

Current challenges for 3D printing complete dentures: experiences from a multi-centre clinical trial

Cecilie Osnes,^{*1} Krishan Davda,¹ T. Paul Hyde,¹ Syeda Khalid,¹ Sean Dillon,¹ Natalie Archer,² David Attrill,² Hugh Devlin³ and Andrew Keeling¹

Key points

This multi-centre clinical trial found that clinicians strongly preferred 3D-printed baseplates over conventional shellac-supported bite rims.

While the stability and retention of 3D-printed dentures were similar to the conventionally manufactured dentures, most patients found the conventional dentures to be more comfortable. This is likely due to the challenge of correctly reproducing the occlusion in the 3D-printed dentures. While individual tooth placement is desirable for aesthetics, this led to errors in tooth position and overall occlusion.

While 3D-printed dentures have the potential to reduce treatment costs and increase predictability and consistency, the technology and materials are still in their infancy and cannot yet be recommended.

Abstract

Aims To develop an optimal clinical and laboratory protocol for the fabrication of 3D printing dentures.

Design A prospective feasibility study across three UK dental schools.

Material and methods Each patient received one conventional and one 3D-printed denture. Both dentures were constructed using the same impression, jaw registration and wax trial denture. Variables investigated included methods of digitisation of the impression and optional use of a 3D-printed baseplate for jaw registration.

Results Clinicians strongly preferred 3D-printed baseplates. Patients felt that conventional and printed dentures were similar in retention and stability. More patients favoured conventional dentures over 3D-printed dentures in terms of comfort.

Discussion It is feasible to combine conventional clinical work with digital techniques to produce 3D-printed dentures. 3D-printed baseplates offer a cost-effective alternative to conventional bases at the jaw registration stage. Challenges were faced in tooth positioning and managing occlusion, particularly where roots required adjustment.

Conclusion 3D printing is suitable for producing baseplates for jaw registration blocks and wax trial insertions. It is feasible to produce 3D-printed dentures using conventional clinical techniques for impressions, jaw registration and wax trial insertion. The workflow used in this study for 3D-printed dentures is not superior to conventional dentures. Further work is required.

Background/aims

The accuracy of the fit of a denture is an important issue for improving comfort, stability and chewing efficiency. Traditionally, dentures are formed by curing acrylic resins with heat while under pressure and encased in a plaster mould. The contraction which occurs

on curing the resin produces distortion.¹ This distortion may impact on the comfort and stability of the finished dentures, requiring further adjustment on fitting. Computer-aided design and computer-aided manufacturing (CAD/CAM) technologies can provide an alternative to conventional denture fabrication and could potentially reduce the number of stages during creation and improve accuracy and patient comfort.

CAD/CAM techniques can be either subtractive (milled) or additive (printed). Milled complete dentures have been reported as a commercially available option for edentulous patients for over a decade.² Srinivasan *et al.* found that the mechanical properties of milled complete dentures were comparable to that of conventional dentures.³ However,

the expense of these systems remains high and the subtractive milling process generates significant waste, which is inefficient and raises environmental concerns. Researchers have turned to the potential of additive manufacturing methods, such as 3D printing, as an alternative. 3D-printing technology can potentially offer advantages of good surface detail, low cost, speed, repeatability and lower material waste.^{4,5}

There is a growing body of literature on CAD/CAM dentures, including Ohara *et al.*'s crossover trial,⁶ but the lack of a standardised clinical protocol and lack of substantial data from randomised clinical trials (RCTs) remain. In this paper, we present a cohort study investigating protocols for producing clinically sound dentures using 3D printing

¹School of Dentistry, University of Leeds, UK; ²School of Dentistry, University of Birmingham, UK; ³School of Dentistry, University of Manchester, UK.

*Correspondence to: Cecilie Osnes
Email address: c.a.osnes@leeds.ac.uk

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without introducing significant adjustments to conventional clinical techniques. We discuss some of the key challenges encountered.

Method

This was a prospective cohort study with the aim to assess the feasibility of different clinical and laboratory workflows to produce high quality 3D-printed dentures.

