Biomechanical Analysis of a Novel 3D Printing Cervical Spine Prosthesis : A Finite Element Study

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Abstract

Background: Our group have developed a new 3D printing cervical composite joint system prosthesis. The corresponding biomechanical effect should be evaluated in the treatment of cervical spondylosis. The purpose of this study was to evaluate the biomechanical properties of the prosthesis using a three-dimensional finite element model.

Methods: CT data were extracted by mimics16.0 software to reconstruct the C3-C7 model of cervical spine. The model was divided into three groups: normal cervical spine group, prosthesis implantation group and ACCF group. The three groups of models in six different motion states (flexion, extension, left and right lateral bending, left and right rotation) were simulated by three-dimensional finite element simulation. The RoM of lower cervical vertebra, RoM between each vertebrae, and the stress of intervertebral disc were compared and analyzed.

Results: Compared with the normal cervical spine, the RoM of C3-7 in the prosthesis implantation group showed a downward trend in six different motion states, with a decrease range of 5.27%. RoM of each segment in the prosthesis implantation group was decreased, and the decrease range was less than 7.34%. In the six motion states, the stress of each intervertebral disc in the prosthesis implantation group and ACCF group was increased. Compared with the prosthesis implantation group, the stress increased significantly at the C3-C4 level in ACCF group.

Conclusion: The novel 3D printing cervical composite joint system prosthesis can not only retain the range of motion of the cervical spine, but also decrease the stress of the upper adjacent intervertebral disc.

Background

Anterior cervical subtotal corpectomy and fusion (ACCF) is a common anterior cervical surgery, which is widely used in the surgical treatment of cervical spondylotic myelopathy, fracture and tumor [1-3]. Compared with anterior cervical discectomy and fusion (ACDF), ACCF has the advantages of larger operation space, sufficient decompression and satisfactory recovery of spinal cord function [4]. However, autogenous iliac bone or titanium mesh bone graft combined with anterior plate internal fixation is needed to maintain the stability of cervical spine and long-term surgical effect [5].

With the gradual promotion and development of the concept of spinal physiological reconstruction, non-fusion surgery has been paid more and more attention by spine surgeons. At present, the most common non-fusion surgery is artificial cervical disc replacement, which can not only restore the stability of the cervical spine, but also retain the motion of the cervical spine [6-8]. Some ACDF have been replaced by it. ACCF may limit the activity of the surgical segment and accelerate the degeneration of adjacent intervertebral disc, which is contrary to the concept of physiological spinal reconstruction. However, there is no non-fusion fixation after anterior cervical subtotal resection.

To solve this problem, a new type of 3D printing cervical composite joint system prosthesis was developed and designed by our group. Although the design of this prosthesis is in line with the concept of physiological reconstruction of the spine, it still needs to verify its corresponding biomechanical effect in the treatment of cervical spondylosis. As a theoretical biomechanical research, finite element (FE) analysis is a reliable and complementary analysis technology with biomechanical test [9]. At present, it has been more and more used in the biomechanical analysis of human motion system [10-12]. The irregular geometry of cervical vertebrae, the complex nature of intervertebral disc and the small joints between adjacent vertebrae make the modeling of cervical spine very complicated [13-14]. Therefore, a lot of work is needed to complete the accurate modeling to provide the real performance of cervical spine behavior. Now the FE mesh can accurately mesh complex structures, such as the spine [15-16].

Therefore, we carried out a systematic biomechanical study on the normal lower cervical spine, new prosthesis implantation and ACCF surgery by FE method, and made a systematic comparative analysis of the overall and each

segment range of motion of the cervical spine. Through the detailed three-dimensional FE simulation of its biomechanical characteristics, it provides a certain theoretical basis and mechanical guidance for the further experimental research and clinical application of 3D printing cervical composite joint system prosthesis.

