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Morphological Design and Study of a 3D Printed Integrated Fusion Device Based on CT Measurement Data Assisted Anterior Lumbosacral Spine

Diseño Morfológico y Estudio de un Dispositivo de Fusión Integrado Impreso en 3D Basado en Datos de Medición de TC Asistida de Columna Lumbosacra Anterior

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SUMMARY: To measure and study the anatomical morphological data of the lumbar 5 to sacral 1 intervertebral space with the aid of CT and design an anatomical anterior lumbosacral 3D printed integrated interbody fusion for the treatment of degenerative lumbosacral spine diseases. 100 adults (50 of each sex) who underwent CT examination of the lumbar spine in our hospital were selected, and their lumbar 5 to sacral 1 intervertebral space anatomical data were measured, including the anterior lumbar convexity angle, different sagittal and coronal heights, and the sagittal and coronal diameters of the superior and inferior endplates. The measured data were also statistically analyzed, and morphological design and study of the 3D printed integrated fusion device in the anterior lumbosacral spine was performed by applying computer software. When comparing the coronal and sagittal diameters of the superior and inferior endplates from lumbar 5 to sacral 1, the differences were statistically greater in men than in women ($P<0.001$). The differences were not statistically significant when comparing the anterior convexity angle of the lumbosacral space ($P>0.001$). When comparing the height at different positions in the median sagittal plane, both males and females showed an anterior high and posterior low pattern. In the coronal plane, both males and females showed the highest height in the middle position ($P<0.001$), and there was no statistically significant difference between the left and the right height ($P>0.001$). CT can measure the anatomical data of the lumbosacral spinal hiatus more accurately. The 3D-printed anterior integrated fusion device of the lumbosacral spine designed according to the analysis of the data results is more in line with the anatomical structure of the lumbosacral spine, fits well with the superior and inferior endplates, and effectively restores the height and anterior convexity angle of the lumbosacral space.

KEY WORDS: Lumbosacral spine; Intervertebral fusion; 3D printing.

INTRODUCTION

Spinal interbody fusion systems are widely used in the field of spinal surgery (Wasinpongwanich *et al*., 2022) with satisfactory results in the treatment of lumbar degenerative diseases, while lumbosacral degeneration has a high incidence and its anatomical specificity as the articulation site between the lumbar and sacral spine is large (Chung *et al*., 2021). The traditional intervertebral fusion device is poorly matched to the superior and inferior endplates and cannot achieve a complete anatomical fit, resulting in slow bone growth into it, sinking of the endplates, and decreased fusion rate after surgery (Phan *et al*., 2016; Abe *et al*., 2017; Quillo-Olvera *et al*., 2018). For this reason, an intervertebral fusion device that conforms to the anatomy of the lumbosacral spine in China needs to be designed. To accelerate the rate of intervertebral fusion, the usual strategy is to optimize the interface morphology of the fusion device and to promote adhesion of surface material (Li *et al*., 2021). The ALIF procedure has better advantages for the operation of the lumbosacral spinal space, which can effectively expose the lumbosacral spinal space and solve the inconvenience caused by the obscuration of the lateral iliac spine of the lumbosacral spinal space (Silvestre *et al*., 2012). 3D printed fusion devices are increasingly valued for their high anatomical

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match, good stability, and fast fusion speed. In this study, we measured the anatomical data of the lumbosacral spinal space with the aid of CT and applied computer software to design an anterior 3D-printed integrated fusion device that conforms to the anatomy of the lumbosacral spine in China.

MATERIAL AND METHOD

General information. One hundred healthy adult volunteers who underwent lumbar spine CT examination with no abnormal findings were selected from the Affiliated Hospital of Beihua University. There were 50 cases of each sex, aged within 18-30 years old, with a mean age of 25.32±3.17 years for males and 25.94±2.95 years for females. The study was approved by the ethics committee of our hospital, and all study procedures were in compliance with medical ethics requirements, and all volunteers were contacted to obtain their consent and sign the informed consent form.

