MAXILLOFACIAL PROSTHESES PRODUCTION THROUGH COMPUTER-AIDED DESIGN AND MANUFACTURING TECHNOLOGIES - REVIEW OF STATE OF THE ART

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ABSTRACT

Many patients suffer facial disfigurements, causing significant psychological trauma. In the past, external maxillofacial prostheses were produced through fabricating wax models and applying carving techniques. Digital imaging technologies, computer-aided design, computer-aided manufacturing and additive manufacturing have opened new approaches to the production of maxillofacial prostheses. In South Africa, the uptake of the newer techniques has been slow, because of a lack of skilled practitioners and limited funds, particularly because many patients are government funded. A project is currently underway to revise and customise the production process chain for the manufacturing of maxillofacial prostheses to address the South African challenges.

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1. INTRODUCTION

The incidence of trauma has shown a constant upward trend worldwide. Many people suffer one or other disfigurement. Facial trauma has been shown to be strongly associated with road traffic accidents, assaults, burns and cancer [1]. The World health Organisation has estimated that more than 3,000 people are killed every day on the road; at least 30,000 others are injured or disabled; over 1.2 million people are killed, and as many as 50 million injured each year. More than 50% of patients with these injuries have multiple traumas requiring coordinated management among various disciplines of anaesthesiology, otolaryngology, trauma surgery, plastic surgery, ophthalmology, and oral and maxillofacial surgery [2]. The high incidence of road traffic accidents and assaults in South Africa, also add to the statistics of facial trauma patients; many from disadvantaged communities.

Globally in 2004, the incidence of burns severe enough to require medical attention, was nearly 11 million people and fourth in all injuries, after road traffic accidents, falls, and interpersonal violence. This number is greater than the combined incidence of tuberculosis and Human Immunodeficiency Virus (HIV) infections, and just slightly less than the incidence of all malignant neoplasms [3]. Burn injuries constitute one of the most important public health issues in developing, as well as in the developed countries [4]. Burns in South Africa have also been considered as one of the major contributors to facial trauma. In South Africa, burns affect 3.2% of the population annually, and are particularly common in children and young adults [5]. Shack fires and primus stoves are of the major sources of burns in South Africa [6].

Congenital or acquired facial disfigurement presents a serious psychological and social challenge to the individual who has to cope with an appearance that is obviously different, hard to conceal, and subject to social stigma [7]. People with facial disfigurements are faced with the challenges of social reactions and their own psychological responses to looking different [7]. They fear of not being accepted in society, being treated as outcasts and often suffer severe depression and social rejection [8]. As a consequence, patients with abnormal facial characteristics are not only rated as significantly less attractive, but also as less honest, less employable, less trustworthy, less optimistic, less effective, less capable, less intelligent and less popular [9]. Therefore, patients suffering maxillofacial disfigurements usually visit medical practitioners requesting some or other reconstructive intervention. Many of these interventions require the reconstruction of anatomical body parts, requiring the manufacturing of facial prostheses.

Prosthetics are a category of medical devices intended to replace missing body parts, either inside or on the surface of the body. As such, the category can include both external prostheses, artificial limbs, and internal prostheses such as joint replacement devices. Maxillofacial prostheses are either external in nature, or internal or both, and are considered by many the primary choice of treatment for functional rehabilitation, aesthetic reconstruction and for the rebuilding of a patient's confidence [10]. Maxillofacial prostheses provide comfort and support to a patient on many levels. These patients demonstrate improved mental health, social engagement and are able to lead productive lives [11]. A good quality and appropriate prosthesis thus has a significant impact on the level of independence of the user and reduces the need for formal support services.

Additive manufacturing (AM) is fast becoming one of the greatest breakthroughs in healthcare. In the field of prosthetics, AM and related technologies are increasingly becoming more established in this health sector [12]. Although this sector of the market is in its infancy, the expectations are high. In 2012, the medical segment of the AM market was only $11 million, but as the cost of the technology decreases, the market is expected to grow to $1.9 billion in 2025 [13]. The promise is to print in remote locations by local distributors and service providers. Thus, delivery of goods will no longer be a restriction [12]. It is estimated that at least in excess of 100 million people (1.5 % of the world's population) are in need of prosthesis, therefore, it is expected that AM can solve these medical problems with extensive benefit to humanity [11].

