Keywords
Individual adaptation cap; complete denture; denture adhesive; dental biomaterials; EVA polymer; oral biomaterial interface; prosthesis retention; edentulous patients

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Clinical-Functional Efficacy of Individual Adaptation Caps for Retention and Fixation of Removable Prostheses in Patients with Complete Tooth Loss: A Prospective Randomised Controlled Trial

Abstract

Background: Impaired retention is still a significant functional problem of conventional complete denture in patients with resorbed ridges, decreased salivary support and/or unstable denture-mucosa adaptation. Individual adaptation caps (IACs) produced by thermoforming ethylene vinyl acetate (EVAc) shell and tissue-conditioning mucosal contact layer could serve as patient-specific oral biomaterial interfaces for better retention and load distribution.

Objective: To evaluate the clinical-functional efficacy, biomaterial tolerability, and therapeutic performance of IACs compared with standard complete dentures and denture adhesive in edentulous patients.

Methods: A 120 completely edentulous patients were enrolled in a prospective, three-arm, parallel-group randomised controlled trial, where they were randomly assigned to one of three groups: standard complete denture alone, standard complete denture plus commercial denture adhesive, and standard complete denture plus IAC. Results were evaluated at baseline, 1 month, 3 months and 6 months and comprised prosthesis retention force, masticatory efficiency, OHIP-EDENT, patient satisfaction, mucosal health, prosthesis stability and adverse mucosal events.

Results: At 6 months, the IAC group showed superior retention force compared with denture adhesive and standard denture groups (16.8 ± 2.7 N vs 9.2 ± 2.0 N and 7.1 ± 1.6 N; $p < 0.001$). Masticatory efficiency was also higher with IACs (74.1 ± 9.4% vs 55.4 ± 8.2% and 44.7 ± 7.1%; $p < 0.001$). OHIP-EDENT scores decreased by 72.5% in the IAC group, while satisfaction reached 8.9 ± 0.7/10. Mucosal health and prosthesis stability were significantly improved, with no increase in adverse mucosal events.

Conclusion: IACs provide a non-drug, biomaterial-based therapeutic interface that improves denture retention, function, mucosal health, and patient-reported outcomes. Their superiority over denture adhesive supports their clinical relevance for prosthodontic biomaterial research.

1. INTRODUCTION

A significant number of adults in the world are completely toothless and the prevalence of complete dentures (CDs) varies across the world regions and age groups (from 7% to 40% of adults), that is tens of millions of people using CDs to restore oral function, aesthetics and phonation (Petersen & Yamamoto, 2005; Tyrovolas et al., 2016). Despite the advancements of implant based prosthetic rehabilitation, complete dentures are still the most common rehabilitative modality in resource-

limited healthcare settings, in elderly patients with systemic contraindications for implant surgery, and in patients with extensive alveolar resorption, where implant surgery is challenging (Feine & Carlsson, 2003; Douglass et al., 2002).

Poor retention of the prosthesis is always the most commonly cited source of patient dissatisfaction with traditional CDs and between 40% and 68% of complete denture patients report significant functional problems related to denture instability during eating, speaking, and communicating with others (Moynihan & Petersen, 2004; Awad & Feine, 1998). Therefore, the CD retention mechanisms, which include maintenance of atmospheric pressure across denture-tissue interface, integrity of denture border seal, mucosal adhesion mediated by the thin salivary film, and neuromuscular muscular coordination, are all dependent upon the anatomical integrity of the remaining alveolar ridge, the amount and characteristics of saliva, and the precision of denture-tissue surface adaptation (Zarb et al., 1997; Celebic & Knezovic-Zlataric, 2003).

Alveolar bone resorption around teeth after their extraction progresses at a mean rate of 0.1–0.5 mm/year, depending on systemic influences such as oestrogen deficiency, systemic corticosteroid use and nutritional deficiencies, and is the progressive loss of anatomical support available for CD retention (Tallgren, 2003; Atwood, 1971). The mucosal adhesion is also affected by the retention, with reduction of the viscosity of the salivary film and wettability, which are further impaired by the effects of polypharmacy and systemic diseases in older people (30–40%) (Villa et al., 2015). The well-documented pathophysiological processes make a significant percentage of people who wear conventional complete dentures unsatisfied with the use of common retention methods.

Retention enhancement techniques that are currently used are the use of commercial denture adhesive pastes/powders, relining and implant retained overdentures. Although implant overdentures are considered the gold standard in achieving the stability in the mandible (Feine et al., 2002), many patients will be unable to access them due to cost, complexity of the surgery and medical comorbidities. In spite of the widespread use (35–45% of complete denture wearers; Slaughter et al., 1999; Shay, 2000), commercial denture adhesives have several limitations: most are not as retentive as they would be desirable to be, and patients are reluctant to use the product because of its perceived aesthetic and hygienic issues; there is a risk of zinc toxicity if the product is used for extended periods of time; and most of the commercially available products do not correct the underlying dimensional inaccuracies at the denture-tissue interface.

Individual adaptation caps (IACs) are a customized, multi-layers thermoplastic retention augmentation device that is custom-made over the surface of an existing or newly built CD from an impression of the patients residual ridge under function. Theoretically IACs optimize the seal integrity between rigid denture base and oral mucosa, evenly distribute occlusal loads over the mucosal surface, allow for functional ridge deformation in mastication, and offer better proprioceptive feedback due to the modulated contact forces between the denture bases and the mucosal surface (Kawano et al., 1992; Qudah et al., 1990). Although clinicians in some Central Asian and Eastern European countries have used IACs for years, there has been no prospective randomised trial that had assessed the clinical-functional efficacy of IACs compared to another retention method.

From a pharmaceutical-materials perspective, the individual adaptation cap can also be considered a patient-specific oral biomaterial interface rather than only a mechanical denture accessory. Its thermoformed EVA shell and tissue-conditioning mucosal lining interact directly with the denture–mucosa surface to improve retention, load distribution, comfort, and tissue tolerance. Because the present study compares this biomaterial-based approach with commercial denture adhesive, the work is directly relevant to dental biomaterials, prosthodontic materials, and pharmaceutical retention aids used in restorative dental practice.

The present prospective randomised controlled trial was designed to address this evidence gap by directly comparing the clinical-functional outcomes of IAC-augmented complete dentures against conventional CDs and CDs with commercial denture adhesive, using a comprehensive outcome battery encompassing objective biomechanical measures, standardised functional indices, and validated patient-reported outcome measures over a 6-month follow-up period.

