Computer-Aided Manufacturing in Medicine

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Computer-aided design/computer-aided manufacturing (CAD/CAM) technology is used to design and manufacture products using digital technologies. The term CAD/CAM implies that an engineer can use the system for designing a product and for controlling manufacturing processes. CAM procedures use manufacturing methods, the goal of which is to convert existing CAD data directly and fast without manual detours or forms in the workflow. For example, once a design has been produced with the CAD component, the design itself can control the machines that construct the object. This technology is widely used today in many different industries.

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CAD/CAM implementation is rapidly changing production cycles in industry. Mass production, based on customized design, is now possible, easy, and efficient for the decentralized production of products in different locations. The development has reached the point at which individual users can produce complex pieces and parts in a small office environment. In 2006, an open source project, “RepRap,” was developed. RepRap was a free, self-replicating, desktop three-dimensional (3D) printer that anyone could build given time and materials, capable of printing plastic objects. The first version of RepRap, released in 2008, could manufacture approximately 50% of its own parts. Further versions of RepRap are currently being developed.

Additive manufacturing

Additive manufacturing, of which rapid prototyping is a subset, augments the traditional removal and assembly methods of manufacturing. This technology overcomes traditional restrictions in manufacturing, with significant commercial and technological implications. The huge potential of this technology led to the rapid development of rapid prototyping, first by Magnus in 1965 and then by Swainson in 1971. The technology for printing physical 3D objects from digital data was first developed by Charles Hull in 1984. 3D CAD models were fabricated using the sequential, or additive, layering of solidified photopolymers to reconstruct the 3D shape. After this, in 1987, the first stereolithography device was developed by 3D Systems. Selective laser sintering (SLS) was then introduced by Electro Optical Systems (EOS, GmbH, Krailing, Germany) in 1990. In 1991, three new technologies were released: fused deposition modeling (FDM) by Stratsys, and solid ground curing and cubital and laminated object manufacturing by Helisys. These technology breakthroughs set the stage for the commercial integration of additive manufacturing within manufacturing industries [1].

Several different additive fabrication processes are commercially available or are being developed. However, each process uses the same basic steps:

1. Create CAD model

For all additive processes, CAD software is used to create a 3D model of the object.

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2. Convert CAD model into a .stl file format.

The STL format has become the standard file format for additive processes. The STL format represents the surfaces of the 3D model as a set of triangles, storing the coordinates for the vertices and normal directions for each triangle.

3. Slice STL model into layers

The software slices the STL model into very thin layers along the $xy$ plane. Each layer will be built on the previous layer, moving upward in the $z$ direction.

4. Build the object, one layer at a time

The machine builds the object from the STL model by sequentially forming layers of material on top of previously formed layers. The technique used to build each layer differs greatly among the additive process, as does the material being used (Fig. 1).

5. Postprocessing of the object

After being built, the object and any supports are removed from the machine. If the object was fabricated from a photosensitive material, it must be cured to attain full strength. Minor cleaning and surface finishing, such as sanding, coating, or painting, can be performed to improve the object's appearance and durability (Fig. 2).

The choice of a particular technology is usually dependent on the required materials for printing, accuracy, material finish, material strength, cost, and the speed of construction. In dentistry, the possibility of product sterilization in a dental office is an important consideration for materials and products to be used.

Additional successfully commercialized technologies include fused deposition modeling, which works by additive layering of a thermoplastic material; selective layer sintering, in which a carbon dioxide layer is used to bind powders to produce solid structures; 3D printing, using inkjet printing technology to deposit a liquid binder accurately; and polyjet or polyjet matrix printing, which allows multiple materials to be deposited simultaneously before solidifying with ultraviolet lasers.

The different production technologies used are as follows:

**Liquid-Based Processes**

These additive technologies, such as stereolithography, use photocurable polymer resins and cure only selected portions of the resin to form each layer of the object. Other processes are based on jetted photopolymer and ink jet printing.

**Solid-Based Processes**

Solid-based processes use a variety of solid nonpowder materials. Most solid-based processes use sheet-stacking methods, in which very thin sheets of material are layered on top of one another. The shape of the layer is then cut out. The most common sheet-stacking process is laminated object manufacturing, which uses thin sheets of paper. FDM uses solid strands of polymer, which are extruded and deposited into layers.

