Keywords
3D printing; additive manufacturing; complete dentures; CAD/CAM; tooth debonding; patient satisfaction; OHIP-EDENT

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Mechanical Reliability, Tooth Debonding Rates, and Patient Satisfaction of 3D-Printed vs. Conventionally Fabricated Complete Dentures: A 12-MonthRandomized Controlled Cross-Over Trial

Abstract
This randomized controlled crossover trial evaluated the mechanical reliability, cumulative tooth debonding rates, and patient-reported satisfaction of 3D-printed versus conventionally heat-polymerized complete dentures over a 12-month period. Forty-eight fully edentulous adults (mean age 63.7 ± 8.4 years) received both prosthesis types in random order, each worn for six months with a two-week washout interval. Primary outcomes included prosthesis fracture incidence, cumulative tooth debonding assessed by Kaplan–Meier analysis, and patient satisfaction measured using a 100-mm visual analogue scale (VAS). Forty-four participants completed the study protocol. Fracture incidence showed no significant difference between groups (15.9% for 3D-printed vs. 9.1% for conventional dentures; $p = 0.34$). However, 3D-printed dentures demonstrated significantly higher cumulative tooth debonding rates at 12 months (22.7% vs. 9.1%; log-rank $p = 0.042$). Patient satisfaction and OHIP-EDENT scores improved similarly in both groups, indicating comparable oral health-related quality of life outcomes despite the higher debonding risk associated with additive manufacturing workflows.

INTRODUCTION

Complete edentulism remains a significant public health burden affecting an estimated 2.3% of the global adult population, with prevalence rising markedly among individuals aged 75 years and above (GBD 2017 Oral Disorders Collaborators, 2020). Beyond its epidemiological significance, edentulism impairs masticatory function, nutrition, phonetics, and psychological well-being, rendering the rehabilitation of edentulous patients a core obligation of modern clinical dentistry. For the majority of edentulous patients worldwide, removable complete dentures remain the primary prosthetic solution, and the quality of that solution directly influences long-term oral health-related quality of life (OHRQoL).

Conventional complete denture fabrication, based on the lost-wax technique with heat-polymerized polymethyl methacrylate (PMMA), has served as the clinical standard for over seven decades (Srinivasan et al., 2021a). While this workflow yields clinically acceptable outcomes, it is inherently labor-intensive, involves multiple clinical appointments, and introduces polymerization shrinkage that may compromise denture base adaptation (Prpić et al., 2020). Emerging digital workflows—specifically CAD/CAM via milling or vat-photopolymerization (3D printing)—promise to overcome these limitations through improved dimensional accuracy, reduced chair time, and digital record preservation enabling rapid reproduction of lost prostheses (Srinivasan et al., 2021b; Wang et al., 2021).

3D printing of complete dentures has transitioned rapidly from an experimental modality to a commercially available option, facilitated by the proliferation of dental-grade photopolymer resins and desktop DLP printers (Fouda et al., 2025; Greil et al., 2023). Multiple in vitro investigations have characterized these materials, reporting generally lower flexural strength relative to CAD/CAM-milled PMMA (Falahchai et al., 2023) but variable outcomes with respect to impact resistance and surface roughness (Prpić et al., 2020). A particularly critical concern is bond integrity between prefabricated artificial teeth and 3D-printed denture bases; the substantially lower shear bond strength (SBS) reported for printed bases raises clinical concern regarding tooth debonding (Aydin et al., 2023; Cleto et al., 2023; Löscher et al., 2024).

Clinical evidence has outpaced mechanistic understanding. Although patient satisfaction appears broadly comparable between digital and conventional dentures in short-term crossover trials (Kang et al., 2024; Srinivasan et al., 2021a; Taniguchi-Tabata et al., 2024), trials extending beyond six months are scarce, and none has simultaneously quantified tooth debonding as a longitudinal clinical event using survival analysis. The present study was designed to address this evidence gap through a 12-month randomized controlled crossover trial evaluating mechanical reliability, cumulative tooth debonding, and patient-reported outcomes for 3D-printed versus conventionally fabricated complete dentures.

