Application of Percutaneous Vertebroplasty Assisted by 3D Printed Positioning Guide Plate in the Treatment of Senile Osteoporotic Vertebral Compression Fractures

Wei Zhang, Zhehui Zhu, Shizhang Liu, Huitong Liu*
Shaanxi Provincial People's Hospital, Xi'an, Shaanxi, China
**Corresponding Author.*

Abstract: This paper aims to investigate the feasibility, treatment points, and clinical effects of percutaneous vertebroplasty (PVP) assisted by 3D printed individual positioning guides for senile osteoporotic vertebral compression fractures (OVCF). Percutaneous vertebroplasty assisted by 3D printed individual positioning guides were used to treat 30 diseased vertebrae of 30 elderly female patients with compression fractures. The NRS and ODI score were compared before the operation, 1 day after the operation, 1 week after the operation, 1 month and 3 months after the operation. All patients successfully completed the operation, and followed up for 3 months. Through statistical analysis of patients' NRS scores and ODI scores, the difference was significantly improved 1 day before and after surgery (P <0.001), and there was no statistical difference between 1 and 3 months after surgery (P>0.05). The improved Macnab score was excellent and good rate Reaching 97%. Preoperative 3D printed individual positioning guide assisted positioning help to reduce the radiation exposures, surgical risks, shorten the surgical time, and obtain good curative effects, high safety, and clinical application value.

Keywords: 3D Printing; Personalized Positioning Guide Plate; Percutaneous Vertebroplasty (PVP); Osteoporotic Vertebral Compression Fracture (OVCF)

1. Introduction

According to the recent research, the prevalence rate of osteoporosis in Chinese women over 50 years old is 32.1%, and the prevalence rate increases rapidly with age [1]. Brittle fractures account for about 81% of fractures in women over 50 years old [2]. Once brittle fractures occur, the risk of refracture is about 10 times higher than that of patients without brittle fractures [3]. Brittle fracture is the sign of osteoporosis (OP), and osteoporotic vertebral compression fracture (OVCF) is also the most common brittle fracture so far [4]. Patients with vertebral compression fractures usually show signs of fatigue and limited activity, and affect daily life [5]. In the past, most patients took conservative treatment and stayed in bed, which led to a large number of bone loss, further aggravating osteoporosis, affecting fracture healing, a vicious circle and long-term non healing [6].

Since Galibert [7] applied percutaneous vertebroplasty (PVP) to cervical vertebral hemangioma for 40 years, it has been widely used in osteoporotic vertebral compression fracture because of its advantages of small trauma, less bleeding and fast recovery [8]. At present, PVP mainly uses the C-arm or G-arm X-ray machine to conduct repeated fluoroscopy, adjust the needle entry angle and direction, ensure the accuracy of surgical operation, and reduce the occurrence of surgical risks and complications [9]. This operation increases the risk of radiation exposure of patients and surgeons, and the research reports of surgical complications are gradually increasing [10-14]. Accurate percutaneous pedicle puncture technique is the key to reduce the operation risk and complications.

At present, a variety of auxiliary technologies appear in clinic to improve the accuracy of PVP. The 3D printing guide plate designed by the preoperative CT imaging data of patients can be used in PVP surgery, which can shorten the operation time, reduce the surgical exposure, and achieve precise puncture [15]. This study was to explore the feasibility, treatment points and clinical efficacy of percutaneous vertebroplasty with 3D printing individualized positioning guide in the treatment of senile osteoporotic vertebral compression fractures.

2. Methods

2.1 Subjects

Between January 2019 and December 2020, 30 diseased vertebrae of 30 elderly female patients with compression fractures which treated by 3D printing individualized positioning guide PVP were retrospectively studied in this research, the distribution range of fractured vertebrae was T6-L5. The average age was 73.2 years (range, 60-83 years). Before operation, the lesion vertebral body was located according to the pain site. X-ray, CT and magnetic resonance imaging (MRI) were performed to determine the location of vertebral fracture. According to the changes of magnetic resonance signal, the fracture was judged as fresh or old fracture. All patients were diagnosed with osteoporosis. The study was approved by the Medical Ethical Committee of Shaanxi Provincial People's Hospital.

2.2 3D Printing Personalized Positioning Guide Plate Production

2.2.1 Computer aided analysis

The DICOM format data of vertebrae were scanned by 256 slice spiral CT (mm, slice thickness 1.0, slice spacing 1.0). The data were processed, calculated and analyzed by mimics 15.0 software of medical image control system, and the three-dimensional models of chest, back and lumbar vertebrae were established. Then the optimal puncture point and puncture channel were designed by Unigraphics nx9.0.

2.2.2 Navigation template for percutaneous vertebroplasty

The designed digital model data was imported into the processing software of creatbot 6.3 rapid prototyping equipment, and the personalized positioning guide plate required for percutaneous vertebroplasty was printed with a 3D printer, and the PVP operation process was simulated through the navigation template of percutaneous vertebroplasty.