2. CONVENTIONAL MAXILLOFACIAL PROSTHESES DESIGN AND PRODUCTION

Until recently, most maxillofacial prostheses manufacturing processes have been 'subtractive' in nature. In these manufacturing processes, the desired artefact is produced by removing undesirable or superfluous material from a three-dimensional preliminary product. The methods differ depending on the type of disfiguration for which a prosthesis is manufactured [14, 15].

Conventionally, external maxillofacial prostheses are fabricated by hand carving the missing anatomic defect in wax and creating a mould into which pigmented silicone elastomer is placed [16]. These conventional techniques include several complex steps and rely on the artistic ability of a maxillofacial technician and the skills of a clinician [15, 17]. 1) An accurate impression of the area requiring prosthesis is taken. This is achieved by selecting the suitable impression material according to the site and size of the defect, and presence or absence of any undercuts in the area of the defect. Impression materials range from soft/flexible to hard/rigid and include hydrocolloid alginates, elastic silicone polymer, and rigid materials such as plaster of Paris [15]. Although plaster of Paris can achieve excellent details of the defect, it cannot be used in the presence of severe undercuts, as fracture of the impression material will occur on removal and/or damage to the soft tissue might occur. Therefore, it is preferable to use flexible or elastic material in cases of moderate to severe undercuts. Presurgical impressions are also used to save details of the area that is going to be replaced. 2) A 'positive' stone plaster version of the 'negative' impression is cast by pouring the impression with stone plaster. 3) Using this stone plaster cast as a reference model, a wax or clay model is built of the anatomy of interest, after which the model is carved until the natural morphological details of the defect are obtained. Often, a maxillofacial technician will make use of details from photos or a mould of the pre-operative condition, or from contralateral structures, such as an ear or an eye. Details may also be obtained from one of the patient's relatives, who have similar facial features. 4) The fit of the wax or clay model of the missing part is then inspected on the patient. 5) The model is then transferred into the final material using conventional flasking methods. After removing the wax and lubricating the cast, suitable silicone rubber is mixed with skin colouring agents and checked against the patient's skin colour. The silicone rubber is then applied to the mould to complete the flasking process. Once the silicone rubber has set within the cast, the facial prosthesis is recovered from the mould, trimmed and extrinsic colorant added if necessary, often by hand-painting.

Conventional methods used for the production of maxillofacial facial prostheses have several limitations. It is a relatively expensive and time-consuming process, both in time and materials, requiring a high degree of technical skill to hand craft such prostheses. Patients also experience discomfort, particularly during the impression taking process [18]. Furthermore, these prostheses do not last indefinitely and undergo deterioration [15]. Changes occur with the colour and consistency of the prostheses, creating colour-matching differences with a patient's skin. A fitted facial prosthesis is in contact with human skin/mucosa for lengthy periods and may absorb skin/oral secretions including sweat, sebaceous secretions and saliva, which may contribute to the degradation of the prosthesis material [15]. The service of maxillofacial facial prostheses is further limited by exposure to sunlight and changes in temperature, humidity and hand contact during cleaning, as well as the use of adhesive on a daily basis [19, 20].

3. NEW APROACHES TO MAXILLOFACIAL PROSTHESES DESIGN AND PRODUCTION

The rapid development of three-dimensional printing (3-D printing), also known as AM or rapid prototyping (RP), and the proliferation of design software have brought about new approaches to customised, personalised prosthetic manufacturing [21]. These combined technologies are generally referred to as Computer-Aided Design (CAD) and Computer-Aided Manufacturing (CAM) and covers a broad range of production technologies that are used to fabricate products layer-by-layer, enabling three-dimensional objects to be 'printed' on demand [22]. The medical industry has found revolutionary ways to implement these technologies [12]. Although AM has existed for over 30 years; only recently has this technology risen in popularity in the field of prosthetic manufacturing [12]. Fabricating custom implants such as hearing aids and prosthetics was one of the first ways that AM transformed the medical industry [23]. Its uptake has been somewhat slow and regarded as being more as experimental [10]. This delay in shift to AM technology in prosthetics can be attributed to a lack of understanding of the AM processes, slow rate of approval of use of new biocompatible AM materials, and possibly the loyalty of doctors to familiar brands of prostheses [10]. Increasingly, CAD/CAM technologies are becoming part of the discourse in the medical field.

