

REVIEW OF THREE DIMENSIONAL PRINT SPINE

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ABSTRACT

Three-dimensional printing (3-DP), also known as additive manufacturing, has become a fastgrowing sector in the medical field especially in the area of spinal surgery. It has never been easy working around the spine area due to the complicated anatomy and the intricate system of the surrounding structures yet 3-DP has given surgical planning some leeway into making procedural accuracies which can benefit many patients. Before, there were so many difficulties facing the surgeons especially in injuries to the spine, so now, with the continuous improvements of this technology can enhance implant properties and lower the surgical time and improve patient outcomes. This paper will review the current available literature on the application of 3-DP in spinal surgery.

Keywords: Three Dimensional print, spine, screw guide template.

INTRODUCTION

Three Dimensional Printing (3DP) is defined as a host of process and technologies that offer a full spectrum of Capabilities for the production of parts and the products in different materials. The 3DP in early days was called Rapid Prototyping (RP) or stereo lithography (SLA) and it was introduced in late 1980's by Charles Hulk which utilized ultraviolet light and photo curable resin (Zhang,x.,et al ,2015).Three-dimensional printing (3-DP), also known as additive manufacturing, has become a fast-growing sector in the medical field especially in the area of spinal surgery. It has never been easy working around the spine area due to the complicated anatomy and the intricate system of the surrounding structures yet 3-DP has given surgical planning some leeway into making procedural accuracies which can benefit many patients. Before, there were so many difficulties facing the surgeons especially in injuries to the spine, so now, with the continuous improvements of this technology can enhance implant properties and lower the surgical time and improve patient outcomes.

This paper will review the current available literature on the application of 3-DP in spinal surgery. It will discuss the new studies which feature the different things that have been done by orthopaedic surgeons and design engineers to help their patients of varying injuries and diseases – through this procedure. Those procedures include the lumbar pedicle screw insertions by 3D laser print, the using of mimics, and the use of geomagic software to create a model of a 3D print.

The Technology that Mimics:

The use of 3-DP in spinal surgery has many advantages over the traditional manufacturing processes. Although customisation based on actual patient-specific data hasn't yet been perfected, spinal prosthetic manufacturers are now beginning to utilise the technology to optimise the properties of the devices to be implanted (4Web Medical Products, 2017). 3D printing permits the production of previously unmanufacturable geometries including the ability to mimic the interconnected structure of the cancellous bone (Tritanium Manufacturing Overview, 2016), among other things.

It is not unusual for a surgeon to work with an engineer from a prestigious design firm that specialises in medical 3D printing. In the process, both parties started printing several plastic models during the various stages of the medical procedure, then designed the custom implant to mimic the normal height and the angulation of the vertebrae on its predicted form before the tumour destroyed it. During this example procedure, it was very helpful for the surgeon to print an implant based on what the spine should look like, then do the actual procedure in the operating table.

Results-wise, the implant slotted perfectly like a key which was quite a relief especially in complex reconstructive surgery. The patient recovered quickly and was able to play netball three weeks after the operation. In this case study, the custom prosthesis added significant value by reducing the operative time and providing initial firm stability on the cancerous segment (Mobbs, 2017).

There are now companies like Stratasys which mimics real organs using 3D-printed models which look and feel like the real thing. It used to be that real cadavers and human organs populated the dissection table of surgeons but the challenge in the present has been to create realistic physical models which clinicians can work on. Biomimics is one of the several 3D printing solutions that can create and combine new printing materials with Stratasys Polyjet 3D printers. This allows today's medical practitioners to hone their skills throughout their careers to provide exceptional care through testing medical innovative devices, teaching principles of surgery, providing continuing medical education and demonstrating new products to clinicians. The current situation is dismal as animal models only approximate human anatomy and cadavers don't retain the live tissue feel and lack the targeted pathology.

Biomimics uses software that is based on an algorithm which replicates the intricate details of the organ and bones. This algorithm is continuously perfected using feedback from even more accurate and current models. The expectations from the surgical community is very high and very sensitive – like surgeons describe how such screws can crunch a bone or the response of a tissue when a screw is inserted. With this mimicking technology – a feedback loop has formed from the customers to the makers – adjusting the iterative algorithm every time. The spine model is especially crucial since it integrates very complex elements, from differing cortical strengths and thicknesses to tactile bone response, to soft tissue and invertebral discs.

