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Ph.D. értekezések

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KÖNIG JÁNOS

Fogorvostudományi kutatások

című program

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ADVANCING TREATMENT POSSIBILITIES IN ORO-MAXILLO-FACIAL REHABILITATION

Ph.D. Thesis

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"The man with a new idea is a crank...

until the idea succeeds."

Mark Twain

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1. List of abbreviations

CD	completely dentate
CE	completely edentulous
EORTC	European Organization for Research and Treatment of Cancer
EORTC HN35	EORTC Head Neck 35-item Questionnaire
EORTC QLQ-C30	EORTC Quality-of-life Questionnaire of Cancer Patients
GRADE	Grading of Recommendations, Assessment, Development, and Evaluations
HAD, HADS	Hospital Anxiety and Depression Scale
ILD	interlandmark distance
MD	mean difference
MDR	Medical Device Regulation
PE	partially edentulous
PICO	population, intervention, control, outcome
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
PROMs	patient-reported outcomes
PROSPERO	International Prospective Register of Systematic Reviews
QoL	quality-of-life
QUADAS-2	Quality Assessment tool for Diagnostic Accuracy Studies 2nd version
SMD	standardized mean difference
UW-QoL	University of Washington Quality-of-Life questionnaire

2. Student profile

Vision and mission statement, specific goals

My vision is that the field of maxillofacial prosthodontics will become more evidence-based. Currently, the improvisatory nature of the treatments is heavily influencing the outcomes that would eventually improve or deteriorate the lives of patients.

My mission is to establish a team at our Department whose members continuously work to reach this vision.

My specific goals include the investigation of the accuracy of scanners capable of digitizing a human face, as well as the assessment of outcomes regarding various kinds of rehabilitation in patients after maxillectomy.

Scientometrics

Table 1. Scientometrics of the Candidate (accessed on January 20th, 2025

Number of all publications:	8
Cumulative IF:	10.7
Av IF/publication:	1.34
Ranking (Sci Mago):	D1: 3, misc.: 5
Number of publications related to the subject of the thesis:	2
Cumulative IF:	7.5
Av IF/publication:	3.75
Ranking (Sci Mago):	D1: 2
Number of citations on Google Scholar:	9
Number of citations on MTMT (independent):	0
H-index:	1

Future plans

Over the next years, I plan to continue providing patient care, as I am trusted by multiple centers that directly refer patients to me. This trust is a significant asset, and I am committed to using this opportunity to advance scientific trials. A dedicated team of five dental students has been assembled over the last two years to provide the human resources required to orchestrate future projects.

3. Summary of the PhD

The field of maxillofacial prosthodontics is poised for significant advancement, with growing recognition of its importance and an increasing number of patients seeking treatment at specialized centers. This necessitates the adoption of streamlined, evidence-based rehabilitation processes to ensure effective and efficient care.

One of the key challenges hindering the accessibility of facial prostheses is the limited number of trained professionals and the high costs associated with technical fabrication. These barriers can be addressed by embracing digital advancements, which have the potential to simplify processes, reduce costs, and broaden access to care.

In contrast, for patients requiring rehabilitation following maxillectomy, healthcare providers face a complex dilemma: determining whether the optimal outcome can be achieved through prosthetic solutions or surgical interventions. This decision underscores the need for a nuanced, patient-centered approach in this specialized domain of rehabilitation.

Our analyses revealed that while optical scanning shows promise, current evidence is insufficient to confirm its widespread applicability due to variability in results across studies. Similarly, comparing rehabilitation modalities for maxillectomy patients identified no conclusive superiority of one method over another, underscoring the need for further high-quality research.

In conclusion, these findings highlight the untapped potential of digital innovations in prosthodontics while emphasizing the necessity for further studies to validate their clinical effectiveness. These insights contribute to advancing personalized care in maxillofacial rehabilitation and lay the groundwork for future research.

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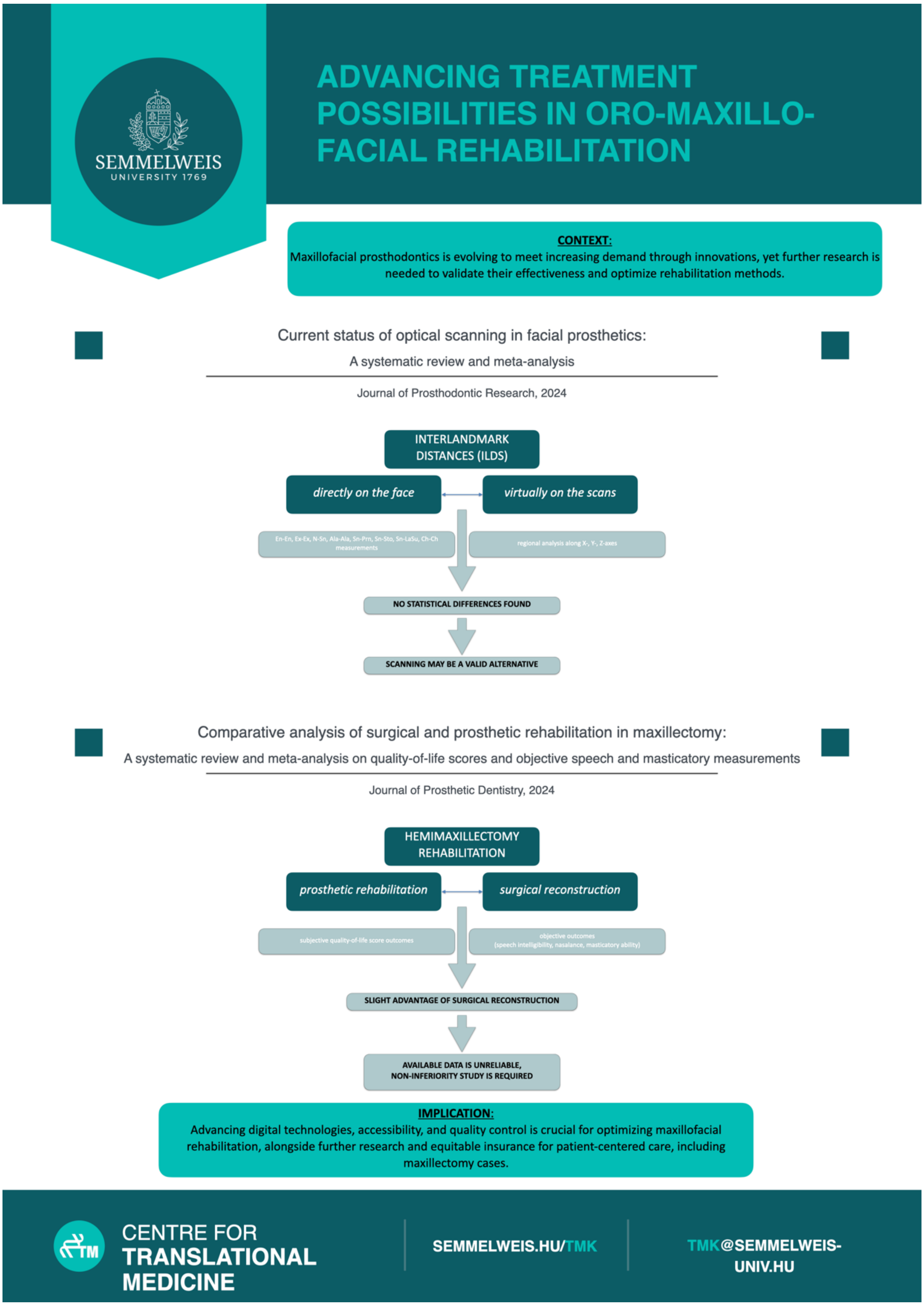
4. Graphical abstract



5. Introduction

5.1 Overview of the topic

5.1.1. What are the topics?

We investigate the possibilities on scanning a face contactless for creating prosthetic appliances. We also studied the prognosis of quality of life in patients with post-maxillectomy defects whether prosthetic or surgical reconstruction provides the better-functioning outcome.

5.1.2. What are the problems to solve?

Creating life-like facial prosthetics is difficult, partly because of capturing the positive-likeness of the prosthesis-bearing tissues. The low number of personnel, centric distribution of patient care facilities are the reason of inaccessibility. Another question in the field, how maxillectomy patients should be rehabilitated to achieve the highest possible postoperative quality of life. One must choose surgical over prosthetic reconstruction methods. The choice is still controversial, no hard evidence suggest clear indication.

5.1.3. What are the importance of the topics?

5.1.3.1. Facial defects

Globally, over 650 000 people develop head and neck cancer annually, resulting in the death of 330 000 individuals (1). Patients with a tumor in the maxillofacial region often find themselves in a vulnerable situation after cancer ablation: the defect is surgically unrepairable using conventional interventions (2). Unrestored facial defects can lead to stigmatization, social isolation, and severe psychological issues. The number of patients requiring facial prostheses is increasing (3). Due to the high costs, complex technicality, and unavailability of skilled caregivers (4), proper care is inaccessible for most people in need.

5.1.3.2. Oroantral and oronasal defects

The occurrence of oral cancer is a major global burden, with an estimated 377 713 new patients a year (5). As the prevalence of these cancers grows, the allocation of more resources in healthcare for effective treatment and, crucially, the rehabilitation of patients is urgently needed (5). The prevalence of maxillary sinus cancer is approximately 0.5 to 1 (6), and minor salivary gland tumors 0.16 to 0.4 per 100 000 people annually (7). Surgical resection is the primary and most effective treatment, but it can result in the patient being unable to speak, masticate, and swallow because of the communication created between the nasal and oral cavities (8). Surgical excision may also be necessary for benign tumors, traumatic injuries, or mucormycosis affecting the maxilla (9).

5.1.4. What would be the impact of our research results?

At first sight, technological advancements have even narrower accessibility. However, according to the "trickle-down effect," this is the initial step of any advancement (10).

Providing evidence-based insights into the comparative benefits of prosthetic and surgical reconstruction of maxillectomy defects would help clinicians make informed decisions and ensure that patients receive the most effective rehabilitation strategy. The need must be highlighted for broader accessibility to high-quality care, potentially influencing healthcare policy and resource allocation (11).

5.2. Understanding the complexity of rehabilitation plays a key role in the management of maxillofacial patients

5.2.1. Contactless imaging and digital planning

The reconstruction of extraoral facial abnormalities, known as anaplastology, differs significantly from traditional prosthodontic procedures. Simultaneously, the arsenal and production techniques are founded on prosthodontic principles. Maxillofacial prosthodontics is progressively adopting digital technologies, albeit at a slower rate than other disciplines (12). The existing craft-based fabrication techniques are inefficient, costly, and necessitate highly skilled and experienced technicians (13). The lack of a quality control standard complicates the assessment of treatment efficacy, hence predominantly depending on the acceptability of the prosthesis (14).

The emerging challenges can be addressed by a team with expertise (15), but this prolongs working hours and expenses with unpredictable outcomes (16). Utilizing digital technologies can enhance certain maxillofacial prosthodontic operations, improving the fit and positioning of prostheses with superior edge quality (17). Additionally, a computerized tool would enhance process efficiency by aligning the prosthesis shade with the skin tone (18). Digital workflows facilitate the efficient fabrication of symmetry and the precise molding of prostheses to conform to the patient's facial structure (19). Minimizing the duration and, consequently, the expense of prosthesis fabrication is a significant factor, given that prostheses must be periodically reconstructed for the same patients every few years (20).

5.2.2. Choosing the most appropriate postoperative rehabilitation

Choosing the mean of rehabilitation is a critical decision best made preoperatively with a multidisciplinary team, including prosthodontists. Prosthetic rehabilitation, despite challenges such as removability, retention, and aesthetics, offers a cost-effective (21), expedient solution while allowing surgeons clear access to monitor the surgical site. Failure to plan effectively can result in suboptimal outcomes, making early involvement of prosthodontists essential to tailoring a rehabilitation strategy that considers factors like patient age, defect size, and overall health (22).

While smaller defects often benefit from surgical closure and larger ones may necessitate prosthetic solutions, a one-size-fits-all approach is rarely suitable. General guidelines may provide a foundation, but decisions must be patient-specific, incorporating individual needs, economic considerations, and the complexity of the defect. Developing evidence-based algorithms that balance these factors can offer a structured yet flexible framework to optimize rehabilitation outcomes.

6. Objectives

6.1. Study I

No specialized hardware or optimized software for face prostheses exists. Industrial scanners and their associated software are occasionally employed to scan human faces, but thus far, no device has been validated for this purpose. Studies reporting on the application of digital technologies in this field often fail to mention the accuracy of the digital models of faces. Conversely, studies reporting on the accuracy of scanning systems often conclude that the scanner in question accurately reproduces the dimensions of the face. Nevertheless, the investigations did not take into account facial prosthetics. In our systematic review and meta-analysis, we assessed the precision of digital scanning technologies by comparing interlandmark distances (ILDs) measured directly (comparator) and virtually on the facial surface (intervention) of volunteers (population). We aimed to examine the precision of different scanning methods. Furthermore, we attempted to examine the level of accuracy of scanners across various facial regions along many axes within a 3D coordinate framework.