Results

Validation of normal lower cervical spine model

The C3-C7 three-dimensional FE model of normal cervical spine was successfully established (Fig. 3). The mesh generation of C3-C7 model of lower cervical spine was 46086 nodes and 202973 tetrahedral elements. The solid element mesh was used for each vertebral body, intervertebral joint and intervertebral disc of the lower cervical spine. 1D two node nonlinear element was used for each ligament, which was defined as spring element attribute. Each structure keeps the grid nodes coordinate and contact with each other completely.

The network nodes of each structure coordinate and contact with each other and the appearance is lifelike. The structure is complete and the accuracy is high. The ROM of each segment of normal lower cervical spine FE model were calculated in this study compared with those of Zhang et al and Panjabi [20, 24]. Compared with the published biomechanical experimental data in vitro and the finite data, it was found that the relative range of motion and the change trend of the lower cervical vertebrae in this study were basically consistent with those reported in the literature (Fig. 3). It is believed that the cervical spine model is correct and effective, which can be further used in subsequent experimental studies.

Comparative analysis of ROM data of C3-C7

The ROM data of C3-C7 in each group in the 6 loading directions were obtained by FE simulation calculation. The results were summarized into Table 2, with normal lower cervical spine data as control. Compared with the control group, the ROM loss of ACCF group was as high as 30%, especially in flexion-extension and rotation. However, there was little effect on the ROM change in the prosthesis group, with a decrease range of 5.27%, which was close to the overall ROM value of normal cervical spine.

Comparative analysis of ROM in operative segments

The percentage of ROM relative to normal condition was fed back by histogram of each group, as shown in Fig. 4. Compared with the control group, ROM of C4-C5 and C5-C6 in the prosthesis implantation group decreased in the 6 loading directions. The flexion-extension decreased by 4.95%, lateral bending decreased by 1.64%, rotation decreased by 2.02% at the C4-C5 level. The flexion-extension decreased by 3.33%, lateral bending decreased by 2.32%, and rotation decreased by 2.14% at the C5-C6 level. The ROM loss was obvious in the ACCF group compared with the control group. The flexion-extension decreased by 94.40%, lateral bending by 91.79% and rotation by 91.70% at C4-C5 level. While at the C5-C6 level, the flexion-extension decreased by 94.74%, lateral bending by 89.78% and rotation by 91.34% (Table 2 and Fig 4).

Comparative analysis of ROM in adjacent segments

Compared with the control group, the ROM of C3-C4 and C6-C7 levels in the prosthesis implantation group decreased. The flexion-extension decreased by 2.13%, lateral bending decreased by 1.36%, rotation decreased by 3.29% at the C3-

C4 level. At the C6-C7 level, the flexion-extension decreased by 1.14%, lateral bending decreased by 2.32%, and rotation decreased by 3.43%. The ROM of C3-C4 and C6-C7 in ACCF group were increased significantly compared with the control group. The flexion-extension increased by 36.33%, lateral bending increased by 50.54%, rotation increased by 34.88% at the C3-C4 level. The flexion-extension increased by 26.90%, lateral bending increased by 42.56%, and rotation increased by 33.73% at the C6-C7 level (Table 2 and Fig 4).

Comparative analysis of the stress of intervertebral disc in surgical segment

Compared with the control group, the stress changes of C4-C5 and C5-C6 levels in prosthesis implantation group were as follows. The stress of C4-C5 increased in different degrees in the 6 loading directions, the stress increased 147.01% during flexion-extension, increased 338.15% during lateral bending, increased 160.08% during rotation. While the change of C5-C6 intervertebral stress was less obvious. The stress increased 44.96% during flexion-extension, increased 41.64% during lateral bending, increased 4.81% during rotation (Table 3 and Fig. 5).

In the ACCF group, the stress of C4-C5 increased with different degrees in the 6 loading directions, the stress increased 75.53% during flexion-extension, increased 25.19% during lateral bending, increased 37.45% during rotation. While the change of C5-C6 intervertebral stress was less obvious. The stress increased 6.16% during flexion-extension, increased 35.59% during lateral bending, increased 4.05% during rotation (Table 3 and Fig. 5).

