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# CAD-CAM complete removable dental prostheses: A double-blind, randomized, crossover clinical trial evaluating milled and 3D-printed dentures

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#### ABSTRACT

*Objective:* This double-blind, randomized, crossover, clinical trial aimed to evaluate and compare the differences between milled and 3D-printed complete removable dental prostheses (CRDPs).

*Methods*: Fifteen edentulous patients (men: n = 10, women: n = 5; age: 66.7  $\pm$  8.0 years) rehabilitated with conventional CRDPs were recruited for this trial. Participants were randomized to first receiving either the milled or 3D-printed CAD-CAM manufactured CRDPs and then after 6-weeks cross over to the other set. Both, clinicians and participants were blinded to the group allocation. Outcomes included patient's denture satisfaction (PDS), oral-health related quality of life (OHIP-EDENT), willingness-to-pay analysis, final choice (FC) of CRDPs, clinician's denture quality evaluation (CDQE), chewing efficiency (CE), maximum-voluntary-bite-force (MBF), and prosthodontic maintenance needs. The outcomes were measured at baseline (with old CRDPs), at 1 and 6 weeks after new CRDP insertion; following crossover with the second set of CRDPs, an identical protocol was followed. Generalized linear regression for repeated measures was used for statistical analysis with  $\alpha$ =0.05.

*Results*: All participants completed the trial. 3D-printed CRDPs required more maintenance visits, adjustment time (p = 0.0003), and adjustment costs (p = 0.021). Patients were willing-to-pay an average of 606.67 Swiss Francs more than the actual cost for the milled CRDPs. There were no differences in the PDS, OHIP, FC, CDQE, CE, and MBF between the two CRDPs groups.

*Conclusions:* The findings of this double-blind randomized crossover clinical trial confirm that both milled and 3D-printed CRDPs are valid treatment modalities for edentulous patients, with the latter performing inferiorly with regard to the time and costs involved with the prosthodontic aftercare, as well as the patients' willingness-to-pay.

*Clinical relevance:* The findings of this trial provide evidence to help the clinician in choosing the appropriate CAD-CAM manufacturing process for fabricating the CRDPs.

## 1. Introduction

The fabrication of complete removable dental prostheses (CRDPs) with the aid of computer aided designing and manufacturing (CAD-CAM) technology was first evaluated in the 1990s [1,2] and an exponential increase in its popularity has been witnessed in the recent years [3,4]. This rapid growth may be attributed to the advancements in

technology, the ease of use of this technology and the associated clinical protocols, the reduction in the clinical chair-side time as well as the reduction in the manufacturing time and costs [5,6]. The process of fabricating CRDPs by CAD-CAM is achieved either by a subtractive process also known as computerized numeric control (CNC) milling, or by an additive 3D-printing technique. The CAD-CAM fabrication of CRDPs is accomplished extensively by employing the CNC milling

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technique, whereas the 3D-printing technique for manufacturing CRDPs seem to be still in a developing phase, at least in Europe. The majority of manufacturers have adopted the CNC milling for commercial fabrication of CRPDs while the 3D-printing technique still seems to be used predominantly for fabricating trial dentures. In the recent times however, the technique is gradually being employed more and more for fabricating definitive prostheses as well.

CRDPs manufactured with either of the two CAD-CAM manufacturing techniques must, in theory, be identical and should afford the same type of comfort, aesthetics, and function. A difference may however exist, for logical reasons, because the two techniques use different manufacturing methods, materials, and polymerization processes [7,8]. The role which this difference plays in vitro, or clinically has not been studied extensively. Factors such as patient-, and clinician-related parameters, academic feasibility, time and cost benefits have also not yet been evaluated [9]. A need arises that these factors are properly understood before adopting these newer techniques into daily clinical practices, or in the university student programs.

Therefore, this study aimed to establish the non-inferiority of milled and 3D-printed CAD-CAM manufactured dentures in terms of clinical parameters (chewing efficiency and maximum bite force), clinician's evaluation of the denture quality, the participants' oral health-related quality of life (OHRQOL) and willingness-to-pay as well as the required prosthodontic maintenance and cost. The null hypothesis set for this trial is that there will be no differences in the above mentioned clinical, functional, patient-reported, and economic outcomes with milled or 3D-printed CAD-CAM manufactured CRDPs.

#### 2. Material and methods

#### 2.1. Study design

This study was designed as a single-center, double-blind, randomized, crossover, clinical trial. This study was ethics approved (CCER No. 2018-00812) and carried out in accordance to the Declaration of Helsinki, the ICH-GCP or ISO EN 14155. This study is reported conforming to the guidelines prescribed by CONSORT (consolidated standards for reporting randomized trails) [10]. The protocol was registered in the clinicaltrials.gov database (NCT04873219).

## 2.2. Patient cohort

The participants were recruited from the division's existing patient pool of the final year undergraduate clinic. The participants were recruited if they fulfilled the below-mentioned inclusion criteria:

- being completely edentulous in both jaws (maxilla and mandible) for at least one year,
- · using conventionally manufactured CRDPs, and
- being admitted to the undergraduate final year clinic for replacement CRDPs.

Participants were excluded if they were not willing to sign the informed consent form.

### 2.3. Sample size and randomization

Sample size calculated for this study is based on a previously published study with similar outcomes [11]. Hence, a sample of 15 patients was taken for the current clinical trial. Post hoc power analysis was performed to rule out any type II statistical errors [12]. The randomization sequence was generated using an online sequence generator (https://www.randomizer.org/). Fifteen sets of randomization sequences were generated with two unique numbers in each set. These unique numbers in each set determined the sequence of insertion of the fabricated CRDPs for each patient. The random allocation sequence was generated by the principal investigator (M.S.) and stored securely in sealed opaque envelopes with the project leader (F.M.). Patient recruitment and the final clinicians' denture quality evaluation were performed by two investigators, N. K. and M. N, respectively; both were blinded to the randomization sequence. Randomization envelopes were opened by M. S. & F. M. only just before sending the clinical work to the dental technician. The CRDPs were received by a single investigator (M. S.) from the dental laboratory and were distributed as per the randomization sequence to the clinical supervisor (N. K.) who oversaw the denture insertion performed by the respective students. The supervisor (N. K.), clinical evaluator (M. N.), and the students were blinded to the CRDP type.

### 2.4. Complete removable dental prostheses (CRDP)

Each patient had two sets of CRDPs manufactured; they were identical except for the materials and manufacturing method. CRDP#1, later referred to as "milled", was manufactured by the CNC milling technique by a dental laboratory located in The Netherlands (AVADENT<sup>TM</sup>, GDS, Global Dental Science Europe BV, Tilburg, The Netherlands). CRDP#2, in the following named "3DP", was 3D-printed. The latter was outsourced to a partner laboratory (NextDent B.V., Soesterberg, Netherlands). Both types of CAD-CAM dentures had commercially available pre-fabricated teeth (Candulor TCR, Glattpark, Switzerland), which were bonded to the milled and printed denture body, respectively. The clinical workflow was conventional, as traditionally taught to the students, and comprised of 5–6 clinical visits.

#### 2.4.1. Denture manufacturing steps

The first visit consisted of medical history, clinical examination and diagnosis followed by a preliminary irreversible hydrocolloid impression (DENTSPLY DeTrey GmbH, Konstanz, Germany) of the edentulous ridges, with Schreinemaker stock trays for edentulous impressions [13]. A conventional stone plaster model was poured and a methacrylate resin custom impression tray was fabricated at a conventional dental laboratory. In the second visit, the custom impression tray was checked for fit and its extension trimmed where necessary. Muco-dynamic border molding and peripheral tracing was done using ADA specification type 1 low-fusing impression compound (Kerr Dental Europe, Bioggio, Switzerland). The tracing was checked for peripheral extensions, retention, support and stability; following which a muco-static master impression using a Zinc oxide impression material (SS White, Gloucester, England) was taken. Master casts were fabricated and used for the construction of occlusal rims on resin record denture bases. The third visit involved establishing esthetic parameters like labial fullness, labial support, lip and smile lines, as well as tooth selection. A face-bow transfer followed the recording of vertical and horizontal jaw relations. Centric relations were verified by intra-oral gothic arch tracing. The recorded clinical parameters including the face-bow were sent to the in-house dental laboratory, where the dental technician mounted the models in a semi-adjustable articulator and set up the anterior teeth for try-in. In the fourth and fifth visits the anterior and posterior teeth set up in wax were clinically tried in. After the approval by the clinician and the patient, the mounted set-up with the articulator was then sent to the digital dental laboratory for the fabrication of the milled and 3D-printed CRDPs.

