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HABILITATIONSSCHRIFT

Digital Workflow of Facial Prostheses Manufacturing

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von
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CONTENT

ABBREVIATIONS

Anaplastology	A term used for maxillofacial prosthetics in English speaking countries.
AM	Additive manufacturing
Auricle	Ear
Artec Space Spider	A portable extraoral structured light scanner
Boolean	Virtual function combining two parts, subtracting one from another, or creating a new part based on the intersections of two others—developed by George Boole
CAD	Computer-aided design
CAM	Computer-aided manufacturing
CBCT	Cone beam computer tomography
DW	Digital workflow
DBB	Digital data base
DLP	Direct light processing—an AM method based on solidifying photosensitive resin with a light beam
DMM	Direct mold making
DICOM	Digital imaging and communication in medicine—a data format from CT and MRI
Drop-on-Demand	An AM technique for silicone printing
Exenteration	Removal of the orbit’s entire contents
FDM	Fused deposition modelling—an AM method based on preheated filament extrusion
Haptic	Sensation of touch
IMM	Indirect mold making
IOS	Intraoral scanner

LCD	Liquid crystal display—an AM method based on solidifying photosensitive resin with a light beam from a liquid crystal display
MFT	Maxillofacial technician
MRI	Magnetic resonance imaging
Primescan	An intraoral scanner
Polyjet	An AM method that has several extruders and is capable of printing wax
RM	Rapid manufacturing
RP	Rapid prototyping
SLA	Stereolithography—an AM method based on solidifying of photosensitive resin with a laser beam
SLS	Selective laser sintering—an AM method based on powder solidifying
STL	Standard tessellation/triangulation language—universal 3D data format
Trios	An intraoral scanner
Zbrush	A free form CAD software for animation and rendering by Pixologic Inc.

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1 INTRODUCTION

1.1 A facial prosthesis

As a result of tumors in the head and neck region, trauma or congenital malformation, patients may be afflicted with severe facial deformities [1]. Some of these defects can be treated by means of reconstructive surgery. However, this approach is dependent upon the operators' craftsmanship, and the final esthetical outcome is difficult to predict [2, 3]. Furthermore, as reported by Burget et al., surgical reconstruction may require three to 15 operative sessions within 4 to 49 months, which is quite a prolonged period [4].

A prosthetic appliance poses a valid alternative to cover the lesion and, whenever possible, to restore the former facial anatomy when surgical reconstruction is not feasible [5-7]. Such an approach also enables constant malignance checks [8]. For decades, interdisciplinary medical teams featuring maxillofacial surgeons, dentists and maxillofacial technicians (MFTs) have fabricated removable facial prostheses manually (Fig. 1). This approach provides the operator and patient with full control over color, shape and position of the restored facial part [9]. According to the Medicines and Healthcare products Regulatory Agency (MHRA), a maxillofacial prosthesis is "a custom made medical device for replacement or modification of anatomy" and it does not pose any risk for the patient [10]. The Glossary of Prosthodontic Terms defines a maxillofacial prosthesis as "any prosthesis used to replace part or all of any stomatognatic and/or craniofacial structures" [11]. A maxillofacial prosthesis aids a patient's physiological state and increases the quality of life [12-15].

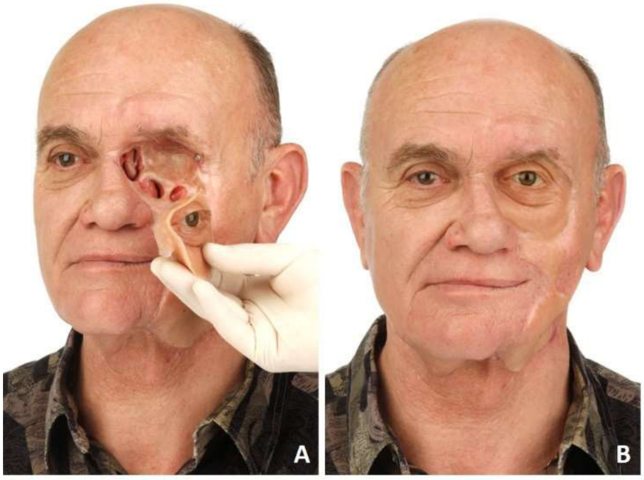

Figure 1 A removable customized silicone facial prosthesis. A: an orbital defect; B: a silicone orbital prosthesis in situ.

Thus, there has been an increased need for prosthetic rehabilitation in the last decade. In developed countries, up to 64,000 prostheses are needed each year [16]. Various types of maxillofacial prostheses have been described [17-19]. Many articles provide new technical solutions on manufacturing processes of nasal [20], orbital [21], auricular [22], intraoral obturator prosthesis [23] and a combination of extra- and intraoral prostheses [24]. This thesis deals exceptionally with extraoral facial prosthetics.

A nasal prosthesis is required for patients who have a portion of or their entire nose removed. These prostheses are often extended over lips and paraorbital soft tissue in cases of huge midfacial defects. Providing normal breathing through the prosthesis is a primary challenge in such rehabilitation. Such nasal prostheses are often anchored using implant-supported magnets, bar clips or eyeglasses [17, 25, 26].

An orbital prosthesis is required after exenteration. An artificial eye is often provided by the ocularist or can be ordered from a catalog of premanufactured parts. The orbital tissue portion is made of silicone and retains the ocular unit. Orbital prostheses are anchored using anatomical undercuts of the orbital cavity or magnets [17].

The manufacturing process of an auricular prosthesis includes mirroring the ear anatomy of the contralateral side. For bilateral defects, the prosthesis can be made from scratch. The main challenge is to create a smooth transition of frontal prosthesis margins into the temporomandibular area, as it moves during speech and mastication [27]. An ear prosthesis can be anchored utilizing bar clips, magnets or special adhesives [17, 28].

1.2 Conventional workflow of facial prosthesis manufacturing

For decades, facial prostheses have been manufactured in an analog way. The conventional production chain currently relies on technically complex and labor-intensive techniques and requires an inordinate amount of time and handcrafting skills by MFTs [29-31]. Figure 2 presents the conventional workflow stages.

