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Review Article

Review of the Utility of 3D Printing in Pediatric Orthopedics

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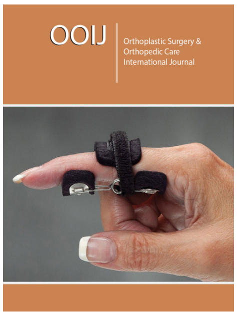

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Abstract

Three-dimensional printing (3DP) is an evolving field that presents new and innovative solutions aiding in the advancement of modern healthcare. The continuous improvements seen in imaging, computer-assisted interventions, and simulations provide novel pathways for current physicians to administer quality individualized healthcare. The purpose of this review is to present a detailed synopsis of 3DP as well as its potential role in pediatric orthopedic surgery. We performed a review of current literature on 3DP and a MEDLINE search was used for references. Our search indicates there is exponential advancement in the technology, and a growing understanding of its role in medicine. However, being that the technology and its employment in clinical settings is relatively new, a review of existing work highlighting outcomes of 3DP implementation can allow for a wider discussion of the benefits of said technology specifically within pediatric orthopedic surgery. Consequently, larger scale studies are necessary to further evaluate the advantages and disadvantages alongside long-term follow up of surgical case studies.

Keywords: 3D printing; Additive manufacturing; Preoperative planning; Surgical training; Complex deformities; Pediatric; Orthopedic surgery

Abbreviations: 3D: Three Dimensional; 3DP: Three-Dimensional Printing; AM: Additive Manufacturing; MRI: Magnetic Resonance Imaging; CT: Computed Tomography; FDM: Fused Deposition Modeling; SLA: Stereolithography; SLS: Selective Laser Sintering; SLM: Selective Laser Melting

Introduction

The use of 3DP is becoming increasingly more prevalent in numerous medical and surgical applications as the scope of the technology expands. With the printer, three-dimensional renderings can be combined in order to produce physical objects that can be applied to perform patient-specific procedures [1]. The process of 3DP, also known as Additive Manufacturing (AM), involves depositing materials layer by layer in a semiliquid, liquid or powder form to produce a graspable 3D framework from a virtual model [2]. The technical pathway for 3DP is broken down into two distinct phases. The design phase begins with image acquisition where MRI or CT data is acquired and stored as DICOM images on an archiving and communication system [2]. Next, image processing involves segmentation and creation of the 3D model where a 3D printable computer model is generated from the acquired data sets. After image processing is complete, the pre-printing process retains only the anatomical structures in regions of interest needed for visualization. The second phase of this technical pathway is known as the manufacturing phase where 3DP and post processing occurs. After layers of semi-liquid, liquid or powder materials are deposited, they are then solidified by light energy, chemical binders, or electron beams.

3DP is increasingly being applied to all areas of orthopedic surgery. It has the ability to enhance a surgeon's knowledge of the patient's precise patho-anatomy, thereby making preoperative planning significantly more accurate. Increased customization from 3DP introduces a higher level of precision in the placement and positioning of an implant, which can produce better surgical outcomes [3]. Due to the nature of pediatric anatomy, utilizing

3DP in pediatric cases is especially effective for tactile guidance, reduction of surgery time, and improvement of diagnosis. With rapidly growing research involving 3DP, there is sure to be fast adoption of this technology by orthopedic surgeons. The purpose of this review article is to present a detailed synopsis of 3DP as well as its potential role in pediatric orthopedic surgery.

Methods

A review of literature was conducted. Using the MEDLINE database and Google Scholar search engine, publications in the English language were queried in regards to use of three-dimensional printing in pediatric orthopedic surgery. Example search queries included "3D printing in orthopedic surgery" and "advantages three-dimensional printing". Bibliographies of chosen studies were searched for additional sources. A total of 29 sources involving were included in the review.

Discussion

Technologies and Materials

There are four classes of material that are used in 3DP: polymers, metals, ceramics, and biological materials. The methods, printing processes, applications, and cost of using these materials can vary greatly, even within the four classes. Metals can be used in joint replacements and other implantable devices in which mechanical properties such as tensile strength and elasticity are important. Polymers tend to be used in the preoperative planning process, surgical training, and as guides generally. Within the class of polymers, there are elastomers and rigid polymers. This distinction is particularly useful when creating models for the purpose of surgical training where bone can be approximated with rigid materials and soft tissue with elastomeric materials. The main 3DP technologies that are used to create plastic parts in orthopedic applications are Stereolithography (SLA), Selective Laser Sintering (SLS), and Fused Deposition Modeling (FDM). The dimensional tolerances are larger in FDM, and the quality of the prints are diminished due to the limitations of this technology. The main advantages of SLS and SLA are the quality of the print and the ability to autoclave some materials. SLS and SLM are closely related and are commonly used in metal 3DP. In this process, metal in a powdered form is melted or sintered using a laser and the powder spared by the laser can function as support material for the subsequent layer.