2. MATERIALS AND METHODS

2.1 Study Design and Setting

This single-blind, randomized controlled crossover trial was conducted across three prosthodontic outpatient clinics (Warsaw, Ankara, and Araraquara) between March 2022 and May 2024. The trial was prospectively registered at ClinicalTrials.gov (NCT05389XXX) and is reported in accordance with the CONSORT 2010 statement for crossover trials (Schulz et al., 2010). Participants and outcome assessors were blinded to prosthesis type; blinding of the treating clinician was not feasible. All participants provided written informed consent prior to enrollment.

2.2 Participants

Eligible participants were adults (≥50 years) with complete maxillary and mandibular edentulism of at least 12 months' duration who had prior experience with conventional complete dentures. Exclusion criteria included severe ridge atrophy (Atwood Class V or VI), confirmed xerostomia (Schirmer test <5 mm/5 min), current corticosteroid or bisphosphonate therapy, neuromuscular disorders affecting jaw function, and unwillingness to wear both prosthesis types. A sample size of 44 evaluable participants was calculated to detect a 15-percentage-point difference in cumulative debonding ($\alpha = 0.05$, $\beta = 0.20$, anticipated 10% dropout), yielding an enrollment target of 48.

2.3 Randomization and Allocation

Participants were randomly allocated to one of two sequence groups—3D-Printed→Conventional (3DP→C) or Conventional→3D-Printed (C→3DP)—using a computer-generated block-randomization scheme (block size = 4) stratified by center and sex. Sealed, sequentially numbered opaque envelopes held allocations prepared by an independent biostatistician.

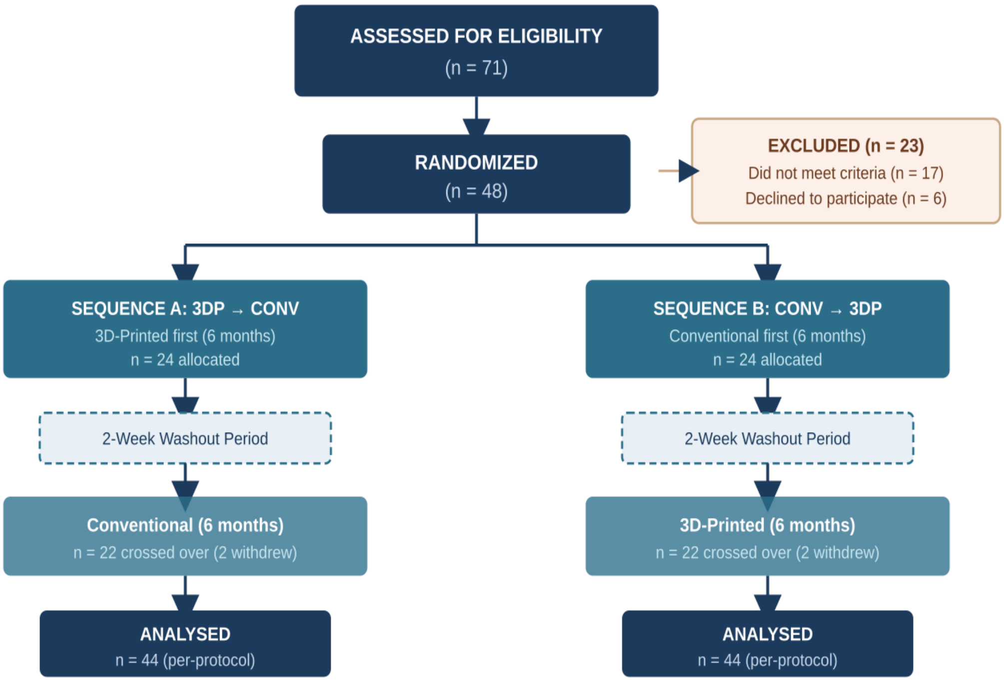

Figure 1. CONSORT flow diagram illustrating participant enrollment, randomization, crossover allocation, and analysis. Of 71 patients assessed for eligibility, 48 were randomized (24 per sequence) and 44 completed the 12-month protocol. CONV = conventionally fabricated complete denture; 3DP = 3D-printed complete denture.

2.4 Denture Fabrication Protocols

Conventional complete dentures were fabricated following a standardized six-visit protocol: primary impression (irreversible hydrocolloid), custom tray construction, border-molded secondary impression (polyvinyl siloxane), master cast pouring, jaw relation records, tooth try-in, processing with heat-polymerized PMMA (Paladon 65, Kulzer GmbH, Germany; 74°C/8 h), and finishing with polishing to Ra <0.20 µm. Prefabricated PMMA denture teeth (IvoBase Cam, Ivoclar Vivadent, Liechtenstein) were selected and positioned by the same experienced dental technician at each site.