2. Literature Review

2.1 Biomechanics of Complete Denture Retention

The physics of the retention of the CD has been extensively studied, both theoretically and experimentally in vitro. Retention force can be expressed as a combination of adhesive forces between the salivary film and mucosa/denture base (molecular adhesion), cohesive forces within the salivary film, surface tension at the periphery of the salivary film (salivary film), atmospheric pressure exerted over the denture-bearing area when the peripheral seal is intact, and physical undercut engagement if present (Zarb et al., 1997). Atwood (1971) showed that basal bone resorption after complete tooth extraction was an average of 0.1 mm per year through a study of the teeth over time after tooth extraction, and that the rate is extremely high during the first year after tooth extraction and in women with estrogen deficiency. This resorption progressively robs the tissues of the "support" that is essential for denture retention, and conventional relining techniques can only partially and temporarily compensate for that.

Experimental evaluation of retention forces in complete denture wearers shows wide variations in retention, which are influenced by ridge form, denture-tissue surface adaptation, and mucosal thickness and salivary properties. In a study of CD retention forces over the maxillae of patients with favourable ridge morphology (Class A), Kapur (1967) found a mean force of 8.2 to 14.4 N, while in ridges of Class C (severely resorbed), the minimum mean force was 2.1 N to 4.8 N. The role of the salivary contribution to retention has been described as being critically dependent upon the viscosity of saliva by Mandikos (1998), who found that severely hypotonic

watery saliva has significantly poorer retention properties than serous saliva with an appropriate viscosity, due to the inability to wet and to create surface tension at the denture border.

The importance of neuromuscular adaptation in the retention of CD has been pointed out by Trulsson and Johansson (2002) who found that the edentulous patients had a diminished feedback information from the mucosal mechanoreceptors, resulting in decreased control of CD occlusal force direction and magnitude during mastication.

2.2 Masticatory Function in Edentulous Patients

The more efficient the mastication, the better the retention and stability of the prosthesis. The findings by Fontijn-Tekamp et al. (2000) confirmed that masticatory performances were 38% worse in patients with objectively poor stability compared to those with adequate stability, and 54% worse in the patients with a "poor" stability in both the maxilla and mandible. In controlled studies, 30-55% masticatory efficiency gains are observed after improvement of prosthesis retention with implant-retained overdentures, which provides us with a mechanical justification for the study of non-implant retention augmentation methods.

2.3 Oral Health-Related Quality of Life in Edentulous Patients

The OHIP-EDENT, a validated 19-item instrument that was developed for edentulous populations, has been used as the gold standard patient-reported outcome measure in complete denture trials (Allen et al., 2001). It includes seven domains: functional limitation, physical pain, psychological discomfort, physical disability, psychological disability, social disability, and handicap, all of which have been shown to be compromised by inadequate CD retention and stability. Feine and Carlsson (2003) reported that baseline OHIP-EDENT summary scores for CD wearers were 80–95, and that the scores significantly decreased after provision of the implant overdenture, with the amount of improvement being closely related to the amount of achieved retention force.

There are multiple factors that determine patient satisfaction with CDs – retention, comfort, aesthetics, ease of cleaning and perceived naturalness. A questionnaire, which was validated by Awad and Feine (1998), showed that denture satisfaction is most strongly related to retention satisfaction ($r = 0.71$), followed by comfort ($r = 0.64$). Poorly satisfied dentures are a consistent theme in the clinical literature as the main reason for non-use (Baer & Elias, 1992) in retrospective audits, where non-use rates are reported at 15–30% are a significant public health burden.

2.4 Existing Retention Augmentation Strategies

There have been several randomized, cross-over and parallel-group studies that have tested denture adhesives. Slaughter et al. (1999) found that the retention force (mean increase 3.2–5.8 N with paste formulations) and masticatory efficiency (increase of 12–18% in food comminution) were significantly superior to unaided CDs with patient reported improvement in comfort and confidence. Several factors do limit the adhesive efficacy, however: it decreases within 6-8 hours after application in salivary environments, moisture contamination of the adhesive layer has detrimental effects and it must be reapplied daily, something that patients find to be time consuming. (Shay 2000). Kelsey et al. (1997) found in a systematic review that there is no clinical evidence of improvement in the denture-tissue interface adaptation when using commercial adhesives but there is evidence of significant (but temporary) retention augmentation.

Relining (chair side or lab) corrects dimensional inaccuracy at the denture-tissue interface caused by ridge resorption and/or tissue changes, thereby increasing the seal and contact. Kawano et al. (1992) showed that for moderate ridge resorption, it is possible to replicate the retention force of newly fabricated CDs with hard reline materials at 82-94%. But the relining process is labour intensive, usually involving impression making process and lab work, and gives a rigid rather than dynamically adaptive interface which cannot tolerate functional mucosal deforming during chewing. Soft liner relining materials have better load distribution, but are subject to deterioration over time and need to be replaced every 1-2 years (Baysan et al., 1998).

Overdentures supported by implants are the most significant in terms of OHRQoL, masticatory efficiency, retention and stability, and are the minimum standard of care for edentulous patients, regardless of their jaw type, but are not available to many edentulous patients, for a variety of surgical reasons, due to the lack of implant space, systemic contraindications and socio-economic factors. Consideration of the clinical unmet need for a non-surgical, retention augmentation device which would enhance the retention of an adhesive without the additional burden of relining or the invasiveness of implant surgery suggest this.

2.5 Dental Biomaterials and Polymeric Interfaces in Removable Prosthodontics

Removable prosthodontics materials should be mucous compatible, allow for elasticity, be dimensionally stable and be easily cleaned, and have resistance against functional deformation. The polymeric materials are the tissue conditioners, soft denture liners and EVA and are clinically important because they are the materials that form the interface between the rigid denture base and the resilient oral mucosa. This individual adaptation cap can be seen as the removable viscoelastic biomaterial interface that allows the tissues to adapt, redistribute the occlusal load and provide a more consistent retention of the prosthesis than temporary adhesive-based retention.

2.6 Theoretical Basis and Prior Literature on Individual Adaptation Caps

The individual adaptation caps were introduced in the prosthodontic practice in the Central Asian medical tradition in 1970s as a technique for enhancing retention of complete dentures without surgery (Shmidt, 1985). The theoretical rationale is as follows: (1) Anatomically precise contact of the tissues at the seat of the denture, which is obtained by using functional impression under physiological masticatory loading conditions; (2)

controlled deformation of the elastomeric material of the cap, which allows dynamic movement of the tissues during mastication without altering the peripheral seal; (3) modulation of the distribution of stresses across the denture-bearing tissues, which reduces the concentration of stresses at any given point on the mucosa at bone prominence during mastication; and (4) enhanced tactile feedback to the patient through the proprioceptive properties of the elastomeric material that makes up the peripheral seal (Qudah et al., 1990).