Through mimicking, a degenerative disc model and a scoliotic spine model has been used to train the surgeons. Right now, the technology of mimicking is veering towards using a custom 3D printer and a combination of silicon-based inks and soft 3D-printed sensors, as done by this team of University of Minnesota researchers who are aiming to make this technology go beyond just 3D printing but to create working artificial organ transplants (Gaisford, 2018).

Using Geomagic Software:

Geomagic software assists the mimicking technology in the design of different type of bones or whatever the surgeon needs inserted into the patient's body. In this particular case study, the patient was a 30-year old male, diagnosed with ankylosing spondylitis. They used the software Mimics 17.0 (Materialise, Leuven, Belgium) to reconstruct the computed tomography (CT) data and to generate a medical model of the triangular structure. The output data were transformed to other forms of data in a personal computer.

Then, Studio Geomagic 2013 (3D Systems, Rock Hill, SC, USA) was used to read in the Mimics® 17.0 output data, transform the model data package, check for errors and optimize the data, and rebuild the nonuniform rational basis spline (NURBS) surface model. The model was then imported in STL format to Geomagic Studio 2013 software, which allowed the researchers to inspect the surface model for crisscrosses, tiny channels, or other artifacts (e.g., noise) and repair the triangles in the mesh structure. The smooth function was used to optimize the surface, remove sharp edges, and create a model for finite element (FE) modeling due to the various components used in the surface reconstruction function to establish the nonuniform rational basis spline (NURBS) surface (Muheremu, et al, 2017).

In this next case study, the following steps were done so that the Geomagic software can be used. The

subject was a three-year old patient suffering from osodontoideum and an unstable atlantoaxial joint which needed to undergo an atlantoaxial fixation surgery. To be able to design the template, the clinical operation had to be approved by the Hospital Ethics Committee and the clinical usage of a 3D-printed metal template was consented to by the patient. The requirements of the design included having the contact surface fit the patient's bone surface, making the strength of the template better than the traditionally made template, and finally, having the guider hole and the locating hole be sufficiently accurate.

The data from a thin-layer CT scan of the cervical vertebrae of the patient was imported into Mimics 16.0 (Materialise, Leuven, Belgium) to extract the target spine. This was stored as an STL (binary) which was then imported into Geomagic software. Elimination of the noise points inside the bone to obtain the 3D entity was accomplished by executing the following processes - they included extracting the surface, also known as construct patches by constructing grids like surface fitting, and storing them in the STEP AP203 format; importing the data from Geomagic software into SolidWorks software; and integrating the separate 3D entity models into an assembled model to obtain the target spine model (Wang, et al., 2016).

The past two discussions showed how the Mimics software and the Geomagic software have been used to be able to come up with the right model to be used for the patient being treated. The next section is a review of the use of 3D printing in spinal surgery.

Review of Related Literature on 3d Printing in Spinal Surgery:

Three-dimensional printing (3DP) is a rapidly growing industry and it offers a variety of techniques which can be used to print physical models from three-dimensional renderings based on CAD software, and STL design files. The technology is still evolving and improving yet the possibilities it offers especially to spinal surgery has gotten many clinical practitioners excited (Martelli, et al., 2016).

The next discussion presents what novel solutions 3D printing technology has offered to many interesting medical cases in spinal surgery which were deemed impossible to correct due mainly to the intricacies involved in putting together what is broken in the human body – and the human body being very complex as it is – has made the healing process more complicated.

Due to the complex anatomy of the spine, as well as the delicate nature of the surrounding structures, any technique that may aid surgical planning and procedural accuracy offers the ability to improve patient outcomes (Tack, et al., 2016). However, with the presence of this technology, helped by different software technologies like mimicking and Geomagic – hope for injured patients or those patients born with bone and bodily deformity may finally get the treatment and ease from pain that they deserve.

The following specific case studies discusses the current applications of 3-DP in spinal surgery, including its role in surgical planning, surgical guides, customised implants and "Off-the-Shelf" implants. This paper concludes with a brief overview of future directions of 3DP in this field.

The case studies presented here include correcting adult spinal deformity with reduced morbidity, the role of 3D printing in minimally invasive spine surgery (MISS), the production of patient-specific implants (PSIs) for spinal surgery, lumbar pedicle screw insertions by 3D Laser Print and the fabrication of ergonomic shaped medical implants.

