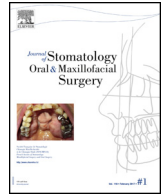




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Review

A systematic review of the computerized tools and digital techniques applied to fabricate nasal, auricular, orbital and ocular prostheses for facial defect rehabilitation



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ABSTRACT

A systematic review was conducted in early 2019 to evaluate the articles published that dealt with digital workflow, CAD, rapid prototyping and digital image processing in the rehabilitation by maxillofacial prosthetics. The objective of the review was to primarily identify the recorded cases of orofacial rehabilitation made by maxillofacial prosthetics using computer assisted 3D printing. Secondary objectives were to analyze the methods of data acquisition recorded with challenges and limitations documented with various software in the workflow. Articles were searched from Scopus, PubMed and Google Scholar based on the predetermined eligibility criteria. Thirty-nine selected papers from 1992 to 2019 were then read and categorized according to type of prosthesis described in the papers. For nasal prostheses, Common Methods of data acquisition mentioned were computed tomography, photogrammetry and laser scanners. After image processing, computer aided design (CAD) was used to design and merge the prosthesis to the peripheral healthy tissue. Designing and printing the mold was more preferred. Moisture and muscle movement affected the overall fit especially for prostheses directly designed and printed. For auricular prostheses, laser scanning was most preferred. For unilateral defects, CAD was used to mirror the healthy tissue over to the defect side. Authors emphasized on the need of digital library for prostheses selection, especially for bilateral defects. Printing the mold and conventionally creating the prosthesis was most preferred due to issues of proper fit and color matching. Orbital prostheses follow a similar workflow as auricular prosthesis. 3D photogrammetry and laser scans were more preferred and directly printing the prosthesis was favored in various instance. However, ocular prostheses fabrication was recorded to be a challenge due to difficulties in appropriate volume reconstruction and inability to mirror healthy globe. Only successful cases of digitally designed and printed iris were noted.

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1. Introduction

Recent studies show that there has been a significant increase in the reported usage of Digital technologies in maxillofacial prosthetics [1]. Digital technologies serve as adjuncts, and in some cases complete replacement steps in the fabrication of facial prostheses with the purpose of improving the current conventional methods [2]. However, as various authors successfully recorded multiple techniques in the computerized fabrication

of maxillofacial prosthetics, as of yet there is no singular set of standards of fabrication exclusive to digitally designed facial prostheses. In theory, each technique should come with its own set of pitfalls and challenges. These should be evaluated and compared against others to identify and address issues as well as make learned suggestions on which procedures can produce the clinician with their desired outcome.

The general process of digital workflow for the fabrication of a prosthesis [3] begins with data acquisition; usually Magnetic resonance imaging (MRI), Computed tomography (CT), 3D Photogrammetry, Laser scanning or ultrasound. Each method possesses their own advantages and disadvantages [4], which should be studied to determine the impact they have on the digital

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workflow for prosthesis design. If data is acquired by CT or MRI, these data are processed into a format called Data Imaging and Communication In Medicine (DICOM). Once processed, these data are converted into standard tessellation language (STL) format and prepared for editing using CAD software. The type of software, as well as the way it is used by the operator to produce results could influence the end outcome of the prosthesis. The STL model of the prosthesis is then printed using Selective laser scintering (SLS), fused deposition modelling (FDM), Stereolithography (SLA), Multi-jet modelling (MJM), etc. having their own benefits and consequences.

So putting the aforementioned issues into perspective, and also considering the limited number of studies and reports on digitally designed non-surgical maxillofacial prosthetic rehabilitation [5], this systematic review was done after setting out the objectives.

2. Objectives

2.1. General objective

To compile all the information and outline the general process of digitally designing each of the prostheses, as explained by the authors in a way to serve as a guide for the practicing clinician, should they wish to implement such technology in their practice.

2.2. Specific objectives

Main objective: to identify the recorded cases of orofacial rehabilitation made by maxillofacial prosthetics using Computer assisted 3D printing.

Secondary objectives: to analyze the methods of data acquisition recorded with their overall impact in the workflow and to record the techniques, challenges and limitations recorded with various software in the workflow.

2.3. Research question

From the objectives laid out, a general research question was created: Can digitally designed maxillofacial prostheses replace every aspect of conventional fabrication of auricular, orbital, ocular and nasal prostheses for the rehabilitation of orofacial defects?

3. Methodology

3.1. Creation of eligibility criteria

3.1.1. Include

The following were excluded:

- published observational studies or clinical case reports of Maxillofacial prostheses that outline the process of non-surgical prosthetic rehabilitation with integrated digital workflow for auricular, nasal and orbito-ocular defects ;
- articles describing rapid prototyping and 3D printed auricular, nasal, ocular and orbital prostheses for patients with mention of method of data acquisition and software used for design.

3.1.2. Exclude

The following were excluded:

- CAD and other 3D procedures used to produce dental-only prostheses, solely surgical or implant-based rehabilitation;
- articles that do not explain in details the method of data acquisition or computerized data processing;

- publication in languages other than English without accompanying translation.

3.2. Study selection

The search was conducted by two reviewers using online databases and search engines provided by PubMed, Scopus and Google Scholar. The Search was made in early 2019 and screening was carried out.