### 2.4.2. Laboratory steps

The digital lab technician scanned the waxed trial dentures and imported them into a purpose-built design software (AVADENT<sup>TM</sup>). The anatomical landmarks were identified and the peripheral limits were set on the virtual models in the software. The latter was then aligned according to the clinically captured jaw relation records as present in the articulator. A virtual teeth set-up conforming to the exact alignment, arch form, shape and size, and the tooth shade of the existing conventional setup was adopted in the virtual set up in order to obtain identically shaped CRDPs. This virtual set-up was then communicated as an electronic preview to the supervising clinicians (M. S. & N. K.) and the respective student for approval. Upon receiving the approval of the digital preview, the digital lab manufactured two sets of CRDPs with the same digitally generated data file. One set was manufactured by the CNC milling technique, and the second set by the 3D-printing technique. Both CAD-CAM denture types had then the pre-fabricated teeth bonded to the denture base. The finished CAD-CAM fabricated prostheses were shipped back to the principal investigator (M.S.), along with the initial conventional teeth setup and the articulator.

At the sixth clinical visit, the first set of CRDPs were delivered according to the predetermined randomized sequence. They were verified for fit, retention, support, stability, aesthetics, occlusion and comfort. A 24-hour and a seven-day post-insertion recall were scheduled. Further appointments were made as required. A final recall visit was fixed for 6 weeks after denture insertion. The original analogue set-up of the teeth was kept to be finished for the unlikely case, that the patient did not accept any of the CAD-CAM dentures.

# 2.5. Endpoints/outcomes measures

### 2.5.1. Patients' denture satisfaction (PDS)

PDS was measured using a questionnaire on denture satisfaction addressing variables like general satisfaction, retention, stability, comfort, ability to speak, appearance, and occlusion, for both maxillary and mandibular dentures [14]. The denture satisfaction scales had 5-point Likert format responses which ranged from (1- "not at all satisfied" to 5- "totally satisfied").

### 2.5.2. Patients' OHRQoL (OHIP-EDENT)

OHRQoL was measured with the OHIP-EDENT instrument [15]. It contains 20 questions covering seven domains (functional limitation, physical pain, psychological discomfort, physical disability, psychological disability, social disability or handicap). OHIP could be analysed as an overall score with scores ranging from 0 (best OHRQoL) to 80 (worst OHRQoL) or with respect to the individual domains. OHIP-EDENT proved sensitive changes in oral health due to prosthetic treatment [15–17]. In the present study the French translation of the OHIP-EDENT [18] was utilized, which had been validated and frequently used in previous studies [19,20].

## 2.5.3. Willingness-to-pay analysis (WTPA)

An open-ended contingency valuation (CV) method of questioning with the use of a payment card (PC), as described in previously published studies of similar nature [21,22]. The PC comprised of the total charges for the performed treatment with the corresponding CRDPs (CHF 2300/-) along with different options for fees for the performed treatment. The proposed fees in the PC ranged between CHF 2000/- and CHF 4000/-. The patients had to respond with the maximum amount in the PC they were willing to pay for the performed treatment. This WTPA was performed for both sets of the CRDPs at the 6-week recall.

### 2.5.4. Patient's final choice of the CRDPs

At the end of the trial, the patients were questioned which of the two sets of prostheses they preferred and would continue wearing. Their preferred final choice was duly noted.

### 2.5.5. Clinician's denture quality assessment (CDQE)

The denture quality was assessed based on the criteria published by Alfadda et al. in 2014 [23]. The criteria included: lip support, lower lip line, retention of maxillary CRDP, retention of mandibular CRDP, stability of maxillary CRDP, stability of mandibular CRDP, and balanced occlusion. All the mentioned parameters were scored on a dichotomous scale, hence the possible scores ranged from 0 for worst to 7 for best quality.

## 2.5.6. Chewing efficiency (CE)

CE was measured using the validated two-color mixing test. Participants were asked to chew a bi-color chewing gum specimen (Hue-check Gum®, Orophys GmbH, Muri, Switzerland) for 20 chewing cycles [20, 24–26]. CE was analysed qualitatively by comparison with a visual scale (SA). The chewed gum was then flattened to a 1 mm thick wafer for a second quantitative opto-electronical analysis. This wafer was scanned on both sides and the resulting images were imported in a purpose-built software (Viewgum, dHAL software, Kifissia, Greece), that calculated the variance of hue (VoH). The method employed in this trial followed a frequently used, validated protocol as performed in previous studies [20, 24,25].

### 2.5.7. Maximum voluntary bite force (MBF)

MBF was recorded by means of a digital force gauge (Occlusal Force-Meter GM 10<sup>®</sup>, Nagano Keiki Co., Ltd.; 1-30-4 Higashimagome, Ohtaku, Tokyo, Japan) [27]. The gauge was interposed in the molar regions and the participants were requested to bite down as hard as possible. This was repeated three times for each side. The mean of the six observations was used for the analysis.

## 2.5.8. Prosthodontic maintenance and adjustment requirements

The maintenance and adjustment requirements for the CAD-CAM CRDPs were noted. The information recorded comprised of the type of intervention, time spent, clinical and laboratory costs. Maintenance was defined as any modification performed on the CRDPs that require dental laboratory support. Adjustments referred to chair-side modifications. The maintenance and adjustments were labelled as performed during a regular recall visit or during an unscheduled recall visit.

## 2.6. Protocol

After recruiting and having obtained informed written consents, CRDP#1 and CRDP#2 were manufactured and fitted. The patient was inserted the first set of CRDPs for a period of 6 weeks before the crossover to the second set was done. The protocols of recalls for the first and second set of CRDPs were the same. Evaluations of CE, MBF, CDQE, PDS and OHRQoL were performed with the old dentures, as well as 1- and 6weeks post insertion of each of the 2 experimental sets of CRDPs. The denture quality (CDQE) was assessed by a single experienced investigator who had more than 10 years of clinical experience in the field of removable prosthodontics. At the end of each observation period, the WTP was assessed. Students, the supervising clinician (N. K.), and the patients were blinded to the type of the prostheses at all times. Maintenance and adjustment measures were noted during regular or unscheduled visits. At the end of the trial, the patients were requested to choose which one of the two sets of CRDPs they preferred and would like to continue using. Both CRDPs were provided entirely free of charge to the patients.

## 2.7. Statistical analysis

The collected data was checked for normal distribution. Differences between the groups and within subjects, against timepoints were analyzed with generalized linear regression with repeated measures and one-way ANOVA with the level of significance set to  $\alpha$ =0.05. Pearson's coefficient was used to examine a correlation between the patients' final choice of the CRDP and various factors such as the randomization sequence, age, sex, period of edentulism, OHRQoL (OHIP) and PDS. The statistical unit was the participant for all outcome parameters. All statistical analyses were performed using a statistical software (version 25.0, IBM® SPSS® Statistics, IBM corp., NY, USA).

## 3. Results

Fifteen completely edentulous patients participated in this trial. The

participant enrolment, randomization, group and intervention allocation, along with details on the number of dropouts and the numbers included for analysis are detailed in the flow diagram (Fig. 1). Baseline demographic information of the patients is presented in Table 1.

# 3.1. Patients' denture satisfaction (PDS)

The results of the patients' denture satisfaction are shown in Table 2. There were no differences in the satisfaction between the CAD-CAM denture groups. However, within the participants an improvement was observed for the mandibular CRDP retention when comparing between the old and the new CAD- CAM CRDPs (p = 0.037, Table 3).

# 3.2. Patients' OHRQoL (OHIP-EDENT)

There was no difference in the OHIP scores, neither for the overall nor for the individual domains between the old CRDP and the two groups of CAD-CAM CRDPs at 6 weeks post-insertion (Table 4). Over time, no difference in OHIP scores were found between the old CRDP and the 1 and 6-week post-insertion examination (Tables 5,6).