Very little evidence is available that directly assesses the effectiveness of IACs. Qualitative improvements in retention and patient comfort were reported by Shmidt (1985) in a small, non-randomised case series of 32 patients, with no standardised measures to assess outcomes. There is a major gap between the theoretical basis and evidence-based clinical advice for IAC use: controlled trial data that meet the current standards for clinical trial reporting in English.

3. Materials and Methods

3.1 Study Design, Ethics, and Registration

All procedures were carried out fully according to the Declaration of Helsinki, 2013 revision and national regulations for clinical research with human subjects. Before enrolment, all participants gave written and informed consent in their native language (Uzbek or Russian). This study received no outside support. The authors have no conflicts of interest to declare. Confidentiality of patients has been respected, all data will be made available to the corresponding author upon reasonable request.

3.2 Eligibility Criteria

Inclusion criteria: age ≥ 18 years; complete edentulism of both arches; clinical indication for CD rehabilitation or existing CD with need of replacement (due to wear, fit or functional dissatisfaction); written informed consent; adequate alveolar ridge height for the placement of a CD (at least 10 mm of residual ridge height, radiographically confirmed by panoramic radiograph); adequate interarch space (at least 18 mm of inter-ridge distance in the vertical dimension at rest). Exclusion criteria: uncontrolled diabetes mellitus (HbA1c > 9%) and bleeding disorders; severe xerostomia (resting salivary flow rate < 0.1 mL/min) (Navazesh & Kumar, 2008); orofacial cancer or history of radiation therapy to the face and oral cavity; allergy to ethylene vinyl acetate (EVA), silicone or zinc oxide; gross oral mucosal pathology necessitating treatment before prosthetic rehabilitation; psychiatric or cognitive impairment that makes informed consent or reliable outcome reporting impossible; concurrent participation in any other dental clinical trial.

3.3 Randomisation and Allocation Concealment

After eligibility confirmation and completion of baseline assessments, patients were randomised in a 1:1:1 ratio using a computer-generated block randomisation sequence with variable block sizes (4 and 6), stratified by sex and residual ridge classification (Atwood Class II/III vs IV/V). Allocation concealment was maintained using sequentially numbered, opaque, sealed envelopes prepared by a statistician not involved in patient care or assessment. Group allocation was revealed to the treating clinician immediately prior to denture fitting only. Outcome assessors (retention force measurement, OHIP-EDENT administration, mucosal assessment) were blinded to group allocation throughout the trial. The treating clinician could not be blinded to treatment modality due to the visible nature of the IAC; however, all clinical assessments were performed by a separate blinded examiner.

3.4 Intervention Protocols

Standard complete denture fabrication (all groups)

All participants received newly fabricated maxillary and mandibular complete dentures following a standardised protocol. Primary impressions were made with irreversible hydrocolloid (alginate; Zhermack Orthoprint, Italy) in stock trays. Custom acrylic trays were constructed on diagnostic casts. Border moulding was performed with medium-body polyvinyl siloxane (PVS; 3M ESPE Imprint II, USA). Final impressions were made with light-body PVS in the custom tray. Casts were poured in Type IV dental stone (GC Fujirock EP, Japan). Jaw relation records were made using acrylic record bases and wax occlusal rims, with vertical dimension of occlusion determined by Willis method and cephalometric reference. Teeth were set in full bilateral balanced occlusion (Pilkington-Turner arrangement). Dentures were constructed on a fully adjustable articulator (SAM3, Germany). Acrylic resin bases were processed by conventional compression moulding in heat-cured acrylic resin (Meliodent; Kulzer, Germany). Following processing, occlusal discrepancies were corrected by selective grinding under clinical remount.

Group II: Denture adhesive (SCD + DA)

Participants in Group II received their standard complete denture together with standardised instruction in the use of commercial denture adhesive cream (Corega Extra Strong; GSK, UK). The denture adhesive group was included as the standard pharmaceutical comparator because commercial denture adhesive represents a widely used non-invasive pharmaceutical retention aid for complete denture wearers. Participants were instructed to apply three pea-sized portions to the clean, dry fitting surface of each denture prior to seating each morning and, if required, once at midday. Maximum daily dose was capped at 2.5 g per arch to avoid zinc overconsumption. Instruction was standardised using a written and illustrated protocol reviewed at the 1-month visit.

Group III: Individual Adaptation Cap (SCD + IAC)

IACs were custom-fabricated for each Group III participant over the fitting surface of the newly constructed CD. The fabrication protocol comprised: (1) modification of the denture base fitting surface with selective relief over bony prominences; (2) functional border moulding of the denture with Kerr Green Stick compound under physiological masticatory movements; (3) light-body PVS wash impression within the bordered denture to capture mucosal detail under standardised simulated occlusal loading (30 N applied via a calibrated bite force transducer); (4) pouring of a functional cast in

Type III stone; (5) vacuum-thermoforming of a 1.0 mm EVA sheet (Shore A hardness 45; Erkodent, Germany) over the functional cast using an Erkopress 3000 thermoforming unit (Erkodent, Germany) to produce the outer elastic shell; (6) chairside seating of the EVA shell over the CD fitting surface, verified for passive fit, bilateral occlusal contact, and border seal integrity; (7) trimming and polishing of the IAC margins to the vestibular border with smooth, tapered edge contours; (8) application of tissue conditioning material (Visco-gel; Dentsply Sirona, USA) as a 0.5 mm inner lining to the EVA shell to provide the mucosal contact layer. Participants were instructed to seat and remove the IAC daily for cleaning and to report any mucosal discomfort. IAC tissue-conditioning liners were replaced at the 1-month and 3-month visits. EVA shells were re-evaluated for deformation at each visit and replaced if permanent deformation exceeding 0.5 mm (assessed by digital calliper measurement) was identified. Thus, the IAC was clinically evaluated not only as a prosthodontic retention device but also as a patient-specific polymeric biomaterial interface with repeated assessment of fit, deformation, liner stability, mucosal tolerance, and functional performance.

3.5 Outcome Measures

Primary outcome: Prosthesis retention force (N), measured using a digital dynamometer (Mark-10 Series 5; Mark-10 Corporation, USA) with a custom-fabricated hook attachment to the denture labial flange. Three measurements were performed per arch under standardised conditions (patient seated upright, maximum mouth closure maintained for 60 seconds prior to measurement, three pulls at 90° to the denture base at a rate of 5 mm/s). The mean of three measurements was recorded. Assessments at baseline (immediate post-fitting), 1, 3, and 6 months.