Fig. 1. Functional principle of laser sintering. (*Courtesy of EOS GmbH, Münich, Germany; with permission.*)
Powder-Based Processes

In powder-based processes, such as SLS, direct metal laser sintering (DMLS), and 3D printing, only a selected portion of powdered material is melted or sintered to form each object layer. The use of powder enables objects to be fabricated using different materials like polymers, metals, or ceramics. The mechanical properties of these objects are normally very good and stable.

Applications

3D printing techniques have been used for a range of applications from product design, manufacturing, building biologic tissues, and large-scale housing production. Inkjet technology is ready for deployment in manufacturing processes and has already been used to deposit adhesives that bond chips to substrates in the production of memory chips. Scientists and engineers have experimented with using inkjet technology and 3D printing to print simple electronics and prototypes of other products.

Research is underway to increase the range of materials that can be used in 3D printing technologies. Recent progress has been made in printing glass and complex plastics [2]; however, the ability to print electronic components is still limited. This area is of significant interest. Advances in nanoscale electronic components, such as nanocapacitors and logic gates, would circumvent the issues with depositing larger components. Research is also underway for the 3D printing and assembly of nanostructures, both for functional components and to act as scaffolds [3,4].

3D printing techniques have also been scaled up to allow construction of large structures. The first 3D-printed building was constructed by D-shape, a company that uses granular sand to generate artificial sandstone structures with reduced construction times and costs.

The cost of commercial 3D printers has decreased from $500,000 in 1999 to approximately $10,000. Personal fabrication may have significant implications for product customization and new models of distributing and manufacturing. Inkjet technology would significantly reduce the need to transport finished goods around the world, causing substantial effects on the transportation industry and a reduction in fuel use. Home-fabricated goods would have a small carbon footprint, provided the raw materials used to make them were produced locally. The technology could be used to make a vast range of products, from domestic goods to simple and cheap solar energy–powered devices.

Limitations of 3D printing technologies

Although 3D printing technologies offer critical advantages over traditional manufacturing processes, the technologies have inherent limitations. In their current form, 3D printing processes are limited for mass production purposes. An injection molding machine, however, is capable of making several similar parts in less than a minute. Although 3D printing processes will continue to increase in speed, they are unlikely to be able to create objects as fast as molding technologies. The bottleneck lies in the fundamental physics of the processes; scanning a material with a laser (and cure the material, and recoat each layer) at a speed comparable to that of injection molding is impossible.
Nevertheless, this limitation is only valid for the production of several thousand of a common object. Because tooling must be created for each unique object one wishes to injection-mold, 3D printing is the preferred process when custom parts or low-volume production runs are needed. Moreover, if production is decentralized, the production may be performed near the source of demand around the world, rather than at one factory producing thousands of the same item. The same printers can also be instantly reprogrammed to produce different products as demanded.

Most 3D printing processes use polymers that are weaker than their traditionally manufactured counterparts. The strength of the objects produced is also not uniform in many 3D printing machines. Parts are often weaker in the direction of the build because of the layer-by-layer fabrication process. Obviously, different machines can often have varying properties.

3D printing technologies applicable to the medical industry

The following are the predominant technologies currently used in 3D printers:

- Stereolithography
- FDM
- Multi jet modeling
- SLS
- 3D printing.

Stereolithography

Stereolithography (a compound from the words *stereo*, from the Greek *stereos*, meaning “hard, physically” and also spatially, and *lithographie*, from the Greek *lithos*, meaning “stone,” and *graph* meaning “letters”) is a technical principle of rapid prototyping.

The process begins with a 3D model of the object, usually created with CAD software or a scan of an existing object (Fig. 3). Specialized software slices the model into cross-sectional layers, creating a computer file that is sent to the stereolithography machine. The manufacture begins in a bath filled with the basic monomers of the photosensitive plastic. This light-hardening plastic, such as epoxy resin, is hardened by a laser in thin layers [5]. The standard layer thickness ranges from 0.05 to 0.25 mm. A building platform is immersed in the tank filled with liquid photosensitive resin. A laser beam is projected onto selected regions of the resin surface. When the laser hits the resin, the monomer solidifies from a photochemically induced reaction. After the laser beam has scanned all regions of the layer to be solidified, the object is coated with a fresh layer of liquid resin. A laser beam is projected onto selected regions of the resin surface. When the laser hits the resin, the monomer solidifies from a photochemically induced reaction. After the laser beam has scanned all regions of the layer to be solidified, the object is coated with a fresh layer of liquid resin. This function is typically achieved by lowering the object on the building platform and recoating the surface using a wiper blade. Because a solid model in a liquid is being developed, supporting structures are necessary. In large construction projects, overhanging objects must be removed from these supporting structures.

