

A Prospective, Single Blind, Crossover, Clinical Trial to Assess the Outcomes of Computer-Engineered Complete Dentures from Impressions and Intra-Oral Scans of the Edentulous Arches: A Pilot Study

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Dental Surgery (D. Ch. Dent.) (Prosthodontics)

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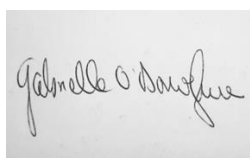
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DECLARATION

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SUMMARY

Computer-engineered complete dentures (CECDs) have documented clinical applications with advantages for the clinician and patient. Intra-oral scanning (IOS) of the edentulous arches is possible, with reported advantages over conventional impression-making. The application of intra-oral scanning of edentulous arches within CECD protocols is feasible, however, the evidence for its use as the definitive impression technique was limited to technique articles, case reports, and clinical trials with low numbers of participants.

A pilot clinical trial was conducted to investigate and compare the clinical outcomes and patient-related outcomes of CECDs made from conventional impressions and from intra-oral scans of the edentulous arches. Five participants were recruited to the study following application of inclusion and exclusion criteria and the informed consent process. A prospective, crossover design was implemented. Preliminary record making was completed at the first clinical visit, including preliminary conventional impressions of the edentulous arches and a preliminary maxillo-mandibular relationship record. The edentulous arches were scanned using an intra-oral scanner. Custom-designed occlusal record blocks were fabricated in the dental laboratory and used to make definitive conventional impressions and a definitive maxillo-mandibular relationship record at the second clinical visit. Two sets of CECDs were designed using computer-aided design software: one set was based on conventional impressions and the second on intra-oral scans. The CECDs were fabricated through computer-aided manufacturing in the laboratory. The order of delivery of the dentures was randomised via a coin toss. One set of dentures was fitted and assessed by two independent prosthodontists for their clinical outcome and acceptability. The participant wore the CECDs for one month, and completed two patient

satisfaction surveys in this time. The participant's existing complete dentures were returned to them for a period of one month. The second set of CECDs were fitted and assessed by the two independent prosthodontists. The participant wore the second set of CECDs for one month and again completed two patient satisfaction surveys. The participant preference for the impression technique and CECDs was determined at the end of the study period.

The results indicated that the application of intra-oral scanning of the edentulous arches was feasible within the chosen CECD system. There were no differences found between the dentures with respect to their clinical outcomes, including fit, function, aesthetics, occlusion, and overall score. The participants were significantly more satisfied with all dentures after one month when compared to one week. No significant differences were found for patient satisfaction between impression-based and scan-based CECDs. A participant preference towards intra-oral scanning as an impression modality was noted. The null hypotheses were not rejected in that the clinical and patient-related outcomes of milled CECDs fabricated from intra-oral scans of the edentulous arches were similar to the outcomes of milled CECDs fabricated from conventional impressions.

Limitations of this study included low participant numbers. This pilot trial analysed only one specific CECD system and IOS scanning strategy. Other systems and their respective workflows may yield different outcomes. Future studies should include a greater number of participants and stratify the participants according to personality type and edentulous arch morphology.

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LIST OF ABBREVIATIONS

CECD(s)	Computer-engineered complete denture(s)
IOS	Intra-oral scanning
CD(s)	Complete denture(s)
OHRQoL	Oral health-related quality of life
PMMA	Polymethylmethacrylate
CE	Computer-engineering
CAD	Computer-aided design
CAM	Computer-aided manufacturing
CNC	Computer numerical controlled
3D	Three dimensional
RP	Rapid prototyping
SLA	Stereolithography
DLP	Digital light projection
SLS	Selective laser sintering
UV	Ultraviolet
RDP	Removable dental prosthesis
VPS	Vinylpolysiloxane
STL	Standard tessellation language
RCT	Randomised controlled trial
OVD	Occlusal vertical dimension
CR	Centric relation
VAS	Visual analog scale
PROM(s)	Patient-related outcome measure(s)
OHIP	Oral Health Impact Profile
ZOE	Zinc oxide eugenol
FDP	Fixed dental prosthesis
DDUH	Dublin Dental University Hospital
ACP	American College of Prosthodontists
JREC	Joint Research Ethics Committee
RVD	Resting vertical dimension
BP	Bi-pupillary
CE	Camper's plane
CECDs(imps)	CECDs based on conventional impressions
CECDs(scans)	CECDs based on intra-oral scans
MIP	Maximum intercuspation position

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CHAPTER ONE: LITERATURE REVIEW

1.1 Description of the Condition

Life expectancy is increasing worldwide (1), with the global population over 60 years of age expected to surpass two billion by 2050 (2). The rate of tooth loss increases as a consequence of advancing age (3,4). The global prevalence of edentulism was reported to range from 2.8 to 14.5% (5), varying within populations as a result of gender (6), socioeconomic status (7), education (8), dental awareness (9) and patient to dentist ratio (10). The rate of edentulousness has decreased within the Irish population, from 72% of adults aged 65 years and older in 1979 to 41% in 2002 (11). However, when considered in the context of an ageing population, there is still a need for the effective management of the edentulous patient.

1.2. Complete Dentures

1.2.1. Conventional Complete Dentures

Conventional tissue-supported complete dentures (CDs) are the standard treatment modality for the management of edentulism and remain the most cost-effective treatment (12). A complete denture is defined as “a fixed or removable dental prosthesis that replaces the entire dentition and associated structures of the maxillae or mandible” (13). Implant overdentures are effective in improving denture support, stability, and retention. However, a number of factors were reported to preclude the use of implants, including the general health of the patient (14, 15, 16), unfavourable anatomical conditions of the residual alveolar ridges (17) and associated structures (18, 19), and finances (20).

1.2.2. Treatment Objectives

The goals of tissue-supported conventional CDs are to maintain oral health and comfort, improve oral function, restore facial aesthetics, and promote psychological well-being (21, 22). Ill-fitting and unstable CDs were reported to diminish masticatory performance and speaking ability, thereby having an impact on the patient's oral health-related quality of life (OHRQoL) (23, 24). Successful CDs were reported to be well supported (25), stable (26), and retentive (27, 28). Support refers to the resistance of the CD to forces directed towards the basal tissues (13), whereas stability was defined as "the resistance of a CD to movement as a result of forces with a horizontal component (13). Overall patient satisfaction with CDs was associated with stability of maxillary and mandibular complete dentures in clinical studies evaluating the prostheses of 222 and thirty-three participants, respectively, using questionnaires (29, 30). Factors that contribute to stability include anatomy of the edentulous arches including ridge height and configuration (31, 32), denture base adaptation to the mucosal tissues (26, 30), and an accurately designed occlusal scheme (33). Retention describes resistance of the CD to displacement in a vertical direction (13). The posterior palatal seal (34, 35), adaptation of the denture base to the mucosal tissues (28, 34), neuromuscular control (36, 37) the morphology and resilience of the denture bearing mucosa (38, 39), and the viscosity and film-thickness of saliva (40, 41) were all reported to contribute to retention of the CD.

1.2.3. Fabrication

Conventional CD fabrication involves clinical appointments to make impressions and maxillomandibular registrations, and to clinically evaluate the tooth arrangement (42-44). The first clinical appointment involves an initial assessment and making of preliminary maxillary and

mandibular impressions. Maxillary and mandibular custom trays are fabricated in the laboratory. The definitive maxillary and mandibular impressions are made at the second clinical visit. The master casts are fabricated in the laboratory, followed by fabrication of maxillary and mandibular record bases with wax occlusal rims. The occlusal wax rims are contoured at the third clinical appointment. A facebow transfer record is made in addition to the definitive maxillo-mandibular relationship record. The master casts and record bases are mounted on the articulator in the laboratory, and the denture tooth arrangement is completed in wax. The trial denture arrangement is evaluated for the functional, occlusal, and aesthetic parameters at the third clinical appointment. The tooth arrangement and waxing are completed in the laboratory, and the dentures are invested and processed. A clinical remount procedure is completed at the fifth clinical visit prior to fitting the definitive dentures.

1.2.4. Conventional CD Materials

Polymethylmethacrylate (PMMA) has been utilised in conventional CD fabrication since 1936 (45). PMMA resin materials are heat- or auto-polymerised in a free radical vinyl polymerisation process (46). PMMA is a desirable denture base material due to its adequate flexural strength (47, 48, 49), satisfactory aesthetics (49, 50), and ease of maintenance (46). On the contrary, PMMA resins are not an ideal denture base material because of poor impact strength (43, 47, 50), and porosity (52). Limitations with the use of PMMA are related to polymerisation shrinkage during processing (47, 53, 54), fracture strength (55, 56), and dimensional and colour stability (57, 58). The polymerisation shrinkage of heat-cured PMMA was recorded as 0.5-0.58% (47, 59). With respect to the material's biocompatibility, the cytotoxic potential of residual monomer in PMMA resins (60), and the risk of possible patient allergy has been deemed concerning (61, 62).

1.2.5. *Conventional CDs: Clinical Outcomes*

Conventional CD fabrication has produced clinically-predictable results for over seventy years (63). Survival time was defined as the time between the date of insertion and the date of renewal for any clinical reason, and was found to be 19.4 and 15.8 years for maxillary and mandibular dentures, respectively, in a retrospective study (64). The tooth arrangement is customisable to each individual and amenable to their input. Highly aesthetic CDs have been fabricated with the clinician, patient and dental technician working together (65-67). However, conventional protocols for CD fabrication are challenging and time-consuming both clinically and technically (22, 43), and is dependent on the experience and skill of the operator (68, 69). Numerous clinical appointments are required, which may be difficult for patients to attend, especially for the elderly (70). From a laboratory perspective, traditional processing techniques for CDs are costly with respect to labour, materials, and shipping expenses (71). Conventional heat polymerisation processes result in catastrophic damage to the master casts, leading to limited retrievability of the clinical records (72). Conventional fabrication of CDs was open to cumulative error at every step due to both processing error, namely the inherent polymerisation shrinkage of the material (54), and human errors, as identified in a recent survey in a student clinical setting (73). Increased time and cost were associated with the correction of such errors (74). Conventional CDs were at higher risk of fracture from a sustained impact due to flexural fatigue as the denture base withstands cyclical loading during mastication (75, 76). Laboratory and clinical remount procedures of CDs were indicated to correct occlusal discrepancies resulting from denture tooth movement during acrylic polymerisation (77-79).

1.3. Computer Engineering in Dentistry

1.3.1. Definition

Computer engineering (CE) technologies evolved for use in dentistry over the preceding five decades (80). CE involves the use of software algorithms to permit data acquisition, the design and manufacture of dental restorations (81, 82). The acronym CAD/CAM, denoting computer-aided design/computer-aided manufacturing, is an alternative term for CE. CE is employed in prosthodontics to fabricate fixed restorations (83), removable prostheses (84, 85) and dental implant prostheses (82, 86, 87). The first documented application of the use of CAD/CAM in restorative dentistry involved the design and fabrication of a single tooth-borne indirect restoration (88, 89). Use of adjunctive CAD/CAM prostheses, like surgical guides, were reported to improve the efficiency of the surgical placement of dental implants, and facilitated efficiency in the subsequent restorative treatment stages (90, 91).

1.3.2. Computer Engineering: Workflow

Data acquisition may be completed using intra-oral scanning (IOS) (92), digital radiographs (93, 94), and clinical photographs (95). Alternatively, impressions and casts may be digitised using an extra-oral benchtop scanner (96). The clinical information is stored as stereolithography files, a format native to CAD/CAM systems (13), which are transferred to the CAD software where the prosthesis is designed (97). CAM methods may be classified as subtractive or additive in nature (Fig.1.1) (83). Subtractive manufacturing involves creating objects by modification of pre-fabricated blocks of material (83), and includes techniques such as spark erosion and computer numerical controlled (CNC) milling (98, 99). Spark erosion is a precision metal removal technique using an accurately controlled electrical discharge to erode material in a liquid dielectric medium (13). Specific geometries are created by grinding the material block with sharp cutting tools, like

diamond and carbide burs, in CNC milling (98). Material is physically removed to achieve the prescribed geometry (100). The CAD design is automatically transferred into the tool pathway for CAM in the CNC machine (89, 101), which directs the milling process, including sequencing of the milling tools, along with the direction and magnitude of tool motion (101). Different types of milling machines are available, with variations in the number of possible working axes for the cutting tools (101, 102). Subtractive milling is utilised more frequently for dental purposes, namely for the fabrication of single full and partial coverage fixed dental restorations (80). Milling processes have produced clinically acceptable (<100microns) marginal and internal fit for lithium disilicate (103) and zirconia (104) full and partial coverage restorations in-vitro. Concerns regarding the high volume of material wastage post-milling have been raised (105, 106).

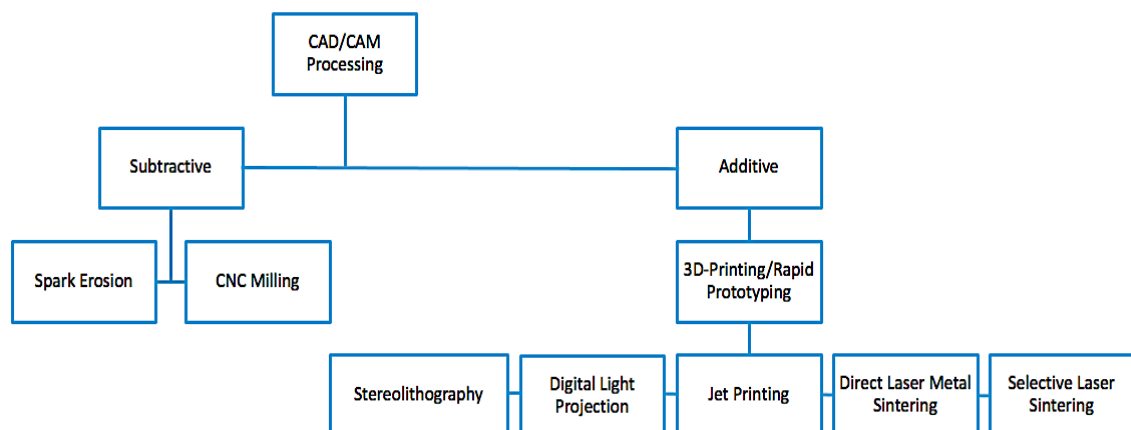


Figure 1.1 CAM processing techniques

Additive manufacturing is the process of fusing layers of material to make three dimensional (3D) geometric objects from CAD data (107). Rapid prototyping (RP) is a generic term to describe additive manufacturing techniques involving automated and repeatable processes that result in the production of a physical object (100). Synonyms include 3D-printing, photo-solidification,

solid freeform fabrication or layered manufacturing (100). RP was used to reproduce anatomical objects as 3D models in medicine, and particularly in maxillofacial surgery, for over twenty years (108) and recently evolved for applications in prosthodontics (109, 110). Additive RP techniques include stereolithography (SLA), digital light projection (DLP), jet printing, direct laser metal sintering and selective laser sintering (98). SLA and DLP are examples of vat photo-polymerisation technology where an ultraviolet (UV) laser or high-powered light projection is used to polymerise visible light-sensitive PMMA resins (111) layer-by-layer in a vat to build an artefact of specific geometry (112, 113). Following the creation of the shape, the material is processed post-printing using a light-emitting diode light source (114). SLA and DLP are used for manufacturing dental casts, copings and metal prostheses as alternatives to cast, injection-molding and thermoforming processes (114). Jet printing utilises a series of ink-jet print heads to incrementally extrude material onto a support structure to create each layer, which is then cured with a UV lamp, light or heat source (115). Jet printing is employed to create dental casts, surgical guides, wax patterns and RDP frameworks (116). Selective laser sintering (SLS) employs a high power laser, such as a carbon dioxide laser, to fuse small particles of plastic, metal, ceramic, or glass powders into a mass with a desired 3D form (100). Partial removable dental prosthesis (RDP) frameworks (117) and prototype restorations (118) are manufactured additively from UV-sensitive liquid resins. DLP is being explored for CD manufacture (119). Additive manufacturing boasts several advantages. It is capable of building complex geometries, including hollow shapes, which remain challenging to mill (120). Its additive nature limits the volume of material waste generation (105, 121). The equipment required for RP is generally less expensive than the initial high procurement costs for milling machines (122-124). However, a limitation of additive manufacturing is that its application printing ceramics is only an experimental stage (125).

1.4. Computer-Engineered Complete Dentures (CECDs)

1.4.1. History

The development of CAD/CAM processes was applied to the design and fabrication of CDs (121) and has the potential to overcome the disadvantages associated with conventional CD fabrication (126, 127). The first documented report of a CECD was published in 1994 (128), where extra-oral scans of maxillary and mandibular impressions were made and CAD was employed to outline the denture base and complete a virtual denture tooth arrangement (128). 3D-laser lithography was employed to fabricate the CD base in a resin composite material along with plastic shells of the teeth (128). Several theoretical models and protocols for CECD fabrication have been described subsequently (129-122). CDs were duplicated by scanning the prostheses with a non-contact measurement system and milling of modelling wax thereafter (134). A virtual tooth arrangement based on traditional guidelines for tooth positioning was described (135), and permitted the design and CNC milling of denture bases (130). This provided proof of concept for CD fabrication within a digital workflow (131). The first clinical report of a two-step CAD/CAM protocol for maxillary and mandibular CECDs (AvaDent®, Global Dental Sciences LLC, Arizona, USA) was published in 2014 (136). Definitive impressions of both arches were made in thermoplastic trays using vinylpolysiloxane (VPS) material, and the definitive maxillo-mandibular relationship record was made using an anatomic measuring device (AvaDent®, Global Dental Sciences LLC, Arizona, USA) and gothic arch tracing at the first clinical appointment. The definitive clinical records were sent to the laboratory to permit the fabrication of a maxillary and mandibular complete dentures in two clinical appointments.

1.4.2. CECDs: Data Acquisition & CAD

The typical digital workflow for CECDs is similar to other CE dental processes. Data acquisition is achieved through digitisation of an impression or cast in the laboratory using light scanning technology in an extra-oral scanner (86, 137, 138). CECD software programmes enable the digital design of complete denture prostheses, where stereolithography files of the clinical records are mounted on a virtual articulator to spatially orient the maxillary and mandibular casts. The denture base contour, thickness, extensions, and tooth arrangement are defined. 3Shape Denture Design® (3Shape, Copenhagen, Denmark), Full Denture Module (exocad Inc., Darmstadt, Germany) and DWOS® Full Dentures (Dental Wings Inc., Montréal, Canada) are examples of popular CAD software packages for CECDs.

1.4.3. CECDs: CAM

There are several methods of employing CAM for the manufacture of CECDs (139) (Fig.1.2), with subtractive milling most commonly used by commercial laboratories (127). A technique article described the completion of a conventional wax tooth arrangement on milled CD bases followed by conventional processing of the definitive prostheses (140). PMMA denture bases were milled with specific alveoli for the corresponding prosthetic tooth arrangement, followed by luting of the denture teeth with a PMMA resin (136, 141). Monolithic CECDs were described where the entire denture base and tooth arrangement were milled from a single PMMA resin blank comprising of tooth and gingiva-coloured PMMA (91, 142).

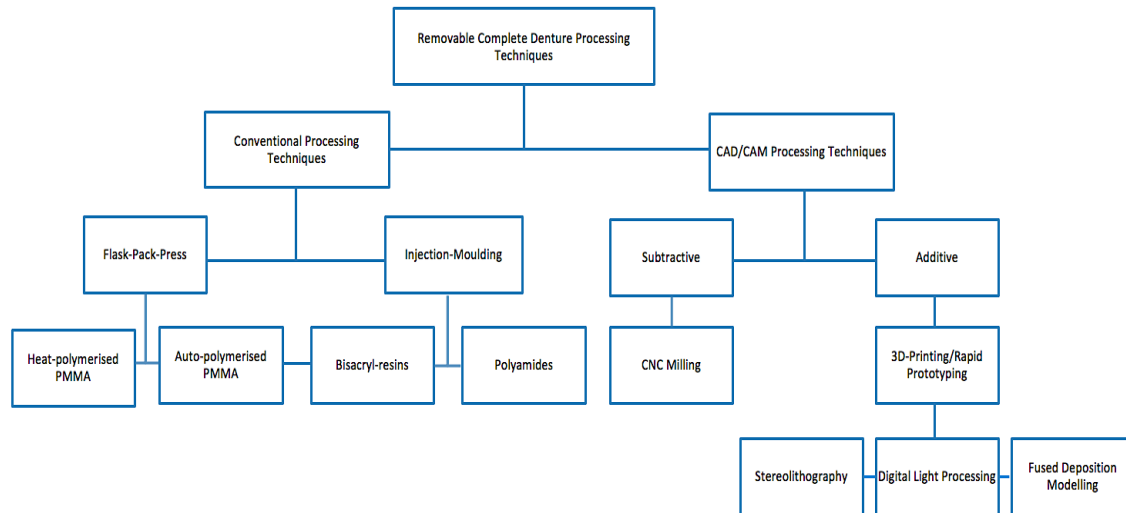


Figure 1.2. Removable CD fabrication techniques (adapted from Srinivasan et al. 2021 (139))

CECDs can be fabricated by RP (62), and have documented advantages over milled prostheses. In an in-vitro study of maxillary complete denture bases, DLP demonstrated significantly better tissue surface adaptation to the master cast than milled and conventionally fabricated denture bases when standard tessellation language (STL) files of the samples were super-imposed using point-to-point matching and best-fit alignment (143). A randomised controlled trial (RCT) demonstrated significantly higher mean retention values using a force gauge for 3D-printed CECDs six months after insertion when compared with conventionally fabricated CDs (144). A prospective clinical study investigating the satisfaction of ten participants with RP trial prostheses found no significant difference compared to conventional wax tooth arrangements in terms of final denture shape, stability, comfort or overall satisfaction when using a visual analog scale (132). 3D-printed denture bases modified with the microencapsulation of phytochemicals demonstrated significant anti-fungal activity against *candida albicans* in-vitro (145). In an in-vitro study evaluating the flexural strength, impact strength, hardness and surface

roughness of 3D-printed denture base resin (NexDent®, NexDent B.V., Soesterberg, The Netherlands), significantly lower values for all tested properties were recorded between conventional heat-polymerised PMMA samples and the test material (145). Following ageing processes, additively manufactured denture base resins demonstrated more colour change when measured with a spectrophotometer following four ageing processes than conventional heat-polymerised PMMA and milled resins in-vitro (147). In light of these limitations, and the lack of clinical evidence regarding wear resistance and ageing (148), RP is generally employed for interim CECDs (149).

1.4.4. CECDs: PMMA Material

1.4.4.1. Mechanical Properties

The CAM material blanks for CECDs are PMMA resin blocks, previously polymerised under high heat and pressure, resulting in a highly condensed polymer (150). In an in-vitro study, the flexural strength, flexural modulus, and impact strength of milled PMMA blanks were significantly higher than those of conventional heat-polymerised PMMA for “pack-and-press” techniques; this was attributed to the lack of porosity generated by the fabrication process (151). Monolithic CD bases exhibited less distortion, because of the absence of polymerisation shrinkage during fabrication of the prosthesis (127). In a clinical study with twenty participants, a significant increase in retention was found for milled PMMA maxillary denture bases (AvaDent®, Global Dental Sciences LLC, Arizona, USA) when compared with conventional heat-polymerised bases using an advanced digital force gauge (126). This was attributed to the increased density of the pre-polymerised acrylic blanks. The flexural bond strength between commercial denture teeth and milled PMMA bases after thermocycling was significantly lower than heat-polymerised resin in-vitro, with the dominant mode of failure being cohesive in nature for the milled samples and

adhesive in the conventional group (153). The risk of potential prosthetic complications regarding fracture and debonding of denture teeth from milled CECD bases was highlighted. Furthermore, milled PMMA blanks are costly (154).

1.4.4.2. Biocompatibility

Conventional processing of CDs produces gaseous porosity in the denture base resulting in rough surface irregularities (155, 156). Surface roughness contributed to microbial colonisation of denture bases, potentially eliciting localised mucosal infection, and being potentially implicated in the aetiology of aspiration pneumonia in dependent older adults (157). An in-vitro study demonstrated that pre-polymerised PMMA samples were found to have the lowest pre-polishing surface roughness values, and the lowest bacterial adhesion after ninety minutes of incubation compared to heat-polymerised and 3D-printed resin samples using scanning electron microscopy (158). Microbial adherence of *candida albicans* to milled PMMA samples was significantly lower in-vitro compared to RP and heat-polymerised specimens (159). Another in-vitro study reported no statistically significant differences in terms of biocompatibility with human epithelial and gingival cell growth between milled PMMA (AvaDent®; Global Dental Sciences LLC; Arizona, USA) and 3D-printed specimens (NexDent®; NexDent B.V.; Soesterberg, The Netherlands) (160). Similarly, an in-vitro study concluded that milled PMMA (AvaDent®; Global Dental Sciences LLC; Arizona, USA) was equally biocompatible to conventional heat-polymerised PMMA with respect to human primary osteoblasts and mouse embryonic fibroblasts (161).

Longer chain polymers are created in the production of CAD/CAM PMMA blanks, resulting in a higher rate of conversion and minimal residual monomer, with resultant minimal intermolecular distances and less internal stress and flaws (162). The higher flexural strengths reported for milled PMMA samples have been associated with higher degrees of monomer conversion in-vitro (163). High-performance liquid chromatography was used to compare the concentration of residual free monomer of four CECD systems (Baltic Denture Systems, Vita Vionic, Wieland® Digital Dentures, Whole You Nexteeth) with conventionally-processed heat-polymerised PMMA dentures (163). The weight, volume and density of the dentures was evaluated in-vitro following storage in water for seven days, and no significant differences were found in the concentration of free monomer released from the specimens. It was postulated that the level of free monomer released from CECDs may have been due to a methacrylate-based agent used to fix the denture teeth in the milled base, and thus, may have affected the results of the study (163). With regard to photopolymers indicated for 3D-printing, total monomer conversion was not found after polymerisation of two materials in-vitro using infrared spectroscopy (164). The result of incomplete conversion is that free monomer remains suspended within the end-product, with possible leaching out causing tissue irritation (165). In a cross-sectional, retrospective study investigating the clinical performance of CECDs, concerns were raised regarding non-polymerised material, where one participant developed a suspected allergic reaction to the base material (AvaDent®, Global Dental Sciences LLC, Arizona, USA), which manifested as epithelial sloughing (166). This sloughing resolved after provision of a conventionally-processed denture. Therefore, the extent of free residual monomer concentration within milled and 3D-printed CECDs and resultant tissue effects requires further investigation in-vivo (167).

1.4.5. *CECDs: Commercial Systems*

Several commercial CECD systems are available (136, 168-170). Popular commercial systems include the Ivoclar® Digital Denture System (Ivoclar Vivadent AG, Schaan, Liechtenstein), AvaDent® Digital Denture Solutions (Global Dental Sciences LLC, Arizona, USA), Ceramill Full Denture System (Amann Girrbach AG, Koblach, Austria), and the Baltic Denture System® (Merz Dental GmbH, Lütienburg, Germany). Most protocols involve subtractive milling of CDs in a closed system (169, 171). The decision on which system to use depends on the clinician's prosthodontic experience and the need for denture characterisation (172, 173).

1.4.6. *CECDs: Clinical Applications*

The clinical applications of CECDs have been described in the literature. A maxillary complete denture and mandibular implant overdenture were fabricated for a male patient in a two-appointment protocol similar to that described previously (Section 1.4.1.) in one of the first documented applications of CECDs (133). The intimate fit of both dentures was reported, followed by chairside incorporation of mandibular dental implant attachments (133). A similar protocol was described for a patient requiring an immediate maxillary denture designed on a severely atrophic edentulous ridge, and a successful outcome was defined in terms of an aesthetically pleasing stable prosthesis requiring no post-insertion adjustments (174). An immediate maxillary denture was designed on a severely atrophic edentulous ridge, and a successful outcome was defined in terms of an aesthetically pleasing stable prosthesis requiring no post insertion adjustments (174). Several other variations of the AvaDent® (Global Dental

Sciences LLC, Arizona, USA) protocol were described. Rapid prototyped denture bases and occlusion rims were used to make an interocclusal record for the fabrication of a maxillary CECD and mandibular complete overdenture (123). The fabrication of interim CECDs for a patient with Class II edentulous ridges (175) and a skeletal class I arch relationship was described, whereby the mandibular complete denture was subsequently converted to a provisional fixed complete denture at the time of implant placement. The stored data was used to fabricate the definitive monolithic milled implant-retained fixed complete denture thereafter (91). The management of a patient with myasthenia gravis with a maxillary CD and rebasing of her mandibular fixed dental prosthesis was outlined (176). The cameo and intaglio surfaces of the existing prostheses were scanned using an intra-oral scanner to facilitate fabrication of the wax trial denture. The fabrication of monolithic AvaDent® CECDs was feasible in a reduced number of clinical appointments (176). Monolithic definitive CECDs were provided in a four-step protocol for a patient with moderate resorption of the maxillary arch, hyperplasia of the anterior ridge, and severe resorption of the mandibular ridge (177). A conventional mandibular occlusal rim was used in this report to facilitate successful recording of the maxillo-mandibular relationship in the presence of increased inter-arch distance (177). Similarly, the combination of CAD/CAM processes and traditional clinical records facilitated the rehabilitation of a male patient with CECDs fabricated through milling of the denture base and subsequent bonding of commercial teeth in a three-step protocol (127).

A technical report outlined the fabrication of maxillary and mandibular CECDs for two patients, using the AvaDent® and Dentca™ CECD systems respectively (178). The Dentca™ protocol differed from that of the AvaDent® system, whereby definitive conventional impressions were made in system-specific stock trays for the Dentca™ system. The posterior

section of the trays were detached in order to attach a gothic arch tracing device and to enable recording of the maxillo-mandibular relationship. The length of the upper lip was measured to determine the maxillary incisal edge position prior to transfer of the clinical records to the laboratory. 3D-printed CECD prototypes functioned as radiographic guides during computed topography to facilitate the digital design of the mandibular denture (Dentca™, DENTCA Inc., California, USA) with relief over the mental foramen for a patient with paraesthesia of the lower left lip and chin (179). A case report outlined the fabrication of maxillary and mandibular CECDs (Dentca™, DENTCA Inc., California, USA) in a three-appointment protocol whereby a neutral zone impression technique was employed and transferred to the CAD software to ensure the denture teeth and flange forms were appropriately designed (180).

