Title

A Pilot Randomised Controlled Trial to compare 3D printed versus conventionally fabricated complete dentures

Abstract

Objectives:

This pilot randomised controlled trial assessed the acceptability of 3D printed complete dentures versus conventionally manufactured dentures. It aimed to identify the sample size needed for a full-scale trial and refine digital fabrication and trial protocols.

Methods:

A multi-centre, double-blinded, cross-over design was used with 17 participants (14 completed), all aged 60+ and complete denture wearers. Each participant received 3D printed and conventional dentures, worn for eight weeks each. Tooth positioning and denture shape were standardised. The OHIP-EDENT questionnaire measured comfort, retention, stability, and chewing efficiency.

Results:

A sample size of 35 is recommended for a definitive trial. Participants preferred conventional dentures. Issues with 3D printed dentures included unreliable tooth placement and structural failures. Seven breakages (one denture broke four times) and six tooth debondings occured in the 3D printed group.

Conclusions:

A sample size of 35 participants is recommended for a definitive trial, post adjustment. 3D printing offers potential benefits, but this study found lower patient satisfaction and material challenges in the 3D printed dentures. Technical and protocol refinements are needed before 3D printed dentures can be recommended for routine use.

Clinical Relevance:

Until fabrication issues are resolved, conventional dentures remain the more reliable option in prosthodontic care.

Keywords: Dentures; 3D printing; prosthodontics; edentulous;

Introduction – Background and Objectives

Edentulism has a significant impact on oral and general health. Treatment with complete dentures is still the most economical and popular option [1]. Despite a falling incidence of edentulism, the rise in the ageing population is maintaining a large number of edentulous patients both in the UK [2] and globally [3,4].

In the UK, 5% of the adult population are edentate[5], with an uneven distribution based upon age, socio-economic factors, geographical location, and gender. For many of these patients in the United Kingdom, we can expect them to rely on the National Health Service (NHS) to provide dental treatment due to financial constraints. The quality of dentures that patients receive directly impacts on their quality of life and nutritional status [6]. It follows that the nutritional status and the quality of life of edentulous individuals may be improved by the provision of better-quality dentures.

Experts in prosthodontics concur that the accuracy of the fit of a denture is an important issue for improving comfort, stability, and chewing efficiency of the denture. Traditionally, dentures are formed by curing acrylic resins with heat, under pressure and encased in a plaster mould. The contraction which occurs on curing the resin produces a well-documented distortion of the dentures [7–9]. This distortion has the potential to impact on the comfort and stability of the finished dentures. It is not uncommon for dentures to require adjustment when they are fitted. Furthermore, the traditional manufacturing methods are time-consuming, requiring many hours of skilled labour, and places a lower bound on price which may be out of reach for disadvantaged patients.

3D printing may offer the possibility of reduced distortion during denture production, reduced manufacturing cost, and improved fit. Very few clinical trials investigating the potential of 3D printed dentures have been undertaken [10,11]. The former was not a crossover design, meaning each subject was only provided with one of either 3D printed, milled, or conventional denture sets, reducing the power of the study protocol. They found no significant difference in patient reported outcomes between the groups. The latter study was a crossover design and found a significant patient preference for conventional dentures over 3D printed ones. However, this study ran between 2017 and 2020, using older 3D printers and resins, both of which have undergone rapid development in recent years. In all previous studies, no attempt has been made to ensure the *shape* of conventional and digital dentures is identical, leading to possible systematic bias (for example if digital CAD design tends to produce thicker baseplates, this may lead to decreased patient acceptance despite good accuracy).

The primary aim of the current study was to compare 3D printed and conventionally produced dentures in a randomised controlled trial (RCT) pilot study, with a crossover design, in order to enable a sample size calculation for a future RCT. The trial was designed to ensure both arms produced identically shaped dentures, to reduce confounding factors and enable direct comparisons.

The secondary objectives assessed were:

- Participant preference for the finished dentures before adjustment.
- Participant preference for the finished dentures after adjustment.
- Impact of the dentures, after an eight-week period, on participants' perceived oral health quality.
- Participant assessment of comfort, stability and chewing efficiency for dentures produced by traditional methods versus 3D printing, before adjustment.