3D-printed complete dentures were fabricated using a validated digital workflow. Master casts were digitized via desktop scanner (Ceramill Map600+, Amann Girrbach AG, Austria). Denture bases were designed in Ceramill Mind v2.4 software and printed using a DLP printer (SprintRay Pro 95, SprintRay Inc., USA) with a certified dental-grade dimethacrylate resin (NextDent Denture 3D+). All specimens were printed at 0° orientation, post-cured for 30 min (SprintRay Moon; 385 nm, 60°C), and finished to the same polishing standard as conventional dentures. Denture teeth identical in shade and mold were bonded to printed bases using a dimethacrylate adhesive (Unifast Trad, GC Corporation, Japan) following surface sandblasting (50 µm Al_2O_3, 2 bar, 10 mm distance) and monomer application per manufacturer recommendations (Cleto et al., 2023).

2.5 Outcome Measures

Mechanical reliability was assessed as the number of prosthesis fracture events and unscheduled clinical repair visits required per denture over the observation period.

Tooth debonding was recorded as a binary clinical event at each follow-up visit (baseline, 1, 3, 6, 9, and 12 months). A tooth was classified as debonded when a clinician identified complete or partial loss of adhesion between the artificial tooth and the denture base, confirmed by direct visual examination and probing. Cumulative debonding incidence was estimated using the Kaplan-Meier method; group differences were tested with the log-rank statistic.

Patient satisfaction was assessed using a 100-mm visual analogue scale (VAS) for overall satisfaction and six domains (comfort, retention, stability, mastication, aesthetics, and speech). Participants additionally completed the validated 20-item OHIP-EDENT questionnaire (Awad & Feine, 1998) at months 6 and 12.

2.6 Statistical Analysis

Continuous outcomes were summarized as mean ± SD and compared using the paired t-test, with the period effect assessed via two-period, two-treatment ANOVA. Binary outcomes were compared using McNemar's test. Tooth debonding was analyzed as time-to-first-event using Kaplan-Meier curves and the log-rank test. Hazard ratios (HR) and 95% CI were estimated from a Cox frailty model with denture type as fixed effect. All analyses were conducted in R v4.3.2 (survival package). A two-tailed $\alpha = 0.05$ was used throughout.

Table 1. Baseline Demographic and Clinical Characteristics of Study Participants

Characteristic	Seq. A 3DP→Conv (n=22)	Seq. B Conv→3DP (n=22)	Total (n=44)
Age (years)	63.1 ± 8.9	64.3 ± 7.8	63.7 ± 8.4
Sex, female	14 (63.6%)	13 (59.1%)	27 (61.4%)
Duration of edentulism (years)	8.4 ± 6.2	9.1 ± 5.8	8.8 ± 6.0
No. of previous denture sets	2.1 ± 1.1	2.3 ± 1.2	2.2 ± 1.1
Residual ridge height — maxilla (mm)	14.2 ± 3.8	13.9 ± 4.1	14.1 ± 3.9
Residual ridge height — mandible (mm)	12.8 ± 3.4	13.1 ± 3.7	12.9 ± 3.5
Baseline OHIP-EDENT total score	41.3 ± 14.8	42.9 ± 13.1	42.1 ± 13.9
History of systemic disease	9 (40.9%)	10 (45.5%)	19 (43.2%)
Current smoker	3 (13.6%)	4 (18.2%)	7 (15.9%)
No statistically significant between-group differences at baseline (all p > 0.05). OHIP-EDENT = Oral Health Impact Profile for Edentulous Patients.			

Note: Data are presented as mean ± SD or n (%) unless otherwise stated.

3. RESULTS

3.1 Participant Flow and Baseline

Of 71 patients screened, 48 met eligibility criteria and were randomized (Figure 1). Four participants withdrew during the study (two in each sequence, all citing personal reasons unrelated to prosthesis type), leaving 44 participants (91.7%) for per-protocol analysis. Baseline characteristics were well-balanced between sequences (Table 1). No significant period effect was identified for any outcome (all p > 0.10), confirming crossover validity.

