Pre-operation on 3D-print Model Can Improve Curative Effect of Percutaneous Kyphoplasty (PKP)

yuxin shen (✉ 05lcyxsyx@163.com)

Orthopedics department Huzhou first people's hospital

Shitong xing

first people's hospital of huzhou

Research Article

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Abstract

Background: The 3D-print technology has been widely used in the medical field. The purpose of this study is to investigate the advantages of 3D-print model pre-operation for percutaneous kyphoplasty (PKP).

Methods: Before the operations of 25 Osteoporotic vertebral body compression fractures (OVCF) cases as the experimental group, and 35 cases of the same disease in the same period were retrospectively selected as the control group without pre-operation. The 3D-print model was made by CT image. The puncture point and insertion angle were determined by the pre-operation on that model. The data recorded included data about operation time/fluoroscopy times/Changing channel times and preoperative and postoperative VAS(Visual Analogue Score), JOA(Japanese Orthopedic Association) score, Cobb's angles.

Results: There are significant advantages in the 3D printing group compared with the control group in the time of operation, the number of tunnel changes and the number of perspectives ($p<0.05$). The postoperative Cobb's angle is significantly improved ($p<0.05$) in both the short and long term compared with the control group. The recent postoperative VAS score is significantly lower than that in the control group ($p<0.05$), and there is no significant difference in the long-term postoperative VAS score. There is no significant difference between the two groups of JOA functional score and improvement index.

Conclusions: preoperation with 3D-print model can significantly improve the accuracy, reduce the change times of tunnels, shorten the operation time and reduce the number of fluoroscopy. Postoperative pain can be better relieved.

Introduction

With the population aging in China, the incidence of Osteoporotic vertebral body compression fractures (OVCF) increases and becomes a common disease¹. Slight violence can cause pain on the back and the limitation of its mobility. The life quality of patients with mild conditions decreases, while severe patients will be unable to stand or walk and need special care. For now the treatments for that include conservative treatment and surgical ways. Percutaneous kyphoplasty (PKP), as a sort of minimally invasive surgical treatment, has been widely used because of its definite curative effect and convenience for application².

PKP surgery has been carried out for many years in our department. And we have accumulated a large number of cases and a lot of clinical experience. We've also found the following complications in practice: 1. Nerve injury caused by breaking pedicle wall and iatrogenic pedicle fracture. 2. Inflated balloon cannot recover the height of vertebral body. 3. Polymethylmethacrylate (PMMA) leakage. 4. Vascular injury caused by perforation of the anterior edge of the vertebral body³. All above complications had a common cause - —displacement of the working tunnel —including improper insertion point, tilt

angle or convergence angle deviation⁴, vertebral body's front wall breaking caused by misjudgment of the length due to C-arm fluoroscopy's projection⁵.

It reminds us that sole dependences on the operator's sense and C-arm X-ray images has the risk of failure. In order to reduce the risk of working tunnel displacement, we intend to use the 3D printing technique (AM, Additive Manufacturing) to build a patient's 3D vertebral model before the operation. And we can get information of the tunnel's needle point and determine the needle angle by means of the model, so as to avoid complications and reduce the operation time and improve therapeutic effects.

General information:

Inclusion criteria: From January 2015 to January 2016, admitted to hospital, due to osteoporotic vertebral compression fractures (OVCF) identified through MRI as fresh fracture, a total of 60 cases. Informed consent was obtained from all subjects. This project was approved by Ethics committee of huzhou first people's hospital. Reference number is 2017012. Consent to participate was obtained from the participants. He or she add signature to hospital's consent when just check in.

Grouping: A total of 25 cases were preoperative 3D printing models, as the experimental group. And 35 cases of the same disease in the same period were retrospectively selected as the control group without pre-operation.

3D Printing method: the raw material is high-precision CT scanned images, and they are saved in the DICOM format. The data are imported into Mimics17.0 software. The vertebral body is extracted according to the density threshold value. 3-D modeling is made for the pathologic vertebrae, and the result is exported in the STL format, and then given to a network provider to print out the finished product.