The search was made in the database to primarily look for titles concerned with maxillofacial prosthetics fabrication for ocular, auricular and nasal defects which had "CAD-CAM/Digital design/Digital workflow/computer assistance/3D print*/rapid prototyp*/additive manufacturing/solid free form*" in the title. After removal of duplicates, an abstract screening was done to exclude irrelevant articles based on the eligibility criteria. Only English abstracts related to maxillofacial prosthetic rehabilitation published from 1992 to 2019 were deemed relevant. The selected articles were categorized and full papers were reviewed.

4. Results and discussion

A total of 39 papers were selected for this systematic review. Fifteen papers were of Nasal Prosthesis, 15 of Auricular and 9 for orbital and ocular prostheses explained using PRISMA flowchart (Fig. 1). To the best of the authors' knowledge, no similar systematic reviews have been conducted in the past. The first 3-Dimensional printing devices and workflow were made available to the general population and saw mass production in the year 1992 [2]. Any studies or reports prior to 1992 would have been carried out using experimental models and workflow with errors involved. Thus articles prior to the said date were not considered for this systematic review as they would not properly reflect on the workflow available for mass consumption today. However The first maxillofacial prosthesis recorded using digital technology was by Penkenner in 1999 [6].

4.1. Nasal prostheses digital workflow

For nasal prostheses, 15 studies were selected (Table 1) and all were dated from 2009 to 2019.

4.1.1. Defect data acquisition

The process begins with data acquisition by CT scan [7–10], laser/light scanning [11–17] or 3D photogrammetry [18–21], sometimes in combination to improve the precision and reduce the risks of ill-fit by undercuts missed during a single scan [9,16,17]. Sun et al. [16] mentioned that the use of a combination of CT and laser scan would give the aesthetic precision of laser scans and volume depth of CT scans. Nuseir et al. [10] also stated that the slice interval of CTs can attribute to the overall design of a prosthesis which fits ideally onto the defect with 16 nm slices providing them with better results.

The authors who used CT scans as their primary means of data acquisition, also reported the use of software like Mimics and Simplant by Materialise (Leuven Belgium) to handle the DICOM file of CT [7,10,16] and convert to Solid object (STL) to be modified in CAD software. This step was not generally present in the case of laser/light scanning and photogrammetry.

4.1.2. Acquired data processing

The use of Geomagic studio (Geomagic Inc., NC, USA) [7,15,19,20,22] was most recorded. Some of the other recorded software were Zbrush (Pixologic, Los Angeles) [8,10,17], Rapidform

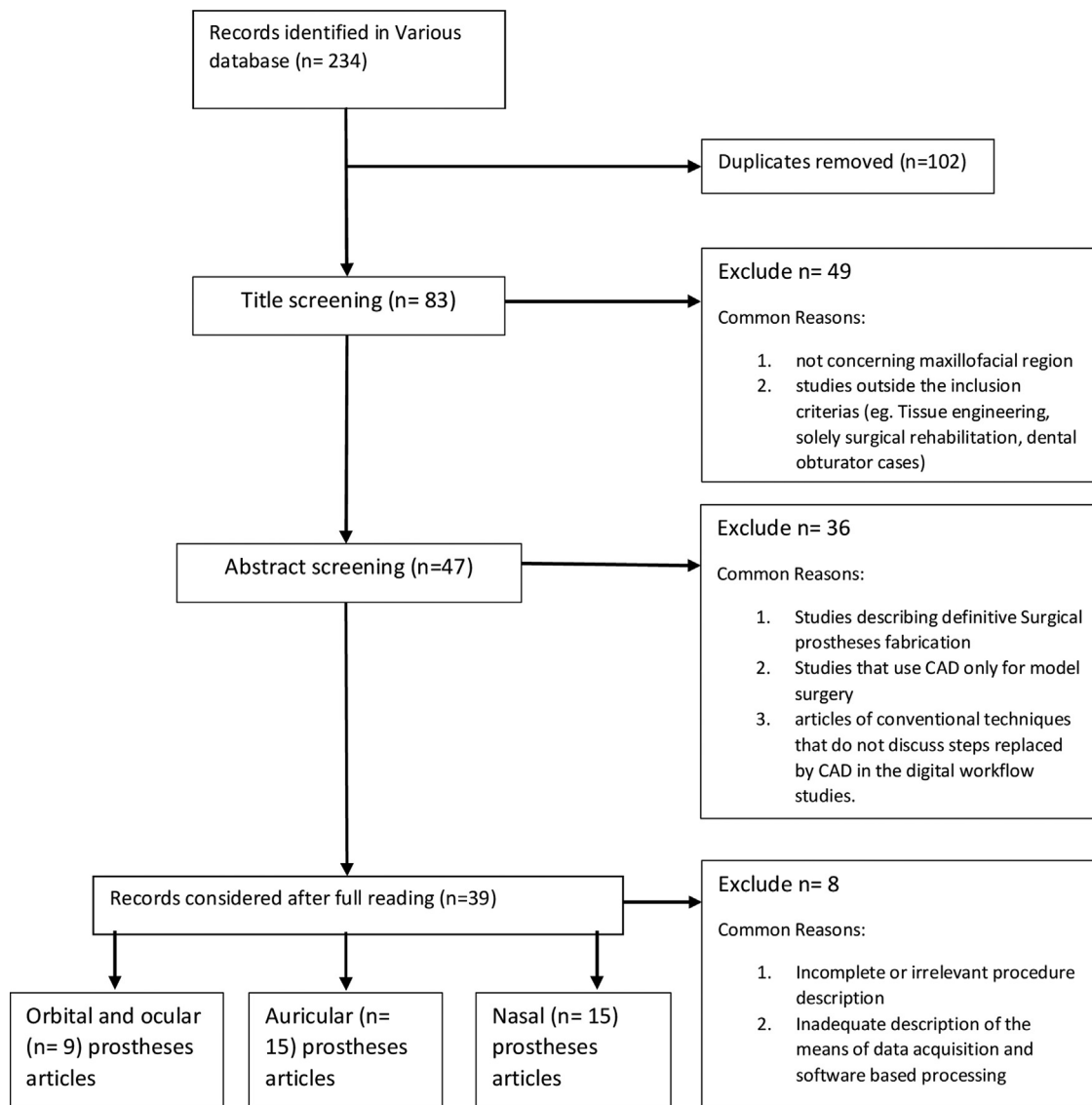


Fig. 1. Systematic review screening process PRISMA flowchart.

