

A Detailed Review on Additive Manufacturing Methods for Healthcare Sector

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ABSTRACT

Healthcare engineering has developed an environment in which advancements in the lifesciences are not only possible, but also needed, in order to solve complex biological problems. Different applications of additive manufacturing technology in the medical field were investigated in order to determine the current state of the art and future directions. To demonstrate the advantages of additive manufacturing technology in medical applications, as well as current and potential applications. A literature review-based research on additive manufacturing that is useful in a variety of ways to treat medical conditions has been completed, as well as bibliometric analysis. The study of primary applications of additive manufacturing for medical purposes, as well as their significant achievements, was briefly mentioned. The ongoing study is often divided into categories based on the application of additive manufacturing in medicine, including requirements, accomplishments, and references. The main medical fields where additive manufacturing is used, as well as key sources, aims, and benefits, have been established. The aim of this paper is to conduct a literature review on the medical applications of additive manufacturing and their potential prospects. Medical models that are customised and sourced from the data of a single patient and differ from one patient to the next can be easily updated and printed. Medical AM involves the use of human capital in the fields of reverse engineering, medicine, and biomaterials, as well as the design and manufacture of bones, implants, and other medical devices. Additive Manufacturing has the potential to help solve medical issues while also benefiting society as a whole.

KEYWORDS: Additive Manufacturing, 3-D Printing, Medical Devices, Medical Instruments, Review

1. INTRODUCTION

Healthcare [1] plays a vital role and growing at a faster rate in the western markets; it has characteristics that differentiate it from other more conventional markets, and present challenges in both the application of current technologies and the development of new technologies. Medical researchers are seeking innovative manufacturing methods to produce healthcare products alike; artificial limbs, prosthetic, implants, customized orthotic device/customized insoles, foot and surgical-planning models of internal body structures quicker and largely precisely [2]. World considerations which are turning towards India, because of its predominant development in the field of healthcare, political and socioeconomic transformation [3]. The demand for healthcare service has increased in India; major portions of healthcare services are provided by private hospitals and practitioners; these institutes have expanded widely in urban and rural parts of India [4]. Unfortunately in India, the prevalence of all diseases is higher in the rural areas when compared to urban area, urban people have accepted to use of healthcare services, but rural people have refused to properly access healthcare services [5]. One of the largest sectors in India is healthcare in terms of employment and revenue; this area is rapidly expanding and the growth in 1990's 16%, today the market value is thirty four billion US dollars [6]. Healthcare industry is getting the benefit from the advanced technology by providing personalized medical devices or aids to the treatment to get more precise results [7]. With the above literature, the explicit scope in the development of new or innovative customized healthcare products is found to be a requirement. Further, the literature survey to unfolds the major research areas

of (i) health issues, (ii) healthcare product and (iii) Manufacturing methods in the development of customized healthcare product.

Additive manufacturing for advanced medical device applications includes a diverse and expanding collection of technologies for layer-by-layer synthesis of new 2-D and 3-D materials for both living and supporting devices. Feedstock material is separated from a bulk to form therapeutic implant materials or support structures in conventional medical device manufacturing processes. Additive processing, on the other hand, deposits, fuses, or otherwise recreates layers of material. Additive manufacturing, especially for biologics, consists of layering endothelial cells oriented in a circle upon several layers of polymer to create a 3-D blood vessel analogue [8]. Additive manufacturing enables the precise manufacture of products that would otherwise be difficult or impossible to produce using conventional manufacturing methods. Biological additive manufacturing techniques as well as diagrams of each are shown in Fig. 1.