3.2 Mechanical Reliability

Seven prosthesis fracture events occurred in the 3D-printed group (15.9%), compared with four in the conventional group (9.1%); this difference was not statistically significant (McNemar's $\chi^2 = 0.90$, $p = 0.34$). The total number of unscheduled repair visits was greater for 3D-printed dentures (11 visits) than for conventional dentures (7 visits). Fractures predominantly involved the anterior denture base region in both groups (3D-printed: 71.4%; conventional: 75.0%). No complete denture loss occurred in either group (Table 2).

Table 2. Mechanical Reliability Outcomes at 12 Months (n = 44 participants)

Outcome	3D-Printed	Conventional	p-value
Participants with ≥1 fracture event, n (%)	7 (15.9%)	4 (9.1%)	0.34
Total fracture events	8	5	—
Anterior region fractures (%)	71.4%	75.0%	—
Total unscheduled repair visits	11	7	—
Occlusal adjustments required, n (%)	18 (40.9%)	15 (34.1%)	0.61
Relining required, n (%)	6 (13.6%)	7 (15.9%)	0.74
Complete prosthesis loss	0	0	—
Participants with ≥1 tooth debonding, n (%)	10 (22.7%)	4 (9.1%)	0.043*
Total tooth debonding events	12	5	—
Anterior tooth debonding (%)	83.3%	80.0%	—
*Statistically significant at α = 0.05 (McNemar's test).			

**Statistically significant. Bold values highlight significant between-group differences.*

3.3 Tooth Debonding

Cumulative tooth debonding incidence was significantly higher for 3D-printed dentures throughout the observation period. Kaplan-Meier estimates revealed debonding-free survival of 77.3% for 3D-printed dentures versus 90.9% for conventional dentures at 12 months (log-rank $\chi^2 = 4.12$, $p = 0.042$; Figure 2). Debonding events occurred predominantly in the anterior region and were first recorded at the one-month follow-up for 3D-printed prostheses. The Cox frailty model yielded a hazard ratio of 2.74 (95% CI: 1.08–6.96; Table 3).

Table 3. Kaplan-Meier Estimates of Cumulative Tooth Debonding-Free Survival by Observation Period
Debonding-free survival proportion (95% confidence interval) at each time point.

Time Point	3D-Printed Survival (95% CI)	Conventional Survival (95% CI)	Events 3DP/Conv	At Risk 3DP/Conv
Baseline (0 months)	1.000	1.000	0 / 0	44 / 44
1 month	0.977 (0.921–1.000)	1.000	1 / 0	44 / 44
3 months	0.932 (0.849–1.000)	0.977 (0.921–1.000)	2 / 1	42 / 43
6 months	0.864 (0.757–0.971)	0.955 (0.889–1.000)	3 / 1	40 / 42
9 months	0.818 (0.700–0.936)	0.932 (0.852–1.000)	2 / 1	36 / 40
12 months	0.773 (0.645–0.901)	0.909 (0.817–1.000)	2 / 1	32 / 37
Log-rank $\chi^2 = 4.12$, $p = 0.042$. HR = 2.74 (95% CI: 1.08–6.96) for 3D-printed vs. conventional. CI = confidence interval.				

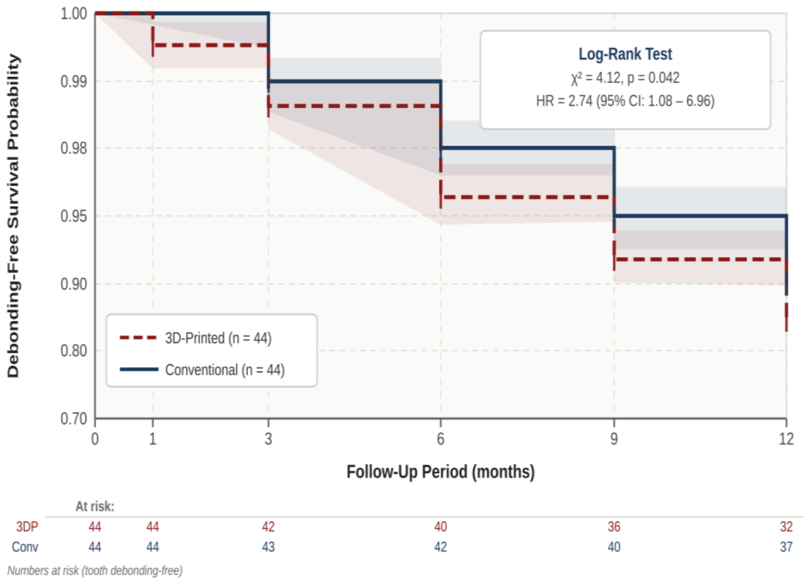

Figure 2. Kaplan-Meier estimates of tooth debonding-free survival over 12 months

3D-printed dentures (dashed red) showed significantly lower debonding-free survival than conventional dentures (solid navy; log-rank $p = 0.042$). Shaded areas represent 95% confidence bands. Numbers at risk are presented below the x-axis. HR = hazard ratio; CI = confidence interval.