One key advantage of stereolithography is that it is currently the manufacturing method with the highest geometric resolution and very high surface quality. Recently developed resins allow for the fabrication of objects with mechanical properties comparable to many engineered polymers. After production, the stereolithography object can be modified with a large number of molding techniques, such as investment casting or silicone molding.

![Fig. 3. CAD of a drill guide.](image-url)
Stereolithography has several disadvantages. The necessary support structures must be removed manually or machined, usually leaving a surface finish inferior to unsupported surfaces. Because the monomer shrinks during polymerization, the buildup of internal stresses can lead to warpage later. Because of the development of advanced resins and building strategies, this problem has been minimized recently. Stereolithography can only process photopolymers or powder filled photopolymers, clearly limiting the number of available materials and certain material groups entirely. The materials can contract during production, resulting in a finished product that may show variations in volume and dimension.

Application
The production of prototypes (concept, geometry, opinion, working models) used in mechanical engineering, particularly in automotive manufacturing and medicine, uses similar product development procedures to stereolithography. An increasing trend is the direct production of final products using stereolithography ("rapid manufacturing"). An example of its use in the medical field is the production of individual housings for hearing aids and of surgical guides in dentistry [6–9].

FDM
FDM is a manufacturing method in the range of rapid prototyping. In this process, a plastic or wax material is extruded through a nozzle that traces the planned object’s cross-sectional geometry layer by layer. The nozzle contains heaters that keep the plastic at a temperature just above its melting point so that it flows easily through the nozzle and forms the layer. During the cooling that follows, the material solidifies immediately after flowing from the nozzle and bonds to the layer below. Once a layer is built, the platform lowers and the extrusion nozzle deposits another layer [10]. The layer thicknesses depend on application, usually 0.017 to 1.25 mm, with a wall thickness at least approximately 0.2 mm. A range of materials are available, including acrylonitrile butadiene styrene (ABS; a common photoplastic material), polyamide, polycarbonate, polyethylene, polypropylene, and investment casting wax (Figs. 4–6).

This process requires neither dangerous materials and techniques nor investments in space ventilation and air conditioning. FDM is suitable for the in-office environment and does not require the use of technical specialists. FDM uses very sturdy thermoplastics, and therefore climatic influences do not change the mass of the built objects. FDM units are accurate, stable, and durable. Compared with the stereolithography process, ABS plastic is not hydroscopic. Therefore, on a long-term basis, created objects form with stability and are nearly completely free of remaining monomer. Like the stereolithography process, the FDM process requires support structures, depending on the object orientation and design. After the model is printed, it is simply taken out of the printer and the support structure can be manually removed (Fig. 7).

![Fig. 4. CAD of a drill guide based on a cone beam CT dataset of a human mandible.](image-url)
Application

New biocompatible materials used by Stratasys (Eden Prairie, MN, USA) are compatible with U.S. Food and Drug Administration (FDA) requirements and fulfill the standard ISO 10.993. The material can be sterilized through gamma radiation or the ethyloxide method. Additionally, the biocompatibility of the materials and mechanical characteristics are noticeable improvements over conventional ABS [11].

Multi Jet Modeling

Multi jet modeling is a rapid prototype technology developed and commercialized by 3D Systems. The principle of this technology is based on inkjetting wax droplets onto the build platform through a large number of nozzles (approximately 300). The wax solidifies after being printed onto the build platform. Through turning the nozzles on and off individually, the object can be printed (Fig. 8).

The key advantages of these technologies are that they can be used in an office environment and their build speed is high (because of the use of a large number of deposition nozzles).