6.2. Study II

The rehabilitation of patients following maxillectomy necessitates a collaborative effort among specialist healthcare professionals, including otolaryngologists, head and neck surgeons, plastic surgeons, oral surgeons, and prosthodontists. In light of the increase in maxillectomy defect surgeries in the last decade, it is crucial to develop a customized algorithm for the rehabilitation of each patient.

This systematic analysis aimed to assess the subjective and objective effects of prosthetic interventions and surgical reconstruction alternatives for rehabilitating patients who underwent maxillectomy. The null hypotheses state that no differences would exist in quality of life, speech, or masticatory efficiency between the two therapies.

7. Methods

The systematic reviews and meta-analyses were performed in accordance with the PRISMA 2020 guidelines (23), following the instructions of the Cochrane Handbook. The study protocol was registered with PROSPERO (registration number of Study I: CRD42021282584, Study II: CRD42022334908), with adherence to its guidelines.

7.1. Literature search and eligibility criteria

We performed a systematic literature search in five databases (MEDLINE via PubMed, CENTRAL [The Cochrane Central Register of Controlled Trials], Embase, Scopus, and Web of Science) in Study I, and four medical databases (MEDLINE, CENTRAL, EMBASE, and Web of Science) in Study II. The original publications list the search dates and queries (24, 25).

In Study I, studies reporting on human volunteers or live patients with or without facial deformity (Population). The distance between anthropometrical landmarks was used to indicate accuracy: the ILDs are measured on the virtual facial models made with any non-contact scanning technology (Index test, “Intervention”), and directly on the subjects’ faces (Reference standard, “Comparator”). The deviation from the comparator in various ILDs was the desired outcome, confirming the accuracy of the virtual models (Outcome). Different scanning technologies were handled in subgroups. There were no restrictions regarding language or the time of publication. Studies measuring facial deformity in patients were included, while cadavers or inanimate objects were excluded.

In Study II, the PICO format was used for eligible studies P: human patients who underwent surgical ablation of the maxilla that resulted in an open palatomaxillary defect. Defects originating from congenital causes were excluded. I: prosthetic restoration of the palatomaxillary defect, using either surgical or definitive obturators. C: surgical reconstruction using any flap or graft. Surgical restoration of oro-antral or oronasal communication after tooth extraction was excluded. O: both objective outcomes and subjective outcomes specifically in the form of patient-reported outcome measures (PROMs) and quality-of-life (QoL) questionnaires. No restrictions were placed on the time of publication or language. Experimental trials (randomized or nonrandomized controlled trials) and observational studies were included. Case-control studies and case reports were excluded.

7.2. Study selection and data collection

We utilized EndNote X9 (Clarivate Analytics, Philadelphia, PA, USA) for the selection of articles. Two independent writers evaluated the papers individually for the title, abstract, and complete text, with discrepancies addressed by a third author.

Two authors separately extracted data into a previously established Excel spreadsheet (Office 365, Microsoft, Redmond, WA, USA), while a third reviewer adjudicated the differences.

The following data were collected from each eligible article in Study I: first author, year of publication, number of subjects involved, nasolabial morphology of the involved subjects, age of the subjects, scanning technology, aspect of view, interlandmark distance, region, orientation, mean, and standard deviation. If the data were not presented in the article, it was excluded because of data insufficiency. Twelve authors were approached through an email directed to the corresponding author, inquiring about their willingness to submit data for the study; however, no responses were received. In Study II: first author, year of publication, study design, number of participants, age, sex ratio, maxillary dental status, defect size, number of patients who received radiotherapy, and which outcome measures were used by the authors and the outcome values. If multiple studies used the same compatible outcome, they were included in the quantitative analysis.

7.3. Quality assessment

The risk of bias assessment was carried out separately by two reviewers using the QUADAS-2 tool (26) in Study I. According to the instruction manual of the tool, the signaling questions were tailored to accommodate the review's focus by adding a question (In the "Reference test" domain: "Were the examiners blinded to the results?") and omitting another one (In the "Index test" domain: "If a threshold was used, was it prespecified?"). The latter question was not applicable to any of the included studies, therefore we removed it. The same authors performed the risk of bias assessment using the ROB-2 for randomized (27) and the ROBINS-I tools for observational studies in Studíy II (28). A third author was involved if disagreements arose.

Egger's test and funnel plots were applied to report and visualize publication bias if there were a minimum of ten studies involved in the analysis(29).

7.4. Data synthesis and analysis

All statistical analyses were performed using a statistical software program (R version 4.2.0; https://www.R-project.org/), supplemented with the "meta" package (Schwarzer G. General Package for Meta-Analysis Available at: https://cran.r-project.org/web/packages/meta/meta.pdf). Throughout the analyses, the recommendations of Harrer et al. (30) were followed. As all the selected outcomes were continuous, the differences between the means of the intervention and control groups were used to measure the effect size. Random-effects meta-analyses were conducted on all of the datasets because there was anticipated significant heterogeneity between studies.

In Study I, the mean differences (MDs) and their confidence interval were calculated for the most frequently measured ILDs. In the analysis regarding the comparison of regions and technologies, the standardized mean differences (SMDs) and their confidence intervals were calculated. Since the different ILDs had different magnitudes, comparing the differences without any adjustments would result in distorted calculations. The MDs were transformed into SMDs to make them comparable. To keep track of the direction of the dimensional change, a negative sign denotes shrinkage and a positive sign denotes magnification or expansion. Subgroup analyses were also conducted based on the three different major scanning technologies, assuming that the subgroups share a common τ^2 value, as we did not anticipate a difference in the between-study heterogeneity. To assess the difference between the subgroups, Cochran's Q test was used between the subgroups (30).

In Study II, based on a previous systematic review and meta-analysis (31), the populations and reported outcomes were expected to exhibit significant heterogeneity. Consequently, the populations were stratified. The defect size was characterized as either small or large (Figure 1).

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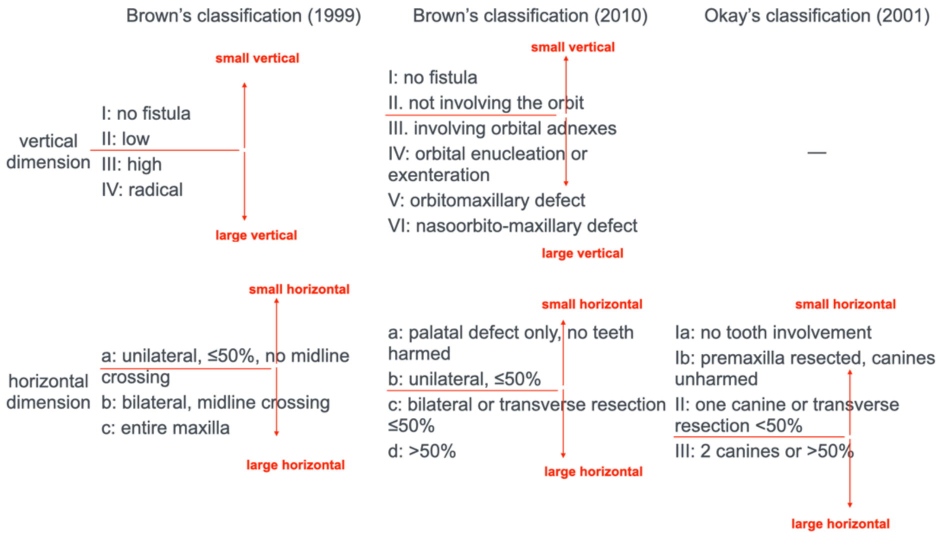

Figure 1. Defect classification based on vertical and horizontal extents using three validated systems (25)

The defect size was measured with the Brown 1999 (32) and 2010 (33) classifications for vertical and horizontal or the Okay 2010 classification (34) for horizontal dimensions. For simplicity, an arbitrary threshold for size was established: a defect was considered vertically small if it did not reach the nasal cavity and horizontally small if it was unilateral without crossing the midline. The degree of maxillary edentulism was categorized as completely dentate (CD), partially edentulous (PE), or completely edentulous (CE).

A linear transformation of QoL ratings was executed to ensure comparability, as outlined in the EORTC QLQ-C30 instruction manual, which indicates that a difference of 20 points or more may denote a clinically significant difference (35) citing Osoba et al. (36) Only the domains of the same aspect of life were assessed with different questionnaires (if the questions and the answers were sufficiently similar). Lower scores indicated improved quality of life, and the values should be on a scale from 1 to 100. The methodological heterogeneity of the masticatory indicators rendered this modification inapplicable.

As all the selected outcomes were continuous, the differences between the means of the intervention and control groups were used to measure the effect size. As previously mentioned, all comparable QoL questionnaire-based outcomes were adjusted to a 1 to 100 scale, and these transformed variables were used to calculate mean differences. Mean differences with 95% confidence intervals, were established for quality-of-life scores of different domains, speech intelligibility, and nasalance scores. In several circumstances, the application of mean differences was inappropriate due to uncertainty over the consistency of the method used or its slight modifications employed to evaluate the identical end variable. In these instances (masticatory indices), the standardized mean differences (SMD, Hedges G) were computed with 95% confidence intervals.

In all situations, random-effects meta-analyses were performed by using an inverse variance weighting method. As for both large and small study numbers, the Hartung-Knapp adjustment provides a more reliable estimate, this adjustment was used for each analysis.(37, 38) Heterogeneity was assessed by using Higgins and Thompson I^2 statistics, and $\tau 2$ using the restricted maximum-likelihood estimator with the Q profile method.(39)

Subgroup analysis was performed using the different QoL measurements. For this subgroup analysis, a mixed-effects model was used, assuming the subgroups shared a common $\tau 2$ value. To assess the difference between the subgroups, a Cochrane Q test was used (α=.05).

The certainty of the evidence was evaluated by using the GradePro tool.(40)

8. Results

8.1. Search and selection

8.1.1. Study I

In total, 5090 studies were identified by our systematic search. Before the screening, 1367 duplicates were removed. During the screening, 3688 articles were excluded by titles and abstracts. The level of agreement was κ = 0.79. For full-text screening, nine articles were not retrievable. The remaining 26 full texts were carefully read by the authors. Sixteen articles were excluded from the quantitative synthesis for the following reasons: 13 for insufficient data (41-53), one for lacking caliper measurements as the comparator (54), one article had a different aim (55), and one article only presented data mixed with scanning of non-living structures (56). The value of Cohen's kappa was κ = 1.00. **Figure 2**. shows the flowchart of selection.

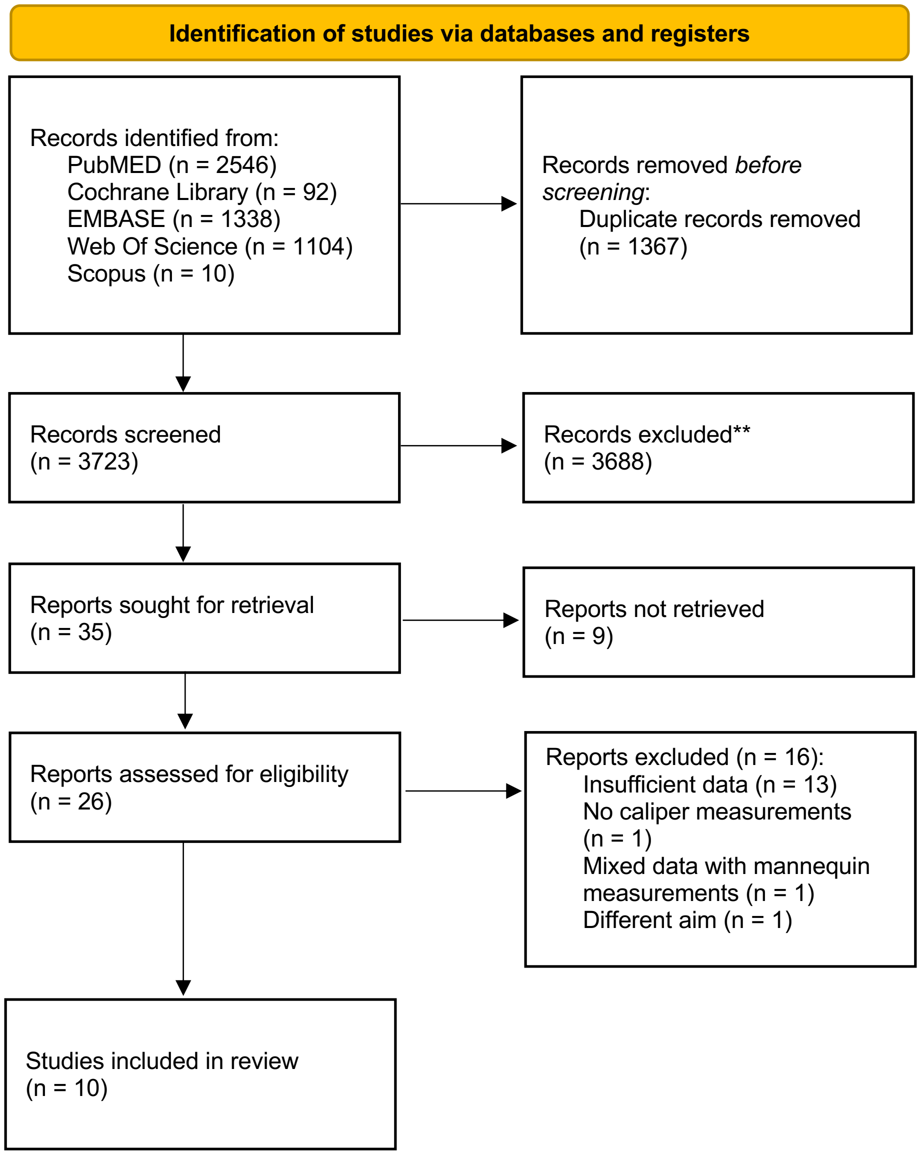

Figure 2. PRISMA 2020 flowchart representing study selection process of Study I (24)

The baseline characteristics of the enrolled studies are detailed in Table 2.