AM has been referred to a disruptive technology that will fundamentally influence many processes such as production, supply chain design, logistics and consumer behaviour [24]. AM has the potential to replace many conventional manufacturing processes and to stimulate a plethora of new business models, new products and product supply chains. Two important characteristics of AM's disruptive potential are: Firstly, it enables direct production of physical objects from digital design data, and provides new opportunities for freedom of design. Customised products can be manufactured without high surpluses of conventionally connected with one-of-a-kind manufacturing [24]. Secondly, AM allows private and industrial users to design and produce their own goods.

CAD/CAM technologies in maxillofacial prosthesis manufacturing, follows broadly the same major steps as the conventional method. In the conventional method, data collection of a patient's anatomy involves the impression taking process, which is replaced by obtaining 2D digital images in Digital Imaging and Communications in Medicine format (DICOM) with computed tomography (CT) or magnetic resonance imagining (MRI) (Figure 1) [25]. In contrast to the negative impression of the conventional method, the digital images are a positive representation of the patient's anatomy. The DICOM file is then exported to medical imaging editing software. A skilled medical designer compiles and reconstitutes a virtual 3D view of the patient's anatomy, referred to as a geometry. The geometry is further processed through volume rendering functions to display a 3D image of all tissues, after which the digital data of the patient's anatomy of interest is isolated. At this stage, the digital data can be exported as a stereolithography (STL) file to a 3D printer or to CAD software for further design enhancements and corrections [26]. Once a final geometry has been designed, a digital mould is also designed for the geometry and 3D printed. Finally, a silicone prosthesis is cast in a similar way as in the conventional method.

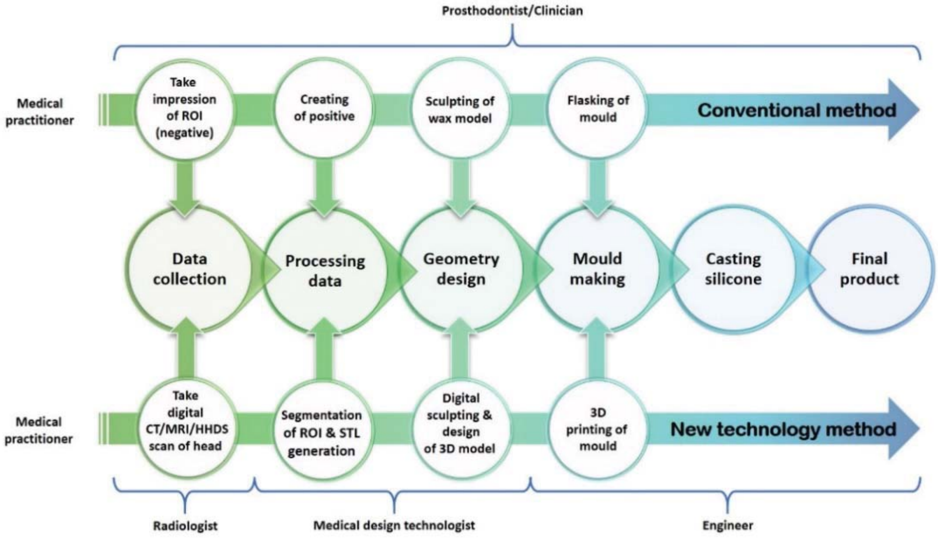

Figure 1: Comparison of Conventional and current methods of prosthesis manufacturing in maxillofacial reconstruction.