Taking an impression of the defect side and adjacent facial anatomy is a crucial production stage to ensure that the prosthesis provides a good fit and marginal integrity [32]. A range of impression materials is available for this purpose, including irreversible hydrocolloids, polyether, polysiloxanes and polyvinylsoloxanes [33]. The impression taking process is associated with several challenges, such as displacement of soft tissues, capturing the hollowness of defect anatomy and providing normal breathing during the material application [34, 35]. The working cast of the defect, unaffected side and, in some cases, the whole face is poured from dental stone based on the obtained impressions. The prosthesis pattern is then carved using the special sculpting wax. For implant-retained prostheses, the wax pattern must also incorporate magnets or a bar clip, which adds complexity to the entire manufacturing process.

A try-on session of the sculpted prosthesis pattern is an inherent part of the conventional production chain. This step allows for better understanding of the patient’s facial symmetry, which helps integrate the prosthesis design in the overall facial anatomy [36]. The adjusted wax pattern is then submerged into the dental stone to create a two- or three-part stone mold. Afterward the medical-grade room temperature vulcanized condensation or platinum (addition) cure silicones are applied to the mold [37]. A facial prosthesis can be colorized intrinsically while applying silicone into the mold or extrinsically after the silicone vulcanization by using special pigments for subsequent individualization [17, 38].

1.3 Digital workflow of facial prostheses manufacturing

In the last decade, the medical field has been widely impacted by advancements in computer-driven technologies. In prosthetic dentistry, conventional production processes were complemented by computer-aided design (CAD) and manufacturing (CAM) [39-43]. This has also impacted maxillofacial rehabilitation, and the benefits of facial prostheses manufactured by digital means were acknowledged in a series of studies. Benefits include increased quality, workflow reproducibility, higher predictability of the clinical outcome and reduced manufacturing time and costs [31, 44, 45]. Furthermore, the utilization of CAD/CAM technologies for manufacturing facial prostheses has been reported to enhance patients' quality of life [46].

The DW of facial prostheses manufacturing can be broadly divided into three main technical fields: digitization of the defect, prosthesis design (CAD) and prosthesis delivery (CAM). Figure 2 presents an overview of the DW.

Rehabilitation process		Workflow			
		Conventional	IMM	DMM	RM
Digitization	Defect	First silicone impression	Within one or two scans	Within one or two scans	Within one or two scans
	Contralateral side	Second silicone impression			
	Face in general	Third silicone impression			
	2D Photo	Obligatory			
Design	Virtual design		CAD	CAD	CAD
	Retention elements	Manually	Backwards planning	Backwards planning	Backwards planning
	Prosthesis pattern	Manual sculpting	3D printing		
	Try-in	Chairside	Chairside		
Prosthesis delivery	Mold making	Dental stone	Dental stone	3D printing	
	Silicone flasking	Manually	Manually	Manually	
	Excesses trim	Manually	Manually	Manually	Manually
	Retention elements integration	Manually	Manually	Manually	Manually
	Coloring	Intrinsic & Extrinsic	Intrinsic & Extrinsic	Intrinsic & Extrinsic	Extrinsic

Figure 2 An overview of conventional and digital approaches for manufacturing facial prostheses. IMM, indirect mold making; DMM, direct mold making; and RM, rapid manufacturing.

1.4 Digitization of the defect

By using medical imaging techniques, information about the treated defect's topography and anatomy can be gathered digitally and exported in various formats for further processing [47-53]. Standard tessellation language (STL) has been recognized as the mostly used file format for virtual data manipulation.

All acquisition modalities may be classified in those with radiation exposure, such as computer tomography (CT) and cone beam computer tomography (CBCT), and without radiation [54, 55]. Utilization of CT, CBCT and magnetic resonance imaging

(MRI) necessitates additional software packages to transfer the data from a digital imaging and communication in medicine (DICOM) format into STL [16, 56-61].

Radiation-free digitizers can be described as surface scanners because they provide information only about the object surface and are unable to penetrate the deeper tissue portions [45]. The digitizers send a light beam toward the object surface, which follows its whole geometry and attains the undercuts from various angles. Structured light scanning has been reported for capturing of all types of facial defects [62-64]. Alternatively, a laser beam can be used for tracing the relief of a defect [22, 65, 66]. The 3D photogrammetry poses a viable option for digitization of a broad range of defects [36, 67-69]. Intraoral scanners (IOS) are also used in maxillofacial prosthetics [70]. Recently, smartphones have been employed for virtual data capturing in the rehabilitation field [71-73]. In general, digital data acquisition was found more beneficial than a traditional impression because it is contactless and causes neither pressure nor irritation to the soft tissues [74-76].

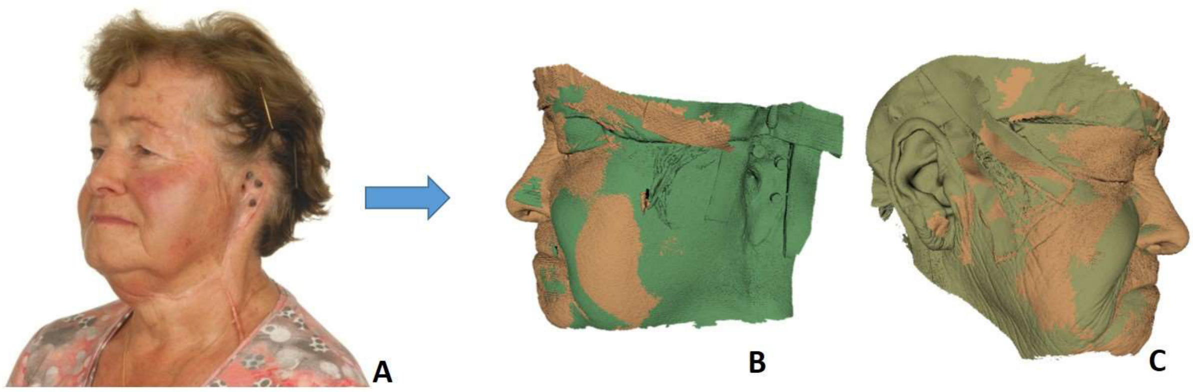

Figure 3 Digitization process of the facial anatomy using structured light scanning. A: a facial defect (here auricular defect) with retention magnets; B: digitized auricular defect; C: digitized intact auricle on the contralateral side.