Research Methodology. The 128-level spiral CT scan data of the lumbar spine of 100 volunteers were copied to a DVD-R-4.7GB disk, and then imported into the medical image analysis software Mimics 21.0, where the interactive MPR function was used to perform planar localization and 3D reconstruction. The software's own ruler tool was applied to measure the L5 to S1 intervertebral space in the bone window and the 3D reconstruction. The default unit of length is "mm" and the unit of angle is "°". The measurements are accurate to 0.01 mm for length and 0.01° for angle.

Measurement metrics. Sagittal and coronal diameters of the superior and inferior endplates of the lumbosacral space: the sagittal and coronal diameters of the inferior endplate of the L5 vertebral body and the sagittal and coronal diameters of the superior endplate of the S1 vertebral body were taken respectively (Fig. 1).

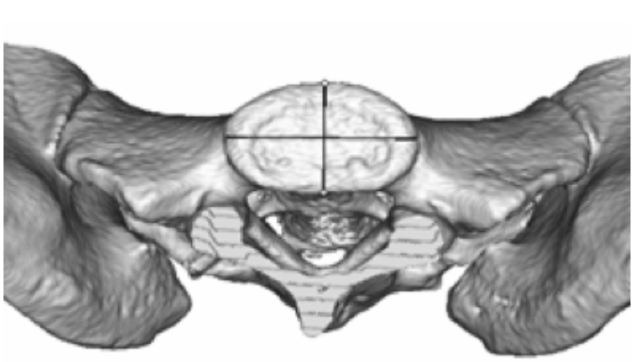

Fig. 1. Schematic diagram of the coronal and sagittal diameters of the lumbosacral intervertebral space.

S**agittal measurement index.** In the median sagittal plane, six positions were taken in equal parts, and the height of the gap at different positions was measured, in order of anterior height, 1/5 position height, 2/5 position height, 3/5 position height, 4/5 position height, and posterior height (Fig. 2, blue line).

Coronal measurement index. The height of the gap at the vertebral body margin was measured in the coronal plane at the 1/5 position and at the 4/5 position (shown by the red line in Fig. 2), respectively, as left height, middle height, and right height.

Anterior convex angle. The angle made by the sagittal diameter line of the superior and inferior end plates (Fig. 2).

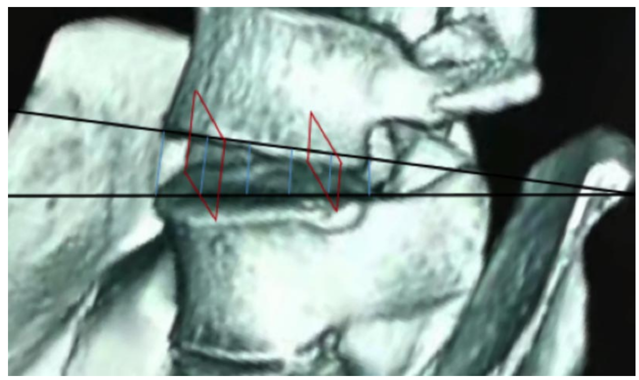

Fig. 2. Schematic diagram of the lumbosacral spinal space.

Statistical methods. SPSS 26.0 was used for statistical analysis of the measured data. The obtained data were expressed in the form of mean ± standard deviation (). One-way ANOVA was performed for the lumbosacral spinal space parameters. The sagittal and coronal diameter parameters of the inferior endplate of L5 and the superior endplate of S1 were tested by two independent samples t-test. $P<0.05$ was considered a statistically significant difference.

RESULTS

For the lumbosacral spinal space, coronal diameter of the superior and inferior endplates compared with the sagittal diameter, was greater in males than in females ($P<0.001$), as shown in Figure 3. There was no statistically significant difference in the anterior convexity angle of the lumbosacral spinal space between males and females, as shown in Figure 4. When comparing the height of the lumbosacral space at different positions in the median sagittal plane, the height decreased gradually in both males and females from anterior to posterior ($P<0.001$), with no statistically significant difference at 2/5 and 3/5, and the greatest decrease in height at 4/5 and posterior height, as shown in Figure 5. In both males and females, the intervertebral space height was greatest at the mid-height

(P<0.001) in both the 1st and 2nd coronal planes, and the difference between the left and right heights was not statistically significant, as shown in Figures 6 and 7.

