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A Review on Patient specific drill guide for spine surgeries.

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Abstract: The Rapid Prototyping has a wide application including in medical field also. The complex shapes which otherwise are very difficult to build can be easily fabricated through RP. One significant region in spine for screw insertion is spine pedicle. But, this is most crucial area due to its proximity with spinal cord and nerves. Designing personalized drill-guide will not only enhance accuracy but also provide better accuracy. In this paper, the various designs made so far had been reviewed and through them some basic features and principals are drawn. This paper has an objective of presenting a review of different customized patient-specific drill that is used for inserting screw in pedicle of spine in human body. The paper tried to investigate certain criteria for designing (like landmarks based on anatomy, accuracy, stability by unique placement, etc.). Based on these, some new proposals are implemented to make the design more effective.

INTRODUCTION:

Rapid Prototyping is a group of modern technique of manufacturing really challenging and complex geometrical shaped 3-dimensional objects with high precision and accuracy using Computer Aided Design (CAD) data. It is a very time saving and cost efficient technology. The basic principal of RP is based on either addition or subtraction of material in the layered form to get final shape. But, the major RPs are using the concept of additive manufacturing. As the name states Additive – in this model is created by computer controlled adding layer on layer of material. It can be thought of adding one playing card on the other until the full deck of cards is formed. This manufacturing process is real fusion of mechanical, electronics and computer assistance to reach excellence. One of the very widely used fields of RP is Health care sector specifically in orthopedics in which various surgical equipment and implants are made with help of RP. Spine surgery is one such surgery which requires very precise tools to get results. Fixing screws in pedicles is one of the very frequent procedures in Nuoro surgeries. A lot of precision and accuracy is required in order to avoid any misplacement which could deteorate the vessel, nerves and even viscera. It can affects the bone stability and even led to lesion of spinal cord, Nerve root and blood vessel [1]. The limited area of visibility of the various anatomic features, which works as landmarks, makes the surgery even more complex and requires the need of a lot of experience. The accuracy of insertion depends mainly on the surgical ways. The very primary method of this surgery is freehand. It makes use of the experience of surgeon in making out the anatomical landmarks to use them as a reference and insert the screw. But this method is really tough to get expertise. A lot of other methods have been developed so far, some of them are:

1.) Interaoperative fluoroscopy
2.) Fluoroscopy
3.) CT-guided computer-assisted surgery (CAS).
4.) Surgery using pedicle probe (guiding the screw insertion using ultra-sound or tissue conducting measurements)
5.) Electrophysiological monitoring technique.

Literature work shown that misplacing error in case of freehand technique is about 21% which could be reduced to 3%[2]. Although the above techniques showed a lot of improvements but again they have teir own drawbacks[1]:

1.) They have a very high learning time as well as curve.
2.) Surgeons' tool can obstruct the optical arrays of light.
3.) These techniques required a lot of additional sensors for tracing, display systems for surgeons to read and even robotic systems.

Keeping view of these above problems for reducing the surgery cost and learning time a new method of using a drill-guide is an innovating step had been developed in last 5-6 years[3-5]. But, again as every patient have its unique shape and contour on bone, so guides should be customized to make it patient specific. Earlier it seems to be a complicated problem, but now it become a much easier task with the invention of various biologic specific software like MIMICS (and 3-Matics) which helps in converting the DICOM format file of CT-scan data into 3-D stl fomat model on which further designing can take place. After designing the model, it can be built by RP techniques. Using RP in medical field serves a lot of purpose:

1.) Visualizing the details.
2.) Planning the surgery and simulating it.
3.) Improving communication with patient/medical[7-8] specialist
4.) Obtaining scoffolds for tissue engineering
5.) Biological Implants[9]
6.) Prosthesis manufacturing[11]
7.) Surgical templates[7-12].

