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RESEARCH ARTICLE

PATIENT SPECIFIC IMPLANTS (PSI) IN MAXILLOFACIAL REHABILITATION- A SYSTEMATIC REVIEW

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Abstract

Patient-specific implant (PSI) is a personalized approach to reconstructive and esthetic surgery. This is particularly useful in maxillofacial surgery as well as prosthodontics, in which restoring the complex three-dimensional (3D) contour can be quite challenging. In certain situations, the best results can only be achieved with implants custom made to fit a particular need. Among the various alloplastic materials, polyether-ether ketone (PEEK) has emerged as an attractive option for the PSI. Significant progress has been made over the past decade in the design and manufacture of maxillofacial PSIs using additive manufacturing (AM) technology. This paper gives a brief review of Patient Specific Implants, its manufacturing, indications and materials used in maxillofacial surgery.

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Introduction:-

The surgical repair and reconstruction of maxillofacial defects, congenital and acquired, are challenging even for many surgeons. This is attributed to the complex anatomy, patient expectations, and defect uniqueness. The advent of additive manufacturing, 3–dimensional (3D) printing, and the recent advances in those technologies has positively influenced the biomedical field, leading to the utilization of patient-specific implants (PSIs) in the surgical repair of maxillofacial defects [1]. Advanced imaging modalities, such as CT, work with AM technologies to fabricate PSIs that are unique to each defect. With its introduction in the late 1980s, along with a paradigm shif from the old mass production system of medical implants to customized implant production system, AM has attained a signifcantplace in medical implant manufacturing industry[2]. Several organizations worldwide are manufacturing PSI using various AM technologies with computational tomography (CT) scan data[3]. With CAM, the virtual model can then be fabricated into a solid model. The solid models can be manufactured out of several materials including titanium[4.] The process from CT data to virtual model and to solid model/ implant manufacturing is complex due to conversion of data at several steps.

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Indications for Patient-Specific Implants

1) Maxillofacial PSIs have both reconstructive and esthetic indications. Volume loss that is evident as part of the aging can result in contour irregularities. One option for rejuvenating the aging face is to replace the lost volume using facial implants. PSIs may be useful in patients who have had unacceptable results with stock facial implants. Patients with unique contour defects may also benefit from customized implants[5 6.]

2) Congenital facial syndromes can be associated with skeletal deficiencies and facial deformities that are extremely difficult to reconstruct.

3) Osteotomies, bone distraction and grafting to improve facial contour. PSIs can be fabricated and used in an onlay manner to restore the facial contour needed. In cases wherein the deformity involves only one side of the face, the implant can be manufactured using a mirror image of the normal side [8]. There are several published reports of the use of maxillofacial PSIs in reconstruction of congenital facial deformities [5 7.]

4) PSIs can be particularly useful in the reconstruction of complex posttraumatic maxillofacial defects[9 10]

5) CAD/CAM technology has been utilized for several years for preoperative planning of resection of maxillofacial tumors and reconstruction of the resulting defects. Using preoperative imaging, custom cutting guides can be fabricated to be used intraoperatively for making precise bone cuts during tumor resection and reconstruction. Patient-specific reconstruction plates can also be used incombination with bone grafts to restore contour following tumor resection [11 12].

6) Orthognathic surgeries.

7) Temporo-mandibular joint replacement

Surgery/Applications of PSI
Mandibular reconstruction
Mandibular distraction osteogenesis
Implants
Orthognathic surgery
Facial asymmetry
Auto transplantation

Digital Manufacturing of PSI.

Manufacturing of maxillofacial PSIs begins with image acquisition; either CT or MRI scans of the area of interest. Thin slice CT is the most commonly utilized imaging modality for maxillofacial PSI production. The two-dimensional (2D) digital imaging and communication in medicine CT data are reformatted into 3D images and loaded into CAD software. Using the CAD software, a 3D implant is designed to precisely fit the defect. In the case of a unilateral defect, the implant may be designed using a mirror image of the normal side. The designed implant data are transferred into CAM software for fabrication. Implant manufacturing techniques fall into two main categories: subtractive manufacturing and additive manufacturing.