A case series described the rehabilitation of fifteen participants, with a mean age of 65 years, using the Wieland® Digital Denture System (181). The four-step protocol involved making preliminary impressions in stock trays and a preliminary maxillo-mandibular relationship record using a proprietary dual-loaded tray (Centric Tray®, Ivoclar Vivadent AG, Schann, Liechtenstein) at the first clinical visit. Definitive impressions were made with VPS in custom-fabricated trays, and the definitive maxillo-mandibular relationship record was made by recording a gothic arch tracing. Trial denture prototypes were milled in white PMMA prior to assessment at the third clinical visit. Milled denture teeth were bonded to the milled denture bases using a proprietary bonding agent to complete the definitive prostheses thereafter (181). The authors reported difficulties in treating participants with retrognathic mandibles, especially when attempting gothic arch tracings, due to interference between the trays and the retro-molar pads. 3D-printed duplicates were made from intra-oral scans of a patient's current dentures, and served as custom trays for definitive impression making and recording of the interocclusal record in another case

report (182). Trial prototypes were 3D-printed (Form 2, Formlabs Inc, Massachusetts, USA) prior to milling definitive monolithic CECDs (Harvest Dental Products LLC., California, USA) (182). Duplication of the existing prostheses helped to reduce the amount of laboratory procedures and the number of clinical appointments required for completion of the prostheses. A technical report described a workflow entitled the “Geneva Protocol” for the fabrication of milled CECDs (183). A manufacturer-independent three-visit protocol employing conventional preliminary clinical records was described, where two-stage definitive impressions were made using novel custom trays modified with integrated occlusal wax rims before being digitised and inputted into the software for CAD design.

1.4.7. CECDs: Clinical Outcomes

1.4.7.1. Number of Clinical Appointments

Manufacturer protocols for CECDs ranged from two-visits, such as the AvaDent® Digital Denture system (184, 185), to four visits, as for the Ivoclar® Digital Denture System when a trial prosthesis was included in the workflow (181, 186). In a systematic review, the reduced number of clinical appointments required compared to conventional processing was purported to be one of the main advantages of CECDs (187). However, the number of clinical appointments necessary for fabrication of said CECDs was greater in the literature than that purported by manufacturers, with more appointments being required primarily for aesthetic purposes (188). In a cross-sectional study, a total of 5.4 appointments were required for CECD fabrication in a four-visit protocol (189). The mean number required to insert definitive prostheses using the AvaDent® Digital Denture system in a two-step protocol was 2.39 in a cross sectional study (190). A retrospective cross-sectional review was completed to assess the number of appointments required for fabrication of conventionally-fabricated CDs and CECDs (AvaDent®, Global Dental

Sciences, Arizona, USA), with 242 and thirty-nine patients receiving conventional and CECD prostheses, respectively (191). Conventionally-fabricated CDs required a significantly greater number of clinical appointments when compared with CECDs. Half of the conventional prostheses required six or more clinical visits compared to only 5% of the CECDs. In a retrospective pilot study involving ten participants, the mean number of clinical appointments required for fabrication of CECDs with the Ivoclar® Digital Denture System was found to be 4.6 (188). This figure was similar to that of conventional processing described earlier, but the authors reported their results may have been affected by the level of experience of the operators fabricating the CECDs (189).

1.4.7.2. Prosthesis Survival

Survival of CECDs was defined as the time period between insertion and replacement (188). In a university setting, a retrospective pilot study of ten maxillary and mandibular CECDs fabricated using the Ivoclar® Digital Denture System demonstrated a 100% survival rate of CECDs over a 2.54 year study period (188). In a cross-sectional study of forty-eight participants investigating the clinical performance of CECDs (AvaDent®, Global Dental Sciences LLC, Arizona, USA), one implant-supported overdenture fractured, equating to a fracture rate of 2.08% (190). Thus, the rate of CECD prosthesis fracture was determined to be comparable to that of conventional dentures in a systematic review of the clinical complications associated with CECDs (192). Overall, the reported total incidence of remakes of CECDs was less than 10% (192).

1.4.7.3. Retention

A systematic review showed that a lack of retention was the second most common complication for maxillary and mandibular CECDs (192). In a cross-sectional retrospective study of AvaDent® maxillary and mandibular CECDs, 16.66% of participants reported inadequate denture retention to be a common complication and required relining (166). The authors postulated that the high prevalence of poor retention may have been due to improperly-made definitive impressions, operator inexperience, or the omission of the posterior palatal seal in the maxillary CECD CAD, however, none of these variables were accounted for in the study (166). A prospective cohort study involving monolithic maxillary and mandibular CECDs fabricated using the AvaDent® system in a two-visit protocol showed that 50% of participants reported inadequate retention at insertion (193). Furthermore, in a prospective pilot clinical trial of milled CECDs, two of five mandibular CECDs (Wieland® Digital Denture System) were reported to be loose at insertion, and required relining (189).

1.4.7.4. Aesthetics

The aesthetic result of CECDs relies on the comprehensive assessment of the CAD virtual tooth arrangement. This was found to be difficult and resulted in unpredictable aesthetic results in a clinical study of CECDs which omitted the trial denture visit (195). The objective assessment of the proposed virtual tooth arrangement in CAD previews was acknowledged as a unique complication of CECDs (192, 195). Aesthetic complications with CECDs have been reported in several studies (136, 166). In a pilot clinical study of the Ivoclar® Digital Denture System with five participants, two instances of midline discrepancies were recorded, incorrect denture tooth size was recorded in two CECDs and one case had an incorrect horizontal and vertical overlap of the anterior teeth (188). The optional trial dentures were not used in the study protocol (188). A high incidence of aesthetic corrections was also reported in another pilot clinical trial, of five

participants with CECDs using the Wieland® Digital Denture System (189). The numbers of complications were not reported, but aesthetic corrections were required due to midline deviations, errors with the occlusal plane orientation and excessive lip support (189). In a literature review, it was recognised that omission of the trial denture step precluded the clinical evaluation of the CDs by operators and patients prior to final manufacturing of the prostheses (196). It was suggested in a cross-sectional study examining the clinical performance of monolithic CECDs (AvaDent®, Global Dental Sciences LLC, Arizona, USA) that the omission of a trial denture step was a reason for high complication rates with respect to aesthetics (166). Therefore, a try-in appointment was recommended for all CECDs to negate these unwanted aesthetic outcomes that resulted in costly remakes of CDs (195). Difficulties in communication with the dental technician regarding aesthetic requests have also been reported in numerous case reports (178, 183, 185, 189, 193, 194, 197, 198).

1.4.7.5. Occlusion

In a prospective pilot clinical study investigating the Wieland® Digital Denture System, CECDs required intra-oral adjustment in all participants to achieve the bilateral balanced occlusal scheme (189). In a systematic review of clinical complications associated with CECDs, the incidence of occlusal vertical dimension (OVD) and centric relation (CR) errors reported to be 11.32% and 7.32%, respectively. No reasons for these inaccuracies were investigated (192). The application of virtual articulators to simulate mandibular movements for CECDs is unfounded in the literature (199), unlike fixed restorations (200, 201), and requires further investigation. Digital casts of the edentulous arches are mounted in the virtual articulator according to average measurements and in an arbitrary manner relative to the transverse hinge axis (200, 202, 203). Thus, performing a clinical remount procedure prior to fitting of a CECD was deemed beneficial

by investigators to overcome these limitations and develop a fully balanced occlusal scheme in a clinical study examining the clinical and patient-related outcomes related to monolithic CECDs (AvaDent®, Global Dental Sciences LLC., Arizona, USA) (193).

1.4.7.6. Patient-Related Outcome Measures

A literature review concluded there were more favourable patient-related outcome measures (PROMs) for CECDs when compared with conventional CDs (127). In a cohort pilot study, a prospective assessment of patient-centred outcomes was completed for nine implant-retained, milled mandibular overdentures and five mandibular CECDs (AvaDent®, Global Dental Sciences LLC., Arizona, USA) over a twelve month study period (193). A 100mm visual analog scale (VAS) was used to measure twelve outcomes at insertion and one year follow-up, including retention, stability, overall aesthetics, occlusion, speech, OVD and intimate adaptation of the denture bases (193). Three participants withdrew from the study due to dissatisfaction with aesthetics, occlusion, and comfort. 79% of participants were satisfied with their CECDs overall, however, approximately half of them did not rate retention, stability, and adaptation of the bases as “good” or “excellent”. With respect to the presence of localised mucosal trauma, and the treatment time to denture insertion, statistically significant improvements in participant ratings were recorded from baseline to one year review for the CECDs. Five participants reported minor complications with regard to loss of retention, excessive wear of denture teeth, and the requirement for extra clinical visits (193).

A retrospective survey of patient preferences and satisfaction with CECDs (AvaDent®) fabricated in a university setting were evaluated using a ten-item questionnaire on denture retention, aesthetics, comfort, denture hygiene, and patient expectations (190). A response rate

of 38% of fifty participants was reported, and involved forty-nine maxillary and thirty-five mandibular CECDs. The mean period of wear was twenty-one months. Patient expectations with their prostheses were fulfilled for 63% of respondents, with overall patient satisfaction reported of 74%. 78.95% were satisfied with the aesthetic outcome, while 78.57% rated the new CECDs as better than their previous set. 68.42% rated the CECDs as comfortable, and would recommend the treatment to others. 57.89% reported an improvement in speech and chewing abilities with the digital CDs. Just over half stated their CECDs fit well and stayed in place during function.

In a prospective pilot clinical trial involving five participants, patient-related outcomes of two different methods for CECD fabrication were assessed (189). Two pairs of dentures were fabricated for each participant in a four-step protocol (Wieland® Digital Denture System). One trial denture was milled in PMMA from the CAD design and was evaluated for both intervention groups. Definitive denture bases were fabricated either by milling or injection-molding using the same CAD data. No major functional complications were observed for either group. Participants scored each denture equally for the aesthetic result, however, minor complications regarding incorrect midlines, discrepancies with occlusal plane angulation, excessive lip support, and excessively small buccal corridors were reported at the trial stage (189).

1.5. CECDs and Conventional CDs

1.5.1. Post-Insertion Adjustments

In a retrospective chart review comparing conventionally fabricated CDs and CECDs (AvaDent®, Global Dental Sciences LLC, Arizona, USA), the number of post-insertion appointments required for conventional dentures was significantly higher than CECDs (191). Of

note, pre-doctoral students were required to conduct three post-operative appointments following denture insertion at the university, and thus, may have impacted their results. On the other hand, a clinical study investigating the number of post-insertion appointments required for CECDs (AvaDent® CORE) and injection-molded CDs (SR Ivocap® Injection, Ivoclar Vivadent AG, Schaan, Liechtenstein) showed no statistically significant difference between the number of appointments after denture insertion over a study period of one year (204). In a retrospective clinical study involving thirty-two edentulous participants in a university clinic no significant differences were detected in the number of post-insertion adjustments for areas of excessive mucosal pressure, relines, or repairs between conventional CDs and CECDs (AvaDent® and Wieland® Digital Denture Systems) (170). Inconsistencies in the data of these studies might be due to several variables, including participant personality types (205-207), unfavourable anatomy, or varied expertise of clinicians (166). A mean of 2.08 post-insertion adjustment visits were deemed necessary for CECDs, with 33% of participants in a clinical study attending for one such visit, 29% for two, and 12% not requiring an adjustment visit (166). In another clinical study, an average of 3.3 (range 0-10) prosthesis adjustments were necessary over a one year period (193). In a retrospective pilot study involving five participants, the presence of localised mucosal trauma was cited as the major complication for CECDs (Ivoclar® Digital Denture System) more than four weeks post-insertion (188). No reasons were provided by authors as explanation for this finding.

1.5.2. Chairside and Manufacturing Time

Milled CECDs were reported to be more efficient compared to conventional CDs with respect to clinical chairside time (139). Time savings ranging from one hour to 205 minutes were noted in clinical studies (204, 166). A significantly greater clinical time was recorded for conventional

CD fabrication compared to CECDs (AvaDent®) fabricated in a two visit protocol, where the total clinical treatment time for the fabrication of the conventional CDs was 3.5 hours longer (185). Similarly, a clinical study involving twelve pre-doctoral dental students reported significant differences in the clinical time spent fabricating conventional CDs and CECDs (AvaDent®) (208). Mean differences of 108 minutes for a single arch and 233 minutes for CD pairs were recorded, with CECDs requiring clinical less time (208). In a prospective, crossover RCT, CECDs (Baltic Denture System®) required one hour less chairside time and five hours less laboratory time for fabrication compared to conventionally fabricated CDs (209). In a prospective clinical trial comparing both prosthesis types in a pre-doctoral setting, the average clinical time to fabricate conventional compression-molded CDs was 205 minutes longer than CECDs (AvaDent®) fabricated in a two-step protocol, and was deemed statistically significant (185). Conversely, no significant differences in the production time and overall time post-insertion between conventional and CECD groups (AvaDent®/Wieland® Digital Denture Systems) were found in a university clinic (170). In a cross-sectional study, the reduced chairside time required for CECDs was offset by the time spent in communication with the laboratory during the fabrication process (166).

1.5.3. Chairside and Manufacturing Costs

In a recent meta-analysis, conventional flask-pack-press CDs were found to be more cost-effective than milled CECDs with respect to clinical costs (139). However, milled CECDs were more cost-effective from a laboratory perspective, and overall (139). A cost comparison of AvaDent® CECDs and heat-polymerised conventional CDs revealed that while the material costs for the CECDs were higher, overall, the laboratory costs were lower (208). This result was attributed to a greater technical workload with conventional processes (208). In a retrospective

analysis, the costs of conventional CDs and CECDs fabricated by a specialist prosthodontist were evaluated from the clinical records of thirty-two patients receiving conventionally fabricated CDs, AvaDent® and Wieland® Digital Denture® prostheses over a four year period (170). Costs were divided into treatment costs (clinician's fees and materials), dental laboratory costs, and total costs. While no differences in the clinical costs were recorded, the results indicated that the laboratory costs and total costs associated with the conventionally fabricated CDs were significantly higher than the Wieland® Digital Denture® CECDs, which in turn were significantly higher than the costs associated with the AvaDent® prostheses (170). One factor that resulted in the laboratory and total costs of the Wieland® Digital Denture® CECDs being more expensive was due to the inclusion of a trial prosthesis (170). A retrospective comparative analysis of the costs associated with CECDs (Ivoclar® Digital Denture System) fabricated in a four-visit protocol and conventional CDs requiring five visits indicated that the CECDs were significantly less expensive (210). The use of 3D-printed record bases and the laboratory procedures being completed within the institution were attributed to lowering the costs (210).

1.5.4. Trueness of Fit

Trueness was defined as the “closeness of agreement between the arithmetic mean of a large number of test results and the true or acceptable reference value” by the International Standard Organisation (211). Trueness of fit refers to the fit of the intaglio surface of CECDs relative to conventional CDs (212), or in other words, how closely the fitting surface of a CECD prosthesis matches that of a conventional prosthesis (213). An in-vitro study was carried out to compare the trueness of fit of milled CECDs (AvaDent®) with injection-molded and conventionally-processed dentures (214). Digital scans of the fitting surface of the dentures were superimposed on a reference master model of the edentulous arch seven days after processing,

and after a period of immersion in artificial saliva for twenty-one days. All groups demonstrated clinically acceptable trueness of fit (214). No significant differences in trueness were noted between the specimens immediately after processing. Conventionally fabricated CDs demonstrated a significant improvement in trueness of fit following immersion in artificial saliva for three weeks (214). With the exception of the maxillary tuberosities, the CECD group demonstrated the closest fit, particularly in the vestibular flange area, with negative values measured indicating compression of the tissue in these areas (214). A meta-analysis investigating the trueness of fit of milled CECDs, printed CECDs and conventionally fabricated CDs showed the trueness of printed CECDs to be significantly better than the conventionally fabricated CDs (139). No significant difference was shown between milled CECDs and conventionally fabricated CDs. It was concluded that all fabrication methods under investigation produced dentures with a clinically acceptable trueness of fit (139). In an in-vitro study comparing the fit of milled denture bases (AvaDent®) to a reference master cast with compression- and injection-molded bases, the greatest amount of misfit was found on the intaglio surface at the posterior palatal border and border seal areas when using the silicone replica technique (215). An in-vitro study was conducted to investigate the surface adaptation of four commercially available CECDs (AvaDent®, Baltic Denture System®, Whole You Nexteeth, Wieland® Digital Dentures®) and conventionally fabricated CDs (216). The master casts and corresponding denture bases were digitised and matched, and incongruences were measured. All CECDs demonstrated lower mean incongruences than the conventionally fabricated dentures. The fit of AvaDent®, Wieland® Digital Dentures® and Whole You Nexteeth prostheses were significantly better than the conventionally fabricated CDs. In addition, thermocycling had no impact on the precision of fit for any of the prostheses (216). A clinical study evaluated the tissue surface adaptation of denture bases fabricated by milling, DLP and conventional fabrication techniques by measuring the thickness of indicator material remaining on the fitting surface after placement intra-orally (217). Both CECD

bases demonstrated more intimate tissue adaptation in the mandibular lingual flanges than conventional CDs. The DLP maxillary CDs exhibited more intimate tissue adaptation at the residual ridge and mid-palatal suture compared with conventionally fabricated denture bases. However, no statistically significant differences in the absolute tissue surface adaptation were noted among the three denture base fabrication techniques for either arch (217).

1.5.5. Retention

A systematic review concluded that CECDs exhibited greater retention than conventionally fabricated CDs (139). In a clinical study, the retention of maxillary milled CECD bases (AvaDent®) were compared with conventionally fabricated denture bases, where each denture was pulled vertically using a digital force gauge three times at ten-minute intervals (126). Significantly higher retention values were observed for the milled CECD bases, with the authors attributing the results to the high dimensional stability of the pre-polymerised PMMA CAM blank (126). In another clinical study, significantly higher retention was measured using a digital force gauge for milled maxillary denture bases when compared with heat-polymerised PMMA denture bases (218). In a pilot clinical trial, better retention of milled maxillary CECDs (Wieland® Digital Denture System) was reported by participants compared to conventional injection-molded CDs using a six-point questionnaire (189).

1.5.6. Mechanical Properties of Denture Base Materials

An in-vitro study was conducted to compare the mechanical properties of pre-polymerised PMMA employed for CECDs (AvaDent®) with conventional heat-polymerised PMMA resin specimens using nanoindentation tests, three-point bending tests, and laser profilometry (161).

The results indicated that both groups demonstrated a similar flexural modulus, but the pre-polymerised PMMA had a superior ultimate strength, yield point, strain at yield point, and toughness compared to the conventional heat-polymerised PMMA samples. Another in-vitro study showed that pre-polymerised PMMA resin had a higher elastic modulus, Young's modulus, and plastic energy than heat-polymerised PMMA resin (161). A further in-vitro study demonstrated that pre-polymerised PMMA resin had a significantly higher flexural modulus and surface hardness than conventional heat-cured PMMA (219). In addition, gas chromatography showed that pre-polymerised PMMA specimens had a lower concentration of residual free monomer than conventional heat-polymerised PMMA specimens, and the authors postulated that this result was attributable to the method of polymerisation under high pressure (219). A meta-analysis comparing the mechanical properties of CECDs and conventionally fabricated denture bases showed that CECD denture bases had significantly higher flexural strength, flexural modulus, yield strength, and surface roughness than the conventionally fabricated denture bases (139). The flexural strength and flexural modulus of milled denture bases was significantly greater than 3D-printed denture bases (139). An in-vitro study comparing three PMMA resins used for CECD fabrication with a compression-molding resin and auto-polymerisation material showed that the mechanical properties of the CECD specimens were similar to the other groups in terms of flexural strength, nanohardness elastic modulus and surface hardness (220).

Hardness is a measure of the resistance to localised plastic deformation induced by either mechanical indentation or abrasion (13). In a systematic review and meta-analysis, the hardness of milled CECDs was not significantly different to conventional pack and press and injection-molded PMMA, or to 3D-printed dentures (139). The results of another in-vitro study showed that milled denture bases (IvoBase® CAD, Ivoclar Vivadent AG, Schaan, Liechtenstein)

demonstrated lower hardness values when compared with conventional pack and press and injection-molded denture bases (221). In contrast, another in-vitro study showed that milled denture bases (Ivobase® CAD, Ivoclar Vivadent AG, Schaan, Liechtenstein) had greater surface hardness than injection-molded denture groups (168). However, no differences were observed between milled and pack and press groups. An in-vitro study comparing milled and 3D-printed PMMA denture bases with conventional pack and press and injection-molded denture bases reported that the injection-molded group demonstrated the lowest surface hardness (222).

The breaking load, fracture toughness, and elastic moduli of commercially available CECD base resins were compared to conventional heat- and auto-polymerising resins in-vitro (195). The five pre-polymerised resins investigated included AvaDent®, Baltic Denture System®, Vita Vionic, Whole You Nexteeth, and Wieland® Digital Denture samples (195). The Wieland® Digital Denture specimens demonstrated a statistically significant increased mean breaking load (fracture resistance) and higher mean fracture toughness versus the conventionally cured PMMA controls (195), where the higher fracture toughness indicated slower crack growth in this group. All CAD/CAM resin specimens demonstrated significantly higher elastic moduli compared to heat-polymerised resin, with the exception of the AvaDent® specimens (195).

1.5.7. Tooth Movement During Final Processing

Movement of the denture teeth may occur during closure of the flask when fabricating dentures in the conventional manner and this has been attributed to the natural setting expansion of gypsum (223) and the pressure exerted upon closure of the flask (224, 225). Denture tooth movement of five CD processing techniques (pack and press, fluid resin, injection-

molding, and CAD/CAM milling) were compared (226). Digital images of the processed dentures were made before and after processing. The tooth movement was assessed by superimposing the images and measuring at sixty-four sites. The results indicated that the degree of tooth movement of the milled CECDs was significantly less than the other groups. Increased positive occlusal tooth movement was found for compression techniques (pack and press and injection-molding) when compared with the fluid resin technique and CAD/CAM milling. The resultant effect of this positive movement resulted in an increase in OVD, necessitating a clinical remount procedure (226).

1.5.8. Occlusion

No significant differences in the quality of tooth arrangement, occlusion, or accuracy of CR records were recorded using a five-point ordinal scale when CECDs (AvaDent®) and conventional CDs were compared clinically for fifteen participants (185). A preference for CECDs over conventionally-fabricated prostheses was demonstrated with respect to occlusion by participants in a pilot clinical study investigating patient-centred outcomes of CECDs (Wieland® Digital Denture System) (189). In a prospective clinical trial comparing the occlusal forces generated with milled and 3D-printed CECDs and conventionally-fabricated CDs using a digital occlusal force analyser, occlusal parameters for CDs were found to be affected by the fabrication technique and occlusal scheme (227). These parameters included force distribution, force differences between right and left sides of the mouth, maximum bite force, and force centralisation (227). CECDs retained the occlusal schemes better than conventional prostheses during the fabrication process, with 3D-printed dentures with bilateral balanced occlusion and lingualised occlusion providing centralisation of forces, better distribution and high maximum occlusal force percentage (227).

1.5.9. Aesthetics

No significant difference between the aesthetics of CECDs (AvaDent®) or conventional CDs were found in a pre-doctoral clinical study (185). The criteria by which the aesthetic result was assessed were not explained by the authors, however, subjective patient factors impacting the evaluation of aesthetic parameters may have been responsible for this finding. A pilot clinical study indicated that clinicians felt a preference for the aesthetics of conventional CDs (189). However, when conventional artificial denture teeth were fixed to a milled CECD base, no significant differences between milled CECDs and injection-molded CDs were found (189). A meta-analysis showed that the spectrophotometric colour stability of pink PMMA for milled CECDs and conventionally-fabricated CDs was similar in terms of colour difference after thermocycling and immersion in various ageing media such as coffee and wine, and was superior to 3D-printed CECDs (135). Additionally, the colour stability of the pink PMMA of injection-molded CDs was superior to CECDs. The tooth coloured PMMA had similar colour stability in all groups (135). In a case report, milled bases for overdentures had unsatisfactory aesthetic outcomes regarding the alignment, shape, and size of maxillary overdenture teeth, with the patient preferring a conventional alternative (228).

1.5.10. Patient-Related Outcomes Measures

There is a paucity of studies comparing PROMs of CECDs with conventionally fabricated CDs (135). In a three-arm, single blind, randomised controlled trial over a six month study period, patient satisfaction and prosthesis retention with heat-polymerised conventional CDs, 3D-

printed maxillary CECDs and milled maxillary CECDs were compared (144). The patient-reported outcomes were assessed over five domains – functional complaints, overall masticatory ability, masticatory ability with different food types, effect on mental and daily life, and overall denture satisfaction – in a questionnaire. Retention was measured concurrently using a force gauge, with significantly greater values recorded at six months compared to baseline for all groups. However, no statistically significant differences were found between the other patient-reported outcomes for each denture group throughout the study period. These results suggested that maxillary denture fabrication techniques had no influence on patient satisfaction (144).

A prospective, crossover, double-blind RCT was conducted to investigate the time-dependent change in OHRQoL and the time for fabrication of CECDs (Baltic Denture System®) compared to conventionally fabricated CDs (209). Sixteen participants were provided with one CECD in a two-visit protocol and one CD fabricated in a conventional five-visit workflow in a randomised order. No differences in OHRQoL scores were found between the prostheses using the German version of the Oral Health Impact Profile (OHIP) questionnaire at baseline, fourteen days, and three-months post-denture insertion. A number of limitations of the study design were acknowledged, namely the small sample size, inclusion of participants with favourable maxillo-mandibular relationships only, and the absence of a wash out period. In a prospective, single-blind, clinical trial, conventional compression-molded CDs were inserted and an edentulous OHIP assessment (OHIP-20E) was completed by the participants at two weeks, one, two, and three months (229). CECDs with a milled denture base were inserted one week after removal of the conventionally fabricated dentures, and the same assessment carried out after similar time intervals. A chewing efficiency test was completed three months after wearing each CD using absorbance spectrophotometry. OHIP-20E scores were higher for CECDs than conventionally

fabricated CDs in all aspects, with statistically significant differences found for psychological discomfort and total score. There were no significant differences with respect to chewing efficiency. The results indicated that the therapeutic efficiency of CECDs with milled bases was equal to conventionally fabricated CDs in terms of patient satisfaction and chewing efficiency (229).

A prospective cohort study examined prosthodontist-reported clinical outcomes and PROMs of milled CECDs (AvaDent®) over a one year study period (193). The clinical outcomes of retention, stability, extensions, lip support, and patient-centred outcomes of tightness, absence of rocking, bulk, and aesthetics, were independently assessed using a visual analog scale at the time of fit and at one year review (193). The CECDs were rated better by the participants than by the clinicians. A retrospective cohort study investigated PROMs of milled CECDs (AvaDent®), including improvement on previous dentures, ability to chew, aesthetics, speech, ease of cleaning, fit, fulfilment of participants' expectations, comfort, recommendation to others, and overall satisfaction (190). A patient questionnaire indicated that participants were satisfied with their milled CECDs; the milled CECDs did not differ significantly from their previous conventionally fabricated CDs (190). A prospective, crossover, non-randomised clinical study was conducted in a pre-doctoral clinic to compare milled CECDs (AvaDent®) and conventional compression-molded CDs with respect to total clinical time required for fabrication, clinical outcomes and PROMs for fifteen participants (185). Two sets of CDs were fitted for each participant. Prosthesis quality was independently assessed by two faculty members for tooth arrangement, fit, denture base contour, retention, stability, occlusion, aesthetics, and prognosis. PROMs, including assessment of fit, stability, aesthetics, ability to chew, comfort, and operator preference, were assessed using satisfaction questionnaires. A validated, five-point Likert scale

(230) was used for evaluation. Significantly higher average clinical scores were observed for milled CECDs for denture base contour, fit, extension, stability, and retention. Significantly higher average participant response scores were recorded for the milled CECDs than for the conventionally fabricated CDs for comfort, chewing efficiency, and prosthesis preference. Both pre-doctoral students and the participants preferred the milled CECDs to the conventional prostheses. Limitations of this study were acknowledged, namely that the prosthesis type was easily recognised, so it was not possible to blind the faculty evaluators to the prosthesis type. Additionally, participants were chosen based on favourable edentulous arch anatomy. Therefore, the outcomes could not be generalised to include patients with advanced resorption of the edentulous ridges.

1.6. Edentulous Arch Impressions

1.6.1. Conventional Impressions

A dental impression is defined as “a negative imprint or a positive digital image display of intra-oral anatomy; used to cast or print a 3D replica of the anatomic structure that is to be used as a permanent record or in the production of a dental restoration or prosthesis” (13). Definitive impressions for CDs should be accurate replications of the edentulous arches and denture bearing areas (137, 213) and register the dynamic movements of the soft tissues at the denture borders. In this way, the impression contributes to the degree of intimate contact of the base with the denture-bearing tissues both at rest, and during function (28).

Impressions for CDs are made using one- (simplified) or two-stage protocols (Fig.1.3) (232-234), with the former being described in classical publications (235). The two-stage protocol

involves preliminary impressions, typically made with irreversible hydrocolloid in a stock tray (235), followed by definitive impressions made using a variety of materials in a custom tray (236). Definitive impressions may be made using open- or closed-mouth techniques, in one or two steps (232-234, 237). The two-step impression technique involves border molding with a low-fusing impression compound (238) followed by impression making of the entire denture bearing tissues with a low viscosity material (239). Border molding is defined as “the shaping of impression material along the border areas of an impression tray” (13). It aims to determine the appropriate extension of the flanges of a prosthesis through recording the functional border movements performed by the patient or manual manipulation of the tissues by the operator (13, 233). Numerous techniques have been described for the low-viscosity impression in the two-step technique (240), and have been grouped as follows: mucostatic impressions (241), mucocompressive impressions (43), selective pressure impressions (232), functional impressions (242), and neutral zone impressions (243, 244) (Fig.1.3). Alternatively, border molding and definitive impression making are completed simultaneously using a one-step technique (231, 238, 245).

Numerous materials are recommended for making impressions (246), including impression plaster (247), resinous wax (248, 249) zinc oxide eugenol (ZOE) (250), irreversible hydrocolloid (sodium alginate) (251), polysulfide rubber (252), addition silicone (231, 253), and polyether (238) (Fig.1.4). Vinylpolysiloxane (VPS) was reported to be the most commonly used material for definitive impressions for CDs in postdoctoral prosthodontic programmes in the United States of America (239). A recent Cochrane review assessed the effects of various final impression materials and techniques used to make CDs and RDPs on the retention, stability, comfort, and quality of life (240). While there was a high risk of bias with the eight randomised controlled trials

included in the review, it was concluded that there were no clear advantages when different techniques and materials for edentulous arch impressions were compared (240).

