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Evaluation of Percutaneous Unilateral Kyphoplasty Results in Osteoporotic Vertebral Compression Fractures Using Individual 3D Printed Guide Template Support

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ABSTRACT

AIM: To compare the clinical and radiological outcomes of unilateral percutaneous kyphoplasty (PKP) surgeries performed using 3D printing technology in patients with osteoporotic compression fractures to conventional unilateral PKP surgeries.

MATERIAL and METHODS: Patients with acute painful single-level osteoporotic vertebral compression fracture (OVCF) who need surgical treatment were divided into two groups: group A (patients who had 3D template-guided PKP) and group B (patients who conventional PKP). To compare the two surgical procedures, Total Absorbed Radiation Dose (TARD), pre- and postoperative visual analog scale (VAS) scores, and Total Surgery Time (TST) were calculated and compared between groups in both surgical groups.

RESULTS: A total of 44 patients with single-level OVCF who were experiencing acute pain were successfully operated on, with 22 patients in each group. TARD (2.6 ± 0.4 mGy vs. 6.1 ± 1.9 mGy, $p<0.05$) and TST (12.4 ± 2.6 min vs. 20.2 ± 3.2 min, $p<0.05$) differed significantly different between groups A and B. There was no statistically significant difference between the patient groups in preoperative and postoperative VAS values ($p>0.05$). Cement leakage was lower in group A (3/22, 13.6%) than in group B (6/22, 27.3%) ($p>0.05$). There were no neurological complications or infections in either group.

CONCLUSION: When compared to the conventional procedure, the unilateral percutaneous kyphoplasty method was supported by a 3D printing guide template. By reducing operative time and radiation exposure, tt has resulted in a more effective surgical procedure for patients and a safer surgical procedure for surgeons and anaesthesiologists.

KEYWORDS: Osteoporotic vertebral compression fractures, Percutaneous unilateral kyphoplasty, Three-dimensional printing technology

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INTRODUCTION

Osteoporosis is becoming more common as people live longer lives (4,11). One of the most common problems in osteoporotic patients is Osteoporotic Vertebral Compression Fractures. According to the literature, it affects approximately 1.4 million people worldwide each year (4,11).

Osteoporotic Vertebral Compression Fractures (OVCF) are a significant clinical problem today due to their potential to cause long-term morbidity and persistent low back pain (9). The percutaneous vertebroplasty and kyphoplasty techniques are used to inject polymethylmethacrylate (PMMA) into the vertebral corpus with fractures detected. These surgical procedures are among the most commonly used treatments for OVCFs (3).

The surgeon's experience and conventional C-arm fluoroscopy shots are important factors in kyphoplasty surgery outcomes. Choosing the best pedicle entry sites during surgery, on the other hand, necessitates several C-arm fluoroscopy shots. This situation exposes patients, surgeons, and anesthesiologist to high levels of radiation. Percutaneous vertebroplasty (PVP) surgery exposed physicians to an average radiation exposure of 1,661 mGy, according to Fitousi et al. This value indicates that a surgeon can perform 150 PVP procedures in a year without exceeding the safe radiation levels (7). According to Harstall et al., long irradiation durations are required for vertebroplasty and kyphoplasty procedures performed under fluoroscopy, (8). As a result, surgeons are 25 times more likely than the general population to develop thyroid cancer.

According to research, unilateral PKP has advantages over bilateral PKP, such as faster healing times, less radiation exposure, and lower costs (5,6,16). However, a larger inclination angle is usually required in the unilateral PKP technique to effectively distribute the cement within the vertebral body, which increases the risk of complications (15). The difficulty of unilateral PKP varies according to anatomical differences across levels, gender, and age groups.

Hu et al., bilateral PVP cases performed with preoperatively created guide templates using a three-dimensional (3D) printing method to PVP cases performed using a standard method. It was discovered that radiation exposure and operation time were significantly reduced when guide templates were created using the 3D printing method (10). The goal of this study was compare the clinical and radiological outcomes of unilateral PKP procedures performed in patients with osteoporotic compression fractures using 3D printing technology to traditional unilateral PKP procedures.