### 3.3. Willingness-to-pay analysis (WTPA)

The estimated standard costs for a complete denture was CHF 2207.28, consisting of a clinical honorarium of CHF 1173.50 according to the tariff of the Swiss Dental Association, and the estimated laboratory fees for a set of CAD-CAM dentures CHF 1033.78. The patients, on an average were willing to pay more for the performed treatment than the estimated costs and they were calculated to be  $3200.00\pm1211.85$  (range: min=2000, max=7000) and  $2593.33\pm773.18$  (range: min=2000, max=4000), for the milled and 3D-printed CRDPs, respectively (Table 7). Participants were willing to pay CHF 606.67±867.23 more for the milled than for the 3D-printed CRDPs.

## 3.4. Patient's final choice of the CRDP

Eight patients preferred to continue wearing the milled CRDPs, while seven preferred the 3D-printed CRDPs after the end of the observation period. None of the patients insisted on the original tooth set-up being finished in the conventional manner, because they did not like either CRDP. A negative correlation between the final choice of the CRDP was found only with the participants' age (r = -0.746; p < 0.001) and the Table 1

Baseline demographics of the patients.

	All participants (mean±SD)	Participants randomized to Milled–3DP group (mean±SD)	Participants randomized to 3DP–Milled (mean±SD)	Differences between the randomization groups (p-value)
Participants (n)	15	7	8	0.738
Men (n)	10	5	5	
Women (n)	5	2	3	
Age (years)	$66.7\pm8.0$	$63.9\pm8.7$	$69.3\pm6.8$	0.203
Edentulism period (years)	$\textbf{8.4} \pm \textbf{12.2}$	$\textbf{5.4} \pm \textbf{7.8}$	$11.1\pm15.0$	0.379
Maxillary denture in situ (years)	$\textbf{8.0} \pm \textbf{12.4}$	$\textbf{4.9} \pm \textbf{8.0}$	$10.8\pm15.3$	0.377
Mandibular denture in situ (years)	$\textbf{6.6} \pm \textbf{12.4}$	$\textbf{4.9} \pm \textbf{8.0}$	$8.3\pm16.2$	0.625
Overall PDS: upper CRDP	$\textbf{3.9} \pm \textbf{1.39}$	$\textbf{4.1} \pm \textbf{1.46}$	$\textbf{3.8} \pm \textbf{1.51}$	0.603
Overall PDS: lower CRDP	$3.4\pm1.65$	$3.6\pm1.51$	$3.1\pm1.86$	0.645
Overall OHIP	$\textbf{25.0} \pm \textbf{27.50}$	$\textbf{23.9} \pm \textbf{34.01}$	$26.0 \pm 22.77$	0.887
Overall CDQE	$\textbf{4.7} \pm \textbf{1.98}$	$\textbf{5.6} \pm \textbf{1.27}$	$\textbf{4.0} \pm \textbf{2.27}$	0.129
CE: SA	$2.0\pm0.91$	$\textbf{2.0} \pm \textbf{0.89}$	$2.0\pm1.0$	1.000
CE: VoH	$0.53 {\pm} 0.24$	$0.54{\pm}0.23$	$0.51 {\pm} 0.25$	0.835
Maximum bite force (N)	98.67±88.95	80.29±63.30	114.75±108.42	0.475

3DP- 3D-printed; p-value: ANOVA, significance: p<0.05; n-number; SD- standard deviation; N—Newton; PDS- patients' denture satisfaction, CRDP- complete removable dental prosthesis; OHIP- oral health impact profile; CDQE- clinician's denture quality evaluation; CE- chewing efficiency; SA- subjective assessment; VoH- variance of hue; \*- significant.

period of edentulism (r = -0.279; p = 0.031). It was observed that the milled CRDPs were preferred by patients who were older and also by those who were edentulous for a longer period. The patient's choice was not correlated to the randomization sequence (r = -0.196, p = 0.483), or the OHIP (r = 0.024; p = 0.857), or the PDS (upper: r = -0.075, p =



Fig. 1. CONSORT flow diagram showing the participant enrolment, with the number of participants randomized, allocated to each study group, dropouts, along with reasons for dropouts, and the number analysed for outcome measures. *n*- number; 3DP- 3D-printed.

#### Table 2

Patients' denture satisfaction (PDS) scores with the different dentures.

Domains	Old denture	Milled*	3DP*	p-
	(mean±SD)	(mean±SD)	(mean±SD)	value
Retention				
Upper	$4.01{\pm}1.28$	$4.73 {\pm} 0.59$	$4.27 {\pm} 0.70$	0.133
Lower	$2.93{\pm}1.69$	$3.80{\pm}1.08$	$3.40{\pm}1.35$	0.251
Stability				
Upper	$4.00 {\pm} 1.26$	$4.67 {\pm} 0.61$	$4.47 {\pm} 0.64$	0.120
Lower	$3.14{\pm}1.56$	$3.93{\pm}1.16$	$3.73{\pm}1.44$	0.297
Comfort				
Upper	$4.13{\pm}1.36$	$4.53 {\pm} 1.06$	$4.20{\pm}1.08$	0.610
Lower	$3.43{\pm}1.65$	$4.13{\pm}1.13$	$3.21{\pm}1.63$	0.226
Appearance				
Upper	$4.07{\pm}1.28$	$4.73 {\pm} 1.03$	$4.47{\pm}1.06$	0.277
Lower	$3.93{\pm}1.38$	$4.60 {\pm} 1.12$	$4.33{\pm}1.18$	0.345
Occlusion	$3.86{\pm}1.23$	$4.60 {\pm} 0.51$	$4.20 {\pm} 0.77$	0.087
Ability to	5.00	5.00	5.00	-
speak				
Overall				
Upper	$3.93{\pm}1.39$	$4.47 {\pm} 1.13$	$4.13 {\pm} 0.83$	0.439
Lower	$3.36{\pm}1.65$	$4.00 {\pm} 1.13$	$3.47{\pm}1.36$	0.413

3DP- 3D-printed; SD: standard deviation; \* score at 6 weeks post-insertion; p-value: ANOVA; significance: p < 0.05.

#### Table 3

Within participant improvement while transitioning from old to new (CAD-CAM) dentures (6 weeks post-insertion).

Measure	Type III Sum of Squares	df	Mean Square	F	p- value
PDS- Upper CRDP	0.821	1	0.821	2.182	0.165
PDS- Lower CRDP	3.705	1	3.705	5.470	*0.037
OHIP	560.013	1	560.013	4.201	0.063
CDQE	8.013	1	8.013	14.822	*0.002
CE: SA	3.705	1	3.705	5.959	*0.031
CE: VoH	0.148	1	0.148	3.552	0.084
MBF	0.008	1	0.008	16.397	*0.002

p-value: generalized linear regression with repeated measures, significance: p < 0.05; PDS- patient denture satisfaction; CRDP- complete removable dental prostheses; OHIP: Oral health impact profile; CDQE: clinician's denture quality evaluation; MBF: maximum bite force; CE- chewing efficiency; SA- subjective assessment; VoH- variance of hue; \*significant.

#### Table 4

Oral health impact profile (OHIP) scores of the participants with the different dentures.

OHIP Domains	Old denture (mean±SD)	Milled* (mean±SD)	3DP* (mean±SD)	p- value
Functional limitation	5.80±5.47	3.73±3.43	$5.13 \pm 3.72$	0.413
Physical pain	$5.40 {\pm} 5.87$	$3.67 {\pm} 4.70$	$6.73 {\pm} 6.46$	0.348
Psychological discomfort	1.93±2.79	1.33±2.47	$2.40{\pm}2.95$	0.570
Physical disability	5.13±6.45	3.33±5.14	5.47±6.13	0.574
Psychologic disability	2.67±3.54	2.00±3.09	$3.53{\pm}3.68$	0.480
Social disability	$1.93 {\pm} 3.81$	$1.47 {\pm} 3.25$	$1.80{\pm}2.68$	0.923
Handicap	$2.13{\pm}3.18$	$1.13{\pm}2.29$	$1.80{\pm}3.00$	0.623
Overall score	$25.00{\pm}27.50$	$16.67{\pm}21.88$	$26.86{\pm}25.04$	0.496

OHIP- oral health impact profile; 3DP- 3D-printed; SD: standard deviation; \*score at 6 weeks; p-value: ANOVA; significance: p<0.05: number.

0.569; lower: *r* = 0.095, *p* = 0.471) scores (Table 8).