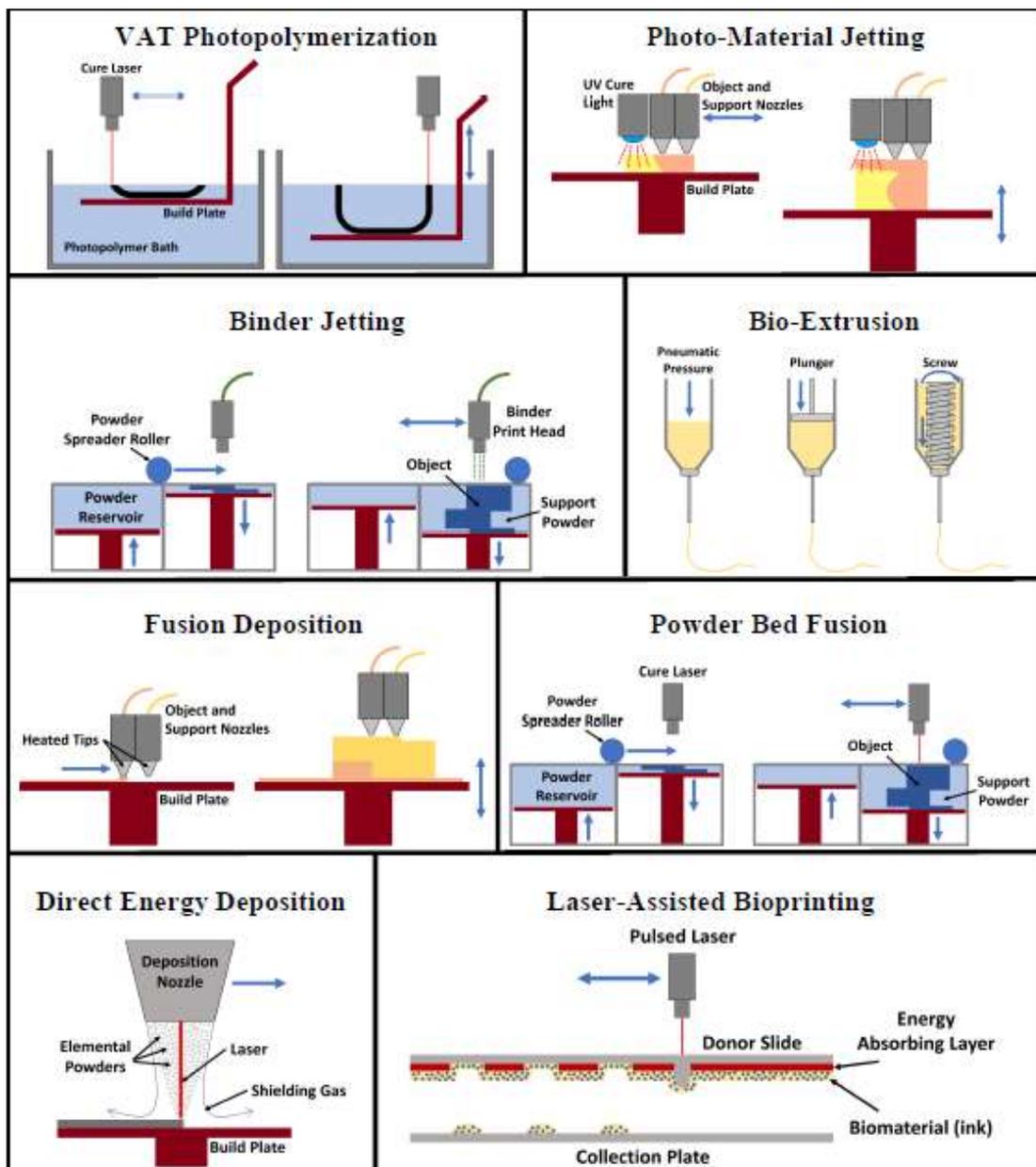


Fig. 1. Diagram of commonly used AM modalities

2. LITERATURE REVIEW

The new product development starts with the idea creation and ends with physical product, firms started developing products according to the market need [9], [10], stated that innovation was determined by science and its turn into technology and application. The firms identifying new product development as one of the growth strategies undergo this as a key activity within the organization because of market instability. This is with the realization that, products do not have an endless life so firms add new products to its product portfolio to timely replace the product that are nearing the end [11].

The next product type is platform products, which are derived from a product platform that is to satisfy a variety of market positions (examples – Sony Walkman) [12]. Many companies are applying platform based product development to improve the effort of customization in the extremely competitive world market [13]. According to [14], the platform product will improve the response to customer requests, increases product variety, reduces lead time, cost in design and manufacture of the product. Also, it is found that platform; intensive process and high-risk product are out of the research scope, with this idea further literature survey is focused to narrow down the technology push and customized product in the healthcare. The following section provides insight to current status of healthcare issues in India.