Table 2. Characteristics of included studies in Study I (24)

Study	Year	No. of patients	Presence of defects?	Prior landmark marking	No. of interland-mark distances	Technology	Device	Software	Comparator measurements	Attention to avoid recall/ observer bias
Aung et al.	1995	30	none, healthy patients	no	41	Laser scanning	not stated	not stated	not stated	none
Ayaz et al.	2020	50	none	yes	21	Laser scanning Stereophotogrammetry	Planmeca ProFace Vectra H1	Proplan CMF Vectra Mirror	digital sliding caliper	two observers took the measure-ments independently
Chen et al.	2015	10 volun-teers	none, healthy ears	yes with a fine-point ink marker	13	Stereophotogrammetry	3dMDface System	3dMD Vultus software	sliding caliper (Metrology Pro-Instrument with a 0.01 mm/150mm accuracy)	covered LED display of the digital sliding caliper, recorded by a third person
Chong et al.	2021	20 young volun-teers	none, healthy volunteers	no	21	Structured light	Apple iPad (Face ID-capable) with MeiXuan app	Geomagic Wrap 2017	digital caliper to the nearest 0.01 mm	two people took the measurements independently
de Sá Gomez et al.	2019	15 adults	none	yes, with liquid eyeliner	14	Structured light	Artec Eva	Artec Studio	digital caliper with a 0.1 mm resolution (Agro)	-

Dinda-roglu et al.	2016	80 white partici-pants	none	yes	11	Stereophotogrammetry	3dMD flex system	3dMDpatient	digital caliper	direct measurements were taken on a different day to avoid interference, measurements taken in a randomized manner
Düppe et al.	2018	10 volun-teers	not stated	only the subnasale point was marked	20	Stereophotogrammetry	3dMD trio system	3dMDpatient	caliper with a digital display with an accuracy of 0.01mm	first, one rater performed the measurement twice, 7 days apart further measurement session was done for interrater and intrarater reliability
Ghod-dousi et al.	2007	6 female volun-teers	none	yes, with an eyeliner	14	Structured light	not stated	Visual Analysis Measurement (VAM) software	ruler	not applicable, accuracy analysis was only done on inanimate objects
Guo Y. and Hou X. et al.	2020	46 indivi-duals	none	no	24	Stereophotogrammetry	Vectra M3	Vectra Mirror®	sliding caliper	after photo capture of each subject, by a single observer
Guo et al.	2021	50 healthy volun-teers	none, healthy volunteers	no	8	Stereophotogrammetry	Vectra M3	Vectra Mirror®	sliding caliper	none
Jodeh et al.	2019	20 pediatric patients under-going minor surgery	normal nasolabial morphology	no	14	Stereophotogrammetry	Vectra H1	Vectra Mirror®	Castroviejo caliper and ruler	none

Kim A. et al.	2018	5 subjects	normal	yes	29	Stereophotogrammetry	Vectra M3 Vectra H1	Vectra Mirror®	150mm and 80mm digital calipers were used	two sets of measurement by two operators on each subject
Joe et al.	2012	9 subjects	none	yes with a washable marker	10	Laser scanning	Vivid9i	Rapidform XOR	spreading calipers	Measure-ments were collected in one set three times, by one observer, recorded by the subject
Li G et al.	2013	10 patients	unilateral cleft	no	12	Structured light	3DSS	Geomagic Studio 10.0	spreading and sliding caliper	Measure-ments by one person five times in two different sessions 72 hours apart
Liu J et al.	2020	40 volun-teers	none	no	none, mean areas of known objects were calculated	Stereophotogrammetry	Vectra M3	not stated	caliper with an accuracy of 0.05 mm	not stated
Liu S et al.	2019	12 comp-letely eden-tulous patients	none	yes	8	Stereophotogrammetry	6 Canon DSLR cameras	Meshlab	measuring caliper (Inox, Knuth Gmbh) precise to 0.01 mm	three set of measurements by two examiners
Naini et al.	2017	6 subjects	none	yes for direct anthropometry	14	Stereophotogrammetry	3dMD face system 4th gen.	3dMD Vultus	sliding, spreading calipers and measuring tape	single operator performed the measurement twice on each occasion (6 occasions in total, 1 week apart)

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Piedra-Cascón et al.	2020	10 comp-letely dentate patients	none	yes with adhesive stickers	6	Structured light	Face Camera Pro Bellus	Meshlab	FINO digital caliper with an accuracy of 0.01 mm	2*2 sets of measurements for each patient
Savol-delli et al.	2019	1 volun-teer	none	yes with dermographic pencil	11	Stereophotogrammetry	Vectra H1	Vectra Analysis Module (VAM)	sliding caliper with an accuracy of 0.01 mm	6 raters performed the measure-ments in random order
Ramieri et al.	2006	6 volun-teers (and a manne-quin)	none	yes	6	Laser scanning	Cyberware 3030RGB	Rapid Form 2004	manual anatomic caliper, unknown accuracy	not stated
Top-sakal et al.	2021	16 subjects	none	no	14	Structured light	iPhone X and Samsung Galaxy S7 Edge with Bellus3D app	digital-rhinoplasty.com web app	caliper or ruler, unknown accuracy	not stated
Oth-man et al.	2020	37 cleft patients	yes, repaired cleft lip or cleft lip and palate	yes, with a liquid eyeliner (15 out of 25)	19	Stereophotogrammetry	Vectra M5	Vectra Mirror®	sliding caliper (Pro-Max, Mitutoyo) to the nearest 0.01 mm	two sets of measurement with at least 15 min between them, by a single operator
Wein-berg et al.	2004	20 subjects	no obvious craniofacial dysmorphology	yes with a black, quick-drying liquid eyeliner (15 out of 17)	19	Structured light	Genex Rainbow 3D	3D Surgeon	digital calipers	twice by the first observer, once by the second observer; all measurement that shared the same landmark as endpoint

										were treated as separate entities
Wong et al.	2008	20 normal adults	none	yes with a sharpened eyeliner pencil, but only for the direct measurements	17	Stereophotogrammetry	3dMDface system	3dMDpatient	measuring calipers	a minimum of 24 hours elapsed between measurement sessions
Ye et al	2016	10 healthy volunteers	none	yes with stickers depicting a black circle with a white center by one person (14 out of 16)	21	Stereophotogrammetry Structured light	3dMDface system 3D CaMega, BWHX	Corresponding software	vernier caliper (with an accuracy of 0.01 mm)	all measure-ments were done three times

8.1.2. Study II

The systematic search identified 5383 studies, of which 3437 were assessed by title and abstract. The level of agreement was κ=0.92. Altogether 36 full-text studies were identified, and an attempt was made to retrieve and carefully evaluate them. Finally, 13 records were included in the quantitative synthesis of the review (Figure 3).

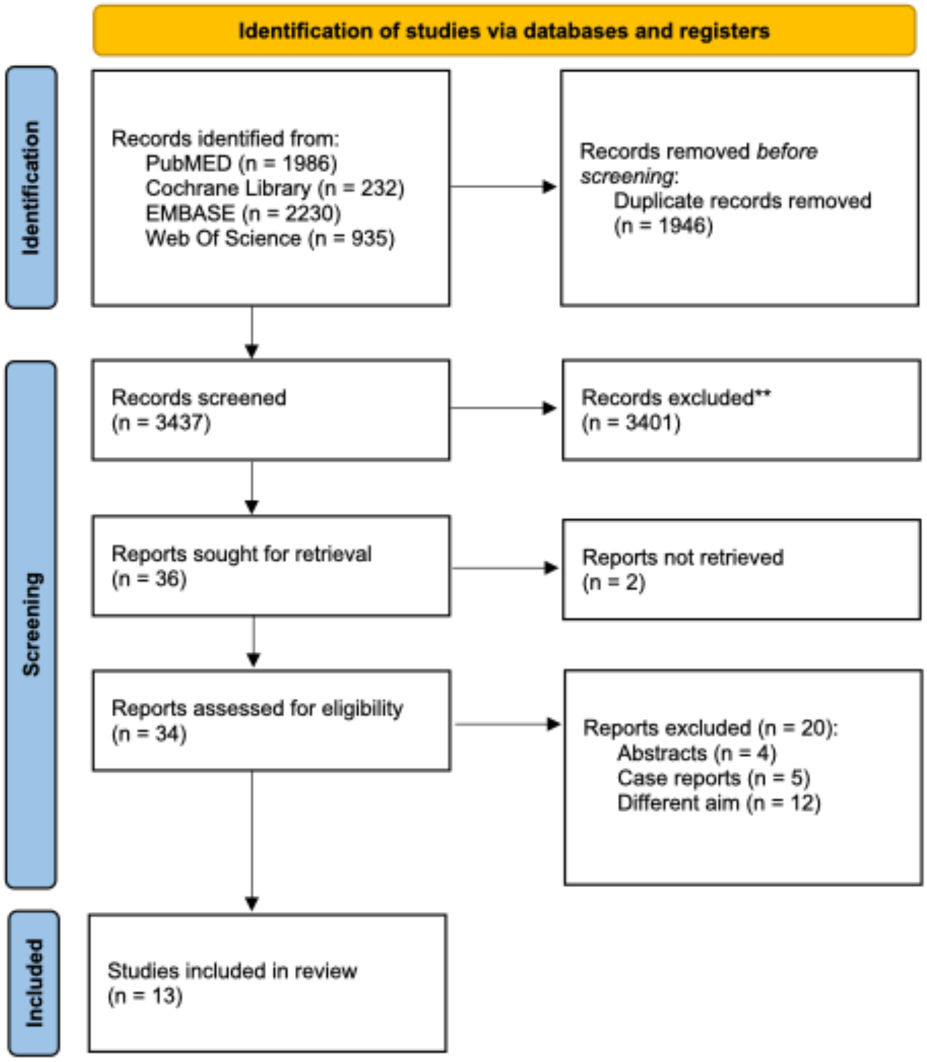


Figure 3. PRISMA 2020 flowchart representing study selection process of Study II (25)

The baseline characteristics of the analyses included are detailed in **Table 3**. The studies were published between 2003 and 2022. The included studies were cohort studies, with retrospective, (57-62) prospective, (63-67) or both directions of data collection. (68) The randomized controlled trial design was used by Aladashi et al. (69) The number of participants who underwent surgical reconstruction was 206, whereas 260 participants received prosthetic obturators. The sex ratio showed more male participants, but data were not available in all studies.(66) Not all studies(57, 59-62, 64, 66, 70) specified explicitly the edentulous state of the participants. The age of participants ranged widely, with the youngest being 22, and the oldest 88. The central tendency was for middle-aged participants. All the studies included investigated people with oncological disease.