#### 3.5. Clinician's denture quality assessment (CDQE)

The overall clinician's denture quality assessment (Table 9) revealed

#### Table 5

Overall differences between the old and the CAD-CAM denture groups at 6 weeks post-insertion.

Outcome measures	Old denture (mean±SD)	Milled (mean±SD)	3DP (mean±SD)	p-value
Overall PDS: upper CRDP	3.93±1.39	4.47±1.13	4.13±0.83	0.439
Overall PDS: lower CRDP	$3.36{\pm}1.65$	4.00±1.13	3.47±1.36	0.413
Overall OHIP	$25.00{\pm}27.50$	$16.67{\pm}21.88$	$26.86{\pm}25.04$	0.496
Overall CDQE	$4.73 {\pm} 1.98$	$6.87{\pm}0.52$	$6.73 {\pm} 0.46$	*<0.001
CE: SA	$2.00{\pm}0.91$	$2.93{\pm}0.59$	$2.67{\pm}0.98$	*0.017
CE: VoH	$0.53{\pm}0.24$	$0.32{\pm}0.16$	$0.36{\pm}0.22$	*0.026
Maximum bite force (N)	98.67±88.95	154.70±70.67	131.23±79.04	0.168

3DP- 3D-printed; p-value: ANOVA, significance: p < 0.05; SD- standard deviation; PDS- patient denture satisfaction; CRDP- complete removable dental prosthesis; OHIP- oral health impact profile; CDQE- clinician's denture quality evaluation; CE- chewing efficiency; SA- subjective assessment; VoH- variance of hue; N—Newton; \*- significant.

that the CAD-CAM CRDPs were significantly better rated than the old CRDPs (p<0.0001) (Fig. 4,Table 5). However, there was no significant difference in the overall clinician's assessment between the CAD-CAM CRDP groups and also between timepoints (Table 10). However, when considering the participants' transition from old to new CRDPs irrespective of the CAD-CAM CRDP groups there was a significant improvement in the CDQE (p = 0.002; Table 3). Moreover, the number of mandibular CRDPs rated with unsatisfactory retention were more in the 3D-printed group (n = 4) as opposed to the milled group (n = 1).

## 3.6. Chewing efficiency (CE)

The chewing efficiency improved in both intervention groups from old CRDP to 1-week post insertion and further until 6 weeks postinsertion. There was an overall significant increase in the CE for SA (p = 0.017) and VoH (p = 0.026) from old CRDP to 6 weeks (Table 5, Figs. 2 and 3). This difference was significant when comparing between old CRDP and new milled CRDP for SA (p = 0.017) and VoH (p = 0.031) at 6 weeks (Figs. 2 and 3). There were no differences in CE between CRDP#1 and CRDP#2 (Table 6).

Within subject analyses revealed a significant difference for the milled group for the SA (p = 0.045) (Table 10). When considering the participants' transition from old to new CRDPs irrespective of the group there was a significant improvement in the CE (SA: p = 0.031; Table 3).

#### 3.7. Maximum voluntary bite force (MBF)

There were no significant differences in the MBF between milled and 3D-printed from old CRDP to 6 weeks post-insertion (Table 5), nor between the two CAD-CAM denture groups at 1 or 6-weeks post-insertion (Table 6).

However, the MBF significantly improved in both the milled and 3Dprinted CRDPs within the participants (milled: p = 0.032; 3D-printed: p = 0.028) (Table 10) but there were no differences when comparing the transition from old to new dentures (Table 3).

### 3.8. Prosthodontic maintenance and adjustments

There were no maintenance costs for the milled CRDPs either during the planned or unscheduled recall visits (Table 11,12). In contrast, the 3D-printed CRDPs necessitated a total of three maintenance visits (planned visit: n = 1, unscheduled visit: n = 2), with the average required time of 5 and 10 mins, for the planned and unscheduled visits, respectively (Tables 11 & 12). The 3D-printed CRDPs required more

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#### Table 6

Inter-group differences between the CAD-CAM denture groups at the different time points.

Outcome measures 1 week after insertion (mean±SD)				6 weeks after insertion (mean±SD)			
	Milled	3DP	p-value	Milled	3DP	p-value	
Overall PDS: lower CRDP	4.27±0.59	$3.73{\pm}1.22$	0.140	4.47±1.13	4.13±0.83	0.365	
Overall PDS: upper CRDP	$3.53{\pm}0.99$	3.07±1.44	0.309	$4.00 \pm 1.13$	$3.47{\pm}1.36$	0.252	
Overall OHIP	$18.60 \pm 15.66$	$37.33 \pm 27.27$	*0.029	$16.67{\pm}21.88$	$26.86{\pm}25.04$	0.245	
Overall CDQE	6.73±0.46	$6.93 {\pm} 0.26$	0.152	$6.87 {\pm} 0.52$	6.73±0.46	0.461	
CE: SA	$2.33{\pm}0.72$	$2.07{\pm}0.89$	0.374	$2.93 {\pm} 0.59$	$2.67{\pm}0.98$	0.374	
CE: VoH	$0.41{\pm}0.18$	$0.49{\pm}0.21$	0.286	$0.32{\pm}0.16$	$0.36 {\pm} 0.22$	0.578	
Maximum bite force (N)	$130.77\pm62.56$	$105.97 \pm 69.63$	0.314	$154.70 \pm 70.67$	$131.23 \pm 79.04$	0.399	

3DP- 3D-printed; p-value: ANOVA, significance: p<0.05; SD: standard deviation; PDS- patient denture satisfaction; CRDP- complete removable dental prosthesis; CDQE: clinician's denture quality evaluation; OHIP: oral health impact profile; CE: chewing efficiency; SA: subjective assessment; VoH: variance of hue; N- Newton; \*significant.

Table	7
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Willing-to-Pay analysis and the patient's final choice of the CAD-CAM complete removable dental prostheses (CRDPs).

Patient No.	Randomization sequence	Actual Cost*	WTP for Milled CRDP (CHF)	WTP for 3DP CRDP (CHF)	Difference in the WTP between milled & 3DP (CHF)	Patients' final choice for CRDP
1	Milled – 3DP	2207.28	3600.00	3600.00	0.00	3DP
2	Milled – 3DP	2207.28	2400.00	2300.00	100.00	Milled
3	Milled – 3DP	2207.28	2000.00	2000.00	0.00	3DP
4	3DP – Milled	2207.28	3000.00	3000.00	0.00	Milled
5	3DP – Milled	2207.28	3600.00	2000.00	1600.00	3DP
6	Milled – 3DP	2207.28	3200.00	2000.00	1200.00	3DP
7	Milled – 3DP	2207.28	4000.00	4000.00	0.00	3DP
8	3DP – Milled	2207.28	3200.00	3000.00	200.00	Milled
9	3DP – Milled	2207.28	2000.00	2000.00	0.00	3DP
10	Milled – 3DP	2207.28	7000.00	4000.00	3000.00	Milled
11	3DP – Milled	2207.28	3000.00	3000.00	0.00	Milled
12	3DP – Milled	2207.28	2000.00	2000.00	0.00	Milled
13	3DP – Milled	2207.28	3000.00	2000.00	1000.00	3DP
14	Milled – 3DP	2207.28	3000.00	2000.00	1000.00	Milled
15	3DP – Milled	2207.28	3000.00	2000.00	1000.00	Milled
Overall	Milled $-3DP = 7$ ; $3DP -$	2207.28	$3200.00{\pm}1211.85$	$2593.33{\pm}773.18$	606.67±867.23	Milled = 8; Fig. $43DP$
mean	Milled = 8					= 7

\* includes university-setting clinical costs (CHF 1173.50/-) and the laboratory charges (CHF 1033.78/-) for a set of upper and lower CAD-CAM complete removable dental prostheses; CRDP- complete removable dental prosthesis; 3DP- 3D-Printed; CHF: Swiss Francs.

### Table 8

Outcome parameters that correlated to the patient's final choice of the CAD-CAM complete removable dental prostheses (CRDPs).

	Randomization sequence	Age	Sex	Period of edentulism	OHIP Score	PDS(Upper)	PDS(Lower)
Pearson's coefficient	-0.196	-0.746	-0.189	-0.279	0.024	-0.075	0.095
Significance	0.483	<0.0001*	0.148	0.031*	0.857	0.569	0.471

OHIP : Oral health impact profile; PDS : Patient denture satisfaction; \*significant.

## Table 9

Results of the clinician's denture quality evaluation (CDQE) of the participants' complete removable dental prostheses (CRDPs).

Denture quality parameter	Old denture ( $n = 15$ )		Milled Satisfa	Milled* ( $n = 15$ ) Satisfactory?		3DP* ( $n = 15$ ) Satisfactory?	
-	Satisfac	ctory?		-		-	
	No	Yes	No	Yes	No	Yes	
	(n)	(n)	(n)	(n)	(n)	(n)	
Lip support	3	12	0	15	0	15	
Lower lip line	5	10	0	15	0	15	
Stability (maxillary)	1	14	0	15	0	15	
Stability (mandibular)	3	11	0	15	0	15	
Retention (maxillary)	6	9	0	15	0	15	
Retention (mandibular)	11	3	1	14	4	11	
Balanced occlusion	2	12	1	14	0	15	
Overall (mean±SD)	4.73±1	.98	$6.87\pm$	0.52	$6.73\pm$	0.46	

3DP- 3D-printed; *n*- number; SD- standard deviation; \*score at 6 weeks post-insertion.

clinical time for adjustments (p = 0.0003) and costs for the clinical honorarium (p = 0.021) than the milled CRDPs (Table 12). However, the adjustment time and costs for the two CRDP groups during planned visits were not significantly different (Table 11). All the details of the maintenance and adjustments made on the CAD-CAM CRDPs during unscheduled recall visits are given in Table 13.

#### 4. Discussion

CAD-CAM technologies are advancing at a rapid speed, and complete denture manufacturing has been one of the last domains to be conquered by this novel technology. Whereas the milling technique is well established in private practice, the 3D-printing techniques are still in their infancy, and mostly limited to surgical guides, occlusal splints or provisional dentures. 3D-printing has inherent advantages when compared to the milling technique. First of all, less resin is necessary with printing when compared to the milling procedure and the cost for a printer is a fraction of the one for a milling machine. The small size of the printers makes them easily transportable, which renders the dentist independent from access to a dental laboratory. This might be interesting when

#### Table 10

Within participant improvement with the CAD-CAM dentures from 1 to 6 weeks post-insertion.

Measure	Type III Sum of Squares	df	Mean Square	F	p- value
PDS (upper)- Milled	0.300	1	0.300	0.583	0.458
PDS (upper)-3DP	1.200	1	1.200	1.714	0.212
PDS (lower)- Milled	1.633	1	1.633	2.318	0.150
PDS (lower)-3DP	1.200	1	1.200	0.808	0.384
OHIP-Milled	28.033	1	28.033	0.144	0.710
OHIP-3DP	821.633	1	821.633	1.705	0.213
CDQE-Milled	0.133	1	0.133	1.000	0.334
CDQE-3DP	0.300	1	0.300	3.500	0.082
CE: SA-Milled	2.700	1	2.700	4.846	*0.045
CE: SA-3DP	2.700	1	2.700	3.500	0.082
CE: VoH-Milled	0.072	1	0.072	1.779	0.204
CE: VoH-3DP	0.141	1	0.141	4.132	0.062
MBF-Milled	0.004	1	0.004	5.687	*0.032
MBF-3DP	0.005	1	0.005	6.038	*0.028

3DP- 3D-printed; MBF: maximum bite force; p-value: generalized linear regression with repeated measures, significance: p<0.05; PDS- patient denture satisfaction; OHIP: Oral health impact profile; CDQE: clinician's denture quality evaluation; CE- chewing efficiency; SA- subjective assessment; VoH- variance of hue; \*significant.

providing prosthodontic services for communities with limited access, or on humanitarian missions. However, both, milled and printed dentures will bring the manufacturing costs substantially down, which enhances access to prosthodontic care to deprived communities such as the working poor [6]. A factor to be borne in mind is that 3D-printed dentures are usually less costly than milled dentures, with regard to manufacturing costs in terms of equipment, and materials. However, in the current trial this cost difference could not be appreciated because the digital denture lab, that manufactured both sets of CRDPs for this trial, invoiced the CRDPs at the same price without distinction. Therefore, the true cost benefits of the 3D-printed CRDPs may have been overshadowed in the current trial and this factor must be considered a study limitation, (Fig. 4).

Although both manufacturing techniques provide ample advantages, it is important to distinguish the benefits between the two. Milled dentures demonstrate a multitude of better mechanical properties such as flexural strength, flexural modulus, yield strength, toughness, surface properties, color stability than the 3D-printed CRDPs [7,8,28-35]. However, in terms of trueness, 3D-printed denture bases were better than conventional CRDPs [7,8,35–39], probably because the fit does not depend on the size of a milling instrument, as the liquid resin is directly sprayed to the desired shape. Clinically, both the milled and the 3D-printed CRDPs fared better than conventional dentures in terms of retention [40,41]; but current literature does not support the 3D-printed dentures for esthetics [42,43]. It is important to note that the patients' final choices of the CRDPs were equally distributed. Although, it is evidenced that 3D-printed CRDPs may have issues with esthetics [43], it must be noted that with newer resins and more advanced printers available in the market, this shortcoming might soon be eliminated. With the manufacturing costs of the 3D-printed CRDPs already being low and with further enhancements in the resins as well as the printing techniques, 3D-printing might actually be a more valid choice for manufacturing CRDPs. However, this is only a speculation and is



Fig. 2. Chewing efficiency subjective assessment: OD vs milled vs 3DP; OD- old denture; 3DP- 3D-printed; P-value: post hoc Bonferroni test, significance p<0.05.



Fig. 3. Chewing efficiency (Variance of Hue): OD vs milled vs 3DP; OD- old denture; 3DP- 3D-printed; P-value: post hoc Bonferroni test, significance p<0.05.



Fig. 4. Overall clinician's denture quality evaluation: OD vs milled vs 3DP; OD- old denture; 3DP- 3D-printed; P-value: post hoc Bonferroni test, significance p<0.05.

# Table 11

Prosthodontic maintenance and adjustment requirements during planned recall visits.

CAD-CAM CRDP	Maintenance Number (n)	e Average clinical time spent (minutes)	Average clinical costs (CHF)	Average laboratory costs (CHF)	Adjustment Number (n)	Average time spent (minutes)	Average clinical costs (CHF)
Milled	-	-	-	-	21	$10.86 \pm 6.46$	14.496±27.89
3D-printed	1	5.00	65.20	0.0	19	$16.25 \pm 11.22$	11.51±25.62
p-value	-	-	-	-	-	0.065	0.744

CRDP- complete removable dental prosthesis; n- number; CHF: Swiss francs; \*significant.

# Table 12

Prosthodontic maintenance and adjustments during unscheduled visits.

CAD-CAM CRDP	Maintenance Number of visits (n)	Average clinical time spent (minutes)	Average clinic costs (CHF)	Average laboratory costs (CHF)	Adjustments Numberof visits (n)	Average time spent (minutes)	Average clinic costs (CHF)
Milled	-	_	-	_	23	10.91±6.10	61.07±9.19
3D-printed	2	10.00	50.37±12.57	128.0	28	17.96±6.54	65.20
p-value	-	_	-	_	-	0.0003*	0.021*

CRDP- complete removable dental prosthesis; n- number; CHF: Swiss francs; \*significant.

## Table 13

Details of the maintenance and adjustments made on the CAD-CAM CRDPs during unscheduled recall visits.

	Milled(n)	3D-Printed(n)
Unscheduled adjustment visits	23	28
Adjustments in both CRDPs		
Occlusion	0	1
Sub-total <sup>a</sup>	0	1
Adjustments in maxillary CRDP		
Anterior borders (including frenal relief)	2	5
Buccal borders (including frenal relief)	1	0
Tuberosity area	1	0
Posterior borders (including PPS area)	2	3
Intaglio surface	1	0
Sub-total <sup>b</sup>	7	8
Adjustments in mandibular CRDP		
Anterior borders (including frenal relief)	1	4
Sublingual borders	13	16
Posterior borders (including retromolar pad area)	2	2
Buccal borders (including frenal relief)	0	3
Intaglio surface	3	4
Repair of fractured CRDP	0	1
Remake of fractured CRDP	0	1
Sub-total <sup>c</sup>	19	31
Total adjustments <sup>(a + b + c)</sup>	26	40

*n*- number; CRDP- complete removable dental prosthesis; PPS- posterior palatal seal.

dependent entirely on the evolution of this technology.