Designing custom drill guides:

The very first step to determine the optimum size and entry point for pedicle screw with the help of surgeon who on the basis of pedicle shaft. The designing procedure basically uses a reverse engineering approach. Literature had shown of approaching two ways - making negative of the vertebrae surface is used as an anti-template which matches physical casting in a lock-and-key fashion[1] and making support of knife edge of V- or U- shape to get fit on spine's transverse process[6]. The obvious geometric features of guides are[6]:

1.) Cylinders: which give way to drill as per planned trajectories indicating drill depth.
2.) Support: which provide stability with relating to anatomical land and avoiding rotation.
3.) Connecting arches: which connects the cylinder with support.

One author also provide some basic principles for harm-free design:

1.) Avoiding the use of vertebrae-ligament's area as their difficulty of removing.
2.) Selecting easily removable soft tissues.
3.) Avoiding nearby area of vertebrae-column joints.

There are also certain areas not to be selected these are:

1.) Inter-spinal ligament
2.) Facet capsulary ligament.

The cover area can be chosen lower lamina as their rough edges make it suitable for stability of guide. After deciding cover area, supporting platforms are decided. Sleeve diameter are slightly larger than guide pins.

Evaluating accuracy in placement of Pedicle screw:

The most used evaluating way is with the help of flouroscopy in which X-rays are used and then screws are studied. Various authors use various comparisions like Jing Jing Fank[1] uses Four parameters these are- angle of insertion deviation in transverse and sagittal view and entry point deviation in transverse and sagittal view. The other classification “in”,”out” or “questionable”, lateral pedical breach of >,=,< 2mm[13-14]. Many times compring is done using vertebral body[3/30]

VARIOUS DESIGNS:

The first probable design for insertion of screw in pedicle of spine vertebrae was brought by Van Brussel et al.[15]. The design used the negative of spinous process as a base on the 3D model of the spine.

Stiffness, Strenght and stability analysis of model done by non-linear Finite element analysis by selecting 3D tetrahedral element.

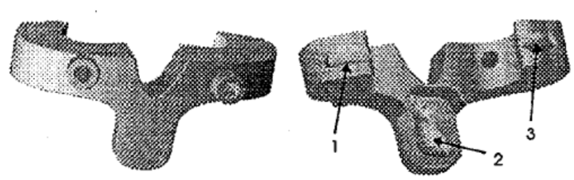

Figure1: Finite element meshing of drill guide for analysis.

Further development is done by Berry et al.[16]. The design is not only for one vertebrae but for multiple vertebrae at the same time can be screwed using single model as can be ssen in figure 2. The designs are different for different section of spine (cervical, thoracic and lumbar). A direct use of drill template made of duraform polyamide and manufactured with RP (SLS) technique is shown in figure [3].