In addition to 3DP with traditional materials, it can also be used with biological materials. Extrusion based bioprinting technology is surprisingly similar to FDM; however, rather than a hot end extruding a melted polymer, biological materials and a scaffold are extruded using pressure. This technology can incorporate multiple bio-inks and thus several cell types into a single print job. The cells are cultured in a lab and can either be autografts or allografts. Following the printing and any necessary post-processing, these cells can begin to communicate with each other in a similar fashion to how they would in vivo. Within the realm of orthopedics, the ability to print collagenous and bony structures shows promise [4].

Economics

Utilizing 3DP in surgical care is time efficient which consequently is economically conserving. On average, 62 minutes of surgery time is saved, which translates to $3,720 of savings per case [5]. While medical 3DP appears resource-intensive, 3DP constructs used in patients' operative care provide considerable downstream value to the health system via reduction of operative room costs secondary to shortening of procedure times. In a comprehensive systematic review of the literature and a meta-analysis using Medline, Ovid, and Embase database from inception to February 8, 2018, Morgan et al. [6] suggests the use of 3DP—especially in orthopedic trauma surgery—reduced operating time by 19.85%, intraoperative blood loss by 25.73%, and frequency of fluoroscopy use by 23.80% [6]. In another study that included randomized controlled trials, case-control studies, and cohort studies, Zhang et al. [7] found that with 3DP, surgery time decreases by 45 minutes (approximately a 20% reduction on average), transitively saving $2,700 per case for a pediatric population [7].

Serrano et al. [8] indicates that material and labor costs for creating 3DP models and guides of varying complexity along with an annual fixed operation fee consisted of $150,000 per year: $120,000 for salary/percent effort for personnel performing the majority of segmentation and overseeing the printed process, $20,000 for a segmentation software license, and $10,000 of facilities operational costs, printer maintenance, and unexpected purchases [8]. However, Dhawan et al. [4] demonstrates that the use of 3DP models in surgeries recoup the costs involved in employing 3DP technology. With each minute in the operating room costing $62, these net savings range from $19,384 to $129,589 for low (5%) and $77,536 to $518,358 for high (20%) utilization rates [4].

Limitations and Regulations

Despite the exponential advancement in the field of 3D implantation in surgical settings, the current technology of 3DP implants limit the modularity inherent in typical implant systems. For instance, interbody fusion operations among many other surgeries require a degree of intraoperative flexibility from a surgeon to meet the patient's specification of varying cage widths, heights, and degrees of lordosis [9]. With 3D implants, it is cost-prohibitive to produce multiple patient-specific implants of various degrees of modularity. More importantly, many pediatric patients undergo rapid physical growth, requiring re-implantation and frequent outsizing of the customized prostheses — another possible increased cost toward producing advanced technological implants that require high complexity and specific modification. There is also cost associated with energy usage, maintenance and repair expenditures, storage, encryption, sterilization, among many other miscellaneous expenditures [10]. Beyond the cost involved in the technicality of implementing this new technology, there are considerable costs involved in improving medical education to increase performance and foster rapid learning of 3DP patient specific models: in order for cadaver dissection to model the reproducibility and safety of using 3DP in a clinical setting, 3D printers in education centers must have the capability to print different densities and colors to accentuate the anatomical details, which are most often expensive [11]. Furthermore, the 3DP process is a technically demanding process as it relies greatly on advanced computer skills and medical imaging technology. In order to produce patient-specific implants for tumor reconstruction, the 3D template is accompanied by a CT scan, which makes the process more expensive and ultimately requires additional radiation exposure to patients as compared to a conventional surgical approach [12]. In a systematic review of a total of 158 studies on 3DP applications in surgery published between 2005 and 2015 using a PubMed and EMBASE search, 34 studies emphasized the inaccuracy of the 3DP technology employed in an operating room, while 30 studies expressed the additional costs as the important limitation for routine use of 3DP [9].

Being that 3D technology is a nascent technology, there is no solidified regulation set for it. The customization of 3D-printed devices brings new complexities to drafting a design control model for FDA consideration of market approval, highlighting the unique challenges —patient safety above all — to rapidly expanding technology [13]. With the rate of innovation in medical devices with novel composition and structure and in the field of rapidly altering technology, both regulatory agencies and medical scientists must answer whether 3DP should be applied the same design and quality control strategies utilized in standard manufacturing methods: they must coordinate to establish which quality control measures will be necessary to protect the patients.