- Participant assessment of comfort, stability and chewing efficiency for dentures produced by traditional methods and by 3D printing, after adjustment.

Methods – Trial Design, Participants, Interventions, Sample Size

This was a patient-centred, multi-centre, cross-over, double-blinded, randomised, controlled clinical pilot trial, which would provide data to inform future research. The specific design for this pilot RCT was based on a published protocol, which has been successful in robustly differentiating participant preferences for different types of dentures [12,13]. In addition, the protocol for construction of the 3D dentures was informed by a previous protocol trial, performed by the same three research trial sites [13]. 17 participants were recruited from the routine clinics and/or waiting lists for replacement of complete dentures at Leeds Dental Institute (LDI), the University Dental Hospital of Manchester, and Birmingham Dental Hospital over a period of 9 months. The trial took place between the 25th of May, 2021 and the 8th of November, 2022. Sample size was determined by looking at previous crossover RCTs in denture studies with the estimated number of cases needed being 16.

The inclusion criteria for the study were patients who:

1. Are edentulous with existing dentures.
2. Are available for follow up appointments.
3. Require replacement complete dentures.
4. Are able and willing to complete the informed consent process.
5. Are aged over 60 years at the time of signing the Informed Consent Form.

The exclusion criteria included patients who:

1. Have (or have had) an oral tumour.
2. Require an obturator.
3. Have extreme xerostomia (e.g. Sjögren's syndrome).
4. Have denture stomatitis.
5. Have a known hypersensitivity to dental materials used in the research.
6. Are incapable of providing informed written consent.

For each participant, two sets of dentures were produced. A single set if primary and secondary impressions were recorded, likewise a single jaw registration. As conventional denture teeth were used in both study arms, two wax trial dentures were deemed necessary. This was due to the material limitations of the 3D printed dentures which require a minimum 2mm thickness to reduce the chances of material fractures. As a result, the physical teeth frequently required adjustments at the root to ensure consistent thickness. One denture set was produced by traditional processing and the other by 3D printing the pink gingivae and palate of the denture (using Formlabs Denture Base resin, Formlabs, MA, USA) before fitting conventional denture teeth to this (Natura, Davis Schottlander & Davis Ltd, Letchworth, UK). The conventional denture material was strained to remove "veins" to ensure both denture sets had a similar appearance, to enable blinding.

After fitting both sets of dentures, the participants were asked to specify their preferred set of dentures; assessing the comfort, stability, and chewing efficiency of each set. The participants then completed the OHIP-EDENT (Oral Health Impact Profile for Edentulous People) questionnaire which enquired about their quality of life while wearing each of the dentures over two sequential eight-week Adjustment Periods. Within the constraints of the study timelines and the participating research sites' appointment systems, there were no limits on the number of return visits each participant could request.

An initial period of two weeks was included prior to each denture Adjustment Period. In this Initial Habituation and Assessment Period (IHAP), participants were given both sets of dentures. The purpose of this period was two-fold; firstly, to establish whether either set of unadjusted dentures was preferred and secondly, to allow the participant to habituate to the feel of the new dentures before individually assessing them.

Next, the participant was given a (randomised) set of dentures to wear for the first eight-week Adjustment Period. Following a clinical review, the participant was asked to wear the alternative dentures for another eight weeks. Participants remained blinded.

Following the two Adjustment Periods, a two-week Confirmation Period allowed the participant to take away both sets of dentures and identify which denture they preferred. The participants returned for a final clinical visit to complete their formal assessment of the dentures. The full schedule is outlined in Tables 1 and 2. See full trial diagram in Figure 1.

Interventions

Table 1: Overview of clinical visits and associated laboratory procedures. Clinical visits are highlighted in blue. The 3D printed dentures were produced by the NHS Dental Laboratory (Leeds Dental Institute) in collaboration with the Prosthodontic Research Team at the University of Leeds. The conventional dentures were produced at each participating NHS site as part of the participant's standard NHS treatment. The clinical visits and associated laboratory procedures for denture production are listed.

