A study of design and digital simulation of a anterior internal fixation system

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Abstract. At present, anterior cervical discectomy and fusion often use internal fixation system to assist fixation of surgical segments, and the design of internal fixation system profile has an important influence on postoperative complications such as vertebral injury. In this study, a triangular anterior internal fixation system was designed to reduce the risk of postoperative complications. In this study, a intact C1-C7 segment finite element model was established and verified. Based on this model, a quadrilateral fixation system (QFS) and a triangle fixation system (TFS) implanted model were established. The stress distribution and peak value of the screw holes were compared during the postoperative flexion, lateral bending, rotation and extension motion patterns. Compared with the QFS, the stress ratio of the bone-screw interface of TFS is 40% smaller on average. After TFS implantation, in addition, because of the TFS screw hole beard less stress, it has certain advantages of screw loosening and reducing the risk of vertebra damage at the screw hole.

1. Introduction

Since the 1980s, anterior cervical discectomy and fusion (ACDF), using a bone graft-intervertebral cage and anterior cervical plate (ACP), was the gold standard in the treatment of cervical spondylotic radiculopathy, myelopathy, trauma, and other cervical spondylopathy [1].

Although ACP increased postoperative stability, such as screw loosening, bone damage at the screw hole, and after implantation complications have been confirmed by many reports, and occur 12-24 months after surgery ratio reached 15% [2]. Epstein et al. [3] shows that the bone damage at the screw hole is due to the excessive rigidity of the ACP system, which causes most of the load to be borne by the external device, and the load is transmitted through the screw. So the vertebrae and the screw junction will be subject to greater stress. It may increased the risk of screw loosening and re-fracture of the vertebrae. Some studies designed and evaluated the biomechanical effects of new anterior internal fixation systems after implantation to reduce the potential risks of the above complications. Şimşek et al. [4] designed a hinged and assembled quadrilateral fixed plate, and evaluated the impact of the pre-bending of the new fixed plate on the biomechanics after implantation; Peterson et al. [5] analyzed the impact of load sharing of ACP stiffness by designing a quadrilateral fixed plate with different stiffness. Mackiewicz et al. [6] explored the difference in stability and mechanical performance of trapezoidal fixed plates, quadrilateral fixed plates and semi-constrained fixed plates after single-level ACDF.

These single-level ACP profile designs are mostly rectangular or rectangular-like quadrilaterals, which need to be fixed with four screws, However, the design of triangular fixing plate with three screws has not been reported. The risk factors for complications after ACDF shows that the difference
of the anterior plate profile and the number of screws could an independent reason of these complications [4-6]. Therefore, the biomechanical evaluation of the triangular anterior fixation system is necessary. In this study, the triangular fixation system (TFS) and the quadrilateral fixation system (QFS) were designed. According to establishing two finite element models of ACP implantation to analyzed for the stress of the implanted segment vertebral screw hole, which provides new ideas and theoretical basis for the design of ACP.

2. Materials and Method

2.1. Complete cervical spine C1-C7 model construction

A digital model establishment of animal cervical vertebrae was used to analyze the finite element (FE) method. This allowed data, that was difficult to obtain clinically and experimentally, to be displayed using FE calculation results. Moreover, the established cervical spine model was able to reproduce injuries and clinical operations, which enabled us to successfully study the prevention, diagnosis, and treatment of spinal diseases [7].

In this study, a 26-year-old, 60 kg weight, 178 cm height healthy adult cervical spine CT scan was performed. The cervical data was obtained using a CT scan with a DICOM format imported into Mimics17.0 (Materialise Inc., Leuven, Belgium). The geometric 3D model of each vertebra was then reconstructed and a spatial geometric configuration of the entire cervical spine was rebuilt based on a restored 3D model (Figure 1b). Using 3-Matic (Materialise., Inc) in the Mimics, a solid model of the C1-C7 vertebrae was created (Figure 1c).

Figure 1. Schematic diagram of model establishment. (a) The CT image of cervical spine; (b) The geometric 3D model; (c) The solid model.

The meshing and material definition of the complete cervical spine solid model were performed in Hypermesh 14.0 (Altair Engineering, Inc., Troy, Michigan, USA). The vertebral body is divided into cortical bone, cancellous bone, endplate and posterior structure. Cortical bone and endplate are defined as thin shells with a thickness of 1mm [5]; cortical bone, endplate and posterior structure were constructed with linear elastic isotropic materials cancellous bone is simulated by linear elastic anisotropic material [8]. The intervertebral disc part includes matrix, nucleus pulposus and fibrous annulus. The nucleus pulposus occupies about 30% to 40% of the entire intervertebral disc volume. It uses incompressible superelastic materials [6]. The fibrous annulus is determined according to previous studies, and non-linear elastic isotropic materials are used to simulate [7]. The facet joint
cartilage uses linear elastic isotropic materials, and the nonlinear surface-to-surface contact simulation with a friction coefficient of 0.1 is used between the cartilages [9]. The ligament part considers the anterior longitudinal ligament (ALL), posterior longitudinal ligament (PLL), ligament flavum (LF), interspinous ligament (ISL), joint capsular ligament (CL), using non-linear elastic isotropic materials [8], and the ligament positions were determined according to anatomy.

2.2. Design and modeling of fixation and fusion systems

Some studies have reported that C5-C6 is the segment with a high incidence of cervical spondylosis [6], therefore the simulated fusion cage and ACP are implanted in the C5-C6 segment. The restricted Orion fixation plate commonly used in ACDF surgery is selected as a control. According to the clinical application, the size and material of the novel designed triangular fixation plate following requirements: the thickness is the same as the Orion fixation plate; the height should be 5 mm apart from the adjacent intervertebral discs to prevent bone impact between the internal fixation plate and the anterior edge of the adjacent vertebral body; and the material is also the same as the Orion fixation plate, both of which are medical titanium alloys.

Both internal fixation systems use cancellous bone screws. The screw material is made of medical titanium alloy with a length of 14 mm and a diameter of 3.5 mm. In the modeling process, a simplified model without threads was used.

Polyetheretherketone (PEEK) is used as the cage material. In standard ACDF surgery, the contact area between the cage and the adjacent endplate should be no less than 30%-40% of the endplate area. Meanwhile, the cage was designed to maintain a distance of 1.5 mm and 3 mm from the anterior and posterior edges of the vertebral body, respectively, to minimize damages from cage slipping and protrusion into the spinal cord.

In this study, SolidWork 2013 was used to design and assemble two ACP systems to simulate the surgical implantation process and generate a solid model. In Hypermesh 14.0, screws, titanium alloy plates, cages and bone grafts are all set to linear elastic isotropic materials.

The established model are shown in Figure 2. Import the normal human body model, QFS implant model, and TFS implant system model into ANSYS 17.0(ANSYS, Ltd., USA) software, and assign unit types and material properties. The material properties and unit selection of each component are based on the literature review, the detailed parameters are shown in Table 1[5-9].

![Figure 2. post-implantation model. (a) The model after QFS implantation; (b) The model after TFS implantation.](image-url)
Table 1. Unit selection and material parameters of each part of the cervical spine model.

| Model components | Element type | Young modulus (MPa) | Poisson ratio |
|-------------------|--------------|---------------------|---------------|
| Cortical bone     | SHELL181     | 10000               | 0.3           |
| Cancellous bone   | SOLID185     | 450                 | 0.25          |
| Endplates         | SHELL181     | 500                 | 0.31          |
| Annulus grounds   | SOLID185     | 3.4                 | 0.4           |
| Nucleus pulposus  | SOLID186     | 1                   | 0.49          |
| Facet cartilage   | SOLID185     | 10.4                | 0.4           |
| ALL               | LINK180      | 30                  | 0.4           |
| PLL               | LINK180      | 20                  | 0.4           |
| LF                | LINK180      | 10                  | 0.4           |
| ISL               | LINK180      | 10                  | 0.4           |
| CL                | LINK180      | 20                  | 0.3           |

2.3. Boundary conditions and loads
In the intact C1-C7 models, the C1 vertebral body centroid was calculated and the centroid point was coupled with the C1 vertebral body to prevent stress concentration caused by the concentrated force load. A vertical downward 50N was applied representing the head mass and a 1.0Nm moment was applied in different directions mimicking the flexion, extension, lateral bending, and axial rotation motion of the cervical spine [10]. The constraints of the above three FE models restrict all degrees of freedom of the lower surface of C7. Finally, the model validity was established by analyzing each segment of the model and its range of motions (ROM) under different motion conditions, along with a comparison with ROM in previous literature.

3. Results

3.1. Model Validation
This study, the finite element model was compared with Panjabi et al. [8], Zhang et al. [9], Yu et al. [10] in the ROM of each segment in each motion patterns, as shown in Figure 3. The results show that the model simulation results of this study have similar kinematic responses to the previous simulation results and experimental data, but there are have some differences. There are several possible reasons for these discrepancies. Firstly, differences can be introduced when using cadaver spines experiment data for FE analysis; Secondly, various research segments may cause diffing in the ROM response. Thirdly, differences in the element type, mesh quality and boundary conditions set by the researcher. And fourth, difference in the profile characteristics of individual cervical spines. based on these factors difference, the calculation results of the finite element model of the cervical spine established in this study are still within in vitro experimental data, so the validity of the model has been verified.

![Figure 3](image-url)
3.2. Comparison of stress distribution and peak value of vertebral screw hole

The screw hole Von-Mises equivalent stress distribution after TFS and QFS implantation under the flexion, lateral bending, axis rotation and extension is shown in Figure 4. TFS stress is mainly concentrated on the edge of the screw hole of C5 segment, and QFS stress is mainly concentrated on the edge of the screw hole of C6 segment, which indicates that the edge of the screw hole is a risk part of causing vertebral damage. As shown in Figure 5, the stress of the QFS screw hole is 140% and 100% larger than that of the TFS during forward flexion and rotation. During lateral bending and extension motion pattern, the stress on the QFS screw hole is 15% and 8.2% larger than that of the TFS respectively. This indicates that the QFS has a higher impact on the screw hole in the flexion and rotation modes after implantation.

Figure 4. Von-Mises equivalent stress cloud diagram of TFS and QFS screw holes during different motion patterns.

Figure 5. Comparison of peak stress in screw holes between the two internal fixation systems.

4. Discussion

The strong stability of the ACDF surgical segment is mainly attributed to the anterior internal fixation and interbody fusion. In the early stage, the anterior fixation plate can immediately stabilize the cervical spine segments and restore the physiological curvature of the cervical spine, which helps to reduce the sinking rate of the cage and promote bone fusion [1]. Therefore, the use of additional ACP
for ACDF surgery has become the most popular surgical method for the treatment of cervical spine diseases.

However, some studies reported that local stiffness of the cervical spine, loosening of screws and damage to the vertebrae at the screw holes had appeared after the implantation of restricted ACP [2-3]. In order to reduce the complications caused by restricted ACP, semi-restricted ACP has been used, but due to the characteristics of semi-restricted, there are complications such as segmental cervical kyphosis or intervertebral foraminal stenosis caused by large ROM after implantation [8]. Therefore, there is no consensus on the ideal device to increase the stability of ACDF and reduce the risk of vertebral injury. It is very important to explore and optimize ACP.

Ning et al. [11] conducted a retrospective study of 2233 ACP implanted patients with an average follow-up of 1.3 years. There were 37 cases of screw loosening and vertebral screw hole damage at the fusion, which was caused by the abnormal load of the screw-vertebral interface, and the loosening of the screw is one of the most dangerous complications in ACDF surgery. Therefore, it is necessary to compare the peak stress at the screw hole of the vertebral body after TFS and QFS implantation. It can be seen from Figure 5 that during flexion and rotation, the stress on the QFS screw hole doubles that of TFS, and the stress on the QFS screw hole during lateral bending and extension is also higher than that of TFS. This indicate that the TFS system reduces fatigue at the screw hole interface and can reduce the risk of screw loosening and vertebral damage.

There are some limitations in this study. Firstly, this study established a FE model based on the cervical CT data of a healthy volunteer, the analysis data after implantation cannot be representative of other general population. But just like other similar FE analysis of biomechanical, FE method is more about providing a trend, not the actual data. Secondly, intact cervical spine model and two implanted models not consider the muscle structure during the modeling process, and could not more accurately simulate the motion state of the cervical spine, which may have some influences on the FE analysis results. Finally, the factors such as the angle and depth of screw implantation may have some effect of the performance of TFS and QFS implanted. The impact on the biomechanics of implantation should be studied further during these factors were coupled together.

5. Conclusion
In summary, compared with QFS, TFS stress on the screw hole of the vertebra is less, which reduced the risk of screw loosening and vertebra injury at the screw hole. Therefore, compared with the traditional quadrilateral internal fixation system, the triangular anterior internal fixation system designed in this study has certain advantages in biomechanics, but the actual implantation effect still needs further clinical verification.

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