Comparative analysis of the stress of intervertebral disc in adjacent segment

Compared with the control group, the stress increased 57.37% during flexion-extension, increased 156.36% during lateral bending, increased 9.39% during rotation at the C3-C4 level in prosthesis implantation group. The stress increased 63.11% during flexion-extension, increased 38.69% during lateral bending, increased 65.60% during rotation at the C6-C7 level in prosthesis implantation group. Compared with the prosthesis implantation group, the stress increased significantly at at the C3-C4 level in ACCF group. The stress increased 89.30% during flexion-extension, increased 243.90% during lateral bending, increased 39.60% during rotation at the C3-C4 level. The stress increased 26.51% during flexion-extension, increased 26.13% during lateral bending, increased 70.64% during rotation at the C6-C7 level (Table 3 and Fig. 5).

Results of prosthesis fatigue analysis

The fatigue analysis results of prosthesis are shown in Fig. 2B-D. The fatigue analysis of the prosthesis internal fixation device was carried out by FE method in the 6 loading directions: flexion and extension, left-right lateral bending and left-right rotation. The maximum stress was 188 MPa, which was obviously less than 817 MPa of titanium alloy (Ti-6Al-7Nb). Three kinds of fatigue analysis results showed that the life span of prosthesis was at least 106.28 cycles, and the maximum was 10^7 cycles, which could be regarded as infinite life.

Discussion

The concept of physiological reconstruction of spine promotes the emergence of non-fusion surgery, such as artificial cervical disc replacement. Some ACDF operations have been replaced by non-fusion surgery. However, the non-fusion

technology for ACCF operation is still a blank. Therefore, our research group has developed a new 3D printing cervical composite joint system prosthesis. In order to verify the biomechanical effect of our newly developed prosthesis in the treatment of cervical spondylosis, we conducted a detailed biomechanical study on the prosthesis by using FE analysis method.

Experimental biomechanics and theoretical biomechanics are two of the most common spinal biomechanics research methods. Compared with experimental biomechanics, theoretical biomechanics has its unique advantages: it can not only avoid high experimental costs and limited material sources, but also realize the prediction of the internal stress-strain field of the spine [25-26]. As a theoretical biomechanical research method, FE analysis has been used for many years in the research of spinal mechanics [27-28]. As an efficient and commonly used algorithm, the basic principle of the FE analysis method is discretized into a finite aggregate, and the whole motion is decomposed into the motion of FE [29-30]. The FE biomechanical research of cervical spine has been paid more and more attention by spine surgeons. The use of computer technology to explore cervical spondylosis has gradually become one of the focuses of researchers.

After the establishment of the FE model, in order to determine whether the model is reliable and whether it can truly reflect the normal cervical function, it is a very necessary process to verify its validity. At present, the more common method to verify the validity of the model is to use authoritative in vitro biomechanical experimental data to simulate the biomechanical characteristics of the reconstructed model. Then compare whether the difference is within the allowable range. After the validation of the newly established FE model, the continuous improvement of the model and finally reaching the experimental application standard is an essential key link of FE analysis [31-33].

In this study, we verified the ROM of each segment, the maximum value of disc stress and the stress of each segment in the normal lower cervical FE model under six motion states (flexion, extension, left and right lateral bending, left and right rotation). The experimental data of in vitro biomechanics were obtained from the published results of Panjabi and Zhang et al [17-18]. The results of the first mock exam showed that our experimental results of three-dimensional FE models are in line with the results of previous studies. This indicates that the research has successfully established a correct and effective lower cervical spine model, which provides a reliable model foundation for the next biomechanical research.