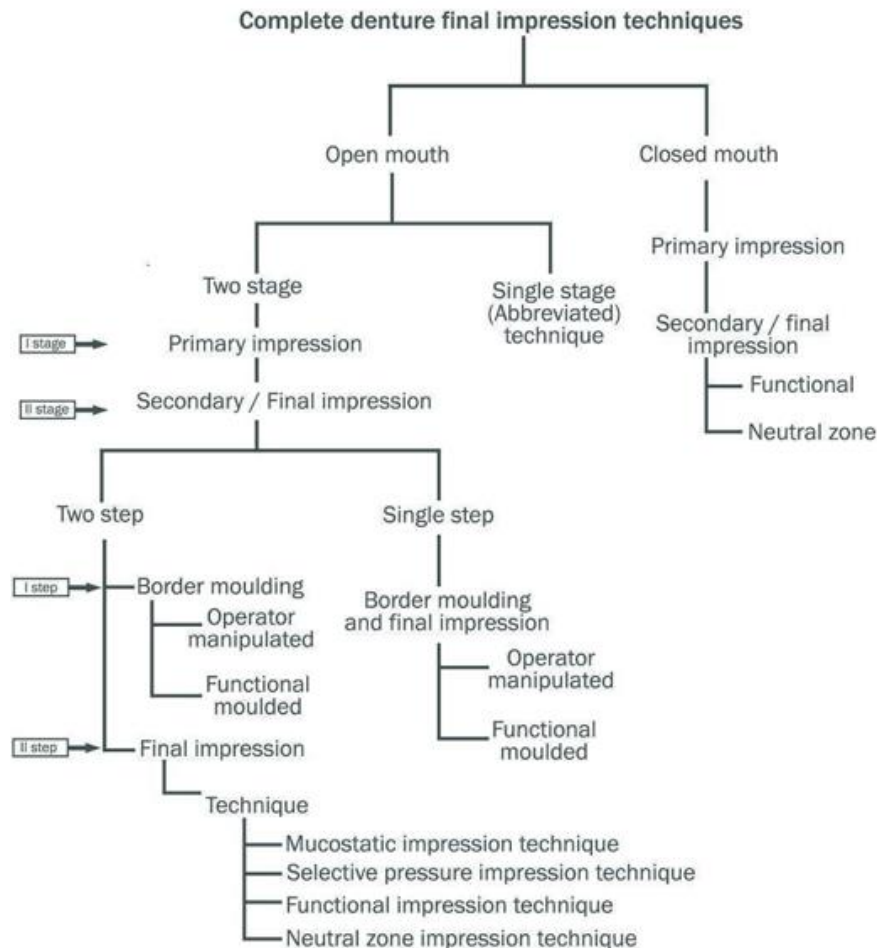


Figure 1.3. Complete denture final impression techniques (from Jayaraman et al. 2018 (240))

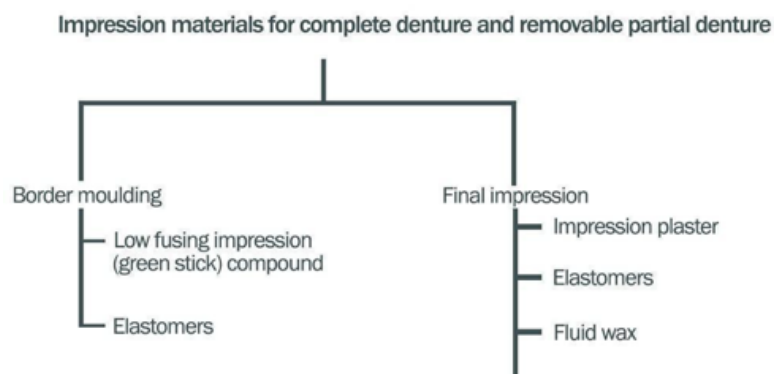


Figure 1.4. Impression materials for complete denture and removable partial denture (from Jayaraman et al. 2018 (240))

When making impressions of edentulous arches, the appropriate management of mobile compressible and immobile uncompressible soft tissue is challenging. Edentulous stock trays, made from metal or plastic, are used in a variety of shapes and sizes for preliminary conventional impressions (43, 254, 255). In an in-vitro study examining the influence of tray choice, impression material and time on the dimensional accuracy of dental casts, plastic and perforated metal stock trays were not found to contribute to distortion of the resultant dental cast (255). Impression materials like VPS (255-257) and polyether (258) were shown to be dimensionally stable over time, however, they can be distorted by inappropriate storage or inadvertent force being applied to the material or tray (259). In an in-vitro study, polysulfides exhibited the greatest amount of permanent deformation on application of a tensile force in comparison to silicone and polyether impression materials (260). Separation of impression material from the tray is usually due to the improper use of tray adhesive (259). Distortion and separation of the impression can result in inaccurate master casts (255, 261). The impression making procedure may be an uncomfortable experience for the patient (262, 263); patients have reported the taste and smell of impression materials objectionable (264). Difficulties managing gag reflexes in adults and children were reported (265).

Results of recent clinical studies suggested that simplified protocols for making edentulous impressions produced satisfactory support, stability, retention, and effective function of CDs (266, 267). These techniques included hydrocolloid impression material in stock tray functioning as the definitive impression to fabricate the master cast, thereby eliminating the need for a custom tray and second impression appointment (268). A randomised trial investigated the influence of this protocol for complete denture fabrication on prosthesis quality and patient perception for forty-two participants in comparison to a protocol incorporating a two-stage

impression made in a custom tray (268). No differences with respect to oral health-related quality of life, denture quality and general satisfaction were found between the groups. A single-centre, single-blind, crossover RCT compared the effect of conventional mandibular CDs fabricated using two different impression methods on participant-reported outcomes (269). A simplified technique using a stock tray with alginate and a conventional two stage protocol involving VPS impression made in a custom tray that was border molded with impression compound were compared. A wash out period of one month was set. The primary outcome measure was general participant satisfaction and the secondary outcome was OHRQoL, measured using the Japanese OHIP-EDENT questionnaire. No significant differences were noted between the groups. A four-armed, double-blinded, RCT investigated the influence of procedural variations during the laboratory phase of complete denture fabrication on patient satisfaction and denture quality for forty participants (270). Conventional dentures fabricated in a protocol utilising irreversible hydrocolloid (sodium alginate) in a perforated stock tray as the definitive impression were compared to those fabricated from two-stage definitive impressions in custom trays. No statistically significant differences were reported for patient satisfaction or for the prosthodontist's ratings of denture quality in terms of extensions, interocclusal space, occlusion, and overall quality (270). Similarly, a systematic review found no significant differences in participant ratings for general satisfaction or OHRQoL between CDs fabricated using a two-stage impression technique with custom trays and a single-stage technique with irreversible hydrocolloid in a stock tray (234). No clear evidence was identified advocating the need for definitive impressions in a custom tray for CDs (234).

1.6.2. *Intra-Oral Scanning (IOS)*

Digital impressions made using intra-oral scans is the first step in data acquisition for digital CE workflows in prosthodontics (121). The objective of IOS is the direct digital recording of the 3D geometry of an object. IOS involves the use of a handheld 3D-camera, the intra-oral scanner, to obtain optical images of the dentogingival tissues, dental arches, or implant scan bodies. Acquired images are converted into a virtual 3D cast using a computer and associated software (92, 271, 272). Making a digital impression involves holding the camera at right angles to the object (273), within the focal range of the camera, and moving it in a specific pathway, termed the scanning strategy, according to the manufacturer's instructions. The system generates a digital 3D model by merging (stitching) the two dimensional images, reflecting the configuration of teeth and soft tissues in colour (271).

The Standard Tessellation Language (STL) file format is the most widely used format for IOS (271). STL describes a succession of triangulated surfaces where each triangle is defined by three points and a normal surface (271). Projection of lights are recorded as individual images and compiled by the software to form a composite 3D image (271). Ultrafast optical sectioning and confocal microscopy are technologies employed by some scanning systems. Confocal microscopy is an imaging technique based on the acquisition of focused and non-focused images from selected depths (264). Variations in the focal plane of the pattern over a range of positions are recognised, when a fixed spatial relation of the scanner to the object of interest is maintained (271). Quick scanning speeds reduce the influence of relative movement between the scanner probe and teeth (274, 275). The sharpness of the scanned object is detected to infer distance to the object that is correlated with the focal length of the lens (271). Successive images made at

different focal lengths and aperture values, and from different angles reconstruct the teeth and soft tissues (271).

1.6.3. *Intra-Oral Scanners*

Several intra-oral scanners are available commercially. Trios® is a powder-free, non-contact, structured light scanning system introduced in 2011 by the 3Shape company (3Shape, Copenhagen, Denmark) (272), and currently marketing its fifth generation product (276). Trios® is an open system that permits the export of 3D data either as STL or encrypted files. Proprietary encrypted files can only be manipulated with 3Shape's specific CAD software. Shade matching is automated, which permits the acquisition of high-definition colour photographs. Other scanning systems include iTero® (Align Technology Inc., California, USA) (277) and Primescan® (Dentsply Sirona Inc., North Carolina, USA) (278).

1.6.4. *IOS: Advantages*

IOS eliminated the need for direct recording of intra-oral structures with conventional impression making (279), thereby overcoming limitations with respect to tray selection, manipulation of materials and the shortcomings of physical impressions (280, 281). A saving was made on the monetary cost of conventional impression materials and trays (279). There was no requirement for disinfection of the impression (279). The potential for allergy to dental impression materials was no longer a consideration (282). The working time required for IOS with three different intra-oral scanners was reported to be less for a single abutment, short-span fixed dental prosthesis, and a full-arch prosthesis when compared to conventional impression materials in-vitro (283). IOS enabled the operator to modify digital impressions by erasing and

correcting the acquired images without the need to repeat the entire impression process (284). IOS facilitated a direct passive recording of the edentulous arches by avoiding physical contact with the denture bearing tissues (282-287). The application of pressure to the tissues was avoided, thus recording them in a state of rest in a mucostatic impression (288). IOS was shown to improve patient comfort when compared with conventional impressions (281, 289), particularly for patients with trismus or limited mouth opening (290, 291) and for those with a hyperactive gag reflex (292-294). Adopting an entirely digital workflow including IOS positively influenced the prosthodontic management of young patients with special needs via a successful cooperation strategy (295). A systematic review examining patient-centred outcomes reported that digital impressions were more comfortable, led to reduced anxiety, and caused less nauseous sensations when compared with conventional impressions for implant- and tooth-supported fixed dental prostheses (284). A randomised controlled trial comparing patient-centred outcomes during digital and conventional impressions for single tooth implant-supported crowns recorded a greater overall patient preference for the digital workflow with respect to convenience, speed, and overall satisfaction (296). Another clinical study also showed patient preference for complete-arch digital impression techniques than for conventional impressions (297). IOS allows direct transfer of data to the dental production laboratory, with savings in associated time and cost (298). A significant time saving was noted in foregoing the production of stone casts, and a cost saving on materials was observed (208, 299, 300). Archiving of digital STL files facilitated storage requirements of clinical records because the need to store gypsum casts was eliminated (289, 299). The ability to capture the colour of the soft tissues was advantageous to facilitate visualisation of the posterior extension of a maxillary denture base that might otherwise be difficult on a gypsum cast (292, 301).

1.6.5. IOS: Disadvantages

The implementation of IOS is limited by the high initial cost in acquisition of the equipment and annual software licencing subscription fees (92). However, the relative cost of digital scanning over conventional impressions is related to the number of impressions being made (280). Subgingival finish lines were difficult to detect with IOS (302). IOS still demands soft tissue management with respect to gingival retraction (264). Moisture control (bleeding, saliva, crevicular fluid) is equally important with IOS as with conventional impression making (303). IOS was complicated by mandibular movement (304) and the difficulty in obtaining repeatability of scans due to the mobility of intra-oral soft tissues (305). Difficulties in stitching newly captured images with previously captured data was also a recognised difficulty (288). The practitioner requires additional training and experience in IOS techniques to become sufficiently skilled in order realise the time saving advantages (306, 307). Different scanning strategies can influence the final result (305). In addition, the size of the intra-oral scanner tip had the potential to limit intra-oral access in a clinical report detailing IOS use in the fabrication of an implant-supported overdenture (307). Complete scanning of the palatal tissue morphology in patients with a deep palatal vault may be prevented with large tips (307), resulting in possible missing data for CECD design.

1.6.6. IOS: Accuracy/Trueness/Precision

Accuracy has been defined as the combination of trueness and precision (211). Trueness with respect to IOS has been described as the deviation between digital scans of each test impression to a reference conventional impression (105, 138). Precision has been defined as the “closeness of agreement between different test results” (211), or in other words, the repeatability of the intra-oral scan (105). A recent systematic review of nineteen articles concluded that the accuracy

of digital impressions is at the same level as conventional impression methods for the fabrication of single tooth-supported crowns and short fixed dental prostheses (308). In an in-vivo study, digital impressions using intra-oral scans (iTero®, Align Technology Inc., California, USA) were more accurate for the marginal fit of zirconia crowns than silicone impressions (309). No statistically significant differences were found in-vitro in the marginal fit of zirconia four-unit fixed dental prostheses based on intra-oral scans (Lava™ Chairsides Oral Scanner (3M ESPE AG, Seefeld, Germany) and iTero™ (Align Technology Inc., California, USA)) compared to restorations fabricated from conventional polyether impressions (310). In another in-vitro study, the precision of intra-oral scans obtained using seven different intra-oral scanners was significantly better than irreversible hydrocolloid for full arch impressions for five dentate participants (311). Digital impressions obtained using Trios® (3Shape, Copenhagen, Denmark), Trios® Color (3Shape, Copenhagen, Denmark), and CEREC Omnicam® (Dentsply Sirona Inc., North Carolina, USA) intra-oral scanners reached the same high precision level for complete arch dentate impressions in-vivo as polyether and vinylsiloxaneether conventional impressions (311). The accuracy of four intra-oral scanners (CS3600®; Trios3®; Omnicam®; TrueDefinition®) in scanning a partially edentulous model with three implants and an edentulous model with six implants was investigated in-vitro (312). IOS datasets were superimposed on a reference model and onto one another using reverse engineering software, to determine trueness and precision, respectively. The trueness and precision values obtained in the partially dentate model were significantly better than those for the edentulous model for all scanners, but no statistically significant differences were found between them. Of note, the Trios3® intra-oral scanner demonstrated the best precision in the edentulous model.

Studies examining the accuracy of IOS in digitising edentulous arches were limited in number. An in-vitro study demonstrated the feasibility of IOS to record an edentulous cast, but noted significant differences in the accuracy of scans between four intra-oral scanners (Cerec AC Bluecam®, Zfx IntraScan®, iTero®, and Lava COS®) (313). Scans were superimposed and compared to reference measurements of two edentulous arch casts acquired using an industrial laser scanner. Indistinguishable and poorly traceable structures, which are characteristic of edentulous arches, resulted in incorrect stitching of the scanned images, with the greatest errors reported in palatal areas (313). A clinical study compared the trueness of maxillary edentulous impressions made with irreversible hydrocolloid, VPS, VPS modified with ZOE, and an intra-oral scanner (Trios®) to the trueness of a conventional border-molded ZOE impression (the control) (138). Mean measurements made over the impression surfaces and border areas deviated for all techniques when compared with the control, with the greatest deviations noted for irreversible hydrocolloid. Trueness of IOS was not significantly different from that of VPS or VPS modified with ZOE impressions. These results indicated that digitising maxillary edentulous arches was feasible, and yielded results comparable to conventional impression techniques (138). Another in-vivo study compared IOS with a closed-mouth simplified impression technique in a novel tray and a conventional two-step open-mouth impression technique (control) in edentulous participants (314). The control impression was made with VPS in a custom tray border-molded with modelling compound. Gypsum casts poured from the impressions were digitised and all files were superimposed using 3D analysis software. Discrepancies between the impression surfaces and the intra-oral scans were not significantly different, thereby indicating that IOS made accurate impressions of the edentulous arches (314).

An in-vivo pilot study was conducted to evaluate the suitability of an intra-oral scanner (Trios®3) to digitally record the edentulous maxillary arch and make comparisons with conventional irreversible hydrocolloid impressions (264). The impressions were digitised and compared with the IOS using 3D evaluation software. While the differences between the digital and conventional impressions in the recordings of the border tissues ranged from 219-347 microns, the clinical significance of these differences was not known (264). Another clinical study was conducted to evaluate 3D differences between intra-oral scans and conventional impressions of maxillary and mandibular edentulous arches (315). A custom tray was 3D-printed from each intra-oral scan for an impression with polysulfide elastomer which was digitised using a benchtop laboratory scanner. The STL files of the intra-oral scans and the impressions were superimposed using two-phase best-fit alignment in a reverse engineering software program. The differences between the groups were attributed to the mucosal deformation as a result of the impression technique (-0.02 ± 0.05 microns) and not to an inaccuracy in the intra-oral scanning technique. No statistically significant differences between the two methods were identified (315).

1.6.7. IOS: Indications

Partial and full coverage tooth- and implant-supported prostheses have been fabricated using digital casts (310, 316). IOS is used to record the position and angulation of implants with scannable implant-level impression copings for the fabrication of partial and complete-arch implant-supported fixed dental prostheses (FDPs) (317, 318). In maxillofacial prosthodontics, the feasibility of digitising edentulous maxillectomy defects using an intra-oral scanner (3M™ True Definition; 3M ESPE AG; Seefeld, Germany) was demonstrated in a clinical study comparing its accuracy with conventional impression making (319). Clinical reports have described the

application of IOS to make a digital impression for the fabrication of removable partial dental prostheses (RDPs) (320). A case report detailed the use of IOS and 3D-printing for the fabrication of an RDP for a patient with limited mouth opening (321, 322). Similarly, the use of IOS facilitated 3D-printing of a maxillary RDP metal framework with acceptable fit and satisfactory clinical outcomes in a case report (281). IOS was applied to remove the risk of conventional impressions causing displacement and unwanted extractions of mobile teeth (323-325). IOS was utilised for preliminary impression making for the rehabilitation of an edentulous patient with microstomia, immovable soft tissues, and reduced salivary flow following surgical management of a squamous cell carcinoma of the lower lip (326). Primary maxillary and mandibular casts were 3D-printed to fabricate a custom tray and make definitive conventional impressions. Despite numerous case reports outlining the efficiency of IOS in removable prosthodontics, a recent literature review highlighted the need for higher quality clinical studies to clarify IOS protocols that would yield reliable data (327).

The feasibility of making satisfactory intra-oral scans of edentulous arches was established in several studies (328-334), but difficulties were acknowledged (335). It is most challenging to produce accurate scans of moveable soft tissue (336). In addition, there are insufficient fixed reference points in the edentulous arches for the intra-oral scanner to identify (337), the stitching process involved more time and the data file sizes were large (335). Scanning of the mandibular edentulous arch is made difficult as a result of tongue movement. Due to these difficulties, the routine use of IOS for edentulous arches was not recommended (317, 322).

Scanning strategies for edentulous arches influenced the precision and trueness of the scans in-vitro (338), where the scanning strategies aimed to facilitate effective stitching of the digital

images (301, 315, 338). It was recommended to scan the vestibules in one smooth movement in-vivo (339) to minimise changes in the tissue position that could be generated from a back-and-forth movement of the scanner head (198, 288), especially where a minimal amount of attached mucosa existed (198). Retraction of the mobile soft tissues was recommended to facilitate stabilisation (339) and recording of the functional depth of the vestibular sulcus (288). In a technical report adopting this technique, retraction of the mobile soft tissue facilitated development of acceptable flange extensions and a satisfactory border seal of the resultant prostheses. However, no quantitative measure of retention was reported (198). The lingual border extensions and retro-mylohyoid areas were reported to be the most difficult areas of the mandibular arch to scan because of the mobility of the floor of the mouth (198). A dental mirror was recommended to displace the tongue, thereby allowing visualisation of the lingual vestibule (288). Use of a large scanner head was reported to aid soft tissue retraction (198). A flexible aluminium frame was recommended to retract the soft tissues during IOS of the edentulous arches, to permit passage of the scanner head unimpeded from the anterior to the posterior vestibule (339). Similarly, the use of a flexible retractor (Optragate®, Ivoclar Vivadent AG, Schaan, Liechtenstein) was also recommended to retract the lips (138). In a technique article, it was recommended to clean and dry the edentulous soft tissue prior to IOS (339). Reduced trueness and precision were reported in the presence of saliva and other contaminants (303).

One reported scanning strategy for the maxilla began on the residual ridge crest, covered the palate, and ended in the buccal and labial vestibules (198) (Fig.1.5a). Another recommended strategy started at the distobuccal vestibule, moving over the ridge crest in a zig-zag pattern to the contralateral side before recording the palate (264, 339, 340). A third reported scanning strategy commenced at the distobuccal vestibule on one side, moved towards the anterior ridge

before scanning the hard and soft palate, returned to the anterior ridge and finished at the distobuccal area on the contralateral side (341). Scanning strategies for the mandibular arch started at the posterior ridge crest proceeding to the other side and then to the vestibules, ending ended on the lingual borders (198) (Fig.1.5b.). A further strategy described a zig-zag pattern beginning at the distal aspect on one side and proceeding over the residual ridge crest to the other side (314, 341). Strategies for scanning both edentulous arches were recognised to be technique-sensitive (198), and no consensus on the most appropriate scanning strategy currently exists.

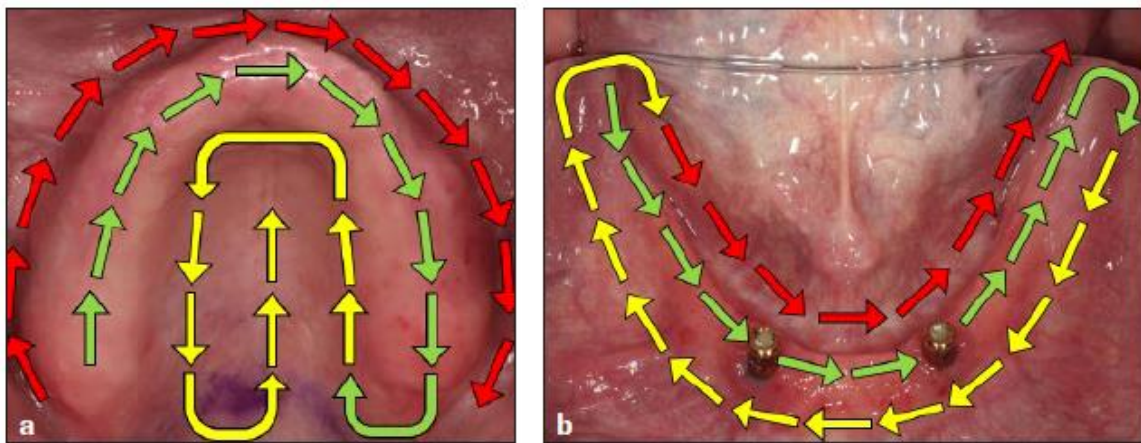


Figure 1.5. Suggested edentulous arch scanning pathways. a: maxilla; b: mandible (from Goodacre et al. 2018 (198))

To overcome the difficulty in stitching errors in IOS of the edentulous arches as a result of a lack of fixed reference points in the edentulous arches, the use of fiducial markers on the tissue surface was investigated (342). In one technical report, irregular shapes were drawn over the residual ridge and connected on the hard palate using a mixture of pressure indicating paste and ZOE temporary cement, which facilitated the effective acquisition of digital impressions (342). Drawing of irregular shapes connected by zig-zag lines on the immobile soft tissue with calcium hydroxide medicament was shown to reduce the time required for IOS (324). Similarly, an

alumina marker was shown to reduce the time required for IOS of long edentulous spaces on a mandibular cast in-vitro and improved accuracy of the scan (335). In another technique, resin-based composite spheres were secured on the tissue surface using a cyanoacrylate-based tissue adhesive to facilitate IOS of a maxillary arch with a broad palatal vault (343). In a clinical report, five sphere-shaped, self-adhesive markers were fixed on the keratinised mucosa of the hard palate, alveolar ridge, and RMPs to facilitate STL file superimposition for the fabrication of a complete-arch implant prosthesis prototype (344). In a clinical report, four radiopaque adhesive markers and scanning spray applied to palatal tissue to facilitate the fabrication of a milled denture base (AvaDent®) were compared with IOS without the use of makers (198). No differences in adaptation and retention of the denture bases were noted, thereby indicating that the use of fiducial markers for IOS of the edentulous maxilla was not necessary in order to produce a clinically acceptable prosthesis (198). Use of a tissue disclosing medium (Dr Thompson's Colour Transfer Applicators, Great Plains Dental Products, Kansas, USA) to identify the posterior palatal border for IOS was described in a case report (198), and light-polymerised gingival barrier material was used in another clinical study (138).

1.7. Impressions for CECDs

1.7.1. Conventional Impressions

Commercial systems for fabricating CECDs require conventional preliminary and definitive impressions which are subsequently digitised using a benchtop laboratory scanner (189, 345, 346). A closed mouth impression technique is used in current CECD impression protocols (231, 253, 347, 348). The recording of the maxillo-mandibular relationship for CECDs is carried out in a manner similar to that for conventionally fabricated CDs (349).

1.7.2. *IOS for CECDs*

Border molding is not as critical for mucostatic impressions as for functional impression techniques according to the philosophy, because denture retention is dependent on the intimate contact of the intaglio surface of denture base with underlying tissues and not on the creation and maintenance of a peripheral seal (28, 350). Thus, the limitation of not precisely recording the functional depth and width of the vestibules with IOS was compensated for by generating and intimate fit of the intaglio surface of the CECD base and the denture bearing tissues (351). In a case report, a maxillary CECD fabricated on the basis of an intra-oral scan of the edentulous arch was rated as good for both function and retention by the recipient (351). In a technical report, obtaining a mucostatic impression using IOS was advantageous for hyperplastic anterior maxillary tissue, whereby the combination of conventional impressions and IOS eliminated the application of pressure to the tissue (352). In a clinical report, intra-oral scans of the edentulous arches resulted in underextended denture flanges, however, the authors stated that the definitive milled CDs (IvoBase CAD, Ivoclar Vivadent AG, Schaan, Liechtenstein) demonstrated satisfactory retention (353). In a case report, definitive impressions made using IOS enabled the fabrication of CECDs (AvaDent®) in two visits (288). A clinical study examining IOS time and cost efficiency calculated an average IOS time of two and five minutes for the maxillary and mandibular arches, respectively (288), whereas, fifty-three minutes of clinical time was required to complete a conventional two-stage definitive impression in a university setting (354). In a clinical report, the fabrication of a maxillary CECD utilising IOS of the edentulous arch required less than one hour of clinical time, ninety minutes of laboratory time, and four hours of total milling time (351). The immediate digitisation of the edentulous arches through IOS eliminated the labour and time involved in scanning conventional impressions for CECD CAD in these reports (355). The use of IOS of the edentulous arches for the fabrication of computer-engineered custom trays omitted the need for stock trays and irreversible hydrocolloid material in a

technique article (356). IOS permitted the use of open access technologies for CECD production, as outlined in technical reports, thus eliminating the need for proprietary software (351, 357). In a technical report, the merging and alignment of intra-oral scans of the edentulous arches with scans of the perioral area and nose using the Trios®3 (3Shape, Copenhagen, Denmark) scanner facilitated the tooth arrangement (358).

Difficulties in capturing all the desired denture border extensions have been cited as the main limitation of IOS for edentulous arches (343, 359-361). A conventional reline impression was made inside trial prostheses at the second clinical visit due to under-extended denture borders resulting from the difficulties in recording the full vestibular depth during the mandibular intra-oral scan in the fabrication of CECDs (AvaDent®) (288). The relined prototype was scanned, and the CAD of the denture base adjusted accordingly prior to milling of the definitive prostheses in this case report. In a clinical report, a mandibular denture required relining after using IOS for the definitive impressions to ensure adaptation of the denture base (355). In another case report, trial prostheses were fabricated to determine the suitability of intra-oral scans as the definitive impressions for CECDs (362), because insufficient recording of the mandibular vestibular areas necessitated a second registration to capture missing areas on the intra-oral scan (362). A recent systematic review concluded that IOS of edentulous arches should only be considered for preliminary impressions because accuracy was only found to be comparable to conventional impressions if the ridges were firm and covered with attached mucosa (363).

1.7.3. *Applications of IOS for CECDs*

A case report outlined a technique for providing immediate CECDs for a partially dentate male patient using digital impressions of the edentulous arches and interocclusal records (362). The remaining teeth on the digital cast were erased using the CAD software, the extensions of the denture base were outlined, and the tooth arrangement completed prior to milling the prostheses. Another case report outlined the use of IOS to facilitate the design and 3D-printing of a maxillary denture base, and re-mounting on a semi-adjustable articulator, prior to tooth arrangement and processing in the conventional manner (323). The use of IOS in a CECD system (AvaDent®) was described in a case report detailing the provision of definitive dentures for a male patient in a three-appointment protocol incorporating a trial prosthesis (198). Initially, the edentulous arches were scanned and a gothic arch tracing device was used to make a CR record, which was digitised along with the current prostheses. The virtual casts were digitally articulated, and trial dentures were designed with a tooth arrangement similar to that of the current prostheses. The definitive CECDs were milled following intra-oral assessment of the denture prototypes, and inserted at the next clinical appointment following a clinical remount procedure (198). In a technique article aimed at fabricating CECDs using an entirely digital workflow, intra-oral scans were made using the Trios®3 (3Shape, Copenhagen, Denmark) intra-oral scanner (358). Closely adapted record bases were designed and 3D-printed for the fabrication of occlusal rims for the definitive maxillo-mandibular relationship record, made at the second clinical appointment and scanned. The digital casts and maxillo-mandibular relationship record were aligned with facial scans obtained using a mobile telephone application (Bellus Dental Pro; Bellus3D Inc; California, USA) to facilitate the denture tooth arrangement using the 3Shape Denture Design® (3Shape; Copenhagen, Denmark) software.