1.5 Prosthesis design and CAD

The acquired 3D images of the deficient area in STL format are used for the virtual reconstruction of the missing tissue portion. The future prosthesis is digitally modelled with the use of virtual clay tools and haptic devices, with which the user can physically manipulate the clay using the force-feedback technology [60, 77]. The missing facial part can be adopted from the contralateral side using mirror-imaging [63]. In case of a bilateral defect or nasal defect, where the former facial anatomy is missing, an anatomical template can be downloaded from the digital database of facial parts [66, 78, 79]. In the STL format, suitable anatomy can be adjusted on the deficient side in terms of its size, position and marginal adaptation. The last option is to design the prostheses from scratch, which requires advanced modelling skills.

At this stage, the virtual planning of retention elements can be considered, and the manufacturers can provide the STL files for the anchoring parts, which makes it possible to integrate them into the virtual prosthesis design [28, 78, 80].

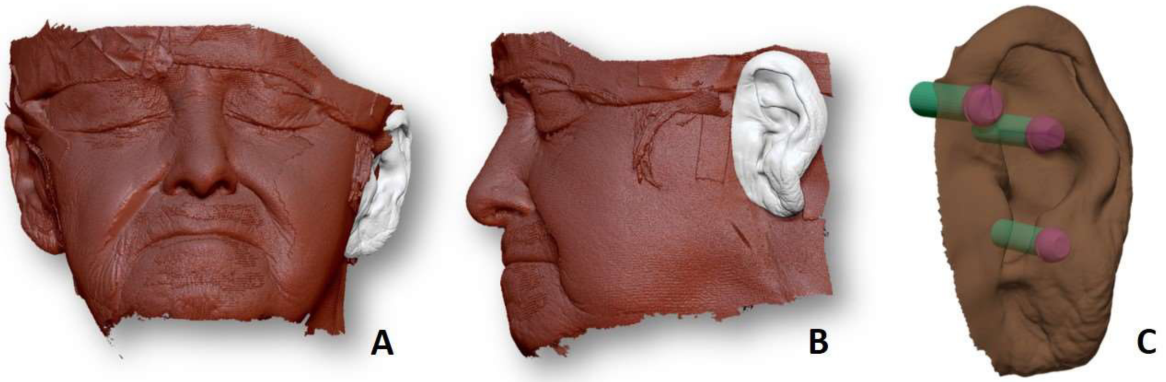

Figure 4 A, B: virtual design (CAD) of auricular prosthesis using the mirror-imaging technique. C: final prosthesis design with virtually integrated retention magnets.

1.6 Prosthesis delivery and CAM

In the last decade, additive manufacturing (AM) has been widely employed in medicine and has touched upon maxillofacial prosthetics. Nowadays, there are many AM technologies, but all share the same layer-by-layer working principle. This nature of building up objects allows for manufacturing complex geometries, including hollowness, undercuts and internal details. Such methods as fused deposition modelling (FDM) [25, 79, 81], direct light processing (DLP) [82], stereolithography (SLA) [27, 59, 83] and Polyjet [63] found their applications in maxillofacial prosthetics.

1.6.1 *Types of AM*

FDM is an extrusion-based method [84]. A molten solid filament is extruded layer-by-layer trough a printer nozzle onto a build platform. The printing head traces the CAD geometry in the x-y direction. When the layer is finished, the fused material solidifies through cooling [85]. The build platform moves in the z-direction, and the next layer is extruded on top of the previous one. Acrylonitrile butadiene styrene (ABS) and polylactic acid (PLA) are the most used materials in maxillofacial prosthetics [62].

SLA is the oldest AM system [86]. SLA builds models through layer-by-layer solidifying of a photosensitive resin and applies a laser beam for tracing the object geometry from point to point [87, 88]. The build-up process may contain layers that greatly overhang the layers below, thus demanding support structures be applied [89, 90]. Concerning maxillofacial prosthetics, SLA has been widely employed to produce prostheses patterns [27, 59, 91].

The basic working principle of DLP is similar to SLA and is associated with layer-by-layer fabrication of the object on a two-dimensional plane (X- and Y- directions) for a three-dimensional construction (Z direction) [92]. However, in contrast to SLA, DLP utilizes a digital micromirror to cure a complete resin layer in one moment [93].

Polyjet is another UV-cured printing technology that utilizes multiple print heads simultaneously. In this manner, various supporting materials, such as wax, gel-like polymers or even different building materials with different properties, can be co-deposited onto the printing platform [88]. In some cases, the objects can be printed entirely from wax, which is particularly applicable in maxillofacial prosthetics for prosthesis pattern fabrication and subsequent mold fabrication [63].

1.6.2 *Technical approaches*

Three approaches to AM utilization can be considered to deliver the final silicone prosthesis. The first two entail the fabrication of a negative mold for the casting of a definitive prosthesis [94, 95]. This can be achieved directly, whereby the negative mold is designed virtually based on an inverted STL file of prosthesis prototype/pattern (**direct mold making, DMM**) or indirectly by printing the prosthesis prototype from wax or resin for subsequent mold fabrication (**indirect mold making, IMM**). The printed prototype can be tried on the patient and adjusted in terms of shape, size and marginal fit [36, 63]. Once the prosthesis prototype is made from wax, it can be easily put in dental stone and then burned out, thus making a negative mold. However, if a prototype was printed from resin, it first must be duplicated in wax by using silicone rubber molding [96]. Whichever option is chosen, medical grade silicone is applied to the negative mold for casting of the final prosthesis.