Study Stage	Study Activity
1.	Clinical visit 1: primary impressions (Imprep AC Putty – Soft Rapid, Unodent)
2.	Dental Laboratory: construction of customised impression tray
3.	Clinical visit 2: secondary impressions (Extrude Heavy and Light, Kerr Dental)
4.	Dental Laboratory: casting of impressions and construction of jaw registration blocks
5.	Clinical visit 3: jaw registration
6.	Dental Laboratory: articulation, production of two identical wax trial dentures
7.	Clinical visit 4: wax trial denture insertion
8.	Dental Laboratory: processing of dentures into acrylic and 3D printing
9.	Clinical visit 5: denture fit
10	Two-week Initial Assessment/Habituation Period (IAHP)
11.	Clinical visit 6: review
12.	First eight-week Adjustment Period
13.	Clinical visit 7: review
14.	Second eight-week Adjustment Period
15.	Clinical visit 8: review
16.	Two-week Confirmation Period
17.	Clinical visit 9: final review

Table 2: List of additional procedures required, with references to study stages as identified in table 1.

Additional procedures required were:
1. Pre-treatment baseline assessment of denture related quality of life was undertaken using the Oral Health Impact Profile questionnaire (OHIP-EDENT).
2. An impression scan and a scan of the corresponding cast allowed for the creation of a hybrid scan. These baseline scans were undertaken in the digital laboratory after Stage 3. They did not involve any extra participant contact.

3.	Two identical wax trial dentures were produced using a previously published protocol (Dillon, Hyde and Brunton, 2008)
4.	One trial denture was scanned and the scan merged with the hybrid scan of the fitting surface to produce a printable digital file; again, this was undertaken in the digital laboratory after the wax trial denture insertion (Stage 7). There was no additional participant contact for this procedure.
5.	The 3D printed dentures were printed and polished; a process undertaken in the dental laboratory during Stage 8. There was no additional participant contact for this procedure. The teeth from the wax trial were used in the final denture to ensure optimal and identical aesthetics compared to the conventional denture.
6.	An assessment of the two sets of dentures was undertaken by the participant during the two-week Initial Habituation and Assessment Period where the participant rotated the wearing of the dentures and recorded their comments in a structured diary; Stage 10.
7.	Primary outcome of the participant's preferred denture was recorded at Stage 11.
8.	The participant was given one set of dentures to wear for the first eight-week Adjustment Period (Stage 12).
9.	Participant returned and completed OHIP-EDENT assessment of quality of life (Stage 13 above).
10.	The participant was given the alternative set of dentures to wear for an eight-week Adjustment Period. (Stage 14)
11.	Participant completed OHIP-EDENT assessment of quality of life (Stage 15)
12.	Participant was given both sets of dentures for the two-week Confirmation Period (Stage 16).
13.	Participant assessment of comfort, stability and chewing capacity of both sets of dentures was recorded during Stage 17.
14.	Final choice of the adjusted dentures took place during the final clinical visit (Stage 17).

Participants underwent two randomisations using a colour coding system. Both randomisations were undertaken through sealed envelopes and blocked using random block sizes to ensure balance between groups. Participant study ID numbers were pre-allocated in advance of the trial starting to evenly distribute the randomisation allocations across the three participating research sites. The participants and the clinical members of the study team providing the intervention at each site were blind to the allocations.

The purpose of the initial randomisation was to establish the order of testing during the Initial Habituation and Assessment Period. This initial randomisation took place once the finished 3D printed dentures were delivered to a research site, to determine the colour marking (yellow/blue) of the dentures and the order in which they were tested during this Initial Habituation and Assessment Period [IHAP].

The participants were randomised so that half of the trial cohort wore the conventional dentures first and half started with the 3D printed dentures; blue and yellow colour codes distinguished the two dentures for each participant, but the meaning of each colour was randomised evenly across the cohort to prevent clinicians from learning that a particular colour represented a particular method. This was achieved by laboratory staff at each site placing coloured dots (specified at the randomisation stage) in the dentures and the dentist asking the participants to wear the yellow colour-coded dentures first.

The aim of the second randomisation was to establish the order of testing during the two eight-week Adjustment Periods. This second randomisation occurred at the conclusion of the IHAP to determine the colour re-marking (red or green) of the dentures; the two sets of dentures for each participant were marked as red or green, with the meaning of each colour randomised evenly across the cohort as before. This colouring process was again performed by laboratory staff at each participating site and the dentist asking the participants to wear the red colour-coded dentures first. This second randomisation was balanced for order of testing in the Initial Habituation and Assessment Period.

