs

During the conduct of the research, the researchers may use or share your health information with each other and with other researchers involved with the study.

If all information that identifies you is removed from your health information, the remaining information is no longer subject to the limits of this Authorization or to the HIPAA privacy laws. Therefore, the de-identified information may be used and released by the researchers (as permitted by law) for other purposes, such as other research projects.

You will not have access to the health information related to this research study until the study is done. However, this information is available to your doctor in the case of an emergency. At the end of the study, you will again have access to health information that is normally within your medical records (treatment, insurance and billing information). However, the researcher may not give you access to the research records or information that is not usually kept in your medical record, as it is not required by HIPAA.

**How will your health information be protected?**

The researchers agree to protect your health information and will only share this information as described within this research consent/authorization form.

When your health information is given to people outside of the research study, those agencies that receive your health information may not be required by federal privacy laws (such as the Privacy Rule) to protect it. They may also share your information with others without your permission, if permitted by laws that they have to follow.

**What are the costs for participating in this research?**

If you take part in this study, you may have to pay extra costs. The following items and services will be provided to you free of charge by the UIC College of Dentistry:

• Digital fabricated dentures.

You or your insurer will be responsible for paying for the cost of the following:

• Conventional fabricated dentures – two arches: **870.00$**;
• Travel expenses.
If you have health insurance the insurance may or may not pay for your participation in the research. You will have to pay for any co-payments, deductibles or co-insurance amounts that your insurance coverage requires. The director of the prosthodontic clinic, Ms. Stephanie Clarke, will help you to contact your insurance company and to fill in the request. If you do not have insurance, you will be billed for the amount you have to pay.

**Will I be reimbursed for any of my expenses or paid for my participation in this research?**

You will not be offered payment for being in this study.

**Can I withdraw or be removed from the study?**

If you decide to participate, you are free to withdraw your consent and discontinue participation at any time without affecting your future care at UIC. You have the right to leave a study at any time without penalty. For your safety, however, you should consider the investigator’s advice about how to leave the study. If you leave the study before the final planned study visit, the investigator may ask you to complete the final steps.

The researchers and sponsor also have the right to stop your participation in this study without your consent if:

- They believe it is in your best interests;
- If you experience a severe discomfort with one of the dentures sets;
- If you do not follow the study procedures.

Your Authorization for release of health information for this research study expires at the end of the study, but can be canceled sooner if you decide to withdraw your permission.

You may change your mind and cancel this Authorization at any time. To cancel this Authorization, you must write to:

**Manzotti Anna**  
UIC College of Dentistry - Room 304  
801 S. Paulina St.  
Chicago, IL - 60612
If you cancel this Authorization, you may no longer be allowed to take part in the research study. Even if you cancel this Authorization, the researchers may still use and disclose health information they have already obtained as necessary to maintain the integrity and reliability of the research and to report any adverse (bad) effects that may have happened to you.

Who should I contact if I have questions?

Contact the researcher Dr. Anna Manzotti at (312) 996-9223 or email address manzotti@uic.edu:
- if you have any questions about this study or your part in it,
- if you feel you have had a research-related injury (or a bad reaction to the study treatment), and/or
- if you have questions, concerns or complaints about the research.

What are my rights as a research subject?

If you have questions about your rights as a research subject or concerns, complaints, or to offer input you may call the Office for the Protection of Research Subjects (OPRS) at 312-996-1711 or 1-866-789-6215 (toll-free) or e-mail OPRS at uicirb@uic.edu.

If you have questions or concerns regarding your privacy rights under HIPAA, you should contact the University of Illinois at Chicago Privacy Officer at Ph: (312) 996-2271.

Right to Refuse to Sign this Authorization

You do not have to sign this Consent/Authorization. However, because your health information is required for research participation, you cannot be in this research study if you do not sign this form. If you decide not to sign this Consent/Authorization form, it will only mean you cannot take part in this research. Not signing this form will not affect your non-research related treatment, payment or enrollment in any health plans or your eligibility for other medical benefits.

What if I am a UIC employee?

Your participation in this research is in no way a part of your university duties, and your refusal to participate will not in any way affect your employment with the university, or the benefits,
privileges, or opportunities associated with your employment at UIC. You will not be offered or receive any special consideration if you participate in this research.

**Remember:**

Your participation in this research is voluntary. Your decision whether or not to participate will not affect your current or future relations with the University. If you decide to participate, you are free to withdraw at any time without affecting that relationship.

**Signature of Subject or Legally Authorized Representative**

I have read (or someone has read to me) the above information. I have been given an opportunity to ask questions and my questions have been answered to my satisfaction. I agree to participate in this research. I will be given a copy of this signed and dated form.