Figure 5 Try-on session chairside. A, B: a Polyjet printed wax prosthesis pattern; C: an FDM printed resin prosthesis pattern.

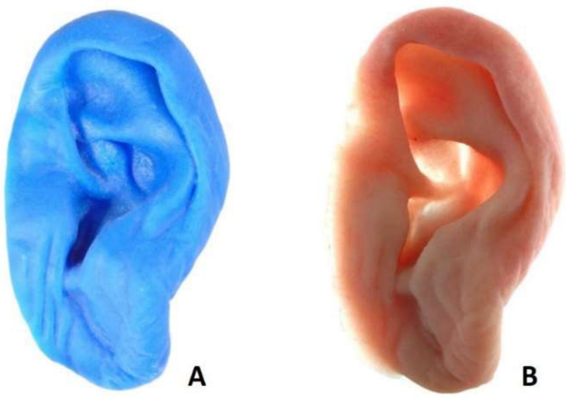

Figure 6 A a Polyjet printed wax prosthesis pattern; B: a final individualized silicone auricular prosthesis.

Figure 7 A, B, C: a final individualized silicone auricular prosthesis in situ.

The third approach involves a direct printing of the final prosthesis from silicone (**rapid manufacturing, RM**). This method has not been employed widely in clinical practice because printable biocompatible silicone materials are still being developed [97, 98]. Since 2010, there have been clinical reports on rubber-like printable soft polymers, but the biocompatibility is questionable [36, 57, 99].

Figure 8 A prosthesis patterns printed directly from silicone using the drop-on-demand technique

1.7 Current state of the topic and problem identification

Due to significant advancements in surgical techniques and improvements in early-stage cancer detection, there has been an increased number of post-surgical defects recently [16, 28]. Such patients require prosthetic appliances, which increases the interest in maxillofacial prosthodontics. Significant emphasis in clinical research was on the utilization of CAD/CAM technologies in the rehabilitation field in recent years [29, 45]. El. Bashti et al. reported that, among 87 clinical cases in the last decade that covered DW in maxillofacial prosthetics, 61% utilized digital data acquisition, 66% used CAD and 66% used CAM [44].

However, the integration of DW in this field of rehabilitation might be associated with some difficulties. First, the learning curve to apply digital technologies in maxillofacial prosthetics is even longer than in restorative dentistry [28]. Second, there is no specifically developed CAD software for facial prostheses design, such as DentalCAD (ExoCAD, Darmstadt, Germany) and Dental Designer (3Shape, Copenhagen, Denmark) in the dental field. Third, there have been few educational courses in this field of knowledge or in the acquisition of CAD soft skills. Rather, certain expertise in CAM application is acquired through the "learning by doing" concept. These facts lead to a lack of appropriately devised and implemented DW in this field of rehabilitation [16].

The topical literature has plenty of case study articles describing the technical feasibility of DMM, IMM and RM. A critical evaluation of these technical approaches and DW in maxillofacial prosthodontics in general has not been performed. A systematic assessment of dimensional accuracy in practice, novel materials for 3D printing, reproducibility of prosthetic approaches, time and financial investments are lacking and require further research in this field [31].

Regardless of the chosen technical approach, the final prosthesis must fulfill certain quality criteria, which determine the success of rehabilitation [28, 31].

- Accurate shape (dimensional trueness to former anatomy)
- Accurate position and relation to the contralateral side and anatomical landmarks
- Life-like texture and surface relief
- Fit of the retentive components
- Sufficient retention

Whether these criteria can be met within the DW must be assessed in future research. For this reason, the current thesis was intended to investigate some crucial aspects of DW in maxillofacial rehabilitation. It touched upon three areas of interest: digitization, prosthesis design (CAD) and materialization (CAM). Each area of interest consisted of several working packages and covered the aspects of dimensional accuracy, technical feasibility, skin surface reproduction and data management (Figure 9).

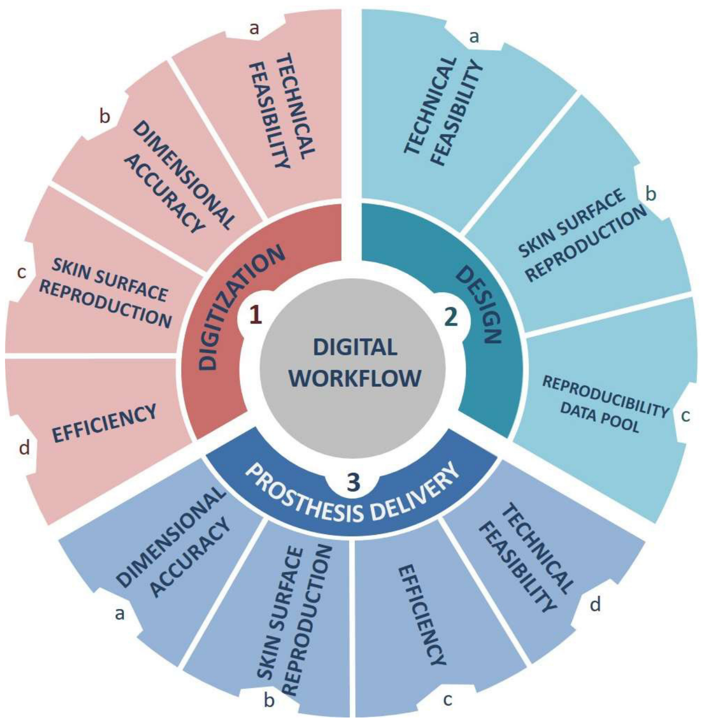

Figure 9 Three main fields of DW: digitization (1), prosthesis design (CAD) (2) and prosthesis delivery (CAM) (3). Various working packages are marked with bold letters.

Within the applied thesis, the following questions have been processed.