Protocols incorporating IOS for the fabrication of CECDs using the Ivoclar Digital Denture System® (Ivoclar Vivadent AG, Schaan, Liechtenstein) in three clinical appointments and two laboratory steps was described in a recent narrative article (364). IOS of the edentulous arches was completed at the first visit, in addition to scanning of the preliminary maxillo-mandibular relationship record. In the laboratory, the monolithic trial dentures were designed and fabricated before being returned for evaluation and definitive jaw registration record. Milling of the definitive CECDs was completed thereafter (364). A monolithic CECD and mandibular implant-supported overdenture (AvaDent®; Global Dental Sciences LLC; Arizona, USA) was fabricated in a three-step protocol involving intra-oral scanning of the edentulous arches (198). The existing dentures were digitised with the intra-oral scanner, to provide sufficient information for the virtual tooth arrangement and maxillo-mandibular relationship. Trial prostheses were fabricated for functional and aesthetic assessment prior to milling. The definitive prostheses were reported to demonstrate good retention and stability (198).

1.7.4. IOS for CECDs: Maxillo-Mandibular Relationship

The alignment of the intra-oral scans of the edentulous arches cannot be achieved in a completely digital workflow, and requires the use of a physical interocclusal record (365-367). Wax occlusion rims on 3D-printed trial denture bases were suggested to enable stabilisation of the digital impressions for virtual mounting (365). Alternatively, the scanned image of a VPS jig fabricated intra-orally to stabilise the opposing edentulous arches was used as a preliminary jaw registration record (137). In another report, relined edentulous stock trays modified with wax occlusion rims have also served to align the intra-oral scans (353). Alternatively, in other case reports, trial denture prostheses were used to verify the maxillo-mandibular relationship (132, 353).

1.7.5. *IOS for CECDs: Outcomes*

In an in-vitro study, the trueness of the intaglio surface of monolithic milled CECDs fabricated from intra-oral scans of edentulous arches (Trios®3; 3Shape; Copenhagen, Denmark) was deemed to be accurate using colour deviation map analysis (368). However, a statistically significant difference in the absolute mean deviation values for maxillary and mandibular dentures was found (368). With regard to clinical studies, only case reports and case series relating to the outcomes of CECDs fabricated using IOS as the definitive impression technique were available. A case report indicated that the retention, stability, and the aesthetic result of CECDs (AvaDent®; Global Dental Sciences LLC; Arizona, USA) fabricated using an intra-oral scan of the maxillary arch and a relined impression of the mandibular trial CECD were clinically acceptable (198). In a further case report, the retention and the ability to chew with a maxillary CECD fabricated using an intra-oral scan of the edentulous maxillary arch was rated good by the patient (340). Furthermore, a maxillary CECD fabricated using an intra-oral scan of the maxillary arch was deemed excellent with a patient reporting no difficulties with mastication and satisfaction with the aesthetic outcome (339). Similarly, in another clinical report, satisfactory retention for a maxillary milled CECD opposing a milled implant-retained overdenture fabricated using intra-oral scans of the respective arches was recorded (353). The fit, retention and stability of a maxillary CECD (AvaDent®, Global Dental Sciences LLC; Arizona, USA) and computer engineered mandibular removable partial denture fabricated from intra-oral scans were deemed excellent in a case report (183).

CHAPTER TWO: AIMS AND HYPOTHESES

2.1. Statement of the Problem

Clinical studies available on the digital workflows for CECDs were limited in number, sample size, and had short study periods. Despite the documented use of CAD/CAM for the design and fabrication of the CECDs, current commercially available digital systems require that impressions are made conventionally. The use of IOS to make impressions of the edentulous arches would offer material and clinical benefits, and would introduce a completely digital workflow for CECDs. Case reports demonstrated the feasibility of making a digital impression of an edentulous arch using an intra-oral scanner, and suggested that a satisfactory and functional CECD could be designed and fabricated. On the contrary, other case reports documented difficulties associated with IOS of edentulous arches. No clinical trials that reported on objective clinical outcomes and patient-centred outcomes of milled CECDs based on IOS as an impression technique were available. The need for more information regarding the capability of IOS to accurately replicate the edentulous ridge morphology to facilitate the fabrication of CECDs as an alternative to conventional impressions is necessary.

2.2. Aims of the Study

1. To compare the clinical outcomes for milled CECDs made with conventional impressions and CECDs made using intra-oral scans (digital impressions) of the edentulous arches.
2. To compare the patient-related outcomes (satisfaction) with milled CECDs made using conventional and digital impressions.

2.3. Objectives

The primary objective was to establish the clinical success of CECDs fabricated using conventional impressions and CECDs made with digital impressions using IOS of edentulous arches. The secondary objective was to assess patient satisfaction with CECDs made from both impression workflows through the use of participant evaluation questionnaires, in order to determine the relative outcome of treatment.

2.4. Study Design

This study was designed as a prospective, crossover, pilot trial. It was performed in full accordance with the guidelines of the Helsinki Declaration.

2.5. Null Hypothesis

1. There was no difference in the assessor-determined clinical evaluation between the CECDs made using conventional impressions and CECDs made using intra-oral scans (digital impressions) of the edentulous arches.
2. There was no difference in participant satisfaction between CECDs made from both impression techniques.

CHAPTER THREE: METHODOLOGY

3.1. Recruitment of Study Participants

The study population comprised edentulous adult patients attending the Dublin Dental University Hospital (DDUH) for prosthetic rehabilitation. Potential participants were identified from the incoming referrals of edentulous patients for prosthodontic treatment at the Division of Restorative Dentistry and Periodontology. Following an initial assessment in the Division of Restorative Dentistry and Periodontology Assessment Clinic, the potential participants were approached by the gatekeeper to request their participation in the study. The potential participants were provided with written information about the study ("Patient Information Leaflet"; Appendix 1), and the contact details of the Principal Investigator (Dr. Brendan Grufferty). The potential participants were allowed seven days to reply to the Gatekeeper. If the potential participant agreed to participate in the study, an assessment appointment was made with the Principal Investigator. All participants meeting the inclusion criteria and amenable to participation completed a written informed consent form prior to enrolment ("Study Consent Form"; Appendix 2).

3.2. Inclusion Criteria

For inclusion in the study, the potential participants were aged 18 years and older at the time of recruitment. Potential participants were able and willing to complete the informed consent process. They were in good general health, with healthy oral mucosa, and a history of edentulism of at least three months. Potential participants were experienced complete denture wearers and required replacement maxillary and mandibular CDs. They had the ability to understand and respond to self-reporting measurement scales and questionnaires. They were available and

willing to participate for the study period and were available for recall appointments. Furthermore, potential participants under all classifications of edentulous arches (Class I – IV) according to the American College of Prosthodontists (ACP) Classification of Complete Edentulism (175) were listed for inclusion (269).

3.3. Exclusion Criteria

Potential participants lacking the capacity to complete the informed consent process or to comprehend and complete questionnaires were excluded. Any disorder (including psychiatric disorders) that prevented the potential participant from objectively participating precluded their inclusion in the study. Participants with debilitating systemic diseases, medical complications, and inherited or acquired oral defects were excluded. Similarly, the presence of an oral tumour, chronic mucosal lesions, or xerostomia, excluded participants from the study. Potential participants with a need for immediate CDs or obturator prostheses, or potential participants who did not have a current set of CDs were also excluded. Non-compliant participants were excluded. Participants not meeting the inclusion criteria or those unwilling to partake in the study were referred to other clinical settings within the dental school for appropriate management.

3.4. Baseline Characteristics

A unique study identification number was assigned to each participant upon enrolment, in accordance with the ethical approval. Demographic data was collected for each participant at the first visit, including participant age, gender, and information on their previous denture-wearing experience (193). Participants' personalities were classified as exacting, indifferent,

hysterical, or philosophical (205) to denote their individual psychological traits and attitudes towards denture treatment (206, 207). The prognostic quality of the supporting tissues was assessed and classified as Class I, II, III, or IV according to the ACP Classification System for Complete Edentulism (175). Reasons for the need to replace their existing prostheses were recorded, including dissatisfaction, tooth wear, compromised aesthetics or function. The information and data from each potential participant were stored on a password-protected computer accessible only to the Co-Investigator (Dr. Gabrielle O'Donoghue).

3.5. Ethical Approval

The research protocol received Level 2 ethical approval from the St. James's Hospital/Tallaght University Hospital Joint Research Ethics Committee (dated 14th December 2020; JREC Reference: 2020-12 List 45). The following forms were approved for use in this study:

1. Patient Information Leaflet (Appendix 1)
2. Study Consent Form (Appendix 2)

3.6. Study Protocol

The potential participants attended an appointment with the Principal Investigator. The purpose of the appointment was to undergo a comprehensive clinical assessment, and included a thorough history (dental-, prosthetic-, medical- and social-), extra-oral examination, including a screening of the masticatory system and an intra-oral examination of the mucosa and the current prostheses. Following the clinical assessment, the potential participant signed the informed consent sheet to indicate that they were willing to participate in the study.

3.7. Preliminary Work

3.7.1. *In-Vitro Feasibility Study of Making Digital Impressions of Edentulous Mannequins*

A preliminary in-vitro study was conducted to develop a scanning strategy for the Trios®3 Cart (3Shape, Copenhagen, Denmark) intra-oral scanner for IOS of edentulous mannequins (B-3 CSP Edentulous Typodont, Frasco USA, North Carolina, USA). The importance of a defined scanning strategy was highlighted in an in-vitro study investigating the influence of various scanning strategies on the accuracy of full arch scans compared to a reference dentate maxillary model using the Trios® Pod scanner (3Shape; Copenhagen, Denmark) (338). Whilst the trueness across three different scan strategies did not differ significantly, significantly lower precision was found for a strategy beginning at the buccal surfaces and moving to the occlusal-palatal surfaces compared to a strategy beginning on the occlusal-palatal and moving to the buccal surfaces, and to a single pass strategy (338). An effective scanning strategy would produce an intact complete arch scan without interruptions or discontinuities. The scanning strategies employed for the maxilla and mandible are illustrated in Figure 3.1a,b. Scanning commenced at the arrowheads and followed the red arrows. The scanner head was replaced where the scanning started and the strategy followed the white arrows. The digital casts generated using the scanning strategies outlined are illustrated in Figure 3.1c,d.

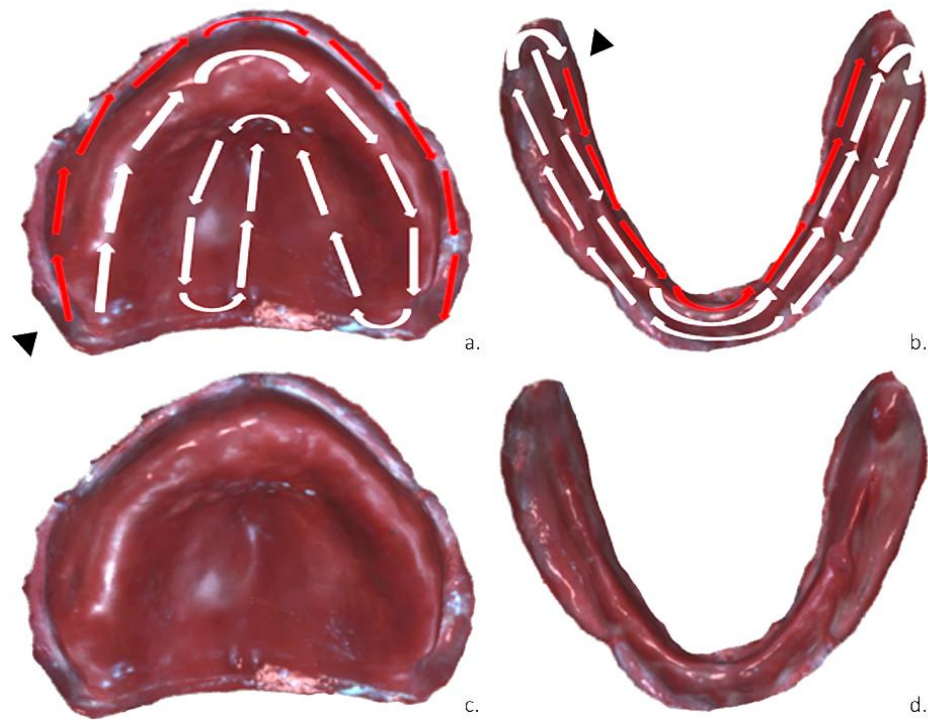


Figure 3.1. In-vitro scanning strategies a: maxilla, b: mandible. Resultant scans on intra-oral scanner c: maxilla, d: mandible. ► = starting point

3.7.2. *In-Vivo Feasibility Study of Making Digital Impressions of the Edentulous Arches*

Making an intra-oral scan of a mannequin head does not consider the effects that the lips, cheeks, tongue, saliva and patient movement have on the ability to generate an accurate digital cast. Therefore, a feasibility study was conducted to verify the IOS scanning strategy for the edentulous arches in vivo. A patient receiving treatment in the DDUH provided verbal consent to IOS of the edentulous arches for the purposes of verifying the scan strategy developed for this study. An Optragate® (Ivoclar Vivadent AG, Schaan, Liechtenstein) cheek retractor was used, and moisture control maintained through use of the saliva ejector. The Trios®3 Cart (3Shape, Copenhagen, Denmark) intra-oral scanner was used to scan the maxillary and mandibular edentulous arches (Fig.3.2a,b) using the same scan strategy in Section 3.7.1. The scan strategy was modified to ensure complete stitching of the 2D images on the intra-oral scanner. The scan

strategy adopted for the maxillary and mandibular arches (Fig.3.2c,d) and the respective digital casts generated using the strategy are illustrated in Figure 3.2e,f.

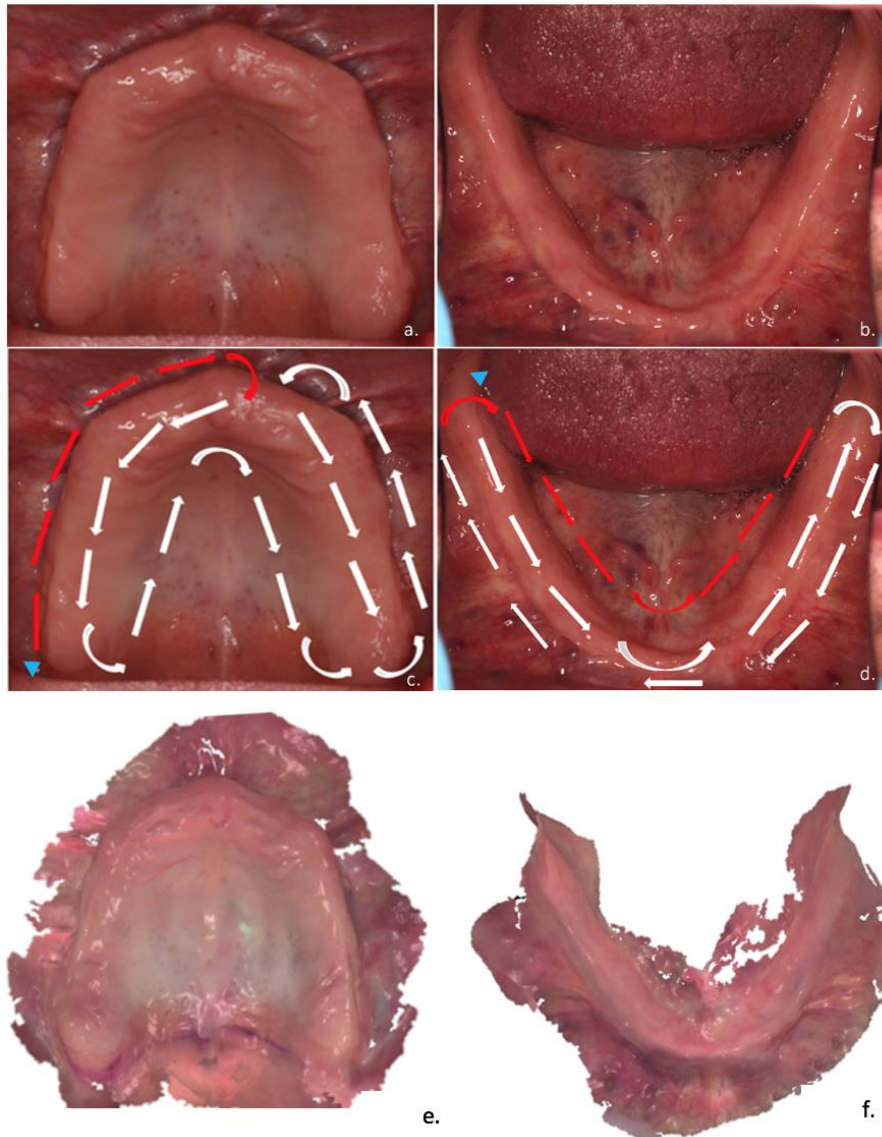


Figure 3.2. Clinical photos. a: edentulous maxillary arch. b: edentulous mandibular arch. c: maxillary scan strategy. d: mandibular scan strategy. e: maxillary arch scan. f: mandibular arch scan. ▶ = starting point for scanner head

3.8. Ivoclar® Digital Denture System

The Ivoclar® Digital Denture System (Ivoclar Vivadent AG, Schaan, Liechtenstein) protocol for CECDs was described in the literature (185, 364). The acquisition of the 3Shape Denture Design® (3Shape, Copenhagen, Denmark) software by the DDUH enabled the use of the system in this clinical study. The clinical steps involved in the fabrication of the intervention impression- and scan-based CECDs are represented in Figure 3.3, and described below.

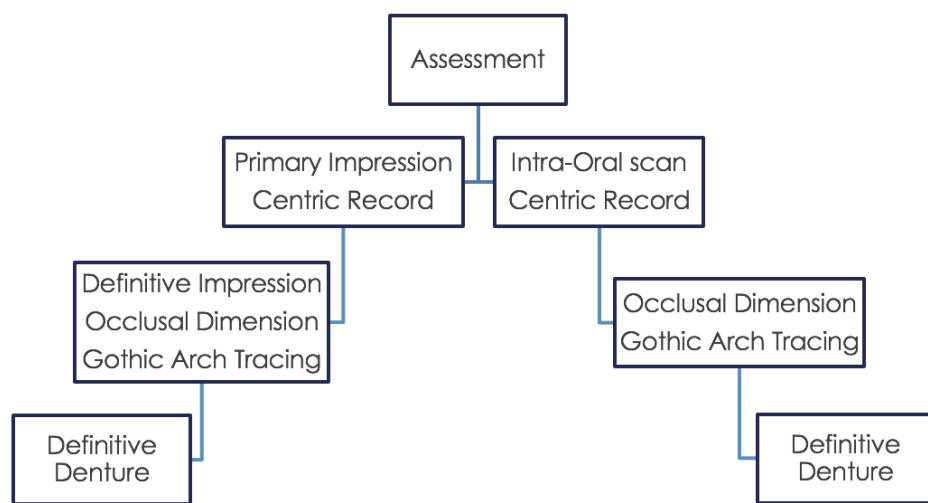


Figure 3.3. Clinical steps in the fabrication of the CECDs. L: Impression-based CECDs. R: Scan-based CECDs.

3.8.1. First Clinical Appointment

A full history including prosthetic history was taken from the participant at the first clinical appointment. A clinical examination was completed, which included a thorough assessment of the oral mucosa and an assessment of the size and configuration of the edentulous arches (175). The antero-posterior and transverse relationships of the maxillary and mandibular arches were noted. Two arbitrary marks were made on the participant's nose tip and chin using the surgical

skin marker. Whilst in the upright position, the physiological rest position was determined by asking the participant to touch their lips together and articulate “m” sounds. A digital calliper (Henry Schein Inc., New York, USA) was used to measure the distance between marks placed on the nose and chin to determine the resting vertical dimension (RVD) (369) (Fig.3.4). The occlusal vertical dimension (OVD) was calculated by subtracting 3mm from the RVD (369).



Figure 3.4. Recording of resting vertical dimension using the digital calliper

The current CDs were examined extra-orally with respect to tooth arrangement, arch symmetry, tooth wear and denture finish. They were examined intra-orally to assess flange extensions, visibility of the maxillary central incisors at rest, the level and angulation of the occlusal plane, the occlusal scheme, phonetics, support, stability and retention. The occlusal vertical dimension (OVD) with the existing CDs in situ was measured between the same two extra-oral reference marks with the gauge, and compared to the previously calculated value. The existing CDs were removed for the remainder of the visit. Plastic edentulous stock trays (Henry Schein Inc., New York, USA) of an appropriate size were chosen and checked intra-orally for fit. The stock trays were heated, cut, or adjusted using impression compound additions, as required.

Preliminary anatomical impressions were made by functionally molding with putty (VPS Hydro Putty, Henry Schein Inc., New York, USA) and light body vinylpolysiloxane (VPS Hydro Light Body, Henry Schein Inc., New York, USA) using a one-stage technique (Fig.3.5).

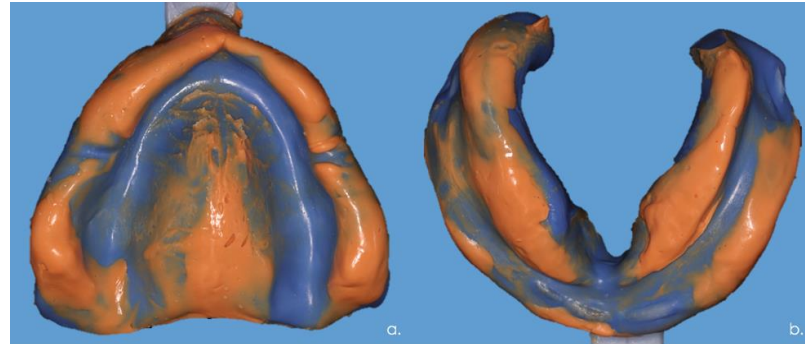


Figure 3.5. Preliminary anatomical impressions. a: maxillary arch. b: mandibular arch

The participant was placed in the supine position. The lips were lubricated with Vaseline® (Unilever UK Ltd., Surrey, UK) and the Optragate® (Ivoclar Vivadent AG, Schaan, Liechtenstein) soft tissue retractor was placed to retract the lips. Digital impressions of the maxillary and mandibular arches were made with the Trios®3 Cart (3Shape, Copenhagen, Denmark) intra-oral scanner using the scan strategy outlined (Section 3.7.2). Tissue landmarking using a surgical marker (Viscot™ surgical marker 1451, Viscot Medical LLC, New Jersey, USA) was employed if difficulty was encountered obtaining an intact digital impression. The Centric Tray® (Ivoclar Vivadent AG, Schaan, Liechtenstein) impression tray was inspected intra-orally for fit (Fig.3.6).

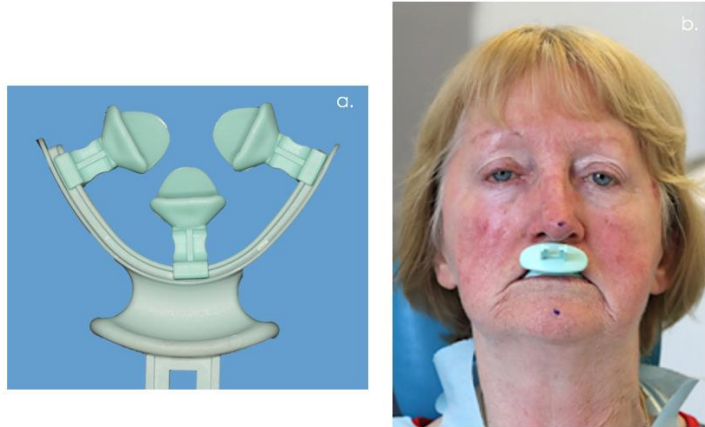


Figure 3.6. a: Centric Tray® impression tray. b: Centric Tray® checked intra-orally for fit

Irreversible hydrocolloid (sodium alginate) (Henry Schein Inc., New York, USA) with a stiff consistency was loaded onto the superior and inferior portions of the Centric Tray®, and positioned intra-orally between the edentulous ridges. The participant was asked to close slowly into the irreversible hydrocolloid and to swallow, thereby encouraging the mandible into the participant's habitual position at the OVD. The OVD was measured using the digital callipers and the mandible was stabilised until the material had set (Fig.3.7). The Centric Tray® record was removed and inspected for sufficient anatomic detail to permit orientation and alignment of the maxillary and mandibular primary digital casts (Fig.3.8).



Figure 3.7. OVD verified with completed Centric Tray® impression in place intra-orally

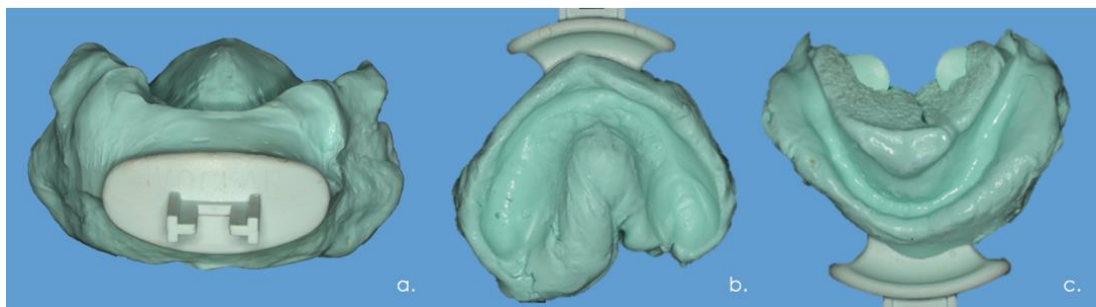


Figure 3.8. Preliminary maxillo-mandibular relationship record using the Centric Tray® impression tray a: frontal view. b: maxillary arch. c: mandibular arch

The Centric Tray® record was re-inserted intra-orally, and the proprietary UTS CAD® (Ivoclar Vivadent AG, Schaan, Liechtenstein) device (Fig.3.9) was attached to record the orientation of the occlusal plane in the frontal and sagittal planes. The horizontal component of the UTS CAD® was adjusted until the horizontal arm was parallel to the interpupillary line, and the “bi-pupillary” (BP) figure, was recorded as a positive or negative number on the scale (Fig.3.10a,b). The orientation of the occlusal plane in the sagittal plane was determined by adjusting the arm of the UTS CAD® to be parallel to the ala-tragus line and the “Camper’s plane” (CE) value was recorded (Fig.3.10c,d).



Figure 3.9. UTS CAD® device (Image available from: <https://www.ivoclardigital.com/en/laboratory/material/removable-prosthetics>)

The maxillary and mandibular aspects of the Centric Tray® record were scanned extra-orally with the Trios®3 intra-oral scanner as a preliminary maxillo-mandibular registration record. The maxillary and mandibular intra-oral scans were aligned with the scan of the Centric Tray®.

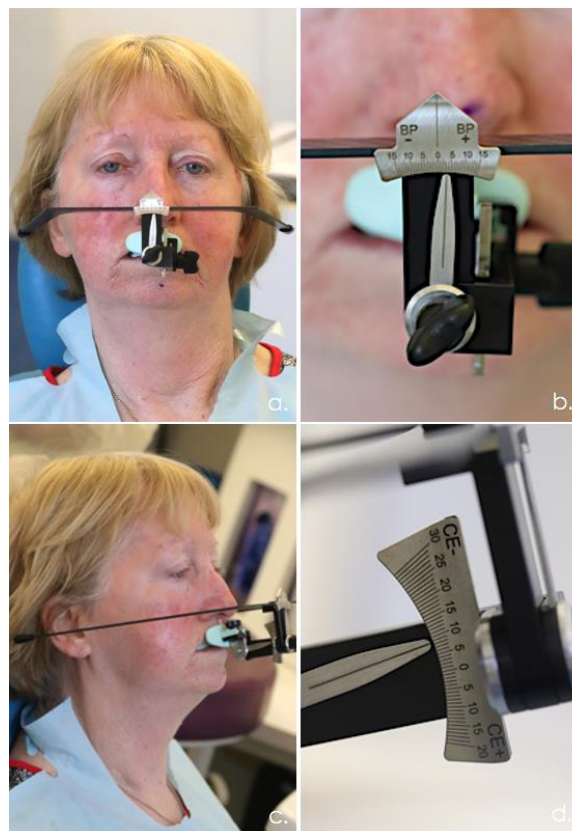


Figure 3.10. a: UTS CAD® frontal view. b: bi-pupillary (BP) value. c: UTS CAD® sagittal view. d: Camper's plane (CE) value

3.8.2. Computer Aided Design of UTS Biteplates

The primary edentulous impressions and the Centric Tray® record were digitised extra-orally in the benchtop laboratory scanner (R/D2000 3Shape scanner, 3Shape, Copenhagen, Denmark). The three scans were saved as STL files and uploaded to the Ivoclar® Digital Denture CAD software (3Shape Dental System® version 1.7.19.0, 3Shape, Copenhagen, Denmark). The vestibular sulci were outlined to generate preliminary digital casts (Fig.3.11).

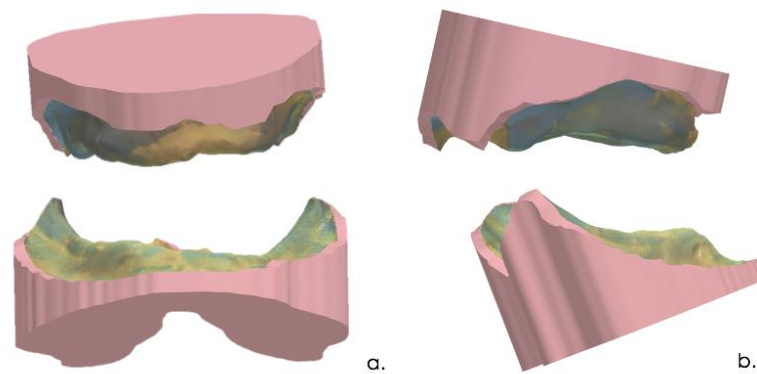


Figure 3.11. The virtual primary casts. a: frontal view. b: sagittal view

The digital casts were oriented in the digitised Centric Tray®. The occlusal plane was positioned in the inter-arch space within the CAD software, at the level of the expected incisal edge of the mandibular incisors and at a level corresponding to half the height of the retro-molar pads (Fig.3.12). The BP and CE values recorded previously from the UTS CAD® were imputed to correct the orientation of the digital casts in the frontal and sagittal planes on the digital articulator.