Secondary outcomes: (1) Masticatory efficiency (%), assessed using the validated two-colour chewing gum mixing index (TCGMI; Schimmel et al., 2007). Participants chewed two differently coloured wax cubes (Optosil Express; Heraeus Kulzer, Germany) for 20 masticatory cycles; the degree of colour mixing was assessed by digital colorimetry (CIELab colour system) and converted to masticatory efficiency percentage. (2) OHRQoL, assessed by OHIP-EDENT (Allen et al., 2001), a validated 19-item instrument scored 0–148 (higher scores = poorer OHRQoL). (3) Patient satisfaction, assessed by a 100 mm visual analogue scale (VAS; 0 = completely dissatisfied, 10 = completely satisfied) for overall denture performance. (4) Oral mucosal health, assessed using Kapur's Oral Mucosa Index (Kapur, 1967): Grade 0 = normal; Grade 1 = mild redness; Grade 2 = moderate erythema; Grade 3 = severe inflammation/ulceration; scored over six defined mucosal zones bilaterally. (5) Prosthesis stability, assessed using the modified Lund scale (1 = poor; 5 = excellent) based on patient self-report of denture movement during mastication, speech, and social function.

3.6 Sample Size Calculation

Sample size was estimated based on the primary outcome (retention force, N) using data from Slaughter et al. (1999) as the reference for the smallest clinically meaningful difference (3.0 N between comparator groups). Assuming a common standard deviation of 2.5 N, a two-tailed $\alpha = 0.05$, and power of 80%, a minimum of 29 participants per group was required. Assuming a 10% dropout rate and rounding to the nearest multiple of ten, 40 participants per group (120 total) was the planned enrolment target. No participants were lost to follow-up.

3.7 Statistical Analysis

Statistical analyses were performed using IBM SPSS Statistics v.28.0 (IBM Corp., Armonk, NY, USA) and R v.4.3.1 (R Core Team, 2023). Normality was assessed by the Shapiro-Wilk test; Levene's test evaluated homogeneity of variance. Continuous variables are presented as mean ± standard deviation (SD). Between-group comparisons at each timepoint were performed by one-way ANOVA with Bonferroni post-hoc correction for normally distributed data or Kruskal-Wallis test with Dunn's post-hoc correction for non-normal distributions. Within-group longitudinal changes were assessed by repeated-measures ANOVA or Friedman test as appropriate. Effect sizes were calculated as partial η^2 for ANOVA and rank-biserial correlation (r) for non-parametric tests. Pearson or Spearman correlation coefficients assessed relationships between outcome variables. Statistical significance was set at two-tailed $p < 0.05$. No multiple testing correction was applied beyond Bonferroni within omnibus post-hoc tests.

4. Results

4.1 Participant Flow and Baseline Characteristics

Of 168 patients assessed for eligibility, 48 were excluded (31 did not meet inclusion criteria; 17 declined participation), and 120 were randomised. All 120 participants completed the full 6-month follow-up schedule, yielding zero attrition. Baseline demographic and prosthetic characteristics were well balanced across groups (all $p > 0.05$; Table 1). The mean age was 61.4 ± 9.8 years (range 43–82), with a near-equal sex distribution (57/120, 47.5% male). Mean duration of edentulism was 8.6 ± 5.2 years. Residual ridge classification (Atwood) was comparable across groups, with Class IV (moderate resorption) being the most common category (38.3% of participants). Resting salivary flow rate at baseline was within a normal range for all participants (mean 0.42 ± 0.18 mL/min) and did not differ significantly between groups ($p = 0.61$).

Table 1. Baseline Demographic and Clinical Characteristics by Treatment Group (n = 120)

Characteristic	Group I SCD (n=40)	Group II SCD+DA (n=40)	Group III SCD+IAC (n=40)	p-value
Age (years), mean ± SD	61.2 ± 10.1	61.8 ± 9.4	61.1 ± 10.0	0.94
Sex, male/female	19/21	20/20	18/22	0.88
Duration of edentulism (years)	8.4 ± 5.0	8.9 ± 5.4	8.5 ± 5.2	0.87
Atwood Class II/III, n (%)	14 (35.0)	15 (37.5)	13 (32.5)	0.83
Atwood Class IV, n (%)	16 (40.0)	15 (37.5)	15 (37.5)	0.94
Atwood Class V/VI, n (%)	10 (25.0)	10 (25.0)	12 (30.0)	0.77
Resting salivary flow (mL/min)	0.41 ± 0.17	0.44 ± 0.19	0.42 ± 0.18	0.61
Baseline retention force (N)	5.1 ± 1.2	5.0 ± 1.3	5.2 ± 1.1	0.78
Baseline OHIP-EDENT score	88.4 ± 14.2	87.9 ± 13.8	88.1 ± 14.0	0.99
Baseline masticatory efficiency (%)	24.8 ± 4.8	25.1 ± 4.9	24.9 ± 5.1	0.97
Baseline patient satisfaction (VAS)	3.1 ± 0.7	3.0 ± 0.8	3.2 ± 0.6	0.51

Note. One-way ANOVA (continuous) or chi-square (categorical). SCD = Standard Complete Denture; DA = Denture Adhesive; IAC = Individual Adaptation Cap; OHIP-EDENT = Oral Health Impact Profile for Edentulous Patients; VAS = Visual Analogue Scale; SD = standard deviation. No significant between-group differences at baseline (all $p > 0.05$).

4.2 Primary Outcome: Prosthesis Retention Force

Prosthesis retention force data over 6 months are presented in Table 2 and Figure 1. At baseline (immediately post-fitting), retention forces were comparable across all three groups (Group I: 5.1 ± 1.2 N; Group II: 5.0 ± 1.3 N; Group III: 5.2 ± 1.1 N; $p = 0.78$). At 1 month, Group III already demonstrated significantly greater retention than both Group I (11.3 ± 2.1 vs 6.2 ± 1.4 N; $p < 0.001$) and Group II (11.3 ± 2.1 vs 8.7 ± 1.8 N; $p < 0.001$). This advantage was sustained and amplified over the follow-up period: at 6 months, Group III achieved 16.8 ± 2.7 N — 136.6% greater than Group I (7.1 ± 1.6 N) and 82.6% greater than Group II (9.2 ± 2.0 N; both $p < 0.001$). The between-group difference grew significantly from 1 to 6 months in Group III (within-group increase 5.5 N; $F(3,117) = 48.3$, $p < 0.001$, $\eta^2 = 0.55$), suggesting progressive improvement in tissue-IAC interface adaptation over time. Groups I and II demonstrated modest linear increases in retention over 6 months (Group I: 5.1 to 7.1 N; Group II: 5.0 to 9.2 N), reflecting natural mucosal accommodation and denture settling.