3D Systems (Rock Hill, SC, USA) currently offers two different build materials. One is used for fabricating patterns for investment casting (where the focus is on a good surface finish), and the other can be used for printing objects that are used as visual aids or concept models, which require a higher strength than the wax parts for investment casting (Fig. 9).

SLS

SLS is an additive process that fuses together small particles of powder using a high-powered laser (Fig. 10).
SLS has two basic types of processes: (1) thermal energy from a high-powered laser enables the system to fuse together powder particles, and (2) platforms are controlled with three pistons. Two of these are feed pistons responsible for controlling the powder supply. The third is a build platform that gradually moves downwards, one layer-thickness at a time. As the subsequent layers of powder are added, the two-dimensional cross-sectional solidification is completed. A new layer of material is then applied and all the operations are repeated. The powder is maintained at a temperature just below its melting point, helping to minimize the laser output required for fusion (Fig. 11) [12–14].
For the fabrication of metallic SLS objects, two approaches are currently in use: (1) the direct approach, in which particles like metal are directly fused together, and (2) the indirect approach, which uses polymer-coated particle powder. The laser beam partially melts the polymeric skin of the metal powder and the liquid polymer sinters the particles together. Further processing is needed to obtain a dense object. In the case of metal, the object can be either infiltrated with a low-melting metal or sintered to full density after thermally removing the polymer binder. In both cases (especially during sintering), the dimensions of the object can change. This change must be compensated for through adjusting the CAD models that are input into the machine. The same process can be used for different materials, such as glass ceramic bone replacements or bioactive scaffolds (Fig. 12) [15,16].

Fig. 9. 3D Systems ProJet HD 3000plus printer. (Courtesy of 3D Systems, Rock Hill, SC; with permission.)

Fig. 10. Laser sintering process. (Courtesy of EOS GmbH, Munich, Germany; with permission.)
3D Printing

3D printing is a process that was first commercialized by Z Corporation (“zCorp”). Recently, 3D Systems Corporation announced it completed acquisition of zCorp and Vidar Systems (“Vidar”). This technology is based on selectively bonding powder particles through infiltrating them with a polymeric binder that is printed using inkjet technology. After the build platform is completely coated with a layer of fresh powder, the inkjet head starts to print the polymeric binder onto the loose powder, which bonds the loose powder particles together. When the printing process is complete, the next powder layer is deposited onto the build platform and the process is repeated until all layers are
built. A fairly large number of materials can be processed with 3D printing. Commercial suppliers offer starch- and mineral-based, metallic, and ceramic powders.

Besides the already commercialized 3D printing process, science-oriented projects rely on inkjet printing to deposit functional and structural arrays with arbitrary geometry. One advantage of this process is the minimal consumption of materials; droplets are only deposited where material is required.

**Subtractive technologies**

In addition to additive 3D technologies, subtractive technologies are commonly used. Subtractive processes, also called *machining*, such as milling, turning, or drilling, use carefully planned tool movements to cut away material from a work piece to form the desired object. Consolidation processes, such as casting or molding, use custom-designed tooling to solidify material into the desired shape.

Dental laboratories have used lightweight computer numerical control specialty mills for low-volume zirconia machining since the late 1990s, but high-volume ceramic machining is different. Professional computer numerical control machines are considerably more powerful, and constructed much more solidly than the lightweight machines. Equipped with 30,000 rpm 20-taper spindles and automatic tool changers, they are well suited for continuous production (Figs. 13–15).

This technology allows prosthetics, crowns, and bridges to be made quickly on the premises. The accuracy of the prosthetic frameworks for implants and dentures is improved with this digitalized technique. In addition to the accuracy of the prosthetics, the turnaround time is reduced, resulting in less time for patients to receive a final prosthesis.

A cost-efficient way to produce a functional and long-lasting implant is to mill it out of a single material, such as titanium or zirconium oxide. In certain circumstances, anatomic complexity will determine the use of a custom implant. Subtractive technology is ideal for the production of complex geometries. These customized and geometrically accurate implants have become a proven technology.

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**Fig. 13.** CAM production of a dental restoration.

**Fig. 14.** Occlusal surface of the restoration in Fig. 13.
and are getting increasingly popular. Surgeons prefer customized implants because they reduce the operating time and they are reliable and low cost. Additionally, a minimal excision of tissue is possible and a second surgical site can be avoided.