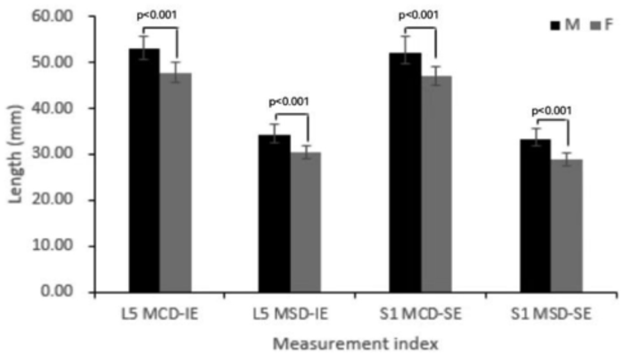

Fig. 3. Comparison of coronal and sagittal diameters of the superior and inferior endplates of the lumbosacral spinal space between genders. L5 MCD-IE: L5 Median Crown Diameter-Inferior Endplate, L5 MSD-IE: L5 Median Sagittal Diameter- Inferior Endplate, S1 MCD-SE: S1 Median Crown Diameter- Superior Endplate, S1 MSD-SE: S1 Median Sagittal Diameter- Superior Endplate. M: Male, F: Female.

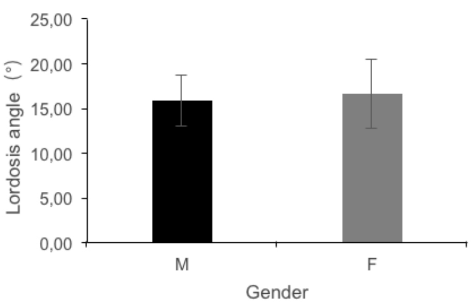

Fig. 4. Comparison of lumbosacral hiatus anterior convexity angles between sexes. M: Male, F: Female.

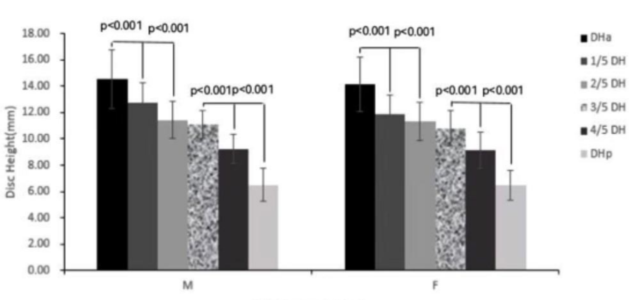

Fig. 5. Comparison of intervertebral space heights at different locations in the median sagittal plane of the lumbosacral spinal space. DHa: Anterior Disc Height, 1/5 DH: 1/5th Disc Height, 2/5 DH: 2/5th Disc Height, 3/5 DH: 3/5th Disc Height, 4/5 DH: 4/5th Disc Height and DHp: Posterior Disc Height. M: Male, F: Female.

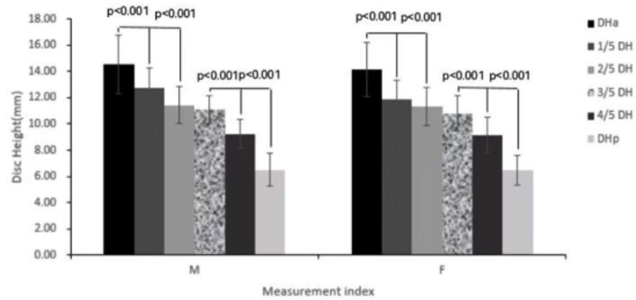

Fig. 6. Comparison of intervertebral space heights at different positions on the 1st coronal plane. LH: Left height, MH: Middle height, and RH: Right height. M: Male, F: Female.