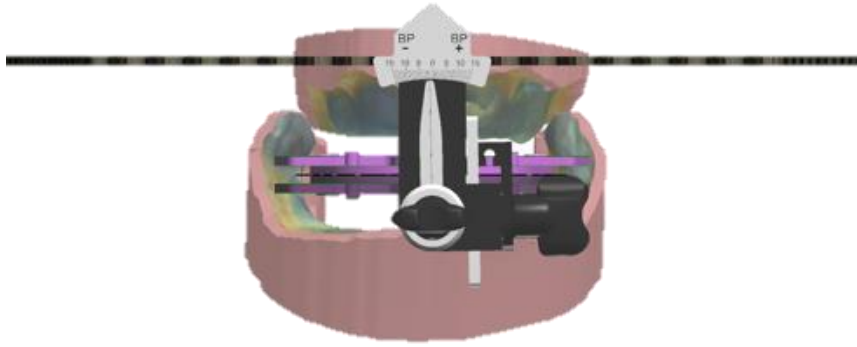


Figure 3.12. Orientation of occlusal plane

The UTS CAD® biteplates were designed to function as close-fitting custom trays for the definitive impressions and to make the definitive maxillo-mandibular relationship record. The digital casts were oriented to define the path of insertion, undercuts were blocked out and the flange extensions were outlined on the digital casts to within 2 mm of the vestibular depths. A set of UTS CAD® biteplates were then designed on the digital casts (Fig.3.13).

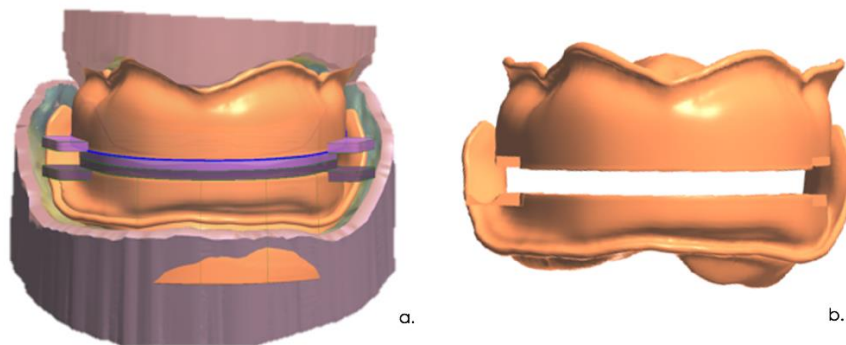


Figure 3.13. UTS CAD® biteplates designed using the CAD software. A: frontal view on primary casts. b: UTS CAD® biteplates

A similar set of UTS CAD® biteplates were designed after extending the flanges to the full vestibular depth and these UTS CAD® biteplates would be used to orient the digital casts made

with the intra-oral scans. The design features on the occlusal surface of the UTS CAD® biteplates used to accommodate the Gnathometer CAD® are illustrated (Fig.3.14). The designs for both sets of UTS CAD® biteplates were saved as STL files, and transferred for 3D-printing (Ivoclar Vivadent AG, Schaan, Liechtenstein) (Fig.3.15).

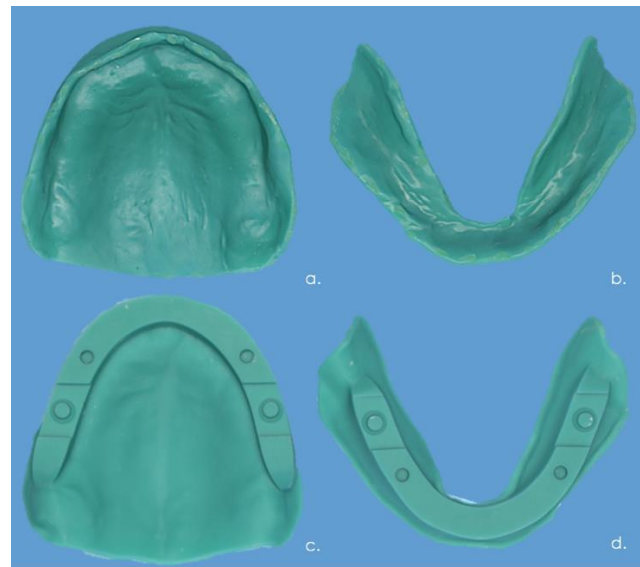


Figure 3.14. UTS CAD® biteplates. a: maxillary fitting surface. b: mandibular fitting surface. c: maxillary occlusal surface. d: mandibular occlusal surface

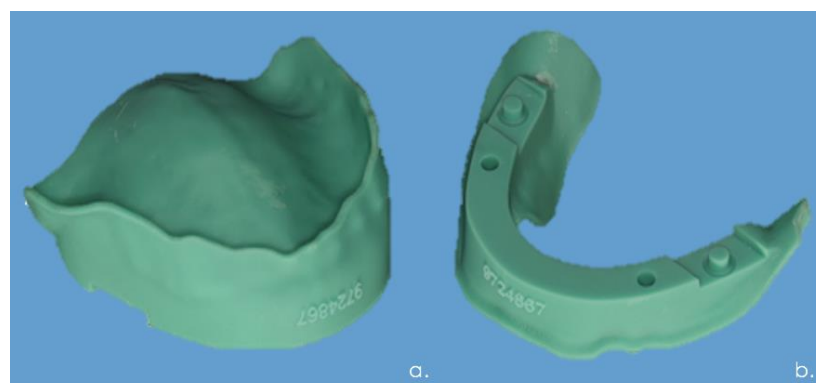


Figure 3.15. Customised 3D-printed UTS CAD® biteplates. a: maxillary biteplate. b: mandibular biteplate

3.8.3. Second Clinical Appointment

The fit of the UTS CAD® biteplates was verified and the horizontal and vertical dimensions were assessed to ensure that the occlusal surfaces of the UTS CAD® biteplates occluded bilaterally at the proposed OVD. Wax (Anutex modelling wax, Kemdent Works, Swindon, UK) was added to the occlusal portions of the biteplates to establish the OVD where necessary. Adjustments were made to the flange lengths of the UTS CAD® biteplates as required, and the position of the posterior palatal border was verified. The biteplates were border molded in both arches with VPS putty (VPS Hydro Putty, Henry Schein Inc., New York, USA). A closed-mouth impression of the maxillary arch was made with light-bodied VPS (VPS Hydro (Light Body), Henry Schein Inc., New York, USA) (Fig.3.16a) while occluding with the mandibular biteplate. A closed-mouth definitive mandibular impression was made (Fig.3.16b) while the biteplate occluded with the maxillary impression. The UTS CAD® was used to assess the orientation of the occlusal plane in the frontal and sagittal planes as described previously (Section 3.8.1) and angular deviations from the interpupillary and Camper's lines were recorded.

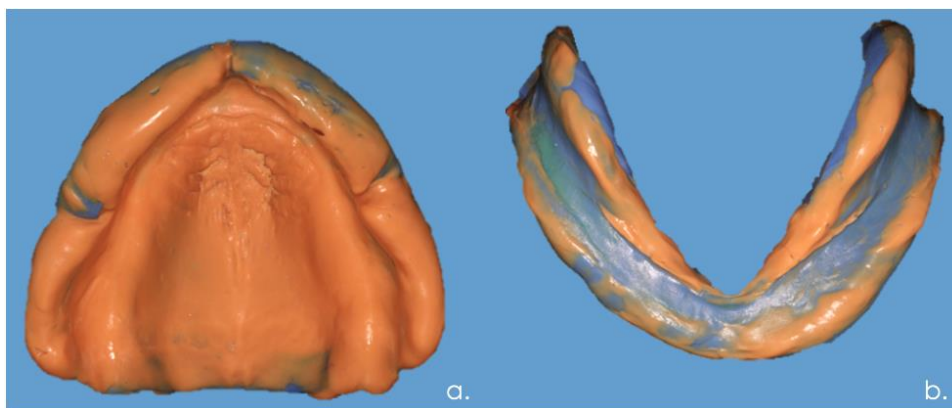


Figure 3.16. Definitive conventional impressions. a: maxillary arch. b: mandibular arch

With the participant sitting upright, the physiologic position of rest of the mandible was measured as previously outlined (Section 3.8.1). The Gnathometer CAD® (Fig.3.17) is an intra-oral registration device to record mandibular movement in the horizontal plane. The circular receiving plate (Fig.3.17b) was coated with a disclosing medium – nail varnish (Maybelline, New York, USA) - and attached to the mandibular biteplate. The central bearing device (Fig.3.17a) was attached to the maxillary biteplate and adjusted to re-establish the OVD.

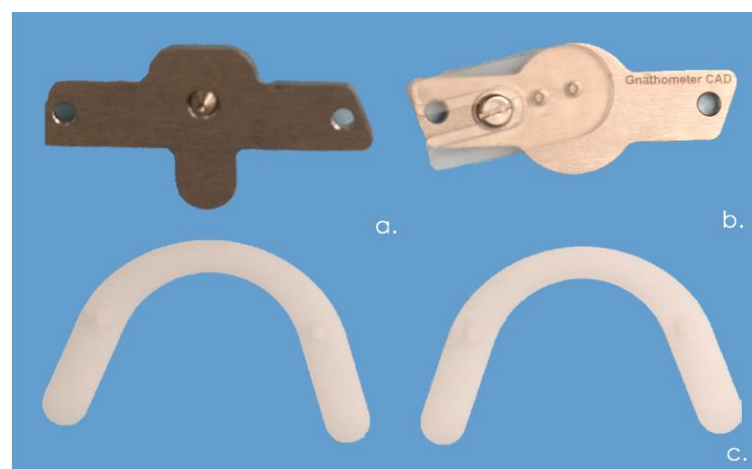


Figure 3.17. Gnathometer CAD® components. a: central tracing device. b: receiving plate and plastic lock. c: removable occlusal rims

A gothic arch tracing was completed in the conventional manner (370). The participant was instructed to carry out protrusive and lateral mandibular movements multiple times whilst maintaining the tracer in contact with the receiving plate. The path of mandibular movement was traced on the receiving plate and the apex of the gothic arch arrow indicated the centric maxillo-mandibular position (Fig.3.18).



Figure 3.18. Completed gothic arch tracing of excursive mandibular movements on tracing plate

A proprietary plastic locking component (Fig.3.17b) was attached the receiving plate and adjusted until the pre-fabricated hole was aligned over the apex of the gothic arch tracing and repeatability of the mandibular reference position was verified intra-orally (Fig.3.19).

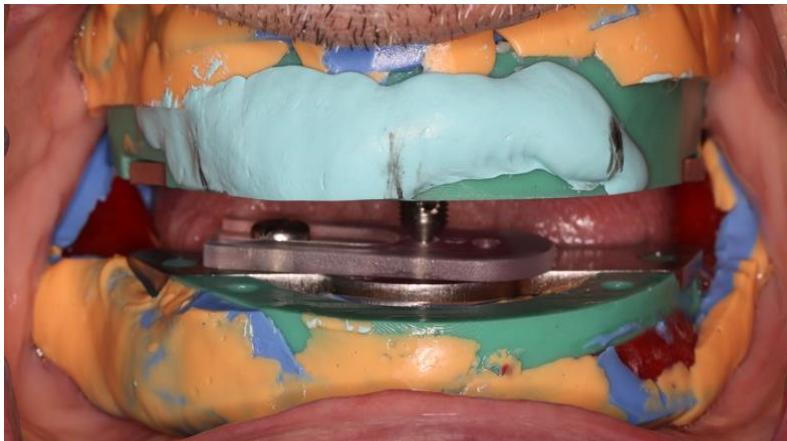


Figure 3.19. Verification of centric maxillo-mandibular relationship intra-orally

A silicone interocclusal recording medium (Take1® Advanced™, Kerr Dental, California, USA) was injected between the UTS CAD® biteplates, and the participant was instructed to remain still while the interocclusal recording material polymerised (Fig.3.20). A silicone interocclusal recording medium (Blu-Mousse® Bite Registration, Parkell, New York, USA) was placed on the labial aspect of the maxillary biteplate, and functionally molded to record the extent of lip

support required, thus indicating the labial-palatal position of the maxillary anterior teeth. The level of the resting upper lip was indicated by the inferior portion of the silicone material, thus indicating the level of the maxillary occlusal plane. The maxillary centre line, smile line, canine lines and resting lip level were recorded on the material with a marker (Sharpie® Permanent Marker, Newell Brands, Georgia, USA) prior to removal of the entire definitive impression and maxillo-mandibular record assembly (Fig.3.20). A suitable denture tooth mold and shade were selected.

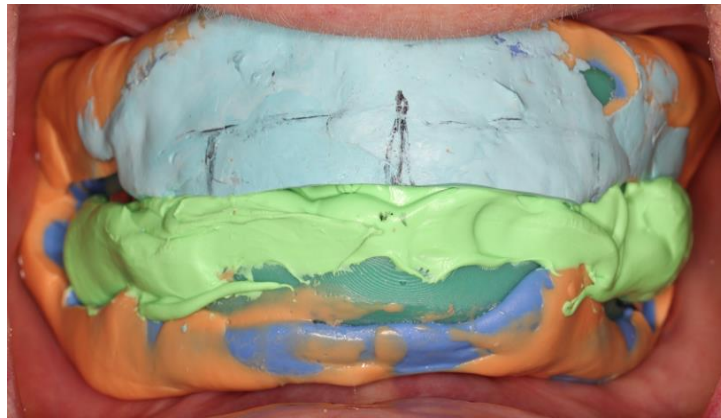


Figure 3.20. Completed definitive impressions and maxillary-mandibular relationship record

3.8.4. Third Clinical Appointment (Records for the Digital Impressions)

The UTS® CAD biteplates were assessed for fit, soft tissue support and OVD as described (Section 3.8.3) (Fig.3.21a). The frontal and sagittal angular deviations of the maxillary biteplate from the bi-pupillary and Camper's lines were recorded using the UTS CAD® as described (Section 3.8.1). The central bearing device and receiving plate of the Gnathometer CAD® were attached to the biteplates and the gothic arch tracing was completed as described previously (Section 3.8.3) (Fig.3.21b). The inter-occlusal record and extent of lip support required was completed as described previously (Section 3.8.3). The resting upper lip, maxillary centre line, smile line and

canine lines were recorded on the silicone registration material with a marker (Sharpie® Permanent Marker, Newell Brands; Georgia, USA) prior to removal of the entire definitive maxillo-mandibular record assembly (Fig.3.21c). The same tooth mold and shade previously chosen were recorded.

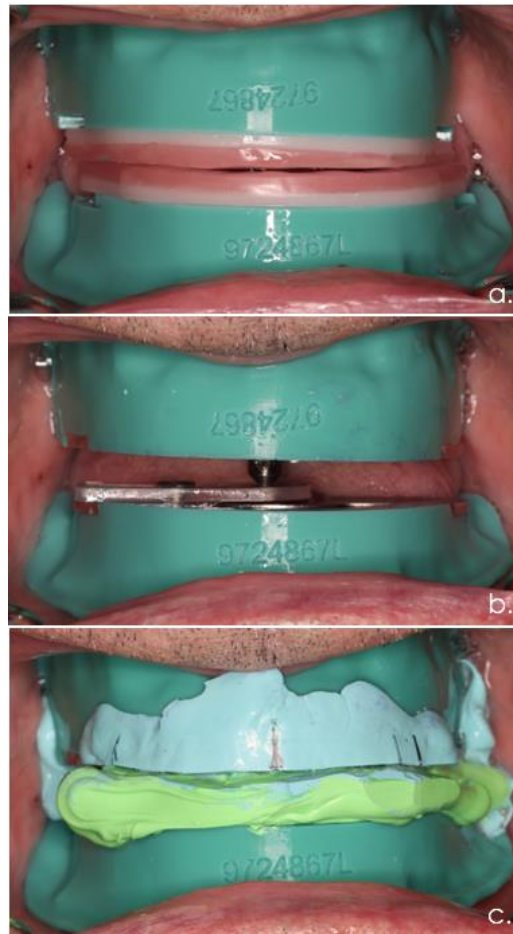


Figure 3.21. Definitive maxillo-mandibular relationship. a: vertical and horizontal dimensions verified. b: centric maxillo-mandibular position. c: definitive maxillo-mandibular record

The entire biteplate-Gnathometer CAD® assembly was scanned extra-orally with the Trios®3 intra-oral scanner and served as the definitive inter-occlusal record to align the maxillary and mandibular intra-oral scans. The participant's existing maxillary and mandibular CDs were

scanned extra-orally with the Trios®3 intra-oral scanner and served to provide the technician with a guide for tooth arrangement .

3.8.5. CAD of the Prostheses

Both sets of CECDs were designed simultaneously. The definitive impressions and maxillo-mandibular relationship record were digitised using the extra-oral scanner (R/D2000 3Shape scanner, 3Shape, Copenhagen; Denmark). The resultant scans were then exported as three STL files, and imported to a new order entitled on the design software (144). The digital master casts were mounted on the virtual articulator using the interocclusal record scan (Fig.3.22).

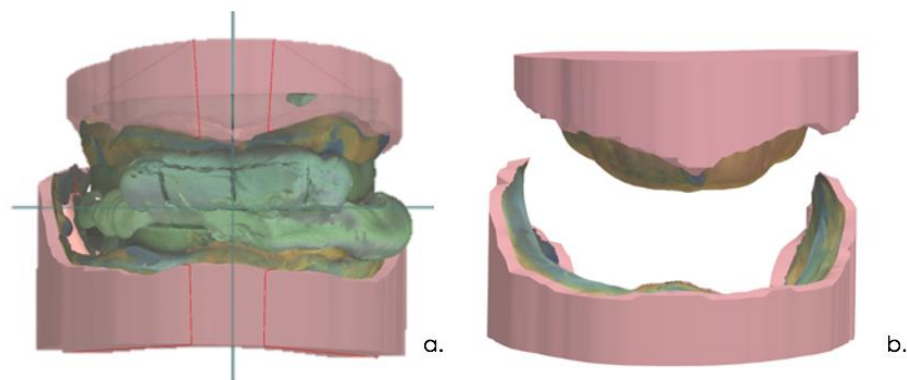


Figure 3.22. a: Impression-Gnathometer CAD® assembly used to orient virtual master casts in the definitive maxillo-mandibular relationship. b: oriented virtual master casts

Using the CAD software, unwanted undercuts on the digital master casts were blocked out and the extensions of the dentures were outlined on the digital casts (Fig.3.23). The orientation of the occlusal plane was corrected using the “BP” and “CE” values previously recorded using the UTS CAD® (Fig.3.24).

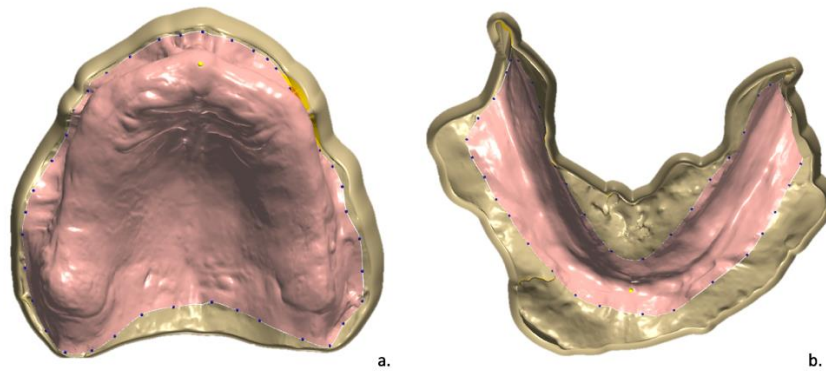


Figure 3.23. Denture extensions outlined on virtual master casts. a: maxilla. b: mandible

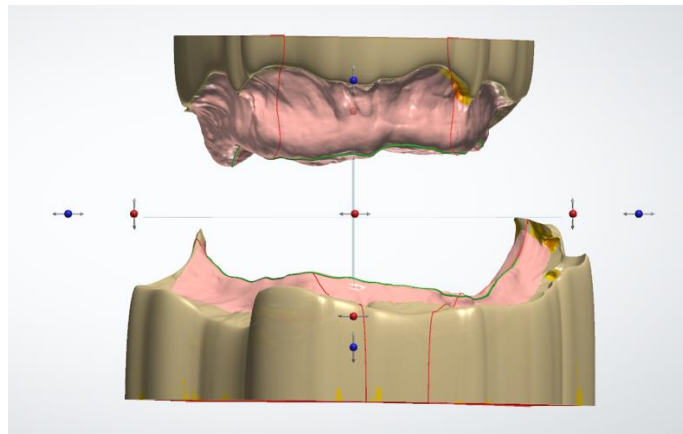


Figure 3.24. Orientation of virtual master casts and occlusal plane

The horizontal distance between the vertical inter-ala lines on the facial surface of the impression-Gnathometer CAD® was measured, and determined to be the inter-canine distance. The vertical distance between the line denoting the cervical position of the maxillary anterior teeth and the proposed central incisal edge position was measured. An appropriately sized maxillary anterior tooth mold corresponding to these measurements was selected from the tooth library. The maxillary anterior six teeth were arranged in the inter-arch space at the level of the occlusal plane, re-sized to fit the available space and within the limits defined for the level

of lip support. The mandibular anterior teeth were selected from the same mold within the library, and arranged using the anatomic landmarks on the digital cast. Semi-anatomic posterior denture teeth were chosen from the digital tooth library and positioned according to anatomical reference points on the maxilla (canine tooth tips and maxillary tuberosities) and the mandible (canine tooth tips, centre and distal extent of the retro-molar pads). The posterior denture teeth were automatically incorporated over the crest of the residual ridges. A Class I buccal segment relationship was defined and the positions, inclination, and angulation of the posterior teeth were refined (Fig.3.25).

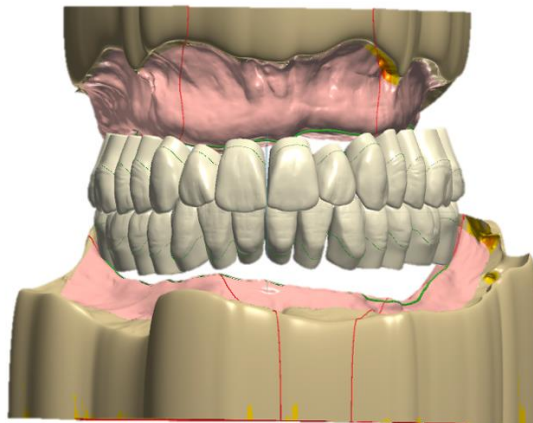


Figure 3.25. Virtual tooth arrangement

The labial and palatal/lingual gingival margins of the maxillary and mandibular tooth arrangements were outlined, and the smooth surface contours of the proposed CD were characterised to create root prominences and inter-radicular contours (Fig.3.26). This completed the CAD process for the CECDs based on conventional impressions (CECD(imps)) (Fig.3.27).

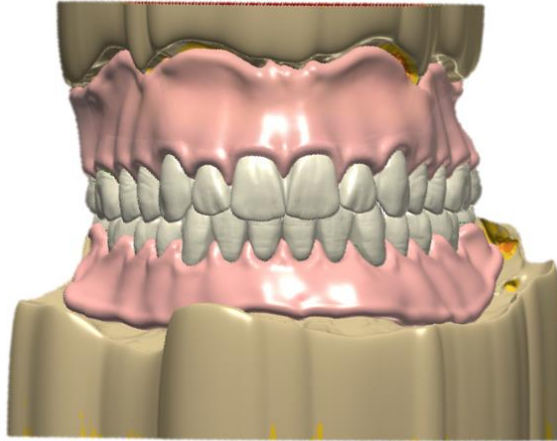


Figure 3.26. The smooth surface contours and base extensions of the CECDs

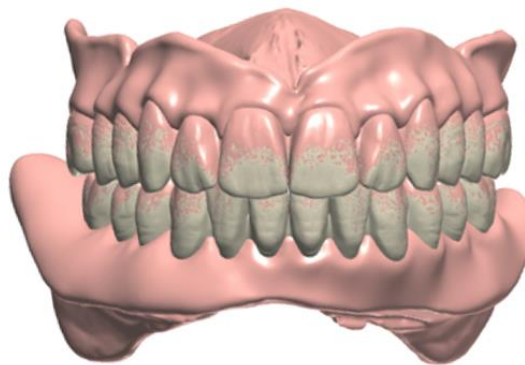


Figure 3.27. Completed CECD CAD

The virtual master casts derived from the intra-oral scans of the edentulous arches were orientated in the definitive maxillo-mandibular relationship on the virtual articulator using the scan of the biteplate-Gnathometer CAD® assembly (Section 3.8.4.). The digital tooth arrangement defined for the impression-based CECDs was duplicated and copied into the inter-arch space. The contour of the denture smooth surfaces was designed in the same manner (Section 3.8.5.). This completed the CAD process for the CECDs based on intra-oral scans (CECDs(scan)).

The CAD files for both sets of dentures were exported to the computer serving the Roland Milling machine (Zenotec Select Hybrid, Wieland Dental + Technik GmbH & Co. KG, Pforzheim, Germany). The monolithic polychromatic pre-polymerised PMMA product “Ivotion™” (Ivoclar Vivadent AG, Schaan, Liechtenstein) (Fig.3.28a,b) was placed in the milling machine. This product incorporated both the pink and tooth-coloured PMMA for the denture base and denture teeth in a single puck (371). The transition at the tooth-denture base junction was scalloped, and positioned within the puck based on standardised data points (371). The standard dimensions of the “Ivotion™” CECD pucks were 98.5 mm in diameter and 38 mm in depth (371).

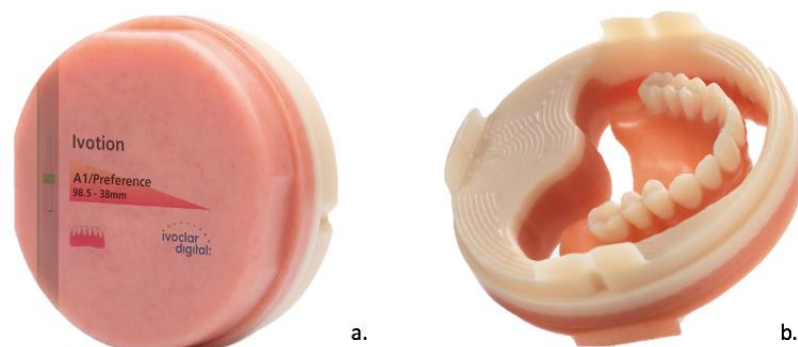


Figure 3.28. Monolithic PMMA blanks available for use within Ivoclar® Digital Denture System (Ivoclar Vivadent AG Schaan, Liechtenstein). a: Ivotion™ puck. b: milled monolithic PMMA CECD in Ivotion™ puck (Image available from: <https://highlights.ivoclar.com/lab/en/sr-vivodent-cad-and-ivobase-cad> (371))

The two sets of dentures were milled (Fig.3.29; Fig.3.30). Following completion of the milling cycle, the CECD was removed by cutting the supports, and was polished using pumice and polishing compound (Acrilustre, Buffalo Dental Manufacturing Co. Inc., New York, USA). A remount cast for each CECD were fabricated in Type III gypsum stone to facilitate a clinical remount procedure prior to insertion of the dentures.

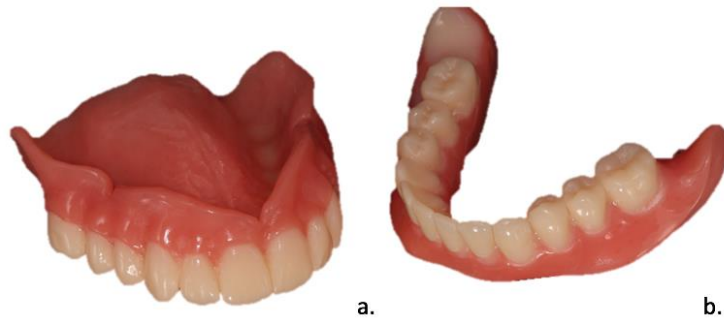


Figure 3.29. Milled CECDs based on impressions. a: maxilla. b: mandible

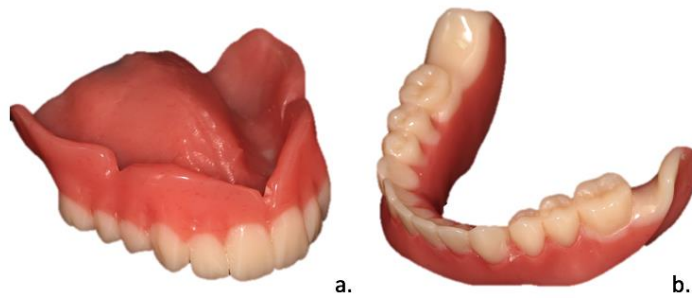


Figure 3.30. Milled CECDs based on intra-oral scans. a: maxilla. b: mandible

3.8.6. Fourth Clinical Appointment

The order of delivery of the CECDs was determined by a coin toss prior to the fourth clinical visit (185). Thus, the patient was blinded to the prosthesis type. Pressure indicating paste (Mizzy™ Pressure Indicating Paste; Mizzy Inc., New Jersey, USA) was applied to the fitting surfaces of both maxillary and mandibular CECDs, and adjustments were made to the fitting surfaces and to the extensions accordingly. A clinical remount procedure was completed in the conventional manner (Fig.3.31) (79). An ear bow transfer record was made with the maxillary CECD using impression compound (Impression Compound Green Sticks, Kerr Dental, California, USA) on the bite fork (Whipmix Model #8645 Quick Mount Facebow, Whipmix Corporation,

Kentucky, USA). An interocclusal record was made with dental wax (Aluwax™, Aluwax Dental Products Co., Michigan, USA). The CECDs were mounted on a semi-adjustable articulator (Whip Mix Model 2240 Articulator, Whip Mix Corporation, Kentucky, USA). Selective occlusal grinding was completed to facilitate balanced occlusion in the maximum intercuspation position (MIP), lateral and protrusive mandibular movements. The CECDs were polished and fitted intra-orally (Fig.3.32).

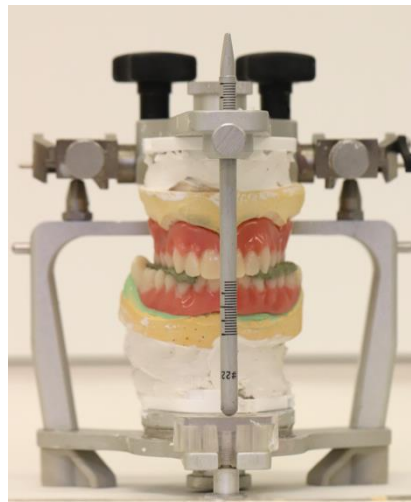


Figure 3.31. Clinical remount of CECDs



Figure 3.32. CECDs fitted intra-orally

Two independent prosthodontists evaluated the condition of the oral tissues and the CECDs extra- and intra-orally (193). Both were blinded to the prosthesis type, and the clinical assessment was completed sequentially using the “CECD Assessment: Clinical Evaluation” form (Appendix 3). These criteria evaluated were based on a previous clinical study evaluating CECDs (185) and included denture base contour and finish, denture tooth arrangement, aesthetics, lip support, support, stability, retention, MIP, OVD, and phonetics (Table 1). The overall result, clinical acceptability, and expected prognosis for the CECDs were determined (185). The participant was provided with hygiene instruction and instructions on the care of the prostheses. The participant’s existing CDs were disinfected and stored with the remount casts by the Co-Investigator.