Table 1:- Types of Manufacturing.

SUBTRACTIVE MANUFACTURING	ADDITIVE MANUFACTURING
1) Computer numerical control (CNC) milling	**1) Binder jetting technique**
	2) Direct Metal laser sintering (DMLS) or Laser engineered shaping (LENS)
	3) Electron beam melting (EBM)
	4) Fused deposition modeling (FDM)

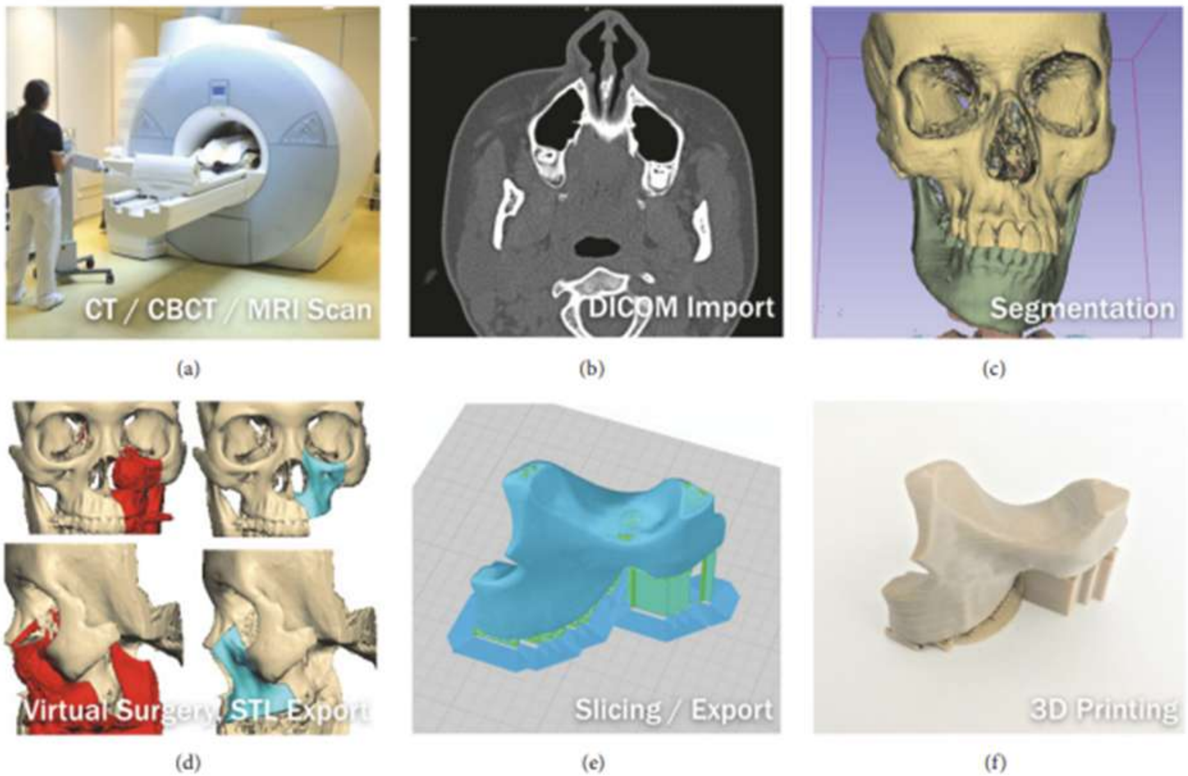

Figure 1:- Workflow to generate a 3-D model.

Additive Manufacturing –

The advancement of AM techniques and the medical modelling software has significantly improved the ability to fabricate complex design implant structures with high degree of accuracy[13]. Using AM technique, it is now possible for the doctors and engineers to produce organic and custom sized prosthesis with a variety of biocompatible material. .Some of the common AM technologies in medical applications are fused deposition modelling, selective laser sintering, and Electron Beam Melting.