Applications

3DP models of the patient's anatomy can be created from their preoperative CT or MRI scans, which are already standard of care for many procedures. With that being said, radiation exposure should be carefully considered in pediatric cases. It is common knowledge that utilizing 3DP in the preoperative planning process is most advantageous in complex cases, especially for newer surgeons. Kang et al. [14] discovered that physicians rated the usefulness of 3D printed models in the preoperative planning for complex fractures as a 6.63 out of 10 on average. This paper also found that 9% of experienced surgeons and 74% of inexperienced surgeons changed the plate that they would use for a complex fracture fixation after incorporating 3D printing in preoperative planning [14]. From the perspective of process, regulation, and materials, preoperative planning is the simplest way for practitioners to implement 3D printing into their care of patients.

Amputations in the pediatric population can be devastating. In general, aggressive attempts at limb salvage are attempted prior to amputation. However, it is not always avoidable. In these cases, 3DP is an option to provide either a transitional or permanent prosthesis. One study mentions the use of 3D printed hand prostheses as a transitional device to increase range of motion and forearm circumference in pediatric patients with upper limb deficiencies [15].

Joint replacement is another area of orthopedic surgery that could be impacted greatly by 3DP. For example, studies have shown viability in using 3D printed surgical instruments in total knee arthroplasty, which allows the surgeon to make bony cuts specific to the patient's anatomy, without requiring the additional balancing that is typically done in surgery [16,17]. In addition to using 3D printed instruments, implanting patient-specific prostheses can restore the patient's own knee kinematics [17].

In a case of pediatric hip dislocation due to osteomyelitis, the surgeon used a 3D printed model of the patient's anatomy to determine the optimal osteotomy site and correcting angle, and they were able to use this approach to compare the affected and unaffected limbs [18]. In cases of pediatric spine surgery where the anatomy is complex and the potential for severe neurologic damage is notable, 3D printing can be a valuable tool for planning. Coote et al. [19] explored using 3D printing in planning approaches for three pediatric spine cases, two of which were scoliosis and the other being atlantoaxial instability and cervical stenosis. In addition to aiding surgeons, they used the models to help educate the families of the patients. Two of the three families reported increased comprehension of the pathology and treatment as a result of the incorporation of these models [19]. Due to 3D models being most useful in planning for complex cases, large scale randomized control trials and other high-quality studies are generally difficult to achieve. However, a randomized control trial was carried out in a total of 48 patients with complex fractures (AO type C of the distal radius) to determine the efficacy of 3D models in preoperative planning. This study found that this approach reduced blood loss, operating time, and frequency of intraoperative fluoroscopy; however, it did not find significant improvement in the postoperative function. This study also reports that the surgeons viewed these models as helpful for patient education, but not as helpful for preoperative planning. With that being said, all of the cases occurred within the course of a year so this operation was routine for this group [20]. Thus, the literature is still fairly limited in determining the impact of using 3D printed models in the preoperative planning process.

Surgical Training

For those in the medical field who are learning and enhancing their surgical qualifications, practicing directly on real patients and on cadavers has traditionally been the method of training. However, aspects such as ethical dilemmas, availability, and restrictions on patient safety must also be accounted for simultaneously. Thus, with the advent of new technology, 3D representations can serve as educational tools for both patients and those in the medical field such as medical students, residents, and surgeons. Literature has shown that 3D printing could potentially have tremendous utility in improving a practicing physician's comprehension of complex anatomy and surgical technique [21].

In a randomized study conducted by Uygur et al. [22] twenty-eight residents (study group) and ten senior surgeons (control group) were sampled to determine the usefulness of utilizing 3D modeling of foot deformities for education of orthopedics and traumatology residents. Ten adult cases of foot deformities were evaluated, and 3D models of each deformity were produced with the hospital's PACS. These 3D models were sterilized and placed on the surgical table during the operations. The study found that both the study and control groups were satisfied with the models that they could physically touch and re-examine while on the operating table. The residents were significantly more satisfied than their senior surgeons, giving the highest scores for understanding of the deformity and clarity of the model (p=0.01). Uygur et al. concluded that 3D modeling of foot deformities is more informative than virtual 3D videos, giving more details for young surgeons in surgical training [22].

In another study, twenty-six surgical trainees were assigned randomly to either use a 3D printed teaching aid or receive traditional surgical live teaching to prepare for a surgery simulation test and questionnaire over total hip arthroplasty of adult developmental dysplasia. In the teaching aid group, hemipelvis models were printed, connected to an operating table, and simulated soft tissues were added. The use of the 3D printed models was found to have a greater training effect, especially for Crowe's classifications III and IV. The model-based training was also found to improve the accuracy of the cup location and direction in Crowe's classification III. This study also mentions the relative ease in acquiring these 3D printed models in comparison with cadavers [23].