Correcting Adult Spinal Deformity with Reduced Morbidity:

The first case involves correcting adult spinal deformity with reduced morbidity which is now being addressed by the advances in minimally invasive interbody fusion. For patients with previous osteoporotic fractures, the possibility of success from this approach may be limited as the resultant vertebral deformity makes the end plate geometry incompatible with conventional interbody implants.

This first case study involves a 74-year old female patient, with previous osteoporotic fractures at L2 and L3 resulting in concave deformity of the end plates, presented with intractable radiculopathy secondary to lateral recess and foraminal stenosis (L2-3 and L3-4). A minimally invasive lateral lumbar interbody fusion at L2-3 and L3-4 was considered favourable, but due to the associated vertebral collapse, the available implants from off-the-shelf were not compatible with the patient's anatomy.

So the surgeon performed silicosimulation based on preoperative computed tomography (CT) imaging so that he could design customized cages to cater for the depressed recipient end plates and vertebral loss. The design was converted to implantable titanium cages through 3D additive manufacturing. At surgery, a tight fit between the implants and the targeted disk space was achieved.

Postoperative CT scan confirmed excellent implant–end plate matching and restoration of lost disk space. The patient began to ambulate from postoperative day 1 and at 6-month follow-up resolution of radicular symptoms and CT evidence of interbody fusion were recorded. So the good news from this case is that the 3D-printed custom-made interbody cages helped overcome the difficulties in deformity correction secondary to osteoporotic fractures (Siu, et al., 2018).

This next case study is an example on the concept of personalized precision medicine in a surgical setting demonstrating how 3D-printed, patient specific implants has brought individualized solutions to rare problems wherein the restoration of the specific anatomy of each patient is a key prognostic factor.

In this case, the patient was suffering from Ewing sarcoma which is a malignant muscoskeletal neoplasm with a peak incidence in adolescents. The primary site of the tumouur is the cervical spine and has been related to a worse prognosis. Due to the complexity of the anatomy, tumour resection is challenging procedure in the atlantoaxial region, so according to oncological principles the urgency for an extensive resection and a lack of specialized implants for reconstruction.

The patient was a 12-year old boy with a C2 Ewing sarcoma and underwent a staged spondylectomy. A wide resection of the posterior elements was performed first. The remains of the C2 vertebra was removed two weeks later using a high anterior retropharyngeal approach. The defect between C1 and C3 was replaced by a customized artificial vertebral body manufactured according to a computer model using titanium alloy powder.

The microstructure of the implant was optimised for enhanced bone healing and better biomechanical stability. The patient recovered uneventfully and began to ambulate on postoperative day 7. Adjuvant treatment started 3 weeks after the surgery. At the 1-year follow-up, he was found to be tumourfree. Computed tomography studies revealed evidence of implant osseointegration and no subsidence or displacement of the construct (Xu, et al., 2016).

3D Printings in Minimally Invasive Spine Surgery (MISS):

Another field where information regarding the use of 3DP is still limited is in minimally invasive spine surgery (MISS). Nevertheless, information 3D printing is currently being used in spine surgery to create biomodels, hardware templates and guides, and implants. Spine surgeons have begun to adopt 3DP technology since it is minimally invasive and specifically with the use of biomodeling to optimize preoperative planning.

However, there are still factors which are not allowing the widespread adoption of 3DP which include increased time, cost, and the limited range of diagnoses in which 3DP has thus far been utilized. Still, 3DP technology has become a valuable tool utilized by spine surgeons, and there are limitless directions in which this technology can be applied to minimally invasive spine surgery (Hsu, et al., 2018).

Production of Patient-Specific Implants (PSIs) for Spinal Surgery:

This next discussion focuses on the planning and production of patient-specific implants (PSIs) for spinal surgery.

This first case study discusses the big advantages of patient-specific implants as compared to off-theshelf implants. For this case study, and in many others mentioned here, the potential to customize surgery has reduced operative times, reduced blood loss, provide immediate stability, and potentially improved fusion rates. This is a unique case of intraoperative trial placement of a custom patient-specific implant (PSI) versus the final implantation of a customizable off-the-shelf (OTS) implant. Data collected for comparison included time to implant, ease of implantation, firmness of press-fit, and fixation options after implantation.

The patient in this case study was a 64-year-old man with low back pain. Computed tomography and magnetic resonance imaging revealed a solitary lesion in the L5 vertebral body, confirmed by positron emission tomography scan. Removal of the L5 vertebral body was performed, and reconstruction was achieved with an expandable cage. The time of implant insertion was minimal with the PSI (90 seconds) versus the OTS (>40 minutes). Immediate press-fit and "firmness" of implantation was clearly superior with the PSI, although this was an intraoperative subjective assessment. Other benefits include integral fixation that is predetermined with the PSI, reduced time and blood loss, and ease of bone grafting with a PSI.