1) EBM technology– It is a novel AM technique which uses computer controlled electron gun to fabricate fully dense, porous and hybrid surgical implants from metal powder. When one layer of metal powder (slice) is finished, the powder bed moves down and a new layer of material is added which is again selectively melted driven by a 3D-CAD (Computer aided design) software and added up till the complex 3D structure is built. The resulting 3D structure is of high quality, as the entire process is conducted in a vacuum and held at high temperatures during the entire operation. The EBM technology consists of three stages- pre-processing, building and post-processing. Pre-processing Stage: In this stage, the input file can be from any design CAD software, or from a CT/MRI scan file or reverse engineering file which needs to pre-processed and saved in Stl file format. This stl file is then imported in MaterialiseMagics software to remove the Stl type errors such as overlapping, intersecting triangles. The Stl treated file is imported into Arcam's build assembler software which slices the files into 2D compressed layer files readable by the EBM machine. Building stage: The .abf file created using build assembler is sent to Arcam's EBM machine (A2) and the material (Ti-6Al4V) theme and process parameters are defined and selected for built process. Post processing stage: In post processing, the produced Titanium part is removed and placed in the Powder recovery system (PRS) to remove the supports generated on the build part. The leftover powder from the PRS is recycled and placed back onto the EBM A2 machine for next built.

2) Selective Laser Sintering-This technology has been brought into usage since mid1980s and was developed by university of Texas. A fine material powder is fused by scanning laser, to build up structures incrementally. As a powder bed drops down, a new fine layer of material is spread uniformly over the surface. A high (60µm) level of resolution may be obtained. No support material is required as the structures that are printed are supported by the surrounding powder[14].Production of facial prosthesis makes use of polymers scaffolds (poly

amide or poly Caprolactone). Selective laser sintering is used in fabrication of anatomical study models, cutting and drilling guides, dental models, and also for engineering/design prototypes [15]. Advantages are ease of autoclavability of the materials used, full mechanical functionality of the printed objects, lower cost materials if used in large volume. Disadvantages are powders are messy with increased inhalation risk, techno logy is expensive, and significant climatic conditions such as compressed air are required [15 16]

3) Fused Deposition Modelling-Fused Deposition Modelling developed by Schott Crump. A thermoplastic filament material is extruded through a nozzle controlled by temperature and the material hardens immediately (within .1 sec) after extrusion. The motion of the nozzle head is controlled by a processor and traces and deposits the material in extremely thin layer on to a subsidiary platform. Materials such as acrylonitrile butyrostyrene ABS, polycarbonates and polysulfones are used. Building complex geometries usually necessitates the usage of a second extruder – for example, might extrude a water soluble support material[17]. Accuracy will depend upon the speed of travel of the extruder, as well as the flow of material and the size of each ‘step’. This is the process that is used by most low cost ‘home’ 3D printers. It allows for the printing of crude anatomical models without too much complexity, for example, printing an edentulous mandible [18 19]