2.3 Surgical Methods

After surgical disinfection and anesthesia, determine the corresponding projection position of the injured vertebral body on the patient's back skin from the perspective of the C-arm or G-arm X-ray machine, and make parallel marks on the lower edge of the upper vertebral body and the upper edge of the lower vertebral body with a sterile marker pen. After routine disinfection and towel laying, the sterilized percutaneous vertebroplasty positioning guide was placed on the patient's marked skin surface, and the horizontal upper and lower edges of the percutaneous vertebroplasty navigation template and the lower and upper edges of the upper and lower vertebrae marked on the skin surface were anastomosed in parallel. A Kirschner wire with a diameter of 1.5 cm was placed in the puncture guidance channel of the positioning guide, Again, the C-arm or G-arm X-ray fluoroscopy machine was used to confirm whether the injured vertebral body was located at the mark window of the injured vertebral body on the individualized positioning guide plate for percutaneous vertebroplasty and whether the position of the extension line of the Kirschner wire was the puncture design route. After determining the position of the navigation template for percutaneous vertebroplasty and the injured vertebral body, the puncture needle was used to puncture through two puncture channels on the navigation template. In order to avoid accidents, fluoroscopy monitoring was carried out in the process of puncture needle puncture and bone cement injection. The rest of the program is the same as the traditional PVP. (Figure 1)

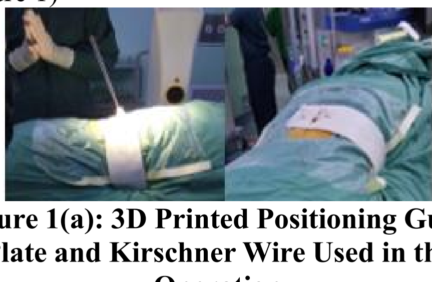

Figure 1(a): 3D Printed Positioning Guide Plate and Kirschner Wire Used in the Operation

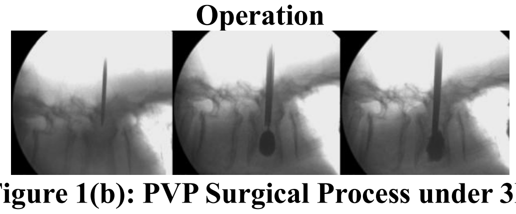

Figure 1(b): PVP Surgical Process under 3D printed Positioning Guide Monitored by X-ray Fluoroscopy

Figure 1. 3D Printed Positioning Guide

2.4 Postoperative Patient Management

About 0.5 hours after operation, the patient could turn over in bed. At the same time, anti-osteoporosis drugs were used for treatment. Lumbar and dorsal muscle function exercise was performed. On the first day after operation, they could get out of bed under the protection of waist brace. Pain intensity was assessed by NRS, and dysfunction was assessed by modified Macnab evaluation criteria and ODI score. All the data were recorded before the operation, 1 day after the operation, 1 week after the operation, 1 month and 3 months after the operation.

2.5 Statistical Methods

The data were statistically analyzed by SPSS 22.0 statistical software package (SPSS Inc, version 22.0, Chicago, IL). The results were expressed in the form of mean ± standard deviation, and the data between groups were analyzed by normality test and variance homogeneity analysis. On the premise of meeting the normality test, the statistical method of paired sample t test was used, and the test level was set to 0.05, that is, the difference was considered statistically significant with $P<0.05$.

3. Results

3.1 NRS, Modified Macnab and ODI Score

Table 1. NRS and ODI Score before and after Operation (N=30)

	NRS	ODI
before the operation	7.87±0.8	82.47 % ±7.9%
1 day after operation	2.20±0.6	25.13 % ±6.3%
1 week after operation	2.00±0.4	24.60 % ±5.7%
1 month after operation	1.90±0.4	24.20 % ±4.9%
3 months after operation	1.83±0.4	24.13 % ±4.7%

A total of 30 cases of osteoporotic vertebral compression fractures in the elderly were studied. The Digital Rating Scale (NRS) and ODI scores of patients was evaluated before operation, 1 day and 1 week after operation, 1 and 3 months after operation were compared, and so as the modified Macnab evaluation criteria. The results are shown in the table below. (Table 1, Table 2)

Table 2. Modified Macnab Evaluation Criteria after Operation (N=30)

	Excellent	Good	Fair	Poor
1 day after operation	3(10%)	19(63 %)	8(26%)	0(0)
1 month after operation	5(17%)	23(76 %)	2(7%)	0(0)
3 months after operation	6(20%)	23(76 %)	1(3%)	0(0)

3.2 Statistical Results

Based on the data obtained, paired sample t-tests were used for statistical analysis: before and 1 day after surgery, 1 day and 1 week after surgery, 1 day and 1 month after surgery, and 1 month and 3 months after surgery. After analysis, there were significant differences, as shown in the table below. (Table 3)

Table 3. NRS and ODI Score Compared before and after Operation

	NRS		ODI	
	P value	*t*	*P* value	*t*
before the operation	-	-	-	-
1 day after operation	0.000	38.686	0.000	29.373
1 week after operation	0.012	2.693	0.003	3.247
1 month after operation	0.083	1.795	0.083	1.795
3 months after operation	0.161	1.439	0.326	1.000