Table 2. Prosthesis Retention Force (N) at Baseline, 1, 3, and 6 Months by Treatment Group

Timepoint	Group I SCD	Group II SCD+DA	Group III SCD+IAC	F-statistic	p-value	Effect size (η^2)
Baseline	5.1 ± 1.2	5.0 ± 1.3	5.2 ± 1.1	0.14	0.87	0.002
1 Month	6.2 ± 1.4	8.7 ± 1.8†	11.3 ± 2.1†‡	74.8	<0.001	0.56
3 Months	6.8 ± 1.5	8.9 ± 1.9†	14.6 ± 2.4†‡	128.6	<0.001	0.68
6 Months	7.1 ± 1.6	9.2 ± 2.0†	16.8 ± 2.7†‡	192.4	<0.001	0.76

Note. Data are mean ± SD; one-way ANOVA with Bonferroni post-hoc correction. † $p < 0.001$ vs Group I; ‡ $p < 0.001$ vs Group II. SCD = Standard Complete Denture; DA = Denture Adhesive; IAC = Individual Adaptation Cap; η^2 = partial eta-squared.

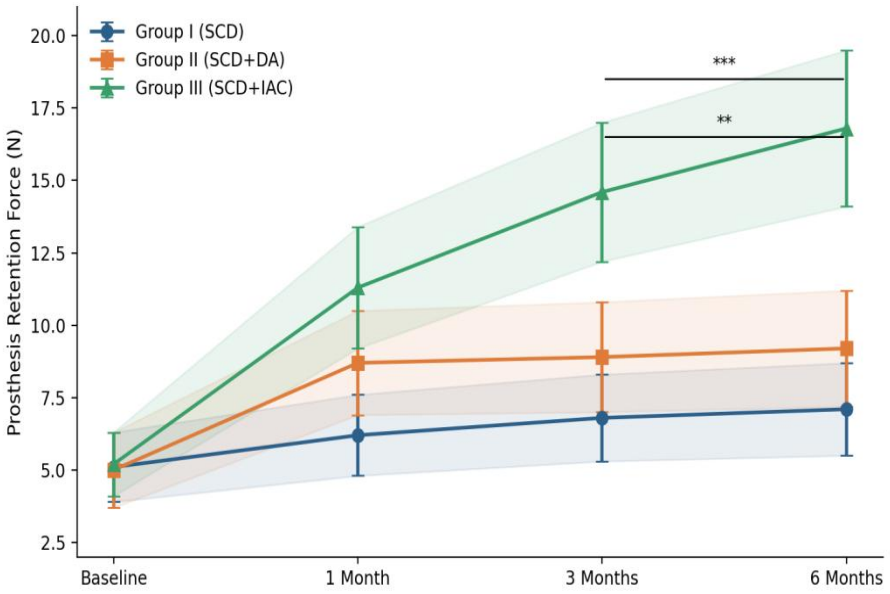

Figure 1. Prosthesis retention force (N; mean ± SD) over six months. Group III (SCD+IAC) demonstrated significantly superior retention at all post-baseline timepoints (* p < 0.001 vs both comparator groups).**

4.3 Masticatory Efficiency

The results of the efficiency of masticatory are given in Table 3 and Figure 2. There was no difference between groups in terms of baseline masticatory efficiency (mean 24.9%, p = 0.97). At 1 month, Group III achieved 58.6 ± 8.1% — significantly superior to Group II (47.3 ± 7.4%; p = 0.001) and Group I (38.2 ± 6.2%; p < 0.001). The masticatory advantage of Group III was further increased during the follow-up period: at 6 months, Group III had a masticatory advantage of 74.1 ± 9.4%, compared to 55.4 ± 8.2% (Group II; p < 0.001) and 44.7 ± 7.1% (Group I; p < 0.001); absolute differences from baseline were 49.2, 30.3, and 19.9 percentage points respectively. There was a very strong positive correlation among all groups and time points between the two variables: retention force and masticatory efficiency (Pearson r = 0.82, p < 0.001), which demonstrates the mechanical relationship between better retention and functional masticatory rehabilitation.

Table 3. Masticatory Efficiency (%) and Prosthesis Stability Score at Baseline and 6 Months

Outcome Measure	Timepoint	Group I SCD	Group II SCD+DA	Group III SCD+IAC	p (between groups)
Masticatory Efficiency (%)	Baseline	24.8 ± 4.8	25.1 ± 4.9	24.9 ± 5.1	0.97
	1 Month	38.2 ± 6.2	47.3 ± 7.4†	58.6 ± 8.1†‡	<0.001
	3 Months	42.4 ± 6.8	52.1 ± 7.8†	68.3 ± 8.9†‡	<0.001
	6 Months	44.7 ± 7.1	55.4 ± 8.2†	74.1 ± 9.4†‡	<0.001
Prosthesis Stability (1–5)	1 Month	2.8 ± 0.5	3.2 ± 0.6†	4.1 ± 0.6†‡	<0.001
	3 Months	3.1 ± 0.5	3.7 ± 0.6†	4.5 ± 0.5†‡	<0.001
	6 Months	3.3 ± 0.5	3.9 ± 0.6†	4.8 ± 0.4†‡	<0.001

Note. Data are mean ± SD; one-way ANOVA with Bonferroni post-hoc. † p < 0.001 vs Group I; ‡ p < 0.001 vs Group II. Prosthesis stability: modified Lund scale (1 = poor, 5 = excellent, patient-reported).