(INUS Technology Inc., Seoul, Korea) [11,12,14], Freeform Model Plus (SensAble Technologies, Boston, Massachusetts, USA) [18], Spectrum 510, Z-corporation [9]. The main function of the software was to create a virtual prosthesis, by triangulating the prosthesis onto the face according to the midline and merging the peripheries with the scanned healthy tissue for seamless margins.

4.1.3. Challenges in digital workflow for nasal rehabilitation

Mutlib [23] stated that the extension of the periphery of the prosthesis would have aided in better retention but could not be done because of the movement of the facial muscles. To address the said issue, Coicca [12] discussed the use of CAD to design thin overlapping silicone at the margins to mimic facial muscle movement and maintain integrity. Sun et al. [16] recorded the use of CT data with Simplant XOS (Materialise Co.) to differentiate rigid and non-rigid/moveable structures to better aid in the prosthesis design and margins.

Matsouka et al. [20] designed a homologous model of nasal prosthesis capable of recording various facial expressions while retaining marginal integrity in a patient. This was designed by superimposing various facial expressions of normal subjects over

subjects with facial defects. The mean percentage of < 0.3 mm difference between homologous models and scanned models was 97.5% for neutral expression in normal subjects, 97.3% for neutral expression in patients, 96.9% for smiling normal subjects, 96.8% for smiling patients, 93.5% for open-mouthed normal subjects, and 92.6% for open-mouthed patients. The difference between normal subjects and patients was not significant for any expression. The author also discussed the difficulty of reproducing perfect boundaries in moist margins like orbit, nostril and lips. This has been stated [23] to be an issue, even for the conventional process as well with authors explaining that vapor from exhalation and sebum from skin make retention of nasal prostheses difficult.

4.1.4. The need for a digital database

Although creating the nose from a scratch in CAD has been demonstrated effectively [8,10,17], multiple authors recommended the use of a digital ear and nose library to store and retrieve data to ease the process [7,14,15,21]. However, not everyone has access to such database, for which Reitemeier et al. [15] and Fantini et al. [14] demonstrated how to create an online database by digitally scanning patients and casts of patients respectively.

Table 1
Literature review on nasal prosthesis.

Author	Year	Data acquisition	Software used	Notes of significance
Abdullah et al.	2019	Laser scanner	Geomagic (Geomagic Inc.)	Suggested FDM printing to be more cost effective but filament diameter to be crucial in the final outcome
Nuseir et al.	2019	CT scan	Makerware (Makerbot inc.) Materialise Suite	Suggested the use of Spectromatch (Bath, UK) for color accuracy
Matsouka et al.	2019	3D photogrammetry (3dMD face System)	Zbrush (Pixlogic) Geomagic (Geomagic Inc.)	Suggested 16 nm slice CT to give better results Designed a system which creates prostheses with good margins on expressions Discusses the difficulty of reproducing perfect boundaries in moist margins like orbit, nostril and lips
Unkovskiy et al.	2018	3D photogrammetry (pritiface; pritidenta GmbH)	Zbrush (Pixlogic)	From the results obtained, the author discussed directly printing the prosthesis eliminates the try-in phase and thus led to poor color match and marginal adaptation
Abdulameer and Tukmachi	2017	Light scanner (Artec Spider; Artec 3D) CT scan	Zbrush (Pixlogic)	The author discusses the difficulty of finding a comprehensive digital database of prosthesis templates and even when there is one, becomes time consuming to match each one
Hsu et al.	2015	3D Photogrammetry (M300 LT)	Geomagic	Accuracy of 3D camera was stated ± 0.25 mm and resolution, 1.0 mm
Palousek et al.	2014	3D Photogrammetry (ATOS scanner)	Pro-E software Rhinoceros (McNeel)	Suggests retaining a digital copy of the nose before surgical resection for better facial symmetry Advocates the use of Nasal model databases
Reitemeier et al.	2013	laser scanner (G-scan; IVB Jena, Germany)	Geomagic Epitecture (Epitecture Studio, Sussex)	Discussed the creation of a digital nose database based on: dimensional categorization: width, length, bridge length and depth; general categorization: broad, narrow and medium; shape categorized according to nasal tip projection, nasolabial angle and nasal bridge profile
Fantini et al.	2013	3D laser scanner (NextEngine Santa Monica)	Rapidform XOS (Inus)	Demonstrated a process of creating an ear nose digital library
Sun et al.	2013	Laser scanner Konica Minolta VI-9i CT scan	Rhinoceros (McNeel) Simplant (Materialise)	Discusses the use of laser scanner for designing superficial contour and CT scan for inner surface model to eliminate each other's weakness
Eggbeer et al.	2012	Laser scanner (Ariel scanner)	FreeForm Modelling Plus (SensAble)	Thickness of the digital mold was reduced to 2.5 mm to reduce cost
Qui et al.	2011	3D photogrammetry (3DMD, Face Capture system) CT scan	Mimics (Materialise)	The author suggested retaining the mold as silicone deteriorates every 2 years
Sun et al.	2011	Laser Scanner	Geomagic C++ and Visual Toolkit (VTK)	Discussed indirect printing subjected the prosthesis to skill dependent external coloration Suggested laser scanning is the better choice for data imaging of facial prostheses with measurement error and uncertainty being 0.04 and ± 0.035 mm
Coicca et al.	2010	Laser scanner (Next Engine scanner, Santamonica)	Rapidform XOS	The author discussed the use of CAD to design thin overlapping silicone at the margins to mimic facial muscle movement and maintain integrity
		Laser Scanner. Konica Minolta VIVID 9i	Rhinoceros (McNeel)	The author stated it is not necessary to have a library if the contralateral side is alright The author pointed out that they needed 2 appointments before delivery thanks to CAD with total clinical time at 3 hours and 40 minutes. Total laboratory time was 27 hours (19 hours unattended for manufacturing) The author estimates the cost of production by conventional means of 811 Euros with 3D printed costing 413 Euros
Coicca et al.	2009	Laser scanner (NextEngine Desktop 3D Scanner)	Rapidform (INUS technology)	The authors mentioned a total recorded time was 8 hours 33 minutes spread over the course of 3 sessions and a total cost of 37.43 euros