If you have not already received a copy of the Notice of Privacy Practices, you should ask for one.

Your signature below indicates that you are providing both consent to participate in the research study and authorization for the researcher to use and share your health information for the research.

_________________________  ____________
Signature                      Date

_________________________
Printed Name

_________________________  ____________
Signature of Person Obtaining Consent  Date

_________________________
Printed Name of Person Obtaining Consent
Signature of Witness               Date

Printed name of Witness

Describe why a witness signature is required and the relationship to the Subject.
APPENDIX B (continued)

Data Collection Tables/Forms

Attachment #7:

Key file:

<table>
<thead>
<tr>
<th>Subject ID Number</th>
<th>Patient Name</th>
<th>Patient's Address</th>
<th>Telephone Number E-mail</th>
<th>Medical Number (Axium)</th>
</tr>
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<tbody>
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<td>20</td>
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</tbody>
</table>
APPENDIX B (continued)

Demographics:
Subject’s ID#

1) Age____________________

2) Race:
   □ American Indian or Alaska Native. A person having origins in any of the original peoples of North, Central or South America and who maintains tribal affiliation or community attachment.

   □ Asian-A person having origins in any of the original peoples of the Far East, Southeast Asia or the Indiana subcontinent, including for example Cambodia, China, India, Japan, Korea, Malaysia, Pakistan, the Philippine Islands, Thailand and Vietnam. (Note: Individuals from the Philippine Island have been recorded as Pacific Islanders in previous data collection strategies.)

   □ Black or African American-A person having origins in any of the black racial groups of Africa. Terms such as Haitian or Negro can be used in addition to Black or African American.

   □ Native Hawaiian or Other Pacific Islander-A person having origins in any of the original peoples of Hawaii, Guam, Samoa, other Pacific Islands.

   □ White-A person having origins in any of the original peoples of Europe, the Middle East or North Africa.

   □ Other

   □ More than one race-It is preferred that this be selected in addition to the selection of the specific races listed above but also may be solely selected.

   □ Unknown

3) Gender:____________________

4) Years of wearing dentures:____________________
## Prosthodontic Diagnostic Index (PDI) Classification System

<table>
<thead>
<tr>
<th>Prosthodontic Diagnostic Index Complete Edentulism Checklist</th>
<th>Class I</th>
<th>Class II</th>
<th>Class III</th>
<th>Class IV</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Bone Height-Mandibular</strong></td>
<td></td>
<td></td>
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<tr>
<td>21 mm or greater</td>
<td>✔️</td>
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<tr>
<td>16-20 mm</td>
<td>✔️</td>
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<tr>
<td>11-15 mm</td>
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<td>✔️</td>
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<tr>
<td>16 mm or less</td>
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<tr>
<td><strong>Ridge Morphology-Maxilla</strong></td>
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<tr>
<td>Type A - resists vertical &amp; horizontal, hamular notch, no tori</td>
<td>✔️</td>
<td>✔️</td>
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</tr>
<tr>
<td>Type B - no bucc vest, poor hamular notch, no tori</td>
<td>✔️</td>
<td>✔️</td>
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<tr>
<td>Type C - no ant vest, min support, mobile ant ridge</td>
<td>✔️</td>
<td>✔️</td>
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<tr>
<td>Type D - no ant/post vest, tori/redundant tissue</td>
<td>✔️</td>
<td>✔️</td>
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<tr>
<td><strong>Muscle Attachments-Mandibular</strong></td>
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<tr>
<td>Type A - adequate attached mucosa</td>
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<td>✔️</td>
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<tr>
<td>Type B - no bucc mucosa (22-27), + mentalis m</td>
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<td>✔️</td>
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<tr>
<td>Type C - no ant bacular (22-27), + genio &amp; mentalis m</td>
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<tr>
<td>Type D - no ant mucosa in post only</td>
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<tr>
<td>Type E - no ant mucosa, cheek lip moves tongue</td>
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<td><strong>Maxillomandibular Relationships</strong></td>
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<td>Class I</td>
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<td>Class II</td>
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<td><strong>Conditions Requiring Preprosthetic Surgery</strong></td>
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<tr>
<td>Minor soft tissue procedures</td>
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<tr>
<td>Minor hard tissue procedures</td>
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<td>Correction of dentoalveolar deformities</td>
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<td>Hard tissue augmentation</td>
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<td>Major soft tissue revisions</td>
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<tr>
<td><strong>Limited Interarch Space</strong></td>
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<tr>
<td>18-20 mm</td>
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<td>✔️</td>
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<tr>
<td>Surgical correction needed</td>
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<td><strong>Tongue Anatomy</strong></td>
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<td>Large (includes interdental space)</td>
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<td>Hyperactive - with retracted position</td>
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<td><strong>Modifiers</strong></td>
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<td>Oral manifestation of systemic disease</td>
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<td>Mild</td>
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<td>Moderate</td>
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<td>Severe</td>
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### ICD-9-CM Diagnostic Codes