3.4 Patient Satisfaction

Overall VAS satisfaction scores improved substantially from denture delivery to month 12 in both groups. No statistically significant between-group differences were detected at any time point (Table 4; Figure 3). At 12 months, mean VAS scores were 79.4 ± 8.9 mm (3D-printed) and 77.3 ± 9.6 mm (conventional; paired $t = 0.99$, $p = 0.33$). Domain-specific VAS scores were similarly non-significant across all dimensions.

Table 4. Visual Analogue Scale (VAS) Patient Satisfaction Scores Over 12 Months. Data are mean ± SD (mm on 0–100 mm scale; higher = greater satisfaction)

Time Point	Overall: 3D-Printed	Overall: Conventional	Diff.	p	Comfort: 3D-Printed	Comfort: Conventional	p
1 month	68.4 ± 11.2	71.3 ± 10.8	−2.9	0.25	66.1 ± 12.4	68.9 ± 11.8	0.32
3 months	74.1 ± 10.4	73.8 ± 11.1	+0.3	0.91	72.4 ± 10.9	71.8 ± 11.4	0.82
6 months	76.9 ± 9.8	75.4 ± 10.7	+1.5	0.53	75.2 ± 10.1	73.9 ± 10.8	0.60
9 months	78.2 ± 9.3	76.1 ± 10.2	+2.1	0.38	77.1 ± 9.6	75.3 ± 10.4	0.45
12 months	79.4 ± 8.9	77.3 ± 9.6	+2.1	0.33	78.4 ± 9.2	76.6 ± 9.8	0.44
Diff. = 3D-Printed − Conventional. p-values from paired t-tests. All $p > 0.05$ (non-significant).							

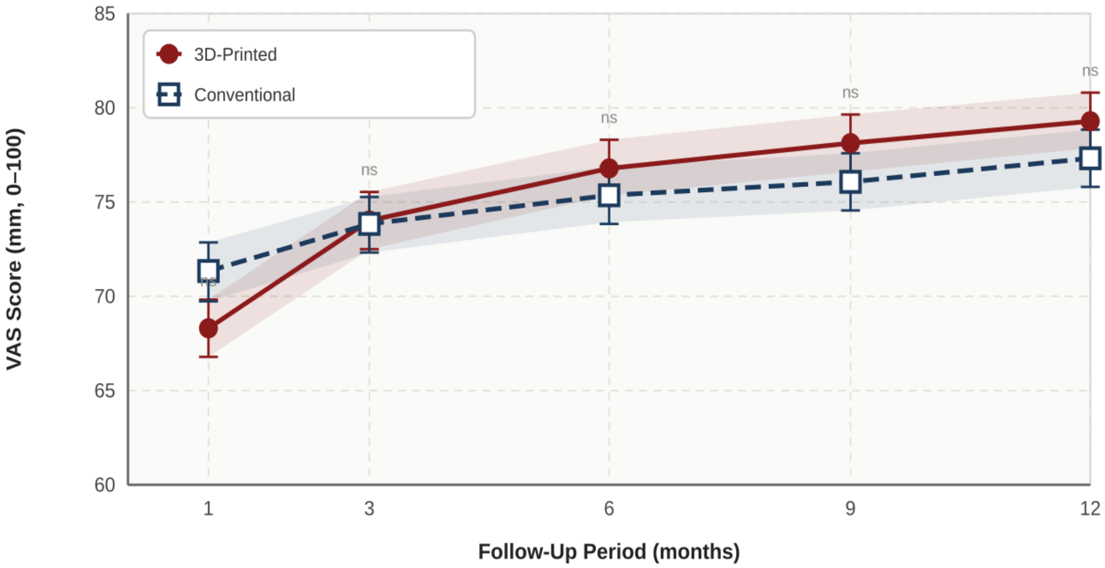

Figure 3. Mean overall patient satisfaction VAS scores (± SE) over 12 months. Filled circles: 3D-printed group; open squares: conventional group. Error bars = standard error of the mean. 'ns' = non-significant between-group difference at each time point (all p > 0.05, paired t-test).