Table 1. Criteria for assessment of clinical outcomes for CECDs

Clinical Outcome	Variable	Assessment
Denture Base	Contour	Outline form; Root prominences
	Shade	Appropriateness
	Polish & Finish	Surface texture; Polished appearance
Tooth Arrangement	Position	Arch symmetry; Position relative to anatomical structures; Incisor relationship; Crossbite
	Form	Dimensions; Inter-alar width; Shape
	Shade	Appropriateness
Aesthetics	Tooth display at rest	As per conventional guidelines
	Tooth display in smile	
	Occlusal plane	
	Midline	Co-incident with facial midline
	Gingival margin	Arch symmetry; Outline
Lip Support	Lip support	Nasolabial angle
Fit	Retention	Peripheral seal bilaterally at first premolar sites
	Extensions	Vestibular depth
	Support	Resistance to vertical rocking across the arch
	Stability	Resistance to horizontal rotation across the arch
Occlusion	MIP	Co-incident with centric relation; Bilateral contacts
	Excursions	Bilateral balance
OVD	OVD	Interocclusal space; Lower facial height
Phonetics	Phonetics	Speech
Overall Result	Overall result	Overall result
Prognosis	Expected prognosis	Expected prognosis

3.8.7. The CECD Review Process

A review appointment was arranged seven days after insertion of the CECDs. The participant completed a self-rated satisfaction questionnaire to assess the patient-related outcome measures associated with the CECDs ("CECD Assessment: Patient Satisfaction" form, Appendix 4). The questionnaires were administered in interview form by the operator. Based on a previous clinical study, the maxillary and mandibular CECDs were evaluated by the participant for retention, aesthetics, function, comfort, phonetics, and overall satisfaction (Table 2) (185). The process of reviewing the participant and their CECDs was repeated at seven day intervals for four weeks to manage post-insertion denture complications. At the final review appointment, the participant satisfaction questionnaire was repeated. The CECDs were returned to the Co-Investigator, stored with the remount casts, and the participant's existing CDs were reinserted. The participant was instructed to use their existing CDs for four weeks throughout the "wash-out" period (269).

Table 2. Criteria for evaluation of participant satisfaction with CECDs

Outcome	Assessment of Satisfaction
Retention	How well does the denture fit?
Support	How "tight" does the denture feel?
Stability	How stable does the denture feel when you move the teeth?
Appearance	How well do the gums look?
	How well do the teeth look when you are relaxed?
	How well do the teeth look when you are smiling?
Function	How well can you speak?
	How well can you eat and chew?
Occlusion	How even is the bite?
	How well can you slide your teeth around?
Comfort	How comfortable are the dentures?

3.8.8. Fifth Clinical Appointment

The second set of CECDs were inserted after the wash out period was completed. They were evaluated, adjusted, and a clinical remount procedure was carried out as described in Section 3.8.6. The same independent prosthodontist assessors evaluated the oral tissues and the CECDs as described in Section 3.8.6. Oral hygiene instruction and denture care instructions were reinforced. The participant's existing CDs were disinfected and stored with the previous CECDs and remount casts.

3.8.9. The CECD Review Process

The review process for the second set of CECDs was conducted as described in Section 3.8.7. A review appointment was arranged seven days after insertion of the CECDs. At the commencement of this appointment, the participant completed the self-rated satisfaction questionnaire to assess the patient-related outcome measures. Review appointments were made at seven day intervals to manage post-insertion complications (193, 269). The participant satisfaction questionnaire was repeated at the final review appointment. Upon completion of the review period, both sets of CECDs and the existing CDs were returned to the participant. The total number of post-insertion appointments over the study period was recorded (42). The participant was asked for their preference of impression technique. Participant preference was established for either of the two CECD sets at the end of the trial.

3.9. Grading Criteria

The grading for the clinical and patient-related outcomes were based on a previously validated Likert five-point ordinal scale (185, 230, 372). The scores and associated key words were as follows:

0. “Unacceptable” necessitating a remake and indicating clinical unacceptability.
1. “Poor” indicating three or more negative findings but clinically satisfactory.
2. “Fair” indicating two negative findings.
3. “Good” indicating one negative finding.
4. “Excellent” indicating no negative findings.

3.10. Calibration of Clinical Assessors

The two independent assessors were prosthodontists and members of the full-time faculty in the Department of Restorative Dentistry and Periodontology at the DDUH. Both assessors were presented with the “CECD Assessment: Clinical Evaluation” form; Appendix 3). The variables and grading criteria for assessment were explained and discussed (Table 1). The techniques used for assessment of the CECDs were outlined for standardisation (Table 1). The evaluation process was rehearsed on a pilot basis using an edentulous patient who was assessed as part of the calibration process. Both assessors evaluated a pair of CECDs during this pilot, and again two weeks thereafter. The consistency of clinical outcome evaluation scores by the assessors, the intra-examiner reliability, was assessed using an average measurement, absolute-agreement, two-way mixed effects model. The inter-examiner reliability between the assessors was also conducted using an average measurement, absolute-agreement, two-way mixed effects model.

3.11. Power Calculation

A power calculation was completed to determine the number of participants required for differences to reach significance. The power calculation was based on an effect size of 0.8, with a two-sided alpha level of 0.05, and a power (1-beta) of 0.90 which calculated the ideal sample size to be 20 participants. Anticipating a potential dropout rate of 10%, the sample size was adjusted to 22 participants.

3.12. Data Handling

The data was collected using Microsoft Excel® for Mac (Version 16.43, Microsoft Corporation, Washington, USA). Data was analysed using Microsoft Excel® for Mac (Version 16.43, Microsoft Corporation, Washington, USA) and IBM® SPSS® Statistics (Version 28.0.1.1., IBM, New York, USA). Descriptive statistics were employed for the participant baseline characteristics, and were carried out using means and medians for the continuous variables. Means and standard deviations were calculated for each outcome parameter, with confidence intervals (CI) set to 95%. Shapiro-Wilk and Fisher's Exact Tests were conducted to test the normality of the data. Wilcoxon signed rank tests were used to assess the clinical evaluation variables and the participant questionnaire scores.

CHAPTER FOUR: RESULTS

4.1. Recruitment

A total of eight potential participants were assessed by the Principal Investigator for inclusion in the study. One potential participant was excluded because they did not meet the inclusion criteria because they did not have a set of CDs and one potential participant did not agree to participate. Both patients were referred to other clinics within the DDUH for treatment. Six participants were recruited to the study. Each participant had healthy oral mucosa, required replacement dentures, and had the capacity to provide informed consent and complete the patient satisfaction survey. One participant was excluded as a result of poor compliance and attendance during treatment. Therefore, five participants completed the study.

4.2. Baseline Characteristics

The study participants comprised four females and one male. The age of the participants ranged from 66 years to 87 years old, with a mean age of 76.60 years (standard deviation 9.37 years). The participants were using CDs for periods of time ranging from 4 to 10 years, with a mean time period of 7.20 years (standard deviation 2.68 years). The personalities of the participants were classified according to the House Classification (205-207). Three participants (two female and one male) were classified as philosophical, one participant (female) was classified as hysterical and one participant (female) was classified as indifferent.

Four female participants had Class II maxillo-mandibular relationships and one male participant had a Class III maxillo-mandibular relationship. Based on the ACP Classification System of Complete Edentulism (175), the maxillary arches of Participants One and Four (Fig.4.1; Fig.4.2) were classified as Class I on the basis of the residual ridge morphology. The maxillary arches of Participants Two, Three, and Five were classified as Class II due to reduced depth of the buccal vestibules. The mandibular arches of Participant One and Three were classified as Class III on the basis of residual ridge height. The mandibular arches of Participants Two, Four and Five were classified as Class IV, on the basis of residual ridge height.



Figure 4.1. The edentulous arches of Participant Four (frontal view): Class II maxilla and Class IV mandible

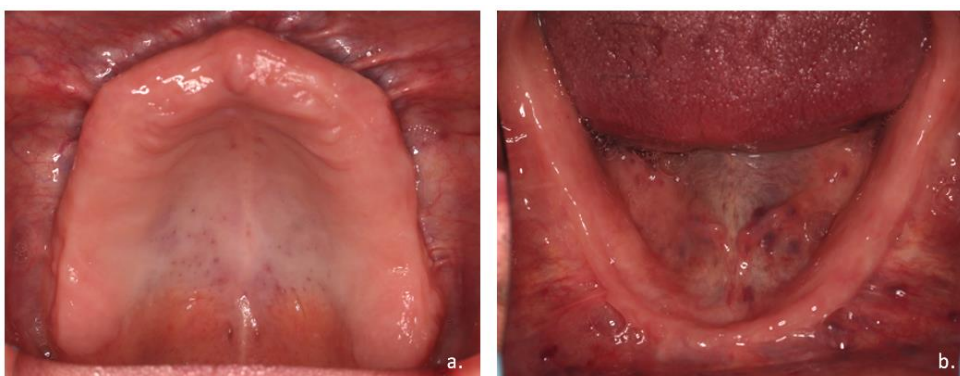


Figure 4.2. The edentulous arches of Participant Four (occlusal view). a: Class II maxilla. b: Class IV mandible

The reasons provided by the participants for the need to replace their current prostheses included wear of the denture teeth, compromised aesthetics, lack of retention, and difficulties experienced during eating due to poor support, stability and retention of their existing prostheses.

4.3. Intra- and Inter-Examiner Agreement

Intra-examiner reliability testing for the independent assessors was conducted using an average measurement, absolute agreement, two-way mixed-effects model. The intra-class correlation (ICC) coefficient for the first assessor (Prosthodontist One) was 0.609 (95% CI 0.225-0.801; $p = 0.004$) and the ICC coefficient for the second assessor (Prosthodontist Two) was 0.648 (95% CI 0.303-0.821; $p = 0.002$). The results indicated that the test-retest intra-reliability of both the assessors based on the correlation coefficients was “moderate” (373). Inter-examiner reliability testing for the independent assessors was conducted using an average measurement, absolute-agreement, two-way mixed effects model. The intra-class coefficient was 0.628 (95% CI 0.284-0.808; $p = 0.002$), indicating “moderate” inter-examiner reliability (373).

4.4. Clinical Assessment

4.4.1. CECDs(Imps) Clinical Outcomes

The coin toss used to determine the order of insertion of the prostheses resulted in four CECDs(imps) and one CECDs(scan) being inserted first. According to the clinical assessment of the prostheses, 80% of maxillary and mandibular CECDs(imps) dentures were rated as “Good” and 20% were rated as “Fair” (Fig.4.3). The mean value of the scores provided by the two

prosthodontists was calculated for each clinical outcome, and ranged from 2.20-3.50 for the CECDs(imps). Retention of the mandibular denture and excursive movements were the lowest rated variables with a mean score of 2.20 respectively, followed by the midline of the mandibular denture teeth, with a mean score 2.3. The angulation of the occlusal plane had a mean score of 2.3 and base contour of the mandibular CECDs(imps) had a mean score of 2.4. The highest rated clinical outcome variable for CECDs(imps) was retention of the maxillary denture and soft tissue support, each with a mean score of 3.5, followed by extensions of the maxillary denture and OVD, each with a mean score of 3.4, respectively.

The mean score for “Overall Result” for the CECDs(imps) was 2.80 (range 2.50-3.00) (Fig.4.3). Thus, when considering the “Overall Result” variable, 100% of the CECDs(imps) were rated “Good”. A mean value of all the clinical outcomes assessed was calculated and referred to as “Total Score”. The mean clinical score of all clinical outcomes for the CECDs(imps) was 2.82, therefore the “Total Score” for CECDs(imps) indicated that 100% were rated “Good”. The prognosis for 80% of the CECDs(imps) was considered “Good” and 20% were considered “Excellent”. The clinical acceptability of the CECDs(imps) was rated 100% and 60% by the first and second assessors, respectively.

4.4.2. CECDs(Scans) Clinical Outcomes

The mean clinical outcome scores for the CECDs fabricated from intra-oral scans (CECDs(scans)) ranged from 2.40-3.60 and indicated that 100% of the maxillary and mandibular dentures were rated “Good” (Fig.4.3). The base contour of the mandibular denture and base polish of the maxillary denture were the lowest rated variables, both with a mean score 2.40.

The base polish of the mandibular denture, tooth position of the mandibular denture, and midline of the maxillary denture were assigned scores of 2.50. The highest rated clinical outcome variables for the CECDs(scans) was support of the mandibular denture, with a mean score of 3.6. The gingival margin of the maxillary denture, gingival margin of the mandibular denture, and stability of the mandibular denture were each assigned scores of 3.3. The mean score for “Overall Result” for the CECDs(scans) was 2.80 (range 2.50-3.00). Thus, when considering the “Overall Result” variable, 100% of the CECDs(scans) were rated “Good”. A mean value of all clinical outcomes assessed was calculated and referred to as “Total Score”. The “Total Score” for the CECDs(scans) was 2.86, and indicated that 100% of the CECDs(scans) were rated “Good”. The prognosis for 20% of the CECDs(scans) was rated “Fair” or “Excellent” and 60% were rated “Good”. The clinical acceptability of the CECDs(scans) was rated 80% by both assessors.

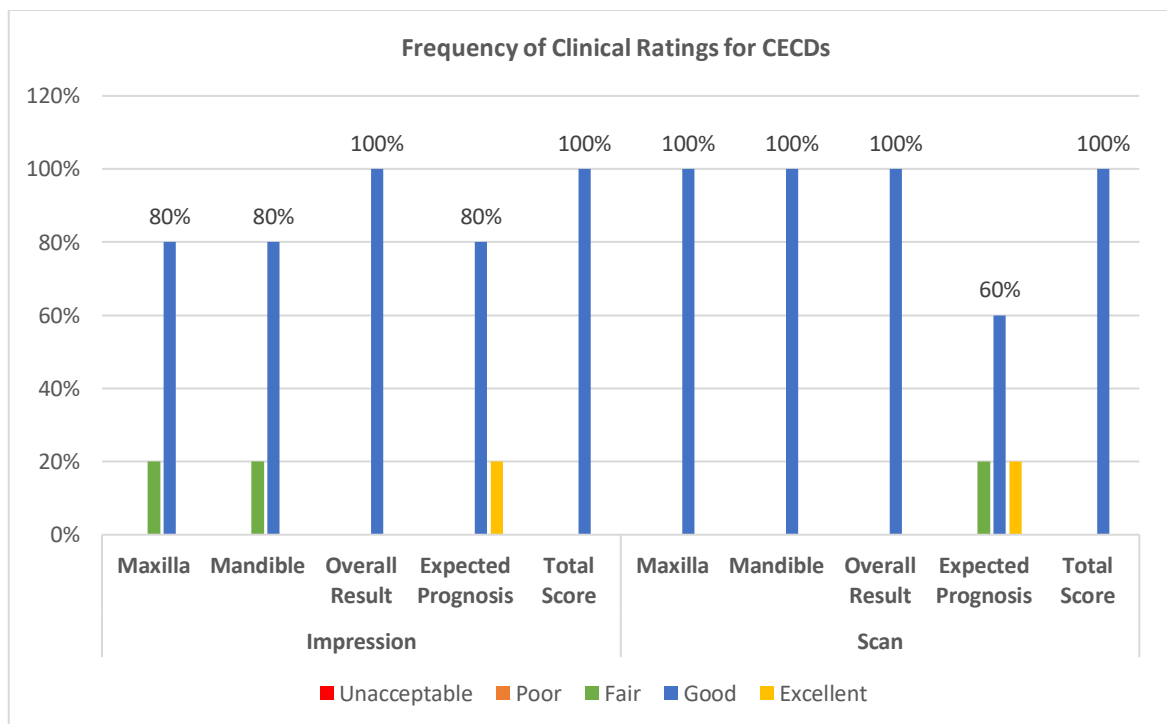


Figure 4.3. Frequency of ratings for clinical assessment for CECDs made from impressions and intra-oral scans.

4.4.3. Comparison Between the Clinical Outcomes of CECDs(Imps) and CECDs(Scans)

The data from the clinical evaluation of the CECDs was grouped as follows. “Denture form” included scores for base contour, polish, tooth position, tooth form. “Denture aesthetics” included scores for base shade, tooth shade, tooth display at rest, tooth display in the smile, gingival margin, and midline. “Denture fit” included scores for support, extensions, stability, and retention. “Denture occlusion” included scores for maximum intercuspation and excursive movements. A Shapiro-Wilk test for normality indicated that the data was not distributed normally ($p>0.05$), therefore, the non-parametric Wilcoxon signed rank test (2-sided test) was used to compare CECDs(imps) and CECDs(scans) when grouped as denture form, denture aesthetics, denture fit and occlusion. There was no statistically significant difference between the clinical outcomes of the CECDs(imps) and the CECDs(scans) for each data group ($p>0.05$). No statistically significant differences were found between the maxillary CECDs(imps) and the maxillary CECDs(scans) ($p>0.05$). No statistically significant differences were found between the mandibular CECDs(imps) and the mandibular CECDs(scans) ($p>0.05$). No statistically significant differences were found between the overall clinical outcomes of CECDs(imps) and CECDs(scans) ($p>0.05$).

4.5. Comparison Between Patient-Reported Outcome Measures of CECDs(Imps) and CECDs(Scans)

The scores for the patient reported outcome measures (PROMs) indicated that all participants rated the CECDs(imps) and the CECDs(scans) higher at the four week review appointment when compared with the first week review appointment (Fig.4.4). Ratings for the CECDs(imps) and the CECDs(scans) were observed to be similar at the one week and the four

week reviews (Fig.4.4). Participants One, Three, and Four were observed to rate the CECDs(imps) and the CECDs(scans) similarly with respect to their mean patient satisfaction scores (Fig.4.5). Participant Two rated the CECDs(scans) higher than the CECD(imps) for mean patient satisfaction (Fig.4.5). Participant Five rated the CECD(scans) lower than the CECD(imps) for mean patient satisfaction (Fig.4.5).

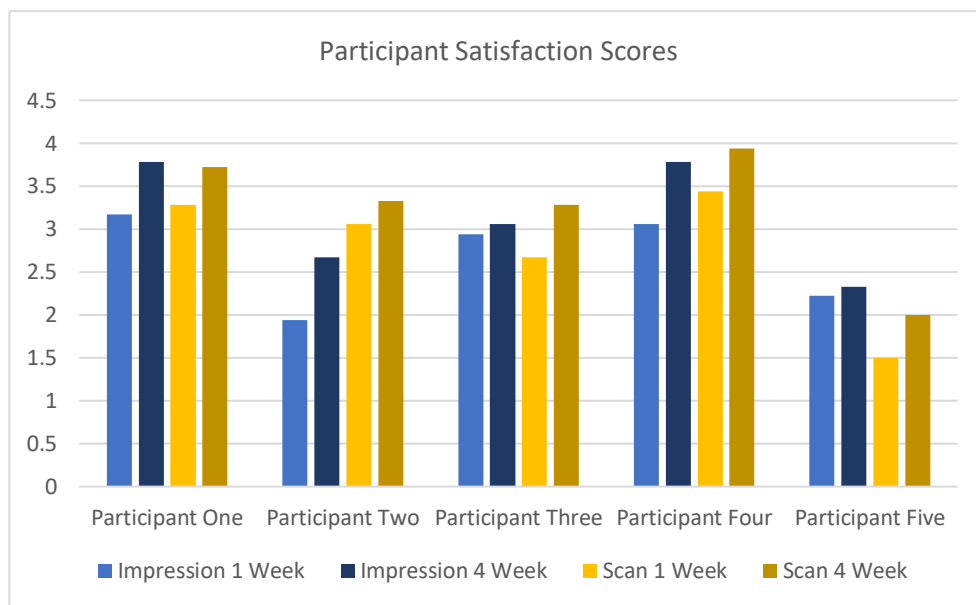


Figure 4.4. Total participant satisfaction scores for CECDs fabricated from impressions and intra-oral scans at week one and week four reviews

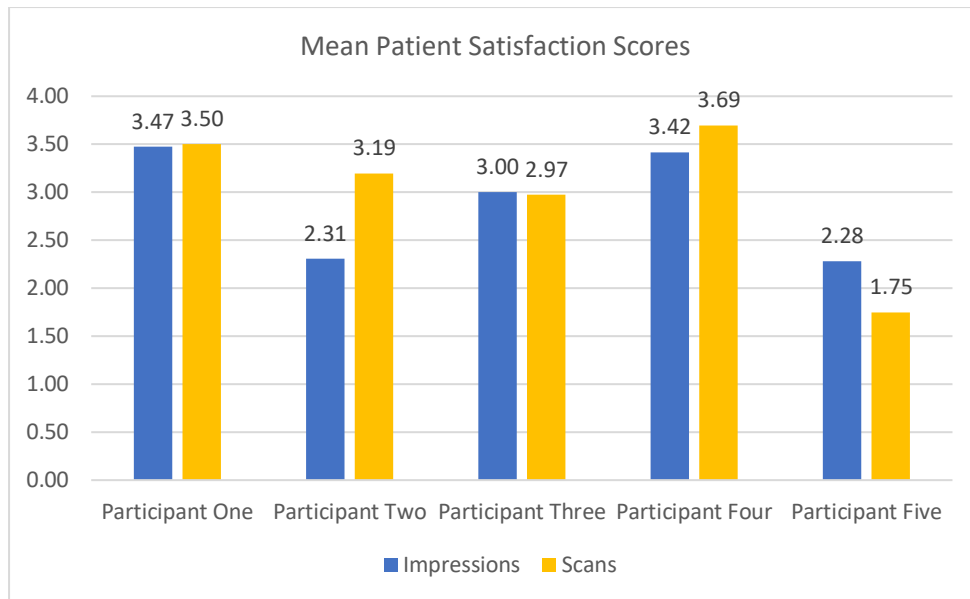


Figure 4.5. Mean participant satisfaction scores for CECDs fabricated from impressions and intra-oral scans

A Shapiro-Wilk test for normality ($p=0.05$) and Fisher's Exact Test ($p=0.05$) showed that the data for the participant related outcome measures were not distributed normally. Non-parametric Wilcoxon signed rank tests (2-sided, $p=0.05$) were used to compare the PROMs for both CECD groups for each participant. For all participants, the mean scores for the PROMs for the CECDs(imps) were significantly increased at week four compared to week one ($p<0.001$). Likewise, for all participants, the mean scores for the PROMs for the CECDs(scans) were significantly increased at week four compared to week one ($p<0.001$). However, there were no statistically significant differences between the PROMs for the CECDs(imps) and CECDs(scans) when compared at week one or when compared at week four ($p>0.05$). The PROM variables and data were grouped as follows. "Fit" included PROM scores for retention, support, and stability. "Aesthetics" included scores for gum display when smiling, tooth display when smiling, and tooth display at rest. "Function" included scores for speech and eating. "Occlusion" included scores for maximum intercuspation and tooth contact excursions (Fig.4.6). The fit of the maxillary and

mandibular CECDs(scans) were observed to be scored higher than for the CECDs(imps). The fit of the maxillary CECDs(scans) were observed to be scored higher than the maxillary CECDs(imps). The Wilcoxon signed rank test indicated that the mean fit (support, stability retention) of maxillary CECDs(imps) was significantly greater than the mean fit of mandibular CECDs(imps) ($p=0.043$) (Fig.4.6). There was no statistically significant difference in satisfaction scores for denture fit between maxillary and mandibular CECDs(imps) and CECDs(scans) ($p>0.05$) (Fig.4.6). There were no statistically significant differences between the aesthetic parameters related to the maxillary or mandibular CECDs(imps) or the CECDs(scans) ($p>0.05$). There were no statistically significant differences between the CECDs(imps) and CECDs(scans) for speech, function, or occlusion ($p>0.05$) (Fig.4.7). The ability to eat with both CECDs(imps) and CECDs(scans) was the lowest rated variable for participant satisfaction with mean scores of 2 and 2.1, respectively (Fig.4.7). No significant differences were found between CECDs(imps) and CECDs(scans) for comfort or overall rating (Fig.4.7).

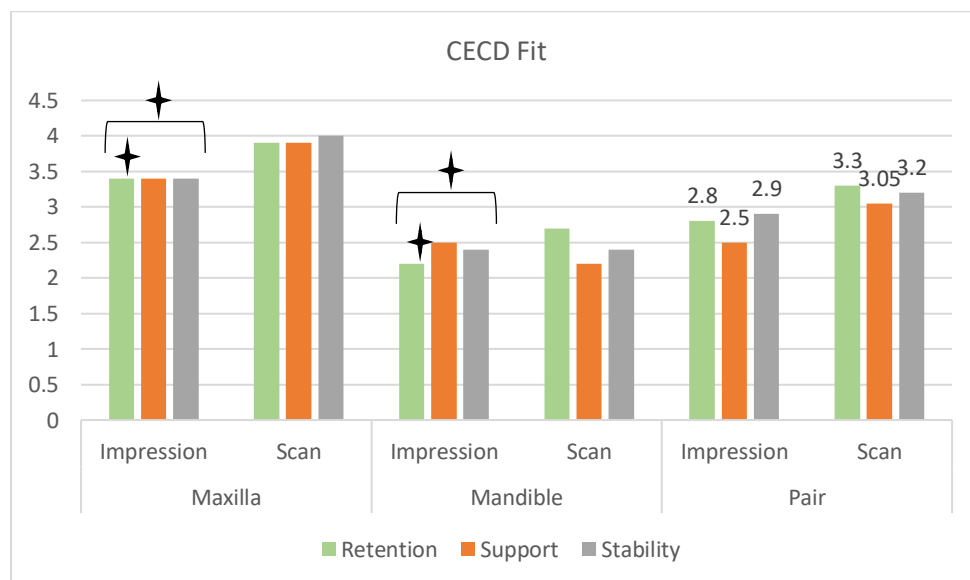


Figure 4.6. Mean participant satisfaction scores for denture fit of CECDs fabricated from impressions and intra-oral scans. ✦ = statistical significance ($p=0.05$)

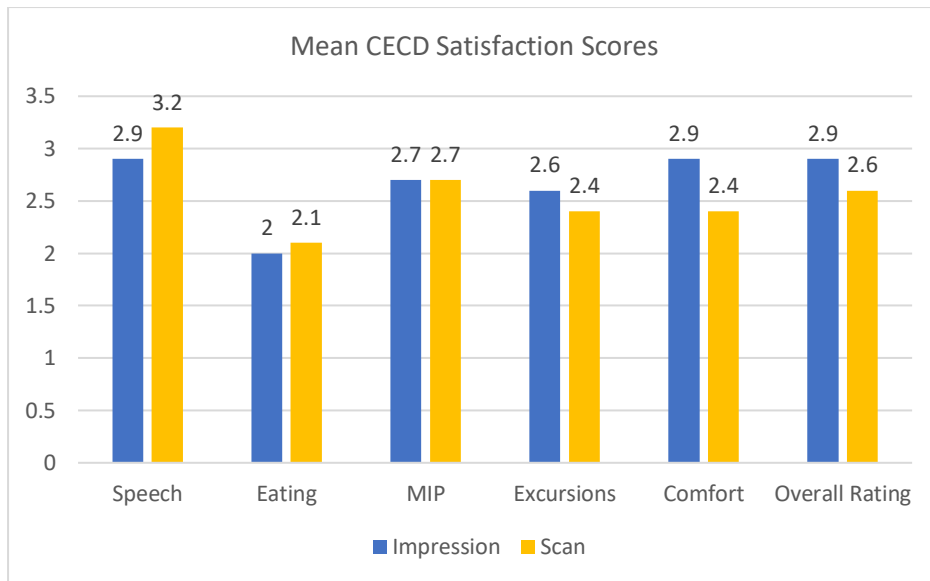


Figure 4.6. Mean participant satisfaction scores for CECDs fabricated from impressions and intra-oral scans

All five participants indicated a preference for IOS as an impression modality. Reasons for this included greater comfort for Participant One who described the IOS experience as “easier for me as a patient”. Participant One preferred IOS due to it being “much faster” [than impression making], and Participant Four indicated a preference for IOS because “you take one film and that’s it, I don’t have to come back”. Participant Three commented that the ability to visualise deficiencies in the digital impressions and make immediate corrections rather than make a further appointment made IOS more convenient. Participant Two expressed a preference for IOS due to their perception that the digital impression was more accurate, stating “scans are computerised and I would rather have more accuracy”. Four participants expressed a preference for the CECDs(scans), citing improved appearance, a reduced number of “sore spots” when compared with the CECDs(imps), and a lack of retention experienced with the CECDs(imps). Participant Three reported the CECDs(scans) to be “the best [dentures] I’ve had”. Participant Five favoured the CECDs(imps), citing improved retention compared to the CECDs(scans). Four participants chose to continue wearing the CECDs(scans), and one participant (Participant Five) chose to continue wearing the CECDs(imps).

4.6. Complications

The rate of re-makes for the CECDs(imps) was 80% for maxillary and 100% for mandibular dentures. The rate of re-makes for the CECDs(scans) was 20%, for the maxillary and the mandibular CECDs(scans) and was related to Participant Three. The CECDs(scans) for Participant Two were deemed clinically unacceptable by Prosthodontist One due to phonetics, and by Prosthodontist Two because the maxillary denture base was excessively thin (Fig.4.8). The CECDs(imps) were re-designed and re-milled for Participant Two due to a perceived lack of tongue space, where the participant reported “I don’t have enough room for my tongue”.