Surgical Guides

Rather than simply using a generic guide, jigs can be created specifically to the patient's anatomy. Where this process diverges from printing a recreation of the patient's anatomy is after the digital model of the scan is created in the form of an STL file, CAD (3-matic) software is used by a professional to create a surgical guide that is specific to the patient. The time and expertise required to design and manufacture 3D printed surgical guides are greater than those for 3D printed models of the patient's anatomy. Close collaboration between the manufacturer and surgeon are vital to create a guide that is helpful for complex operations. In addition to these considerations, the supplemental CAD software presents an extra expense for the institution. These guides can be particularly advantageous in the resection of osteosarcomas, osteoblastomas, and osteochondromas [2]. It was found that in a case of segmental spinal dysgenesis, not only did using 3D printing in the preoperative planning process alter the treatment plan, but it also allowed the care team to create a drill guide that permitted successful occiput to thoracic fusion in a three-year-old boy. In pediatric spinal cases, the use of 3D printed guides is especially useful due to the unstable nature of the pediatric spine and the tactile guidance provided by these guides [24]. In a 15-year-old female with forearm malunion following conservative treatment of a both-bone forearm fracture, the care team implemented a 3D printed template to guide a corrective osteotomy. The procedure achieved a near-anatomic correction with a return of full function of the affected arm three months after the operation.

Implants

Current literature has shown that additively manufactured implants have had notable utility in complex cases. In seven cases of reverse shoulder arthroplasty in patients with tumors of the proximal humerus, implants were created based on preoperative CT and MRI data. In these cases, glenoid prosthesis and a guiding baseplate were additively manufactured; however, the humerus prosthesis was manufactured with traditional methods. The authors found that the custom implants improved function and decreased the complication rate; however, this was a retrospective study, and the sample size was limited [25]. Dow et al. reports using a 3D printed titanium cage in conjunction with intramedullary tibiotalocalcaneal nailing in a pediatric patient with a five-centimeter subsegmental distal tibia bone loss with successful ambulation after a year [26]. An advantage of additive manufacturing is the ability to create geometries that are impossible to reproduce with traditional manufacturing methods. Within the context of orthopedics, there is an advantage in the ability to create porous structures which can be filled with bone graft. A series of six patients with skeletal tumors in various locations received custom 3D printed prosthesis with a vascular flap and bone graft following tumor resection. Within this cohort, no patients experienced early complications and no patients required the removal of the prosthetics; also, the primary osseointegration was achieved at a mean of four months [27]. A similar technique was utilized in two patients who required scapular replacements following sarcoma with similar success [28].

In addition to additive manufacturing being useful in creating prostheses that mimic bone, the utility of printing using bioactive materials is becoming increasingly apparent for the approximation of soft tissue. In mice, using a 3D printed scaffold of polylactic-co-glycolic acid (PLGA) with cell-laden collagen-fibrin hydrogels and stem cells has been shown to have excellent biocompatibility and the ability to degrade *in vivo*. However, the authors point out that this can have clinical repercussions in the repair of massive rotator cuff tendon defects [29].

Conclusion

The incorporation of 3D printing into pediatric orthopedic surgery presents new and innovative solutions to patient treatments. There is immense potential budding as 3DP continues to become implemented in modern healthcare. The materials that can be used for additive manufacturing in a medical setting are diverse, ranging from polymers to metals to ceramics and even biologic materials. One of the most exciting uses of 3D printing is its use in pre- and peri operative settings. Within the context of implants, additive manufacturing has the ability to create geometries that would otherwise be too intricate to produce using traditional manufacturing. This technology is particularly useful in the approximation of soft tissue and creation of porous structures that are filled with bone graft. 3D printed models of the patient's anatomy can guide surgical approaches minimizing time in the operating room and ensuring dimensional accuracy. The literature has shown that utilizing 3DP in one's surgical training can enhance their understanding of complex anatomy and improve surgical technique. 3DP has the ability to serve both as an educational tool for the provider and for their patients.

While the use of 3DP in clinical settings may seem burdensome initially, it shows promising economic efficiency when surgical time is taken into consideration. As mentioned before, the employment of the technology in surgeries saved from 45 to 62 minutes of surgical time on average translating to around $2,700 to $3,700 of savings per case.

Currently, there are noticeable limitations with employing 3DP: this includes the lack of modularity of implants, especially in pediatric populations. Unfortunately, the costs associated with re-implantation to prevent outsizing prostheses in pediatric patients offsets the benefits. Because the technology is still being developed, the miscellaneous costs involved in maintaining the working condition of technology in a hospital are not standardized and can easily be added up to overshadow its benefit. There are no proper regulations set in place to oversee the safe practice of 3DP technology. Sufficient scientific data examining its overall viability remains limited. As with any other area of study, further investigation is needed to build confidence regarding 3DP as a standard method of practice.

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Conflict of Interest

We declare that we have no conflicts of interest in the authorship or publication of this article.

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