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CLINICAL RESEARCH

Improving facial prosthesis construction with a contactless scanning and digital workflow: A feasibility crossover randomized controlled trial of digital versus conventional manufacture of orbital and nasal prostheses

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ABSTRACT

Statement of problem. Research is needed to compare the clinical and cost effectiveness of the digital and conventional manufacturing of facial prostheses. Feasibility trials can help acquire the data needed to plan a definitive randomized controlled trial (RCT).

Purpose. The purpose of this clinical study was to assess the feasibility of conducting a future definitive RCT of the clinical and cost effectiveness of the digital versus conventional manufacture of facial prostheses in patients with orbital or nasal defects. The primary objective was to assess eligibility, recruitment, conversion, and attrition rates. Secondary objectives included synthesizing data on outcomes for a definitive trial.

Material and methods. A multicenter feasibility crossover RCT compared the digital and conventional manufacture of facial prostheses at Leeds Teaching Hospitals NHS Trust and Guy's and St Thomas' NHS Foundation Trust between December 2021 and October 2023. Patients over 16 years of age were eligible if they had acquired orbital or nasal defects and required a replacement facial prosthesis. Centralized allocation used minimization to allocate participants to 2 groups which differed in the order of receiving the intervention and control prostheses. Participants were masked to the manufacturing method by marking the prostheses with color labels. Data were collected on patient flow and the planned outcomes for a definitive RCT (participant preference, generic and condition specific health related quality of life, and costs from the healthcare perspective). Data were analyzed descriptively and narratively.

Results. Fifteen participants were recruited and allocated to receive the intervention (n=7) or the control prosthesis (n=8) first. Analysis of the primary outcomes identified 100% eligibility, 88% recruitment, 100% conversion, and 27% attrition rates. Analysis of secondary outcomes showed the mean ±standard deviation Toronto Outcome Measure for Craniofacial Prosthetics-27 score was 59 ±26% at baseline; the change from baseline was 10 ±14% for the intervention and 13 ±16% for the control. The mean EQ-5D-5L index score was 0.72 ±0.24 at baseline; the change from baseline was 0.07 ±0.12 for the intervention and 0.02 ±0.12 for the control.

Conclusions. A definitive study was determined to be feasible. A recommendation for progression has been made with some modifications to study design. (J Prosthet Dent xxxx;xxx:xxx-xxx)

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Clinical Implications

The digital manufacture of facial prostheses has the potential to offer improved clinical outcomes, enhanced patient experience, and efficient resource use. The technology should be appropriately evaluated, and this feasibility study is a step toward designing a definitive RCT of the clinical and cost effectiveness of digital manufacturing. A definitive study was determined to be feasible and worthwhile, though some modifications to study design have been proposed.

Facial prostheses can help conceal and protect facial defects and improve patients' function, appearance, and health related quality of life (HRQoL).[1–4] Conventional facial prosthesis manufacturing is resource intensive, requiring significant input from a maxillofacial prosthetist and technologist (MPT).[5–7] Facial impressions have been reported to be uncomfortable and claustrophobic.[4,8–10] Sculpting a wax pattern is a time-consuming and artistically driven process,[6,11,12] and prosthetic outcomes can vary with patient, defect, and MPT factors.[4,9,11–13]

Computer-aided design and computer-aided manufacturing (CAD-CAM) may help improve clinical outcomes, enhance patient experience, and support efficient resource use. Facial scanning could be a more comfortable, convenient, and accurate data acquisition method.[9,10] CAD could provide a starting point for prosthesis design, reducing interoperator variability, and freeing up operator time to focus on the more technically demanding stages.[12–14] CAM could improve the efficiency and reduce the costs of rehabilitation.[11,12,15–17]

Despite a rising interest in CAD-CAM, most facial prosthesis research has had observational designs.[18–23] The authors are aware of only 1 previous crossover randomized controlled trial (RCT) that evaluated a specific clinical application of CAD-CAM with a small sample size.[16] Facial prosthesis research tends to focus on patient reported outcomes,[20] but the costs and consequences of a change in manufacturing could also be explored through early health technology assessment.[5,11,24–26] Furthermore, qualitative research has focused on the impact of facial differences, experiences of wearing facial prostheses, and rehabilitation outcomes,[1,27–32] with a scarcity of research into the perceived benefits and limitations of CAD-CAM.[33] Patients could gain additional benefits relating to the way treatment is delivered if a more pleasant or less invasive process is used.[34]

Feasibility trials help plan large-scale and often expensive definitive RCTs by addressing uncertainty, testing performance capability, and assuring deliverability.[35–37] A feasibility trial was proposed to assess the feasibility of a definitive RCT of the clinical and cost effectiveness of digitally and conventionally manufactured facial prostheses in patients with orbital or nasal defects. The primary objective was to assess eligibility, recruitment, conversion, and attrition rates. The secondary objectives were to identify issues with delivering the RCT components according to the protocol and to synthesize data on outcomes under consideration for a definitive RCT.[38] The qualitative substudy aimed to explore patients' perception, lived experience, and preference for facial prosthesis manufacturing methods.[38] The health economic objective was to develop an early-stage health economic model of the cost effectiveness of digital manufacturing. The authors plan to report on the qualitative and health economic substudies separately. The research hypothesis was that a definitive RCT would be feasible to deliver.