Figure 4.8. Thinness of maxillary denture base of CECD based on intra-oral scans for Participant Two

Complications regarding patient satisfaction with respect to comfort were found, with both CECD groups being rated as “Poor” for this variable by participants at week one due to pain as a result of mucosal trauma (Section 4.5). The mean PROM score for denture comfort was recorded as 2.4 at week one, increasing to 3.4 at week four for CECDs(imps), and 2.0 at week one, increasing to 2.8 at week four for CECDs(scans). Participants One and Two commented that the incidence of mucosal trauma associated with the fitting surface of the prostheses was higher and

more severe for CECDs, particularly the CECDs(scans) in the mandibular arch, than they had previously experienced with their current conventionally-processed CDs. The mandibular edentulous ridge (PDI Class III) of Participant One following a period of one week after insertion of the CECDs(scans) is illustrated in Figure 4.9a. Two additional unscheduled appointments were necessary to adjust the fitting surface of the denture, and the mucosal trauma resolved thereafter (Fig.4.9b,c). Labial and lingual hard tissue undercuts were present in the mandibular arch, where the ulceration was located. The CECD(imp) was reported to be more comfortable by Participant One and required less adjustment. Participant Two required adjustment of the posterior palatal border as a result of over-extension of the maxillary CECD(scan). Similarly, two additional unscheduled appointments were necessary for Participant Three to make adjustments to the CECDs(scans) because of ulceration on the anterior mandibular ridge crest.

Additional complications related to aesthetics were reported on by three participants. Participant One requested that the maxillary central incisors for both CECD groups be shortened by 1.5mm and re-contoured to make the teeth appear squarer in shape (an ovoid-shaped tooth mold had been chosen from the tooth library). Participant Two requested adjustment of the palatal and lingual embrasures of the maxillary anterior teeth in the CECDs(imps) and the CECDs(scans) to improve the aesthetics of the interproximal areas. The extent and rapid accumulation of extrinsic staining on the denture teeth and smooth surfaces was recorded as an aesthetic limitation of CECDs by Participant Two. The centre line of the maxillary CECDs for both groups required correction for Participant Four due to malalignment with the centre line of the face.

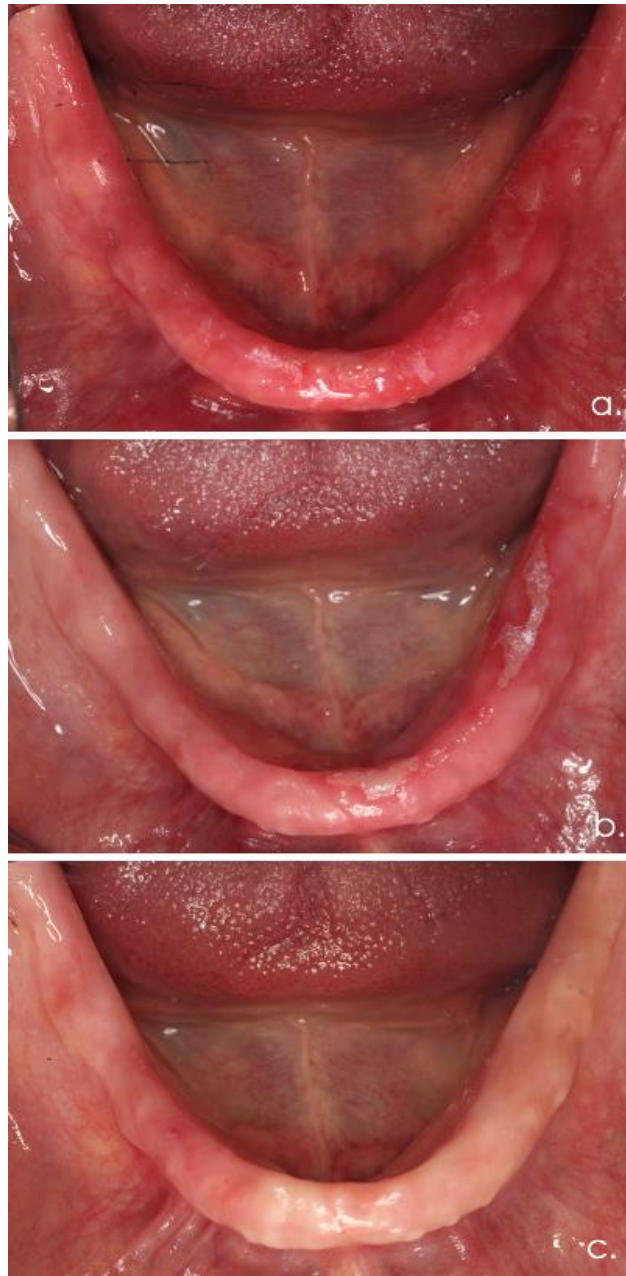


Figure 4.9. Post-operative tissue trauma with CECD based on intra-oral scan. a: one-week review; b: two-week review; c: four-week review

CHAPTER FIVE: DISCUSSION

4.1. Discussion

This pilot clinical trial demonstrated the feasibility of using IOS as a definitive impression technique for the fabrication of monolithic milled CECDs using the Ivoclar® Digital Denture System (Ivoclar Vivadent AG, Schaan, Liechtenstein). No statistically significant differences were found between the clinical variables for the CECDs fabricated with conventional impressions and CECDs fabricated using intra-oral scans of the edentulous arches, thereby failing to reject the first null hypothesis. There were no differences between the PROMs for the CECDs made from the impressions and from the intraoral scans of the edentulous arches, thereby resulting in failure to reject the second null hypothesis.

The recruitment process aimed to include consecutive participants requiring replacement prostheses who fulfilled the inclusion criteria. This was in contrast to the recruitment process used in other clinical studies (185), where the potential participants were recruited based on favourable prognostic factors as outlined in the ACP Classification of Complete Edentulism (175). Potential participants attending this university hospital tended to present as more complex cases, with vertical and horizontal maxillo-mandibular relationship discrepancies, and severe alveolar ridge resorption. Therefore, the recruitment of more participants with favourable Class I maxillo-mandibular relationships and Class I maxillary and mandibular edentulous arches (175) was not possible. Similarly, all personality types as classified by the House Classification were accepted as potential participants, despite the results of a previous prospective cohort study which highlighted treatment failures of monolithic CECDs (Global Dental Sciences, Arizona, USA) being recorded for two hysterical and one exacting participant (193). The exclusion of potential

participants on the basis of their personality types would have limited the clinical relevance of the results of this study, because edentulous patients with all personality types present for CD treatment in clinical practice.

This pilot trial was a prospective, single centre, randomised, crossover study. The crossover design was chosen to eliminate the potential for confounding participant-related variables found in denture construction, for example, salivary flow rates, mucosal quality, and patient expectations (251). Operator-related factors were accounted for by all clinical steps being performed by a single operator, and all technical steps being performed by a single dental technician. Technical construction variables were controlled by using one software system and one material type for the fabrication of the prostheses. A stringent technique for the duplication of the denture design was employed to ensure the prostheses were similar in all aspects except for the technique employed in making the definitive impressions. The standardisation of the tooth arrangement for both CECD groups ensured that any differences in the data recorded would be attributed to the impression technique only.

In a previous randomised trial, the crossover design demonstrated success in differentiating individual preferences for impression procedures when comparing digital and conventional impressions for single tooth implant crowns (296). A limitation of the crossover design is the potential for biased evaluations by the participant (229). It was suggested in a crossover study that participants tended to prefer the second intervention because new CDs feel different to their current dentures, and thus, the first study period is spent habituating to the new prostheses (236, 237). As a result, wearing the second set of CDs has the potential to not elicit as great an

effect on patient-related outcome measures as the first set of CDs. In a randomised controlled trial examining the effect of the impression technique on patient-related outcomes for conventional CDs, a four week washout period was recommended to prevent the second set of CDs being rated more highly (269). Therefore, the potential bias was mitigated for in this clinical study by selecting a similar washout period.

The CECDs(imps) and CECDs(scans) were each worn for a period of one month. This time period was chosen because in previous clinical studies examining the effect of CDs on oral health related quality of life (OHRQoL) for edentulous patients, the first four week period after denture insertion was significant for adaptation with respect to OHRQoL (374) and speech (375). Any differences between the prostheses may no longer be significant if assessed after six months, because the participant's functional adaptation, tissue adaptation of the denture base, and continuous resorption of the residual ridge may confound differences between the interventions (268).

The Ivoclar® Digital Denture System workflow used in the current study facilitated the fabrication of CECDs in three clinical visits and two laboratory procedures. The optional trial denture prosthesis step was omitted in this study to maximise restoration yield (193). In a clinical trial, the use of trial prostheses were advantageous in evaluating the aesthetic and occlusal parameters prior to fabrication of the definitive CECD prostheses (185). One drawback of CAD/CAM trial prostheses, however, is that the tooth positions cannot be altered at the chairside in a similar manner to conventional wax trial dentures, and re-designing is required to allow alterations to the tooth arrangement (194). Nevertheless, it was postulated that the rate of re-

makes of CECDs in this study would have been less if the trial prostheses had been incorporated into the workflow as an additional clinical step (193).

CECDs are fabricated using the Ivoclar® Digital Denture System (Ivoclar Vivadent AG, Schann, Liechtenstein) by milling the CECD base and the denture teeth separately from their respective pre-polymerised PMMA discs in a 5-axis CNC machine before bonding the base and teeth together with a chemically-activated PMMA resin (169, 364). Alternatively, the denture base and tooth arrangement can be milled from a single monolithic PMMA block (Fig.3.27a,b) (91). The monolithic “Ivotion™” (Ivoclar Vivadent AG, Schaan, Liechtenstein) product was used in this study for both prosthesis groups to eliminate confounding variables in the technical construction of the CECDs. The polychromatic puck ensured the denture base and tooth shades were the same for both CECDs(imps) and CECDs(scans) for each participant, and a stringent CAD process was followed in their design. It was impossible for the independent clinical assessors and the participants to differentiate the CECDs(imps) and the CECDs(scans) on the basis of material choice. All dentures were designed and milled by a single dental laboratory technician, thereby, ensuring comparability of the prostheses, and any differences between the CECDs(imps) and the CECDs(scans) could be attributed to the impression modality only. This ensured blinding of the independent assessors and participants to the impression modality being evaluated.

Both of the independent assessors and the participants were blinded to the order of insertion of the CECDs, thereby reducing bias in the evaluation process. The use of two prosthodontists as independent assessors eliminated bias by the Co-Investigator while evaluating the prostheses. Both assessors were calibrated with respect to the clinical evaluation criteria of the CECDs. The

intra- and inter-reliability of the assessors was determined to be “moderate” (Section 4.3). This suggested that the assessors should be recalibrated prior to recruitment of further participants.

In a crossover RCT comparing patient-related outcome measures to assess two impression materials for conventional CDs, it was demonstrated that the ratings for CD comfort changed after adjustment of the dentures (251). Adjusting the CDs effectively eliminated a difference in the comfort ratings between the two prostheses (251). A Cochrane review examining final impression techniques and materials for complete and removable partial dentures determined patient-satisfaction surveys conducted on adjusted dentures to be low quality evidence (240). The potential exists for inflated patient satisfaction scores being recorded when adjustments were conducted until no discomfort or mucosal trauma was reported (268, 354). To mitigate against this, the patient satisfaction questionnaire was completed at the first review appointment in this pilot trial prior to adjustment of the CECDs in this study.

Previous clinical studies implemented a Likert scale to effectively record immediate responses when gauging clinical- and patient-related outcomes of complete dentures (376). The inclusion of open ended questions was designed to allow both the assessors and participants raise any salient points related to the prostheses (376). The disadvantage of the five-point Likert scale was that the responses were limited to whole numbers, which potentially affected the quantification of true clinical and patient outcomes and experience. The potential for an assessor or participant selecting a score with which they did not entirely agree could have been eliminated through categorising options on a numeric scale, such as a visual analogue scale (VAS) (190). Advantages of the VAS instrument is its simplicity and established validity in quantifying,

recording, and evaluating qualitative outcomes that can be difficult to measure quantitatively (377, 378). The VAS allows a comparison of clinical outcomes with patient-related outcomes for comparable variables, like denture fit and denture aesthetics (193). However, a pilot trial comparing monolithic CECDs and implant-retained overdentures showed that the data had a wide distribution, which was considered a disadvantage. The OHIP-14 tool demonstrates validity, precision, and reliability (379). However, the instrument includes zeros and so its ability to detect within-subject change was compromised (380).

The five sets of CECDs from both groups were rated as having a “Good” “Overall Result” and “Total Score” by the clinical assessors. Prosthodontist One determined all of the CECDs(imps) to be clinically acceptable, but determined one of the CECDs(scans) to be clinically unacceptable, and the reason cited was a lisp during speech. Prosthodontist Two also determined the same CECD(scan) to be clinically unacceptable, citing thinness of the maxillary denture base. Therefore, this CECD(scan) was rejected by the assessors based on complaints unassociated with the fit of the denture that could be attributed to the impression modality, or on discrepancies between the efficacy of conventional impressions and intra-oral scans. Discrepancies in the maxillary anterior tooth arrangement and thinness of the denture base can instead be attributed to a technical error with the CAD while completing the virtual tooth arrangement which was not evaluated using a denture prototype.

Data analysis found no differences in the clinical outcomes between milled CECDs fabricated with conventional impressions and using intra-oral scans of the edentulous arches (Section 4.4.3). CECDs(imps) and CECDs(scans) were scored highly for retention by both independent

assessors. The denture base contour of both groups of maxillary CECDs were observed to be similar (Fig.5.1). It was postulated that the high retention scores were due to the absence of polymerisation shrinkage by the milling the CECDs from monolithic pre-polymerised blocks of PMMA because differences were observed between the CECD groups with respect to the flange extensions. For Participant Five, the maxillary CECD(scan) was under-extended bilaterally in the hamular notch area compared to the maxillary CECD(imp) (Fig.5.2). This was attributed to the difficulty in IOS hard tissue undercuts and the inability of the intra-oral scanner to capture the full depth of the sulcus in this area. The posterior palatal seal of the maxillary CECD(scan) was over-extended by approximately 3mm for Participant Two. This was due to the difficulty encountered by the technician in interpreting the correct location of the posterior palatal seal on the intra-oral scan. Disclosing the vibrating line intra-orally prior to impression making and IOS may have prevented this outcome. For Participants Three and Four, the CECDs(scan) were found to be over-extended in the buccal vestibules by the operator (Co-Investigator). However, the appropriate extensions were established with minimal adjustment of the prostheses.



Figure 5.1. Similar denture base outlines. a: CECD based on intra-oral scan. b: CECD based on impression

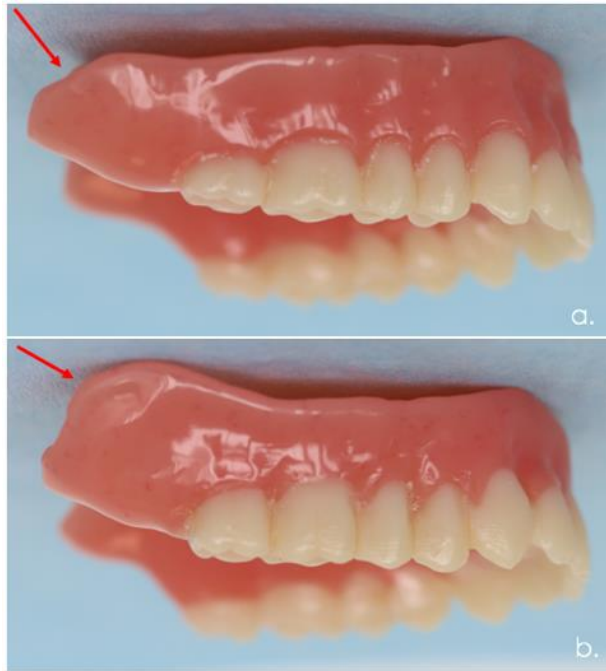


Figure 5.2. Extensions in the hamular notch. a: CECD based on intra-oral scan (under-extended). b: CECD based on impression (correctly extended)

The differences in the extensions of the mandibular CECDs(imps) and CECDs(scan) were more obvious. The mandibular CECDs(scans) were under-extended in the lingual vestibules for Participants Three and Five (Fig.5.3a,b), when compared with the CECD(imp) (Fig.5.3c,d). These occurrences were attributed to the difficulty in recording the depth of the vestibule during IOS due to the mobility of the soft tissue and the floor of the mouth, while physically retracting the tongue. In addition, the mandibular CECDs(scans) were generally under-extended over the retro-molar pads (Fig.5.4a), either unilaterally or bilaterally, when compared with the CECDs(imps) (Fig.5.4b). The difficulty in capturing the full extent of the retro-molar pad area during IOS owing to a lack of distinct reference points was acknowledged as one reason for this, with subsequent difficulties in appropriately extending the denture bases in this area reported by the dental technician.

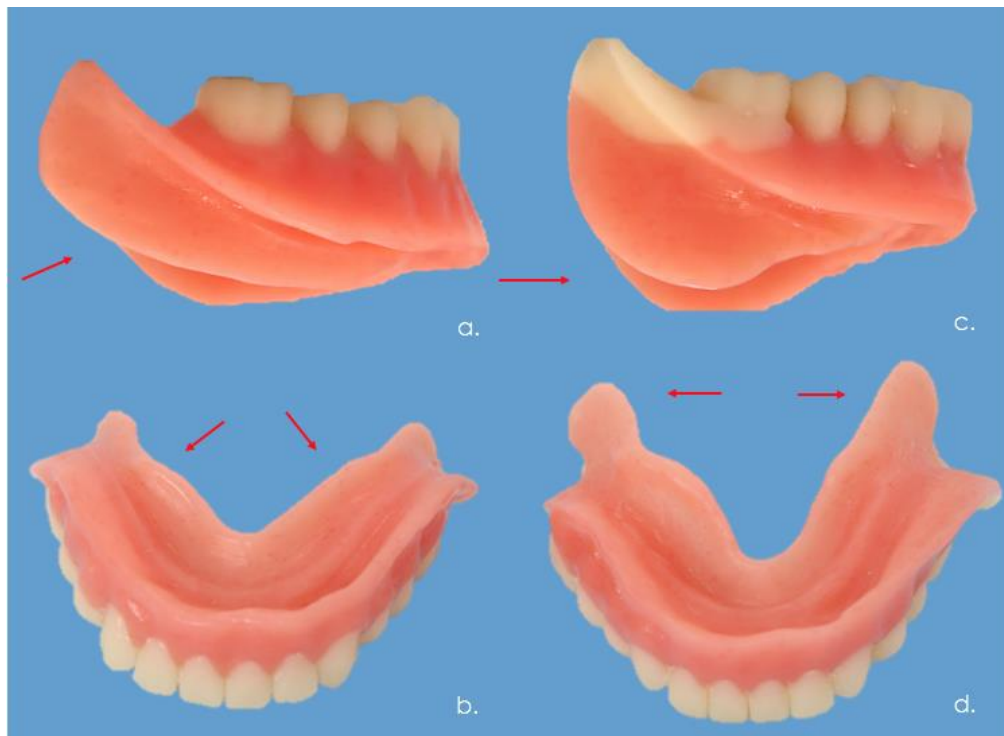


Figure 5.3. Examples of CECD extensions in the posterior lingual vestibules. a,b: CECD(scan) is under-extended. c,d: CECD(imp) is correctly extended

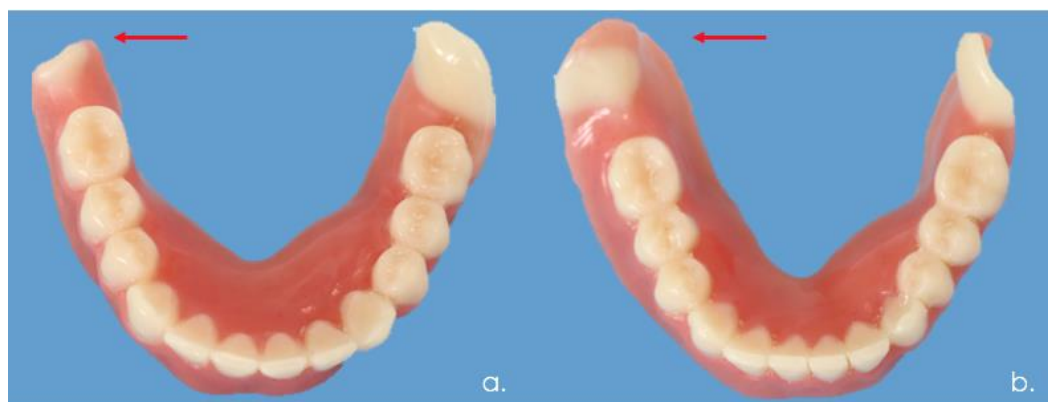


Figure 5.4. Extensions over retro-molar pads. a: CECD(scan) is under-extended. b: CECD(imp) is appropriately extended. The anterior lingual flange is appropriately extended over bilateral mandibular tori for both a and b.

The “Clinical Acceptability” of both CECD groups in this study were similar. While this is not indicative of technical equivalence between the prosthesis types, it may be inferred that CECDs

fabricated from intra-oral scans of the edentulous arches produced comparable clinical outcomes compared to CECDs fabricated from conventional impressions.

The aim of the qualitative aspect of the study was to provide an understanding of the PROMs and preferences for either CECD group from the participants' perspective. The participants evaluated prosthesis success with regard to retention, stability, function, aesthetics, and comfort (185). The PROMs recorded at the first week following insertion of the CECDs indicated that minor complications were experienced with the CECDs of both groups. No statistically significant differences were recorded between the CECDs(imps) and CECDs(scans) at week one. All participants rated the CECDs(imps) and CECDs(scans) higher at the four week review appointment compared to the first week review, indicating adaptation and acceptance of the new prostheses during the review period. This finding conforms with previous studies where the initial four weeks was a sufficient time period for adaptation to new dentures (374, 375). The PROMs at week four were not significantly different when the CECDs(imps) and the CECDs(scans) were compared, indicating similar patient satisfaction with the prostheses made from both impression types.

Three participants rated the CECDs from both groups similarly for all variables. Participant Two rated the CECDs(scans) higher than CECDs(imp), whilst Participant Five rated the CECDs(scans) lower than the CECDs(imps). Participant Two presented with a hysterical personality type, a Class IV mandibular arch, and a four year history of denture-wearing. In contrast, Participant Five presented with a philosophical personality type, a Class III mandibular arch and a ten-year history of denture-wearing. Participant Five expressed dissatisfaction with

the support, stability, and retention of both CECD groups, despite the CECDs(imp) and CECDs(scans) being rated clinically acceptable for these variables by the independent assessors. It was postulated that either personality type or a participant's overall inability to adapt to new mandibular prostheses had a greater influence on their satisfaction scores than the difference in the impression modalities used to fabricate either prosthesis (381).

Participant satisfaction with the retention of the maxillary CECDs(imp) was significantly greater than the mandibular CECDs(imp). Additionally, the fit (support, stability, and retention) of the maxillary CECDs(imp) was significantly better than the fit of the mandibular CECDs(imp). There was no difference in participant-reported satisfaction with the retention or fit of CECDs(imps) compared to CECDs(scans). Furthermore, there was no difference between either CECD group for denture aesthetics, speech, function, occlusion or comfort. The ability to eat and chew was scored lowest in terms of participant satisfaction for both CECD groups at week one. It was thought that these low scores were attributed to the presence of "sore spots" in maxillary and mandibular arches in the period immediately following insertion the prostheses. Nevertheless, the total score reported by the participants for CECDs(imps) was not significantly different to their reported satisfaction with the CECDs(scans). When these results are considered together, it was postulated that digital impressions of edentulous arches produced CECDs with comparable participant-reported satisfaction compared to CECDs fabricated from conventional impressions.

Several clinical and technical challenges were encountered in both workflows. The Class III maxillo-mandibular relationship of Participant Four made the use of the Centric Tray® difficult.

This difficulty was not reported in previous studies because the participants chosen had favourable Class I maxillo-mandibular arch relationships (185). The Centric Tray® is designed for patients with a Class I maxillo-mandibular relationship, however, there were no such participants in this trial. One participant experienced difficulty closing to the proposed OVD and swallowing with the Centric Tray® and irreversible hydrocolloid material intra-orally, and the technique elicited a gag reflex. The presence of undercuts in the mandibular ridge made recording the lingual sulci challenging in another participant. A stiff mix of the irreversible hydrocolloid (higher powder to water ratio than recommended by the manufacturers) in the Centric Tray® was required for all participants to prevent slumping of the material.

For one participant, the borders of the UTS CAD® biteplates were over-extended in both arches, and required significant adjustment to facilitate border molding. This may have occurred as a result of the primary impressions being over-extended. This finding was similar to that described previously for milled biteplates (189). For one participant, the mandibular UTS CAD® biteplates were under-extended bilaterally in the lingual sulci, and under-extended bilaterally over the retro-molar pads for another participant (Fig.5.5). This was attributed to a technical oversight in not extending the borders fully at the design stage. Autopolymerising resin (PATTERN RESIN™, GC America Inc., Illinois, USA) was added to create appropriate extensions (Fig.5.6).

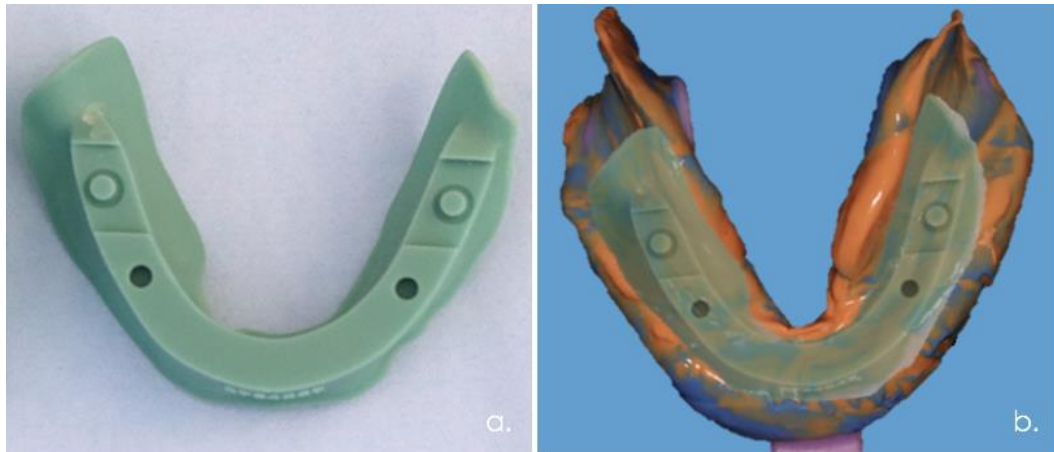


Figure 5.5. a: Mandibular UTS CAD® biteplate. b: Biteplate under-extended distally compared to preliminary impression

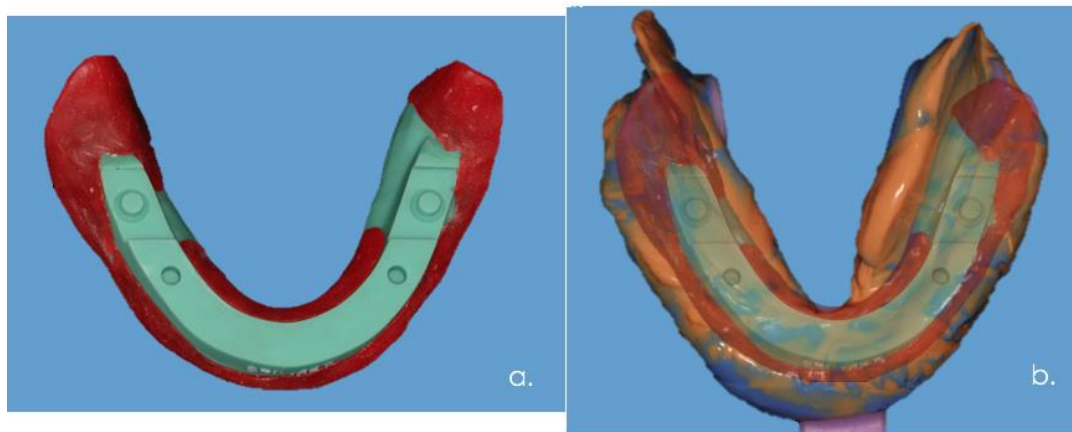


Figure 5.6. a: Adjusted mandibular UTS CAD® biteplate with autopolymerising resin to correct under-extensions. b: Biteplate appropriately extended compared to preliminary impression

For Participants Four and Five, the OVD was reduced when the UTS CAD® biteplates were evaluated, necessitating the addition of modelling wax to the removable plastic rims to restore the vertical dimension, as recommended by the manufacturers. A reduced OVD may have been recorded if the participant elevated the mandible excessively in the Centric Tray® while making the preliminary maxillo-mandibular registration record. For Participant One, the OVD was increased on evaluation of the UTS CAD® biteplates, thereby rendering them unacceptable and necessitating another recording of the preliminary maxillo-mandibular relationship with the

Centric Tray®. The custom UTS CAD® biteplates also functioned to assess the soft tissue support and phonetics. As previous authors acknowledged, it was difficult to test phonetics with the custom biteplates due to lack of retention and the difficulty in adjusting the material (189).

Several attempts at conventional impression making were necessary for two participants to achieve a satisfactory impression. This was due to the presence of lingual and labial undercuts in the mandibular ridge for Participant Three, and the presence of severe mandibular anterior ridge resorption and superficial frenal attachments for Participant Five. A closed-mouth impression technique with maxillary and mandibular UTS CAD® biteplates was adopted according to the manufacturer's instructions. It was postulated that the freedom to choose alternative impression materials would have avoided challenges when making impressions, rather than being restricted to the manufacturer's guideline of VPS for the purpose of this study. The recording of the definitive maxillo-mandibular relationship at the chosen OVD using the Gnathometer CAD® was challenging in Participants Two, Three, and Five. The maxillary and mandibular biteplates contacted posteriorly, thereby preventing these participants from executing mandibular movements. Adjustment of the trays and impression materials was necessary over the maxillary tuberosities and retro-molar pads, in particular, to prevent interferences when completing the gothic arch tracing (356).

Only one Gnathometer CAD® size is currently available on the 3Shape Digital Denture System® software, and the design of the snap-in system for its retention on the biteplates is pre-set. The need for a minimal inter-arch space to incorporate the Gnathometer CAD® apparatus into the customised UTS CAD® biteplates design precluded the use of UTS CAD® biteplates for

Participant One. Conventional wax occlusal rims on record bases (Triad®, Dentsply Sirona, North Carolina, USA) were fabricated for this participant due to the reduced inter-arch space (181). The design of the Gnathometer CAD® is optimised for the Class I maxillo-mandibular relationship (181). The gothic arch tracing was challenging to execute in Participants Two, Three and Five with Class II maxillo-mandibular relationships due to the retrognathic position of the mandible, because the range of mandibular movement in the horizontal plane was greater than the area of contact between the flat surface and the central bearing device for these participants. Additional challenges with the gothic arch tracing were encountered in Participants Three and Five with poor co-ordination of the mandible during lateral excursive mandibular movements. A lack of stability and resultant movement of the UTS CAD® biteplates was encountered for Participants Two and Five during the tracing due to severe residual ridge resorption. The difficulties outlined could preclude the use of CECDs workflows for practitioners.