Coicca [12] also suggested that having a database is not necessary if the defect is only on one half. Then the healthy half of the nose can be mirrored along the midline (either determined by software or by anatomical landmarks such as gnathion, nasion and

pronasale [24]) and blended along the margins. Palousek et al. [21] also suggested to keep a digital copy of the nose before anticipated surgical resection to aid in better symmetry and color match should a digital library not be available.

4.1.5. Nasal prosthesis substructure

Coicca et al. [12] reported making the substructures separately, with authors mentioning the use of CAD software Spectrum 510 (Z-corporation) and Rhino 4.0 (McNeel North America; Seattle, Washington) respectively to assist them in the process. This method could be beneficial for designing a fitting surface which relies on implants or digitally customized eyeglasses [12] for retention.

4.1.6. Direct or indirect rapid prototyping

The process of directly printing out the prosthesis or template is referred to as direct rapid prototyping whereas printing out a mold and manually injecting prosthesis material into it is called indirect rapid prototyping.

Once the prosthesis is made in CAD, based on the type of 3D printer available; the design can be printed directly [10,17,18,21] as a prosthesis or indirectly as a mold [7,11,12,18,19] or template [16]. Unkovskiy et al. [17] found directly printing the prosthesis eliminates the try-in phase but in turn led to poor marginal adaptation. Eggbeer et al. [18] in their study found conventionally packed silicone is more resistant to wear and tear than directly printed ones.

As silicone prostheses deteriorate over approximately 2 years, Qui et al. [7] suggest making and retaining the mold for ease of remanufacture in the future. If the prosthesis is to be printed directly, tools like Spectromatch (Bath, UK) can be used to select the correct shade of color for the prosthesis according to patient's skin tone [10].

The mold is designed by creating a block around the virtual model and creating negative volume (Boolean operation) in place of the virtual prosthesis. Some authors [19,22] report the use of additional CAD software like Makerware, (Makerbot, USA) and Pro-E Software to create molds.

The block can be divided into several segments to create the base, body and lid of the mold [7,19]. Printing a mold would require more material than the actual prosthesis, thus Eggbeer et al. [18] suggested reducing the thickness of the mold by 2.5 mm, which in turn reduces the cost of manufacture.

4.1.7. Time and financial implications

Nuseir et al. [10] compared that if the prosthesis is printed directly, it took 1 clinical session and 1 laboratory session while the same process by conventional means took 3 laboratory sessions and 2 clinical sessions. Palousek et al. [21] added to that discussion the total time taken for the prosthesis fabrication to be 19 hours.

Depending on the complexity of the case, if the prosthesis was made indirectly through a printed mold, the clinical sessions and cost requirement can vary. For one case, Coicca [11] recorded a total time was 8 hours 33 minutes spread over the course of 3 sessions and a total cost of 37.43 euros. While another case [12] needed 2 appointments before delivery with total clinical time at 3 hours and 40 minutes. Of the total 27 hours of recorded laboratory process, 19 hours were accredited to unattended printing of the prosthesis.

Coicca et al. [12] estimated in his case that the cost of production by conventional means required 811 Euros while digitally fabricating the prosthesis cost them 413 Euros with the biggest expenditure in conventional means was the wax up procedures involving the expertise of an anaplastologist costing 600 euros. This cost was eliminated in the digital workflow, which in turn incurred the costs of software and printing technology.

4.2. Auricular prostheses digital workflow

A total of 15 articles involving auricular prostheses were selected (Table 2). Thirteen of the 15 studies published in 2009 to 2019.

4.2.1. Defect data acquisition

The process, similar to digital nasal prosthesis fabrication, began with data acquisition. While most authors relied on laser scanners of various types [24–32], CT scans [6,33–37] and 3D photogrammetry [33,37] were also recorded. One disadvantage of laser scanning patients was anterior edge misfits which the Unkovskiy [31] attributed to the patient moving during scanning and thus stated that in order for proper representation of data, the patient needs to stay completely still during the process. This can be especially difficult to achieve amongst children.