Table 3. Basic characteristics of included studies in Study II (25)

Author	Year	Study design	Location	Group	GR (M:F)	Maxillary dental status CD	PE	CE	Defect size SV	SH	LV	LH	Age (years)	Radio-therapy	Outcomes
Aladashi et al.	2021	RCT	Cairo, Egypt	surg.	12/18	18	12	0	30	2	0	28	59 (11) [a]	0/10	OHrQoL (UW-QoL), masticatory function
				obt.	15/15	16	14	0	30	1	0	29	52.8 (13) [a]	0/10	
Buurman et al.	2020	pro	Edmonton, Canada	surg.	8/3	N/A			7	3	4	8	45.00 (14.28) [a]	3/11	MP, OHrQoL (OHIP overlapping questions)
			Maastricht, The Netherlands	obt.	7/2				9	1	0	8	63.78 (12.05) [a]	5/9	
de Groot et al.	2019	pro and retro	Edmonton, Canada	surg.	3/8	10	0	0	7	N/A	4	N/A	45.0 (14.3) [b]	3/11	MAI, bite force, MMO, OHrQoL (EORTC H&N35)
			Maastricht, The Netherlands	obt.	7/6	3	4	1	13	N/A	0	N/A	70.8 (13.6) [b]	5/13	
	2007	retro		surg.	1/1.4	N/A			9	10	1	0		N/A	nasalance

Eckardt et al.			Hannover, Germany	obt.					10	8	14	0	55.5 (27-83) yrs [b]		
Genden et al.	2003	pro	New York, USA	surg.	3/1	N/A			N/A				51.5 (18-69) [b]	N/A	mastication, SI, speech perception, nasality, nasal emission, nasometry, swallowing, donor site assessment
				obt.	2/2								42 (32-51) [b]		
Moreno et al.	2009	retro	Texas, USA	surg.	26/14	19	14	7	10	23	30	17	50.8 (9-88) [c]	31/40	speech evaluation (Matsui method)
				obt.	36/37	53	0	17+3	49	63	24	10	57.1 (16-88) [c]	50/73	
Narita et al.	2020	retro	Japan	surg.	5/8 (2/5)	mean number of RMT was 3.42 (among QoL respondants 4.07); surg: 2.86, obt.: 5.29			7	0	0	7	72.9 (71) [a]	N/A	OHrQoL (UW-QoL)
				obt.	11/14 (5/2)				7	0	0	7	73.6 (76.7) [a]		

Ohashi et al.	2021	retro	Japan	surg.	3/1	0	4	0	4	0	0	4	58.5 (41-71) [b]	N/A	articulatory function, mastication, swallowing
				obt.	3/5	0	8	0	8	8	0	0	59.5 (58-82) [b]		
Rieger et al.	2011	retro	Edmonton, Canada	surg.	9/7	N/A			N/A	13	9	3	56.0 (22-77) [b]	N/A	facial attractiveness measures, nasometry, aeromechanical speech measures, SI
				obt.	11/12					23	3	2	51.4 (22-79) [b]		
Rogers et al.	2003	retro	Liverpool, UK	surg.	11/18	N/A			12	9	5	7	66 (14) [a]	3/16	OHrQoL (UW-QoL, EORTC QLQ C30, EORTC H&N35, HAD, BSS), oral symptoms checklist, denture
				obt.	7/10				9	7	1	2	57 (8) [a]	1/10	

															satisfaction, OFS
Said et al.	2016	pro	Japan	surg.	16/3	0	18	1	N/A	7	N/A	12	65 (52-75) [d]	2/19	OHrQoL (GOHAI), food mixing ability, masticatory score
				obt.	10/9	0	17	2		13		6	65 (59- 79) [d]	6/19	
Sreeraj et al.	2017	pro	Kochi, India	surg.	N/A	N/A			10	N/A	0	N/A	N/A	N/A	mastication, swallowing
				obt.	N/A				10		0				
Wang et al.	2017	pro	Shanghai, China	surg.	12/8	0	15	5	N/A	16	N/A	4	45.6 (14.1) [a]	6/20	OFS, OHrQoL (EORTC H&N35), MHI
				obt.	11/7	0	14	4		14		4	56.2 (12.3) [a]	5/18	

8.2. Results of the synthesis

8.2.1 Study I

8.2.1.1.Scanning systems

Ten records were included in the quantitative synthesis of the review. The publication dates span from 2004 to 2021.

The population consisted of healthy adult individuals (volunteers) in 7 articles(71-76), young children undergoing minor surgery (77), cleft patients (78), and completely edentulous prosthodontic patients (79) in 1-1 article. The most frequently used scanning technology in the included articles is stereophotogrammetry (71, 73, 75-79). The structured light scanning systems were only utilized in three (72, 74, 76) while laser scanners were applied in one included article.

Landmark identification was a noted issue, three papers did not use prior landmark identification (72, 73, 77). The other seven have had some technique to mark the landmarks before scanning.

Most of the articles used a commercially available device with its corresponding software, which is dedicated to surface scanning, the authors of one article, however, utilized digital single-lens reflex cameras and manually stitched them together (79).

8.2.1.2.Difficulties mentioned in the articles

The common difficulties the authors mentioned are collected in

Table 4**.** The most common problems were hairline intrusion, distortions due to blinking, changed facial expressions, motion artifacts, ambient lighting, artifacts during stitching, and camera flash obscuring landmarks.

Table 4. Common difficulties mentioned in the articles about scanning (24)

Article	Technology	Device	Difficulties reported
Aung et al.	laser scanning	laser scanner developed by the Medical Physics Department	quite old study, but horizontal readings may be inacurrate due to the verticality of the laser beam
Ayaz et al.	stereophotogrammetry	Canfield Vectra H1	none stated
Ayaz et al.	laser scanning	Planmeca ProFace	laser scanning showed distortions around the eye region (blinking, facial expressions, longer capture time, chin support)
Chen et al.	stereophotogrammetry	3dMDface System	image artefacts by hairline intrusion
Chong et al.	structured light	Apple iPad (Face ID-capable) with MeiXuan app	The iPad's sensor is not as precise as stationary imaging devices; nose bridge partially blocks the light shining on the subnasale; spending too much time with measurement will increase facial movement
de Sá Gomez et al.	structured light	Artec Eva	landmark identification
Dindaroglu et al.	stereophotogrammetry	3dMDflex	landmark identification
Düppe et al.	stereophotogrammetry	3dMDtrio	landmark identification
Ghoddousi et al.	stereophotogrammetry	DSLRs with VAM software	large device, landmark identification (palpation, light reflection), short distances are inconsistently measureable,

Guo Y and Hou X et al.	stereophotogrammetry	Canfield Vectra M3	landmark identification
Guo et al.	stereophotogrammetry	Vectra M3	landmark identification
Jodeh et al.	stereophotogrammetry	Vectra H1	imaging perspective
Kim A et al.	stereophotogrammetry	Canfield Vectra H1 and M3	landmark identification, high price
Joe et al.	laser scanning	Vivid9i	ambient lighting, scanning protocol, insufficient contrast, compositing of individual scans (minimizing overlaps), facial expression can change during and between scans
Kim S et al.	structured light	Morpheus 3D	image merging (landmarks near the integration line were lost)
Li G et al.	structured light	3DSS-II	respiration influences the scans
Liu J et al.	stereophotogrammetry	Canfield Vectra M3	fixed-direction artefacts
Liu S et al.	stereophotogrammetry	6 Canon DSLR cameras	muscular movement at the angles of the mouths, localizing the same landmarks
Naini et al.	stereophotogrammetry	3dMDface system	landmark identification (hair obstructing tragion, darker complexion), subtle differences in facial expression (mainly in the area of the labial fissure)
Piedra-Cascón et al.	structured light	Face Camera Pro Bellus	artefacts caused by movement during capture
Savoldelli et al.	stereophotogrammetry	Canfield Vectra H1	landmark identification, artefacts during stitching, movement artefacts

Ramieri et al.	laser scanning	Cyberware 3030RGB	no repeatable relaxed expression can be achieved, sensitive for head positioning
Topsakal et al.	structured light	Apple iPhone (Face ID-capable) and Samsung Galaxy S7 Edge with Bellus3D app	improper capture of the 3D structures of the face or issues on the texture image
Othman et al.	stereophotogrammetry	Vectra M5	localizing landmarks, light reflections,
Weinberg et al.	structured light	Genex Rainbow 3D	if a single capture cannot cover the whole region, merging is an option, but introduces errors
Wong et al.	stereophotogrammetry	3dMDface System	inconsistent landmark identification, camera flash obscuring landmarks
Ye et al.	stereophotogrammetry	3dMDface system	landmark identification
Ye et al.	structured light	3D CaMega, BWHX	color information is not capturable

8.2.1.3. Comparison of trueness using indicator interlandmark distances in different regions

Eight interlandmark distances were analyzed. The comparison of virtual and direct measurements revealed the accuracy of virtual models. The accuracy of the model is essential to the entire process, as the final prosthesis can only be as precise. The I-squared test exhibited extremely low (0-27%) heterogeneity, which came from the homogenous population and the same methods of measurement: in the periorbital region, the distance between the endocanthion (0.43 mm; CI: -0.27; 1.14) and the exocanthion points (-0.54 mm; CI: -1.70; 0.62) (**Figure 4**); in the nasal region, the distance between the two alare points (0.46 mm; CI: -0.32; 1.24), the nasion-subnasale (-0.09 mm; CI: -1.19; 1.00) and the subnasale-pronasale distances (-0.43 mm; CI: -0.91; 0.06) (**Figure 5**); in the orolabial region, the subnasale-stomion (-0.27 mm; CI: -1.10; 0.56), the subnasale-labium superius

(-0.15 mm; CI: -0.79; 0.49), and the distance between the two cheilion points (0.43 mm; CI: -0.80; 1.65) (**Figure 6**). All of these differences lacked statistical significance. Nonetheless, each case's confidence intervals were narrower than those of the individual studies, indicating that the imprecisions that were present in the individual studies are eliminated when the populations of the articles are pooled.

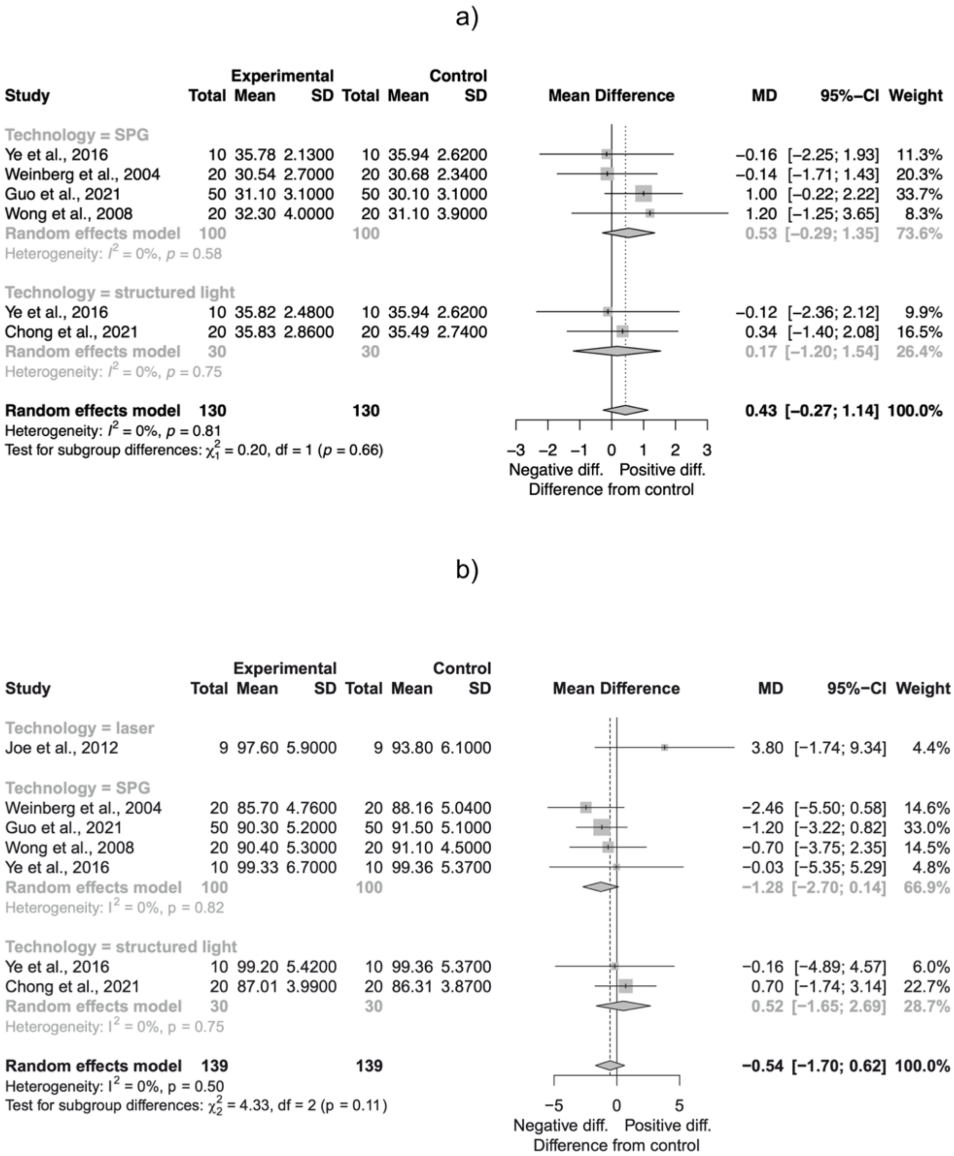
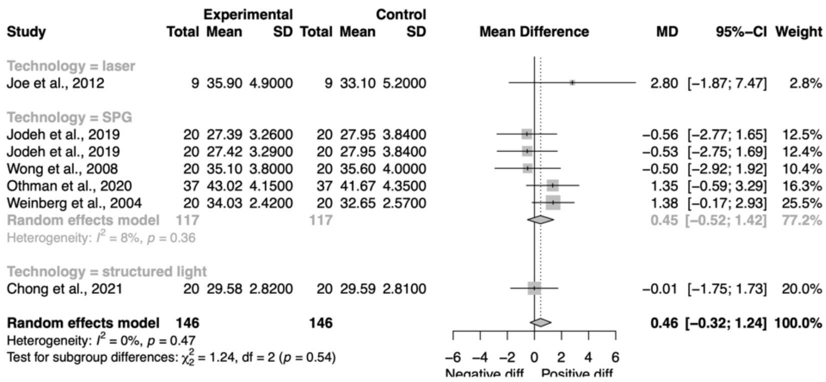


Figure 4. Accuracy of periorbital landmark distances (a) distance between endocanthions (b) distance between exocanthions. Subgroup analysis by scanning technologies.(24)