All surgeries were successfully completed, with a single vertebral body surgery time of 35-50 minutes, averaging 40 minutes; The amount of bone cement injected is 2-5.0 ml, with an average of 3 6 ml. The postoperative pain significantly decreased or disappeared. The NRS evaluation was 2.20 ± 0.6 on the first day after surgery, 2.00 ± 0.4 on the first week after surgery, 1.90 ± 0.4 on the first month after surgery, and 1.83 ± 0.4 on the third month after surgery. The difference between preoperative and postoperative comparison was statistically significant (P<0.05), and there was no significant statistical difference in the results after one week after surgery (P>0.05). The postoperative Macnab evaluation showed an excellent and good rate of 97% and an ODI score of 24%. All cases had no puncture failure, infection, or complications.

4. Discussion

In traditional OVCF patients undergoing PVP surgery, in order to improve the success rate of PVP, puncture positioning is mainly achieved with the assistance of C-arm, G-arm X-ray machines, spiral CT, etc. However, C-arm and G-arm X-ray machines have drawbacks such as unclear imaging, bulky equipment, and difficult positioning. In addition, the decrease in bone density in OVCF patients exacerbates the shortcomings of unclear imaging, leading to multiple fluoroscopic examinations in order to obtain accurate needle insertion points, which increases iatrogenic harm to patients and surgeons. Fitousi et al showed that the average exposure dose for surgeons during traditional PVP surgery is 1.661 mGy [16]. This study suggests that a surgeon can only perform a maximum of approximately 150 PVP surgeries per year to ensure that the radiation dose safety limit is not exceeded. In addition, patients with osteoporosis have osteoporosis, and the shape of the posterior column of the vertebral body is irregular, which increases the difficulty of manually determining the insertion point based on experience. It is inevitable to increase the number of shots to repeatedly correct the insertion point, which not only increases surgical time but also increases the risk of iatrogenic damage to patients and doctors. Repeatedly adjusting the needle insertion point and direction can lead to connectivity between multiple needle holes, increase the chance of bone cement leakage, and increase the risk of surgery. But the personalized positioning guide plate printed in 3D can be adjusted to the optimal intersection route with the fracture line during preoperative design to meet the filling and treatment effects of bone cement.

With the rapid development of science and technology, computer technology and advanced manufacturing technology have entered a new era of digitalization, personalization, precision, and minimally invasive surgery. The improved surgical method combined with traditional surgical methods is gaining more and more favor [17-19]. As a branch of improved surgical methods, 3D printed personalized positioning guides have been applied in the field of spinal surgery [20]. With the help of digital medical technology, we can not only fully understand the injured spine of patients, but also select the optimal puncture point and needle insertion path for vertebral body shaping surgery through computer simulation software based on the fracture situation of the injured spine in three-dimensional space. We can use 3D printing to create personalized positioning guides for percutaneous vertebral body shaping. During the surgical process, the skin on the chest and back corresponding to the injured spine is anatomically appropriate. After confirming the position of the C-arm or G-arm X-ray machine, perform the puncture according to the puncture channel on the navigation template, and finally complete the bone cement injection. Through computer design before surgery, comprehensive observation, planning, and simulation of surgery are carried out to select the optimal puncture point and needle insertion direction, achieving fast, safe, and accurate intraoperative operations. By utilizing the advantages of 3D printed personalized positioning guides to improve surgical accuracy and reduce surgical time [21,22], 3D printed personalized guidance plates have been widely used in the field of spinal surgery.

This experiment used computer-aided design software Mimics 15.0 and Unigraphics NX 9.0 to design a digital model of the personalized positioning guide plate for percutaneous vertebroplasty. The optimal puncture point and direction for vertebroplasty were selected through observation, analysis, design, and simulation in three-dimensional space. Finally, with the help of 3D printing technology, a personalized positioning guide plate for percutaneous vertebroplasty was created and applied to assist in intraoperative puncture positioning. The application effect is good. Not only is the selection of puncture points and needle insertion directions accurate, but the operation is fast and safe. The single vertebral body surgery time in this study was 35-50 minutes, with an average of 40 minutes, which is lower than the 56 reported by Wang Xiaohong et al [23] 53 ± 17 66 minutes is greatly shortened, shortening the surgical time, reducing intraoperative bleeding and surrounding soft tissue damage, which is beneficial for patient prognosis. Moreover, the NRS score and ODI score significantly decreased on the first day after surgery. After a 3-month follow-up, there was no significant change in the score, and the patient's symptoms improved significantly. The improvement of Macnab evaluation showed that the excellent rate increased from 73% on the first day after surgery to 97%, indicating the important value of 3D printed personalized percutaneous vertebroplasty positioning guide in the treatment of elderly osteoporotic vertebral compression fractures.

5. Conclusion

Preoperative 3D printed individual positioning guide assisted positioning help to reduce the radiation exposures, surgical risks, shorten the surgical time, and obtain good curative effects, high safety, and clinical application value.

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ORCID of corresponding author: 0000-0003-4585-7932

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