Multiple authors [25–27] suggest the use of cost effective and time efficient methods of laser scanning technology. However, Ballo et al. [32] stated that although intraoral scanners are fast and efficient, it also exposes the patient to 40–50 cGy of radiation from the scanner.

The use of CT scans to digitally fabricate auricular prostheses have been recorded as early as 1999 by Penkner [6] to create an auricular template. Turgut et al. ensured standardization of DICOM Data by holding a 0.5 mm section 512 × 512 16 bits CT or 256 × 256 MRI.

Some authors however, relied on the conventional impression techniques [6,30,35] to record the defect site for manual adaptation of the printed ear. Jamayet et al. [30] suggested that a conventionally processed healthy ear cast be marked and scanned twice using a desktop 3D scanner with 16 angles per position to increase precision of the digital data once the marks are connected. This could potentially allow the avoidance of radiation induced by other methods of scanning.

4.2.2. Acquired data processing

Once the data is acquired from the patient, it is reverse engineered into a digital format. Data which was obtained from CT scans was processed by software like 3Ddoctor (Able Software Corp, Lexington, MA) [36], Polygon Editing Tool (Konica Minolta) [25,27] and MIMICS (Materialise, Leuven, Belgium) [37], Unigraphic Software (Siemens Nx) [27] or Slic3r [28] and then converted to STL file format and imported into CAD software.

For laser scanners, Unkovskiy et al. [31] mentioned the use of Artec Studio Software (Artec 3D) to process the data after scanning. The author also mentioned placing two fiducial points on nasolabial folds to act as tracing references. Authors discussed the use of Geomagic [27,33], Freeform Modelling Software (Sensable, Inc.) [35], Meshmixer (Autodesk Inc.) [32], Rapidform [26], Rapidworks (3D System, Inc.) [30], Zbrush (Pixlogic) and Z-build (Z-corp) [29,31], Magic and RSM (Materialise) [37] as their CAD tools.

4.2.3. Unilateral vs. Bilateral ear defect

To repair unilateral auricular defect, the general management of choice is to mirror a healthy ear onto the defect side [6,24–37]. In the case of bilateral ear defect, the absence of a healthy ear to mirror by symmetry creates significant challenges for the clinician. This is one instance where authors [26,29] argued the necessity of having a digital database to select an ear based on best fit. The selected ear could then be mirrored onto the other side and two finished products can be printed by either direct or indirect methods.

4.2.4. Direct or indirect rapid prototyping

Rapid prototyping of an auricle requires obtaining the digital midline of symmetry and follow one of two procedures; either merge the margins to adapt to the affected side and directly print the prosthesis [29,32,37], or print a template, convert it to wax which will then be manually adjusted to the patient's defect side [6,35]. The template should then be processed to conventional cast mold and silicone packed accordingly.

Table 2

Literature reviewed on auricular prosthesis.

Author	Year	Data acquisition	Software used	Notes of significance
Ballo et al.	2019	Laser scanner – intraoral (Trios3; 3Shape, Copenhagen, Denmark)	Meshmixer v2.1 (Autodesk, San Rafael, CA)	The author discussed the main advantage being the save in time while disadvantage being 40–50 cGy of radiation from the scanner
Jamayet et al.	2018	Laser Scanner (Next Engine Desktop 3D Scanner, NextEngine Inc.)	Rapidworks64, (3D System, Inc.)	The cast of the healthy ear can be scanned from two angles with 16 points on each side. This increases the accuracy of digital data reproduction
Unkovskiy et al.	2018	Laser Scanner (Artec Spider, Artec 3D)	Artec Studio Software (Artec 3D) Zbrush (Pixologic)	There could be anterior edge misfits in the data obtained from laser scanning if the patient does not remain still Indirect mold manufacturing produces better prosthetic fit If mold is directly designed digitally and segmented, The outer piece could be divided along the posterior auricular edge to ease the undercut and allow for easier packing of silicone
Sanghavi et al.	2018	CT scan	Free Form Software System (SensAble Technologies)	The author suggested the advantage of retaining the ear for future re-fabrications since silicone is prone to tear
Yadav et al.	2017	CT scan	3D modelling Software	The mold can be digitally designed with vents to facilitate flash material to escape Design of the mould can be hollow with a minimum thickness of 3 mm, which in turn saves material while printing and thus saves cost
Wang et al.	2015	CT scan	Geomagic (Geomagic Studio 12.0; Raindrop Geomagic Inc.)	The author discussed the need to have data acquired before and after surgical intervention if the next step of rehabilitation is prosthetic fabrication and fitting
Bai et al.	2014	3D photogrammetry (3DSS; Digital Manu Corp) Laser Scanner (3DSS-STD-II)	“intelligentized simulation design”	healthy ear and mid-plane was mirrored through nasion, pronasale and gnathion The author mentions the additional design of mortise and tenon joints to guarantee a secure seal during processing
He et al.	2014	Laser scanner	Slic3r Rhinceros (Mcneel)	FDM printing results in staircase like contour on print surface The authors devised a polishing device with acetone vapor to address the staircase issue
Watson and Hatamleh	2014	Laser scanner (3 Shape R700)	Z-Build (v7.5; Z-Corp)	RP at its current stage is an additional to the conventional means The author also suggested keeping records of each auricle made in a database to be used for bilateral cases
Tam et al.	2014	CT scan	MIMICS, Magics and RSM (Materialise)	The authors used Soft Touch (BrainLAB, Feldkirchen, Germany) to check for accuracy of the prosthesis in their study
Coicca et al.	2010	Laser scanner (NextEngine Desktop 3D Scanner)	Rapidform (INUS Technology)	Authors suggest surgical reconstruction using bone and cartilage over prosthetic rehabilitation for bilateral ear defects Digital ear and nose library required for bilateral ear defects. A template can be selected and mirrored Author suggests FDM printing The FDM printed mold can be made sparse/hollow which saves more material and decreases cost at the expense of strength of the mold
Singare et al.	2010	Laser scanner (Konica Minolta VIVID 910)	Polygon Editing Tool Geomagics studio Unigraphic Software 3DDoctor (Able Software Corp)	The author discussed rapid prototyping with laser scanner and vacuum casting technologies for making mold is a cost effective way For all the cases, the author ensured standardization of DICOM Data by holding a 0.5 mm section 512 × 512 16-bits CT or 256 × 256 MRI
Turgut et al.	2009	CT scan and MRI	FreeForm Modeling Plus System (SensAble) Polygon Editing Tool (Minolta)	Laser scanning was done to digitally acquire data off the cast made from an impression of the patient's healthy ear The healthy ear is mirrored, printed and manually fitted onto the defect site
Coicca and Scotti	2004	Laser scanner (Minolta VIVID 900)	Rapidform (INUS technology) Medical Diagnostic Computing (MDC), Zeiss Group, Kiel, Germany	An auricular template was fabricated, which bypassed wax sculpting. The rest of the procedure was done manually
Penkner et al.	1999	CT scan		