1) Are modern digitizers capable of capturing sufficient defect morphology, and does the digitization accuracy depend only upon the digitizer or the defect type? (Working packages **1b, 1a** and **1d**).
2) Is it possible, within a DW with modern equipment, to capture the anatomy and skin surface structure directly on the patient and reproduce it correctly throughout the DW into the prosthesis prototype?
   (Working packages **3a, 1b and 3c**).
3) Is it expedient to create a DDB for facial parts and skin surface templates, and how can it aid a more devised DW? (Working packages **2a, 2c** and **2b**).
4) Is it possible to transfer the virtually designed skin surface into the final silicone prosthesis realistically? (Working packages **3b** and **3a**).
5) Would the direct anchoring of retention magnets in the 3D-printed silicone bulk be a valid technical option for the RM approach? (Working packages **3b, 3a** and **3d**).

2 OWN CONTRIBUTION TO THE TOPIC

2.1 Study #1 – Adequate digital image of the defect – the key to success

Unkovskiy A, Spintzyk S, Beuer F, Huettig F, Röhler A, Kraemer-Fernandez P. Accuracy of capturing nasal, orbital, and auricular defects with extra- and intraoral optical scanners and smartphone: An in vitro study. J Dent. 2022 Feb;117:103916. https://doi.org/10.1016/j.jdent.2021.103916. Epub 2021 Dec 5

This study dealt with the assessment of various existing digitizing methods for capturing facial anatomy and covered the working packages **1b, 1a** and **1d** (Figure 9). A stationary and portable extraoral structured light scanner, two modern intraoral scanners and a smartphone were chosen to capture the morphology of auricular, nasal and orbital defects, as well as an intact auricle. Trueness and precision were analyzed for each digitizing method.

Statistically significant interactions were found in the trueness and precision for defect type and scanner type. The first IOS (Primescan) and extraoral light scanner (Artec Space Spider) showed the highest accuracies for the most defect types. Both IOSs failed to capture orbital defects. The smartphone (iPhone 11 Pro) showed clinically acceptable trueness but inferior precision.

The scanning devices demonstrated varying accuracy, depending on the defect type. A portable extraoral optical scanner (Artec Space Spider) is a universal tool for the digitization of oncology defects. Alternatively, an IOS may be employed in maxillofacial prosthetics with some restrictions. Utilizing a smartphone in maxillofacial rehabilitation should be considered with caution because it provides inconsistent accuracy.

2.2 Study #2 – Dimensional accuracy of the DW

Unkovskiy A, Spintzyk S, Axmann D, Engel EM, Weber H, Huettig F. Additive Manufacturing: A Comparative Analysis of Dimensional Accuracy and Skin Texture Reproduction of Auricular Prostheses Replicas. J Prosthodont. 2019 Feb;28(2):e460-e468. https://doi.org/10.1111/jopr.12681.

This study touched upon the following working packages: **3a, 1b and 3c** (Figure 9).

A geometrical trueness to the anatomy of the former facial part, precise marginal fit of a facial prosthesis and well-reproduced surface structure of soft tissues contribute significantly to the camouflage and subjective perception of a facial prosthesis.

The present study investigated geometrical accuracy of auricular prototype manufacturing at each production stage, from original in-vivo anatomy to virtual prototype design, using structured light scanning, as well as physical auricular prototypes 3D-printed with SLA, SLS and FDM methods.

The prosthesis prototype's discrepancies, up to 0.5 mm, compared to the original anatomy were disclosed, which seemed to be clinically irrelevant. The auricular digitization was the main source of errors, rather than 3D printing. The FDM methods demonstrated the best dimensional accuracy and the lowest production costs.

Sufficient reproduction of the skin structure, such as pores, furrows and wrinkles, is important when applying DW in clinical practice. The recent study also dealt with this topic and revealed slight shortcomings in skin surface reproduction. Skin details from 200 µm can be described realistically by using structured light surface scanning and SLA, SLS and FDM methods compared to the conventionally made reference stone casts.

To sum up, the entire DW, including structured light scanning and 3D printing, allowed for manufacturing a prototype with accurate dimensions but failed to reproduce the skin surface structure on an acceptable level.

Thus, the necessary skin details can be applied in the CAD software, either from scratch or from the digital database. The next studies investigated the reproduction of the digitally applied and quantified skin wrinkles until the final silicone prosthesis (2.2 and 2.4).

2.3 Study #3 – "Plug-and-play" solution for maxillofacial prosthetics

Unkovskiy A, Roehler A, Huettig F, Geis-Gerstorfer J, Brom J, Keutel C, Spintzyk S. Simplifying the digital workflow of facial prostheses manufacturing using a three-dimensional (3D) database: setup, development, and aspects of virtual data validation for reproduction. J Prosthodont Res. 2019 Jul;63(3):313-320. https://doi.org/10.1016/j.jpor.2019.01.004.

This study dealt with the creation and approbation of a digital database of facial parts and covered the working packages **2a, 2c** and **2b** (Figure 9).

For extended defects, whereby the former anatomy is missing and must be restored from the beginning, CAD of a facial prosthesis from scratch might be challenging and time-consuming. A database of pre-saved facial anatomical parts helps to reconstruct the deficient areas faster and more efficiently. The current study dealt with the creation of a more extensive database, which includes ear and nasal anatomy and renderings of skin surface details according to gender and age. Moreover, prostheses' retentive elements, such as magnetic copings, bar-clips and scan-bodies, were included.

Within this study, rehabilitation of nasal and auricular defects utilizing the created database was demonstrated. The basic facial anatomy was adopted from the database and adjusted on the defect side. The skin surface features, according to the gender and sex of the patient, were embossed onto the prosthesis surface from the database. Finally, the retention elements were integrated virtually during the prosthesis design, which allowed for a better positioning within the prosthesis bulk. Virtual Boolean out extraction of the virtual retention magnets created the corresponding sockets for further physical anchoring of the same magnets.

Within this study, the reproduction of the applied surface structure was investigated and yielded a loss of up to 40% of virtually applied skin details in the physical prosthesis prototype. However, a question remained: to what extent the skin details can be transferred into the final silicone prosthesis? This aspect was covered in Study 2.4.