**Medical applications**

3D printing has many applications in medicine. Initially, these manufacturing methods concentrated on manufacturing models and prototypes. Recently, the areas of application were expanded, with the term *rapid prototyping* now used. In addition, new procedures based on the same technology have been established, including

- Rapid prototyping: prototypes for visualization, form/fit testing, and functional testing
- Rapid tooling: molds and dies fabricated using additive processes
- Rapid manufacturing: medium- to high-volume production runs of end-use parts.

Medical application of rapid prototyping is feasible for specialized surgical planning and prosthetic applications and has significant potential for development of new medical applications [17]. Clear, custom braces for hundreds of thousands of patients are created across the globe using this technology. Stereolithography is now commonly used to fabricate molds from 3D scan data of each patient’s dental impressions.

**3D Organ Printing**

3D organ printing techniques have been developed that use different techniques to automate construction of 3D structures [18,19]. Organ printing involves deposition of sequential layers of gels containing cells or aggregates onto gel paper to build a 3D structure. The gel is then resorbed to give rise to functional tissues or organs.

**Hearing instruments**

The hearing aid industry currently has one of the most successful production applications of additive manufacturing. 3D technologies are used to produce customized hearing aid shells, which fit more comfortably and reduce acoustic feedback.

**Customized implants**

Customized implants are made for many parts of the human anatomy, specific for an individual patient, to increase function and aesthetic appearance and reduce discomfort. For example, cyclical loading causes wear and degradation of knee and hip joints, leading to knee and hip implant procedures. Chin implants are used to enhance the esthetic profile of a patient. After the digital design of the implant is created, the customized implant can be fabricated. These implants can be produced from ceramics, metals, polymers, and composites. Bioceramic materials are one of the main groups of materials used because they have a chemical composition similar to that of human bone (Figs. 16–18).
Dental restorations

3D manufacturing technology is used to produce dental restorations. Commonly, only the framework is produced with 3D printing. A dental technician then manually veneers the coping with a composite or ceramic material. This combination of an industrial and handcrafted process is a cost-effective approach, while taking care of the customized needs of an individual patient.

A digitalized manufacturing workflow, based on laser sintering technology, allows substantial time savings and the fabrication of objects that have excellent mechanical properties, consistent quality, and high detail resolution. According to EOS, approximately 1.5 million individual dental copings and bridges were manufactured in automated manufacturing centers in the past year using the EOS laser sinter technology. One fully automated laser sintering system can produce approximately 450 high-quality units of dental crowns and bridges in 24 hours, corresponding to an average production speed of approximately 3 minutes per unit, making laser sintering a true industrial process ensuring high productivity at reduced costs. Because no tooling is needed, different types and sizes of copings can be produced for each job, according to demand (Fig. 19).

Dental implant surgical drill guides

Several companies produce drill guides for accurate drilling and placing of dental implants. For example, Materialise (Leuven, Belgium) and Nobel Biocare (Zurich, Switzerland) use the stereolithography technology to produce anatomic models and surgical drill guides manufactured from CT or CBCT data (Fig. 20). Other surgical guides are produced with different additive technologies, such as the FDM process (Fig. 21).
Certain processes are able to produce dental implant surgical guides in a U.S. Pharmacopeia (USP; MD, USA) Class VI–tested material, which may allow for sterilization of the model and limited in vivo exposure to human tissue (for periods < 24 hours). USP is a nongovernmental organization that promotes public health through establishing state-of-the-art standards to ensure the quality of medicines and other health care technologies. “USP Class VI approved” indicates the stereolithography resin has passed a biocompatibility test showing that cured material, postprocessed as per the procedure, did not produce a biologic response in implant testing. Although USP Class VI testing is widely used and accepted in the medical products industry, some view it as the minimum requirement a raw material must meet to be considered for use in health care applications. The

Fig. 18. Customized skull implant, produced with EOSINT P 800, covering the defect. (Courtesy of EOS GmbH, München, Germany; with permission.)

Fig. 19. Zirconium oxide restoration milled with a CAM machine.
medical provider should ensure that the material used for patient treatment at least meets this standard.