Sanghavi et al. [35] discussed the advantage of retaining the auricular template for future re-fabrications since silicone is prone to tear. Qui et al. [7] addressed the same concern regarding silicone however, suggested retaining the mold for nasal prostheses, instead of the template. This requires further studies to determine if the type of imprint (template or mold) affects the way that certain prostheses can be effectively and successfully refabricated for future use.

One other process recorded was mirroring the healthy ear, merging the margins with tissue surface and then applying the negative volume effect to create a segmented mold (indirect rapid prototyping) of the prosthesis [24,26–28,31,34,36]. Some authors mentioned the use of additional software like Rhinoceros (McNeel North America) and Solidworks [28] in order to fabricate the said mold. Yadav et al. suggested adding vent design for flash escape, keeping a minimum of 3 mm thickness of the mold while designing it hollow to save material. Additional design of mortise and Tenon joints was also suggested by Bai et al. to guarantee a secure seal during processing [24,34]. Unkovskiy et al. [31] suggested that the outer piece of the mold be divided along the posterior auricular edge to ease the undercut.

When comparing the accuracy of both techniques, Unkovskiy et al. [31] found template influenced conventional mold (indirect mold) to produce a better fitting prosthesis than a directly printed mold. However, Tam et al. [37], using Soft Touch (BrainLAB, Feldkirchen, Germany) found that of 6 indirect mold prostheses, 4 of 6 had good marginal accuracy and retention while All 6 had symmetry and good position. In order to maintain color accuracy of an auricular prosthesis, past literature [38] suggested using a spectrophotometer (Spectromatch Ltd., Bath, UK) on the nape of neck for darker skin texture and the back of ear for lighter texture.

4.2.5. Time and financial implication

The Fused Deposition Modelling (FDM) printers are known to be affordable when used to print digital designs for auricular defects [26]. According to He et al. [28], the first prosthesis can be fabricated at a cost as low as \$29.1 and cost can decrease on subsequent productions if FDM based desktop printers are used, in contrast to the \$411.80 if printed by a commercial printer. FDM printers, however create step like textures on the printed surface. To overcome this, He et al. [28] used an acetone vapor infused

custom polishing device. FDM can print solid filled mold which is heavier and stronger. On the contrary, if designed sparse/hollow in the CAD software; the mold becomes lighter, weaker, has honeycomb interior but however saves more material. Authors [26] calculate the amount of ABS material for both ears to be 96.7 cm³ and support material to be 22.95 cm³. This led to a production cost of only 36.58 euros and a production time of 10 hours 42 minutes.

CAD designed auricular prostheses in general are known to save the time spent sculpting the ear. This is further confirmed by Jamayet et al. [30] and Bai et al. [24] who describes the same conventional process to take 4 appointments over the course of 3 weeks while digital workflow reduce the worktime to 1 week and total clinical time for each patient over 2 appointments was 4 hours in total respectively. Watson and Hatamleh [29] added that wax template fabrication took 40 minutes while the traditional methods could take 2 hours per ear.

4.2.6. Opinions of experts

Despite the noteworthy advances in digital workflow for auricular prostheses, Coicca suggests surgical reconstruction using bone and cartilage over prostheses while Watson [29] suggests young children should undergo implant supported prostheses for more definitive retention. Watson also pointed out that rapid prototyping and digital workflow at its current stage is an additional to the conventional means for auricular prosthesis fabrication and has not been able to completely replace the conventional process.

4.3. Orbital and ocular prostheses digital workflow

For orbital and ocular prostheses, a total of 9 studies were selected (Tables 3 and 4). Except for one study (2004), all the other studies were published between 2013 to 2019.

4.3.1. Digital orbital prosthesis workflow

4.3.1.1. Defect data acquisition

For an orbital defect surrounding tissue also need to be replaced along with the globe. Conventional management include taking an impression of the defect, creating a wax pattern and selecting a

Table 3
Literature reviewed on orbital prostheses.