- 525.41
- 525.42
- 525.43
- 525.44

**Guidelines for use of the worksheet**

1. Any single criterion of a more complex class places the patient into the more complex class.
2. Initial preprosthetic treatment and/or adjunctive therapy can change the initial classification level.
3. In the situation where the patient presents with an edentulous maxilla opposing a partially edentulous mandible, each arch is diagnosed with the appropriate classification system.
APPENDIX B (continued)

*Questionnaire*

Attachment #8:

First dentures set

Subject’s ID#

Question 1: Did it feel like appointments took a long time when making the denture?

NEVER          SOMETIMES          OFTEN          ALWAYS

Question 2: Was there any discomfort during the denture making?

NEVER          SOMETIMES          OFTEN          ALWAYS

Question 3: Were the instructions given by the dentist difficult to follow during the making of the denture?

NEVER          SOMETIMES          OFTEN          ALWAYS

Please add any additional comments related to the process and steps in making the denture:
______________________________________________________________________________
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__________________________
Second dentures set

Subject’s ID#

Question 1: Did it feel like appointments took a long time when making the denture?

NEVER  SOMETIMES  OFTEN  ALWAYS

Question 2: Was there any discomfort during the denture making?

NEVER  SOMETIMES  OFTEN  ALWAYS

Question 3: Were the instructions given by the dentist difficult to follow during the making of the denture?

NEVER  SOMETIMES  OFTEN  ALWAYS

Please add any additional comments related to the process and steps in making the denture:
______________________________________________________________________________
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**Data Collection Tables/Forms**

Attachment #9:

Extra follow up appointments (first dentures set):

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<th>First additional appointment (mm/dd/yy)</th>
<th>Second additional appointment (mm/dd/yy)</th>
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Extra follow up appointments (second dentures set):

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APPENDIX B (continued)

Questionnaire

Attachment #10:

Questions taken from OHIP using Likert Scale

Subject’s ID#

Functional limitation questions

1. Have you had difficulty chewing any foods because of problems with your dentures?

NEVER   SOMETIMES   OFTEN   ALWAYS

2. Have you had trouble pronouncing any words because of problems with your dentures?

NEVER   SOMETIMES   OFTEN   ALWAYS

3. Have you noticed a denture tooth or teeth that don't look right?

NEVER   SOMETIMES   OFTEN   ALWAYS

4. Have you felt that your appearance has been affected because of problems with your dentures?

NEVER   SOMETIMES   OFTEN   ALWAYS

5. Have you felt that your breath has been bad because of problems with your dentures?

NEVER   SOMETIMES   OFTEN   ALWAYS

6. Have you felt that your sense of taste has worsened because of problems with your dentures?

NEVER   SOMETIMES   OFTEN   ALWAYS
APPENDIX B (continued)

7. Have you had food catching in your dentures?

NEVER	SOMETIMES	OFTEN	ALWAYS

8. Have you felt that your digestion has worsened because of problems with your dentures?

NEVER	SOMETIMES	OFTEN	ALWAYS

9. Have you felt that your dentures have not been fitting properly?

NEVER	SOMETIMES	OFTEN	ALWAYS

Physical pain

10. Have you had discomfort in your mouth associate with your dentures?

NEVER	SOMETIMES	OFTEN	ALWAYS

11. Have you had a sore jaw?

NEVER	SOMETIMES	OFTEN	ALWAYS

12. Have you had headaches because of problems with your dentures?

NEVER	SOMETIMES	OFTEN	ALWAYS

13. Have you had painful gums?

NEVER	SOMETIMES	OFTEN	ALWAYS

14. Have you found it uncomfortable to eat any foods because of problems with your dentures?

NEVER	SOMETIMES	OFTEN	ALWAYS

15. Have you had sore spots in your mouth?

NEVER	SOMETIMES	OFTEN	ALWAYS
16. Have you had uncomfortable dentures?