IOS of the edentulous maxillary arch was uneventful for all participants when the scanning strategies described in Section 3.7.2 were adopted. Several challenges were encountered during IOS of the mandibular arch. Participant Four struggled to maintain the mandible in a static position, with mandibular movement causing movement of musculature and mobility of the soft tissues, which resulted in the need for manual stabilisation of the mandible during the scanning process. For all participants, capturing the lingual sulci in a single pass of the scanner head was critical for an accurate record of the mandibular arch. Difficulties were encountered when attempting to make corrections to an incomplete scan or add to the scan of the lingual vestibules, in particular, owing to the lack of anatomical reference points present in the edentulous mandibular arch. Participant Two displayed severe residual ridge resorption of the mandibular arch. To aid in IOS, an “X” and an “O” shape were disclosed on the tissue on the crest of the

residual ridge in the canine regions using a skin marker (Viscot™ surgical marker 1451, Viscot Medical LLC, New Jersey, USA). In addition, a mix of temporary luting cement was added to the tissue surface in the midline of the edentulous mandible, (Fig.5.7) thereby creating reference points with variable shapes and colours to facilitate scanning. The temporary luting cement was erased from the scanned image, and the tissue re-captured in this site to complete the digital impression. Although the IOS time for each arch was not measured in this study, the operator observed that minimal time was required for scanning of the maxillary arch (approximately ninety seconds), and was completed in one attempt for all participants. However, scanning time for the mandibular arch was relatively prolonged (up to fifteen minutes), and required multiple attempts for all participants. Improvements in the technology of future scanners may reduce the IOS time further (198).



Figure 5.7. Intra-oral scan of the mandibular edentulous arch showing irregular reference marks anteriorly to facilitate scanning completion

The occlusal plane level was indicated by marking the level of the resting upper lip on the VPS registration material on the facial surface of the maxillary UTS CAD® biteplate. However, errors in locating the position of the mark were encountered in the CAD for all participants, and

were attributed to difficulty in visualising it after extra-oral scanning of the clinical records. Within the 3Shape Denture Design® software, the occlusal plane was defined using three reference points, namely the middle of the retro-molar pads, and a point in space at the incisal level of the mandibular central incisors, with the UTS CAD® values inputted to make corrections in the horizontal and sagittal dimensions (Section 3.8.5). In contrast, the AvaDent® Digital Dentures system used a clear plastic template containing the silhouettes of the maxillary anterior teeth affixed to the labial VPS material to indicate the appropriate incisal edge position and form of the maxillary anterior teeth (133). Application of a similar template within the Ivoclar® Digital Denture system could aid in positioning of the incisal edge and maxillary occlusal plane if the mark on the VPS registration material were not clearly visible. Its use would also help the technician in the selection of appropriate anterior tooth mold in the virtual tooth arrangement, and possibly negate these complications observed in this study.

The tooth arrangement algorithm for CECDs using the 3Shape Denture Design® software is ideally suited to those with Class I maxillo-mandibular arch relationships, which facilitates relative movement of the opposing groups of posterior teeth to develop a stable MIP. In this study, the participants had Class II and III maxillo-mandibular relationships, making it necessary to move individual teeth and to omit certain teeth, for example second premolars or second molars. The tooth arrangement for the participants of this study was relatively difficult to execute, and a clinical remount was required to refine the occlusal scheme and achieve bilaterally balanced articulation for all participants. For participants Two and Five, the digitisation of the current CDs was helpful as a reference for the technician to guide the tooth arrangement of the CECDs. The technician was instructed to choose a similar anterior tooth mold according to the participants' requests in these cases. The current CDs were assessed prior to digitisation to confirm that the

existing tooth arrangement was appropriate with respect to function and aesthetics. However, the use of a monolithic system limited the ability to customise individual denture tooth position due to the pre-set positions of the tooth-coloured PMMA within the puck (Section 3.8.5). The inability to produce customised denture teeth is one of the main disadvantages cited for commercial CECD technology (339). Participant Two requested an individualised maxillary anterior segment arrangement, including a diastema and increased embrasure spaces between the denture teeth, which could not be accommodated within this workflow. Assessment of the virtual tooth arrangement and final CECD CAD was difficult, and disconcerting to complete digitally compared to the physical tooth arrangement of conventional dentures.

The rate of re-makes for CECDs was high in this clinical study, and greater than those previously reported in the literature. In a retrospective, cross-sectional study examining the provision of thirty-nine CECDs (AvaDent®, Global Dental Sciences, Arizona, USA) in a university setting (191), five CECDs (13%) were re-made due to requests for change in denture base or tooth shade. The reasons for re-make in this study were varied. The maxillary and mandibular CECDs(scans) were re-made for Participant One due to an unacceptable increase in the OVD (Fig.5.8). The extra-oral scan of the definitive maxillo-mandibular relationship record was re-checked, and the position of the labial flange of the mandibular UTS CAD® biteplate had been misinterpreted by the dental technician in the CAD, thus resulting in an error in the vertical orientation of the virtual casts. The virtual mandibular master cast was re-aligned, the tooth arrangement adjusted, and a replacement denture was milled.



Figure 5.8. Incorrect position of mandibular anterior teeth due to misalignment of the virtual mandibular master cast in CECD based on intra-oral scans

A large discrepancy existed between the widths of the maxillary and mandibular arches of Participant Two. The instruction to create a bilateral balanced occlusal scheme with the mesiobuccal cusp of the maxillary first molar occluding in line with the buccal groove of the mandibular first molar resulted in the dental technician placing the mandibular posterior teeth lingual to the edentulous ridge, thus invading the tongue space (Fig.5.9a,b,c). The virtual tooth arrangement was re-designed with a buccal crossbite bilaterally, the mandibular posterior teeth were re-positioned over the residual ridge crest, and the CECDs were re-milled for Participant Two to provide maximum tongue space (Fig.5.9d,e,f). Nonetheless, three additional unscheduled appointments were requested to adjust the lingual contours and cusps of the mandibular teeth of the re-make prosthesis to create even more space, at the participant's request. The current Ivoclar Digital Denture® protocol is not optimised for edentulous patients where a neutral zone impression technique would be beneficial.

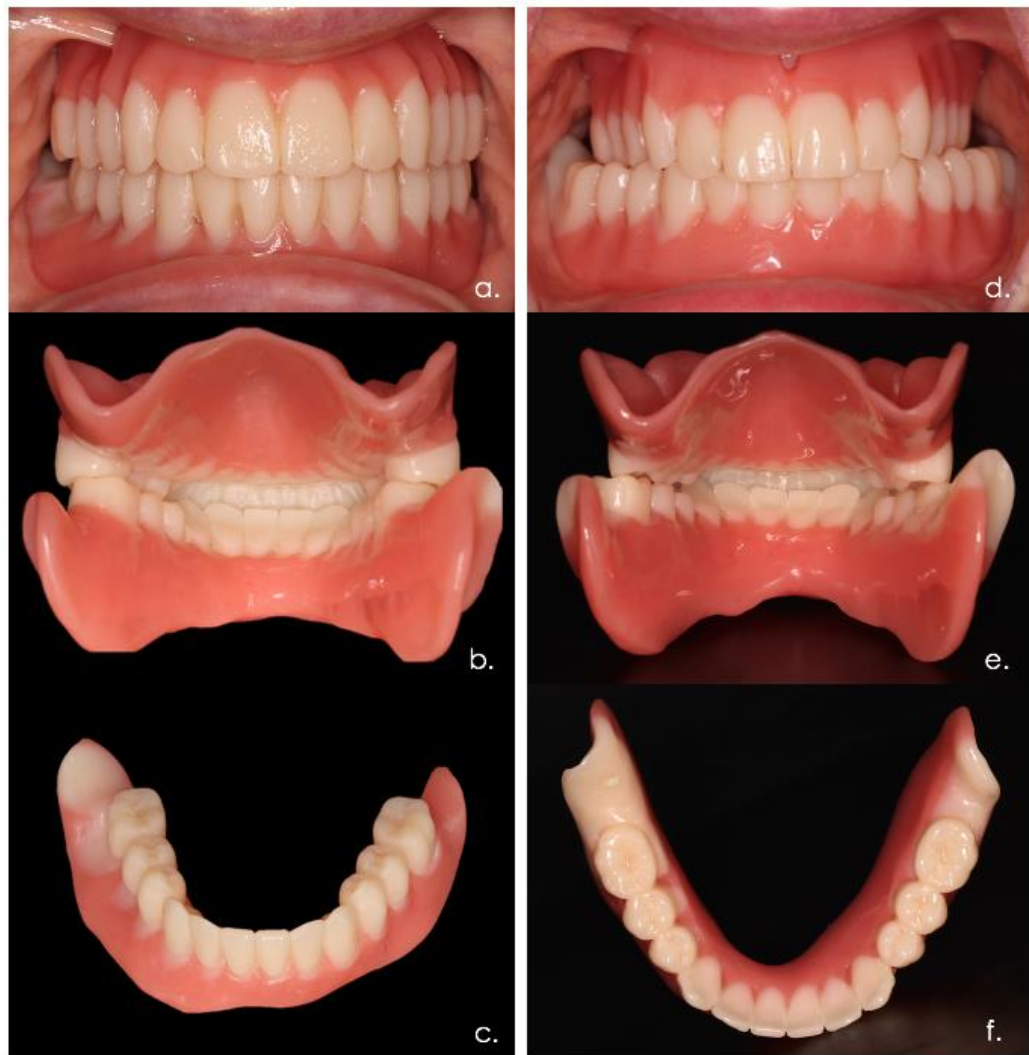


Figure 5.9. Positioning of mandibular posterior teeth for CECDs(imp). a, b, c: teeth positioned lingual to crest of residual ridge. d, e, f: teeth positioned on crest of residual ridge resulting in bilateral buccal crossbite

The CECDs(imps) were re-made for Participant Three with a PDI class III mandibular arch due to lack of retention and under-extended lingual flange of the mandibular prosthesis. This was attributed to the difficulties in capturing the full extensions of the lingual vestibules with conventional impressions due to the presence of hard tissue undercuts lingual to the residual ridge. The definitive conventional impressions were repeated prior to re-making of the CECDs(imps). On the contrary, the lingual sulci of the CECDs(scans) were appropriately extended, because the full extension of the vestibules beneath the undercuts were captured during IOS.

The CECDs(imps) were re-made for Participant Four because the maxillary denture was under-extended in the right hamular notch, and the mandibular denture was under-extended bilaterally over the retro-molar pads. The CECDs(imps) denture extensions were adjusted on the software, the prostheses milled again, and inserted at a subsequent appointment. These complications were attributed to the subjective interpretation of the appropriate denture base extensions on the virtual master casts generated from intra-oral scans (Section 3.8.5). The CECDs(imps) were re-made for Participant Five because the occlusal plane level was incorrectly positioned. The incisal edge position was moved inferiorly by 3mm on the CAD, the virtual tooth arrangement adjusted, and the prostheses were re-milled. The difficulties in interpreting the appropriate level of the occlusal plane on the VPS registration material have been discussed. The inclusion of a trial denture in this protocol to assess functional and aesthetic parameters prior to milling of the definitive prostheses would have minimised these complications in the definitive CECDs.

Other complications noted with CECDs were predominantly aesthetic in nature. The integration of extra-oral photographs or facial scans with the CAD software was not considered in this study, because it is not included in the current Ivoclar® Digital Denture protocol, but may have assisted in the objective assessment of the final CECD design within the context of the participant's facial features, thereby reducing the number of aesthetic complications found for Participants One, Two, and Four. Aesthetic limitations regarding extrinsic staining of denture teeth and smooth surfaces were reported (Section 4.6). After removal of the milled CECD from the milling machine, polishing the PMMA was a more onerous task than polishing a conventionally-processed CD because the milling lines on the denture base and the teeth required removal (Fig.5.10). Failure to adequately polish the CECD surface (Fig.5.11) resulted in an accumulation of extrinsic staining, which was particularly evident on the occlusal surfaces of

the teeth and in the well-defined embrasure spaces for Participant Two. Meticulous polishing of CECDs is necessitated to negate these aesthetic complications.

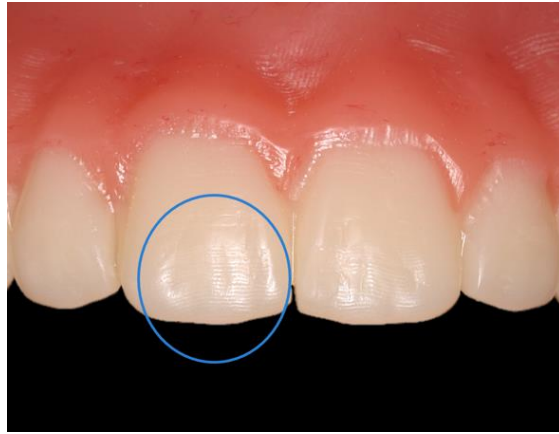


Figure 5.10. Horizontal milling lines evident on surface of CECD



Figure 5.11. Extrinsic staining on CECD teeth

5.2. Limitations of Current Study

A number of limitations of this study were recognised. No participants with Class I maxillo-mandibular relationship or no participants with PDI Class I maxillary and mandibular edentulous arches were recruited for this current study. Thus, the Ivoclar® Digital Denture System protocol was applied to participants for whom it was not optimised. The technique adopted for aligning the intra-oral scans of the edentulous arches in the definitive maxillo-mandibular relationship was dependent on the accuracy of the 3D-printed biteplates, the accuracy of scanning their intaglio surfaces, and the accuracy of “best-fit algorithm” to align the arches to the biteplates. The small sample size did not meet the requirements of the power calculation and was a limitation of the study. Thus, this trial was designed as a pilot study to identify trends and guide a future prospective trial with a suitable number of participants (42). Randomisation of the order of prosthesis delivery ensuring equal numbers in parallel groups was not feasible due to the small population size. While recruiting a diverse range of participants was an attempt to improve the external validity or general applicability of this study, it had the potential to introduce confounding variables that increased the difficulty in delivering successful prostheses. Although the results of this study indicated that the two impression techniques are comparable, the findings may not be applicable generally to other clinical contexts.

5.3. Implications for the Management of Edentulous Patients

The results of this study offer a contribution to the limited amount of in-vivo studies on IOS of the edentulous arches, and its application to the fabrication of CECDs. The feasibility, applicability, and success of incorporating IOS of edentulous arches into a commercially available CECD workflow was demonstrated. The use of IOS to make a definitive impression of the

edentulous arches could eliminate the need for impressions and all of the associated materials and time. Elderly edentulous patients that struggle to attend dental appointments due to general health problems or logistics, would benefit from the reduced number of clinical visits and the simplified procedures offered by the IOS-CECD protocol in particular.

5.4. Future Research

Prospective clinical studies with larger population sizes are required to cultivate evidence-based data on IOS for CECDs. With increasing numbers of participants, allocation into groups according to prognostic factors within the classification of complete edentulism (175) or personality type, would permit stratified randomisation and investigation of the effect of each of these baseline characteristics on the clinical- and patient-related outcome measures. Parallel-group designs are preferred over crossover trials to prevent participants receiving no treatment during the wash out period (269).

Future research should incorporate facial scans into the CAD software to help the clinician and dental technician in assessing the CAD design virtually, reducing the need for trial prostheses and facilitating communication with the patient (215) and the dental technician. A threshold value for the accuracy of intra-oral scans considered acceptable for CECD fabrication has yet to be established. A universal methodological assessment tool for in-vitro studies does not currently exist (382). These two issues should be resolved by future scientific research to identify which clinical situations can garner the greatest benefit from IOS. IOS should primarily serve the patient, and thus, the most critical focus should be on patient-related outcomes.

CHAPTER SIX: CONCLUSION

6.1. Conclusions

Within the limitations of this clinical study, the following conclusions were drawn:

- IOS of the edentulous arches is feasible and generated digital casts that were sufficiently accurate to enable the fabrication of a well-fitting denture base.
- Similar clinical outcomes were reported for milled CECDs fabricated from impressions and milled CECDs fabricated from intra-oral scans of the edentulous arches.
- Patient satisfaction, comfort, ability to function and aesthetic result were similar for both CECD groups.
- Intra-oral scanning is preferred as an impression modality to conventional impression making.
- Milled CECDs fabricated from intra-oral scans of the edentulous arches are preferred to milled CECDs fabricated from impressions.

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APPENDICES

Appendix 1. Patient Information Leaflet

PARTICIPANT INFORMATION LEAFLET

A Prospective, Single Blind, Crossover Clinical Trial to Assess the Outcomes of Computer-Engineered Complete Dentures using Impressions and Intra-Oral Scans of the Edentulous Arches

Principal Investigator(s) and Co-investigator(s):

Principal Investigator: Dr Brendan Grufferty

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Consultant in Restorative Dentistry

Co-Investigator: Dr Gabrielle O'Donoghue

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Doctorate in Clinical Dentistry Postgraduate Student

Introduction

You are being invited to take part in a research study to be carried out at Dublin Dental University Hospital by Dr Brendan Grufferty. Before you decide whether or not you wish to take part, you should read the information provided in this leaflet carefully. Take time to ask questions – don't feel rushed or under pressure to make a quick decision. You should understand the risks and benefits of taking part in this study so that you can make a decision that is right for you. You may wish to discuss it with your family, friends or GP.

PART 1 – THE STUDY

Why is this study being done?

The aim of the research study is to investigate the outcomes of computer-engineered complete dentures made from impressions as compared with dentures made from digital scans of the mouth. The dentures will be examined to compare how well they fit, their appearance and how comfortable they feel while chewing and speaking. This study has educational value in terms of advancing digital workflow protocols and clinical outcomes of computer-engineered complete dentures.

Why am I being asked to take part?

You have been invited to participate in the study because you are attending the Dental Hospital for replacement of your existing dentures. The research aims to survey up to 24 participants over the age of 18.

Do I have to take part? What happens if I say no? Can I withdraw?

Participation is entirely voluntary. You can change your mind about taking part in the study and opt out at any time. If you decide not to take part, or decide to opt out, it won't affect your current or future dental care. You don't have to give a reason for your decision.

What happens if I change my mind?

You can change your mind at any time by contacting the Gatekeeper (who is yet to be identified). If you choose not to take part any more, you will be asked to fill in a withdrawal form. You can ask to have any of your data that has been stored to be destroyed. We will no longer use your data for research from this point onwards. However, it will not be possible to destroy data already used in research studies prior to this time.

How will the study be carried out?

Patients attending for replacement of their complete dentures at the Dublin Dental University Hospital will be invited to participate in the study. Once consent is obtained, participants will attend for clinical appointments to make the new dentures. Participants will receive two sets of dentures, one set made from standard impressions, and a second set made from an intra-oral digital scan of the mouth. One set of dentures will be fitted and evaluated clinically by an evaluator (another dentist). Participants will be requested to wear the dentures for a period of 30 days, before completing a patient-satisfaction survey. Participants will then wear their existing dentures for a period of one month before being given the second set of dentures, which will again be evaluated by an evaluator. Participants will be requested to wear this second set of dentures for a period of 30 days, before repeating the patient-satisfaction survey. Participants will attend for review appointments each week for any adjustments that may be required to ensure their comfort and successful wearing of the dentures.

Participants can exit the study at any point. The consent procedure will be outlined in a Consent Form given at the initial consultation appointment, and in a Consent Statement at the beginning of the satisfaction survey as per ethical approval requirements. This will include the identity of the researcher, contact details, the reason for conducting the survey and the uses to be made of the data.

What will happen to me if I agree to take part?

You will attend DDUH for an assessment appointment, where the details of the research study will be discussed in depth by Dr Brendan Grufferty, the Principal Investigator. Once consent is obtained, you will attend for clinical appointments to make new dentures. Traditional impressions and an intra-oral scans (digital impressions) will be made of your mouth, along with clinical photographs. These are standard procedures. Four or five clinical appointments, each approximately one hour in length and three weeks apart, will be required to complete the dentures. One set of dentures will be fitted for you and evaluated by an evaluator (another dentist). Participants will be requested to wear the dentures for a period of 30 days, and attend for weekly review appointments, before completing a patient-satisfaction survey. You will not know which technique was used to make the denture. You will then wear your existing dentures for a period of one month. A second set of dentures will be fitted for you and evaluated by an evaluator. You will be asked to wear this second set for a period of 30 days, and attend for weekly review appointments, before repeating the patient satisfaction survey. At the end of the study, you may keep both sets of dentures.

Are there any benefits to me or others if I take part in the study?

Taking part in this study will not benefit you directly. You will receive two sets of dentures to wear, and the research results from the surveys you complete may help DDUH to obtain a better understanding of the clinical applications for digital impressions/intra-oral scanning for the complete denture patient. This may contribute to new approaches in the fabrication of complete dentures. By participating, you are helping to advance science and dentistry for future generations.

Are there any risks to me or others if I take part in the study?
--

Intra-oral scan: Digital impressions are non-invasive and their use is well established in dentistry. Patients are reported to find this a more comfortable procedure than traditional impressions you have had experience with previously. There is no ionising radiation involved.

Health Information (Data): There is a risk that a connection to your identity could be made. Great care will be taken to ensure the confidentiality of all data and the risk to participants of a breach of confidentiality is considered very low.

Will I be told the outcome of the study? Will I be told the results of any tests or investigations performed as part of this study that relate to me?

The results of the study will be reported in dental/scientific journals and disclosed at dental/scientific conferences. No information which reveals your identity will be disclosed.

PART 2 – DATA PROTECTION

What information about me (personal data) will be used as part of this study? Will my medical records be accessed?

If you consent, your address, email address or mobile number may be used for correspondence or to send you a link to a patient satisfaction survey. Your medical records will not be accessed. The data relating to you will be pseudonymised (coded) to protect your identity.

What will happen my personal data?

Your personal data will be processed only as is necessary to achieve the objectives of the study and will not be processed in a way that will cause damage or distress to you. Data will only be stored for the legal minimal requirement of 7 years in a coded format . After this time the data will be destroyed.

Who will access and use my personal data as part of this study?

The Principal Investigator, Dr Brendan Grufferty, and Co-Investigator, Dr Gabrielle O'Donoghue, will have access to your pseudonymised personal data as part of this study.

Will my personal data be kept confidential? How will my data be kept safe?

*Your privacy is important to us. We take many steps to make sure that we protect your confidentiality and keep your data safe. Here are some examples of how we do this:
Data will only be stored for the legal minimal requirement. Double encryption will be applied to all computers, laptops and mobiles devices. Personal data will not be stored on portable devices.
A Risk Assessment of the data protection implications of the health research was carried out and an indication of the low level of risk was identified prior to the commencement of this research.*

Any presentation or publication arising from the study will not identify the participant.

The persons carrying out the research are bound by a professional code of secrecy.

Training in data protection law and practice has been provided to those individuals involved in carrying out the research.

What is the lawful basis to use my personal data?

By law,¹ we can use your personal information for scientific research² (in the public interest³). We will also ask for your explicit consent to use your data as a requirement of the Irish Health Research Regulations.

What are my rights?

You are entitled to:

The right to access your data and to receive a copy of it

The right to restrict or object to processing of your data

The right to object to any further processing of the information we hold about you (except where it is de-identified)

The right to have inaccurate information about you corrected or deleted

¹ The European General Data Protection Regulation (GDPR)

² Article 9(2) (j))

³ (Article 6(1)(e)

The right to receive your data in a portable format and to have it transferred to another data controller

The right to request deletion of your data

The right to object to profiling

By law, you can exercise the following rights in relation to your personal data, unless the request would make it impossible or very difficult to conduct the research. You can exercise these rights by contacting Dr Gabrielle O'Donoghue or the Trinity College Data Protection Officer, Secretary's Office, Trinity College Dublin, Dublin 2, Ireland. Email: dataprotection@tcd.ie. Website: www.tcd.ie/privacy.

PART 3 – COSTS, FUNDING & APPROVAL

Will it cost me anything if I agree to take part?

You only have to pay for one new set of dentures. There is no additional cost to you if you agree to take part in the study. The investigators are covered by the Dublin Dental University Hospital Clinical Indemnity Scheme. We are not paying participants to take part in the study.

Who is funding this study? Will the results study be used for commercial purposes?

Dublin Dental University Hospital, Trinity College Dublin, is conducting the research. There is no funding from or commercial purposes associated with this research.

Has this study been approved by a research ethics committee?

Yes, this study has been approved by Tallaght University Hospital/St. James's Hospital Research Ethics Committee. Approval was granted on [14th December 2020].

PART 4 – FUTURE RESEARCH

Will my personal data be used in future studies?

You will only give permission for your data to be used for the current study, and your consent will be sought for use of your data in future research studies. Future intended uses may include other studies on a similar topic, or for use in a publication or presentation at a dental meeting. This may be the Principal Investigator's, or someone else's research.

PART 5 – FURTHER INFORMATION

Where can I get further information?

If you have any concerns or questions, you can contact:

- Gatekeeper: Yet to be Identified
- Principal Investigator: Dr Brendan Grufferty; Email: brendan.grufferty@dental.tcd.ie
- Data Protection Officer, Trinity College Dublin: Data Protection Officer, Secretary's Office, Trinity College Dublin, Dublin 2, Ireland. Email: dataprotection@tcd.ie. Website: www.tcd.ie/privacy.

What happens if I wish to make a complaint?

If you wish to make a complaint, you may contact Ms Susanne Bushe, Patient Services Manager at Dublin Dental University Hospital; Email: Susanne.bushe@dental.tcd.ie.

Under GDPR, if you are not satisfied with how your data is being processed, you have the right to lodge a complaint with the Office of the Data Protection Commission, 21 Fitzwilliam Square South, Dublin 2, Ireland. Website: www.dataprotection.ie.

Will I be contacted again?

If you would like to take part in this study, you will be asked to sign the Consent Form on the next page. You will be given a copy of this information leaflet and the signed Consent Form to keep.

Appendix 2. Consent Form

CONSENT FORM

A Prospective, Single Blind, Crossover Clinical Trial to Assess the Outcomes of Computer-Engineered Complete Dentures using Impressions and Intra-Oral Scans of the Edentulous Arches

To be completed by the PARTICIPANT:

I have read and understood the information leaflet.	YES ☐	NO ☐
I have had the opportunity to discuss the study, ask questions about the study and I have received satisfactory answers to all my questions.	YES ☐	NO ☐
I have received enough information about this study.	YES ☐	NO ☐
I understand that I am free to withdraw from the study at any time without giving a reason and this will not affect my future medical care.	YES ☐	NO ☐
I agree to allow the researchers use my information (personal data) as part of this study as outlined in the information leaflet.	YES ☐	NO ☐
I agree to allow the researchers access my medical records as part of this study <i>(if applicable)</i>	YES ☐	NO ☐
I agree to be contacted by researchers as part of this study <i>(if applicable)</i>	YES ☐	NO ☐
I agree to give a [insert sample] sample(s) as part of this study. <i>(if applicable)</i>	YES ☐	NO ☐
I consent to take part in this research study having been fully informed of the risks, benefits and purpose of the study	YES ☐	NO ☐
I give my explicit consent to have my data processed as part of this research study'	YES ☐	NO ☐
[Statement on future research placed here] <i>(if applicable)</i>	YES ☐	NO ☐

Participant's Name (Block Capitals):	
Participant's Signature:	
Date:	

To be completed by the RESEARCHER:

I have fully explained the purpose and nature (including benefits and risks) of this study to the participant in a way that he/she could understand. I have invited him/her to ask questions on any aspect of the study.	YES ☐	NO ☐
I confirm that I have given a copy of the information leaflet and consent form to the participant.	YES ☐	NO ☐

Researcher's Name (Block Capitals):	
Researcher's Title & Qualifications:	
Researcher's Signature:	
Date:	

Appendix 3. “CECD Assessment: Clinical Evaluation” Form

CECD Assessment: Clinical Evaluation (Prosthodontist-Determined)

Please examine and assess the complete dentures under the following criteria.
Grade your answer from 0-4, with 0 being considered “unsatisfactory” and 4 being considered “excellent” as follows:

0	1	2	3	4
Very poor >3 negative findings Clinically unsatisfactory	Poor 3 negative findings Clinically satisfactory	Fair 2 negative findings	Good 1 negative finding	Excellent No negative findings

Criteria	Feature	Grade			Comment
		Maxilla	Mandible	Pair	
Tissue	Health/condition				
Denture Base	Contour				
	Shade				
	Polish & finish				
Tooth Arrangement	Position				
	Form/Dimensions				
	Shade				
Aesthetics	Display at rest				
	Display in smile				
	Occlusal plane				
	Midline				
	Gingival margin				
Lip Support	Lip support				
Support	Intimate adaptation of bases				
	Extensions				
Stability	Stability				
Retention	Assessment of seal at premolars				
Occlusion	MIP				
	Excursive movements				
Jaw Registration	Vertical dimension of occlusion				
Phonetics	Phonetics				
Overall Result	Overall Result				
Prognosis	Expected prognosis				

Are these Complete Dentures clinically acceptable? Y N Other

Impression Protocol for Complete Dentures Impression Intraoral Scan

Further comments

Appendix 4. “CECD Evaluation: Patient Satisfaction” Form

CECD Assessment: Patient Satisfaction (Participant-Related)

Please rate the complete dentures under the following criteria.

Grade your answer from 0-4, with 0 being considered “unsatisfactory” and 4 being considered “excellent” as follows:

0	1	2	3	4
Very poor >3 negative findings	Poor 3 negative findings	Fair 2 negative findings	Good 1 negative finding	Excellent No negative findings

Criteria	Feature	Grade			Comment
		Upper	Lower	Pair	
Retention	How well does the denture fit?				
	How "tight" does the denture feel?				
Stability	Excursive movement while eating or speaking				
Appearance	How do you rate the look of the gums?				
	How do you rate the look of the teeth when you are relaxed?				
	How well do the denture teeth look when you are smiling?				
Function	How well can you speak?				
	How well can you eat/chew?				
Bite	Rate how the bite feels - are both sides even?				
	How well can you slide your teeth over each other?				
Comfort	How comfortable are the dentures?				
Other	Any other feature?				

Give an overall rating for the dentures

0 1 2 3 4

Give a general comment on what you think about these dentures:
