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*Original Article*

# A Modified Cage Insertion Device For Transforaminal Lumbar Interbody Fusion Surgery

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***Abstract*** - *Transforaminal Lumbar Interbody Fusion is the most widely used approach for treating Spondylolisthesis. Interbody fusion devices are inserted in the Lumbar region for degenerative disc diseases. Use of guideways makes the surgery more complex. The proposed insertion device is an attempt to eliminates the use of a guideway threby providing smooth and injury free surgical operation. The device performs two functions including positioning and holding the cage while performing the surgery. Positioning method and holding mechanism of the device are further discussed in the paper. Transforaminal Lumbar Interbody Fusion (TLIF) device provides suitable disc height and ensured the load bearing capacity of the spine maintained. The prposed device mechanism disclosed is effective to implement than using guideways. Moreover, the provided locking pins provide secure locking of the cage because of its excellent strength. The proposed insertion device is relatively simple and compact in design with maximum insertion tube diameter of 12 mm.*

**Keywords —** *Degenerative Disc Diseases, Pedicle screw, Spine, Spondylolisthesis, Transforaminal lumbar interbody fusion (TLIF)*

## I. INTRODUCTION

Human spine is the vital and complex part of the body. It protects the spinal cord, nerve roots and provides flexibility to the trunk. It is subjected to internal forces along with the body weight. It is divided into five parts namely cervical, thoracic, lumbar, sacral and coccygeal. The spine as a complete structure can undergo axial, lateral and sagittal rotations and axial, lateral and anteroposterior translations. So, the spine has 6 degrees of freedom. A functional spine unit consists of superior vertebra-intervertebral disc-inferior vertebra-osteoligamentous unit. Surgical instrument at least spans one FSU. The lumbar vertebrae are subjected to excessive pressure because they have to bear the stresses induces due to the weight of the body. Degenerative Disc Diseases (DDD) are caused due to spine aging, decrease in protein content, sudden shock to the spine due to accidents. Motions are considered one vertebra relative to another. Spondylodesis is performed to stop the motion at the painful vertebral segment and that should decrease the pain generated from the joint [1-5]. Transforaminal lumbar interbody fusion surgeries are performed in the lumbar region to cure the DDD and maintain the lordosis of the spine. An interbody spacer is inserted in between the vertebrae and then bone graft material is added which eventually causes the vertebrae to fuse into a single solid bone.

**Fig 1. Interbody spacer (cage) used in surgery**

TLIF cages are made using PEEK (Poly Ether Ether Ketone) material. Titanium and Carbon fiber are other alternatives for the cage [6]. PLA (Poly Lactic Acid) cages are under development and testing as a cheaper alternative [7]. The cage as can be seen in figure 1 are manufactured in varying size ranges and used in the surgery considering the requirement of the surgery. For this particular design a cage is designed having length 28mm and breadth 14mm and the thickness range is 6-13mm. Lordotic angle of 500 is considered. The cage is inserted in the body with the help of an insertion device. Depending on the design of the device a guideway may or may not be needed for proper positioning of the cage. TLIF procedure minimizes lamina, facet and parts dissection thereby decreasing the neurological injury and preservation of posterior column integrity [8-13]. TLIF provides an advantage of avoidance of unnecessary exposure of the contralateral structures, less retraction of the cauda equina, less muscle stripping and thus lesser postoperative pain.

Location of the cage in the intervertebral disc space is an important factor for maintaining lordosis of spine. Sometimes according to the requirement of the patient convex-shaped cages are used. Convex cages are designed to fit in the convexity of the vertebral endplates. The convex shaped cages may have the advantages of equivalent lordosis correction and tight endplate fitting. TLIF surgeries are performed along with pedicle screw fixation because it is a unilateral procedure and has to be combined with bilateral pedicle screw fixation. Pedicle screws are made from Titanium. Threads are provided on the cage to avoid slippage of the cage and proper penetration into the vertebrae [14-16].