There are numerous manufacturing technologies that are available for development of the insole, these are classified into additive and subtractive manufacturing techniques [15]. The numerical controlled milling is one of the subtractive manufacturing techniques used in the medical application in which shape of the product or model is milled from the polyurethane or other foams [15]. Computer numerical controlled milling machine is used to manufacture custom-made insole of urethane foam [16], investigated on manufacturing methodology for the personalized sports insoles; they suggested cryogenic machining method as a novel manufacturing method for manufacturing personalized sport insole. In this method, CNC machining is used to produce CAD model from the scanning and assessment methods enables rapid manufacturing of personalized products.

There are several additive manufacturing processes available, but the basic principles of operation are common. The first step is to construct the CAD model and then convert it in to the STL format. Once the model is converted in to the STL file format needed to check and fix the STL file and then generate the support structure, if needed. Next, the STL file is sliced in to a number of layer and produces the physical product layer-by-layer, after the part is built, remove the support structure and post processes the product [17].

In [18], recommended additive manufacturing process for the development of customized or geometrically complex products when compared to other conventional manufacturing techniques like subtractive, formative and joining process. With the objective of the research being to develop customized split insole, it is required to select the suitable additive manufacturing process to develop the customized split insole [20].

Powder bed fusion, material extrusion, VAT photo-polymerization, material jetting, binder jetting, sheet lamination, and guided energy deposition are the seven groups that the ASTM and ISO standardisation organisations divide the additive manufacturing method through Directed Energy Deposition [21]. There are numerous suppliers, solutions, and material choices in each group. The ASTM/ISO categories were used in this article. This was problematic because most research still do not use common terms, and processes are often referred to by trade names. Table 1 lists the names of the process classes and a brief overview, as well as the most popular starting material type, trade names, and how well the process is used to produce plastic products, metals, or ceramics. Some methods, such as directed energy deposition VAT photo-polymerization and material jetting for metals, are in the production and research phase, while others, such as sheet lamination of ceramics or directed energy deposition of plastics and

ceramics, seem to be non-existent. There may be clinical research and trials of these, but there are no commercial providers. New process and material combinations are often produced in response to demand, which typically highlights vast industries and a significant need. Typically, this contributes to the selection of a widely available material that can be used in a variety of applications.

Table 1. Various Additive Manufacturing processes and characteristics.

AM Process	Short Description	Material Form	Plastics	Metals	Ceramics	Trade/Other Names
Powder bed fusion (PBF)	thermal energy fuses regions of a powder bed	powder	+++	+++	+	selective laser sintering (SLS), direct metal laser sintering (DMLS), selective laser melting (SLM)
Material extrusion (MEX)	material dispensed through a nozzle	filament, pellets, paste	+++	++	++	fused deposition modeling (FDM), (fused filament fabrication) FFF
VAT photo-polymerization (VP)	liquid photopolymer in a vat is cured by light	liquid	+++	+	++	SLA, digital light projection (DLP)
Material jetting (MJ)	droplets of material are selectively deposited	liquid	+++	+	+	PolyJet, NJP
Binder jetting (BJ)	a liquid bonding agent is selectively deposited	powder	+++	++	+	3D printing (3DP), ColorJet printing (CJP)
Sheet lamination (SL)	sheets of material are bonded	sheets	++	++	-	laminated object manufacturing (LOM), ultrasonic additive manufacturing (UAM)
Directed energy deposition (DED)	focused thermal energy used to fuse materials by melting when depositing	powder, wire	-	+++	+	laser-engineered net shaping (LENS), EBAM

Note: +++, widely available/many studies exist; ++, available/several studies exist; +, R&D phase/studies exist; -, no studies exist.

3. ADDITIVE MANUFACTURING IN HEALTHCARE APPLICATIONS

Medical additive manufacturing applications may be categorised in a variety of ways [22], but for the purposes of this article, application classes are used. The following classes can be used to categorise additive manufacturing applications: models for pre-operative planning, education and training, inert implants, tools, instruments and parts for medical devices, medical aids, supportive guides, splints and prostheses and bio-manufacturing [23]. For a broader classification, this can be tweaked so that implants aren't required to be inert, and models for preoperative preparation, education, and training can even include postoperative and operative models. Fig. 2 depicts an illustration of each category's application.