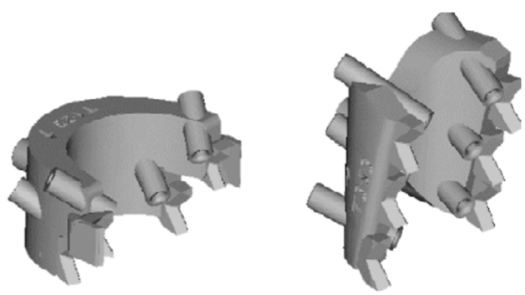

Fig 2: drill guides for single and multiple vertebrae

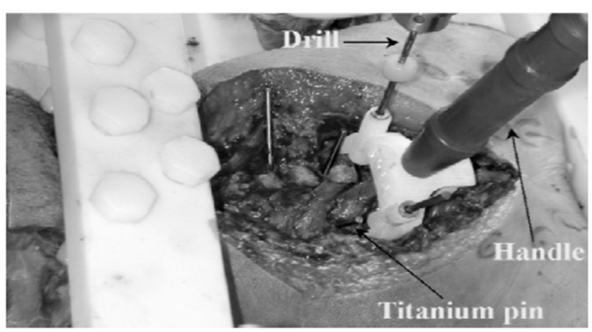

Fig 3: Pdicle Screw insertion image in actual surgery

Porada et al.[17] tried to come out a methodology of design that can be used for Patient specific drill guides in which specification of drill paths are done through software and finally imported to design software for designing its guide. The prototype made actually visualize and give way for drill bit in proper direction. Its shape is supported by spinous and transverse processes (Figure 3). One important design criteria is stability, which can be fulfilled by surgeons' hand as seen in figure. Also, the soft tissues should be secured without compromising the correct position of the guide and for this reason the surface-surface fit is discouraged. Here, the Laser sintering process were used to manufacture guides and tested for accuracy in repeatability use and appreciable results were found.

Figure 4: Stabilizing the guide while surgery

Jamal et al.[18] gave drill guide design for L2 vertebrae of 43 years old patient. After acquiring the image data from a spiral CT scanner, the image was processed MIMICS10 software package. After extracting the stl model of bone treatment plan had been performed through Solidworks. Design was made such that the screws would insert in maximum volume while keeping the nerves at appropriate distance away. The design closely the whole spinous process connected to cylindrical ways with small arches. The design shown did not take support from the transverse process. Prototype was manufactured from the RP machine. To avoid the internal scratching of the device steel tubes were finally attached in the inside diameters of the cylindrical ways.

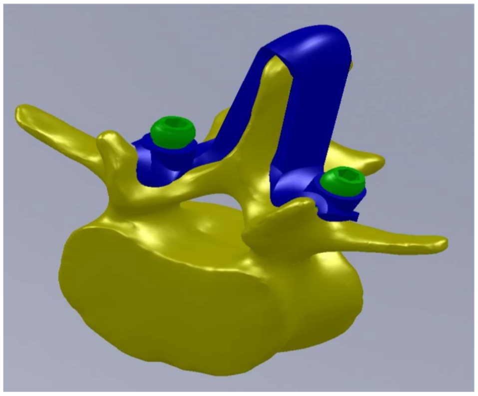

Figure 5: Yellow L2 spine Blue- drill guide Green-Screws

Figure 6: Final RP model of drill guide

Birnbaum[19] used a novel idea of using a transparent material which may help during surgery for more accurate placement of guides over the surface of vertebrae bone. The approach of reverse engineering is being used. The base for designing is taken from the scanning of the patient vertebrae and making its 3D model.

T.S. Yoo et al. found the scope of FDM with medical ABS in surgical planning techniques. They planned and controlled the trajectories of pedicle screws for spine surgery with the goal to conforms the contour of the patient's vertebrae. The jig he constructed corresponding to the trajectories of the pedicle screws guides the drill placement and depth, increasing the accuracy and precision of screw placement (Figure 5). They created a customized device for each individual patient, one per segment, and improve accuracy without the introduction of navigation tools or increased fluoroscopic radiation dose with the intention to use jig to transfer the surgical plan directly to the operating room without introducing additional technology. The shape is not much comfortable to use.

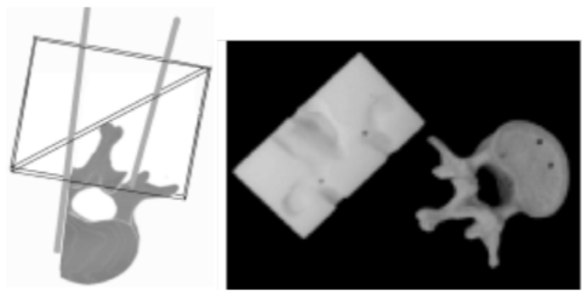

Figure 7: A block designed guide for screw insertion[20].

Groffin et al.[21] compared the two designs each having clamps-one not taking the interference of spinous process and using the lamina of 2nd cervical vertebrae as connection on the other hand the second design considered interface of the the spinal process connecting the lamina. Testing of two designs on cadaver showed the second design to be more stable and accurate on comparing with the first design.