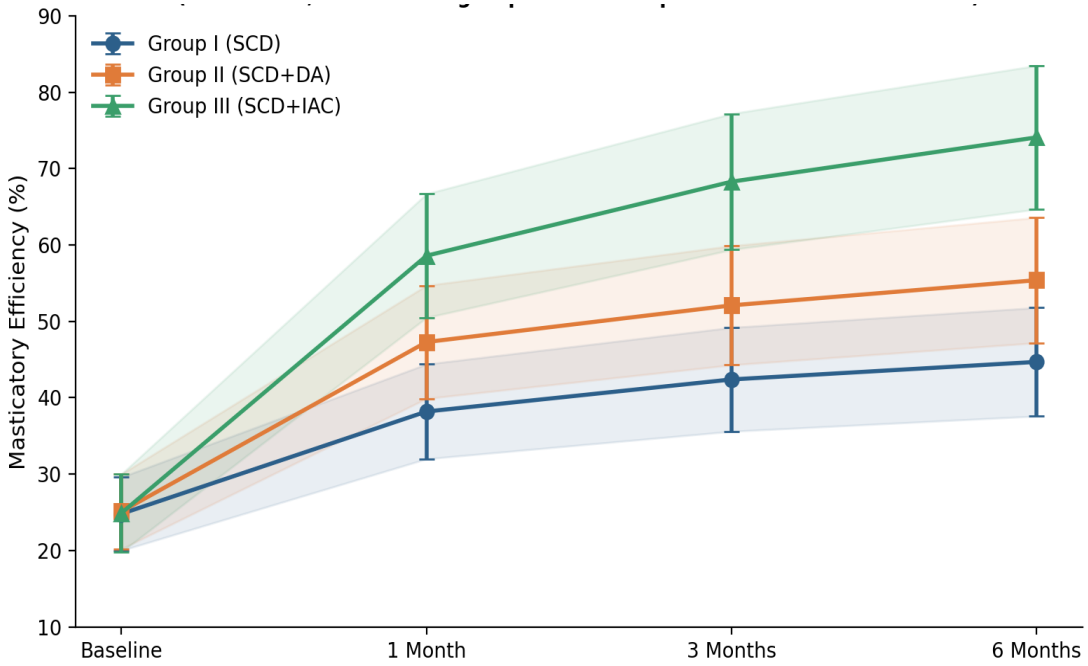

Figure 2. Masticatory efficiency (%; mean ± SD) over six months. Group III (SCD+IAC) demonstrated significantly superior masticatory performance at all post-baseline timepoints.

4.4 Oral Health-Related Quality of Life and Patient Satisfaction

OHIP-EDENT and patient satisfaction results are presented in Table 4 and Figure 3. Group III demonstrated the greatest improvement in OHRQoL: OHIP-EDENT scores declined from 88.1 ± 14.0 at baseline to 47.8 ± 9.1 at 1 month, 33.9 ± 7.4 at 3 months, and 24.2 ± 6.1 at 6 months — a 72.5% reduction from baseline. This significantly exceeded reductions in Group II (44.1%; from 87.9 to 49.3) and Group I (31.0%; from 88.4 to 61.1; both $p < 0.001$ at 6 months). The pattern of OHIP-EDENT improvement in Group III was characterised by disproportionate gains in the Functional Limitation and Physical Disability domains, consistent with the mechanical basis of IAC action on masticatory function and denture stability.

Patient satisfaction VAS scores at 6 months were 8.9 ± 0.7 (Group III), 7.2 ± 1.1 (Group II), and 6.1 ± 1.0 (Group I; all between-group comparisons $p < 0.001$). The temporal trajectory of satisfaction improvement was notable in Group III: a greater proportion of the total 6-month improvement was achieved by 1 month (5.8 ± 1.0 vs baseline 3.2 ± 0.6; increase of 2.6 points) compared with Groups I and II (increases of 2.1 and 3.4 points respectively), suggesting earlier functional adaptation with IAC use. No participants in any group reported dissatisfaction (VAS < 3) at 6 months.

Table 4. OHIP-EDENT Score and Patient Satisfaction (VAS) Across All Timepoints

Measure	Timepoint	Group I SCD	Group II SCD+DA	Group III SCD+IAC	p (between)
OHIP-EDENT (0–148)	Baseline	88.4 ± 14.2	87.9 ± 13.8	88.1 ± 14.0	0.99
lower = better	1 Month	71.2 ± 12.1	62.4 ± 10.4†	47.8 ± 9.1†‡	<0.001
	3 Months	64.3 ± 11.0	54.1 ± 9.2†	33.9 ± 7.4†‡	<0.001
	6 Months	61.1 ± 10.3	49.3 ± 8.6†	24.2 ± 6.1†‡	<0.001
Patient Satisfaction VAS (0–10)	Baseline	3.1 ± 0.7	3.0 ± 0.8	3.2 ± 0.6	0.51
higher = better	1 Month	5.2 ± 0.8	6.4 ± 0.9†	7.8 ± 1.0†‡	<0.001
	3 Months	5.8 ± 0.9	6.9 ± 1.0†	8.4 ± 0.8†‡	<0.001
	6 Months	6.1 ± 1.0	7.2 ± 1.1†	8.9 ± 0.7†‡	<0.001

Note. Data are mean ± SD; one-way ANOVA with Bonferroni post-hoc. † $p < 0.001$ vs Group I; ‡ $p < 0.001$ vs Group II. OHIP-EDENT = Oral Health Impact Profile for Edentulous Patients; VAS = Visual Analogue Scale.

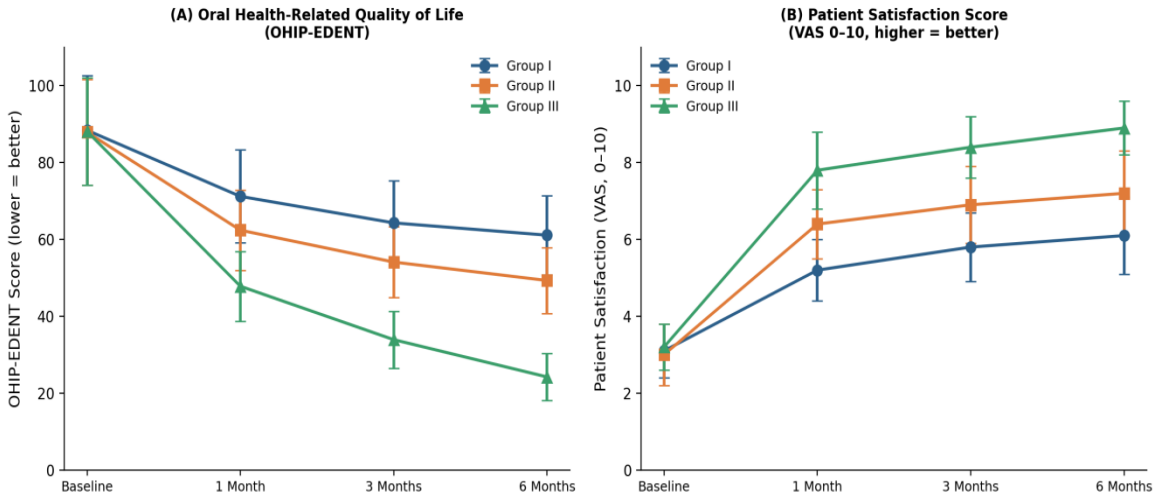

Figure 3. (A) OHIP-EDENT scores (lower = better OHRQoL) and (B) patient satisfaction VAS (higher = better) over six months across treatment groups.