2.4 Study #4 – Quantification of skin surface reproduction

Unkovskiy, A; Spintzyk, S; Roehler, A; Kiemle, T; Huettig, F. Trueness and precision of skin surface reproduction in digital workflows for facial prostheses fabrication; J Prosthet Dent. 2022 Mar 4:S0022-3913(21)00397-8.

https://doi.org/10.1016/j.prosdent.2021.06.050.

This study touched upon the following working packages: **3b** and **3a** (Figure 9).

An adequate level of skin surface details facilitates a more lifelike prosthesis and sufficient defect camouflage. The present study aimed to quantify the amount of skin surface details that could be transferred into the final silicone prosthesis surface from the initial CAD design throughout the digital production chain with the IMM approach. The digitally applied skin surface details were printed with SLA and DLP methods, imitating the IMM approach, with resin prototypes that must be further duplicated in wax. In the other group, the skin surface was printed with Polyjet directly from wax. The study revealed that the IMM approach might be associated with a 7% loss of the digitally applied profile in the case of SLA and 20% with DLP. The Polyjet wax printing provided the most accurate skin details reproduction. The revealed discrepancies in surface reproduction should be fixed during virtual prosthesis design.

2.5 Study #5 – Bonding of retention elements in 3D-printed silicone prostheses

Spintzyk S, Brinkmeier S, Huettig F, Unkovskiy A. Bonding strength of 3D printed silicone and titanium retention magnets for maxillofacial prosthetics application.

J Prosthodont Res. 2022 Jul 30;66(3):422-430.

https://doi.org/10.2186/jpr.JPR_D_21_00019.

This study touched upon the following working packages: **3b, 3a** and **3d** (Figure 9).

In the conventional production chain, retention elements (e.g., magnets and bar clips) are placed in the stone mold directly before the silicone is poured into the mold and prior to silicone vulcanization/polymerization. In the context of the rapid manufacturing (RM) protocol, the prosthesis is printed directly from silicone, and the retention elements must be integrated in the hardened silicone and the corresponding sockets. This may be achieved only adhesively, as the limited space would restrict the mechanical retention. The present study investigated the bonding strength of adhesively integrated commercial titanium (cpTi) magnets in the 3D-printed silicone bulk. Two types of platinum adhesives were tested, revealing G611 and A304 adhesives may be used within the RM protocol. Furthermore, it has been proven that retention magnets are exposed to various forces, including shear, pull and tensile forces. The 45° angulation of force application led to higher stresses compared to those at a 90° angulation.

2.6 Clinical implementation/approbation of gathered results

Unkovskiy A, Wahl E, Huettig F, Keutel C, Spintzyk S. Multimaterial 3D printing of a definitive silicone auricular prosthesis: An improved technique. J Prosthet Dent. 2021 Jun;125(6):946-950.

https://doi.org/10.1016/j.prosdent.2020.02.021.

The gathered outcomes of the cumulated studies were tested clinically on the example of auricular prosthesis manufacturing. Following the outcomes of the Study #1, this clinical case implied scanning with two digitizers: an extraoral structured light scanner to capture the whole facial anatomy, and IOS to capture the position of the implants and intact auricle on the contralateral side. Following the outcomes of Study #3, this clinical case implied DBB utilization for the application of retention magnets and skin surface details according to patients' sex and age. The patient received two prostheses made using the RM and IMM approaches (the publication mentioned above covers only the RM approach). For the RM approach, the virtually designed prosthesis was printed with the drop-on-demand technique from silicone of various Shore A hardness grades. Manual post-processing encompassed prosthesis individualization by means of silicone grinding, sealing, application of a smooth silicone transition on its frontal margin and extrinsic coloring. The magnets were retained in the prosthesis bulk using the acrylic suprastructure.

For the IMM approach, the prosthesis pattern was printed from wax using the Polyjet method following the recommendation of Study #4, which allowed for a successful transfer of applied skin surface details into the final silicone prosthesis (Fig. 10).

Both auricular prostheses manufactured with RM and IMM approaches demonstrated clinically acceptable outcomes. The RM-made prosthesis was devoid of any skin surface structure, as the low layer thickness of silicone printing does not allow for materialization of virtually applied skin details. Both prostheses demonstrated an approach required two appointments, and the IMM approach required three appointments due to a try-on session.

Figure 10 A: a virtual construction of auricular prosthesis with integrated retention elements; B: a Polyjet printed wax prosthesis pattern with prosthesis magnets and implant replicas

Figure 11 a final auricular prosthesis made with the IMM approach

3 DISCUSSION

3.1 Study outcomes

As a part of the applied thesis, these five studies clarified some crucial points and measures (e.g., digitization, CAD and CAM) for successful implementation of the available digital technologies to produce facial prostheses. The summarized results have impacts in two fields. First, they may help the MFTs to choose efficient workflows and facilities for the rehabilitation of facial disfigurements. Herein, the authors expect to reach an esthetically satisfying outcome within the rehabilitation process. Second, the studies revealed the necessity for further research and improvements in the particular technologies investigated.

Study #1 investigated the digitization process. The study's outcomes proposed that digitization accuracy depends on not only the chosen digitizer but also the defect type. Thus, orbital defects were the most complex to scan. An extraoral and intraoral structured light scanner demonstrated adequate accuracy. However, an advanced DW in maxillofacial prosthetics implies manipulation of the entire facial anatomy, even for the reconstruction of small defects. Therefore, a portable structured light scanner may be considered a universal digitizer, as it allows for capturing either small defects or the whole face. Intraoral scanners were designed to capture small areas, such as a single tooth or parts of the jaw.

The utilization of smartphones was demonstrated in 2019 studies [71]. However, the study in 2021 reported higher accuracy than the one in 2019 did. This highlights the rapid progress in scanning hardware development, giving hope for a more accurate digitization in the near future. These developments will make DW more affordable for MFTs.