Failure of TLIF surgery is an uncommon phenomenon. Dislodgement of the cage might be a risk but that can be avoided by using cylindrical threaded cages. There is also a slight possibility of the cage impinging on the nerve root, but that is uncommon [17].

The objective of the present work is to provide a insertion device that offers safe surgery with no damage to the spine muscle. Moreover, the device should provide locking mechanism to secure the cage. It is required that it should rotate up to 18° without disengaging from the cage. Overall, the insertion device should be relatively simple in design and smaller in size with tube outer diameter limited to 25 mm.

## II. METHODOLOGY

Lumbar fusion surgeries are basically performed for diagnosing Degenerative Disc diseases. If the diseases are not possibly cured by physical exercises, medicines the surgeries are highly recommended. PLIF (Posterior Lumbar Interbody Fusion) surgeries were performed in the earlier days for Degenerative Disc Diseases. Further TLIF (Transforaminal Lumbar Interbody Fusion) surgeries have replaced the PLIF surgeries. Cages made of PEEK material are used for these surgeries. The chief advantages of the TLIF procedure compared with the PLIF procedure included a decrease in potential neurological injury and improvement in lordosis alignment given graft placement within the anterior column [18].

These surgeries are performed using medical tools. Some surgeries make use for one tool for insertion and another tool for guiding the tool. With advancements in the design a single tool performing both the functions is manufactured. This tool holds and positions the cage and is comparatively superior to the prior one (figure 2). However, the existing device that is used for performing TLIF surgeries is not very convenient to use by the surgeons as the cage rotates on its own after it is hammered on the back side while performing the surgery. So with the design and fabrication of the device we can help to eliminate these problems. The cage after holding in the designed device will not rotate on its own as there are grooves made inside the cage for holding the cage firmly. And the surgeries can be performed with more convenience. The device performs combined function of holding and positioning of the cage. It can be used by the surgeons all over India for performing Lumbar Fusion Surgeries. This design makes use of positive locking mechanism so no slip occurs between the mating parts [19-23].

TLIF surgeries are gaining more and more popularity these days. The results are also good so there is a huge scope in the modification, fabrication and manufacturing of these devices. Cost optimization can be next step in this project.

Lumbar fusion surgeries are performed for Degenerative Disc Diseases. If the diseases are not possibly cured by physical exercises, medicines the surgeries are highly recommended. For this case the constraint for the rotating cage was 90º and the tool can be rotated upto 18º.

For the forementioned cause, it becomes necessary to provide a mechanism such that two supporting rods will hold the cage circumferncially. These rods are free to move linearly relative to each other. For having the rotating movement of the cage the pivotting of the rod is necessary in the outer tube. So in the mechanicm of proposed device, a rod is provided between two supporting rods which has T projection for locking the cage. CAD design model is prepared for the idea which is proposed with dimensions and constraints.

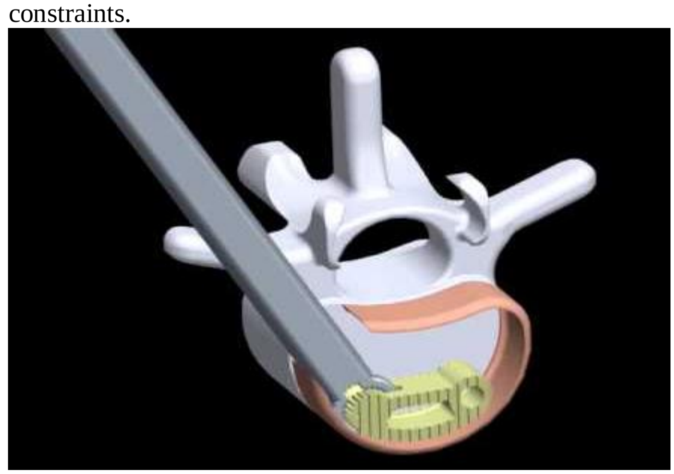

**Fig 2. Positioning of the cage using existing insertion tool**

## III. EXISTING TLIF SURGERY DEVICE

The existing device as can be seen in figure 3 has been used for the surgery of transforaminal lumbar interbody fusion, has the geometric specifications such that supporting rod diameter is 3 mm, central locking rod having diameter of 6 mm the distance between the central rod and the supporting rod is limited to 1.5 mm and the inner diameter of the outer pipe is 20 mm having thickness 2 mm thereby making its outer diameter 22 mm. From the research it was found that the width of the TLIF Cage is 10 mm length of which is 28 mm and the minimum thickness of the cage accounts 6 mm. The thickness of the Transforminal Lumbar Iinterbody Fusion (TLIF) where is from 6 mm to 13 mm depending upon the lumber.