(Imagine 1:how we get a 3D print model before surgery

Imagine 2: Pre-operation on the 3D print model before surgery

Imagine 3: Observe the working tunnel on model by perspective)

Operation Method

The patient takes the prone position, with the abdomen suspended on a cushion.. First the vertebral body is located with the C-arm X-ray fluoroscopy, and a mark is made. Disinfection is made, and the cloth towel is paved. The puncture point is selected. A small incision of 1.5cm-2.0cm in the corresponding vertebral spinous process. The work tunnel is put inside and located on the outer edge of the pedicle projection "eye", commonly known as 1 o'clock azimuth or 11 o'clock orientation. The convergence angle is about 10-20 degrees. The head and tail angles are adjusted from side-position perspective. The working tunnel is tapped with a hammer, and the channel placement is observed in an estimated way through the vertebral arch after it reaches the posterior margin of the vertebral body. If the position is not good, the tunnel should be removed and reset. The ideal working tunnel placement state: penetrating from the

pedicle into the vertebral body, the tunnel's converging angle is proper (reaching the vertebral body's central loading area), reaching the place of 3/1 of the vertebral body back. After that, the needle is pulled out, and a hole is drilled with a fist. The balloon is put into the vertebral body. The operator injects the contrast agent, 3ml each side. The pressure does not surpass 300kpa. Under the C-arm perspective it is observed that if the vertebral body height recovers or not. The contrast agent is extracted and the balloon is pulled out. The PMMA is dissolved into the wire drawing period, and then slowly and uniformly injected into the vertebral body through the injection tunnel to observe the spread of PMMA. In the process, leakage is beware of. In the meantime, anesthesia is used to observe the blood pressure changes. PMMA allergic shock is beware of. In general, the amount of PMMA injected into each vertebral body is about 6-8ml, and after the hardening of the PMMA, the working channel is slowly removed and the skin is stitched directly.

All methods were performed in accordance with the relevant guidelines and regulations.

Evaluation indicators

Including: Operation time lasted, number of intraoperative changes of working channels, the average number of fluoroscopy, intraoperative complications (including perforation of the pedicle, perforation of the vertebral anterior edge, perforation of the end plate, PMMA leakage). Postoperative complications (pain, dysfunction, disability, etc.) are evaluated according to the course record and X-rays for postoperative review.

1. The operation time: according to the Operation Anesthesia Record list assessment. The operation begins when the anesthesia is completed and the posture placement is made (because the vertebroplasty localization is the important procedure which cannot be ignored), and ends at the suture time (unit:min).
2. Number of intraoperative changes of channels: the guide needle's adjustment before it penetrates into the cortex is not counted. After the guide needle pierces the cortex into the pedicle, if the inserting position of the needle is found to be not ideal, it need to be pulled out and reset. It is defined as 1 time channel change.
3. The average number of perspective: C-arm machine is used during operation for perspective, the number of images is counted after the operation .
4. Intraoperative complications: defined as complications that can be found in the surgical process, such as positioning error, perforation of the pedicle, piercing the edge of the vertebral body and through the end plate, PMMA leakage, and allergic reaction. Postoperative complications: defined as observed complications after surgery, such as persistent pain, neurological symptom, long-term vertebral body collapse, end plate fracture.
5. Imaging examination: preoperative and post-operation measurement of the Cobbs angle of the symptomatic vertebra, to observe the correction degree of kyphosis deformity.

6. Pain scoring: using the visual pain scale, evaluate once on the second day before and after the operation and, 3-6 months after the operation, make assessment of pain release.
7. Function scoring: using JOA score, evaluate once on the second day before and after the operation and, 3-6 months after the operation, make assessment of function improvement.

Statistics methods: using software SPSS16.0, quantitative data is tested using t-test, qualitative data is tested using the Chi-square test.

Results

Compared with the control group, the 3D Print group had no significant difference in gender, age, preoperative Cobb's angle, preoperative VAS score and preoperative JOA score.

(table1:preoperative base line data:"gender, age, preoperative Cobb's angle, preoperative VAS score and preoperative JOA score")

There are significant advantages in the 3D printing group compared with the control group in the time of operation, the number of tunnel changes and the number of perspectives ($p<0.05$). The postoperative Cobbs angle is significantly improved ($p<0.05$) in both the short and long term compared with the control group. The recent postoperative VAS score is significantly lower than that in the control group ($p<0.05$), and there is no significant difference in the long-term postoperative VAS score. There is no significant difference between the two groups of JOA functional score and improvement index.

The Cobbs angles of the 3D print group and the control group are both significantly smaller after the operation ($p<0.01$), and there is a significant loss of the Cobb angle after the postoperative period ($p<0.01$). Compared with the postoperative scores, preoperative VAS scores are significantly lower in both groups ($p<0.01$), and there are no statistically significant differences in the postoperative long-term VAS and short-term scores in the control group, but the 3D print group has significantly better long-term VAS scores than the immediate postoperative ($p<0.01$). The JOA scores of both groups are significantly increased ($p<0.01$), and the JOA score is significantly improved after operation ($p<0.01$) in the short term. According to the improved index, the effective rate of 3D print Group is 92%, the control group has an efficiency of 82.9%, and in the long term both groups obtain 100% efficiency.

(table2 : postoperative data)

Discuss

1. PKP Surgery for OVCF is definitely effective, especially for the control of fracture pain⁶⁷. The majority of preoperative patients with moderate or severer pain (VAS score greater than 7), in the immediate postoperative can be significantly relieved, the majority of patients with pain have the score reduced to 4 and even below, and their functions have been recovered. It is found that the operator with the 3D print model practice was highly skilled in operation, with shorter surgery time, less changing times

of tunnels, and fewer perspectives. It is believed that this should be due to the 3D print model exercise, which allows the surgeon to better understand the morphological and anatomical characteristics of the vertebral body, including the fracture compression, the diameter and aggregation of the pedicle, the shape of the articular process, the location of the transverse process, and so on. This information is critical to PKP surgery, and it is important that whether the work tunnels can be built quickly and efficiently or not⁸. It has been proved that the 3D model of the vertebral body can show the anatomical features and allow the operator to be familiar with the relevant steps in the model, and plan a best pathway and make markers.

2. The measurement of Cobbs angle shows that the vertebral body in the 3D printing group is more fully stretched, which is related to a better channel cohesion angle. The best access information could be obtained before operation. Therefore, the tunnel's quality is higher, and the terminate is closer to the weight-bearing area, and more overlapped with the OVCF area⁹. The balloon's expanding can lead to a better effect in the vertebra compression area, obtain better height recovery¹⁰. The control group does not have a preview of the 3D printing model, in order to avoid breaking the internal wall of the pedicle, resulting in a small cohesion angle, the balloon position being far away from the center of the compression area. That makes the vertebral height not sufficiently recovered under the same pressure and perfusion volume¹¹.
3. The VAS score of 3D-print group has a more significant drop than the control group in one week after surgery, and there are two possible main reasons for this. The first one is that the vertebral body is expended more fully¹². The second is that there are less changes in the working tunnel, which reduces the injury to the Paravertebral muscle and vertebra damage, so the immediate postoperative pain is significantly less relieved than the 3D-print group. It is found that both the 3D-print group and the control group receive satisfactory promotion of JOA score, and there is no significant difference between the two groups. After 3-6 months, the situation for both pain and function is better than the recent postoperative situation, which can be attributed to the healing of fractures over time¹³. A lot of related literature works have reported similar results that compared with the long-term effect of conservative treatment and PVP/PKP surgery¹⁴; there is no significant difference between the two therapies.
4. The 3D printing model in this project is only used for preoperative practice, and does not need to be used in sterile environment, so the PVC plastic thermal printing is selected, which has the advantages of low price, fast forming speed, smooth surface and proper hardness, while the disadvantages include low strength, no toughness, easy to break, no high temperature resistance. In practical use, we use CT reconstruction images to produce the 3D model, and then sent it through the network to suppliers. Within 48-72 hours we could receive a finished product, and for some complex difficult cases, we can use 2-3 and even more copies for repeated drills. The difference in sense between the 3D-print model and the realistic vertebra is as follows: First, the operation feeling is different. The PKP working tunnel puncture is with more feelings. Piercing the cortex and into the cancellus is with

totally different feelings. Meanwhile, the serious osteoporosis and a mild case are also very different. Due to modeling accuracy and material, 3D-print model cannot simulate different bone mineral density, even the cortex and cancellous cannot be simulated well. Freehand insertion requires greater force, and the direction is more difficult to control, and sometimes the electric-drill needs to be used to determine the direction. Second, the exposure and the location of anatomical signs are different. The determination of the needle point and the direction in the real PKP operation depend on the perspective of the C-arm machine. Before operating on the model, we can look at the point and angle of the needle, and eliminate the interference of soft tissue, which is very helpful to the improvement of operation precision. For example, if there is too much cohesion in the needle insertion, there is a risk of perforation of the pedicle inner wall. Under C-arm perspective, only a rough judgment can be made relying on the depth of needles and spikes' distance. but it is clear to see on the model if the wall is pierced, and the distance from the inner wall. This advantage are particularly practical for some cases of small pedicle deformity. In general, the 3D printing model is unable to simulate the cancellous and cortical bone tissues. Therefore, the handle feeling is quite different from that in the actual operation. However,, because of its 1:1 duplicate bone structure, it has a great advantage in the operation of simulated surgery, especially for complex cases.