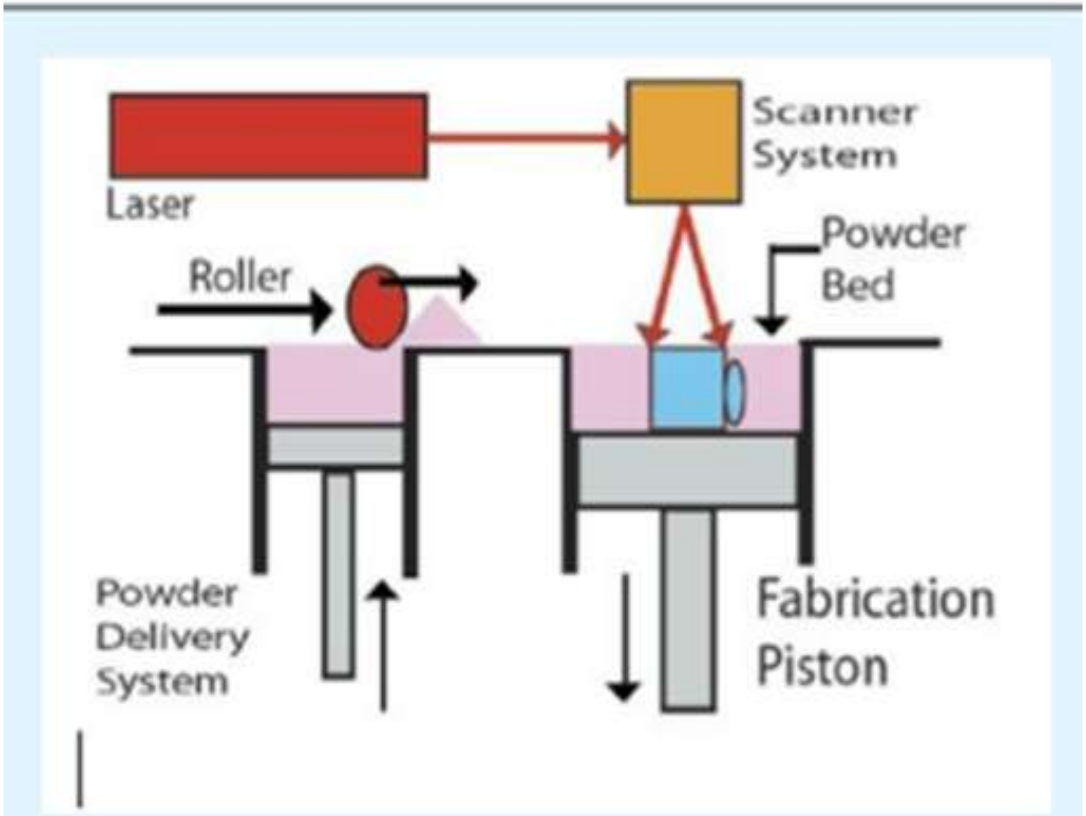

Figure 2:- Selective laser sintering.