MATERIAL AND METHODS

A multicenter feasibility crossover RCT compared the digital and conventional manufacture of facial prostheses. The protocol was made publicly available,[38] and the study was reported according to the Consolidated Standards of Reporting Trials (CONSORT) extensions.[39,40] The study was conducted within the maxillofacial prosthetic services at 2 United Kingdom hospitals: Leeds Teaching Hospitals NHS Trust (LTHT) and Guy's and St Thomas' NHS Foundation Trust (GSTT) and was approved by the Leeds East Research Ethics Committee (reference 21:/YH/0028). The departmental logs were reviewed to identify potentially eligible patients (Table 1). Participant invitation sheets were mailed or offered during routine appointments. Interested patients were invited to a screening visit. Written informed consent was obtained.

For pilot studies, some authors recommend a sample size that gives a 1-sided 80% confidence interval that excludes the minimum clinically important difference expected within a definitive RCT.[41] However, a formal calculation was not possible because of limited data on effect sizes for the outcomes for a definitive RCT.[16,42,43] Alternative recommendations were used which suggested a sample size of 20 to 30 patients to estimate unknown variances in effect sizes in parallel study designs.[41,44–47] A sample size of up to 30 participants was chosen recognizing that a crossover study would require fewer participants to obtain the same precision.[48]

Centralized allocation assigned participants on a 1:1 basis to 2 treatment groups which varied in the order of receiving the intervention and control. Minimization helped balance group sizes and minimization variables (retention method and defect type) with the small sample size.[49,50] Software program commands (RStudio;

Table 1. Eligibility criteria

Criteria	Justification
Inclusion criteria	
Aged over 16 years.	To restrict target population to adults.
Orbital or nasal defects.	3D morphable model used for computer-aided design better suited to design of nasal and orbital prostheses. Specific ear models may be useful for auricular prostheses but not used in study.[58]
Facial defect because of head and neck cancer.	To restrict sample to specific underlying etiologic condition because of small sample size of feasibility trial.
Require replacement facial prosthesis retained by any method.	To ensure patients had worn prosthesis before to minimize burden during early phases of rehabilitation.
Available for follow-up.	Timelines dictated by lead author's thesis submission timelines with limited scope to extend study.
Able to provide informed consent.	Patients must have capacity to make voluntary decision about whether to take part in study.
Exclusion	
Receiving active treatment for head and neck cancer.	To minimize burden on participants undergoing further treatment.
Plans for major reconstructive surgery.	To restrict study to treatment of stable, chronic conditions, important in crossover study design.
Skin conditions which prevent prosthesis provision.	To minimize problems for patients and prevent unwarranted reporting of adverse events in patients with known conditions.
Hypersensitivity to study materials.	

Note: protocol included contingency plan to widen eligibility criteria to other acquired conditions if low recruitment rates encountered[38]; however, this was not required and target population remained focused.

The R Foundation) were generated by a statistician to automate minimization. Participants had a 90% chance of being allocated to the group that reduced imbalances to minimize the prediction of allocations.[49,50] The site teams submitted allocation requests to the trial coordinator (R.J.), who performed minimization, maintained a central log, and sent email confirmations to the site.

The intervention and control prostheses were produced in tandem (Fig. 1, Supplemental Material 1, available online). The intervention facial prostheses were made by using a digital manufacturing workflow previously tested with volunteers.[51] This involved 3 dimensional (3D) facial scanning with an optical scanner, digital design with 3D morphable models, and 3D printing of prosthesis replicas.[51–59] The intervention and control prostheses contained duplicate ocular components for orbital prostheses and retentive components for implant-retained prostheses. They were made in the same silicone material with a colorant recipe obtained with a spectrophotometer, and extrinsic colors were added as required. The prostheses were marked with color labels to mask the treatment allocation from the participants and the statistician providing support for analysis.[60,61] Participants were asked to return their first prosthesis at the 4-week review visit when they crossed over to the second prosthesis.

Primary feasibility outcomes were the eligibility, recruitment, conversion, and attrition rates.[38] Secondary feasibility outcomes included completion rates, estimates, variances, and missing data for the outcome measures for participant preference, generic and condition specific HRQoL, and costs from the healthcare perspective.[38] Other secondary outcomes related to issues with study delivery (such as minimization processes, intervention delivery, outcome measure choice, adverse events, masking procedures, and trial schedule compliance).[38] The qualitative substudy was added as a protocol amendment, and the qualitative outcomes were participant preference for manufacturing method and willingness to wait for their preferred method.[38]

Participant preference for the intervention or control prosthesis was captured at the final review visit 4 weeks after delivery of the second prosthesis. HRQoL was assessed at baseline and at 4 weeks after the delivery of each prosthesis. Generic preference-based HRQoL questionnaires explored broad health concepts applicable to a range of patient groups, and a condition-specific