MATERIAL and METHODS

Study Plan

Between January 2019 and June 2021, 44 patients were admitted to the hospital with acute OVCF and single-segment discomfort. With decision 174-174-07, the Uşak University Clinical Research Ethics Committee approved this study. Participants in the study provided written informed consent. Patients were divided into groups A (those receiving 3D template-guided PKP) and B (patients undergoing conventional PKP). The surgeries were performed by two identical surgeons. All patients received the same brand of surgical materials (bone cement, puncture needle, etc.).

Criteria for Inclusion and Exclusion

Inclusion criteria included: 1) radiologically confirmed acute unilevel OVCF; 2) no previous PKP treatment history; and (3) the patient's willingness to undergo surgical treatment.

Exclusion criteria included: 1) Patients with bone tumors or other bone metabolic diseases; 2) as were those with vertebral posterior column damage on C and 3) those with surgical contraindications.

Creation of 3D Printing Template Guides

Group A patients were operated on using a 3D template. Three radiopaque markers were placed in the midline of the patient's back skin at the vertebral level during the CT scan of all patients. These radiopaque markers served as reference points for positioning the template during the surgical procedure. The patients' CT scans were taken prone, in the position closest to the operating table. The patients' CT images were reconstructed using 120 kVp, 200 mAs, 120 mA, 300 mm FOV, 512×512 grid thickness, and 1 mm slice thickness. CT images were recorded in DICOM format, and DICOM files were transferred to 3D Slicer software (Surgical Planning Laboratory) for 3D vertebral reconstruction. Using the VTK attachment from the 3D Slicer application, a computer-aided 3D model of the vertebrae and adjacent segments to be kyphoplasty was created (Figure 1). The entry and target point of the cannula were determined in the Surgical Simulator add-on, which is an add-on to the 3D Slicer application, using the 3D model, and CT sections. The program calculated the distance between the two points as well as the angle of the cannula with respect to the horizontal axis. Following the saving of the length and angle values, the template was created in the Rhinoceros application. These areas were first drawn on the template using the measured vertebral heights, widths, and disk distances. Then, using the entry-target point, and angle information, cylindrical spaces for the cannula to enter were created. These cylindrical structures were placed on the template based on the 3D model and CT slices' localization (approximately upper 1/3). (Figure 2A, B). The STL model of the template was converted and printed on the Ultimaker 2 Extended 3D printer (Figure 2c, 2d). The printing material was PLA filament.

Surgery Techniques

All patients were operated on while lying on their backs. A 5 ml injection of 1% lidocaine and 1% ropivacaine mixture was used to provide local anesthesia. 6 ml of bone cement was injected unilaterally into the vertebral body of each patient.

Group a Procedures

The patients were placed on the operating table in the same prone position as they were in the CT scan. Following a local anesthetic, the sterile template was adhered to the patient's back with sterile film. Using the placements of the three radiopaque markers (unilateral transpedicular method), the