In the process chain for the manufacturing of maxillofacial prostheses using CAD/CAM technologies, human and non-human material components exist. Typically, the human agents are the client, designer and the maker [27]. In the production of a maxillofacial prostheses, the client is represented by the medical practitioner, who is responsible for collecting the digital data from the patient and for the description of the specifications for the design of the proposed maxillofacial prosthesis. The specifications and digital data are then used by a medical designer to create the geometry for the manufacturing of the proposed maxillofacial prosthesis by the maker, who is represented by engineers or manufacturers. Several iterative communication and action events support the successful outcome of this process chain. Figure 2 demonstrates that the medical designer may communicate with the medical practitioner, as well as with the manufacturer. Similarly, the manufacturer may also have to engage in discussions with the medical practitioner. In this process chain, the medical designer is both a receiver of instructions (specifications) and a creator of an interim artifact, the geometry. The action events result in different non-human components, which include the digital input data, specifications of the proposed maxillofacial prosthesis, the geometry design and the maxillofacial prosthesis.

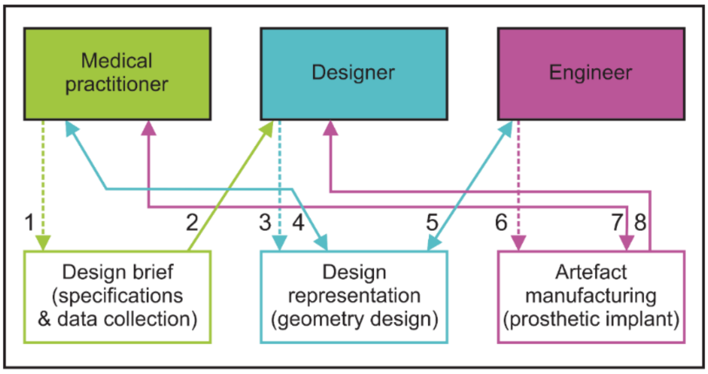

Figure 2: Human and non-components of the process chain for the manufacturing of maxillofacial prostheses. Solid lines represent the communication events; while the broken lines represent action events (adapted from Galle 1999).

There are several advantages in using CAD/CAM technologies in maxillofacial prosthesis manufacturing. A major advantage is the production of a customised digital model without the need for a physical impression. The process of digital image taking has the advantage of being more accurate than conventional impression taking [28]. This eliminates extended clinical time, the risk of leakage of the impression product into the natural facial cavities of the patient and poor tolerance of the patient [29]. These technologies also circumvent the possibility of tissues drooping during the application of the impression material, which may result in a modified configuration. In addition, since silicone prostheses have a limited lifetime, it is a major advantage to have computer backups of the prosthesis designs, allowing for the manufacturing of limitless identical prostheses [30]. Editing and design software provides extensive geometric design freedom, which is not restricted by tool access or material flow limitations [31]. CAD software also provide techniques such as "mirroring", allowing for designing mirror images of contralateral anatomical structures, such as ears. These CAD/CAM technologies thus offer a cost-effective and efficient systems to design and manufacture perfect-fit and custom-made maxillofacial prostheses [32]. A further major advantage is the ability to work remotely.

3.1 Review of medical editing and design software

A literature review was undertaken to obtain some understanding of which software packages were mostly used in maxillofacial reconstruction. Several search terms and combinations of search terms were used to source the literature in ScienceDirect, Elsevier's leading platform of peer-reviewed scholarly literature. Search terms included, medical design software, medical imaging software, medical editing software, digital design for facial reconstruction, digital design for facial prosthesis, maxillofacial facial prosthesis and CAD. During the literature searches, leads presented by the searches were also followed. The literature search revealed 348 literature sources, which were scrutinised to identify those literature sources that mentioned the use of medical image editing and design software in craniofacial reconstruction in the board context. This subset of literature sources was further scrutinised to identify, where possible, whether software was used for the construction of internal facial prosthesis or external facial prosthesis.

The literature search revealed several literature sources, which contained information about medical image editing software. A total of 64 literature sources referred to 20 different medical image editing software packages that were used in craniofacial reconstruction. Of these 20 editing software packages, 20% appeared in 65.6% of the literature sources, as listed in Table 1. The proprietary software, Mimics®, is the most popular and appeared in approximately 52% of the literature sources referring to the top five medical image editing software packages. Two open source editing software packages, 3D Slicer and InVesalius, also made the top five listing.

Table 1: Prominent medical image editing software currently used in craniofacial reconstruction.