Figure 1. Example of intervention and control wax patterns produced for implant retained orbital prosthesis. A, Example of definitive cast and wax pattern for intervention prosthesis. B, Intervention wax pattern modified by MPT to add detail and fine margins. C, Definitive cast and wax pattern for control facial prosthesis. Note partial cast could make spatial positioning of features challenging. MPT, maxillofacial prosthetist and technologist.

questionnaire explored aspects of health relevant to patients with facial prostheses.[62] Adverse events were documented until 1 week after the final review. Participants were invited to take part in semistructured interviews towards the end of the clinical visits. Participants were asked their preference for either of the manufacturing processes and their willingness to wait for their preferred process if both methods produced equal treatment outcomes.[63]

Condition specific HRQoL was captured through the Toronto Outcome Measure for Craniofacial Prosthetics (TOMCP); a reliable and valid questionnaire for exploring new facial prosthesis materials and techniques.[64,65] The shorter version was used to minimize response burden and comprised 27 items across 9 domains with responses on a 7 point Likert scale.[64] Responses were added together to calculate domain and overall scores, which were transformed into a percentage scale and inverted so that a higher score represented a better HRQoL.[64,66]

The EQ-5D is the National Institute for Health and Care Excellence's preferred HRQoL measure in adults,[67] shown to be valid, reliable, and responsive in various populations,[68] with greater discrimination with the 5 level version.[69] The EQ-5D-5L descriptive system evaluated 5 dimensions of health and a summary index value was generated to indicate how good or bad a participant's health state was based on societal preference weights.[68] A mapping function produced summary index values which could range from 1 (full health), through 0 (equivalent to death), to negative values (worse than death).[67,68,70] The visual analog scale (VAS) represented the patient perspective on their health on a scale of 0 (worst) to 100 (best).[68]

The Short Form Health Survey version 2 (SF-12v2), a reliable and valid measure of physical and mental health, was included as an alternative measure of generic HRQoL since the SF-12 had been used in facial prosthesis studies.[71–74] The SF-12v2 comprised 12 items across 8 domains of HRQoL.[74] Data were imported into a software program (PRO CoRE Smart Measurement System; Quality Metric) to generate Physical Component Summary (PCS) scores and Mental Component Summary (MCS) scores. Short Form 6 Dimension (SF-6D R2) utility index scores were derived and ranged from 0 (worst health state) to 1 (best health state).[74–76]

Costs from the healthcare perspective were captured with a microcosting, bottom-up, direct measurement approach because research was insufficient to assign costs directly.[77] Investigators recorded the time spent during each component of treatment excluding setting up or cleaning the clinic. Most processes were completed by MPTs and assigned the average cost for Band 7 and 8a hospital-based professional staff.[78] For the intervention, the average cost of Band 5 and 6 hospital-based professional staff was applied to making the definitive cast and initial wax pattern as they were expected to be provided by a biomedical engineer.[78] The cost of a Band 4 hospital-based nurse was added to all clinical stages.[78] Investigators recorded the amount of consumables used when expected to cost over £10 (British Pound Sterling) per use such as implant components, impression material, 3D printing resin, and silicone material. Reference costs were sourced from manufacturers' websites or hospital suppliers.

Baseline characteristics and primary and secondary feasibility outcomes were described descriptively. The flow of patients was presented in a CONSORT flow diagram.[79] Categorical variables were summarized with proportions. Metric variables were summarized with means, standard deviations (SDs), medians, minimum, and maximum values, or 95% confidence intervals. Analysis was completed in a statistical package (Stata/MP; StataCorp LLC). In accordance with feasibility study recommendations, no statistical comparisons were performed between groups.[36,39,41] Progression criteria were outlined in the protocol.[38]

RESULTS

Recruitment started at LTHT in December 2021 and in May 2022 at GSTT and was extended to January 2023 because of delays in site set up associated with the COVID-19 pandemic. The study ended in October 2023. Figure 2 shows the CONSORT flow diagram.[79] The eligibility rate (eligible/screened) was 100% (15/15). The conversion rate (consented/eligible) was 100% (15/15). The recruitment rate (recruited/invited) was 88% (15/17). LTHT recruited 100% of those invited (7/7); an average of 1 patient every 2 months over 14 months. GSTT recruited 80% (8/10); approximately 1 patient a month over 9 months. The attrition rate (discontinued/recruited) was 27% (4/15). Reasons for withdrawal included ill health (3 participants) and availability (1 participant).