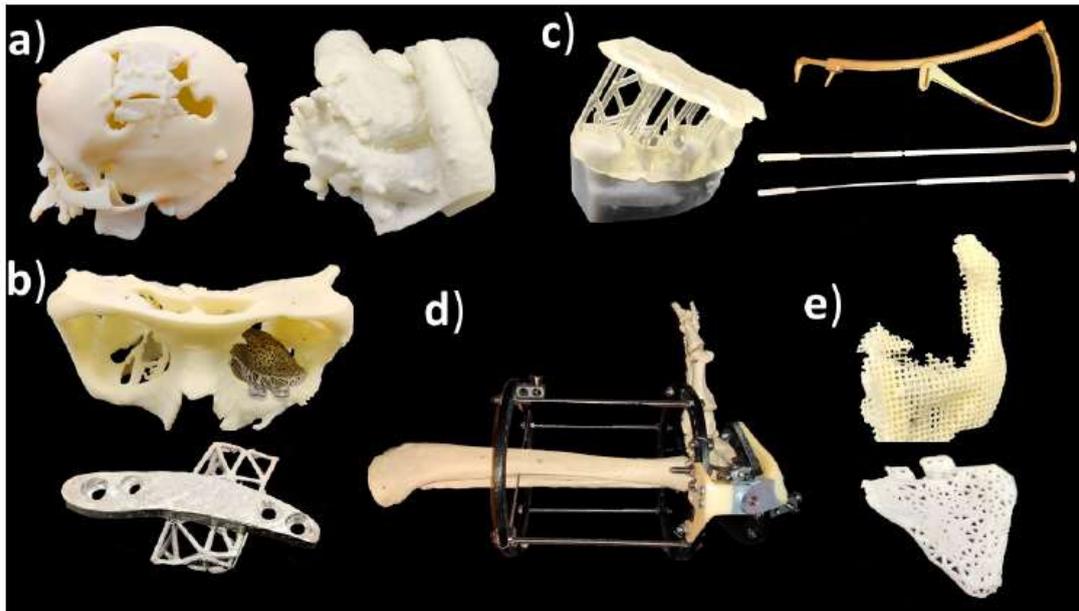


Fig. 2. (a) Medical models (b) implants (c) tools, instruments and parts for medical devices (d) medical aids, supportive guides, splints and prostheses (e) bio-manufacturing

Medical Aids, Supportive Guides, Splints and Prostheses are made with additive manufacturing, these can be combined with standard appliances to allow customization. Long-term and postoperative supports, motion guides, fixators, external prostheses, prosthesis sockets, personalized splints and orthopedic applications are examples of applications in this class [24–26]. Medical imaging can be the first step, followed by segmentation, 3-D scanning, or 3-D measurements, both of which can provide data that can be used directly in the 3-D modelling process. CNC systems are commonly used as alternative processing processes in additive manufacturing. [27]. Depending on the application, parts can need various types of post-processing, such as support removal, heat treatments, and painting or coating. Fig. 3 depicts a standard Additive Manufacturing phase flow for surgical aids, supporting manuals, splints, and prostheses. The example case is a customised and mobilising external reinforcement for a pilon fracture, in which 3-D design is focused on analysing the patient's ankle activity and changing the additive manufacturing parts to position the hinge such that it governs the movement under force near to the ankle's free movement.