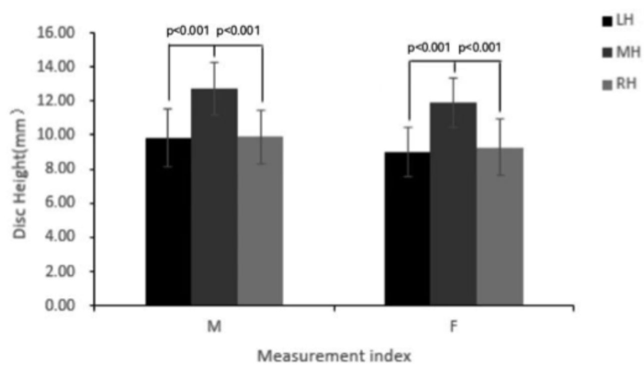

Fig. 7. Comparison of intervertebral space heights at different locations on the 2nd coronal plane. LH: Left height, MH: Middle height, and RH: Right height. M: Male, F: Female.

3D printed fusion device design and fabrication. Statistical analysis was performed based on the measured anatomical data, and CAD 3D modeling software was used to construct the plan view and 3D three-dimensional model, as shown in Figure 8. Figures 8A and 8B showed the coronal and sagittal views of the fusion device placed in the lumbosacral spinal space, respectively. Figure 8C showed the original data of the median sagittal design of the fusion device. Figures 8D, 8E and 8F showed the three-dimensional model of the fusion device. The fusion device as a whole appeared as a wedge-shaped structure with curved surfaces on the superior and inferior surfaces, and the morphology was symmetrical from left to right, with the height of the two sides lower than the middle height. At the posterior end of the fusion device, the curvature of the surface increased significantly, and the overall morphology conformed to the anatomical morphology of the lumbosacral spinal space.

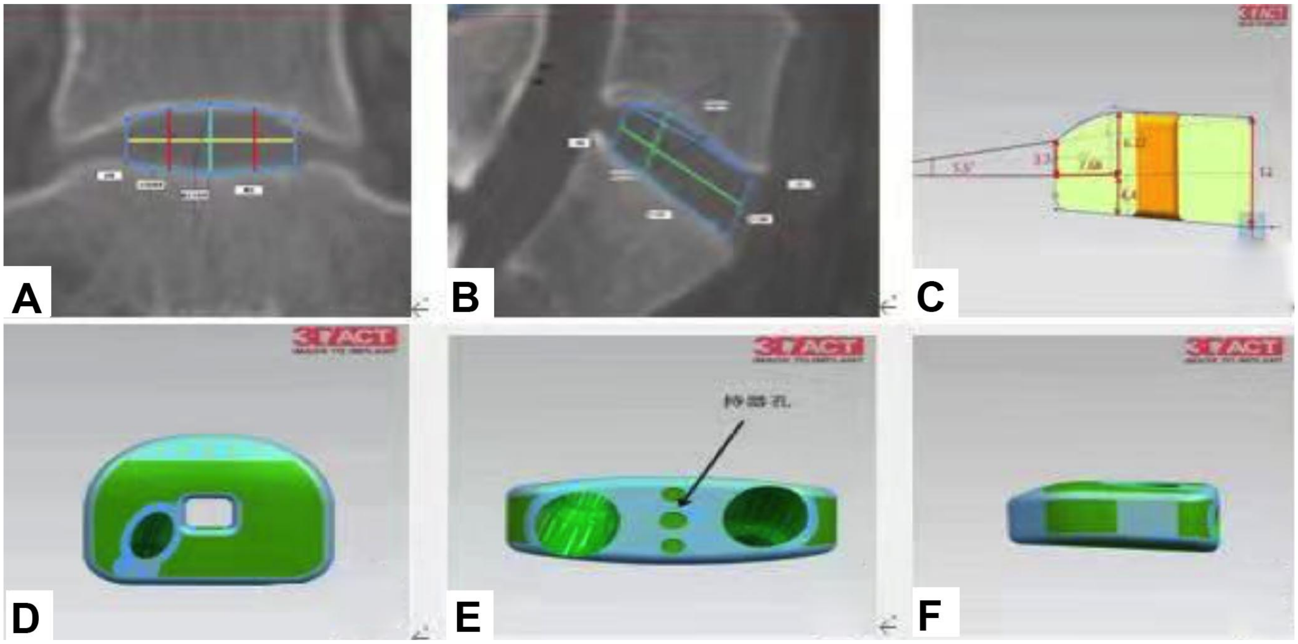

Fig. 8. CAD 3D modeling software to construct the simulation. A, B are the coronal and sagittal planes of the lumbosacral interspace fusion. C was the raw data of the sagittal design. D, E, F were the 3D reconstruction of the fusion, where D was the top view, E was the lateral view, and F was the anterior view.

DISCUSSION

A proper lumbar fusion not only needs to maintain the stability of the adjacent vertebrae and restore the height of the intervertebral space, but the fusion requires a good fit to the superior and inferior vertebrae. Compared with other segments, the structure of the lumbosacral intervertebral space is more complex and special, so a custom-designed intervertebral fusion device is necessary. Foreign scholars have conducted relevant studies in this regard, but there are fewer studies in this area in China. Therefore, in this paper, we measured the anatomical data of the L5-S1 interbody fusion region in Chinese adults and performed statistical analysis and research in order to provide appropriate assistance for further optimization of the design of 3D printed ALIF fusion devices.

Accurate anatomical data is the basis for optimizing the design of fusion devices. In this paper, anatomical data of the lumbosacral spinal space were measured and analyzed by CT in 100 healthy adults (50 of each sex). The results of the study showed that the heights of the symmetrical positions on both sides were not significantly different in either coronal plane for both men and women, but they were significantly different from the median height, and the median height was also the largest on the mean value. Therefore, the height of the median sagittal plane can represent the maximum height of the intervertebral space. In the median sagittal plane, the height change showed a trend of gradually decreasing from the anterior to the posterior side of the intervertebral space, and thus the overall lumbosacral intervertebral space showed an anterior high and posterior low pattern. The measurement data showed that the height variation was greatest from the 4/5 position to the posterior height, indicating that the superior and inferior endplates of the intervertebral space showed a concave ball-and-socket pattern. The sagittal diameter of the superior and inferior endplates of the lumbosacral intervertebral space compared with the coronal diameter was greater in both men than in women, which may be related to the overall stronger stature of men. There was no statistically significant difference between men and women in terms of the anterior convexity index.

In order to ensure the stability of the fusion device, the intervertebral fusion device should be placed in the flat of the concave surface of the superior endplate of S1, and the shape should be as large as possible to avoid the edge of the fusion device partially protruding from the edge of the vertebral body to compress the surrounding neurovascular and spinal cord tissues in the spinal canal. There existed a safe range of 29 mm ¥ 30 mm within the lumbar interspace in the national population, without vascular nerves and other important structures traveling, and this area was equivalent to between the anterior 1/5 and posterior 1/5 of the lumbar vertebral body. Thomas *et al* (Lowe *et al*., 2004) conducted an *in vitro* biomechanical experiment on the degree of pressure resistance of the thoracolumbar spine to investigate the load strength of the thoracolumbar endplate and the optimal location for intervertebral support. After testing, it was found that the stiffness of the central region of the endplate was significantly lower than the epiphyseal rings at the periphery of the endplate from L1 to S1, and that reduced subsidence was achieved when the left and right sides of the fusion were covered with strong epiphyseal rings and the stresses were balanced. Polikeit *et al*. (2003) produced L2-3 finite element models to test the strength of various regions of the endplate and came to the same conclusion that placement of the interbody fusion device in the peripheral strong region of the endplate (i.e., the epiphyseal ring) would produce a stronger bone-implant interface. The design of the fusion device should rely on the strong peripheral portion of the endplate to reduce the risk of subsidence. To restore the original height of the intervertebral space, the implanted interbody fusion should fill the intervertebral space, with the upper and lower surfaces of the fusion fitting the superior and inferior endplates of the vertebral body. According to the anatomical data, the intervertebral space as a whole was anteriorly high and posteriorly low, and there was a concave spherical fossa pattern, so the fusion device should be a wedge-shaped structure with convex curves to ensure a good fit with the contact surfaces of the superior and inferior endplates, which can ensure stability and reduce the occurrence of endplate collapse. As an articulating structure, the anterior convexity of the lumbosacral spinal space accounts for 40 % of the total lumbar anterior convexity angle and is an important indicator of surgical treatment (Chung *et al*., 2021). It is usually assumed that a more anterior fusion results in a greater anterior convexity angle (Shiga *et al*., 2017; Mun *et al*., 2020). However, anterior fusion placement without anterior fixation will tend to be placed in a posterior position (Norotte & Barrios, 2018; Szadkowski *et al*., 2020). In addition, the height of the fusion device and the angle of the convex surface also affect the change of the anterior convexity angle. Therefore, the position, height, and angle of the fusion device need to be considered and custom-designed to ensure the recovery effect. The size of the intervertebral disc varies by sex, and different sizes of fusion devices should be designed separately according to sex differences.