Unblinding was only performed once all clinical assessments for all participants had been completed.

The results from the study were used to produce a sample size calculation, with a statistical power of 90% and a significance level of 0.05, for a definitive RCT to investigate if a preference difference was found between the conventional denture and the 3D printed denture. The unadjusted proportion discordance was retained for this study and a discordant difference of 0.1 was used to calculate the sample size using McNemar's test.

The secondary objectives of the trial were assessed with OHIP questionnaires following the two eight-week Adjustment Periods. Despite this being a pilot study aimed at informing sample size estimation, we used non-parametric tests to explore potential significant differences between the two groups, as well as differences in the number of visits for each group.

Results

17 subjects were recruited, of which 14 completed the trial. Three participants did not complete the trial due to factors unrelated to the study.

A post-adjustment power calculation was determined to be n=35.

Prior to adjustment, four participants did not find either set of dentures satisfactory, five preferred the conventional denture, five preferred the 3D printed denture and one participant found both dentures to be satisfactory. As such, a significant number of participants did not express a preference for either digital or conventional dentures at this stage, indicating no statistically significance difference between conventional and digital dentures.

Following adjustment, two participants did not find either set of dentures satisfactory, eight preferred the conventional denture, two preferred the 3D printed denture and two participants found both dentures to be satisfactory. As such, following adjustment, 71.4% of participants did not express a preference for the digital dentures, while 28.6% of participants did not express a preference for the conventional denture. See Table 3.

Participants reported that the conventional dentures were more comfortable than the 3D printed dentures during clinical visit 6, the first review appointment (median score of 3.0 versus 2.0). Both groups reported a median stability rating of 4.0. Median chewing efficiency rating was 2.0 for both groups. The following visit (visit 7) reported a median score of 4.5 for comfort, stability and chewing efficiency for the conventional group, while the 3D printed dentures produced average scores of 4.0, 3.0 and 4.0. All following review appointments reported identical medians for both groups. See Table 4.

Table 3: Participant preferences before and after adjustment

	Preferred conventional	Preferred 3D printed	Both satisfactory	Neither satisfactory
Pre-adjustment	5	5	1	4
Post-adjustment	8	2	2	2

Table 4: Descriptive statistics and p-value of Mann-Whitney test for the 3D digital denture and conventional denture at each visit. Reported comfort, stability and efficiency in chewing scores across the two study arms for each review

appointment. A 5-point Likert scale (with answers: very comfortable/stable/efficient (5), comfortable/stable/efficient (4), neutral (3), uncomfortable/unstable/inefficient (2) and very uncomfortable/unstable/inefficient (1)) was used.

	Conventional denture	3D printed denture	p- value
Clinical visit 6			
Comfort	3.0	2.0	p=0.525
Stability	4.0	4.0	p=0.655
Efficiency in chewing	2.0	2.0	p=0.525
Clinical visit 7			
Comfort	4.5	4.0	p=0.513
Stability	4.5	3.0	p=0.510
Efficiency in chewing	4.5	4.0	p=0.513
Clinical visit 8			
Comfort	4.0	4.0	p=0.459
Stability	4.0	4.0	p=0.521
Efficiency in chewing	4.0	4.0	p=0.532
Clinical visit 9			
Comfort	4.0	4.0	p=0.558
Stability	4.0	4.0	p=0.359
Efficiency in chewing	4.0	4.0	p=0.558

Comparing the Oral Health Impact Profile [OHIP] prior to intervention and throughout the trial found that the conventional denture group had the lowest mean function limitation score. Both study arms reported a lower mean function limitation score than the baseline score, indicating a reduced level of functional limitation following clinical intervention, implying an improvement in the newly provided dentures.

Both the conventional and digital denture groups had lower mean psychological discomfort scores compared to the baseline group. The digital denture group showed a slightly lower mean psychological discomfort score compared to the conventional denture group, suggesting a potentially lower level of psychological discomfort experienced by some participants.

Overall, both the conventional and digital denture groups had lower mean physical disability scores compared to the baseline group, indicating a potential improvement in physical disability after denture intervention.