In total, 16 patients were recruited at three university dental schools (Leeds, Manchester and Birmingham). The inclusion criteria consisted of patients who: are edentulous; are available for follow-up; have a clinical need for replacement complete dentures; are able and willing to complete the informed consent process; and are over 60 years of age. Patients who were not eligible were those who have (or have had): an oral tumour; denture stomatitis; required an obturator; extreme xerostomia (for example, Sjögren’s syndrome); known hypersensitivity to the dental materials used; or those who were incapable of written informed consent.

This study was undertaken with HRA approval (IRAS ID: 246234). All study participants consented to take part in the trial and to have their data used for research and publication.

Each patient received two sets of dentures, one conventionally produced and one that had been processed digitally. Both types of dentures were constructed using the same impression, jaw registration and wax trial denture. Figure 1 illustrates the stages of denture production, along with the novel laboratory ‘digital’ stages.

The study looked at different ways of producing input data for the printed dentures. Virtual models of the fitting surface of the dentures were obtained in three different ways: by random allocation; the patient’s dentures were created using either a direct scan of the impression; or a direct scan of the cast; or a hybrid scan which combined the impression and cast scans (Fig. 2). This enabled a laboratory study to run alongside this clinical study to obtain real world clinical data to investigate the trueness of fit produced by these three methods of obtaining input data. The results from this investigation (Davda *et al.*, 2020)⁷ are discussed below, alongside the clinical outcome data from this study.

At the jaw registration stage, the clinician was given a choice between conventionally produced jaw registration rims using shellac,

Fig. 1 Diagram outlining the stages of denture production, along with the novel laboratory ‘digital’ stages

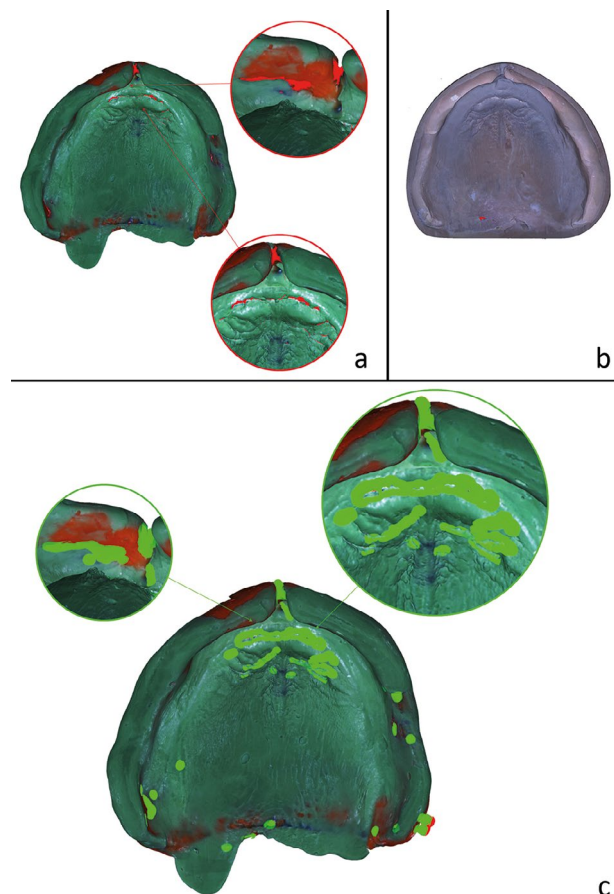
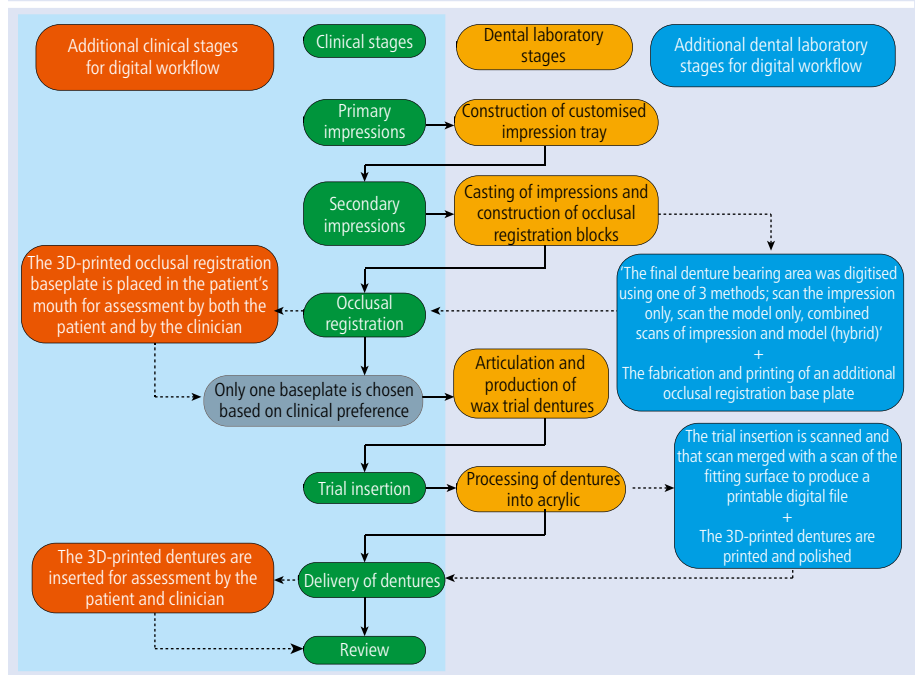