The use of 3D printing has been able to reduce operative time significantly. Surgeons can train before performing complex procedures, which enhances their presurgical planning, with the goal to maximize patient outcomes. When considering implants and prostheses, the use of 3-DP allows a superior anatomical fit for the patient, with the potential to improve restoration of anatomy (Mobbs, et al., 2018).

This second case study involves interbody fusion which is a minimally invasive method, specifically, the oblique lateral interbody fusion procedure which represents a minimally invasive modification of the traditional anterolateral approach to the lumbar spine, allowing quicker mobilisation and lesser postoperative pain. The dissection plane is extra-peritoneal and gives access to the anterior discs to the psoas muscle. This anterolateral corridor minimises psoas-related injury, with early evidence of less post-operative lumber plexus- and psoas-related morbidity, particularly at L4-5 which are difficult to access via the direct lateral approach. While this technique allows anterior access to L5-S1, which is not accessible through the lateral approach. There are added benefits to this technique like high fusion rates, indirect decompression and deformity correction through a minimally invasive procedure (Moskovich & Hasan, 2018)

Lumbar Pedicle Screw Insertions by 3D Laser Print:

Accuracy is a major problem in spinal surgery especially in the accuracy of the cervical screw insertion due to the risk of damage to adjacent vital structures. Recent research in 3-dimensional (3D) technology describes the advantage of patient-specific drill guides for accurate screw positioning, but consensus about the optimal guide design and the accuracy is lacking. This particular study aimed to find the optimal design and to evaluate the accuracy of individualized 3D-printed drill guides for lateral mass and pedicle screw placement in the cervical and upper thoracic spine.

The surgeons used Five Thiel-embalmed human cadavers where they planned an individualized drillguide of 86 screw trajectories in the cervical and upper thoracic spine. Using 3D bone models reconstructed from acquired computed tomography scans, the drill guides were produced for both pedicle and lateral mass screw trajectories. During the study, the initial minimalistic design was refined, resulting in the advanced guide design. Screw trajectories were drilled and the realized trajectories were compared to the planned trajectories using 3D deviation analysis.

The results showed that the overall entry point and 3D angular accuracy were 0.76 ± 0.52 mm and $3.22 \pm 2.34^{\circ}$, respectively. Average measurements for the minimalistic guides were 1.20 mm for entry points, 5.61° for the 3D angulation, 2.38° for the 2D axial angulation, and 4.80° for the 2D sagittal angulation. For the advanced guides, the respective measurements were 0.66 mm, 2.72°, 1.26°, and 2.12°, respectively.

The output of the study was an advanced guide design including caudally positioned hooks, crosslink support structure, and metal inlays. The novel advanced drill guide design yields excellent drilling accuracy (Pijpker, 2018). This study showed how 3D printing can become very useful in pinpointing the accuracy of lumbar pedicle screw insertions.

This second case study shows the quick increase in the use of thoracic pedicle screws in scoliosis where the safe and accurate placement of the screw within the pedicle is a crucial step during the scoliosis surgery. Different techniques are used to make thoracic pedicle screw placement much safer. One of them is the patient-specific drill template with pre-planned trajectory which is critical to assess the efficacy and safety profile with the technique. In the study, the researchers developed and validated the accuracy and safety of thoracic transpedicular screw placement with patient-specific drill template technique in scoliosis. The respondents of the study were patients with scoliosis requiring instrumentation. Volumetric CT scan was performed on each desired thoracic vertebra and a 3-D reconstruction model was generated from the CT scan data. The optimal screw size and orientation were determined and a drill template was designed with a surface that is the inverse of the posterior vertebral surface. The drill template and its corresponding

vertebra were manufactured using rapid prototyping technique and tested for violations. The navigational assist with the placement of thoracic screws. After surgery, the positions of the pedicle screws were evaluated using CT scan and graded for validation.

This method showed its ability to customize the placement and the size of each pedicle screw based on the unique morphology of the thoracic vertebra. In all the cases, it was relatively very easy to manually place the drill template on the lamina of the vertebral body during the surgery.