Seven participants were allocated to Group Int (intervention first) and 8 participants were allocated to Group Con (control first). Baseline characteristics are shown in Table 2. The average age was 63 years and 73% of participants were male. All participants had facial defects resulting from head and neck cancer, and the average time since treatment was 9 years. Facial prostheses were on average 17 months old; the majority

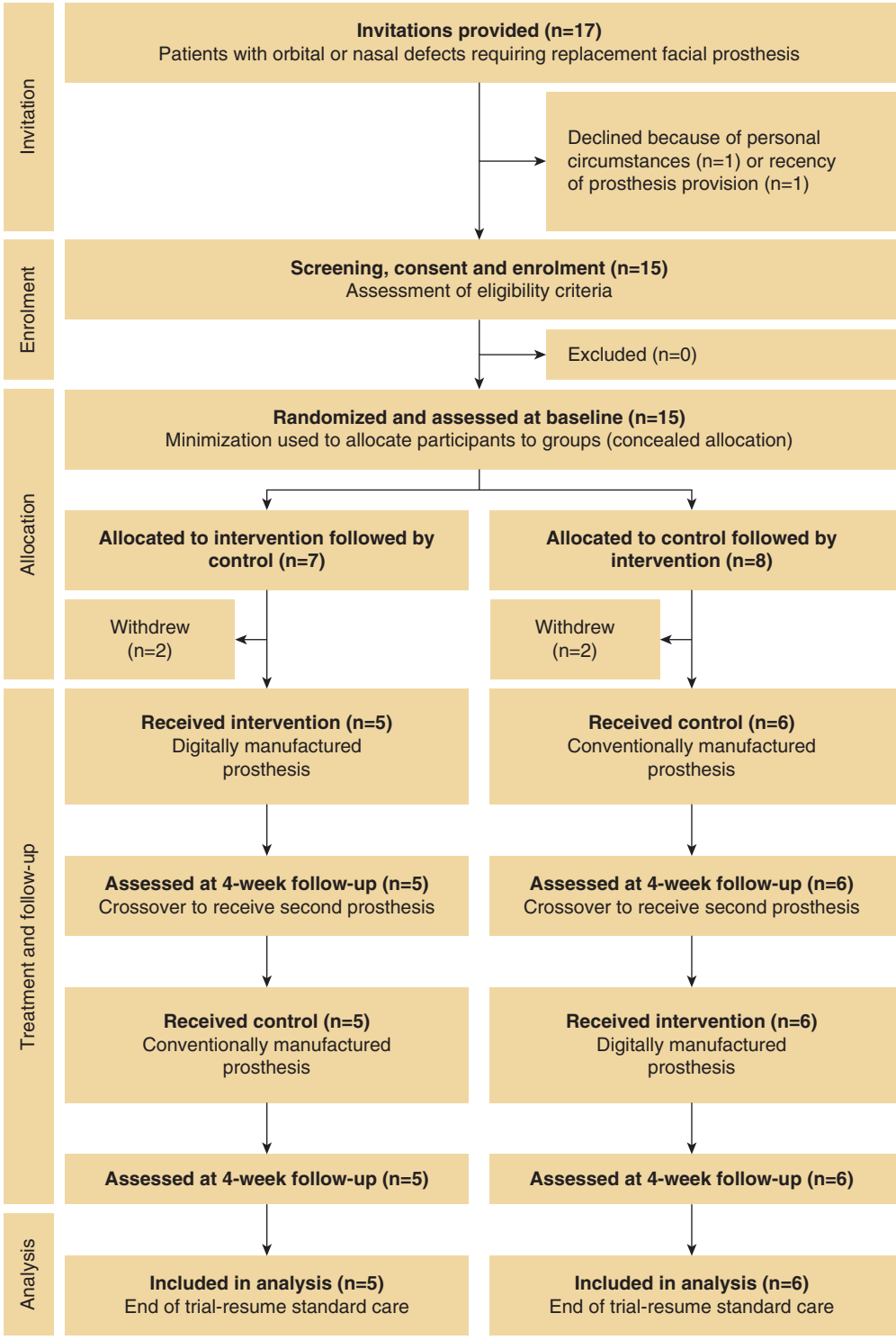

Figure 2. Consolidated Standards of Reporting Trials (CONSORT) flow diagram.

were implant-retained, restored the orbit, and were in a satisfactory condition with minor improvements possible. Group Con had longer times since surgery, were less likely to have had radiotherapy, and had fewer prostheses in a poor condition.

Figures 3 and 4 show examples of the prostheses. Only data from participants who completed the study (n=11) were included in the analysis of the outcome measures for a definitive RCT. Forty-five percent of participants preferred the intervention prosthesis, 27%

Table 2. Baseline characteristics

Demographic Factor		Group Int (n=7)	Group Con (n=8)	Overall (n=15)
Patient factors				
Age (years)	Mean (SD)	65 (12)	62 (14)	63 (13)
Sex (male or female)	Male (%)	71	75	73
Ethnicity	White (%)	100	100	100
Site (GSTT or LTHT)	GSTT (%)	29	75	53
Smoking status	Nonsmoker (%)	29	25	27
	Current (%)	14	25	20
	Ex smoker (%)	57	50	53
Current alcohol consumption (yes or no)	Yes (%)	71	75	73
Etiologic factors				
Etiology	Oncology (%)	100	100	100
Time since surgery (years)	Mean (SD)	7 (6)	11 (11)	9 (9)
Previous radiotherapy (yes or no)	Yes (%)	86	75	80
Prosthetic factors				
Defect type	Nasal (%)	29	38*	33
	Orbital (%)	71*	50	60
	Combined (%)	0	13	7
Prosthesis condition**	Good (%)	0	0	0
	Satisfactory (%)	57	75	67
	Poor (%)	43	25	33
Health of soft tissues***	Good (%)	43	88	67
	Satisfactory (%)	57	13	33
	Poor (%)	0	0	0
Retention method	Adhesive (%)	29	25	27
	Implant (%)	57	63	60
	Other**** (%)	14	13	13
Prosthesis age (months)	Mean (SD)	15 (12)	18 (17)	17 (14)
Baseline questionnaires				
TOMCP–27 (%)	Mean (SD)	62 (32)	64 (19)	63 (25)
EQ–5D-5L index	Mean (SD)	0.68 (0.12)	0.76 (0.29)	0.73 (0.22)
EQ–5D-5L VAS	Mean (SD)	63 (20)	67 (20)	65 (20)
SF–6D R2 index	Mean (SD)	0.68 (0.13)	0.70 (0.18)	0.69 (0.16)