Fig. 2 Hybrid scanning illustrated. a) An inverted scan of an impression where the software has highlighted, in red, areas that could not be scanned. In many scanners, software extrapolates the shape of these areas from the adjacent sections and blends the colour so the repair is invisible to the user. b) Data in the highlighted (red) areas are then automatically obtained from the scan of the cast and patched into the scan of the impression to produce. c) The resultant ‘hybrid scan’ is has greater surface coverage than a conventional scan

and 3D-printed ones (Fig. 3). The registration rim of choice was then used to record the occlusion.

In the laboratory, the rims were used to articulate the case and produce wax trial dentures. After a satisfactory clinical trial insertion, the wax trial dentures were scanned, and that scan, combined with a fitting surface scan, produced the virtual dentures. The denture teeth were digitally removed from the virtual file and individual customised sockets were created using in-house software. The sockets were designed with 'locator' points to aid tooth placement while leaving space for resin with which to aid retention. The dentures were printed and individual denture teeth (Schottlander Enigma) cured into the sockets using printable denture resin (E-Denture, EnvisionTEC, Germany). A custom designed 3D-printed 'occlusal splint' was introduced partway through the study to aid correct occlusion on the printed denture (Fig. 4a). The wax trial denture was processed conventionally, using Metrocyl HI (Metrodent, UK) and Enigma (Schottlander, UK) teeth to produce the conventional equivalent denture.

While feasibility of production methodology was the primary aim of the study, the opportunity was taken to assess the following secondary outcomes:

1. The use of a 3D-printed baseplate for the 'occlusion registration' stage of denture construction, assessed by:

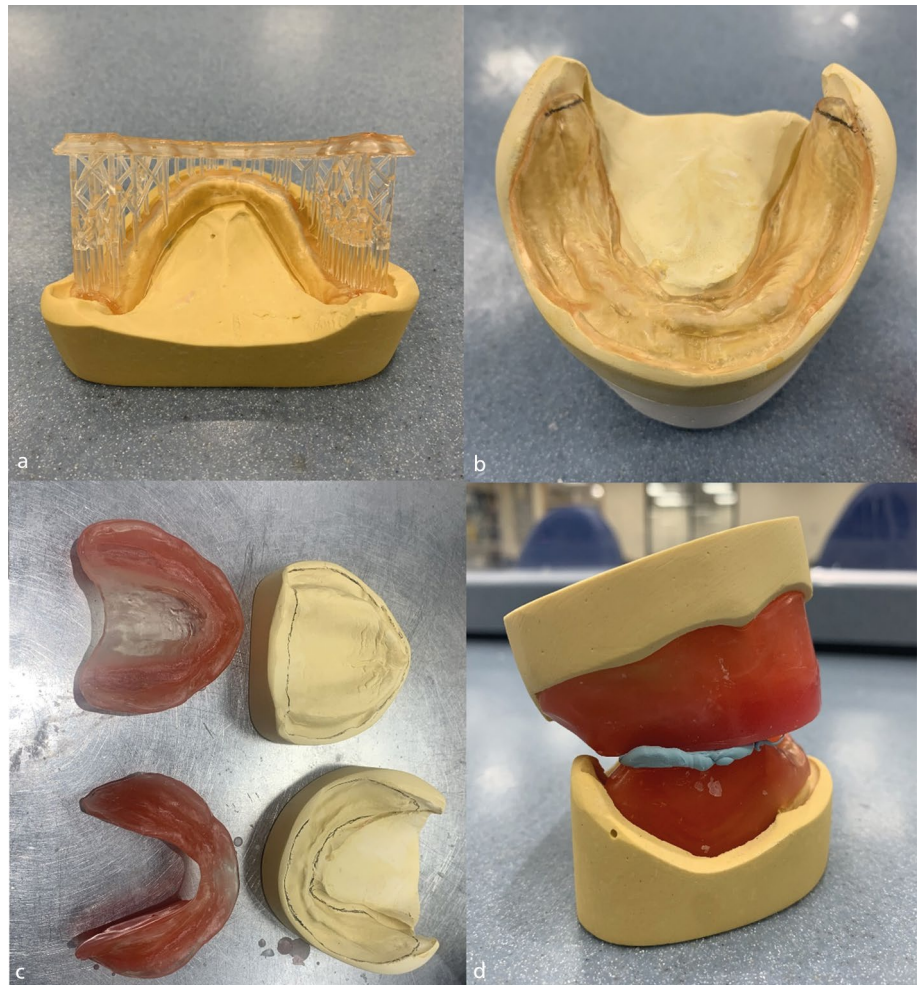


Fig. 3 a, b, c, d) Printing a baseplate for bite blocks was found to facilitate jaw registration