We simulated subtotal resection of C5 vertebral body and performed prosthesis replacement or ACCF respectively. Through the comparative analysis of the experimental data, we found that although the overall ROM decreased in the six motion states. The impact on the overall ROM value was not obvious compared with the normal cervical spine. We found that the new prosthesis can maintain a certain degree of motion, which is closer to the biological characteristics of the real intervertebral disc movement from the physiological and mechanical aspects. However, compared with the normal cervical spine, the ROM values of ACCF decreased significantly in flexion-extension, lateral bending and rotation. Titanium plate and screws are strongly fixed on the vertebral body, which results in greater overall stiffness of cervical spine and loss of local motion after operation. Compared with the normal cervical spine, the loss of ROM after ACCF was significantly than that after prosthesis implantation, especially in flexion, extension and rotation. Therefore, the prosthesis implantation can maintain the ROM of the whole and each segment more effectively than the ACCF operation, and better retain the postoperative range of motion of the cervical spine.

We also compared the stress of adjacent segments of intervertebral disc in the operation level. The results showed that the implant group and ACCF group showed different degrees of increase in six motion states. The average increase of prosthesis group was about 75% at C3/4 disc, which was significantly lower than that in ACCF group (average increase was 130%); the average increase was about 60% at C6/7 disc, slightly higher than that in ACCF group (average increase

was about 40%). The results showed that there is no significant difference between the stress of lower adjacent intervertebral disc caused by prosthesis implantation and ACCF surgery.

In addition, the fatigue analysis of the new 3D printing cervical composite joint system prosthesis was carried out by FE method under three kinds of repeated motion states: flexion and extension, left-right lateral bending and left-right rotation. The maximum stress was 188 MPa, and the yield strength of the model was less than 817 MPa of titanium alloy (Ti-6Al-7Nb). According to the three kinds of fatigue analysis results, the life of prosthesis structure is at least 106.28 cycles. The maximum is 107 cycles, which can be considered as infinite life (the life in blue position is the worst, which is in line with the actual situation). Therefore, from the perspective of FE theory, the prosthesis used in this study can be regarded as having very reliable performance in terms of durability and wear resistance.

There are some limitations in this study. This study is based on the FE method, which belongs to pure theoretical research. The boundary conditions constraints, material properties and other assumptions are different with the actual force and experiment of cervical spine. Therefore, the results of theoretical research should be more from the perspective of trend and qualitative. If more accurate quantitative research or improvement of the existing prosthesis device is needed, some experimental and clinical verification should be carried out combination with theoretical research.

Conclusion

In a word, this experiment carries out quantitative and qualitative biomechanical research on the prosthesis through FE method. The overall range of motion of cervical spine, the relative mobility of each vertebral, the stress of intervertebral disc, and the fatigue strength of prosthesis were systematically analyzed. Based on the mechanical principle and structural engineering idea, the biomechanical characteristics of each structure of lower cervical internal fixation were simulated in detail. The results show that the new 3D printing cervical composite joint system prosthesis can not only retain the range of motion of the cervical spine, but also decrease the stress of the upper adjacent intervertebral disc.

Methods

FE model establishment and validation

The computed tomography (CT) data of the lower cervical spine (C3-C7) were obtained from a healthy man (age 23 years, weight 70 kg and height 172 cm) without a history of cervical disc disease at 1mm intervals. The intact cervical model consists of five vertebrae, four intervertebral discs, and associated ligaments. This study was approved by the Ethics Committee of Xijing Hospital of the Air Force Medical University (KY20202040-F-1). Written informed consent was obtained from the volunteer.

The data were extracted by mimics16.0 software, the C3-C7 model was reconstructed and STL format file was exported. Repairing, noise reduction and surface curving were completed in Geomagic studio 2014 software, and then assemble the model in Pro/E5.0 software. The geometric model of the lower cervical spine was exported to IGES format file, meshed in HyperMesh 13.0 software, and BDF file was exported. The FE mesh secondary processing and various calculation conditions were analyzed in MSC. Patran/Nastran 2012 software.