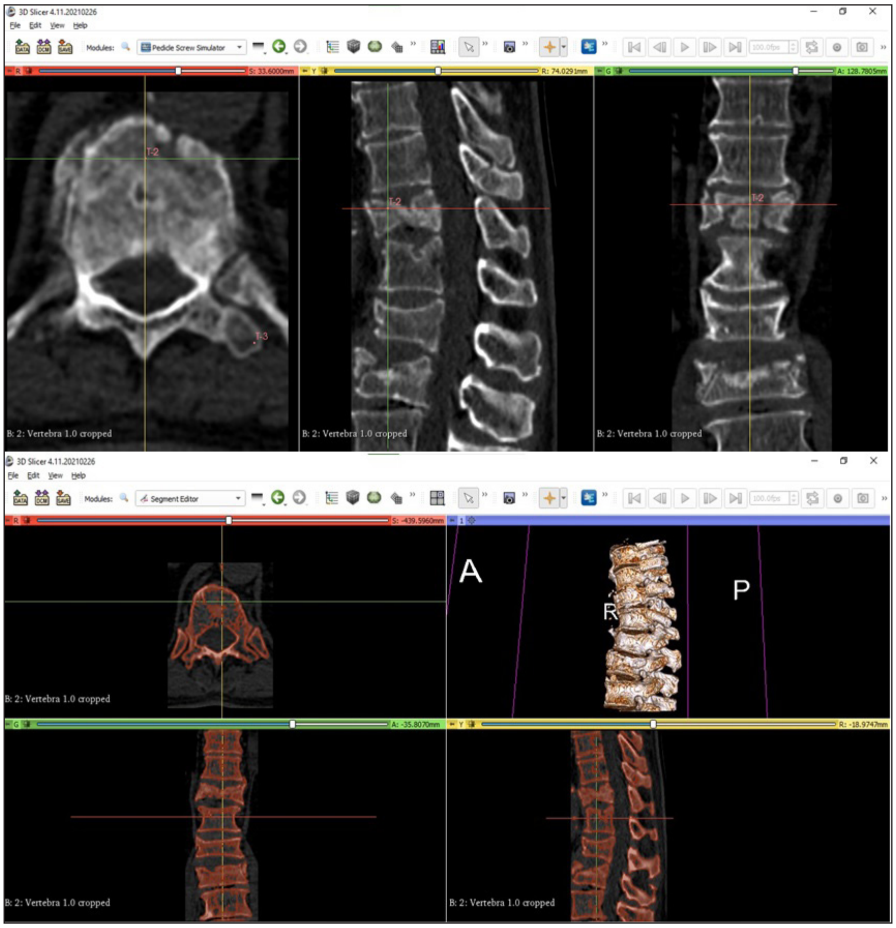

Figure 1: Preparation of 3D vertebra model in 3D Slicer software.

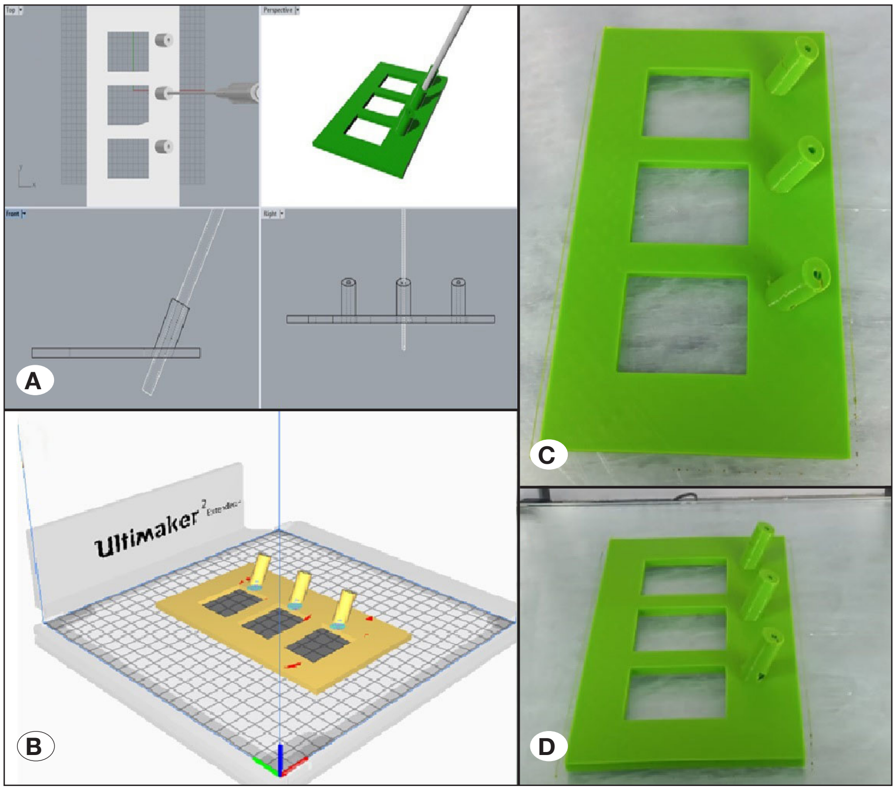

Figure 2: A) 3D modeling of the template. **B)** Preparation of printing parameters in Ultimaker Cura software. **C, D)** Printing the template on the Ultimaker 2 Extended 3D printer.

template was matched to the target area, and entry spots on the skin were chosen along the needle's route on the template (Figure 3A, B). An anterior-posterior (A-P) image was captured using C-arm fluoroscopy to ensure that the entrance locations indicated by the template were correct (Figure 3C). C-arm fluoroscopy was used to assess suitability of the trajectories for insertion by passing the puncture needle through the guide rollers.