Both conventional and 3D printed interventions were somewhat associated with improvements in function limitation, pain, psychological discomfort, physical disability, psychological disability, social disability and handicap. Standard deviations for these results were relatively large, indicating variability in the results. Conventional and 3D printed interventions were generally associated with improvements in OHIP, but the improvements were not as large for all OHIP measures.

A number of participants reported adverse device effects (ADEs) relating to denture breakages and denture tooth loss, all which took place in the 3D printed dentures. There were seven instances of breakages across the lower dentures (with two additional reports of lower breakages post-study). Four of these instances occurred to the same participant's lower denture. One participant had their lower denture fracture on two occasions in different locations, once between LR3/LR4, and once between LR1/LR2. The dental technicians encountered one instance of a breakage during the denture construction stage; no further events were recorded relating to this denture following this occurrence. Five instances of debonded upper teeth were recorded. There was one instance of a debonded tooth in the lower denture. Six participants encountered no adverse device effects.

Out of all the participants, one experienced a non-serious adverse event (bruising on the ridge, lower left quadrant), which was related to the study procedures. There was one death among the participants due to events unrelated to study procedures.

Discussion

The aim of this study was to determine the sample size required for a fully powered clinical trial. An additional aim was to investigate the quality of 3D printed dentures.

This was a double-blind, randomised, patient-centred, multi-centre, cross-over controlled clinical pilot trial conducted to enable a sample size calculation for a future RCT. The sample size was calculated at two points in the trial: prior to any adjustments having been made to the dentures and following the adjustment stage. The pre-adjustment sample was concluded to be very large (approximately 1876 participants), perhaps indicating a high similarity in preference (or lack thereof) between the conventional and 3D printed dentures. Following the clinician adjusting the dentures, the sample size required for ongoing studies was concluded to be n=35.

The statistical analysis supports the notion that the primary endpoint of a future trial should focus on the participant-reported preference for either denture A or denture B following adjustments. However, it should be noted that the protocol dictated no undercut removal during construction (to ensure parity across the groups), with both dentures being unlikely to seat pre-adjustment for this reason. Anecdotally, the high preference for 3D printed baseplates during jaw registration [13] (whose design includes digital undercut removal) implies that digital undercut removal may be a pragmatic and effective choice, despite the academic argument that useful soft tissue undercuts might be removed in addition to hard tissue undercuts.

Secondary objectives within the current trial assessed participant preferences, before and after adjustments, with an overall preference for conventional dentures.

All OHIP measures improved after intervention, regardless of the type of denture. Both conventional and digital dentures appear somewhat associated with improvements in function limitation, pain, psychological discomfort, physical disability, psychological disability, social disability, and handicap. An inclusion criteria for the current trial was that the participants required replacement dentures, leading to the assumption that their existing dentures were suboptimal. The improvement in OHIP measures is therefore to be expected. However, with consideration to the sample size of the current work (n=14), definitive conclusions would require further studies.

The study's merits cover the masking of treatment administration and the utilisation of a cross-over design. In this framework, participants encountered both types of dentures and served as their own

controls. Moreover, the incorporation of a two-week IHAP with a diary for which denture to wear and the secondary random allocation curbed potential influences stemming from the Initial Habituation and Adaptation Period. A limitation of the crossover design is that if participants were closely scrutinising the dentures in the IHAP, they may have been able to identify a preferred set in the Adjustment Periods, thereby introducing a bias to their choices at review stages.

It could be argued that there are two key aspects that might affect the amount of denture adjustment required: the general fit in the mouth, and the tooth placement and resulting occlusion. A previous study [13] reported that the 3D printed baseplates were found to have better retention and fit than their conventional equivalent. From this, combined with the participants' consistent preference for the conventional denture, we may conclude that the weakest aspect of the digital workflow was correctly positioning the teeth in the dentures and accurately replicating the participants' occlusion. The fact that the printed baseplates had good retention and stability implies that the fit surface of 3D printed dentures has the potential to be very accurate. The previous study highlighted issues with individual tooth placement. This finding has been confirmed in the literature [14]. The present study modified the previously used technique, in an attempt to alleviate these issues, by printing tooth jigs, scanning the root shapes of the teeth and incorporating this information into the denture design if the roots had been adjusted. To improve the digital tooth placement, potential future work might investigate printing full dental arches or sections of multiple teeth as one unit to reduce location errors, or using a hybrid technique of printed posteriors combined with the more aesthetic analogue anterior teeth.