Author	Year	Data acquisition	Software used	Notes of significance
Liu et al.	2018	3D photogrammetry (3dMDface System; 3dMD)	Geomagic Studio	The author states the use of custom ocular prosthesis, instead of stock could have better esthetic value in the case of digital orbital prosthesis fabrication
Chiu et al.	2017	Intraoral scanner (TRIOS 2.0; 3Shape) 3D photogrammetry	Autodesk 123D Catch, Autodesk, Inc ZBrush, Pixologic Inc	The author suggested their method was cost effective and had better color matching for maxillofacial prosthetics
Coicca and Scotti	2014	MRI Laser Scanner (NextEngine, Santa Monica)	ClayTools system: Freeform Modeling Plus software and Phantom Desktop Haptic device; (Sensable)	The author stated that MRI could be provide better details of the tissue within the defect as opposed to CT scan
Bi et al.	2013	3D photogrammetry: 3D scanning system (3DSS-STD-II)	Geomagic Studio (Geomagic Inc.)	Macroporosity was projected on the back of the prosthesis design to reduce weight To prevent undercut misrepresentations, two 45 degree scans from left and right were taken and merged Ocular prosthesis was chosen from the prefabricated templates present
Reitemeier et al.	2004	3D Photogrammetry (kolibri-mobile; IVB)	SURFACER (alphacam; GmbH)	The author discusses the use of a thermojet model intermediary to check the fit before conversion into definitive prosthesis

Table 4

Literature review on ocular prosthesis.

Author	Year	Data acquisition	Software used	Notes of significance
Ko et al.	2019	Light intensity scanner (Cara Scan 3.2, Kulzer Inc.) Slit lamp biomicroscope (Haag-Streit AG, Koeniz)	ZBrush 4R7 (Pixologic Inc.) Photoshop CS4 (Adobe Systems Inc.)	The author suggested CT imaging in anophthalmic sockets are poorly distinguishable and can not capture the actual eye To avoid manually painting the iris, a digitally modified printed image of the subject's contralateral eye can be applied on the ocular prosthesis by sublimation technique The author suggested dye sublimation transfer on curved surfaces since heat and pressure do not damage the surfaces
Alam et al.	2018	CT scan	MIMICS (Materialise)	The author CT scanned the wax pattern derived from the patient's socket impression Author designed the prosthesis hollow to reduce weight (custom 2.9 while conventional was 4.4 grams) and increase comfort
Ruiters et al.	2016	CT scan	MIMICS (Materialise, Leuven, Belgium)	The 3D printed prosthesis was smaller than the conventional and had to be readjusted and duplicated CT scan of the orbit exposed the patient to 54 mSv rads
Buzayan et al.	2015	Digital camera	Paint Shop Pro X4; Corel®	The scleral conformer was made conventionally and iris was digitally designed and printed The author suggested diameter should be 1 mm less of the printed iris compared to natural iris to compensate magnification by clear corneal prominence

stock ocular prosthesis which matches the best aesthetics. The combined prosthesis is then processed by packing silicone and/or acrylic into the mold produced by the wax pattern [39].

In the case of orbital prosthesis fabrication by digital workflow, the use of various forms of laser 3D scanners had been reported from 2013 to 2018 [40–42]. Huan Liu [41] also recorded the use of intraoral scanners for data acquisition although the author recognized that once alignment is lost on facial topography is difficult to regain with intraoral scanners. Yunpen Bi [40] suggests in order to prevent undercut misrepresentations, two 45 degree scans from left and right to be taken and later merged in CAD software like Geomagic. Authors like Coicca [42] also integrated MRI with laser scanning for the rehabilitation process. 3D photography has also been found to be a preferred choice for data acquisition [43,44].

4.3.1.2. Defect data processing

Once scanned, the data can be processed by CAD software like Geomagic (Geomagic Studio; Geomagic Inc.) [40,41], ClayTools system (Freeform Modeling Plus; Wilmington) [42], SURFACER (alphacam; GmbH) [43], Autodesk, Inc and ZBrush (Pixologic Inc.) [44]. All of the above software require payment to use except Autodesk, which is free to use.

Each software has their own tool names, but their functions remain invariably the same as auricular prosthesis; determination of the midline and mirroring the unaffected side onto the affected side and merging the margins [40–42,44]. A stock digital eye can also be selected on a trial and error basis should the appropriate digital prosthetic library be available to the user and later printed with the orbital segment of the prosthesis [40]. Macroporosities were also suggested by Coicca and can be digitally designed on the inner surface to reduce weight, while designing the prosthesis to later attach to eye glasses can serve as added retention [42].

4.3.1.3. Direct or indirect rapid prototyping

Once the digital prosthesis is created, it can be printed directly as a prosthesis [43,44], or by converting it into negative volume can be printed as a mold [40–42]. If printed as a mold, it will have to be manually packed using silicone and undergo extrinsic coloration while a direct print of the prosthesis can be digitally color matched and printed, eliminating the need for manual artistic intervention [44].

4.3.1.4. Time and financial implications

The total manufacture time estimated by Bi et al. [40] was of 5 hours over 2 appointments as opposed to 13 hours if made by conventional means.

4.4. Digital ocular prosthesis workflow

4.4.1. The challenge of defect data acquisition

Proper digital fabrication for an ocular prosthesis in most cases remain a challenge. Unlike auricular or nasal defects which are projections on the face, the eye is contained within a socket surrounded by hard and soft tissue. Prolonged periods without an eye would lead to contracture (anophthalmus) of the socket which could be poorly represented in a tomographic scan. Jaesang et al.'s [45] article supported this statement that ocular images of CT are poorly distinguishable and do not represent the actual volume of the eye. Instead, the author used a light intensity 3D scanner to scan a cast made from the physical impression of the socket.