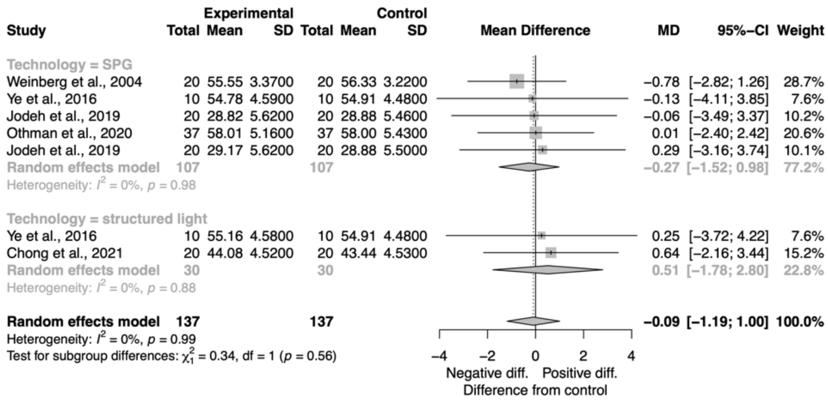
DOI:10.14753/SE.2025.3201

a)



N−Sn − nasal

b)



c)

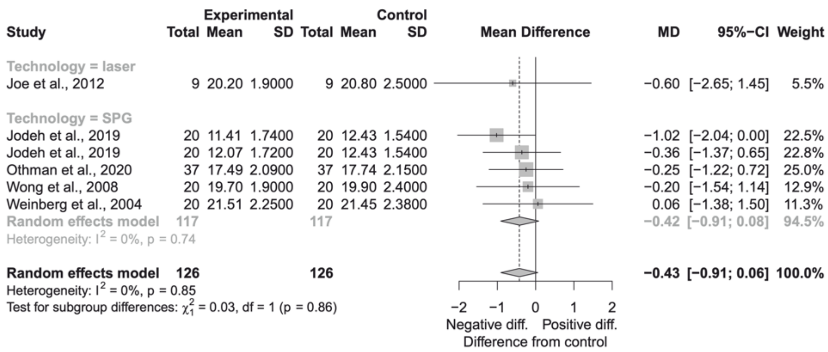
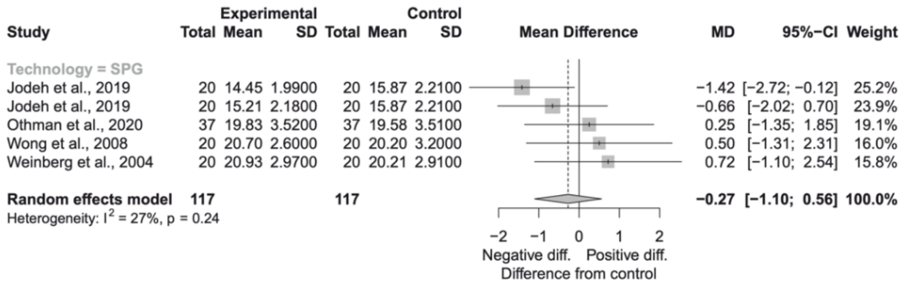


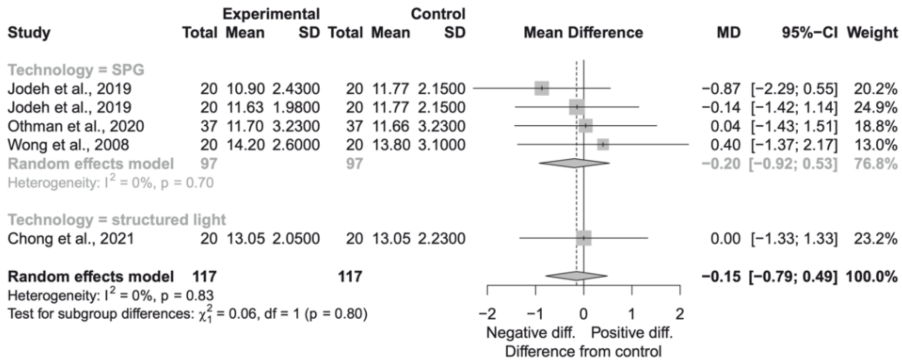
Figure 5. Accuracy of nasal interlandmark distances (a) distance between the alare points, (b) distance between the nasion and subnasale points, (c) distance between subnasale and pronasale. Subgroup analysis by scanning technologies. (24)

DOI:10.14753/SE.2025.3201

a)



b)



c)

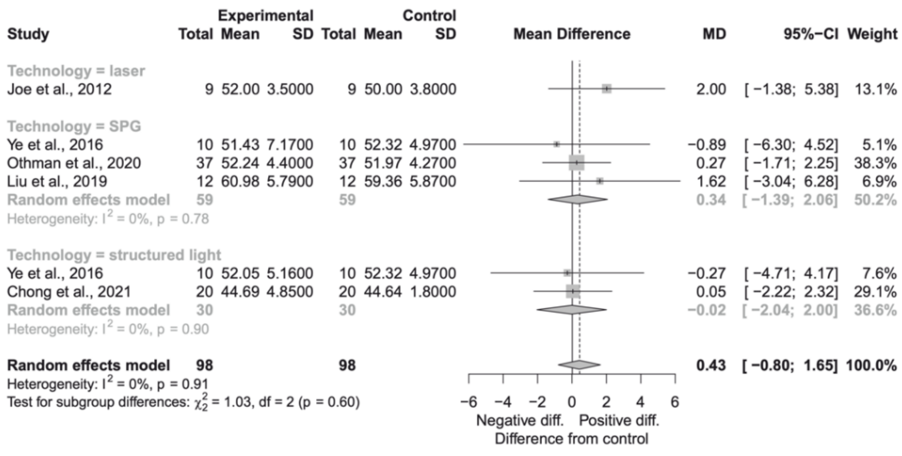


Figure 6. Accuracy of orolabial interlandmark distances (a) distance between subnasale and stomion, (b) distance between and subnasale and labium superius, (c) distance between the cheilions. Subgroup analysis by scanning technologies. (24)

8.3.1.4. Comparison of accuracy of different technologies along different main axes

The ILDs of the face were assigned to a certain region of the face (i.e., auricular, nasal, orolabial, and periorbital), one of the major axes in a Cartesian coordinate system (X-axis for width, Y-axis for depth, and the Z-axis for height). The data in the articles were subsequently categorized into 12 groups based on the region and the axis they represent. Only one paper was identified in the auricular region, and the measurements along the X- and Z-axes in the periorbital region were inadequate for a meta-analysis (see **Table 5**).

Table 5. Summary table of the results and included studies in the regional and dimensional analysis (24)

	interlandmark distances along the Y-axis	**interlandmark distances along the X-axis**	**interlandmark distances along the Z-axis**
orolabial region	SMD: -0.04 95% CI: -0.17 – 0.09 based on 8 articles	SMD: -0.09 95% CI: -0.27 – 0.10 based on 5 articles	SMD: 0.02 95% CI: -0.12 – 0.08 based on 8 articles
nasal region	SMD: 0.08 95% CI: -0.07 – 0.24 based on 8 articles	SMD: -0.01 95% CI: -0.16 – 0.13 based on 8 articles	SMD: -0.01 95% CI: -0.18 – 0.15 based on 5 articles
periorbital region	SMD: -0.03 95% CI: -0.16 – 0.10 based on 8 articles	2 articles	1 article
auricular region	1 article	1 article	1 article

Therefore, eight forest plots were constructed. The I-squared test also exhibits extremely low heterogeneity. Subgroup analyses were performed because of the different scanning technologies. The differences were not statistically significant in any of the subgroups. The effect size was expressed in SMDs because the magnitude of the different ILDs was different. The confidence intervals were also narrower than those of individual studies. Measurements in the nasal region are shown in **Figure 7**, along the X-axis, the effect size is -0.01 (CI: -0.16; 0.15), along the Y-axis, the effect size is 0.08 (CI: -0.07; 0.24), and along the Z-axis, the effect size is -0.01 (CI: -0.18; 0.15).

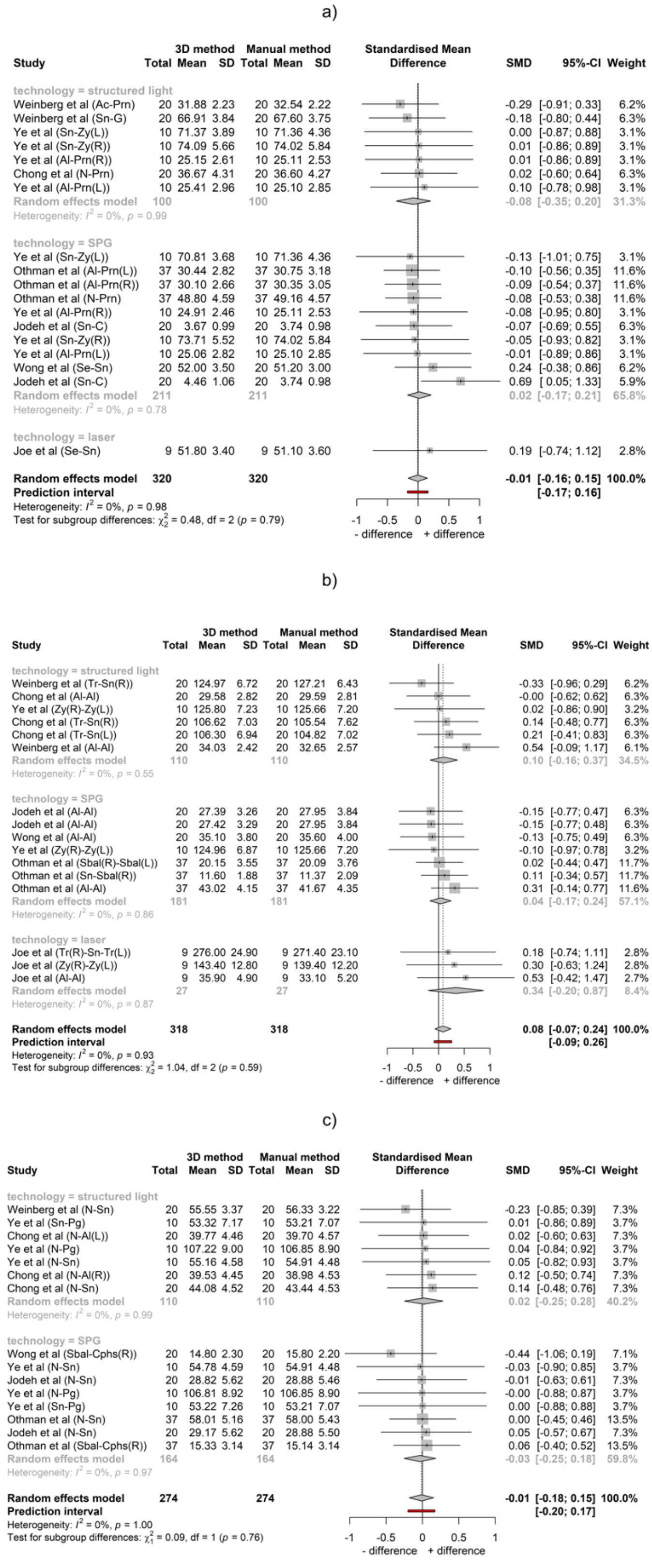


Figure 7. Standardized mean differences in the nasal region along the (a) X-axis, (b) Y-axis, and (c) Z-axis. Subgroup analysis by scanning technologies. (24)

The measurements in the orolabial region are shown in Figure S1. The effect size along the X-axis is -0.09 (CI: -0.27; 0.10), along the Y-axis, it is -0.04 (CI: -0.17; 0.08), and along the Z-axis, it is -0.01 (CI: -0.12; 0.08). The results in the periorbital region are shown in **Figure 8**; along the Y-axis, the effect size is -0.03 (CI: -0.16; 0.10). The calculations were done in the periorbital region along the X- and Z-axes, but these came from a few studies. The results were summarized in **Table 5**.