Conclusions

According to this research, pre-operation with 3D-print model can significantly improve the accuracy, reduce the change times of tunnels, shorten the operation time and reduce the number of fluoroscopy. Postoperative pain can be better relieved.

Abbreviations

Percutaneous kyphoplasty (PKP)

Osteoporotic vertebral body compression fractures (OVCF)

Visual Analogue Score (VAS)

Japanese Orthopedic Association (JOA)

Additive Manufacturing (AM) =3D print

Declarations

Ethics approval and consent to participate:

Ethics committee of huzhou first people's hospital. Reference number is 2017012

Consent to participate was obtained from the participants. He or she add signature to hospital's consent when just check in.

Consent for publication:

Written informed consent for publication of their clinical details and/or clinical images was obtained from the patient. The individual person's data in this article such as CT-images was obtained from that person.

Availability of data and material:

All data generated or analyzed during this study are included in this article. The datasets used or analyzed during the current study are available from the corresponding author on reasonable request. Please contact author for data requests.

Competing interests:

The authors declare that they have no competing interests.

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Authors' contributions:

Dr. Yuxin Shen participated in the design of the study (pre-operation and the real PKP operation) and performed the statistical analysis. Dr. Shitong Xing conceived of the study, and participated in its design , use the CT imagine to build a 3D-printing model and coordination and helped to draft the manuscript. All authors read and approved the final manuscript.

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Source was only from Science and technology projects of Huzhou city. We deny charged patients for the 3D-printing model in this research.

Authors' Information :

Dr. Yuxin Shen is a spine surgeon with seven years of clinical experience, is working to become a specialist. He is Strong interest in digital orthopedics. Dr. Shitong Xing is a chief surgeon of spinal department with 20 years of clinical experience. He is an excellent expert. The two doctors worked together for a long time, and Shared ideas about PKP surgery which led to a research and this article.

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Tables

Table 1 Preoperative basic data

Sub	Group	Results	Sig.
Gender	Control group	Male 7, Female 28	.748
	3D-print group	Male 4, Female 21	
Age	Control group	71.03±7.489	.430
	3D-print group	72.60±7.632	
preoperative Cobb's angle	Control group	26.23±5.892	.523
	3D-print group	25.16±6.962	
preoperative VAS score	Control group	7.09±1.541	.255
	3D-print group	6.60±1.708	
preoperative JOA score	Control group	15.34±2.485	.567
	3D-print group	15.72±2.525	

Table 2 postoperative data

Sub	Group	AVG	SD	Sig.
operation time	Control group	80.89	21.402	.000
	3D-print group	64.00	12.500	
intraoperative changes the channels	Control group	4.17	1.599	.001
	3D-print group	2.72	1.487	
perspective	Control group	79.66	21.372	.046
	3D-print group	69.16	17.004	
preoperative Cobbs angle	Control group	26.23	5.892	.523
	3D-print group	25.16	6.962	
Short-term postoperative Cobbs angle	Control group	10.69	5.217	.014
	3D-print group	8.24	1.877	
Short-term postoperative improvement degree	Control group	15.54	7.346	.465
	3D-print group	16.92	6.855	
long-term postoperative Cobbs angle	Control group	18.31	5.357	.011
	3D-print group	14.76	4.952	
long-term postoperative improvement degree	Control group	7.91	7.402	.177
	3D-print group	10.40	6.258	
preoperative VAS score	Control group	7.09	1.541	.255
	3D-print group	6.60	1.708	
Short-term postoperative VAS score	Control group	2.66	1.349	.020
	3D-print group	2.00	.764	
Short-term postoperative improvement score	Control group	4.43	2.019	.727
	3D-print group	4.60	1.633	
long-term postoperative VAS score	Control group	2.37	1.437	.487
	3D-print group	2.16	.898	
Long-term postoperative improvement score	Control group	4.71	1.979	.585
	3D-print group	4.44	1.805	
preoperative JOA score	Control group	15.34	2.485	.567
	3D-print group	15.72	2.525	

Short-term postoperative JOA score	Control group	22.43	3.354	.036
	3D-print group	23.96	2.150	
long-term postoperative JOA score	Control group	24.89	1.843	.407
	3D-print group	25.32	2.174	
short-term improvement index	Control group	.5052	.25565	.038
	3D-print group	.6175	.15263	
long-term improvement index	Control group	.6837	.15422	.278
	3D-print group	.7281	.15610	