The challenge of reproducing the correct occlusal set up of teeth has been reported previously [15]. In the current study, conventional prefabricated teeth were used to produce two sets of highly similar dentures, as stipulated by the protocol. To aid the dental technician in accurately fitting teeth into the printed denture, a custom designed 3D printed "splint" was utilised. Despite these advancements, instances of misaligned teeth requiring occlusal adjustments during fitting still occurred. This complication mirrors the challenges associated with conventional flasking. However, it can be argued that the study protocol, which mandated the creation of analogous denture sets in an attempt to uphold participant and clinician blinding to the manufacturing process, introduced additional complexities. This required the technician to replicate any adjustments identically across both sets of dentures. In cases where root adjustments were required, this method will have become susceptible to debonding, especially when the adjustment was needed due to limited occlusal vertical dimension. Five instances of de-bonded teeth were recorded, all in the 3D printed arm of the study. The required root adjustments combined with inherent properties of the printing resin could potentially account for these occurrences; findings reported by Choi et al. in 2020 correspond with our findings of limitations in adhesive bond strength of 3D printed materials[16]. The challenge of achieving precise tooth placement and bonding can consequently impact the overall denture occlusion. This obstacle remained significant when crafting denture sets and was indeed encountered in the present study.

The challenged encountered relating to occlusal set-up and adhesive bond strength could be alleviated by using monolithic and high-impact printing methods, or denture teeth compatible with 3D manufacturing methods. Both such alternatives have become available commercially since the present trial was undertaken.

The slight improvement in participant reported comfort, stability, and chewing efficiency for the 3D printed dentures between clinical visit 6 and clinical visit 8 may indicate that the 3D printed dentures needed more adjusting than the conventional dentures. After this appointment, both denture groups reported identical scores for all three factors recorded (See Table 4).

A subset of the cohort experienced fractures. These all occurred in the 3D printed arm. The fractures manifested once during the technician's post-processing procedures and in several instances where participants dropped, mishandled, or were eating with the dentures. This highlights issues with the properties of the printed material, which is further supported by the research of [17], who raised concerns about the suitability of the current ISO standard assessment for denture materials when applied to testing 3D printed denture materials. The study reported that all conventional denture materials performed well above the minimum threshold limit stated by the ISO standards which may indicate that the lower thresholds of these standards have not been rigorously validated. As such it may be speculated that 3D printing materials may not perform as well as conventional materials despite meeting the minimum current ISO standards. Given these observations, further investigation into the material prerequisites specific to 3D printed dentures would offer valuable insights for future developments, notably with the use of high impact 3D printing materials.

It is worth noting that one participant experienced four fractures in two different locations on their lower denture. This may highlight concerns about the validity of repairing 3D printed dentures as opposed to re-printing and equivalent replacement. It also echoes the previous reflection on material properties: perhaps 3D printed dentures, or the denture creation method used in this trial, have a greater minimal thickness requirement than conventional materials manifesting itself as multiple fractures in patients with a reduced occlusal vertical dimension (OVD) or increased height of alveolar ridge, where inter-ridge space is compromised. (See fig. 2.) If so, there is a possibility that ‘mono block’ colour 3D printed denture production methods would produce dentures less likely to fracture. This would benefit from future investigation.

3D printed dentures are often associated with commercial dentistry which focuses on fewer appointments than that required to produce conventional dentures. The present study did not make any attempt to reduce the number of appointments.

The current study focused on a cohort aged 60 and older. It could be argued that our findings may not reflect the broader edentulous population and could have been more generalised if a wider age range of participants had been included.

The present study could have benefitted from investigating the topological variations between dentures, by 3D scanning each denture after every stage. This could have provided insight into the shortcomings and errors in the fabrication processes and clinical interventions, and is recommended for future studies. Additionally, a cost and/or time efficiency analysis of the two workflows would have been insightful and strongly recommended for future studies.