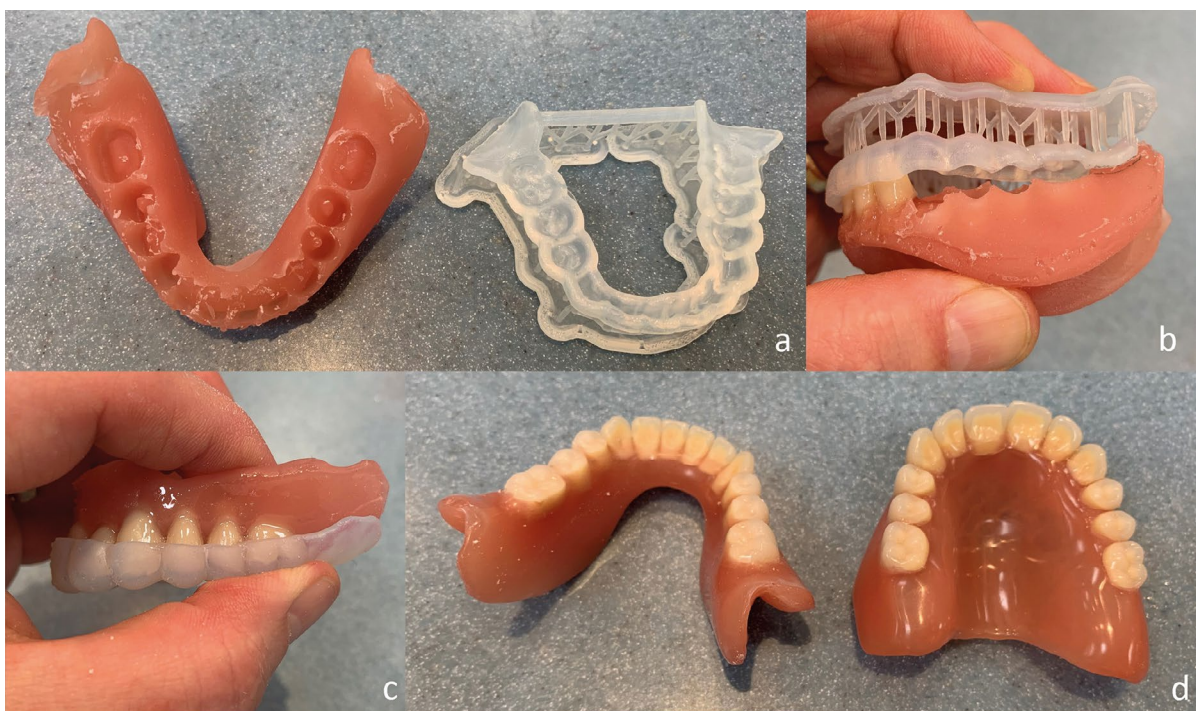


Fig. 4 a, b, c) Printing an occlusal splint from an occlusal scan of the completed wax try-in facilitated an accurate positioning of the individual teeth on the socketed printed baseplate. d) Depicts the final 3D-printed dentures

- The clinician-assessed retention and stability and
 - The clinician's preference.
2. The quality of finished dentures, assessed by:
 - The patient's blind assessment of the dentures for comfort, stability and appearance
 - The dentist's blind assessment of the retention and stability.
 3. The patient's preference for either the conventional denture or the 3D-printed denture.

Results

In total, 16 patients took part in the study. Two withdrew during the trial.

Assessment of the trueness of input data from scans of the impression, the cast and hybrid scans have been published separately.⁷

The clinicians preferred the 3D-printed jaw registration rim in 13 out of 16 cases (see Table 1).

There were five cases where conventional was more retentive than printed and one instance where the digital denture was more retentive than the conventional (Table 2). The 3D-printed denture was equally as retentive as the conventional denture in 6 of the 14 cases.

The conventional denture was reported to be more stable than the 3D-printed in 5 of the 14 cases. There was a single instance of the printed denture being more stable than the conventional. The conventional and printed dentures were considered equally as stable in eight of the cases (Table 3).

Patient feedback is reported in Table 3 and Table 4. Notably, the level of comfort of the conventional dentures were all reported as 'comfortable' or 'very comfortable'. Three of the digital dentures were reported to be 'uncomfortable', with another two being reported as 'neutral'. There was a preference for the conventional denture in 8 of the 14 cases. Two patients preferred the 3D-printed denture, while four patients found both dentures satisfactory (see Table 5).

Discussion

This study explored methods for producing 3D-printed dentures, focusing on the feasibility of combining conventional clinical stages with novel ways to create digital, printable dentures. Custom software was used to obtain input data from conventional impressions, which was combined with scan

data of conventional wax trial insertions to produce printable files.

Overall, the study has shown it is feasible to combine conventional clinical work with

Table 1 Clinicians' preferred jaw registration rim

Clinicians' preferred jaw registration rim	N = 16
Conventional	3
3D-printed	13

Table 2 Clinicians' (blinded) feedback

Patient ID	Conventional		3D-printed	
	Retention	Stability	Retention	Stability
1	Very retentive	Stable	Very retentive	Stable
2	Very retentive	Very stable	Very retentive	Neutral
3	Very retentive	Very stable	Very retentive	Very stable
4	Retentive	Very stable	Retentive	Neutral
5	Retentive	Neutral	Retentive	Stable
6	Retentive	Stable	Neutral	Stable
7	Very retentive	Stable	Retentive	Stable
8	Very retentive	Very stable	Retentive	Stable
9	Retentive	Stable	Retentive	Stable
10	Retentive	Very stable	Unretentive	Neutral
11	Very retentive	Very stable	Retentive	Very stable
12	Very retentive	Very stable	Neutral	Very stable
13	Very retentive	Very stable	Retentive	Stable
14	Retentive	Stable	Very retentive	Stable