Con, control first; GSTT, Guy's and St Thomas' NHS Foundation Trust; Int, intervention first; LTHT, Leeds Teaching Hospitals NHS Trust; SD, standard deviation; SF-6D, Short Form 6 Dimension; TOMCP, Toronto Outcome Measure for Craniofacial Prosthetics.

* Contains 1 participant with combined intraoral and extraoral defect.

** Good, prosthesis in good condition and no intervention required; Satisfactory, prosthesis in satisfactory condition and minor improvements possible; Poor, prosthesis in poor condition and major improvements possible.

*** Good, soft tissues in good condition and no intervention required; Satisfactory, soft tissues in satisfactory condition and minor intervention may be required for example hygiene advice; Poor, soft tissues in poor condition and intervention required.

**** Other retention method refers to magnets connected to obturator or acrylic resin substructure.

Figure 3. Example of orbital prostheses. A, Previous orbital prosthesis. B, Intervention facial prosthesis. C, Control facial prosthesis designed based on participant's previous prosthesis. Note prostheses correspond with wax patterns shown in Figure 1.

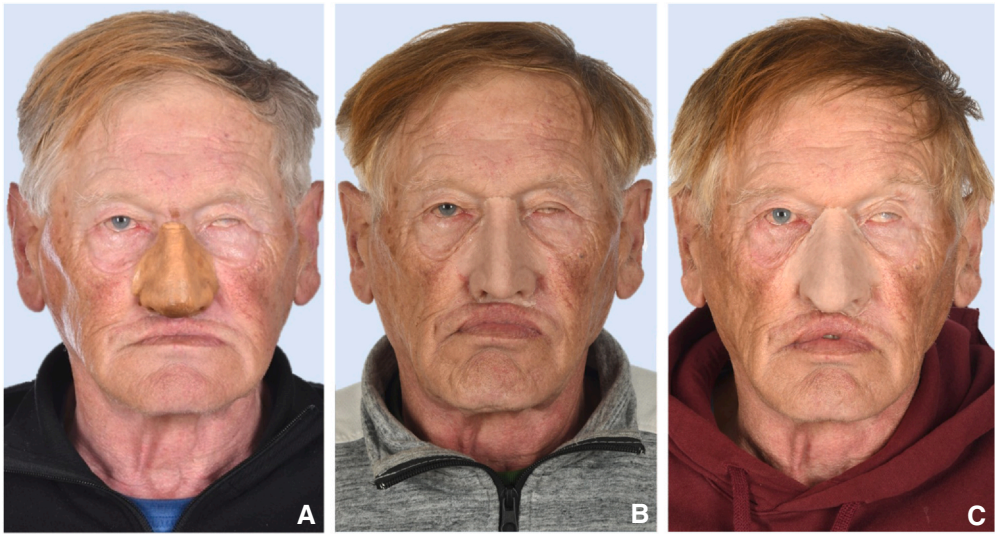

Figure 4. Example of nasal prostheses. A, Previous nasal prosthesis. B, Intervention facial prosthesis. Note intervention wax pattern had been modified by MPT to increase width of nose. C, Control facial prosthesis designed based on participant's previous prosthesis. MPT, maxillofacial prosthetist and technologist.

Table 3. Preference for prosthesis

		Prefers Control	
		Yes	**No**
Prefers intervention	Yes	27% (Equally satisfactory)	45% (Prefers intervention)
	No	27% (Prefers control)	0% (Equally unsatisfactory)

Table 4. Preference for manufacturing process

		Would Wait for Preferred Manufacturing Method	
		Yes	**No**
Preferred manufacturing method	Intervention (digital processes)	60%	30%
	Control (conventional processes)	0%	10%

preferred the control, and the remainder had no preference (Table 3). Ten participants took part in the qualitative substudy, and most preferred the digital over conventional manufacturing processes (90%) (Table 4). Sixty percent were willing to wait for their preferred process, whereas 40% would not wait and would proceed with the alternative. The average time participants were willing to wait for the digital manufacturing process was 3 months.