NEVER           SOMETIMES           OFTEN           ALWAYS

**Psychological discomfort**

17. Have you been self-conscious because of your dentures?

NEVER           SOMETIMES           OFTEN           ALWAYS

18. Have dental problems made you miserable?

NEVER           SOMETIMES           OFTEN           ALWAYS

19. Have you felt uncomfortable about the appearance of your dentures?

NEVER           SOMETIMES           OFTEN           ALWAYS

20. Have you felt tense because of problems with your dentures?

NEVER           SOMETIMES           OFTEN           ALWAYS

21. Have you been worried by dental problems?

NEVER           SOMETIMES           OFTEN           ALWAYS

**Physical disability**

48. Has your speech been unclear because of problems with your dentures?

NEVER           SOMETIMES           OFTEN           ALWAYS

23. Have people misunderstood some of your words because of problems with your dentures?
APPENDIX B (continued)

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24. Have you felt that there has been less flavor in your food because of problems with your dentures?

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25. Have you had to avoid eating some foods because of problems with your dentures?

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26. Has your diet been unsatisfactory because of problems with your dentures?

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27. Have you been unable to eat with your dentures because of problems with them?

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28. Have you avoided smiling because of problems with your dentures?

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29. Have you had to interrupt meals because of problems with your dentures?

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30. Has your sleep been interrupted because of problems with your dentures?

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31. Have you been upset because of problems with your dentures?

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**Psychological disability**

30. Has your sleep been interrupted because of problems with your dentures?

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31. Have you been upset because of problems with your dentures?
APPENDIX B (continued)

32. Have you found it difficult to relax because of problems with your dentures?

NEVER         SOMETIMES     OFTEN      ALWAYS

33. Have you felt depressed because of problems with your dentures?

NEVER         SOMETIMES     OFTEN      ALWAYS

34. Has your concentration been affected because of problems with your dentures?

NEVER         SOMETIMES     OFTEN      ALWAYS

35. Have you been a bit embarrassed because of problems with your dentures?

NEVER         SOMETIMES     OFTEN      ALWAYS

**Social disability**

36. Have you avoided going out because of problems with your dentures?

NEVER         SOMETIMES     OFTEN      ALWAYS

37. Have you been less tolerant of your spouse or family because of problems with your dentures?

NEVER         SOMETIMES     OFTEN      ALWAYS

38. Have you had trouble getting on with other people because of problems with your dentures?

NEVER         SOMETIMES     OFTEN      ALWAYS

39. Have you been a bit irritable with other people because of problems with your dentures?

NEVER         SOMETIMES     OFTEN      ALWAYS
APPENDIX B (continued)

40. Have you had difficulty doing your usual jobs because of problems with your dentures?

NEVER          SOMETIMEs          OFTEN          ALWAYS
APPENDIX B (continued)

If you had to choose, which denture would you like to keep?

First One    Second One

Please add any additional comments:

______________________________________________________________________________
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APPENDIX B (continued)

Attachment #11:

**Drop-out form**

Subject’s ID#

__ Inclusion criteria are no longer met

__ Subject not compliant

__ Subject refusal

__ Other

Comment:

______________________________________________________________________________

______________________________________________________________________________

______________________________________________________________________________

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______________________________________________________________________________
This project seeks to investigate differences between conventionally and CAD/CAM fabricated complete dentures. This research is being done to better understand if there are differences between conventional and digital fabricated dentures. The study will focus on:

- denture fabrication process
- esthetics
- phonetics
- function
- overall satisfaction.

You are being asked to be a subject in a research study about differences between conventional and digital fabricated dentures.

Your participation in this research is voluntary. Your decision whether or not to participate will not affect your current or future dealings with the University of Illinois at Chicago. If you decide to participate, you are free to withdraw at any time without affecting that relationship. During the study, you will be given two sets of dentures fabricated digitally and conventionally. You will be able to keep both dentures at the end of the study.

This research will be performed at the Prosthodontic Clinic (3rd floor – room 361) in the Restorative Department at UIC College of Dentistry – 801 S. Paulina Street, Chicago IL
APPENDIX B (continued)

You will need to come to the study site 17 times over the next 8 months. Each of those visits will take about 1-3 hours.
VITA

Name: Christopher William Coffey

Education: BS, Biology, Loras College, Dubuque, IA 2006

MAS, Molecular and Cell Biology, Illinois Institute of Technology, Chicago, IL 2010

DDS, Indiana University School of Dentistry, Indianapolis IN, 2014

Certificate, Advanced Prosthodontics, University of Illinois at Chicago, 2017

Honors: Carol A. Lefebvre Scientific Poster Award

Professional Membership: American College of Prosthodontists

ITI-International Team of Implantology

Poster: American Academy of Fixed Prosthodontics, Annual Session

Presentations: American College of Prosthodontics, Annual Session Poster Presentation: Differences Between Conventionally and CAD/CAM Complete Removable Dental Prosthesis - Subjective Analysis (2016)