Table 3 Patients' (blinded) feedback (conventional denture)

Patient ID	How comfortable did you find the denture?	How stable did you find the denture?	How satisfied were you with the appearance of the denture?
1	Very comfortable	Very stable	Very satisfied
2	Comfortable	Stable	Very satisfied
3	Comfortable	Very stable	Neutral
4	Comfortable	Very stable	Very satisfied
5	Comfortable	Stable	Satisfied
6	Comfortable	Very stable	Very satisfied
7	Very comfortable	Very stable	Very satisfied
8	Very comfortable	Stable	Satisfied
9	Comfortable	Stable	Satisfied
10	Very comfortable	Very stable	Very satisfied
11	Comfortable	Neutral	Satisfied
12	Comfortable	Very stable	Very satisfied
13	Very comfortable	Very stable	Very satisfied
14	Comfortable	Very stable	Satisfied

digital techniques to produce 3D-printed dentures. Although the sample size was too small to analyse the secondary outcomes quantitatively, there are clear trends.

Clinicians showed a strong preference for 3D-printed baseplates of the jaw registration blocks. These baseplates are economical and the digital software can produce the printable file semi-automatically. However, as this assessment could not be blinded, further work is needed to confirm this finding.

The blind assessments of the dentures themselves, by both the patients and the dentists, show trends which are in favour of conventional dentures. Again, the sample size is too small for detailed statistical analysis but is in acceptance with the recent literature.⁶ The trend was stronger for the patient-reported outcomes, highlighting the importance of this metric as a primary outcome in future trials, as opposed to clinician opinion.

Hybrid scanning

Successful denture treatments rely on capturing the patient's anatomy accurately. This can be achieved by taking an impression or intraoral scanning. Intra-oral scanners are not recommended for complete denture production due to the significantly inferior retention of the baseplate compared with conventional impressions.⁸

Extra-oral scanners can be used to scan the impression or the cast. Undercut areas, in both impression and cast, can be difficult or impossible to record, resulting in voids in the scan. Commercial scanner software will 'fill in' these voids, giving an erroneous representation of the true anatomy. Hybrid scanning optimally combines data captured from a scan of an impression with a scan of the model⁹ (Fig. 2). A recent study found that hybrid scans increased the surface area by an additional 30 mm² of captured data over the denture-bearing area.⁷ A second study found that 'the hybrid technique showed a clinically significant trend with superior surface area coverage'.⁹

For the present study, hybrid scans were used on one-third of the cases. Their use was randomised. The study was not powered to assess the clinical benefits. Further work needs to be done to investigate retention, comfort and amount of adjustment required in hybrid-produced baseplates. However, considering the evidence that hybrid scanning improves surface coverage, it could be beneficial in increasing final denture comfort, support and retention.

Table 4 Patients' (blinded) feedback (3D-printed)

Patient ID	How comfortable did you find the denture?	How stable did you find the denture?	How satisfied were you with the appearance of the denture?
1	Neutral	Stable	Satisfied
2	Neutral	Stable	Neutral
3	Comfortable	Very stable	Neutral
4	Uncomfortable	Very stable	Neutral
5	Comfortable	Stable	Satisfied
6	Uncomfortable	Unstable	Unsatisfied
7	Comfortable	Stable	Satisfied
8	Uncomfortable	Very unstable	Very unsatisfied
9	Comfortable	Stable	Satisfied
10	Comfortable	Very stable	Satisfied
11	Comfortable	Stable	Satisfied
12	Comfortable	Very stable	Satisfied
13	Very comfortable	Stable	Very satisfied
14	Very comfortable	Very stable	Satisfied

Table 5 Patient preferences

Patient ID	Patient preference
1	Conventional
2	Conventional
3	Conventional
4	Conventional
5	Both satisfactory
6	Conventional
7	Conventional
8	Conventional
9	Both satisfactory
10	Conventional
11	Printed
12	Both satisfactory
13	Both satisfactory
14	Printed

Jaw registration

In this study, the clinician was provided with two sets of jaw registration rims, one shellac and wax, and one on 3D-printed bases with wax. The clinician chose a preference based upon stability and retention and proceeded to record the jaw registration using this rim. The clinicians reported that the retention of the printed baseplates was superior in 13 of 16 cases.