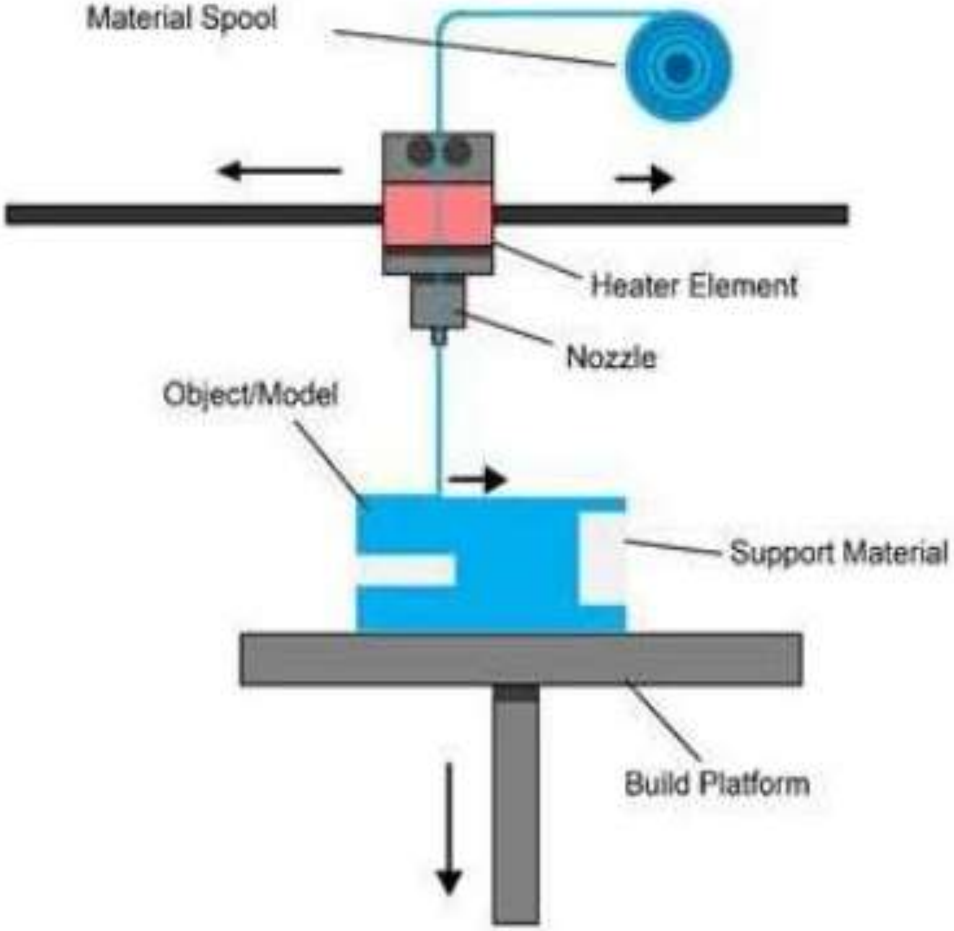

Figure 3:- Fused Deposition Modeling.

Subtractive Manufacturing-

The subtractive implant fabrication process involves subtracting or removing chunks of material from the solid block till the desired shape is achieved. It includes various forms of machining process such as milling, grinding, Computer numerical control (CNC), Electric discharge machining (EDM) etc. EDM combined with laser scanning and CAD-CAM technologies have shown accurate restorations directly from a raw ingot[20.] Application of computer controlled operations has produce implants more efficiently by using less electrode wear while minimizing micro crack defect. Computer numerical control (CNC) machines are used in the cutting, finishing and shaping the dentures in dental implant[21]. They have been used for manufacturing plates used for accurate restoration of skull shape with a high degree of symmetry[22]. Machining accuracy is dictated by the material properties. The higher the hardness of the material the lower is its machinability. Studies have shown the production of implants using machining operations results in 80% material loss due to its subtractive nature. It is estimated that more than 60 percent of the designs submitted for machining will require tools that significantly increase the costs associated with the operation. Also it is difficult to shape or produce complex structures using machining operation.

Advantages and disadvantages of the most commonly used additive manufacturing (AM) methods utilized in dentistry[23 24 25]**Table-2**

Types of printing technique	**Advantages**	**Disadvantages**
1) SLA	- Adaptable to variable material selection - Highest resolution and accuracy - Suitable for fine details and functional prototyping	- High cost per part - Complex post processing - Biohazardous materials are used - The final part is mechanically and vertically weak

		- High maintenance laser
2) SLS	- Low cost for parts - Mechanical properties maintained for functional prototyping, - Wide range of materials	- Polymer must be in powder - Not suitable for large parts - Designs with thing walls (<1mm) have difficulty for print
3) DLP	- Simple components for the machine One of the smoothest finishes on parts is created by DLP	- Larger parts would have lower resolution - Resolution only increases if the available build area is limited, (only visible on highly detailed models) small vertical voxel lines are created
4) FDM	- Low cost - No flammable material hence no risk of explosion - Suitable for complex structures	- Low accuracy and resolution - Parts would need smoothening process after the print

Materials Used In Patient-Specific Implant

Several implant materials have been developed over the past 50 years for both soft tissue and bone replacement. The ideal implant material must be inexpensive, durable, radiolucent, lightweight and biocompatible. Maxillofacial PSIs are commonly manufactured from metals and polymers.

Implant Materials

ABSORBABLE	NON-RESORBABLE
1) Poly-DL-lactic acid (PDLLA)	1) Hydroxyapatite (HA)
2) Polylactide-co-glycolide acid (PLGA)	2) Polymer – PEEK
3) Calcium phosphate	3) Ceramic
	4)Metallic – TI, gold, Co-Cr etc

Table- 3

1) Polymerscommonly used for maxillofacial PSIs include silicone, polymethylmethacrylate (PMMA) and polyetheretherketone (PEEK). Silicone is a polymerized dimethylsiloxane and is one of the earliest and widely used implant materials. Silicone can take the form of solid, liquid or gel depending on the level of polymerization. Maxillofacial PSIs are made from solid silicone and are used for soft tissue augmentation. Silicone implants can be easily modified intraoperatively as needed.