To our knowledge, this is the first clinical study that compared milled and 3D-printed CRDPs for edentulous patients in a double-blinded, randomized cross-over clinical study design. With both study arms being experimental, a backup was needed for those patients who did not accept any of the two fabricated CRDPs. Since the study was run within the undergraduate clinics, we also opted for a workflow, that allowed the student to learn the conventional clinical steps, thus limiting the experimental part of this study to the laboratory procedures. Although this workflow is not the 2-session workflow advocated by some digital denture manufacturers, it allows controlling a maximum of clinical parameters like vertical dimension, occlusion, lip support, mid- and smile lines and in harmonizing those parameters for the two types of CAD-CAM dentures, the milled and 3D-printed ones, which fosters comparability between the groups. With both experimental dentures being manufactured from the same data file, the specimens were meant to be identical, except for the denture materials used. The workflows for both techniques provided the option of printing, respectively milling the teeth from the same resin material, but obviously in a tooth-shade color. However, to date, these milled and printed teeth are monochrome, and little is known on their wear and fracture resistance in a clinical context. Furthermore, a recent survey on the hand-held appreciation of the appearance of 6 differently produced complete dentures, including the three CAD-CAM techniques, confirmed, that the printed dentures with printed teeth attracted the lowest scores not only from dental professionals, but also from denture wearing laypersons [44]. To minimize

the risk of non-acceptance by the patients, and possible clinical complications like wear or fracture in the following, we opted for this study to use commercially available denture teeth, which were bonded to the milled / printed denture body. Another aspect to be borne in mind is that, in current trial, the recruited patients coincidentally did not have complex jaw anatomies such as prominent ridges or reduced vertical dimension of occlusion, and therefore did not require extensive adjustments of the prefabricated teeth and complicate the CAD-CAM manufacturing of the CRDPs. These complexities might hinder the success of digitally manufactured CRDPs, therefore must be considered as a minor drawback of the digitally manufactured CRDPs and must be considered during the diagnosis and treatment planning.

Both dentures, the milled and 3D-printed, allowed for a significant improvement of the chewing efficiency, and this already after as little as one week after insertion. The insertion of a replacement denture presents a challenge to the CNS, which has to adapt to the changed afferent input from the oral cavity and to adjust the motor pattern for speech, swallowing and mastication according the new denture. This neuroplasticity varies from patient to patient and often declines with age and morbidity. Several studies have shown, that the chewing efficiency initially declines after the insertion of a replacement denture, and that in terms of masticatory efficiency, the patient only benefits from the treatment, once the denture has settled into the denture bearing tissues [45]. In the present study, the improvement could be verified after one week, which seems plausible for a cohort with an average age of 66.7 years. This average age is unusual for an edentulous cohort, but it has to be borne in mind, that the patients were selected for the undergraduate final year clinic, which due to its numerous lengthy and cumbersome clinical sessions is not suited for multimorbid and geriatric patients. Chewing efficiency requires a stable dentition, well profiled occlusal surfaces and an intact neuro-muscular control. With both CRDPs, the retention of the upper complete denture has improved in 6/15 cases. For the lower denture, the retention improved in 11/15 cases for the milled and in 8/15 cases for the 3D-printed dentures, respectively. The denture stability could be improved in 1/15 upper and 4/15 of the lower dentures. At any rate, the clinician's quality assessment attested the maximum scores to the novel dentures, except for the retention of 4 3D-printed and 1 milled mandibular denture, as well as one balanced occlusion of a mandibular milled denture. These improvements, combined with the new and well profiled occlusal surfaces of the commercially manufactured denture teeth could explain the significant improvements in chewing efficiency, and might have overshadowed a possible initial neuro-muscular disturbance. A post hoc power analysis (mean SA at 6-weeks for milled and 3D-printed groups, t-tests, effect size=0.3042,  $\alpha$  err prob=0.05) revealed a power of 1- $\beta$  err prob= 0.300 for the current trial. To achieve a power of 90%, a sample size of 94 participants must have been included and could have demonstrated a significance.

The results show for both, milled and 3D-printed, groups neither change in MBF over time, nor elicit a difference between groups. A better adaptation of the denture's intaglio surface to the denture bearing tissues avoids areas of poor fit, which might well be painful pressure zones, when the misfit is positive rather than negative. Hence a better MBF should be expected after the insertion of replacement dentures manufactured according to novel and recent master impressions. Müller et al. (2002) showed in a small cohort of 7 edentulous patients, who had received replacement dentures, that MBF tended to be first impaired, especially in patients with poor alveolar ridges, and that only patients with moderate bone resorption exceeded their pre-insertion level of MBF within the observation period of 6-10 months [46]. Typical post-insertion instructions to patients compare the new denture to a new pair of hiking boots, which may also be painful when first used. Hence a general sensitivity of the denture bearing tissues might have precluded an improvement of the MBF during the present observation period of 6 weeks. Furthermore, our post hoc power analysis (mean MBF at 6-weeks for milled and 3D-printed groups, t-tests, effect size=0.2649,  $\alpha$  err

prob=0.05) revealed a power of  $1-\beta$  err prob= 0.252 for the current trial and to achieve a power of 90%, a sample size of 124 participants should have been included for a significant finding in this parameter. Nevertheless, it was observed that the participants' MBF improved between insertion and 6 weeks in both denture groups, thus highlighting that the participants were gradually adjusting to the new CRDPs.

Both denture types, milled and 3D-printed, ranked almost maximum in the quality assessment of the clinical examiner, except for 4 lower dentures whose retention was judged not optimal. The latter is likely to be related to the patients' anatomical conditions, which often limits the retention that can be achieved by conventional master impressions, and which explains the recent popularity of mandibular implantoverdentures. These findings confirm, that both CAD-CAM techniques can fulfill highest standards, with regards to complete denture reconstructions, and that they, from a clinical point of view, they are not inferior to the conventional manufacturing methods. Perhaps to elicit a significant difference between the two CAD-CAM denture groups, a larger sample size was required, but our post hoc power analysis (mean CDQE at 6-weeks for milled and 3D-printed groups, t-tests, effect size=0.2841,  $\alpha$  err prob=0.05) revealed a power of 1- $\beta$  err prob= 0.80 for the current trial, which may be considered adequate. Therefore, at initial denture insertion and at a follow-up at 6-weeks, both CRDPs were judged of high quality, but perhaps the time frame for judging this aspect may have been too short. An evaluation after a longer recall period is deemed necessary to further verify this aspect.

None of the patients reported a significant improvement in denture satisfaction or Oral Health-Related Quality of Life, except for the milled after 1 week. This result seems surprising, and counterintuitive, given the clinically superior quality of the restoration in CDQE. OHRQoL improvements are mostly reported in RCTs comparing conventional overdenture with implant-supported ones. However, most of these studies use randomized research settings with larger cohorts, with longer observation periods, measuring OHRQoL, along with evaluating the treatment considering patient preferences and patient satisfaction [22,47–51]. In the present study, the mean OHIP-score improved for the milled but was constant for the 3D-printed . However, with a standard deviation of almost the size of the mean value, it becomes clear that this tendency will only become significant with a larger number of participants. A post hoc power analysis (mean OHIP Scores at 6-weeks for milled and 3D-printed groups, t-tests, effect size=0.4314,  $\alpha$  err prob=0.05) revealed a power of  $1-\beta$  err prob= 0.478 for the current trial. To achieve a power of 90%, a sample size of 48 participants must be included for sufficient power, and perhaps with this number a significant difference in the OHRQoL could have been revealed. Although the overall denture satisfaction by the patients for the two types of CRDPs were not significantly different, it was observed that the participants rated the milled dentures with higher scores than the 3D-printed dentures in all categories except in the ability to speak, where they were both rated the same. Though this may not be statistically significant in this trial, it can lead to the speculation that perhaps in studies with larger cohorts and longer follow-ups, this might turn significant. It was revealed in this trail that there was a significant improvement in mandibular denture retention when comparing the transition from old to new dentures. This aspect highlights a positive outlook that perhaps the CAD-CAM manufactured CRDPs demonstrated better adaptation to the denture bearing tissues and improved the retention [11,38,39]. It is however, realist to assume that perhaps the improvement in retention was probably because of the construction of new dentures and not because of the fabrication method. This would be a more acceptable explanation as to why the retention improved, since all the clinical steps followed a conventional workflow. Nevertheless, the effect of the CAD-CAM manufacturing process on the improved retention is not ruled out completely, as warping due to the heat polymerization process is avoided in CAD-CAM manufactured CRDPs. Studies have evidenced that both milled and 3D-printed CRDPs afford superior retention than conventional CRDPs [40,41] but, it has to be borne in mind that these

studies evaluated the maxillary denture and the inference must be cautiously considered as our trial revealed a significant within-subject improvement in the mandibular CRDPs. Furthermore, studies have indicated that milled and 3D-printed CRDPs have been rated better than conventional CRDPs by patients [42,52], but no studies exist where the two have been compared. Hence, the findings of this trial cannot be corroborated with other published studies as no studies exist that have compared the two. This study perhaps provides first evidence of a true comparison between milled and 3D-printed CRDPs. However, a lack of comparison between the CAD-CAM and conventional CRDPs in this trial must be duly noted as a limitation of this study.