Ryken et al.[22]studied the different Rapid Manufacturing process feasibility of making surgical guide templates for spine on already defined trajectories of drill. In other study by Ryken et al.[23], the investigation was done in laboratory for the guides' design placing 3.5 mm diameter screw in C3 to C7 vertebrae in 4 cadavers. A larger surface contact was achieved on cervical vertebrae but again at the cost of removing soft tissues so that template can become more stable by contacting the bone structure of vertebrae as can be seen in figure 7.

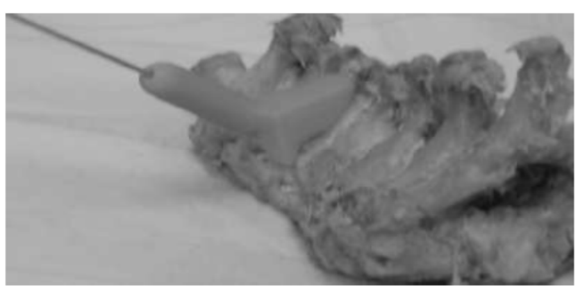

Figure 8: Drill guide on Cadaver vertebrae[23]

The surface-surface contact type of design is also tried by Owen[24] to make a guide for right side's posterior surface of 5th cervical vertebrae.

Lu et al.[25-27] presented the designs of drill guide for cervical and lumbar vertebrae that are C2 and L2 using surface-surface contacts. MIMICS was used to create a 3D model of vertebrae and then for evaluating optimum diameter and orientation, model was exported in UG Imageware. Surgeon on considering the scan images, quality of bone and orientation of pedicle establish a trajectory for insertion. The design considered the spinous process as main landmark from anatomic point of view. Final prototype was made with a polymer have biocompatibility Somos 14120 using a SLA (RP) machine. Test was conducted on 9 patients.

Figure 9: Virtual and physical prototype of lumbar spine and its drill guide

Ma et al.[28] developed the drill guide template for thoracic spine. Design is done by already discussed way using the negative of posterior surface of thoracic vertebrae. Comparing the result of inserting 214 screws with freehand and with guide gave a very positive result encouraging the use of drill guides. The paper also described the time frame of about 1 hour for designing the guide for each vertebrae and also the cost of manufacturing as well as the material was US $50.

Kashani et al.[29] came up with a very innovative idea of designing a drill guide which can incorporate the change in diameter of the drill bit using the CT scan image data of spine vertebrae.

Salako et al[30] gave comparision of two designs – one similar to surface-surface contact method and other point-to-surface method which uses 6 points for support. Both designs have common thing of using spinous process as their main anatomic landmark. Without going to clinical tests the paper concluded that although the second design was reusable but the number of parts are large, hence making it more complex and difficult to use.

Some new drill guides had also came which directly using the metal as their material.

CONCLUSION AND DISCUSSION:

From all the literature work, a common conclusion can be drawn that customized drill-guides are very much accurate in attaining the screw trajectories as planned with computer in actual surgeries. The statistics by testing clinically by different papers showed that not only there is increase in accuracy but also there is decrease in the time of surgery also. The RP techniques are very much suited for developing these guides as they give accuracy required while manufacturing them and even the material used have the properties like biocompatible and stiffness. Different paper shown different designs because of the different landmarks are used during designing. But, the surface (posterior of spine) of spinous process is used as a reference and transverse process is used for supporting and providing stability almost in all the papers. Mainly two approaches point-to-point and surface-to-surface are used. Recent works are mainly focused on fitting the template surface on vertebra surface. The guiding template is highly accurate and provides great assistance in the planning and execution of surgery. The accuracy of screw placement is confirmed with postoperative CT scanning. Many clinical cases are needed to validate the efficacy and compatibility; in the future, surgeon can use the guiding templates to complete more complicated cases such as those involving scoliosis and cervical complication

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