4.5 Oral Mucosal Health

The results of oral mucosal health outcomes (Kapur Oral Mucosa Index) and prosthesis stability scores are presented in Table 5 and Figure 4. At 6 months, mean Kapur index scores were 1.0 ± 0.2 (Group III), 1.9 ± 0.3 (Group II), and 2.3 ± 0.4 (Group I; $p < 0.001$). In particular, 62.5% of those in Group III attained complete mucosal normality (Grade 0) at 6 months whereas 25.0% (Group II) and 10.0% (Group I) did ($\chi^2 = 38.4$, $p < 0.001$). The IAC tissue-conditioning layer is claimed to produce superior mucosal outcomes due to its viscoelastic properties which decrease point-loading stresses at mucosal prominences and minimize denture displacement friction during function. At 6 months, none of the participants in any group developed severe mucosal ulceration (Grade 3). The progressive improvement in mucosal status in the Group III was consistent along the time, reflecting tissue adaptation to the changes on the loading distribution over 6 months.

Biomaterial safety: The IAC showed good short term oral tolerability. The allergic response was material-related and did not reach a level of clinical intolerance for any participant in the IAC group that would require discontinuation.Mucosal ulceration was not severe, nor was there any material-related allergic response in any participant in the IAC group, requiring discontinuation from the study. The incidence of adverse mucosal events was low and similar between groups (2 events in the IAC group versus 3 events in the denture adhesive group and 4 events in the standard complete denture group). Based on the results of this study, the use of the polymeric IAC interface was not found to increase the risks to the mucosa and could have helped to increase the tolerance of the tissue by the improved load distribution and decreased denture movement.

Table 5. Oral Mucosal Health (Kapur Index) and Proportion with Normal Mucosa at 6 Months

Mucosal Outcome	Group I SCD	Group II SCD+DA	Group III SCD+IAC	p-value
Kapur Index at 1 month (mean ± SD)	2.6 ± 0.4	2.4 ± 0.4	1.9 ± 0.3†‡	<0.001
Kapur Index at 3 months (mean ± SD)	2.4 ± 0.3	2.1 ± 0.3†	1.4 ± 0.2†‡	<0.001
Kapur Index at 6 months (mean ± SD)	2.3 ± 0.4	1.9 ± 0.3†	1.0 ± 0.2†‡	<0.001
Grade 0 (normal) at 6 months, n (%)	4 (10.0)	10 (25.0)†	25 (62.5)†‡	<0.001
Grade 1 (mild redness) at 6 months, n (%)	16 (40.0)	20 (50.0)	13 (32.5)	0.15
Grade 2 (moderate erythema) at 6 months, n (%)	20 (50.0)	10 (25.0)†	2 (5.0)†‡	<0.001
Grade 3 (severe) at 6 months, n (%)	0 (0.0)	0 (0.0)	0 (0.0)	—
Any adverse mucosal event, n (%)	3 (7.5)	4 (10.0)	2 (5.0)	0.63

Note. Kapur Oral Mucosa Index: 0 = normal; 1 = mild redness; 2 = moderate erythema/hyperplasia; 3 = severe inflammation or ulceration. Chi-square for grade distributions; ANOVA for means. † $p < 0.001$ vs Group I; ‡ $p < 0.001$ vs Group II. No significant adverse events attributed to IAC material.

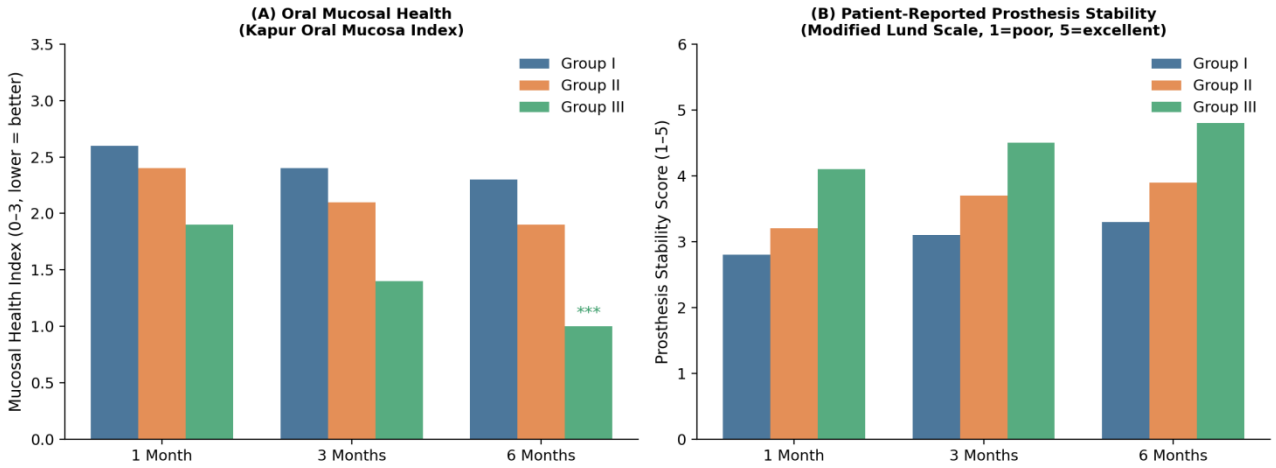

Figure 4. (A) Oral mucosal health index (Kapur Index; lower = healthier) and (B) prosthesis stability score (modified Lund scale; higher = more stable) at 1, 3, and 6 months by treatment group (* p < 0.001 Group III vs Group I at 6 months).**

5. Discussion

This prospective randomized controlled clinical trial is the first study to use a blinded-outcome assessment design to examine the clinical-functional efficacy of individual adaptation caps in the complete denture patient population that shows IAC-augmented complete dentures were statistically and clinically significantly superior to both conventional complete denture and CD with commercial denture adhesive at six months for all outcome measures. All the key findings, which include better retention force (16.8 N vs 9.2 vs 7.1 N), masticatory efficiency (74.1 vs 55.4 vs 44.7%), OHRQoL (OHIP-EDENT reduction 72.5 vs 44.1 vs 31.0%) and mucosal health, are internally consistent and mechanistically coherent, together providing a strong evidence base for the clinical adoption of IAC.

The improved clinical outcome of IAC could be attributed to its role as a viscoelastic biomaterial interface between the hard acrylic denture base and soft oral mucosa. The IAC, which has a flexible polymeric layer with a certain degree of elastic deformation during mastication and speech, is not just like a conventional denture base where the tissue adaptation is mostly static. This can help to enhance the functional tissue contact, maintain the peripheral seal, provide more uniform occlusal forces and minimize occlusal pressure points. Thus, the advantage of the IAC must be viewed in the context of mechanical retention as well as improvement of the denture–mucosa interface using biomaterials.