Study #2 demonstrated that most of the available AM methods could reproduce facial (in this case, auricular) anatomy accurately in a clinically relevant 2-mm threshold [100-

102]. However, reproduction of the original skin surface structure using digitization with a structured light scanner, and its materialization with AM is not possible from the original anatomy to prototype. This is attributed more to the digitization stage than to data materialization with AM. Although the assigned accuracy of Artec scanner was 0.1 mm, it failed to describe 0.094-mm wrinkles. A completely DW allowed 0.19-mm skin wrinkles to be reproduced using donor organ skin on the surface of the final prosthesis, whereas facial wrinkles range from 0.05 to 0.8 mm [103]. This can also be attributed to the scanner software's post processing data. Therefore, the necessary skin details must be added at the CAD stage manually.

When Study #3 was published, only one digital database of facial parts existed, which was developed by Reitemeier et al. [66]. The study's main idea was to create a more extensive database, which included the auricle and nasal anatomies, templates of skin surface structure in accordance with sex and age and the digitized retention elements. This database was created according to similar databases in the dental field. For instance, the DentalCAD (ExoCAD GmbH, Darmstadt, Germany) software includes various templates of tooth anatomy, virtual articulators, abutments, titanium bases and scans from various manufacturers. This allows for a plug-and-play workflow from uploading the initial scan data to exporting the final design for further materialization [104]. Utilization of the mentioned database allows for facial prosthesis designs based on only the commonly preexisting CBCT data and open-source CAD software, (for example Meshmixer, Autodesk, San Rafael, CA, USA), avoiding the purchase of expensive portable digitizers and sophisticated CAD software.

Planning retention elements and their integration at the CAD stage is not the last aspect of DW integration. The composed database allows for a virtual integration of magnets, which facilitates planning and CAD. In the future, integration of all existing brands for maxillofacial prosthetics with presaved scans-bodies libraries and all abutments should be considered.

The skin surface structure can be added from images (for example, in jpeg format) and embossed onto the prosthesis surface using the “alpha” function in the Zbrush software (Pixologic, Angeles, CA, USA). Capturing of skin details in 2D format and transferring them into 3D format appears to be more precise than trying to capture their volume from the very beginning with digitizers. Manual application of skin wrinkles and adjusting them in terms of sex and age might be time-consuming. The DDB makes this process more intuitive and allows for significant time savings.

Study #4 dealt with materialization of digitally applied skin structure and its transfer onto the final silicone prosthesis. The RM approach was not included in the study design, as the given layer thickness of 0.4 mm of silicone printing restricts detail reproduction in the order of 0.1 mm [64]. For this reason, the study dealt with the IMM approach, which implies several technical steps from the CAD data into the final silicone. In each step, a certain amount of detail might be lost. Thus, utilization of DLP and SLA methods lead to a loss of 20%, whereas the direct method using Polyjet printing demonstrated almost no loss of detail. Therefore, the Polyjet method can be recommended for the IMM approach instead of printing a prosthesis pattern in resin and duplicating it manually in wax.

3.3 Outlook and future perspective

The outcomes of these five studies highlighted some limitations of the DW in maxillofacial prosthetics. These aspects call for further research on the topic of data acquisition, CAD and CAM. The main studies conducted in this field of knowledge are performed in in-vitro environments. In-vivo research is lacking and could clarify patient-reported outcomes in terms of patients' appraisal and perception of the DW in comparison to conventional ones. Additionally, the topics of marginal adaptation of IMM- and RM-made prostheses must be evaluated. The clinical case series of Unkovskiy et al. demonstrated that skipping the try-on session may lead to a compromised marginal adaptation [63]. However, such in-vivo research is associated with high production costs, as at least two prostheses (DW and conventional) must be manufactured to enable an objective comparison. Moreover, manufacturing of two prostheses and further clinical study measures may lead to higher burdens for patients and is hardly approvable by any ethical board. Obviously, because of the above-mentioned financial and ethical issues, the topical literature is dominated by in-vitro research or single case studies.

3.3.1 General issues of digitization

The stage of digital data acquisition is crucial to provide a reproducible and accurate DW. Modern medical imaging devices (CT, MRI) cost up to €500,000, which makes such digital data sources affordable only for bigger institutions such as state hospitals, not for private anaplastology (maxillofacial prosthetics) clinics. Study #3 mentioned that extra- and intraoral structured light scanners may pose a valid alternative to medical imaging. Their costs range from €10,000 to €50,000, which may be also financially burdening for MFTs. On the other hand, as reported by Elbashti et al., maxillofacial units have often been organized as an inherent part of prosthodontic department, which makes dental hardware, such as IOS, more attainable for MFTs. An IOS would be sufficient to capture the morphology of defects, but it might be challenging to capture the whole face. Whether a CBCT accompanied solely by IOS within the walls of a dental prosthodontic department would be a viable option for DW should be investigated in further clinical research.

Smartphones are believed to be gaining relevance in the dental field for virtual reality applications, such as for smile design. As pocket devices become more precise, their applications in the maxillofacial field should be reevaluated. For now, utilization of a smartphone (for example, iPhone 11) cannot be recommended for a consistent completely DW for facial prostheses manufacturing. Its application might be considered with caution for a semi-digital workflow, where the model of the defect is printed for a manual wax-up of the prosthesis.

The other concern here may be the fact that as soon smartphone scans achieve higher accuracy, fees for their utilization might increase. For now, there are some open-source applications for smartphones for data processing and exporting of gathered STL files. The most frequently used program (Bellus 3D Dental Pro) already charges for each data export.

Thus, data processing remains an inherent part of digital data acquisition. The tested Artec Space Spider requires the Artec Studio Software package, an additional investment of €1,200. In case of IOS, the data processing software is free of charge.