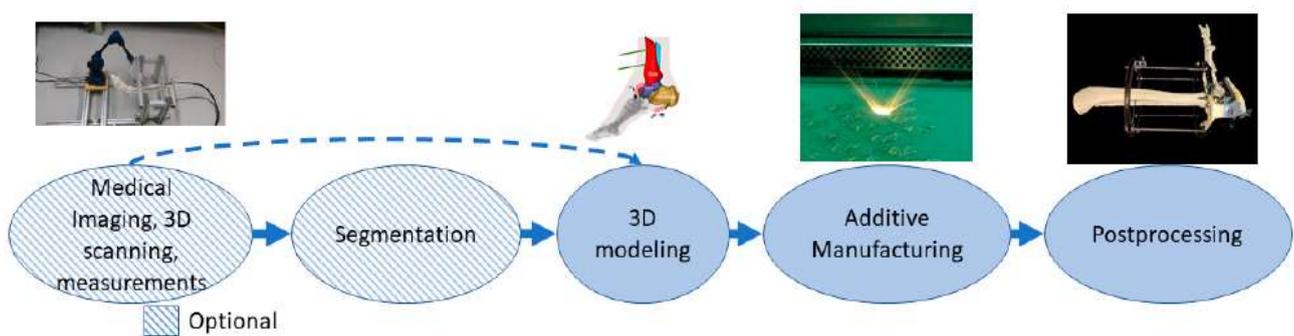


Fig. 3. Process flow for medical aids, supportive guides, splints and prostheses.

One of the greatest chronic diseases in all countries is Diabetes Mellitus, and it continues to increase in number; the impact of diabetes changes the life-style of individual's leads to increased obesity and reduced physical activity [28].

India is becoming the capital of diabetes [29], individual's with diabetes spend double as healthcare expenditure than individual's without diabetes [30]. With this, research is narrowed to focus on diabetic complications. The

following section gives the insight about the diabetes and its complications.

Diabetic neuropathy is the greatest complication among the diabetic population, which affects nearly fifty percent of the diabetic population [31], [32]. Diabetic neuropathy leads to loss of sensation and weakening of intrinsic foot muscles, resulting in biomechanical dysfunction of the foot with abnormal pressure distribution in the lower extremity of foot [33]. Lower extremity complications in diabetic population begin with neuropathy and successively cause diabetic foot injuries, which lead to infection, gangrene and lower extremity amputation [32].

All over the world, diabetic foot ulceration represent a major medical and social-economical problem [34]. Untreated minor trauma in the presence of diabetic neuropathy is the initial stage of ulceration in the diabetic population and inadequate blood supply to acute part contribute to severe infection and further tissue damage and risk of foot ulceration [35]. Surgical procedure to treat multiple diabetic foot complications such as non-healing foot ulcer and gangrene are amputations [36].

From the literature, it is identified that diabetes leads to diabetic neuropathy, and further the diabetic people get affected by foot infection and foot ulcers; untreated infection and foot ulcer leads to lower limb amputation followed by gangrene. The following Figure 4, describes the diabetic foot complications.

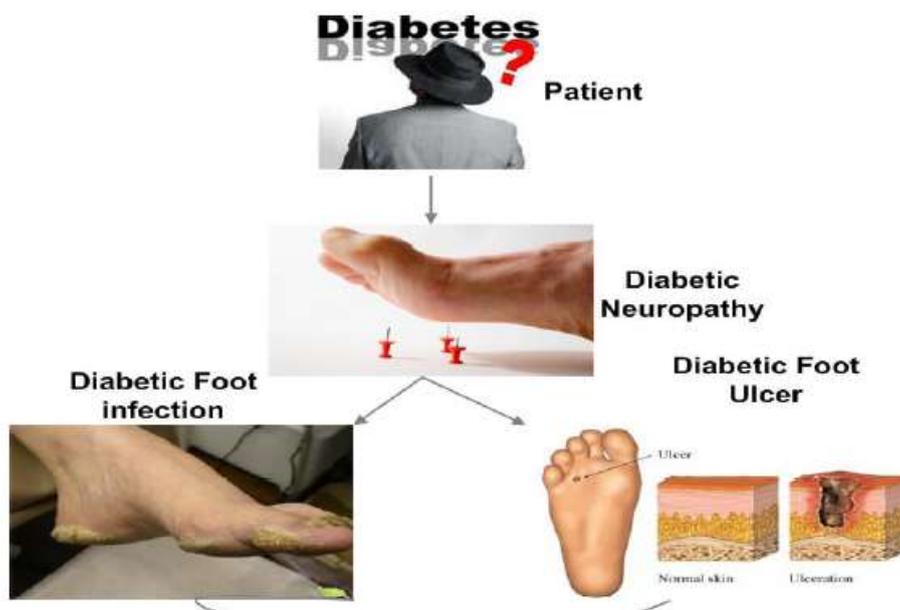


Fig. 4. Diabetic foot complications

Proper foot insole or foot orthoses improves the function of human foot, which provide support and distribution of individual's body weight; foot orthoses also prevent the foot deformities. For reduction of plantar pressure, diabetic footwear and orthotic insoles play the significant role, pint-size of information only exist on the optimum cushioning properties [37].