-**PEEK** was frst developed by a group of English scientists in 1978[26]. In the 1980s, PEEK was used as aircraft and turbine blades and, by the late 1990s, PEEK was used to replace metal implant components, especially in orthopedic and trauma specialities. PEEK has since been used in a wide range of applications owing to its excellent combination of high-temperature performance, chemical resistance, fatigue resistance, lightweight, high yield strength, stifness, and durability. The chemical structure of PEEK exhibit stable chemical and physical properties[27] [28]. It is wear-resistant and stable at high temperatures amongst polymers[29]. It is resistant to attack by all substances apart from concentrated sulphuric acid [26] [27]. It remains stable in sterilization processes. Besides, PEEK exhibits good biocompatibility in vitro and in vivo, causing neither toxic or mutagenic effects nor clinically significant inflammation. The high elastic modulus of Titanium and Cobalt-Chromium alloy increases the stress shielding resulting in bone resorption around the implant and causes the failure of implant. However, since the elastic modulus of PEEK is less than that of human cortical bone (8.3GPa), PEEK can be modified easily by incorporation of other materials like Carbon fibres which will increase the elastic modulus up to 18 GPa, which is compatible to that of 4 human cortical bone. The carbon – reinforced PEEK could exhibit lesser stress shielding when compared to Titanium, when it is used as an implant material[30]. PEEK is also widely used in dentistry as an implant healing abutment, removable prosthesis material, obturators, crowns and CAD-CAM milled fixed partial dentures.Bhoner et al[31] stated that a bioactive material is ‘‘one which has been designed to induce specific biological activity’’. Bioactivity is the characteristics of an implant material which allows it to form a bond with living tissues [32] [33]. Some of the previous studies have shown that PEEK is biologically inert[28]which has limited its potential applications.

Therefore, improving the bioactivity of PEEK is a significant challenge that must be solved to fully realize the potential benefits[28]. Three types of techniques have been advocated to enhance the bioactivity of PEEK. One is by incorporation of bioactive particles during the manufacturing process by either injection moulding or compounding, secondly by physical and chemical surface treatments, and thirdly by incorporation of bioactive surface coatings. The main disadvantage of incorporating bioactive particles is that it may alter the favourable mechanical properties of PEEK.

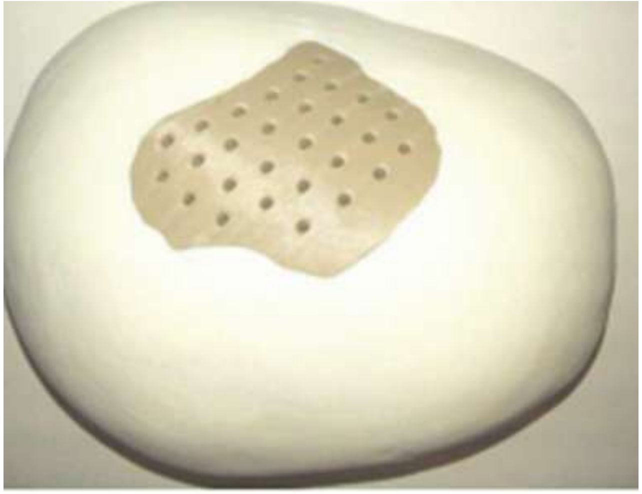

Figure 4:-3D printed PEEK cranioplasty PSI for repair of defects in the cranial vault.

2) Ceramics Ceramics represent another common material for 3D printing approaches, especially in the field of prosthetic dentistry. Ceramics are often utilized in SLA and SLS, in which specific ceramic powder or pre-sintered ceramics are targeted to create strong bonding [34 35 36 37]. Studies have also shown that incorporating calcium and phosphate mineral phases like hydroxyapatite and β-tricalcium phosphate provides ceramics an ability to form a biocompatible microenvironment. This can further allow the ceramics to develop cell-to-cell interactions and promote cell differentiation and proliferation, making them favorable for craniofacial applications [38 39]. However, due to challenges present with post-processing to high density, ceramic powder can only develop porous structures through SLS. In addition, additive manufacturing techniques themselves create limitations as sintering ceramics can lead to anisotropic shrinkage and fabricating leads to stair-step effects on surfaces. Thus, 3D printing for ceramic restorations has been limited, only being viewed in research[25 40 41.]