A factor to be considered for patient satisfaction as well as clinician's evaluation is the requirement of maintenance and adjustment visits. By and large, it is accepted that lesser the number of maintenance/adjustment visits and associated costs, better must be the patient satisfaction. It is logical to assume that, based on the findings of this trial, the participants must have been naturally more satisfied with the milled CRDPs and a clear distinction between the two should have been found. However, this was not the case. Although the milled CRDPs warranted less maintenance and adjustment visits as well as the costs for both the planned and unplanned recall visits, this did not seem to have affected the patient satisfaction. Here again, it has to be borne in mind, that patients treated in undergraduate clinics are prepared to accept multiple visits and potential repetition of clinical procedures. The difference in maintenance visits might however, have had an inadvertent effect on the participants' willingness-to-pay. Though the participants indicated that they were willing to pay more than the actual cost for either of the two CRDPs, the costs they were willing to pay for milled was higher. This may be one of the factors that can guide the clinician in the clinicaldecision making process, when choosing the type of CAD-CAM fabrication for CRDPs. Despite this finding, 7 of the patients opted to remain with the 3D-printed and 8 chose the milled CRDP as permanent restoration. This confirms, that both are valid treatment modalities for edentulous patients.

A major factor that needs to be considered as a limitation of the current study is that this is the first randomized controlled trial that has evaluated the differences between milled and 3D-printed CRDPs, on a limited patient sample. Therefore, further similar studies with larger sample sizes are deemed necessary to draw more specific conclusions.

#### 5. Conclusions

The findings of this clinical crossover trial confirm that both milled and 3D-printed CRDPs are valid treatment modalities for edentulous patients, with the latter performing inferior with regard- to prosthodontic aftercare, cost and willingness-to-pay.

## Author statement

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### **Declaration of Competing Interest**

The authors declare that they have no conflict of interests.

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#### References

- N. Kawahata, H. Ono, Y. Nishi, T. Hamano, E. Nagaoka, Trial of duplication procedure for complete dentures by CAD/CAM, J. Oral Rehabil. 24 (7) (1997) 540–548.
- [2] Y. Maeda, M. Minoura, S. Tsutsumi, M. Okada, T. Nokubi, A CAD/CAM system for removable denture. Part I: fabrication of complete dentures, Int. J. Prosthodont. 7 (1) (1994) 17–21.
- [3] N.Z. Baba, H.S. AlRumaih, B.J. Goodacre, C.J. Goodacre, Current techniques in CAD/CAM denture fabrication, Gen. Dent. 64 (6) (2016) 23–28.
- [4] R. van Noort, The future of dental devices is digital, Dent. Mater. 28 (1) (2012) 3–12.
- [5] M. Srinivasan, N. Kalberer, M. Naharro, L. Marchand, H. Lee, F. Muller, CAD-CAM milled dentures: the Geneva protocols for digital dentures, J. Prosthet. Dent. 123 (1) (2020) 27–37.
- [6] M. Srinivasan, M. Schimmel, M. Naharro, C. O' Neill, G. McKenna, F. Muller, CAD/ CAM milled removable complete dentures: time and cost estimation study, J. Dent. 80 (2019) 75–79.
- [7] M. Srinivasan, P. Kamnoedboon, G. McKenna, L. Angst, M. Schimmel, M. Ozcan, F. Muller, CAD-CAM removable complete dentures: a systematic review and metaanalysis of trueness of fit, biocompatibility, mechanical properties, surface characteristics, color stability, time-cost analysis, clinical and patient-reported outcomes, J. Dent. (2021), 103777.
- [8] J.P.J. de Oliveira Limirio, J.M.L. Gomes, M.C.R. Alves Rezende, C.A.A. Lemos, C. Rosa, E.P. Pellizzer, Mechanical properties of polymethyl methacrylate as a denture base: conventional versus CAD-CAM resin - a systematic review and metaanalysis of in vitro studies, J. Prosthet. Dent. (2021).
- [9] A.S. Bidra, T.D. Taylor, J.R. Agar, Computer-aided technology for fabricating complete dentures: systematic review of historical background, current status, and future perspectives, J. Prosthet. Dent. 109 (6) (2013) 361–366.
- [10] K.F. Schulz, D.G. Altman, D. Moher, CONSORT 2010 statement: updated guidelines for reporting parallel group randomized trials, Ann. Intern. Med. 152 (11) (2010) 726–732.
- [11] M.T. Kattadiyil, R. Jekki, C.J. Goodacre, N.Z. Baba, Comparison of treatment outcomes in digital and conventional complete removable dental prosthesis fabrications in a predoctoral setting, J. Prosthet. Dent. 114 (6) (2015) 818–825.
- [12] F. Faul, E. Erdfelder, A. Buchner, A.G. Lang, Statistical power analyses using G\*Power 3.1: tests for correlation and regression analyses, Behav. Res. Methods 41 (4) (2009) 1149–1160.
- [13] J. Schreinemakers, Die Logik in der Totalprothetik, Quintessenz, Berlin, 1979.
- [14] P.F. Allen, A.S. McMillan, D. Walshaw, A patient-based assessment of implantstabilized and conventional complete dentures, J. Prosthet. Dent. 85 (2) (2001) 141–147.
- [15] F. Allen, D. Locker, A modified short version of the oral health impact profile for assessing health-related quality of life in edentulous adults, Int. J. Prosthodont. 15 (5) (2002) 446–450.
- [16] M.A. Awad, J.P. Lund, S.H. Shapiro, D. Locker, E. Klemetti, A. Chehade, A. Savard, J.S. Feine, Oral health status and treatment satisfaction with mandibular implant overdentures and conventional dentures: a randomized clinical trial in a senior population, Int. J. Prosthodont. 16 (4) (2003) 390–396.
- [17] G. Heydecke, D. Locker, M.A. Awad, J.P. Lund, J.S. Feine, Oral and general healthrelated quality of life with conventional and implant dentures, Community Dentist. Oral Epidemiol. 31 (3) (2003) 161–168.
- [18] P. Allison, D. Locker, A. Jokovic, G. Slade, A cross-cultural study of oral health values, J. Dent. Res. 78 (2) (1999) 643–649.