The cervical spine FE model included the C3-C6 level cervical vertebral bodies, posterior bony elements, annulus fibrosus and nucleus pulposus, inferior and superior vertebral end plates, and ligaments. The vertebral body was divided into cortical bone and cancellous bone and the thickness of the vertebral cortical bone was set at around 0.5 mm. The inferior side and the superior side of the vertebral bone were covered by vertebral endplates with a thickness

of 0.6 mm [17-18]. The annulus fibrosus occupied 60% of the total volume of the intervertebral disc and the nucleus pulposus occupied 40% of the volume [19-20]. The material properties of cervical spine structures were set (Table 1).

Finally, the range of motion (ROM) of C3-C7 FE model (50 N head weight and 1 N.m pure torque) was calculated under six directions (flexion, extension, left and right lateral bending and left and right rotation). The ROM of each segment of the lower cervical spine was verified, and the disc stress of each segment were calculated. The biomechanical experimental results provided by previous literatures were compared to verify the validity of the model.

Development of CAD model of the implanted devices

The new prosthesis and traditional titanium mesh plus plate (Medtronic Sofamor Danek USA Inc, MN, USA) have been used in the models respectively. The prosthesis includes two joint parts at both ends and vertebral part in the middle. The vertebral part is made of titanium alloy, and the joint part is composed of titanium alloy and ultra-high molecular polyethylene (UHMWPE) lining. The prosthesis is designed to allow a minimum of 7 degrees lateral bending (from neutral) and a minimum of 7 degrees flexion/extension (from neutral). The design is also intended to allow unlimited axial rotation (constrained by ligaments and posterior elements). Based on the design, three-dimensional CAD models for the new prosthesis and traditional titanium mesh plus plate were developed. The material properties of different materials, including titanium alloy, polyetheretherketone (PEEK), and bone graft in the prostheses were also listed in Table 1 [21-23].

Establishment of 3D FE model after C5 segment prosthesis implantation and ACCF surgery

On the basis of the three-dimensional FE model of normal lower cervical spine, we carried out the FE simulation analysis of two kinds of surgery (prosthesis implantation and ACCF). There are three groups: normal lower cervical spine group (control group), prosthesis implantation group, ACCF group. In the operation group, anterior longitudinal ligament, posterior longitudinal ligament, part of intervertebral disc and vertebral body were removed. In order to meet the needs of FE calculation, the prosthesis and ACCF surgical materials are simplified, as shown in Fig. 1A-D. The geometric model of the operation is shown in Fig. 1E-F. Then, the FE mesh models of the prosthesis structure and ACCF surgical material structure are obtained by FE mesh generation, as shown in Fig. 1G-J. The FE mesh models of prosthesis implantation and ACCF surgery are shown in Fig. 1K-L.

Calculate the ROM values of the three FE model groups

In the FE analysis software, the C7 vertebral body of the three FE model groups were completely constrained to fix them. A torque of 1NM was applied to the upper surface of C3 of each model, and an additional vertical force of 50N was applied to simulate the head weight. After loading, the model can complete six motion states: flexion, extension, left and right lateral bending, and left and right rotation. After FE calculation, the ROM of C3-C7, surgical segment and adjacent segment were recorded and compared.

Fatigue analysis of the prosthesis

The fatigue strength of the prosthesis was simulated by FE method under theoretical conditions. Without considering the energy damage of the vertebral body, the amplitude cyclic loading of 1, - 1 positive and negative cycles was

adopted, and the maximum load was applied to the prosthesis. The conservative theoretical calculation was carried out. The repeated loading effect of prosthesis under pure bending moment 1N. M under three motion states (flexion-extension, lateral bending and rotation) was studied respectively. The fatigue strength limit of the structure is obtained. Fatigue analysis is carried out by Dassault FE-SAFE analysis software. The loading and boundary conditions, and the maximum value of static analysis stress before loading are shown in Fig 2A.