The HRQoL questionnaires had 100% completion rates and no missing data. The mean ±SD baseline TOMCP-27 score was 59 ±26% (Table 5). The change from baseline was 10 ±14% for the intervention and 13 ±16% for the control. All domain scores increased from baseline (Table 6). The control had higher scores for most domains, though the wide SDs suggest a large variance in the data. The mean ±SD EQ-5D-5L index score was 0.72 ±0.24 at baseline; the change from baseline was 0.07 ±0.12 for the intervention and 0.02 ±0.12 for the control (Table 7). Small changes from baseline were noted in the SF-12v2 derived scores (Table 8).

The mean operator time was 10 hours for the intervention and 9 hours for the control (Table 9). The mean equipment time was 50 hours for the intervention and 12 hours for the control. Mean total costs were similar at

Table 5. Descriptive statistics for TOMCP-27 presented as overall percentage scores at each time point and as change from baseline

TOMCP-27	Timepoint	Mean	SD	Median	Min	Max	95% CI
Overall percentage	Baseline	59	26	65	17	90	41, 76
	Control	72*	24	86	32	93	56, 88
	Intervention	68	24	73	38	98	52, 85
Change from baseline	Control	13	16	17	−15	38	2, 24
	Intervention	10*	14	15	−16	24	0, 19

SD, standard deviation; TOMCP, Toronto Outcome Measure for Craniofacial Prosthetics; 95% CI, 95% confidence intervals.

* Data deviate from normal distribution as indicated by Shapiro–Wilk test.

Table 6. Descriptive statistics for TOMCP-27 presented as percentage score for 9 domains and all domains

		Baseline		Control		Intervention	
Percentage	**Items**	**Mean**	**SD**	**Mean**	**SD**	**Mean**	**SD**
Clinical/technical							
Fit and retention	4	53	34	65	24	64	31
Comfort	1	53	34	68	29	70	28
Esthetics	3	41	24	72	19	65	24
Maintenance	1	70	37	83	32	89	17
Social/psychologic							
Body image	5	58	30	64	30	64	29
Social interactions/roles							
Leisure	4	64	32	75	32	67	31
Work/school	2	59	34	76	36	67	39
Mood	5	68	28	78	25	76	23
Sexuality	2	63	35	73	33	69	34
All domains							
Overall	27	59	26	72	24	68	24

SD, Standard Deviation; TOMCP, Toronto Outcome Measure for Craniofacial Prosthetics.

Table 7. Descriptive statistics for EQ-5D-5L index scores and VAS scores presented at each timepoint and as change from baseline

EQ-5D-5L	**Timepoint**	**Mean**	**SD**	**Median**	**Min**	**Max**	**95% CI**
EQ–5D-5L index	Baseline	0.72*	0.24	0.77	0.09	0.99	0.56, 0.89
	Control	0.74*	0.24	0.77	0.12	0.99	0.58, 0.90
	Intervention	0.79*	0.22	0.85	0.21	0.99	0.65, 0.94
Change in EQ–5D-5L index from baseline	Control	0.02	0.12	0.03	−0.15	0.27	−0.07, 0.10
	Intervention	0.07	0.12	0.05	−0.12	0.27	−0.01, 0.14
EQ–5D-5L VAS	Baseline	69	19	75	24	90	57, 82
	Control	74	17	75	43	100	63, 85
	Intervention	74	18	75	50	100	62, 86
Change in EQ–5D-5L VAS from baseline	Control	5	12	5	−20	19	−3, 13
	Intervention	5	15	10	−30	26	−5, 15

SD, standard deviation; VAS, visual analog scale; 95% CI, 95% confidence interval.

* Data deviate from normal distribution as indicated by Shapiro–Wilk test.

Table 8. Descriptive statistics for SF-12v2 presented as PCS score, MCS score, and SF-6D R2 utility index score at each timepoint and as change from baseline

SF-12-v2	**Timepoint**	**Mean**	**SD**	**Median**	**Min**	**Max**	**95% CI**
PCS score	Baseline	45.10	8.81	45.84	30.74	62.20	39.18, 51.02
	Control	47.64	6.24	46.46	40.34	58.72	43.45, 51.83
	Intervention	48.08	7.77	50.32	33.99	60.07	42.86, 53.30
Change in PCS score from baseline	Control	2.54	9.18	2.48	−12.29	23.48	−3.63, 8.71
	Intervention	2.98	12.02	1.38	−23.41	24.83	−5.09, 11.05
MCS score	Baseline	46.68	13.64	52.91	18.61	60.32	37.52, 55.84
	Control	47.47	12.45	51.49	20.11	61.36	39.11, 55.84
	Intervention	46.63	13.03	46.45	19.88	64.44	37.88, 55.38
Change in MCS score from baseline	Control	0.80	4.41	2.24	−7.35	5.50	−2.17, 3.76
	Intervention	−0.05	6.69	1.27	−15.14	10.99	−4.55, 4.45
SF–6D R2 utility index score	Baseline	0.69	0.16	0.69	0.35	0.92	0.58, 0.79
	Control	0.72	0.16	0.66	0.48	1.00	0.61, 0.82
	Intervention	0.73	0.19	0.72	0.37	1.00	0.60, 0.85
Change in SF–6D R2 utility index score from baseline	Control	0.03	0.11	0.00	−0.15	0.23	−0.05, 0.10
	Intervention	0.04	0.08	0.05	−0.08	0.22	−0.02, 0.09

SD, standard deviation; SF-12v2, Short Form Health Survey version 2; PCS, Physical Component Summary; MCS, Mental Component Summary; SF-6, Short Form 6 Dimension; 95% CI, 95% confidence interval.