Accurate jaw registration is a prerequisite to providing acceptable complete dentures. Unstable record rims can be displaced from the denture-bearing area during registration, leading to an inaccurate record. To ensure stable blocks, the bases can be constructed from heat-cured acrylic, in preference to wax-only, shellac or acrylic. However, this is expensive and not likely to be adopted in

NHS dentistry. By contrast, a 3D-printed baseplate can be fabricated upon which the wax rim can be constructed. This offers the advantages of the heat-cured base at a much-reduced cost.

Management of the occlusion

3D-printed bases were constructed with pre-designed socket spaces for conventional denture teeth (Schottlander Enigma) to be bonded in place (Fig. 4). This technique enabled individual denture teeth to be used with aesthetic benefits in shade, mould and customised tooth position. It further enabled comparison between digital and conventional dentures, with a reduced number of confounders.

CAD/CAM dentures produced by other means are often designed as two separate parts: the pink denture base and the white teeth. The white teeth may be printed or milled. These are then combined to produce the final product.¹⁰ The milling or printing options each come with advantages and pitfalls.

Multi-graded blocks can be used to mill teeth, enabling some aesthetic control over monolithic materials. Milling results in a large amount of waste material, affecting production cost. 3D printing denture teeth would significantly reduce the price but currently available materials tend to be monolithic and aesthetically unappealing.¹¹ The aesthetics of both milled and printed teeth are reliant on hand-finishing by the dental technician, which is unlikely to be afforded much time during NHS denture provision due to additional costs.

Prefabricated denture teeth allow for aesthetic predictability. Attaching individual teeth presents a challenge for correct tooth location and occlusion. In this trial, we found the process technically challenging and prone to debonding, particularly when excessive root reduction of the denture tooth occurred in situations with a limited occlusal vertical dimension. These findings correspond with those reached by a recent similar study.¹²

One solution to overcome retention and alignment problems could be to use digitally manufactured teeth designed to include mechanically retentive features and all, or several, teeth produced as a single unit. If placed correctly, the occlusion would be reproduced robustly and reliably. The key disadvantage of this approach is the lack of control of individual tooth aesthetics and the inability for dentists to move individual teeth during wax trial.

Because this study was designed as a precursor to a crossover RCT, it was important to be able to produce two sets of dentures with the same occlusion to prevent the occlusion being a confounding variable. Duplicating the occlusion is also necessary to preserve blinding. To increase the accuracy of the duplication of the occlusion between the printed and the conventional dentures, a custom designed 3D-printed 'splint' helped to give the dental technician an aid in correctly fitting the teeth (Fig. 4). This method was introduced and refined throughout the trial. Despite this, errors in tooth placement that required occlusal adjustment at fit still occurred.

Based on the occlusal challenges found in this study, for future denture production, one compromise would be to 3D print posterior sections of the dental arch, while utilising conventional denture teeth in the anterior segment. An extension to this ethos might be that only the aesthetically important upper anterior segment would require individual denture teeth, with the lower teeth being 3D printed. For this approach, a conventional wax trial would be beneficial, allowing the possibility for the clinician to move individual teeth, before scanning and printing the block of teeth with the chosen occlusion.

The printed denture bases require the attachment of conventional, milled or 3D-printed denture teeth, with a bonding agent. Studies show the bonding of acrylic teeth to 3D-printed resin is inferior to that of conventional heat-cured acrylic bases.^{13,14} There is less residual monomer in the CAD/CAM milled resins than conventional heat-cured resins.¹⁵ The current study found that the attachment between the conventional prefabricated teeth and printed denture bases did occasionally fail, indicating the need for the use of mechanical retention.