**Fig 3. Existing tool for TLIF surgery**

The existing medical tool for TLIF surgery is made up of biomaterials including stainless steel, anodized aluminium and customised steel which exhibits the the required engineering and physical properties. Stainless steel bing corrosion resistance nonmagnetic and non toxic in nature is widely used for the manufacturing of TLIF surgery device. Being less electrical and thermal conductive in nature, stainless steel makes it most commonly used biomaterial in the field of biomedical and implant manufacturing. The properties of the stainless steel can be altered by composition with another alloying elements. Customised Stainless steel 630 being one of the common compositions of SS because of its excellent resistance to oxidation [24]. Stainless Steel 304 biomaterial provides excellent engineering properties as can be seen in table 1. Anodized aluminium is used because of its desirable properties like high durability, corrosion resistance, excellent hardness, adaptability to fabrication and easy to maintain [19-23].

The tool being popularly used in TLIF has few limitations in its use. The bulky holding mechanism and larger diameter size makes the device more complex and less user friendly. Moreover, there are possibilities of damage to the spinal cord while insertion of the nose of the device. For an easy and injury free surgical operation, it becomes necessary to provide an optimistic medical intrument. The proposed design of TLIF device an attempt to overcome the difficiencies in the existing device. Number of iterations were performed to minimize the limitations and provide more optimistic device. Medical aspects and manufacturing standards were taken into consideration while concluding the final design of the device.

**Table 1. Properties of SS 304** [24]

| Property | Minimum | Maximum | Unit |
|---|---|---|---|
| Density | 7.85 | 8.06 | $Mg/m^3$ |
| Bulk Modulus | 134 | 151 | GPa |
| Compressive Strength | 205 | 310 | MPa |
| Tensile Strength | 510 | 620 | MPa |
| Young’s Modulus | 190 | 203 | GPa |
| Ductility | 0.3 | 0.57 | |
| Elastic Limit | 205 | 310 | MPa |
| Poisson’s Ratio | 0.265 | 0.275 | |

## IV. MODIFIED TLIF SURGERY DEVICE

The proposed design of TLIF surgical tool should eliminate the prior deficiencies in the existing and provide more effective and optimised tool. It is required for the cage of the tool should not rotate while performing the surgical process on its own. Providing grooves to the device can effectively restrict the rotational movement thereby rigidly holding the cage. The tool is designed in such a way that it perform the function of holding the cage and properly positioning during the surgical operation, providing more convenience to the surgeons. The proposed tool provides positive locking mechanism which restrict the motion of the mating parts thereby ensuring no slip condition. Figure 5 shows the design of proposed tool for the TLIF surgery.

The proposed surgical device comprises two locking rods having inverted pains at its end and modified cage design. The cage comprises two holes at its opposite faces thereon to lock the cage with the aid of locking pins and hole. The cage provided with holes restricts the linear motion while allowing rotational moment only thereby providing secure locking of the cage. The angular momentum of the cage is controlled by providing central rod which lock the cage by engaging locking pins in the hole.