£1017 for the intervention and £1065 for the control (Table 10); the intervention had proportionally lower consumable costs but greater staff costs. Timing data were missing for 1 intervention review and the manufacture of 3 sets of ocular components for orbital prostheses. These ocular components were made with photographic techniques, and the timing data were not shared for reasons of intellectual property.

Twelve adverse events occurred that were unrelated to study treatment (Table 11). Two adverse reactions related to the intervention facial prostheses. One participant reported scratching their cheek when removing their prosthesis and another had symptoms of candidiasis; both resolved with self-care advice. Three serious adverse events unrelated to study treatment were reported. All prostheses were deemed suitable for participants to wear upon study completion. Three protocol deviations related to trial schedule compliance (Table 12).[38] No issues were reported relating to minimization, intervention delivery, or masking.

Table 9. Mean (SD) time taken in minutes during manufacturing of intervention and control prostheses

	Control		Intervention	
Stage	**Operator**	**Equipment**	**Operator**	**Equipment**
Data acquisition*	17 (10)	0 (0)	14 (9)	0 (0)
Make definitive cast	16 (7)	35 (14)	69 (24)	1792 (920)
Ocular component*	63 (26)	0 (0)	63 (26)	0 (0)
Ocular component	91 (55)	181 (66)	91 (55)	181 (66)
Make wax pattern	103 (69)	18 (19)	100 (18)	560 (300)
Wax try in*	77 (114)	0 (0)	80 (85)	0 (0)
Adjust wax pattern	79 (67)	5 (10)	103 (59)	8 (13)
Color match*	52 (29)	0 (0)	52 (29)	0 (0)
Make silicone prosthesis	79 (30)	554 (890)	81 (32)	554 (890)
Fit*	45 (37)	0 (0)	40 (40)	0 (0)
Review*	11 (13)	0 (0)	7 (4)	0 (0)
Total (All stages)	550 (256)	694 (870)	614 (239)	2996 (1061)

SD, standard deviation.

Note: 2 prostheses made in tandem during same clinical visits. Asterisk indicates clinical visit (rather than laboratory stage). n=11 except for ocular components for orbital prostheses stage (n=5) and review of intervention stage (n=10).

Table 10. Mean (SD) costs in British Pound Sterling (£) for manufacturing of intervention and control prostheses

	Control			Intervention		
Stage	**Materials**	**Staff**	**Total**	**Materials**	**Staff**	**Total**
Data acquisition*	193 (193)	30 (18)	223 (206)	100 (133)	24 (16)	123 (142)
Make definitive cast	70 (89)	18 (8)	88 (92)	91 (80)	54 (19)	145 (93)
Ocular component*	3 (7)	110 (46)	113 (43)	3 (7)	110 (46)	113 (43)
Ocular component	6 (8)	104 (63)	110 (64)	6 (8)	104 (63)	110 (64)
Make wax pattern	26 (61)	118 (78)	144 (101)	43 (63)	79 (14)	121 (68)
Wax try in*	0 (1)	134 (198)	134 (198)	0 (0)	139 (149)	139 (149)
Adjust wax pattern	0 (0)	90 (76)	90 (76)	0 (0)	117 (67)	117 (67)
Color match*	6 (4)	90 (51)	96 (53)	6 (4)	90 (51)	96 (53)
Make silicone prosthesis	0 (0)	91 (35)	91 (35)	0 (0)	92 (36)	92 (36)
Fit*	0 (0)	79 (65)	79 (65)	0 (0)	70 (70)	70 (70)
Review*	0 (0)	19 (22)	19 (22)	0 (0)	12 (7)	12 (7)
Total (All)	299 (280)	766 (400)	1065 (607)	244 (207)	773 (370)	1017 (481)

SD, standard deviation.

Note: 2 prostheses made in tandem during same clinical visits. Asterisk indicates clinical visit (rather than laboratory stage). n=11 except for ocular components for orbital prostheses stage (n=5) and review of intervention stage (n=10).

Table 11. Adverse events and adverse reactions

Type	Total	Description
Adverse event	12	6 swellings or infections in head and neck region 4 illnesses, frailty or fevers 2 basal cell carcinomas in head and neck region
Adverse reaction	2	1 scratched cheek 1 candidiasis
Serious adverse event	3	1 lower gastrointestinal tract squamous cell carcinoma 1 metastatic prostate cancer 1 progressive interstitial lung disease
Serious adverse reaction	0	N/A
Suspected unexpected serious adverse reaction	0	N/A
Total number	17	N/A

DISCUSSION

The results support the study hypothesis that a definitive RCT of the clinical and cost effectiveness of digital manufacturing of facial prostheses would be feasible to deliver. With a recruitment rate of 88% and attrition rate of 27%, the prespecified criteria for progression to a definitive RCT with remedial action were met.[38] The rates compared favorably with a crossover RCT of facial prosthesis materials which enrolled 34% of those screened (42/124) and had a 33% attrition rate (14/42).[42] The high recruitment may be because of co-design with patient and public involvement, a careful approach to prescreening, or the altruistic motivations of patients with a history of cancer.