In this study, clinicians and patients preferred the conventional dentures, with the trend being stronger from the patient-reported outcomes, indicating that this is a more sensitive metric. The challenges introduced by having to attach the conventional teeth to the 3D-printed baseplates may have contributed to these findings. Where occlusal adjustments were required to satisfy the patient's occlusion, these were made by the technician on the wax trial, and thus on the teeth used in the conventional denture. As these changes were not 'digitised', the same changes needed to be made on the 'digital' denture teeth by eye. Future trials should include digitising and

recreating the root adjustments introduced by the technician into the digital denture, perhaps via the use of two identical wax trials, randomly allocated to conventional or digital production.

Material properties

The polymerisation contraction of conventional denture resins is well-known; the literature suggests that milling and 3D printing may suffer from equivalent, material-related complications and may therefore not necessarily provide superior denture accuracy.³ In printed dentures, although the initial print accuracy is generally assumed to be high, this will depend on the type of printer and the topology of the printed object.¹⁶ There is potential for contraction to occur during post-print curing, which may lead to distortion. Further material science research improving these properties is required. Anecdotally, a number of dentures were reported to have fractured during the trial. This was an unexpected outcome, as commercially approved, CE-marked printing methods and materials were being used. As a result, we are unable to identify the exact number of breakages encountered.

While all commercially available 3D printing denture base materials are required to meet the international standards for their CE mark, some of the material properties of 3D printing resins have been found to be clinically less favourable than those in conventional or milled CAD/CAM denture base materials, both in terms of material strength and structural distortion.² It is noteworthy that a number of the dentures in this study fractured. A possible explanation is the nature of the printing resin. This is supported by Greil,¹⁷ who suggests the current ISO (International Organisation for Standardisation) standard assessment for denture materials may not be appropriate for testing 3D-printed denture materials. We may postulate that conventional denture materials may 'over-deliver' in regards to the ISO 20795-1 requirements. The introduction of novel materials may indicate that the lower limitations specified by the ISO standard are in fact too low to be clinically acceptable in the modern era. Further work into the material requirements of 3D-printed dentures is needed. Alternatively, a deterioration in 3D-printed mechanical properties over time may contribute to the breakages. Here, improved stability of long-term 3D-printed materials may be required.

Conclusions

This study found that it is feasible to produce 3D-printed dentures using conventional clinical techniques for impressions, jaw registration and wax trial insertion, but the workflow used in this study for 3D-printed dentures was not superior to conventional dentures.

3D printing was the preferred method for producing baseplates for jaw registrations blocks and wax trial insertions, compared to shellac.

Scanning of either the impression, model or combined (hybrid) showed no measurable clinical difference, although surface area coverage was improved with hybrid scanning. The method of individual tooth cementation in this study cannot be recommended. Further work is needed to explore methods of taking tooth adjustments into account when designing the digital denture and improving tooth retention when designing a protocol for a future RCT.

There is a need for improvement of the physical properties of commercially available, printable denture resins.

Ethics declaration

The authors declare no conflicts of interest.

This study was undertaken with HRA approval (IRAS ID: 246234). All study participants consented to take part in the trial and to have their data used for research and publication.

The data supporting the findings of this study are available from the corresponding author upon reasonable request.

Author contributions

Cecilie Osnes contributed to protocol development, digital denture production, drafting and finalising the manuscript. Krishan Davda contributed to protocol development, clinical work, and finalising the manuscript. T. Paul Hyde contributed to protocol development, clinical work, drafting and finalising the manuscript. Syeda Khalid contributed to protocol development, digital denture production and drafting the manuscript. Sean Dillon completed and quality assured all dentures for the Leeds site and contributed to drafting the manuscript. Natalie Archer contributed to protocol development and clinical work. David Attrill contributed to protocol development, clinical work and drafting the manuscript. Hugh Devlin contributed to protocol development, clinical work, drafting and finalising the manuscript. Andrew Keeling contributed to protocol development, clinical work, denture production, drafting and finalising the manuscript.

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