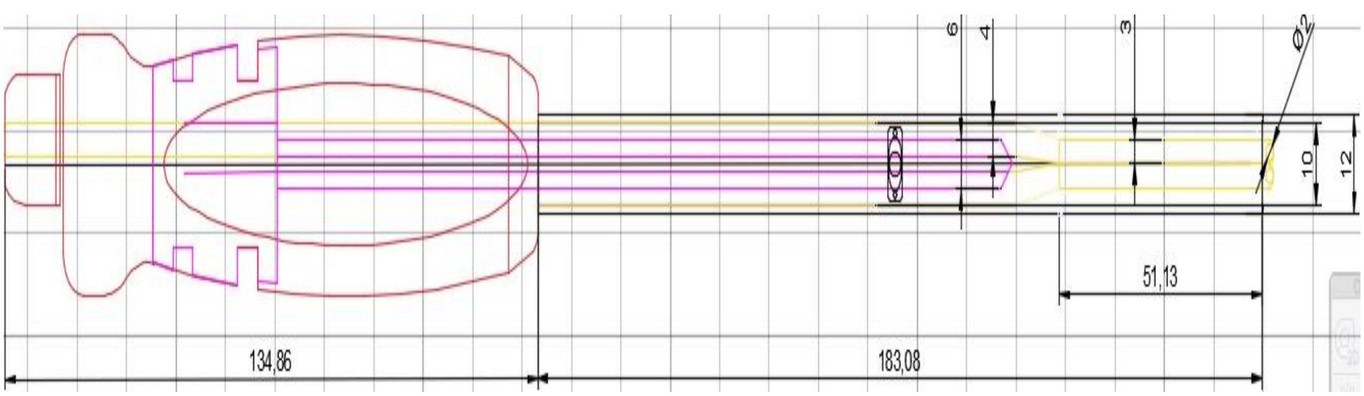


**Fig 4. Dimensional overview of the modified TLIF surgery device**

The entire mechanism is retained in a 12 mm diameter tube (see figure 4). It is undesirable that the frontal diameter of the outer tube exceed the cage thickened. In an attempt to trample the frontal diameter of the tube, it is tapered and flattened to a width of 7 mm. By performing the surgical operation the tool is humbled and forced to twist the cage in the lock position the proposed device provides a rigid grip to the cage. Since the cage is positively locked, the rotational movement is constrained even upon application of hammering force.

The mechanism of the handle is divided into three parts. The outer tube is functioned with the direct aid of handle. The central rod is applicated by secondary portion of handle which limits the rotation of rod to 15 degrees. The rotational movement of the handle and central road is restricted by providing grub screw and ball mechanism in the configuration. The locking rod is passed through the slit provided at the handle. The mechanism provide the realizationa to surgeon regarding the rotation of the rod.

**Fig 5. Proposed cage insertion device for TLIF surgery**

**Fig 6. Exploded view of the modified TLIF surgery device**

As can be seen in figure 6, the locking rod is operated by a thimble provided at the surgeon end of the device which controls the angular moment of the cage. Rods are provided with the guiding plate attached at the outer tube thereby along the linear moment of the locking rod relative to each other in the opposite direction. The resulting movement causes the rotation of the TLIF cage.

Since the geometrical dimensions of the locking rod and pin lies within pivot cage dimensions, the proposed insertion device provides safe surgery with no damage to the spine muscle. Moreover, the the locking pins provide secure locking because of its excellent strength. The proposed insertion device is relatively simple in design and smaller in size with maximum diameter of 12 mm.

## V. CONCLUSION

The present study offers a modified design of the transforaminal lumbar interbody fusion surgery device is to overcome the deficiencies in the existing device including complex design and possibility of damage to the spinal cord while insertion of the nose of the device. The proposed transforaminal lumbar interbody fusion surgery device enables cage to rotate up to 800 without disengaging the tool. With advancements in the design, a single tool can function both the operations of holding and positioning of the cage. The tool holds and positions the cage and is comparatively superior to earlier examples. The device can significantly shorten operative times, as only one instrument is needed for performing transforaminal lumbar interbody fusion surgery. Moreover, it results in less blood loss and less damage to the surrounding tissues. As the number of instruments enagaged for the TLIF surgery are reduced, there is significant decrease in other neurological complications. The use of only one instrument will lead to less risk of nerve damage. Operating the proposed tool will considerably provide smooth and harmless surgery while no injury to the spine structure.

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