Class VI testing is sometimes used in applying for FDA compliance. However, passing the test does not in itself qualify the material as FDA-compliant. USP Class VI testing does not meet the requirements of the ISO 10.993-1 guidelines, which is what the FDA currently uses for medical device approval. Stereolithography parts that are processed for USP Class VI are still not FDA-approved. One printing material that meets both standards, the ISO 10.993-1 and the USP Class VI, is Object Med610 (Rehovot, Israel) [20]. But the company’s disclaimer states the following: “It is the responsibility of the customer and its respective customers and end-users to determine the biocompatibility of all the component parts and materials used in its finished products for their respective purposes, including in relation to prolonged skin contact (of more than 30 days) and short-term mucosal-membrane contact (up to 24 hours).” Of course, doing so is nearly impossible for a surgeon in a dental office who is using a surgical guide produced from these materials. The legal implications of this for the surgeon are interesting and worth considering.

The potential disadvantage of additive 3D technology for dental surgical guides is the need to custom build each guide based on a digital data set derived usually from a cone beam CT (CBCT)/CT. Regardless of whether a scan prostheses is scanned alone in a double-scan process, as in the NobelGuide technology, or in a single-scan process, such as the Materialise technology, the digital duplicate has the potential error of the CBCT/CT scan. This error is then compounded with the
additional error of the stereolithography process. This error might be different, depending on the CBCT machine used and the stereolithography process.

New surgical guide concepts not using additive 3D printing technology attempt to eliminate this error. These drill guide concepts enhance the level of classic dental laboratory-based surgical guides in accuracy and efficiency through creating highly precise prefabricated parts and pieces. In one example of these newer processes, precise prefabricated scan plates, such as the BEGO scan plates sold in Europe (BEGO Medical GmbH, Bremen/Germany), are attached to a conventional scan prostheses (Fig. 22). This prefabricated “scanplate” contains integrated reference markers for the most common implant planning systems on the market. A system of this type is designed as an open system, making it independent of any proprietary implant planning software. After implant planning, the implant positions are sent via email to a company that then precisely transfers these positions into a prefabricated “transferplate.” Because the file size of the implant position data is very small, all data can be simply attached to an email. The transferplate, with inserted drill sleeves, is then sent to the dentist or dental laboratory. The transferplate is then placed onto the original scan prostheses with the attached scanplate. Coupling devices on the scanplate allow precise connection to the transferplate. The scan prostheses can then be transformed into a drill guide through conventional milling and guide sleeve insertion (Figs. 23 and 24). The final surgical guide produced is not based on the anatomy provided by the CBCT/CT data, thereby removing this potential imaging error from the process. The CBCT/CT 3D data set is only used for the implant position planning. Depending on the composite materials used, in-office sterilization of the final surgical guide is possible. The reduction in dental laboratory costs and the easy handling and production of these types of processes may help facilitate the increased use of guided implant surgery [21].
Scaffolding and tissue engineering

Tissue engineering requires the implantation of customized implants (scaffolds) to support tissue regeneration. One of the main characteristics of a scaffold is that it must contain microchannels with a high degree of porosity. This structure allows for the diffusion of tissue cells and nutrients, which facilitates the growth of new cells and tissue. New technologies, such as laser sintering, make this process more predictable [22,23].

Anatomic models

Anatomic models are physical replicas of a patient’s internal or external hard or soft tissue structures. These models are produced using data from optical scans, CT, CBCT, or MRI. Dentists and surgeons can use these to improve their planning of complex reconstructive and surgical procedures, resulting in reduced treatment time and more predictable outcomes (Figs. 25 and 26).

For more complex reconstructive applications, these models can be used for prebending metal reconstruction plates, accurate planning of complex surgical and reconstructive procedures, creating patient-specific facial or onlay implants, and measuring and fitting complex devices meant to lengthen shortened bone, such as those of the leg or jaw (Figs. 27 and 28) [24].
Fig. 26. Multiple anatomic dental models produced at one time. (Courtesy of 3D Systems, Rock Hill, SC; with permission.)

Fig. 27. Prebending of a titanium framework on an anatomic model, before bone graft reconstruction of a maxillary defect from the prior excision of a myxoma.

Fig. 28. Prebending and laboratory surgical trial of a maxillary alveolar distraction device.
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References