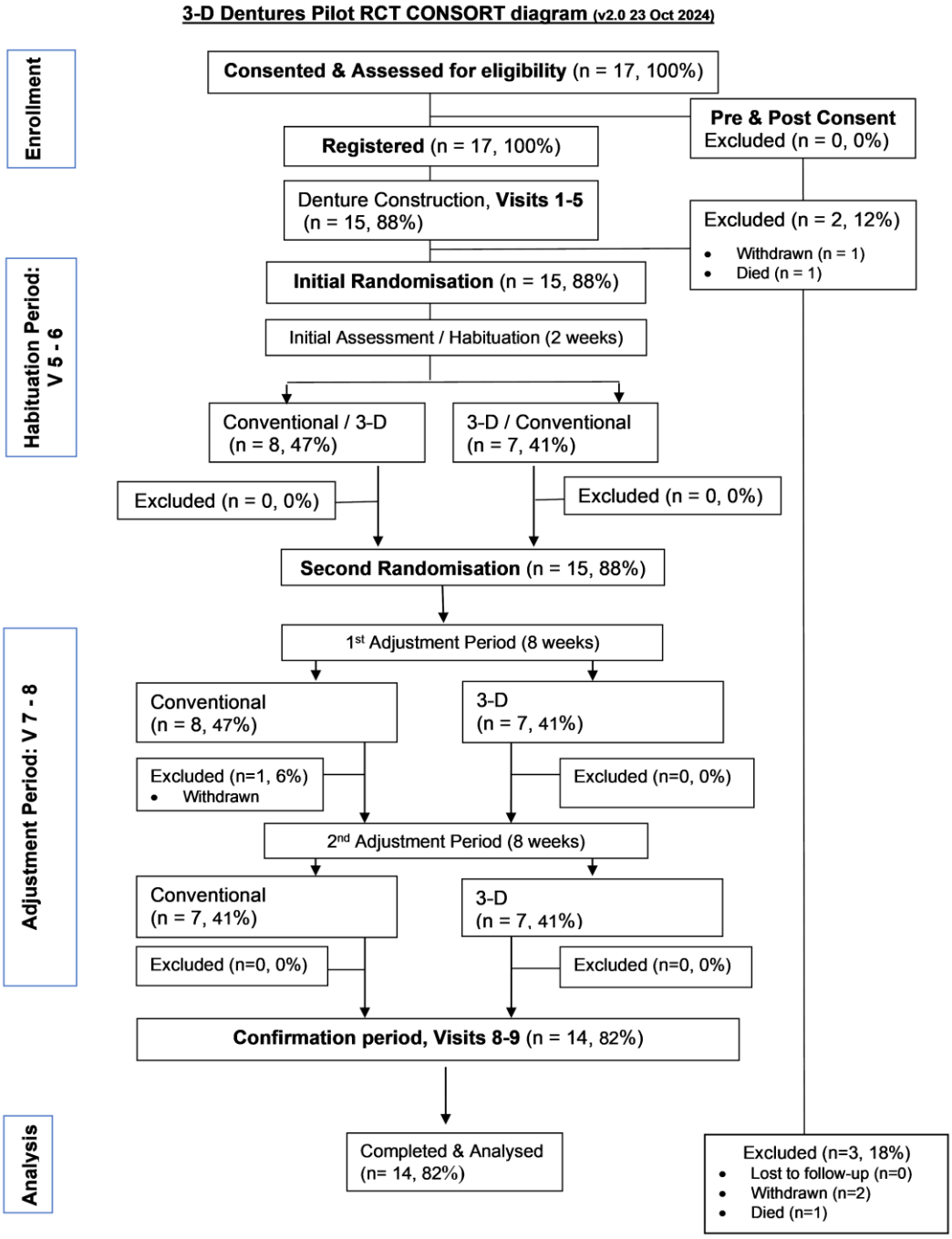

Figure 1: Study CONSORT diagram

Figure 2: Photos of a fractured 3D printed denture. Note the shear fracture, likely an artifact of the material properties of the denture, despite the acrylic base material thickness measuring 5mm at the point of fracture.

Conclusion

A post-adjustment sample size of n=35 is required for a fully powered RCT comparing 3D printed and conventional dentures in a crossover clinical study. Caution should be exercised in producing 3D-printed dentures following the methodology used in this trial due to material limitations and a lack of precision on tooth placement and resulting occlusion.

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