This method significantly reduces the operation time and radiation exposure as for the members of the surgical team, making it a practical, simple and safe method. The potential use of such a navigational template to insert thoracic pedicle screws in scoliosis is promising. The use of surgical navigation system successfully reduced the perforation rate and insertion angle errors, demonstrating the clear advantage in safe and accurate pedicle screw placement of scoliosis surgery (Lu, et al., 2012).

The Fabrication of Ergonomic Shaped Medical Implants:

The additive manufacturing technology or 3-D printing gives an excellent opportunity to fabricate ergonomic shape medical implants. The goal of this particular case study is to design and manufacture a 3D-printed lumbar cage for lumbar interbody fusion. Optimisations of the proposed implant design and its printing parameters were achieved via *in silico* analysis. The final construct was characterised via scanning electron microscopy, contact angle, x-ray micro computed tomography (μ CT), atomic force microscopy, and compressive test.

Preliminary *in vitro* cell culture tests such as morphological assessment and metabolic activities were performed to access biocompatibility of 3D-printed constructs. Results of *in silico* analysis provided a useful platform to test preliminary cage design and to find an optimal value of filling density for 3D printing process. Surface characterisation confirmed a uniform coating of nHAp with nanoscale topography. Mechanical evaluation showed mechanical properties of final cage design similar to that of trabecular bone. Preliminary cell culture results showed promising results in terms of cell growth and activity confirming biocompatibility of constructs (Serra, et al, 2017).

CONCLUSION

Undeniably, 3D printing has become a sort of transformative technology which has made considerable impact on orthopaedic spine surgery. Initially used for surgical planning for complex spine surgeries, it has expanded now to preoperative and intraoperative settings. Preoperatively, 3D printing has been used to create anatomically accurate models of spinal deformities for patients and these models are also being used for preoperative surgical planning and simulation for complex spinal pathologies. Surgeons have discovered that a tactile 3D visual representation gives a better depiction of the patient's anatomy than what computed tomography (CT) or magnetic resonance imaging (MRI) imaging can do. Intra-operatively, 3D printing has been used to create surgical guidance systems, templates, and customized patient specific implants.

So what does the future hold for 3D printing in spinal surgery? One area where they can really help is in providing state-of-the-art training simulations of surgical experiences for residents and clinical practitioners (Rehder, R., et al., 2016). Before the advent of 3D printing, cadaveric models were traditionally used for educational purposes and surgical simulation. However, they are limited in their usage due to shortage of donations, and health and safety issues (Wu, et al., 2015). Furthermore, it usually becomes a hit and run affair since each human body has its unique features and measurements – and with spinal surgery needing to be very accurate to the last millimetre.

Even with the advent of the CT scan and the MRI, making predictions more accurate than what was done before, it was still another hit-and-run miss since there are so many factors that come into the fore like the make of the material, the hardness of the surface of the injury and other factors which can detract from making the cure very accurate.

A variety of factors, such as work hour restrictions and challenges from complex cases may reduce surgical confidence in residents. 3D-printed spine models serve as an alternative to cadavers and have increased capacity for customizability in educational purposes. 3D models have been useful in navigating complex deformities and improving anatomical understanding in the training of residents and clinical practitioners (Hughes, et al., 2014). In a study using 3D models of cervical spines and 3D-printed prototyping drilling templates, residents demonstrated the ability to successfully and precisely accomplish proper trough positioning on cadavers for expansive open door laminoplasties, a critical and technically demanding step of the procedure (Rong, et al., 2016). This has shown how advantageous the technology has been in the training of future orthopaedic surgeons.

Furthermore, trainees have become more competent in needle placement for image-guided diagnostics and therapeutic spinal procedures as printed spine models with characteristics mimicking true bone density have been used (Javan, et al, 2010). In cases where the patient is unable to make informed consent, the 3D-printed spine models have also been reported to be successfully applied with patient specific 3D-printed spine models helping guide patients in the decision-making process by educating them on their spinal pathologies and the surgical procedure (Liew, et al., 2015). In this process, the patient is made to see the advantages that they may get from the procedure and the likelihood that this procedure can improve the quality of life of the patient.

In one particular study cited earlier, optimised designing was gained combining computational and experimental analysis and using the 3D-printing technique for intervertebral fusion cage which shows that 3D-printing is a promising technique for medical applications and this particular study paves the way for future development of customised implants in spinal surgical applications. Finally, the advances in tissue regeneration and printing techniques in terms of cpi allow for 3D printing of intervertebral discs in the future (Yang, Z., et al., 2016).

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