Abbreviations

ACCF: Anterior cervical subtotal corpectomy and fusion

ACDF: Anterior cervical discectomy and fusion

FE: Finite element

CT: Computed tomography

ROM: Range of motion

UHMWPE: Ultra-high molecular polyethylene

PEEK: Polyetheretherketone

Declarations

Ethics approval and consent to participate

This study was approved by the Ethics Committee of Xijing Hospital of the Air Force Medical University (KY20202040-F-1). Written informed consent was obtained from the volunteer.

Consent for publication

Not applicable

Availability of data and materials

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Competing interests

The authors declare that they have no conflict of interest.

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Authors' contributions

XZ and XLW contributed equally to this work. WL and ZXW were responsible for the conceptual design. XZ, XLW, BM and TQL were responsible for data analysis. XZ, XLW, YFF and YZ were responsible for preparing the original draft. All authors critically reviewed and revised the manuscript.

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Tables

Table 1

Structure and tissue properties of lower cervical spine

Material	modulus of elasticity (MPa) [MPa]	Poisson's ratio
Vertebral cortical bone	12000	0.29
Vertebral cancellous bone	450	0.29
The vertebral endplate	500	0.40
The posterior structure of vertebral body	3500	0.29
The annulus fibrosus	3.4	0.40
The nucleus pulposus of intervertebral disc	1.0	0.49
Anterior longitudinal ligament	30	0.30
Posterior longitudinal ligament	20	0.30
Supraspinous / interspinous ligament	1.5	0.30
The intercapsular ligament	20	0.30
Ligamentum flavum	1.5	0.30
Intertransverse ligament	20	0.30
The intervertebral joint	2.0	0.30
Bone mass	450	0.29
Titanium alloy	110000	0.34

Table 2

The ROM data of C3-C7 in each group (°)

Level	Normal cervical spine.			Prosthesis implantation group			ACCF group		
	Flexion- Extension	Lateral Bending	Rotation	Flexion- Extension	Lateral Bending	Rotation	Flexion- Extension	Lateral Bending	Rotation
C2- C7	37.71	26.67	37.06	36.58	26.24	36.05	26.33	21.14	26.77
C3- C4	10.35	7.38	10.32	10.13	7.28	9.98	14.11	11.11	13.92
C4- C5	9.29	6.70	9.40	8.83	6.59	9.21	0.52	0.55	0.78
C5- C6	9.89	6.46	8.89	9.56	6.31	8.70	0.52	0.66	0.77
C6- C7	8.18	6.13	8.45	8.06	6.06	8.16	11.18	8.82	11.3

Table 3

The stress of intervertebral disc in each group(MPa)

Level	Normal cervical spine.			Prosthesis implantation group			ACCF group		
	Flexion- Extension	Lateral Bending	Rotation	Flexion- Extension	Lateral Bending	Rotation	Flexion- Extension	Lateral Bending	Rotation
C3- C4	5.7	3.85	5.43	8.97	9.87	5.94	10.79	13.24	7.58
C4- C5	5.15	4.01	4.86	13.61	17.57	12.64	9.04	5.02	6.68
C5- C6	5.36	2.81	3.95	7.77	1.64	4.15	5.03	1.81	3.79
C6- C7	3.47	1.99	2.18	5.66	2.76	3.61	4.39	2.51	3.72

Figures

Figure 1

FE model model after C5 segment prosthesis implantation and ACCF surgery.

Figure 2

Fatigue analysis of the prosthesis. Before loading (A). The loading effect of prosthesis under three motion states: flexion-extension (B), lateral bending (C) and rotation (D).

Figure 3

The C3-C7 three-dimensional FE model of normal cervical spine (A, B, C), and the relative range of motion and the change trend of the lower cervical vertebrae (D, E, F).

Figure 4

The percentage of ROM relative to normal condition of each group.

Figure 5

The percentage of stress relative to normal condition of each group.