4) Metal- it is the another common material used in dentistry. Its popularity has been further viewed in the field of 3D printing as well, mainly in the use of SLS. In dentistry, metallic materials that were considered included titanium, cobalt-chromium (CoCr) and nickel alloys. However, researchers no longer consider nickel alloy, specifically nickel-chrome (NiCr), as a suitable material for dental prostheses due to possible nickel allergic reactions in the oral cavity. Like ceramics, fabricating metallic dental prostheses using SLS resulted in porous structures and led to using varying diameters and laser strengths. Recent research has led to further improvements of SLS techniques, such as including a vacuum during fabrication processes of metallic dental prostheses [26 42 44]. Titanium and CoCr are highly favourable metallic materials for 3D-printed dental prostheses. Due to their unique physical properties, including favourable levels of strength and ductility, titanium alloys, specifically Ti6Al4V, have demonstrated their capability as maxillofacial prostheses in various clinical trials [35 36 42]. Yet, research on their use has been limited due to the cost of titanium alloys, turning the focus to CoCr alloy, which present numerous advantages. A study by Barazanchi et al. (2020) demonstrates that CoCr materials fabricated by SLS have a higher bonding capacity with porcelain compared to CoCr materials fabricated by soft milling. These properties further indicate the alloy's good stability in the oral cavity and tolerance against loads, representing it as a preferred material for 3D-printed dental prostheses in long term applications[35]. Furthermore, the use of Direct Metal Laser Sintering (DMLS) on CoCr alloy to produce dental prostheses has demonstrated the elimination of issues present during milling on CoCr alloy, including the shrinking of CoCr materials during casting. This further concludes that CoCr alloy fabricated from 3D printing techniques demonstrates higher biocompatibility in the oral cavity than other metallic materials, such as NiCr alloy, used as alternatives to gold alloy in dental prostheses. Moreover, in vitro studies have demonstrated that CoCr materials fabricated by SLM still had clinically acceptable marginal gap between ceramic and metal

frameworks and metal-ceramic bond strength even after ceramic firing. This further highlights CoCr alloy as a promising material for 3D printed dental prostheses using 3D printing techniques, such as SLM[35 43 44 45 46]. There are various 3D printing methods and materials that can be used commonly in clinical settings. Ceramics, such as zirconia, and metal alloy, such as CoCr, represent ideal materials to form 3D dental prostheses through SLA or SLM. Further research should be conducted to understand better the use and effectiveness of these 3D printing methods and materials in clinical settings.

Summary of materials used for 3-D printing

Plastic
Stainless steel
Zirconia
Titanium
Acrylic resin
PEEK
Cobalt-Chromium(Co-Cr) alloy
Amorphous Magnesium Phosphate (AMP) blended with PEEK

Table-4

Conclusion and Summary:-

Reconstruction of complex maxillofacial defects is challenging, and favorable outcomes are dependent on precise replacement of the missing or deficient tissue. Advances in CAD and CAM technology allow rapid design and fabrication of custom implants bringing us a step closer to achieving the ideal implant. So ,Our need for reconstruction alternatives with synthetic availability that allows for single-staged procedures and avoids donor site morbidity is paramount to the evolution of patient-specific implants. Fortunately, advances in technology and biomaterials provide us with a real opportunity to introduce regenerative products that can be printed in the desired shape, size, form, and architecture. Tools that are readily printable and have the advantage of sterility, antimicrobial properties, and regenerative capability provide for very exciting possibilities. Years of development have brought us to this point, where we are ready to test and develop this technology.Continued research in the fields of bioprinting and tissue engineering may soon yield PSIs manufactured using autologous tissue and biodegradable materials.

Compliance with Ethical Standards

Conflict of interest:

The authors declare that they have no conflict of interest.

Ethical Approval:

The ethical clearance for conducting the study was obtained from ethical committee of the institution.

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