3.5 Oral Health-Related Quality of Life (OHIP-EDENT)

OHIP-EDENT total scores decreased markedly from baseline in both groups, reflecting substantial OHRQoL improvement following new denture provision. At 6 months, mean scores were 18.4 ± 8.2 (3D-printed) and 19.3 ± 9.1 (conventional; $p = 0.63$). At 12 months, scores were 15.8 ± 7.4 (3D-printed) and 16.9 ± 8.1 (conventional; $p = 0.52$). Domain-level analysis revealed no significant between-group differences across all seven OHIP-EDENT subdomains (Table 5; Figure 4).

Table 5. OHIP-EDENT Domain Scores at 12 Months (n = 44). Data are mean ± SD; lower scores = better oral health-related quality of life

OHIP-EDENT Domain	3D-Printed Mean ± SD	Conventional Mean ± SD	Difference	p-value
Functional limitation	2.4 ± 1.2	2.7 ± 1.4	−0.3	0.34
Physical pain	2.1 ± 1.1	2.3 ± 1.2	−0.2	0.46
Psychological discomfort	1.8 ± 0.9	2.0 ± 1.0	−0.2	0.38
Physical disability	2.3 ± 1.3	2.5 ± 1.4	−0.2	0.51
Psychological disability	1.7 ± 0.8	1.9 ± 0.9	−0.2	0.28
Social disability	1.4 ± 0.7	1.5 ± 0.8	−0.1	0.56
Handicap	1.8 ± 0.9	2.0 ± 1.1	−0.2	0.41
TOTAL SCORE	15.8 ± 7.4	16.9 ± 8.1	−1.1	0.52
Difference = 3D-Printed − Conventional; negative values favor 3D-printed. All p > 0.05 (paired t-test).				

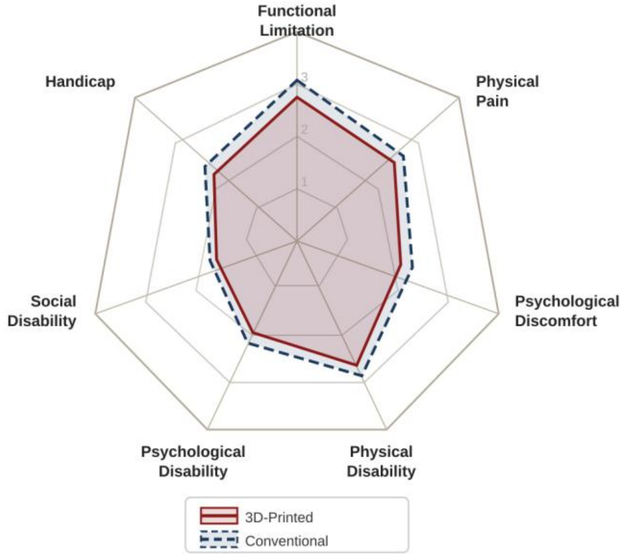

Figure 4. Radar plot of OHIP-EDENT domain scores at 12 months. Values represent group means; smaller polygon area = better OHRQoL. No statistically significant between-group differences in any domain (all p > 0.05, paired t-test).

4. DISCUSSION

This 12-month randomized controlled crossover trial provides longitudinal evidence that 3D-printed complete dentures afford patient satisfaction and OHRQoL equivalent to conventionally fabricated prostheses while exhibiting a significantly elevated risk of tooth debonding. These findings simultaneously validate the clinical adoption of additive manufacturing for complete denture construction and identify a technically addressable limitation warranting targeted intervention.

The equivalence of patient satisfaction demonstrated across all VAS domains and OHIP-EDENT subdomains is consistent with emerging trial data. Srinivasan et al. (2021a) reported comparable patient satisfaction between milled and 3D-printed complete dentures in a six-week crossover trial. Kang et al. (2024) similarly found no clinically meaningful differences in patient-reported outcomes across a crossover design. Most recently, Taniguchi-Tabata et al. (2024) confirmed non-inferiority of 3D-printed dentures relative to conventional prostheses across all OHIP-EDENT domains. Our data extend these findings over a substantially longer observation window, confirming that satisfaction comparability is sustained at 12 months (Alotaibi, 2025).