Software name	Developer	Proprietary/ open Source	Total number of literature sources	Number of literature sources - Internal prosthesis	Number of literature sources - External prosthesis	Estimated cost
Mimics®	Materialise®	Proprietary	22	12	4	≥R180K
OsiriX	Pixmeo®	Proprietary	9	13	2	≥R9K
3D Slicer	The Slicer Community	Open Source	5	3	0	Free
InVesalius	CTI (Renato Archer Information Technology Center)	Open Source	3	2	1	Free
iPlan®	Brainlab®	Proprietary	3	3	0	Not available
Total			**42**	**33**	**7**	

The literature search revealed several literature sources, which contained information about computer-aided design software. A total of 154 literature sources referred to 29 different CAD software packages that were used in craniofacial reconstruction. Of these 29 design software packages, 10 appeared in 77.9% of the literature sources, as listed in Table 2. Proprietary software, developed by 3D Systems®, were the most popular and appeared in approximately 50% of the literature sources referring to the top ten CAD software packages. Two open source CAD software packages, MeshLab and Meshmixer®, made the top ten listing. Two well-known engineering design software packages, CATIA® and Solidworks®, also appeared in the list of software used in craniofacial reconstruction.

Table 2: Prominent computer-aided design software currently used in craniofacial reconstruction.

Software name	Developer	Proprietary /open Source	Craniofacial reconstruction	Internal maxillofacial prosthesis	External maxillofacial prosthesis	Estimated cost
Geomagic® FreeForm®/ Geomagic® FreeForm® (Plus)	3D Systems®	Proprietary	33	9	7	≥R150K
Geomagic Studio®	3D Systems®	Proprietary	28	14	9	≥R150K

CATIA®	Dassault Systèmes	Proprietary	13	1	1	≥R122K-R875K
Solidworks®	Dassault Systèmes	Proprietary	11	6	2	≥R70K
ZBrush®	Pixologic™	Proprietary	11	1	5	≥R12K
Magics	Materialise®	Proprietary	7	4	3	≥R22K
MeshLab	ISTI - CNR research center	Open Source	6	1	1	Free
Rhino3D/ Rhinoceros®	Robert McNeel & Associates	Proprietary	5	1	0	≥R16K
3 Matic®	Materialise®	Proprietary	4	3	0	≥R180K
Meshmixer®	Autodesk®	Open Source	2	1	0	Free
Total			**120**	**41**	**28**	

4. CURRENT STATE OF MAXILLOFACIAL PROSTHESES DESIGN AND PRODUCTION IN SOUTH AFRICA

The uptake of the newer technologies such as, digital imaging technologies, CAD/CAM, in maxillofacial prosthesis production has been relatively slow in South Africa. This can be attributed to a limited number of skilled medical practitioners and technologists that are skilled in the application of these newer technologies. Also, many patients requiring maxillofacial reconstruction are government funded, thus access to these newer technologies is limited. Therefore, in the South African context, a combined approach to maxillofacial prosthesis production is mostly followed, whereby the new technologies are applied sparingly, depending on the availability of skilled practitioners and funds.

5. CONCLUSIONS

Worldwide, CAD/ CAM are undergoing rapid uptake and growth in the medical sector. The expectations are that medical device manufacturing will become a key role player in the global medical landscape. Although the process chain for maxillofacial prostheses manufacturing cannot be replaced in its entirety by these new technologies, some components can be replaced, thereby bringing about a number of advantages. In particular, the most important of these advantages include the manufacturing of more accurate custom-made maxillofacial prostheses and the possibility of remanufacturing identical prostheses on demand, without patient participation. Although the process chain is considered to be rather expensive, particularly for developing countries, the continual introduction of cheaper and free software options will widen access to these technologies. Thus, several aspects will require consideration for a developing country such as South Africa to implement, in the future, CAD/ CAM technologies in a comprehensive way. Besides the current high manufacturing cost of maxillofacial prosthesis, competences in most aspects of the manufacturing process will have to be developed. Skilled medical designers are probably the most limiting skill currently in South Africa, therefore, a combination of the conventional manufacturing and CAD/CAM technologies will persist into near future. As new CAD/CAM technologies are regularly appearing in the market place, it could be envisaged that prostheses manufacturing will become cheaper and more readily available in the near future, thereby opening up new and additional options for access to these technologies.

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