DOI:10.14753/SE.2025.3201

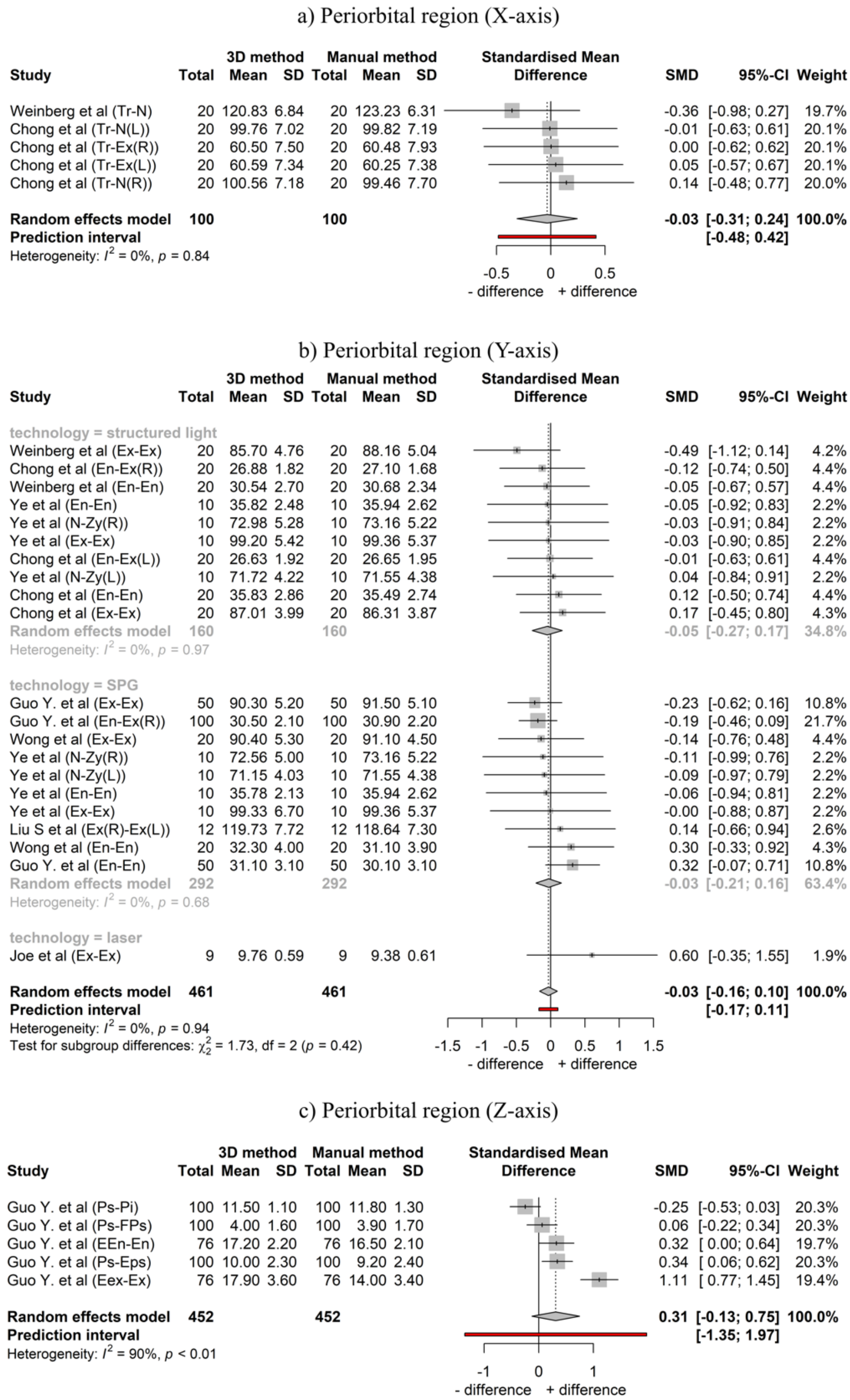


Figure 8. Standardized mean differences in the periorbital region along the X-axis (a), Y-axis (b), and Z-axis (c). Subgroup analysis by scanning technologies. (24)

DOI:10.14753/SE.2025.3201

8.2.2 Study II

8.2.2.1. Quality of life measurements

Three eligible studies contained information on the anxiety levels of patients. Rogers et al. (62) deployed the Hospital Anxiety Depression questionnaire (HAD), (80) whereas Aladashi et al. (69) and Narita et al. (59) used the fourth version of the University of Washington Quality of Life Questionnaire. (81) The pooled difference between the obturator and surgery groups was nonsignificant (MD=−18.99; CI: −55.54, 17.64) (Figure 9).

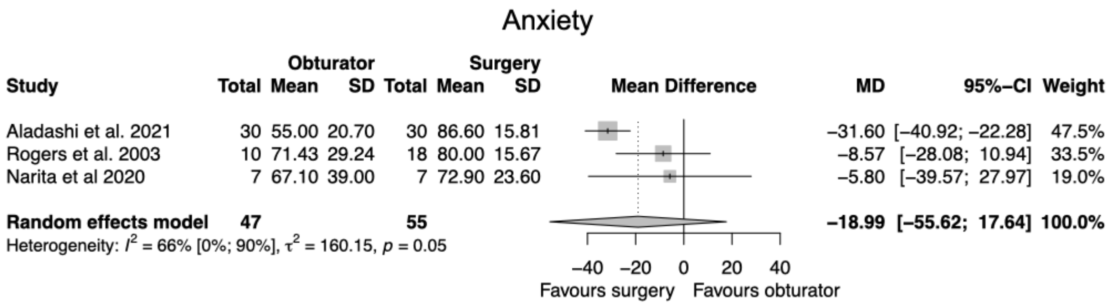


Figure 9. Forest plot of subjective measures on "anxiety" domains. The included RCT study showed statistically significant difference. The -31.60 point difference might be clinically relevant based on the interpretation manual of EORTC QLQ C30. (35)

Regarding pain, data from four articles were found to be suitable for the analysis. Aladashi et al. (69) and Narita et al. (59) used the University of Washington Quality of Life (UW-QoL) questionnaire, whereas de Groot et al. (68) and Wang et al. (67) used the European Organization for Research and Treatment of Cancer Head Neck 35 (EORTC HN35). The data presented by Wang et al. were calculated per item. Therefore, the average scores presented were included in the pooled results. Similarly, no significant difference was found between the two groups (MD=−5.19; CI: −18.59, 8.22) (Figure 10).

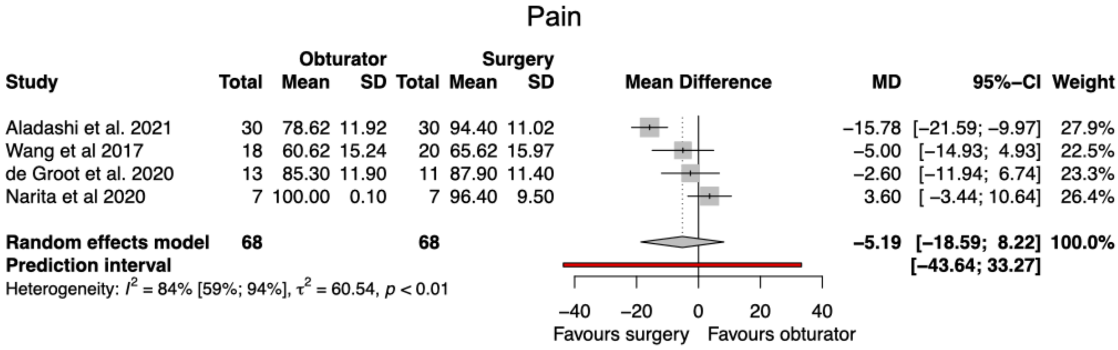


Figure 10. Forest plot of subjective measures on "pain perception" domains. With high heterogeneity there is no significant difference detected.

Three different outcome measures were identified to assess speech quality: nasalance and sentence and word intelligibility, both of which can be objectively measured, and the subjective speech self-perception. The subjective speech self-perception was measured with the UW-QoL by Aladashi et al., (69) Narita et al., (59) and Rogers et al. (62) and with the EORTC HN35 questionnaire by de Groot et al. (68) and Wang et al. (67) The pooled difference was nonsignificant between the groups (MD=−5.66; CI: −23.9, 12.58) (Figure 11). The only significantly different result was from Aladashi et al. who compared reconstruction with submental flaps to surgical obturators. The other findings are distributed along the null-effect line.

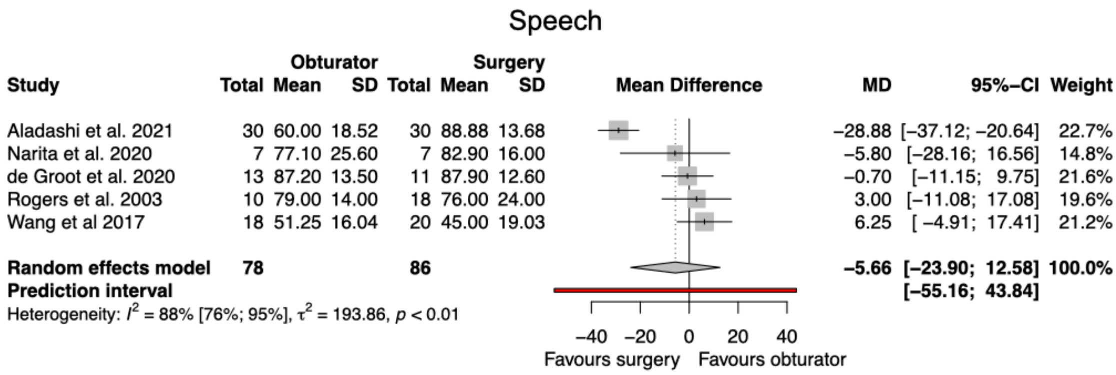


Figure 11. Forest plot of subjective measure on "perception of speech of self" domains. With high heterogeneity there is no significant difference detected.

Four articles were included in the analysis of swallowing. Aladashi et al. (69) and Rogers et al. (62) measured this domain with the UW QoL questionnaire, whereas de Groot et al. (68) and Wang et al. (67) used the EORTC HN35 questionnaire. The pooled results again showed no significant difference (MD=−12.05; CI: −45.27, 21.18) (Figure 12).

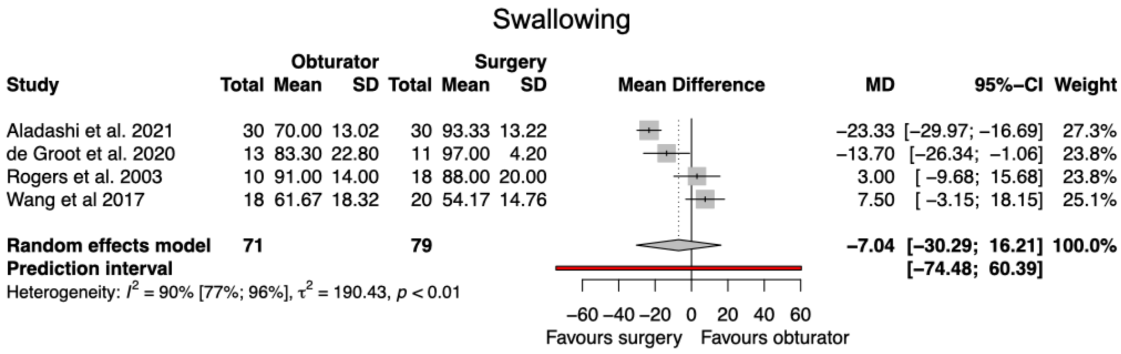


Figure 12. Forest plot of subjective measures on "perception of swallowing ability" domains. With very high heterogeneity there is no significant difference detected.

Aladashi et al., (69) Narita et al., (59) and Rogers et al. (62) reported on the comparison of the two patient groups with the UW-QoL questionnaire. The domains of “activity,” “appearance,” “chewing,” “pain,” “recreation,” “shoulder,” “speech,” and “swallowing” could be compared because of the differences between the first (63) and the fourth versions (59, 69) of the questionnaire. The difference in the domain “activity” was statistically significant, but, because the effect size was MD=1.92 (CI: 0.45, 3.40), this is compatible with no important effect. Differences for other domains were nonsignificant (Figure 13).

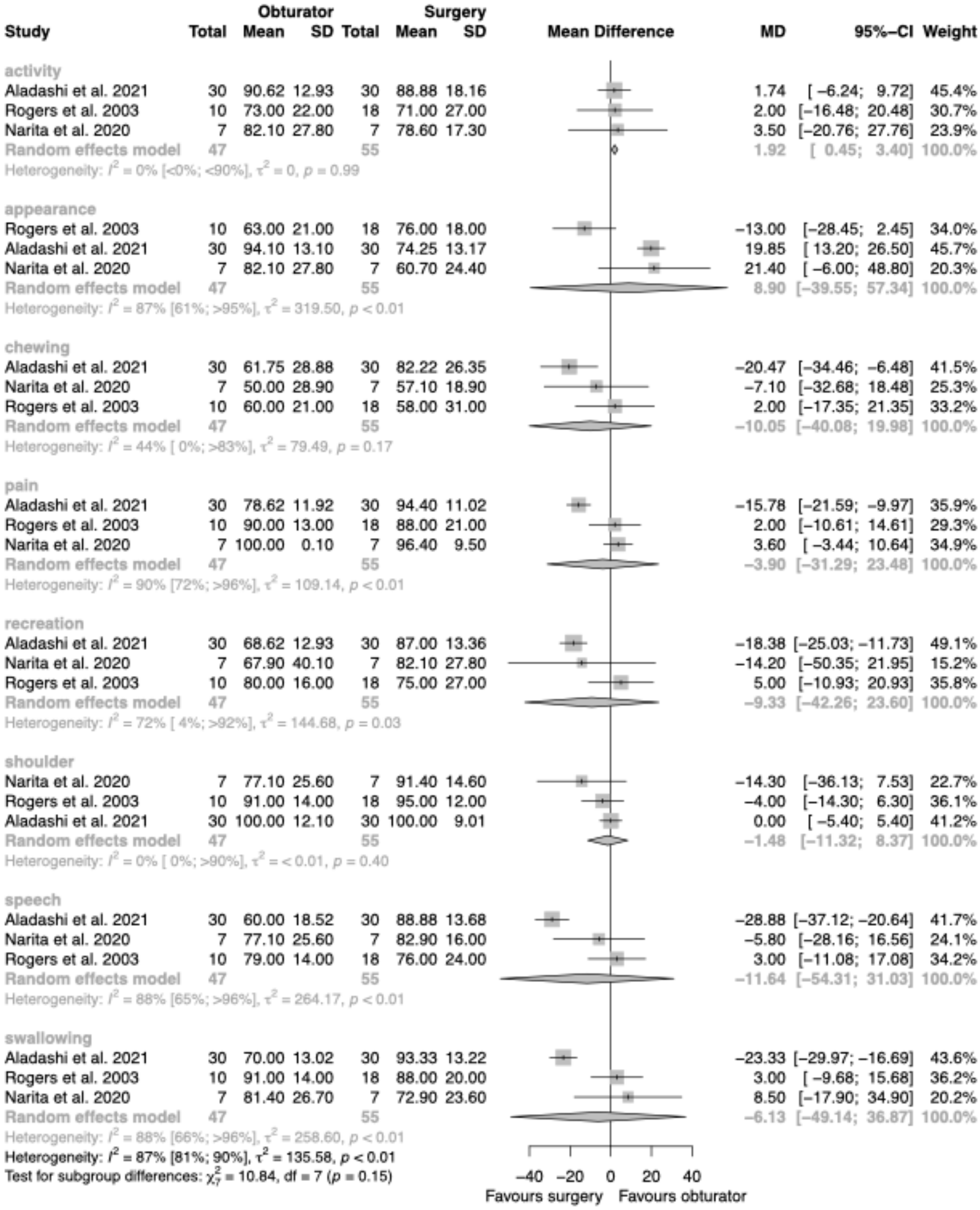


Figure 13. Forest plot of results of University of Washington Quality of Life Questionnaire. With high heterogeneity there is no significant difference detected on any domains.