Alam et al. [46] used CT scan to acquire data from a cast made from the physical impression of the socket instead of using CT to obtain data directly from the patient. Ruiters [47] worked on capturing a CT image on patients. In order to limit the radiation exposure to the patient, the authors opted for Cone beam CT (CBCT). A small stock conformer was placed within the socket, which, in theory would preserve the shape of the socket by separating the palpebra and orbital conjunctiva during the scan. Despite the added precautions, the finished product was still smaller than the conventionally made prosthesis. Adding to this, the author also stated that MRI would also not be a viable source of data acquisition for an ocular prosthesis as it is easily distorted by motion artefact.

4.4.2. The challenge of defect data processing

Once data acquisition is complete, select software are used to process the data. When 3D scanned, some authors [45] used CAD software like ZBrush 4R7 (Pixologic Inc., Los Angeles, CA, USA) to mark the iris and remove noises. The data is then carried on as STL. If the data is acquired from CT scans, it is saved as DICOM format. The cases recorded which use CT as their primary source of data used Mimics (Materialise, Leuven, Belgium) to process the data [46,47]. The software smoothened the edges, added volume mesh and as could make the prosthesis hollow which would significantly

reduce the weight (digital prosthesis was 2.9 grams while if made conventionally was 4.4 grams) of the final printed prosthesis while simultaneously reducing the cost of production [46]. This is also in agreement with other authors [48] who also suggested that reducing the fill density could result in lighter prosthesis and more patient comfort. However, when the authors compared between the two, there was no difference in ocular motility between the conventional prosthesis and the one made by said digital workflow [46] even though most digital workflows eliminate the phase of conformer try-in. The use of a stock ocular prosthesis [49] by conventional means also however eliminates the conformer phase with comparable results.

One possible reason why there are very few recorded cases of digitally constructed ocular prostheses (compared to auricular and nasal prostheses) could account to the fact that volume reconstruction of the globe remains a challenge. Simply mirroring the healthy globe over would lead to poor fit of the prosthesis due to the irregularity of the defect socket, which as authors suggest are poorly represented in scans. Past papers [48] mention trying to develop methods of 3D volume reconstruction for ocular prosthesis. The authors recorded the top surface by replicating the healthy eye by Hough transformation and lower surface and contour from facial edges that fit with a cluster of Fourier Curves assuming that interior ocular difference between lost eye and normal eye will change the exterior surfaces proportionally. The comparison with traditional methods showed % errors of 4.04% on vertical axis, height of 9.38% and horizontal 0.46%.

The conventional direct injection technique of impression taking requires two sessions with the patient while special tray technique requires 4. Regardless of the technique, authors state that the conventional wax try-in gives the best projection as the conformer can be altered as required, especially in contracted or deformed sockets [50,51]. This still remain a challenge to facilitate using digital data acquisition and designing.

4.4.3. Digitizing the iris instead: an alternative workflow

Even if ocular volume remains a challenge in prosthetic reconstruction, authors [45,52] have shown that capturing 3D photographs of the healthy eye (blood vessels and iris) and mirroring it saves a considerable amount of time in the fabrication process. This modification can be done in general photo editing software like Photoshop CS4 (Adobe Systems Inc., San Jose, CA, USA). The print can be fused with the sclera using sublimation technique as suggested by Ko et al. [45] or printed and placed between two layers of acrylic as mentioned in Buzayan's paper [52]. The sublimation technique requires 30–60 minutes which if done manually would have taken 3–4 hours, while digitally printing the iris takes 20 minutes and does not add bulk to scleral thickness [45,52]. Buzayan et al. [52] advice that the diameter should be 1 mm less of the printed iris compared to natural iris to compensate magnification by clear corneal prominence.

5. Conclusion

Outcome and quality of CAD design along with the approaches available is highly dependent on the method of data acquisition as well as the type of product designed in CAD; template, mold or directly printed prosthesis. Printing the template allows for a try-in phase before printing the definitive prosthesis. Authors preferred the digital design of the mold for the prosthesis which allowed for manual color matching and aesthetic contouring. The mold can be made thin and hollow to reduce material and printing expenditures. A directly printed prosthesis can be modified on the fitting surfaces and can be made hollow, which increase the overall comfort to the patient. CAD assisted mirroring technique is most

popular for auricular prosthesis and orbital prosthesis, while a digital library of templates is preferred when mirroring is not an option. However, Digital design for ocular prosthesis still remains a challenge. Finally, parts of the fabrication process still demand conventional human intervention hence no maxillofacial prosthesis has truly shifted completely to digital fabrication.

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Contribution of authors

The first author is currently specializing in Prosthodontics and Maxillofacial prosthetics while carrying out research in digitized maxillofacial prosthetic rehabilitation at Universiti Sains Malaysia. The corresponding author is a 10-years practicing maxillofacial prosthodontist. The other authors are members of the craniofacial imaging and/or are experienced in other branches of digital dentistry. All studies and research have been carried out by Maxillofacial Prosthetic Service, Prosthodontic unit in collaboration with department of craniofacial imaging, School of Dental Sciences, Universiti Sains Malaysia, 16150 Kelantan, Malaysia.

Disclosure of interest

The authors declare that they have no competing interest.

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