CAD 3D modeling software was used to construct the original data pattern and 3D model of the fusion device, and the solid intervertebral fusion device was then prepared by 3D printing technology. The advantage of 3D printed fusion devices is that they can not only be custom designed based on CT measurement data, but also mimic the microstructure of natural bone surface. The fusion device with a surface-controlled microstructure is prepared, thus reducing the possibility of loosening and displacement (Muthiah *et al*., 2022). However, the manufacturing process of custom fusion devices is much more complex due to the shape and function of the spine. As a result, the manufacturing process requires more time, effort and cost compared to conventional fusion devices, which of course also have a better load-bearing surface and a lower risk of displacement and intervertebral fusion subsidence. Therefore, it can be expected that the rate of revision surgery will be reduced after clinical application. The measurement of anatomical data of the lumbosacral spine and the morphological design of the fusion device in this study provide the theoretical premise for the development of an anterior 3D printed fusion device for the lumbosacral interspace, which is worthy of further study.

WANG, X.; LIU, Q.; QI, M. & XIONG, J. Diseño morfológico y estudio de un dispositivo de fusión integrado impreso en 3D basado en datos de medición de TC asistida de columna lumbosacra anterior. *Int. J. Morphol., 42(2)*:692-697, 2024.

RESUMEN: El objetivo de este trabajo fue medir y estudiar los datos morfológicos anatómicos del espacio intervertebral lumbar 5 a sacro 1 con la ayuda de TC y diseñar una fusión intersomática integrada anatómica lumbosacra anterior impresa en 3D para el tratamiento de enfermedades degenerativas de la columna lumbosacra. Se seleccionaron en nuestro hospital 100 adultos (50 de cada sexo) que se sometieron a un examen de TC de la columna lumbar y se midieron los datos anatómicos del espacio intervertebral lumbar 5 al sacro 1, incluyendo el ángulo de la convexidad lumbar anterior, diferentes alturas sagital y coronal, y los diámetros sagital y coronal de las placas terminales superior e inferior. Los datos medidos también se analizaron estadísticamente y se realizó el diseño morfológico y el estudio del dispositivo de fusión integrado impreso en 3D en la columna lumbosacra anterior mediante la aplicación de software informático. Al comparar los diámetros coronal y sagital de las placas terminales superior e inferior desde lumbar 5 hasta sacro 1, las diferencias fueron estadísticamente mayores en hombres que en mujeres ($P < 0,001$). Las diferencias no fueron estadísticamente significativas al comparar el ángulo de convexidad anterior del espacio lumbosacro ($P > 0,001$). Al comparar la altura en diferentes posiciones en el plano mediano, tanto hombres como mujeres mostraron un patrón anterior alto y posterior bajo. En el plano coronal, tanto hombres como mujeres mostraron la altura más alta en la posición media ($P < 0,001$), y no hubo diferencia estadísticamente significativa entre las alturas izquierda y derecha ($P > 0,001$). La TC puede medir los datos anatómicos del hiato espinal lumbosacro con mayor precisión. El dispositivo de fusión anterior integrado impreso en 3D de la columna lumbosacra diseñado de acuerdo con el análisis de los resultados de los datos está más en línea con la estructura anatómica de la columna lumbosacra, se adapta bien a las placas terminales superior e inferior y restaura eficazmente la altura y la parte anterior del ángulo de convexidad del espacio lumbosacro.

PALABRAS CLAVE: Columna lumbosacra; Fusión intervertebral; Impresión 3d.

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