8.2.2.2. Objective measurements

Two articles provided data for the speech intelligibility analysis. (61, 64) Rieger et al. (61) calculated word and sentence intelligibility separately. They were pooled together because of the similar nature of the measurement. The results exhibited almost no difference between the effectiveness of the two interventions (MD=−0.47; CI: −4.41,3.47) (Figure 14).

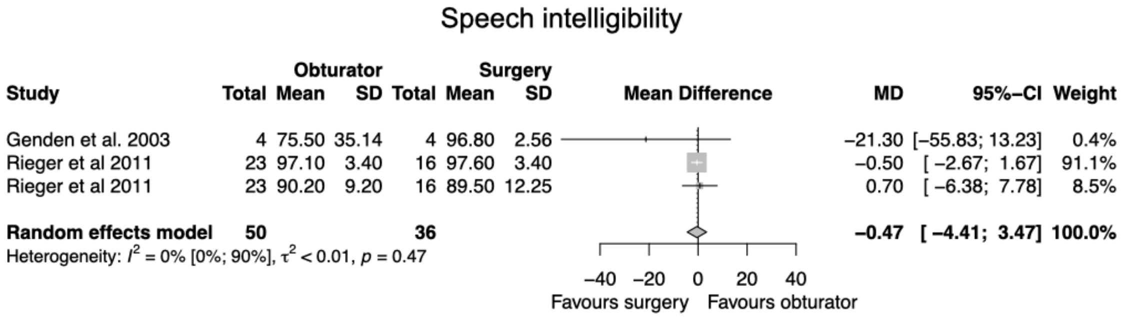


Figure 14. Forest plots of objective measures on speech intelligibility. With high heterogeneity there is no significant difference detected.

Three articles(57, 61, 64)provided data on nasalance.(82) No significant difference was found (MD=0.14; CI: −13.50, 13.78) (Figure 15).

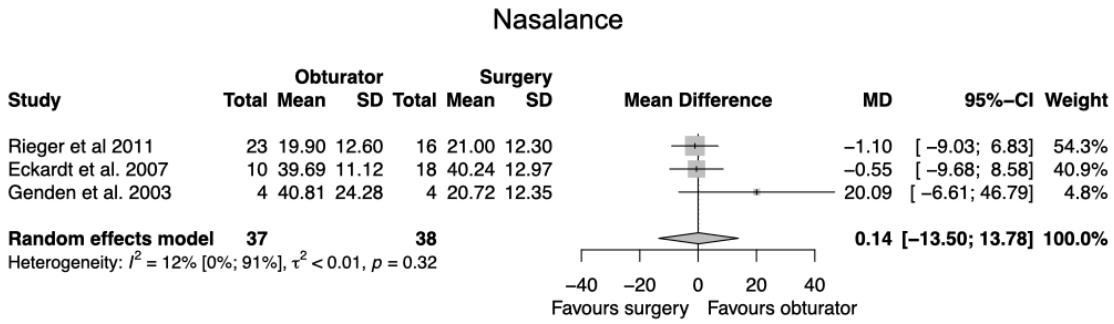


Figure 15. Forest plots of objective measures on nasalance. With high heterogeneity there is no significant difference detected.

Data from three eligible studies were used to assess masticatory ability.(64, 68, 70)These studies proposed objective measurements for the efficiency of mastication.(83) However, as the methodologies of these outcomes were quite different, pooled SMDs were calculated, which showed no difference between the study groups (SMD=−1.01; CI: −3.37, 1.35) (Figure 16).

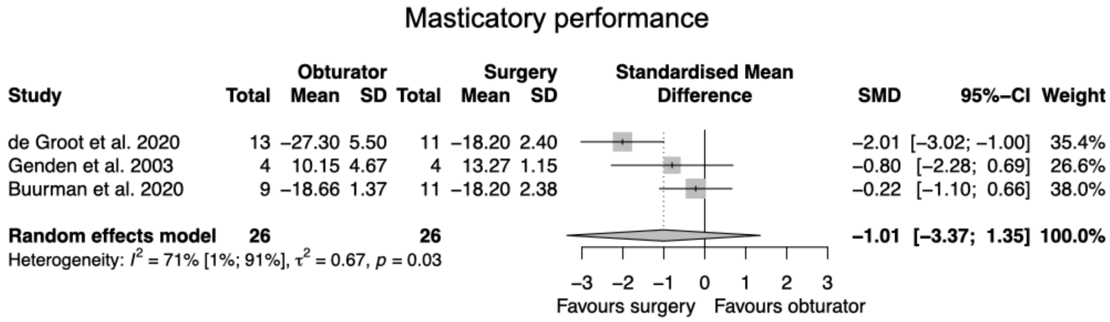


Figure 16. Forest plots of objective measures on masticatory ability. Based on the methodological heterogeneity the standardized mean differences were calculated.

8.2.2.3. Attempt to perform metaregression

Unfortunately, questions on the correlation between quality of life and radiotherapy, remaining dentition, defect size, and age could not be analyzed. The planned meta-regression was not feasible because of the low number of available studies.

8.3. Quality assessment

8.3.1. Study I

Although all of the included studies used the same methodology, this review does contain bias due to a number of factors. The patient selection posed no issue, as all participants were included in both the intervention and control groups, so all measurements were conducted on the same cohort of subjects. If an unsuccessful scan acquisition was mentioned, it was considered to have a high risk of bias (55). The application of the results was ambiguous as the studied populations were predominantly healthy, with one exception (50). Prior landmark identification is a process that reduces the likelihood of inconsistent ILD measurements between identical locations. The landmarks were not marked in ten studies(41, 44, 47, 50, 51, 54, 55, 72, 73, 77).

The distances were measured multiple times to minimize measurement errors. The possibility of prejudice exists if a single measurement of a distance is taken, potentially resulting in the subsequent measurement being rounded to the initial result. The attention to avoiding recall bias was mentioned in most of the articles (except two papers (73, 77)). To address this issue, sufficient time should pass before the next measurement (43, 47, 50, 51, 75, 78), two people should independently take the measurements (42, 48, 53, 72, 74, 79), or a third person (one who is not measuring and is not being measured) should record the results independently (71, 84). If the authors did not take such care, the study was deemed to be at high risk of bias. (41, 44, 45, 52, 54-56, 73, 76, 77) A potential bias exists in the comparison of scanning systems across different generations; nonetheless, no convincing justification was identified for excluding any earlier articles.

Egger's test was employed to assess publication bias in forest plots of 8 or more articles. The possible publication bias was visualized using funnel plots. Based on the funnel plots, all data pairs fall inside the critical area and thus are not considered outliers. Plots are shown in the supplementary materials of the original publication. Egger's tests were applicable for the following analyses: nasal X-axis (P = 0.4685), nasal Y-axis (P = 0.879), nasal Z-axis (P = 0.9003), orolabial X-axis (P = 0.8134), orolabial Y-axis (P = 0.902), orolabial Z-axis (P = 0.7259), and periorbital X-axis (P = 0.279). Based on the results of Egger's tests, the funnel plots showed no considerable outliers; thus, this suggests the publication bias was minimal.

Since most information was from studies with a low risk of bias, the overall risk of bias was negligible. Inconsistency was also considered negligible, because the heterogeneity was low, and the point estimates were close to each other with overlapping confidence intervals. Despite the populations being slightly homogeneous, and there were no differences in the methodology of the comparison of direct and virtual measurements, the indirectness is severe because the included population did not have facial defects requiring prosthetic treatment. Given that the pooled confidence intervals were significantly narrower than those of individual articles, the imprecision was low. Cross-sectional observational studies were the most suitable for this topic, and efforts to address confounding factors justify upgrading the evidence certainty from low to moderate.

8.3.2. Study II

The only examined randomized controlled study had a little risk of bias. However, the majority of other research demonstrated a moderate to severe risk of bias. Confounding variables, such as patient age, defect size, residual dentition, and co-interventions such dental implants, neck dissection, chemotherapy, and radiation, were frequently disregarded in observational studies, rendering data synthesis untrustworthy. The level of agreement between the two evaluators was κ=0.66.

Due to the restricted number of papers in each meta-analysis, evaluating publication bias using funnel plots or Egger tests proved impractical, as these methods require a greater number of studies for precision. Dependence on a limited number of research may result in misleading or inaccurate bias evaluations. Consequently, these methodologies were not employed; rather, the uniformity of results on forest plots was assessed visually.(39)

The results of the certainty of evidence assessment showed as most information was from studies with a high risk of bias, the overall risk of bias was “serious.” Heterogeneity was notably high, causing considerable inconsistency. Indirectness was evaluated as “serious” because of the differences in the interventions. Wide confidence intervals indicated imprecision in many studies. Because of the limited number of studies, the assessment of publication bias was not feasible.

9. Discussion

9.1. Summary of findings, international comparisons

9.1.1. Study I

The dimensional accuracy of the conventional method is unreliable, because of the polymerization shrinkage of the impression material and the elastic deformation upon removal, and/or the dimensional changes of the gypsum(85). The soft tissue drape effect is also an issue, as the sheer weight of the impression material can easily distort the shape of the underlying tissues(86). Our study compared various scanning technologies by measuring ILDs on the virtual representation of the subjects' faces and directly on the faces. The difference between the two measurements showed the accuracy of the virtual model. Although the confidence intervals in our statistical analysis were narrow, there was an inconsistency in the results: measurements between the En-En, Al-Al, and Ch-Ch points demonstrated slight magnification, while Ex-Ex, Sn-Prn, and Sn-Sto exhibited shorter measurements. These suggest that the scanning systems do not operate in the clinically acceptable accuracy and precision range of 0.3 mm.

In a previous systematic review and meta-analysis(87), the authors compared portable devices to stationery scanners with no differences between them. The investigated population was slightly heterogenous with volunteers, cadavers, and mannequins involved. This might explain the high statistical heterogeneity (87.6-95.7%). The accuracy was inconsistent in different facial regions, particularly in people with defective morphology. Their results suggest there are difficult-to-capture and easy-to-capture regions, which could explain the accuracy inconsistency(87). This is extremely important in facial prosthetics since the errors of either an “analog” or a digital impression predictably will not have the same accuracy around different regions(43, 76). Therefore, providing a value for global dimensional accuracy is not a sufficient piece of information. Weinberg et al. (74), Liu S et al. (79), and Ye et al. (76) found scanners with a mean deviation of less than 2 mm, which has been reported to be sufficient for a dental practice. The facial scans in these reports are for evaluating the effect of the intraoral prosthetic appliances on facial morphology, but not for the fitting surface of any prosthetics. Considering that an average human eye can distinguish two dots separated by less than 1 arcminute (88), and that the typical conversational distance is around 1 meter, it can be determined that the least resolvable distance is 0.3 mm. The accuracy threshold may be defined as a gap exceeding 0.3 mm between the skin and the silicone prosthesis, which would be noticeable to an untrained observer. The wrinkle measurements done by Lemperle et al. showed the depth of primary wrinkles ranges from 0.06 mm to 0.94 mm (89). However, hiding the prostheses' margins in wrinkles, sleeving mobile tissue, or tapering the silicone body off around the edges and applying a bit of vaseline or skin adhesive to the margins could prevent gap formation between the skin and the prosthesis (90). It is also advised to place a softer silicone material with a hardness around 5 Shore-A onto the edges of the mold to provide comfort and better adaptability to the moving surrounding tissues (90). The nominal accuracy of several scanners is approximately 0.2-0.3 mm (91). Gallardo et al. found the error of trueness in an in vitro study within this range (92). Eggbeer et al. (93) proposed target specifications for scanners regarding soft-tissue prosthetics construction. They concluded the resolution of a usable scanner should be 0.05 mm (or even less for abutment capture) and the tolerance of ±0.02 mm. This is one order of magnitude less than the previously stated numbers.