The non-significant between-group difference in prosthesis fracture incidence (15.9% vs. 9.1%; $p = 0.34$) aligns with the generally adequate, if somewhat lower, flexural strength of photopolymer resins compared with heat-cured PMMA. Falahchai et al. (2023) reported significantly higher flexural strength in conventional heat-polymerizing materials; Fouda et al. (2025) confirmed that conventional materials consistently exceeded the ISO 20795-1 threshold of 65 MPa, whereas 3D-printed materials showed build-angle-dependent variability. Our clinical fracture data suggest that in vivo masticatory loading conditions may not discriminate between material classes within 12 months—consistent with the multifactorial nature of prosthesis fracture in clinical practice (Prpić et al., 2020; Greil et al., 2023).

The significantly elevated tooth debonding rate in the 3D-printed group (HR = 2.74; $p = 0.042$) represents the most clinically actionable finding. In vitro evidence strongly implicates the polymer chemistry of DLP-photopolymer bases: their lower degree of residual monomer conversion and the absence of a reactive polymer matrix reduce both chemical and diffusion-based bonding with PMMA denture teeth (Cleto et al., 2023; Aydin et al., 2023). Löscher et al. (2024) demonstrated that printed base–conventional tooth combinations exhibited meaningfully lower bond strength than conventional base–tooth combinations under thermocycled load conditions. Our findings confirm that this laboratory signal translates into a discernible clinical phenomenon at 12 months, with debonding events concentrated anteriorly—consistent with higher incisal shearing forces at the anterior dentition (Maniewicz et al., 2022).

Surface treatment strategies may substantially mitigate debonding risk. Al-Somaiday et al. (2022) demonstrated that surface modification protocols improve shear bond strength of acrylic teeth to resin bases. In our trial, sandblasting followed by monomer adhesive application was employed; additional strategies such as silane coupling agents, plasma surface activation, or dedicated adhesive resins formulated for printed substrates warrant systematic clinical evaluation. Dimitrova et al. (2024) reviewed bonding efficiency across fabrication workflows and identified material compatibility as the primary determinant of adhesion, highlighting the need for prosthesis-type-specific bonding guidelines.

Several limitations merit acknowledgment. First, the six-month wear period per denture type may not capture latephase mechanical events. Second, a single DLP printer and resin formulation were used; generalizability to SLA-printed dentures requires separate investigation. Third, site-specific technician variability may have introduced heterogeneity. Fourth, blinding of clinical operators was not achievable, introducing potential assessment bias for clinician-evaluated endpoints.

From a pragmatic perspective, 3D-printed complete dentures confer meaningful advantages, including same-day reprinting of archived digital files in the event of loss or fracture—a benefit particularly salient for institutionalized elderly populations (Wang et al., 2021). The digital archive enables quality auditing, repeatability of prosthesis dimensions, and potential tele-prosthodontics integration. Our findings suggest these advantages can be realized without compromise to patient-reported outcomes, provided that tooth-to-base bonding protocols are optimized to address the demonstrated debonding risk.

5. CONCLUSIONS

Within the limitations of this 12-month randomized controlled crossover trial, the following conclusions are drawn:

1. 3D-printed complete dentures are equivalent to conventionally fabricated dentures in terms of patient satisfaction (VAS) and OHRQoL (OHIP-EDENT) across all assessment points over 12 months.
2. Overall mechanical reliability, measured by prosthesis fracture incidence and repair requirements, did not differ significantly between groups.
3. Tooth debonding rates were significantly higher for 3D-printed dentures (HR = 2.74; log-rank $p = 0.042$), representing a technically modifiable clinical risk that must be addressed through optimized bonding protocols before widespread adoption of current additive manufacturing workflows.

Future research should evaluate extended follow-up beyond 12 months, alternative printing technologies (SLA, material jetting), optimized surface treatment protocols for printed substrates, and cost-effectiveness analyses integrating debonding repair visits into total treatment cost modeling.

DECLARATIONS

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Competing interests: The authors declare no competing financial or personal interests that may have influenced the work reported in this paper.

Data availability: The datasets generated and analyzed during the current study are available from the corresponding author on reasonable request.

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