From the above literature, it is identified that, diabetic neuropathy is a leading cause of lower foot amputation, and customized insole is seen as potential healthcare product or device to reduce the diabetic foot amputation rate. The diabetic foot management objective is to prevent an ulcer in the plantar region [38], [39]. Design and development of the customized insole begin with the objective; the following section provides the basic understanding of insole and input parameters required for designing a customized insole.

The plantar pressure measurement systems available in the market vary in configuration of sensors and application. In [40], reported that based upon the sensor technology and configuration the pressure measurement system is of four types (i) Pressure distribution platforms, (ii) In-shoe systems, (iii) Matrix devices and (iv) Sole system with

discrete sensor. Based on the configuration the system is of three types (i) Pressure distribution platforms, (ii) Imaging technologies with sophisticated image-processing software (iii) In-shoe systems [41]. Most of the gait analyst or researchers focus on interminable pressure measurement to understand the activities [41]. The conventional techniques are not considered for this research, because it provides only the qualitative data. A widely used technique for the measurement of plantar pressure measurement is the pedobarograph system [42 - 45].

This system can be used for both static and dynamic pressure measurement, and it can be used only in the laboratory setting (Rosenbaum & Becker 1997) [46]. The system is fixed in the walkway patients has to contact the system/platform after the number of steps, so the patients were asked to limber up to generate the normal walking pattern [46]. Alternative to the lab equipment is the in-shoe system, Fig. 5, where the pressure sensors are located inside the foot and the pressure distribution pattern can be obtained. The following Fig. 6 shows the pressure distribution platform.

In-shoe pressure measurement system measures the plantar pressure between foot and the shoe [47]. More number of the in-shoe pressure measurement techniques were developed [48]. The limitation of this system is that the data resolution is low, because of fewer numbers of sensor, when compared to the platform system [47].

Understanding the limitation of the existing system, the methodology used in the measurement of the plantar pressure measurement is the pressure distribution platform.



Fig. 5. In-shoe plantar pressure measurement system



Fig. 6. Pressure distribution platform

From the literature, customized insole is identified as the healthcare product to aid the diabetic foot and this was identified to solve in an engineering approach. The following section provides insight to manufacturing method for the development of the customized insole.

6. CONCLUSION

Additive Manufacturing processes are commonly used in a variety of medical fields and have a lot of promise in medical applications. Various applications of additive manufacturing in surgical preparation, simulation modelling, hard tissue, training, prosthetics and implants, tissue engineering, bio-mechanics, and a variety of other fields have opened up a new realm in medical science. Doctors, especially surgeons, are able to do things that previous generations could only dream of thanks to additive manufacturing technology. There are many reviews on the medical applications of additive manufacturing. Most of them focus on certain application areas, such as surgical instruments, orthopedics, cardiology, or have a material focus in certain area such as metals for prosthodontic applications. Some studies have looked at different additive manufacturing processes, for example, material extrusion and binder jetting for producing pharmaceuticals or ceramics for dental applications using material extrusion, binder jetting, VAT photo-polymerization or powder bed fusion processes. Furthermore, some only looked at the general applications of additive manufacturing or the whole process chain developments including, for example, the design phase. There are reviews which focus on applications and even categorize those in some of the additive manufacturing processes, such as VAT photo-polymerization, powder bed fusion and material extrusion, but the other processes are missing.

However, this is just a small step forward. There are several unanswered medical issues, as well as high hopes for additive manufacturing in this area. In terms of speed, flexibility, price, and other criteria, additive manufacturing is progressing well; however, there is still a lot of room for innovation and progression so that this technology becomes commercially competitive and beyond the financial grasp of the common patient. Nonetheless, additive technology has opened new doors for making previously difficult surgical operations practical, and it will help save the lives of many critically ill people.

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