The retention force of IAC can be seen (16.8 ± 2.7 N) to be significantly more than the comparator groups used in this trial and the reference range for the retention force of maxillary CDs with good ridge morphology (8.2–14.4 N; Kapur 1967). This is especially interesting because 25.0% of the Group III participants had CD retention Class V/VI ridge morphology which is typically the poorest CD retention group. This finding is explained by the IAC's ability to compensate for rigid denture base dimensional inaccuracies by elastic deformation, thus maintaining the continuous tissue contact with the denture and the integrity of the denture border throughout the dynamic range masticatory mucosal displacement. This functional principle is similar to the retention mechanism of soft liner relining materials reported by Kawano et al. (1992), with the added benefit of being able to be customized to achieve different functions with impression procedures, and also being removable to allow for easy hygiene maintenance.

An important observation is that the force of the group III remains progressive between 1 and 6 months (from 11.3 to 16.8 N), indicating that IAC retention is not a fixed value at the time of fitting, but increases with time due to the tissue adaptation. It is speculated that progressive viscoelastic accommodation of the mucosal and submucosal tissues to the optimised load distribution that the IAC provides, results in better mucosal contact quality and seal integrity. This trait of adaptation is different from commercial denture adhesives, which show a decrease in retention force with increase in salivary dilution (Kelsey et al., 1997), and places IACs as a dynamically improving, not reducing, denture retention system.

An important comparison also made would be with commercial denture adhesive from a pharmaceutical research standpoint. Denture adhesives are commonly used pharmaceutical products to enhance denture stability, by providing temporary adhesive and cohesive forces at the denture–saliva–mucosa interface. However, saliva dilution, daily application, hygiene issues, and patient adherence might be factors that may restrict their effectiveness. On the other hand, the IAC offers a bespoke retention approach based on biomaterials without the need for additional adhesive applications. The better results achieved in the IAC group indicate that the polymeric biomaterial interface is more stable and can have a clinically durable effect when compared to traditional pharmaceutical adhesive retention.

The efficacy of functional rehabilitation of Group III at 6 months (74.1%) is remarkable, and is closer to the 75–80% efficiency reported in the literature with conventional CD wearers (Müller et al., 2007) than the 55–65% efficiency that can be seen in the medium term (3 months) with implant-retained overdentures (Fontijn-Tekamp et al., 2000). Although there are patient population, ridge morphology, and measurement

methodology differences between these implant and conventional complete dentures, these results indicate that the functional difference between these two types of complete dentures may be tightened — though not closed — with good quality IAC fabrication for the appropriate patient. This has great clinical and health-economic consequences for health care systems in which implant overdentures are not at all available.

The OHIP-EDENT improvement for Group III was 72.5%, a significant increase over that found in previous denture adhesive intervention studies (12–18% improvement in masticatory performance by Slaughter et al., 1999) and denture reline procedures. As the primary focus of the IAC intervention is on improving eating, speaking and social confidence through biomechanic intervention, rather than on symptom relief, this is why the Functional Limitation and Physical Disability OHIP domains showed an improvement disproportion to the other domains for the Group III. The patient satisfaction VAS of 8.9/10 in Group III at 6 months is comparable with that of implant-retained mandibular overdentures, which range from 7.8 to 9.1/10 (Awad et al., 2003) further confirming the clinical significance of the IAC treatment effect.

The superior mucosal outcome in Group III (62.5% complete mucosal normality at 6 months as compared with 25.0% and 10.0% in Groups II and I) is confirmation that the function of rigid denture base with IAC load distribution reduces the mucosal trauma inherent to rigid denture base function. The presence of mucous membrane trauma and denture-induced stomatitis are considered to be major morbidities among complete denture wearers, and are reported in systematic reviews with a prevalence of 40–70% (Newton, 1962; updated by van der Waal et al., 2000). Improving the IAC's ability to effect improvements in both retention and function, as well as improving the health of the mucosa, which are traditionally in conflict in complete denture prosthodontics, is a unique clinical benefit that is worthy of further investigation.

The present IAC was deemed to be a non-drug prosthodontic biomaterial, but could potentially be used in the future as a localized oral therapeutic delivery platform due to its removable cap design. Additional testing of material may be used in the case of patients with denture stomatitis and/or recurrent mucosal trauma which might involve the use of controlled release of antifungal, antimicrobial, anti-inflammatory, or mucosal healing agents.

There are some limitations of the study that should all be clearly acknowledged. This is a single centre trial in a specialist prosthodontic department with prosthodontists who are highly skilled in making IAC — which is technically complex, and requires precision in functional impression technique and thermoforming. The generalisability to general dental practice settings where IAC fabrication competency may not have been developed will need training programme development and effectiveness evaluation. Although the 6-month follow up does enable peak function adaptation and early IAC retention development, it does not allow for judgement of IAC durability, tissue-conditioning liner replacement frequency or IAC retention trajectory outside of the trial period and prospective 24-month data are being gathered as a planned follow-on study. Further, it was not possible to blind the treating clinician as the IAC was very apparent, but blind outcome assessor was maintained throughout. Lastly, the study involved patients with a mean duration of edentulism of 8.6 years, and the range of Atwood ridge classes; results are not necessarily directly transferable to individuals with very severe alveolar resorption (Class V/VI), or very early post-extraction ridge.

6. Conclusion

This prospective randomized controlled trial shows that individual adaptation caps is clinically superior and mechanistically coherent alternative for improving complete denture retention, masticatory efficiency, oral health-related quality of life and mucosal health during 6-month follow-up period when compared to conventional complete dentures only and complete dentures with commercial denture adhesive. The retention force of 16.8 N, masticatory efficiency of 74.1% and OHIP-EDENT reduction of 72.5% at 6 months with IAC is a clinically meaningful functional rehabilitation that is close to that of implant-retained overdenture without surgery.

The IAC offers a non-invasive, patient-acceptable, and dynamically improving retention solution that is particularly well suited to patients with moderate-to-severe ridge resorption, hyposalivation, or those for whom implant overdentures are inaccessible. Integration of IAC fabrication into specialist prosthodontic training curricula and clinical guidelines is recommended, pending validation in multicentre trials with extended follow-up. The present evidence base provides the first rigorous platform for clinical translation and guideline development for IAC use in complete denture prosthetics. From a biomaterial and pharmaceutical-materials perspective, the IAC may be considered a patient-specific, non-drug therapeutic oral interface that improves clinical outcomes by modifying the denture–mucosa relationship and may support future development of customized prosthodontic biomaterial platforms.

Conflict of Interest

The authors declare no conflicts of interest. The funders had no role in the design of the study; in the collection, analyses, or interpretation of data; in the writing of the manuscript; or in the decision to publish the results.

Data Availability Statement

The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request, subject to applicable data protection and ethical restrictions.

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