The difficulties regarding the scanning procedure and the measurements described in the articles were also assessed. In most articles, landmark identification was noted as the most prominent difficulty (43-48, 51, 53, 73, 75, 76, 78). This methodological problem has no relevance to facial prosthetics, as it was only used for dimensional comparison.

The aim of using optical scanners in facial prosthetics is to eliminate the disadvantages of traditional impression-taking (

Table 6). Traditional facial moulage impressions require a longer duration, typically 5-15 min, for completion (94). The traditional method requires a considerable amount of gypsum, and a trained technician to pour it out free from bubbles or voids. Meanwhile, it takes only 1.5 ms to obtain a facial scan and to process the raw scan into a working model (95). Applying the conventional method, in most cases, the eyes must be closed, making the construction of an orbital prosthesis extremely difficult. For nasal or oronasal prosthesis fabrication, the airways would be obstructed by the impression material. Therefore, an aid (exhaustor, straw, or any kind of pipe) must be used during the setting time. If alginate is applied, it is mixed with cold water, causing discomfort in sensitive areas. To make the alginate layer stiffer, gypsum is applied as a second coat. During the crystallization of gypsum, heat is liberated, which is also a disadvantage. However, noncontact scanners do not experience these issues; however, the model-making procedure also appears challenging (96).

Table 6. Comparison of traditional facial moulage impression-taking and digital scanning procedures

	Traditional facial moulage impressions	Digital face scanning
Capture time	with all the preparation of the patient physically and mentally, multiple layers of impression materials, each setting time is around 2-5 minutes, in total 10-15 minutes	depending on the technology: *SPG: 1,5 ms* *LS: minutes*
Requirements for model fabrication	Gypsum or epoxy materials, a trained technician, ~ 1 hour	Depending on the GPU and the software, an experienced software user, ~ immediately
The position of the patient	reclined to 45° to the horizontal plane or lying down	upright
Tissue distortion	Severe from compression (1 to 3 mm in different areas)	None (no contact scanning)
Eyes	closed	open
Breathing	obstructed if taken around the nose and/or mouth	unobstructed

9.1.2. Study II

Since the review by Cao et al. (31), the results of a randomized controlled trial have been published (69), suggesting that surgical reconstruction may offer more improvements in patients' quality of life. The authors stated that the obturator group was administered a surgical prosthesis rather than a final one, rendering the comparison unfair and necessitating careful interpretation. Prior evaluations and the present research suggest a marginal benefit for all results associated with surgical reconstruction. The provided data did not provide sufficient evidence to reject the null hypothesis, indicating no differences in quality of life, speech, or masticatory efficiency between the two therapies. The risk of bias evaluation identified significant problems in the included investigations. The studies lacked sufficient control for significant confounders. Only one research indicated that the populations were defect-matched (64).

The clinical value of scores of QoL questionnaires is difficult to interpret. The scores alone lack valuable information. For interpretation, it is essential to consider group differences, temporal changes, or a threshold value for clinical morbidity. A group may be identified by the percentage exceeding a specified threshold, or outcomes might be analyzed using anchor-based approaches, contrasting score disparities with validated indicators of clinical significance (36).

Nasalance is an interval between the acoustic energies of sound from the nasal and the oral cavity. A critical nasalance score is around 32% (82). Another source claims that normal nasalance ranges between 11.9% and 13.7% (61). In this case, all included patients were mildly hypernasal, but the difference between the rehabilitation could not be detected. To calculate how intelligible the speech of the patient was, the speech was recorded while reading aloud. A third person listened and rated the recordings in a sound-treated room. Rieger et al. (61) compared word and sentence intelligibility, and Genden et al. (64) only measured sentence intelligibility.

Several different methods have been used for assessing masticatory performance. Buurman et al. (70) and de Groot et al. (68) used the same method as Speksnijder et al. (83) with two-colored wax pellets, scoring mastication with pixel analysis. A lower index indicated better mixing ability. Genden et al. (64) used weight percentages of an unsalted peanut bolus that passed through two sieves after 20 strokes. A higher percentage indicated better masticatory efficiency.

9.2. Strengths

Up until the time of publication of Study I, there was no regional analysis regarding the accuracy of scanning technologies in the context of faces.

The included studies utilized similar methodologies. Therefore, by pooling the data from the articles, we would reach mathematical and clinical conclusions. The articles did not examine the scanners' accuracy for the sole purpose of soft tissue prosthetics construction. No prosthetic appliances were fabricated during the investigation to ascertain if the scanner was functioning adequately for its purpose. Nonetheless, case reports exist in which scanners have been used to capture the entire face model and successfully fabricate a prosthesis from it. It is frequently noted that throughout the wax testing, adaption and modification are usually necessary.

In Study II, the attempt to stratify the populations aimed to address baseline differences across studies.

9.3. Limitations

Unfortunately, the limited number of studies prevented the regional analysis in the periorbital and the auricular regions in Study I. The populations of the articles were mostly healthy volunteers, but these people do not represent the population of interest in facial prosthetics. Another limitation is that the anthropometrical interlandmark measurements have their flaws, meaning we should be careful not to distort the tissues during the measurements, the head position influences the soft tissues through gravity, and involuntary muscle activity due to the manipulation in the proximity of the face is also a considerable issue.

The null hypothesis cannot be rejected, but it does not automatically mean it should be accepted. To put the results into context an attempt was made to determine the threshold for acceptability. Unfortunately, no consensus has been established in this regard.

In Study II, the included reports were not high-quality studies, because only 1 study was randomized and there were other issues with the methodologies. The methodological heterogeneity of the studies makes it difficult to draw definitive conclusions. Because of the nature of rehabilitation, double-blind, randomized controlled trials cannot be conducted in this area.

The only way to collect high-quality data is to establish patient registries in which data are collected in a manner that enables stratification of the population according to the major confounders. The low incidence of new maxillectomy patients calls for multicentric registries. These centers should be able to serve both treatment modalities at once, or surgically restored patients need to be matched with obturator patients from other centers.(68, 70) However, this might take a long time to get enough useful information. A consensus conference with surgical and prosthetic experts may expedite the crafting of an algorithm for individualized rehabilitation strategies.

10. Conclusions

The present results suggest that there are no significant differences in linear dimensions, neither between direct caliper measurements nor between measurements taken on the scanned models, scanning technologies, or facial regions. However, this dimensional accuracy in the special clinical environment of facial prosthetics is insufficient. According to our thorough systematic analysis, acquiring a facial model using non-contact optical digitization is desirable over traditional moulage impressions. However, a streamlined device capturing the dimensions of the face reliably and consistently is still to be developed. Shifting the facial prosthetic workflow into a digital environment is vital for the field of anaplastology.

This comprehensive review and meta-analysis concluded that there was no significant difference in quality of life or objective clinical outcomes between obturator devices and surgical reconstruction. The current literature requires more thorough investigation to yield conclusive results. The limited evidence underscores the need for focused research, and established protocols could aid future decisions.

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11. Implementation of practice

Although none of the examined scan measurements showed mathematically significant differences compared to the true values, our results suggest that the representation of the face is not sufficiently accurate. We based our remark on the fact that in the facial prosthetic field, even 0.3 mm is considered a substantial difference. However, the use of scanning systems is still recommended. The drawbacks of the conventional impression-taking procedure undoubtedly surpass those of using scanning technology

Table 6). Therefore, scanning is preferable to traditional impressions. Clinical utility, however, varies between products. The digitized face is either used in conventional techniques (wax try-ins, corrective impressions, etc.) by manufacturing them with computer aid, or in a completely digital workflow (96). However, the latter is still not sufficiently developed.

In the absence of definitive evidence on the optimal rehabilitation for maxilectomy patients, it is essential that the rehabilitation team communicates effectively to ensure informed decision-making regarding patient outcomes. Every member must actively participate in shaping the final treatment plan to ensure that all potential drawbacks of the treatment components are effectively addressed.

12. Implementation of research

The majority of the population in this review included healthy individuals, with one exception (50). Nevertheless, the facial features of individuals requiring prosthetic therapy require additional research. Consequently, further study should be undertaken on individuals with facial deficits. A crucial element of our findings is that the scanning technologies require more advancements prior to adoption. An additional question is regarding their difficulty of use. The learning curve of intraoral scanners has already been investigated before (97). The results showed a drop in scanning time. But we have no information regarding the scanners suitable for capturing extraoral areas. Further investigations should be conducted on the specific features of facial prostheses, which could easily indicate that they are not genuine body parts.

Implementing routine assessments of maxillectomy patient parameters will undoubtedly provide a clearer understanding of the outcomes associated with various rehabilitations. This approach will not only direct individual patient pathways, but the data generated will also lead to broader, more applicable conclusions.

13. Implementation of policymakers

13.1. Promoting access to digital technologies

Expanding access to digital technologies in maxillofacial prosthodontics requires practical approaches, such as public-private partnerships. Subscription-based leasing models, where providers pay a small, manageable fee per patient for using equipment, could make advanced technology more accessible. Companies could also seed future demand by offering scanners and machines to clinics at discounted rates, fostering long-term loyalty.

13.2. Introducing quality control

To ensure consistent and effective patient outcomes, standardizing quality control across prosthodontic practices is essential. Uniform protocols for material selection, design processes, and outcome measurements should be developed and rigorously enforced. This would not only elevate patient confidence in the field but also support the integration of digital advancements, ensuring that innovation is paired with reliability. The introduction of the MDR (Medical Device Regulation) further emphasizes the importance of robust quality control systems in prosthodontics. By setting stringent requirements for safety, clinical evaluation, and post-fitting surveillance, the MDR compels manufacturers and healthcare providers to adhere to the highest standards. Complying with MDR regulations ensures that prosthodontic devices meet rigorous benchmarks, fostering greater trust among patients and stakeholders in the field. (98)

13.3. Expanding insurance coverage: equivalent funding for equivalent alternatives

A critical disparity in healthcare coverage lies in the fact that surgical reconstructions are insured, while prosthetics—particularly facial prosthetics—remain partially uninsured. Recognizing this gap, the Candidate has proposed an expansion of insurance coverage to include prosthetics, advocating for equitable financial support for all forms of rehabilitation. This proposal, officially submitted to the Ministry of Human Resources by the Professional College of Dentists, highlights the urgent need for systemic reforms to address the unmet needs of patients requiring prosthetic care.

14. Future perspectives

SKINMAP study

Skin surface mapping on 3D printed tools by printing parameters and design. A promising alternative method of facial prosthesis fabrication involves digitally constructing the prosthesis's body and manufacturing the flasks through additive manufacturing. However, the skin surface texture is susceptible to artifacts. Additionally, the depth of wrinkles and pores must be slightly exaggerated to be visible on the final products. An in vitro study was designed to answer the question of what are the wrinkle width and depth that are still producible with a 3D printer.

PREDICT study

Prognostic Evaluation of Edentulousness: Inspecting Critical anatomy. Even an experienced professional often finds it challenging to determine what to anticipate from a removable denture and how to effectively convey this prognosis to the patient. Chances are if the provider would know the unfavorable outlook the treatment plan must be adjusted. It is essential to determine how to assess the expected results prior to making a denture. Analyzing the anatomical features and other clinical parameters of the patients can significantly inform our decision-making process. This prospective cohort study aims to identify the key parameters of patients that are essential for achieving a higher quality of life and improved mixing ability. A request was submitted for approval to the Regional and Institutional Scientific and Research Ethics Committee of Semmelweis University on April 10, 2024. The Committee found the research plan appropriate and issued approval under authorization number 79/2024, dated May 14.

Color matching using machine learning

A facial prosthesis blending in with its surroundings is the ultimate goal. Apart from symmetry, shape and size, color is what makes a prosthesis unvisible to the layperson's eyes. The current trial-and-error method for shade matching is long and difficult. Based on the Kubelka-Munk theory a machine learning model could be developed to enhance the accuracy of color mixing.

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16. Bibliography of the Candidate's publications

Publications related to the thesis

1. Kőnig J, Kelemen K, Czumbel LM, Szabó B, Varga G, Borbély J, et al. Current status of optical scanning in facial prosthetics: A systematic review and meta-analysis. J Prosthodont Res 2024;68:1-11.

2. Kőnig J, Kelemen K, Váncsa S, Szabó B, Varga G, Mikulás K, et al. Comparative analysis of surgical and prosthetic rehabilitation in maxillectomy: A systematic review and meta-analysis on quality-of-life scores and objective speech and masticatory measurements. J Prosthet Dent 2023.

Publications not related to the thesis

1. Kelemen K, König J, Váncsa S, Szabó B, Hegyi P, Gerber G, Schmidt P, Hermann P. (2025) Efficacy of different intraarticular injection materials in the arthrocentesis of arthrogenic temporomandibular disorders: A systematic review and network meta-analysis of randomized controlled trials. J Prosthodont Res, doi:10.2186/jpr.JPR_D_23_00272.

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