While a laboratory study had been conducted,[51] the authors had not conducted a clinical investigation of this CAD-CAM approach previously and any trouble-shooting time was included in the analysis. MPTs were able to input into the CAD process, though this was often undertaken by the principal investigator (T.C.) at the remote site. The MPTs fed back that they would have preferred greater input at the CAD stage, which may have helped reduce the time spent manually adjusting the wax pattern. Furthermore, newer technological developments such as large scale or demographically specific 3D morphable models and landmark fitting techniques may help improve the CAD output further.[57,59] With the learning experience from this early clinical research, more efficient processes, lower costs, and improved outcomes may be achievable.

Table 12. Protocol deviations

Component	Description	Actions Taken
Collection of outcome measures	One participant attended review of their first prosthesis 2 weeks beyond maximum timepoint specified in protocol. Participant canceled appointment and experienced difficulties in rescheduling appointment because of patient and staff availability.	Reinforced importance of collecting data within time windows and reminded research team that protocol allows collection of questionnaires over phone to prevent data timepoints from being missed.
Cross-over	One participant took their second prosthesis home and found it interfered with their glasses. Because participant was going on holiday and had limited time, research site agreed participant could return to wearing their first prosthesis and refit second prosthesis subsequently.	Acted in patients' best interests to postpone crossover to second prosthesis. Additional resource use questionnaire completed to capture time and costs of second fitting of prosthesis.
Post treatment facial scan	Facial scans obtained after each prosthesis delivered as record of treatment provided. One scan not obtained because of technical difficulties on day.	Site purchased newer scanner which could be used for post treatment facial scan.

Compared with published RCTs which explored specific aspects of facial prosthesis manufacture or materials,[16,42] this feasibility RCT sought to evaluate the clinical application of digital technology more broadly across 3D facial scanning and CAD-CAM. This study has begun to evaluate digital technology from different perspectives through qualitative inquiry into patients' experiences and collecting data for early health technology assessment. The study was conducted and presented according to reporting guidelines to improve transparency and reproducibility, and the findings should help in the design of a definitive RCT.

Seven MPTs were involved with varying experience and clinical approaches. The lack of masking of MPTs could be a source of bias in a definitive RCT if they had different attitudes toward digital technology.[60,61] To minimize this risk, a masked MPT could quality assure the prostheses, though this may add logistical or resource implications. Furthermore, resources were captured with a detailed recording system, which may have increased the burden and risk of measurement error. Early health technology assessment should explore whether resource use is a key driver of cost effectiveness to inform resource use valuation in a definitive RCT.[77]

Anderson et al[64] reported higher TOMCP-52 scores in a crossover RCT with median (quartile) values for silicone prostheses of 91 (70–95) and chlorinated polyethylene elastomer prostheses of 80 (59–89). Faris et al[24] presented utility values derived by using standard gamble and time trade off methods. Their values for facial prosthetic rehabilitation (0.80 ±0.23 or 0.82 ±0.20) were similar to the EQ-5D-5L index values seen for the intervention.[24] However, their values for nasal defects (0.74 ±0.24) may be overestimated as they are similar to the baseline values in this study for patients with previous prostheses.[24]

The sample size calculation for a definitive RCT should be based on anticipated effect sizes for participant preference or HRQoL to ensure sufficient power. Because of the small sample size of this study, the effect sizes were surrounded by uncertainty, which will impact the sample size estimates.[41] Leveraging data from previous and future studies may help guide the sample size calculation, or an internal pilot design could use early observations in a sample size review.[43] To ensure a sufficient sample size can be achieved, the inclusion criteria could be extended to other etiologic factors or prosthesis types (such as trauma or auricular prostheses). Observational studies may help explore how technological developments such as specific ear morphable models could be used in the workflow to widen the eligibility criteria.

CONCLUSIONS

Based on the findings of this clinical study, the following conclusions were drawn:

1. The recruitment and attrition rates indicated a definitive RCT would be feasible to deliver; some modifications to study design could minimize sources of bias and reduce attrition.
2. Early data were positive in relation to participant preference, HRQoL, and healthcare costs associated with digitally manufactured facial prostheses.
3. Minor protocol deviations arose relating to trial schedule compliance, but no issues were reported relating to minimization, intervention delivery, or masking.
4. Further qualitative and health economic analysis should be conducted to explore patients' lived experience and the drivers of cost effectiveness to inform future studies.

PATIENT CONSENT

Written informed consent to participate was obtained from all participants. Consent to use facial images in publications was obtained.

DATA STATEMENT

The data associated with this article are available from the University of Leeds at https://doi.org/10.5518/1679.

APPENDIX A. SUPPORTING INFORMATION

Supplemental data associated with this article can be found in the online version at doi:10.1016/j.prosdent.2025.03.002.

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