3.3.2 *CAD issues*

After digital data is gathered, it must be transferred for further CAD. Plug-and-play solutions are preferred in the dental field, as each production step in the typical dental CAD packages, such as DentalCAD (Exocad GmbH) and DentalStudio (3Shape), is well elaborated—the user just follows the wizard. Such a CAD solution is missing for maxillofacial rehabilitation, and the virtual design of a prosthesis often refers to utilization of freeform software, such as Zbrush, Rhinoceros (Robert McNeel & Associates, Seattle, USA) and Blender (Blender Foundation, Amsterdam, Netherlands). Although these packages provide absolute digital freedom for the user, they have not been specifically established for medical application, and their utilization prerequisites certain soft skills. Such CAD expertise with regards to facial prostheses design can be gained mostly in terms of learning by doing. The author attained one special course, “Zbrush in Anaplastology,” provided by the German Association of Maxillofacial Technicians (Deutscher Bundesverband der Epithetiker e.V.), which as for now is the only course on the topic. In contrast, the dental field offers a variety of dental CAD education courses and free tutorials.

There have been also some open-source packages, such as Meshmixer. However, their functionality is limited; for instance, embossment of facial skin details onto the prosthesis surface would be restricted. The mentioned software packages also require a high-performance computer.

Thus, the maxillofacial CAD should become more user-friendly, comparable to the dental field. Notwithstanding the fact that the dental field is full of CAD solutions, the learning curve of dental virtual design application is quite long.

The learning curves also differ depending upon the type of software, initial level of expertise and dental specialization [105, 106]. The learning curve for CAD application in maxillofacial prosthetics should be evaluated in further studies.

To simplify the whole DW the study #3 was conducted into creation of a DDB. Whereas a DDB may save some time for MFTs, a certain level of CAD expertise and sophisticated CAD software are still required for adjustment of adopted anatomy, application of skin details and integration of retention elements. Ideally, such databases should be integrated into CAD packages, making one step toward an easier and more user-friendly DW.

The other problem is that for now, not all manufacturers of retention elements provide their products in STL format. Furthermore, specifically designed scanbodies with integrated corresponding digital libraries are missing, which impairs the whole DW.

3.3.3 *Perspective of the IMM approach*

The IMM was shown to be more reliable than RM and remains one of the main technical options in DW [36, 107]. Study #4 demonstrated that Polyjet is the most accurate method in terms of skin detail reproduction. Furthermore, in comparison to SLA and DLP, direct Polyjet-based 3D printing from wax allows the user to skip some technical steps. However, there is only one wax material available (VisiJet, 3D Systems) which among its printability demonstrates sufficient thermoplasticity and allows for easy manipulations and sculpting during the try-on session. This Polyjet method is still based on an industrial 3D printer and is not affordable for MFTs. Outsourcing would be an option; however, one auricular prosthesis pattern may cost around €200. Furthermore, as this VisiJet wax comes from the jewelry industry, its intensive blue (starting from 2021, intensive red) color negatively affects the patient's perception of the prosthesis pattern during the chairside try-on. In contrast, the conventional workflow exploits a skin-like wax color. Alternatively, wax milling might be an option to create a wax pattern (Fig 12). This method has not been explored yet and must be evaluated in further clinical research.

Thus, the current state of IMM approach development calls for an alternative AM approach for 3D printing of skin-like wax, maintaining the great resolution of the Polyjet method (0.016 mm) at the same time. Other AM methods, such as FDM, are capable of 3D printing of wax filaments; however, these do not have the needed thermoplasticity and are in fact only wax-like materials.

Figure 12 a milled auricular prosthesis pattern in context of IMM approach.

3.3.4 *Perspective of RM approach*

Whereas the RM approach is more innovative and has more potential for time and money savings, it restricts the application of skin surface details and still necessitates some manual post-processing. The clinical result of the RM approach is severely dependent on the accuracy of the initial data acquisition. If there is a mismatch between the digitized morphology and a real defect, a poor marginal adaptation is unavoidable. There is currently only one printable silicone material reported for clinical application—ACEO Silicone with the use of drop-on-demand technique. Other researchers invested in the development of printable maxillofacial elastomer, however, reported its clinical application as lacking [97, 98]. Nuseir et al. reported the utilization of a rubber-like material with questionable biocompatibility [57]. A facial prosthesis can be printed from ACEO silicone using their printing service, available on the homepage. Potential acquisition of such printing hardware is debatable, as this printer is not available on the market.

Furthermore, the main technical limitation of silicone printing remains to be the poor layer thickness of 0.4 mm. It causes a visible staircase effect, which must be grinded off or sealed manually afterwards. Multi-material silicone printing allows printing with various Shore A hardness grades, but no multi-color printing. So, the current state of RM development encourages the invention of a new silicone multi-color printing hardware, which would use PLY or VRML data formats, with higher resolution. Such 3D printers would be game-changing and enable the direct manufacturing of fully customized and individualized facial prostheses, reducing the need for post-processing and decreasing overall production costs.

4 CONCLUSION

For a successful DW, an extraoral structured light scanner remains the state-of-the-art digitizer, as it allows for the most universal data capture, including morphology of the defect, contralateral side and the whole face. IOS may be regarded as a viable alternative, if already present at the maxillofacial unit.

Currently, the DW in maxillofacial prosthetics lacks a plug-and-play solution, calling for special software development with a more extensive database of facial parts, retention elements and skin details. A created DDB is an initial step toward the development of such specific software packages.

The evolution of prosthesis delivery in DW seems to follow two parallel avenues: IMM and RM. Both technical options are viable. IMM is more time-intensive but allows for manufacturing of more individualized and adjusted prosthesis with appropriately reproduced skin surface details and customized marginal fit. The RM approach may pose a good alternative and become more commercialized, allowing for a two-appointment prosthesis delivery. Such RM-made prostheses may be also regarded as provisional solutions for temporary wound sealing or additional travel prostheses. A direct integration of retention elements in the 3D printed silicone is possible and allows a user to save time during production of an acrylic superstructure.

Both approaches show a need for improvements. IMM calls for a new wax printing method with skin-like wax and decreased costs. RM calls for a new silicone multi-material and multi-color printing hardware at an affordable price.

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Erklärung

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