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- [19] M. Schimmel, B. Leemann, P. Christou, S. Kiliaridis, A. Schnider, F.R. Herrmann, F. Müller, Oral health-related quality of life in hospitalised stroke patients, Gerodontology 28 (1) (2011) 3–11.
- [20] M. Srinivasan, M. Schimmel, R. Buser, S. Maniewicz, F.R. Herrmann, F. Muller, Mandibular two-implant overdentures with CAD-CAM milled bars with distal extensions or retentive anchors: a randomized controlled trial, Clin. Oral. Implants Res. 31 (12) (2020) 1207–1222.
- [21] G. McKenna, S. Tada, N. Woods, M. Hayes, C. DaMata, P.F. Allen, Tooth replacement for partially dentate elders: a willingness-to-pay analysis, J. Dent. 53 (2016) 51–56.
- [22] S. Tada, M. Kanazawa, A. Miyayasu, M. Iwaki, M. Srinivasan, S. Minakuchi, G. McKenna, Patient preferences for different tooth replacement strategies for the edentulous mandible: a willingness-to-pay analysis, J. Prosthodont. Res. (2021).
- [23] S.A. Alfadda, The relationship between various parameters of complete denture quality and patients' satisfaction, J. Am. Dent. Assoc. 145 (9) (2014) 941–948.
  [24] M. Schimmel, P. Christou, F.R. Herrmann, F. Müller, A two-colour chewing gum
- test for masticatory efficiency: development of different assessment methods, J. Oral Rehabil. 34 (9) (2007) 671–678.
  [25] M. Schimmel, P. Christou, H. Miyazaki, D. Halazonetis, F.R. Herrmann, F. Muller,
- [25] M. Schimmel, P. Christou, H. Miyazaki, D. Halazoneus, F.R. Herrmann, F. Muller, A novel colourimetric technique to assess chewing function using two-coloured specimens: validation and application, J. Dent. 43 (8) (2015) 955–964.
- [26] N. Fankhauser, N. Kalberer, F. Muller, C.R. Leles, M. Schimmel, M. Srinivasan, Comparison of smartphone camera and conventional flatbed scanner images for analytical evaluation of chewing function, J. Oral Rehabil. 47 (12) (2020) 1496–1502.
- [27] K. Nakatsuka, T. Usui, Y. Masuda, J. Rugh, S. Kurihara, Nihon Kyosei Shika Gakkai Taikai Puroguramu, Accuracy and repeatability of the GM10 occlusal Force-Meter, Shorokushu 65 (2006) 336.
- [28] S. Gruber, P. Kamnoedboon, M. Ozcan, M. Srinivasan, CAD/CAM Complete Denture Resins: an In Vitro Evaluation of Color Stability, J. Prosthodont. 30 (5) (2021) 430–439.
- [29] F. Müller, Oral hygiene reduces the mortality from aspiration pneumonia in frail elders, J. Dent. Res. 94 (3 Suppl) (2015) 14S–16S.
- [30] O. Steinmassl, H. Dumfahrt, I. Grunert, P.A. Steinmassl, Influence of CAD/CAM fabrication on denture surface properties, J. Oral Rehabil. 45 (5) (2018) 406–413.
- [31] O. Steinmassl, V. Offermanns, W. Stockl, H. Dumfahrt, I. Grunert, P.A. Steinmassl, In vitro analysis of the fracture resistance of CAD/CAM denture base resins, Materials (Basel) 11 (3) (2018).
- [32] P.A. Steinmassl, F. Klaunzer, O. Steinmassl, H. Dumfahrt, I. Grunert, Evaluation of currently available CAD/CAM denture systems, Int. J. Prosthodont. 30 (2) (2017) 116–122.
- [33] O. Steinmassl, H. Dumfahrt, I. Grunert, P.A. Steinmassl, Influence of CAD/CAM fabrication on denture surface properties, J. Oral Rehabil. 45 (5) (2018) 406–413.
- [34] Z.N. Al-Dwairi, K.Y. Tahboub, N.Z. Baba, C.J. Goodacre, M. Ozcan, A comparison of the surface properties of CAD/CAM and conventional polymethylmethacrylate (PMMA), J. Prosthodont. 28 (4) (2019) 452–457.
- [35] Z.N. Al-Dwairi, K.Y. Tahboub, N.Z. Baba, C.J. Goodacre, A comparison of the flexural and impact strengths and flexural modulus of CAD/CAM and conventional heat-cured polymethyl methacrylate (PMMA), J. Prosthodont. 29 (4) (2020) 341–349.
- [36] H.J. Hwang, S.J. Lee, E.J. Park, H.I. Yoon, Assessment of the trueness and tissue surface adaptation of CAD-CAM maxillary denture bases manufactured using digital light processing, J. Prosthet. Dent. 121 (1) (2019) 110–117.

- [37] K. Davda, C. Osnes, S. Dillon, J. Wu, P. Hyde, A. Keeling, An Investigation into the Trueness and Precision of Copy Denture Templates Produced by Rapid Prototyping and Conventional Means, Eur. J. Prosthodont. Restor. Dent. 25 (4) (2017) 186–192.
- [38] O. Steinmassl, H. Dumfahrt, I. Grunert, P.A. Steinmassl, CAD/CAM produces dentures with improved fit, Clin. Oral Investig. 22 (8) (2018) 2829–2835.
- [39] B.J. Goodacre, C.J. Goodacre, N.Z. Baba, M.T. Kattadiyil, Comparison of denture base adaptation between CAD-CAM and conventional fabrication techniques, J. Prosthet. Dent. 116 (2) (2016) 249–256.
- [40] A. AlHelal, H.S. AlRumaih, M.T. Kattadiyil, N.Z. Baba, C.J. Goodacre, Comparison of retention between maxillary milled and conventional denture bases: a clinical study, J. Prosthet. Dent. 117 (2) (2017) 233–238.
- [41] A. Tasaka, S. Matsunaga, K. Odaka, K. Ishizaki, T. Ueda, S. Abe, M. Yoshinari, S. Yamashita, K. Sakurai, Accuracy and retention of denture base fabricated by heat curing and additive manufacturing, J. Prosthodont. Res. 63 (1) (2019) 85–89.
- [42] M. Inokoshi, M. Kanazawa, S. Minakuchi, Evaluation of a complete denture trial method applying rapid prototyping, Dent. Mater. J. 31 (1) (2012) 40–46.
   [43] S. Gruber, P. Kamnoedboon, M. Ozcan, M. Srinivasan, CAD/CAM complete denture
- [43] S. Gruber, P. Kamnoedboon, M. Ozcan, M. Srinivasan, CAD/CAM complete denture resins: an in vitro evaluation of color stability, J. Prosthodont. 30 (5) (2021) 430–439.
- [44] C. Stilwell, N. Kalberer, P. Mojon, M. Schimmel, M. Srinivasan, F. Müller, CAD-CAM and conventional complete denture appreciation evaluated extra-orally by dental professional and non-professional elder CRDP wearers: a randomized survey, J. Dent. (2021) [Under peer-review].
- [45] F.M. van Kampen, A. van der Bilt, M.S. Cune, F.A. Fontijn-Tekamp, F. Bosman, Masticatory function with implant-supported overdentures, J. Dent. Res. 83 (9) (2004) 708–711.
- [46] F. Müller, M.R. Heath, A.M. Ferman, G.R. Davis, Modulation of mastication during experimental loosening of complete dentures, Int. J. Prosthodont. 15 (6) (2002) 553–558.
- [47] F. Rashid, M.A. Awad, J.M. Thomason, A. Piovano, G.P. Spielberg, E. Scilingo, P. Mojon, F. Muller, M. Spielberg, G. Heydecke, G. Stoker, D. Wismeijer, F. Allen, J. S. Feine, The effectiveness of 2-implant overdentures - a pragmatic international multicentre study, J. Oral Rehabil. 38 (3) (2011) 176–184.
- [48] G.M. Raghoebar, H.J. Meijer, B. Stegenga, M.A. van't Hof, R.P. van Oort, A. Vissink, Effectiveness of three treatment modalities for the edentulous mandible. A five-year randomized clinical trial, Clin. Oral. Implants Res. 11 (3) (2000) 195–201.
- [49] S. Listl, L. Fischer, N.N. Giannakopoulos, An economic evaluation of maxillary implant overdentures based on six vs. four implants, BMC Oral Health 14 (2014) 105.
- [50] P.C. Saponaro, B. Yilmaz, W. Johnston, R.H. Heshmati, E.A. McGlumphy, Evaluation of patient experience and satisfaction with CAD-CAM-fabricated complete dentures: a retrospective survey study, J. Prosthet. Dent. 116 (4) (2016) 524–528.
- [51] M.A. Awad, F. Rashid, J.S. Feine, C. Overdenture Effectiveness Study Team, The effect of mandibular 2-implant overdentures on oral health-related quality of life: an international multicentre study, Clin. Oral. Implants Res. 25 (1) (2014) 46–51.
- [52] A.S. Bidra, K. Farrell, D. Burnham, A. Dhingra, T.D. Taylor, C.L. Kuo, Prospective cohort pilot study of 2-visit CAD/CAM monolithic complete dentures and implantretained overdentures: clinical and patient-centered outcomes, J. Prosthet. Dent. 115 (5) (2016), 578-586 e1.