Furthermore, C-arm fluoroscopy was used to determine whether the needle tips reached their optimal locations when placed on the guide rollers (Figure 4A, 4B). In the vertebra, bone cement was injected. Finally, A-P and lateral images were obtained in order to investigate the distribution of bone cement within the vertebra (Figure 4C). Suturing the incision sites completed the procedure.

Group B Procedures

In the control group, a unilateral transpedicular technique was preferred for PKP. Kirschner wires were used under A-P fluoroscopy to confirm the skin puncture locations of the target vertebra's unilateral pedicle. The entrance sites were placed 0.5–1.0 cm outside the upper-lateral points of the unilateral pedicles to achieve the best abduction angle. Surgeons used fluoroscopy shots to determine optimal puncture trajectories by adjusting the direction of the puncture needles to avoid spinal cord and nerve root injuries. The needles were advanced until they were in the correct position using fluoroscopy control. The vertebral corpuscles were injected with bone cement. To control how much bone cement was distributed throughout the corpus, two more shots were fired, one lateral, and one A-P. Suturing the incision sites completed the procedure.

Statistical Analysis

To compare the two surgical procedures, total absorbed radiation dose (TARD) (1), pre- and postoperative visual analog scale (VAS) scores, and total surgery time (TST) were collected and compared between groups in both surgical groups. CT images from after surgery were used. To analyze our company, we used the SPSS program (version 20, IBM Inc., Armonk, USA). The quantitative data were presented in the form of mean and standard deviation, while the qualitative data were presented in the form of percentages. Chi-square/Fischer comparisons between categorical variables were considered significant if the p-value was less than 0.05.

RESULTS

Clinic Data

The 44 patients in the study had a single-level, acute painful OVCF. Group A included 22 patients with a mean age of 57.1

Figure 3: A) The template was matched to the target location (unilateral transpedicular approach) with reference to the positions of the three radiopaque markers. **B)** Entry points on the skin were determined along the trajectory of the needle on the template. **C)** Anterior-posterior (AP) view of C-arm fluoroscopy was used to confirm whether the puncture points determined by the template were optimal insertion points.

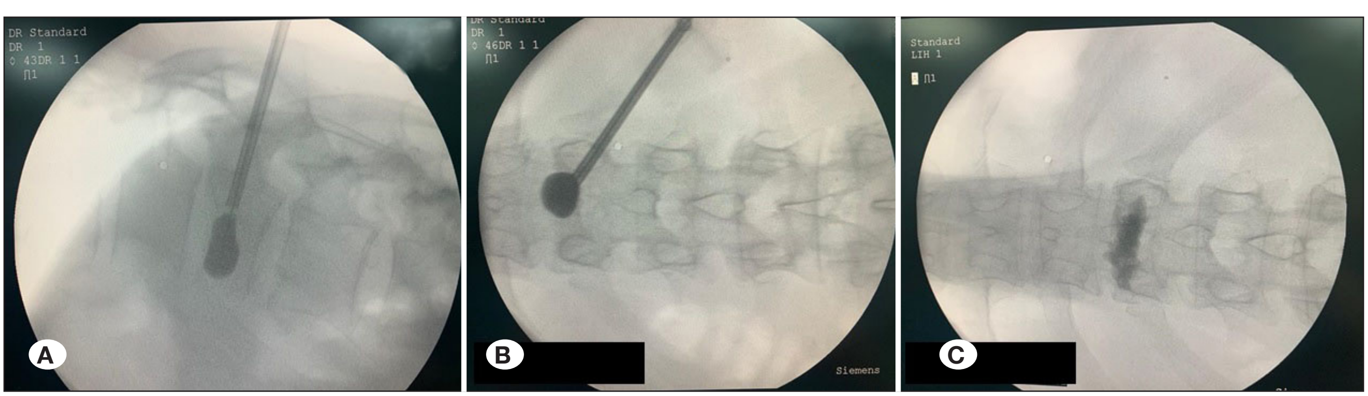

Figure 4: A) During the operation, lateral view of fluoroscopy. **B)** During the operation, anteroposterior view of fluoroscopy. **C)** After the operation, anteroposterior view of fluoroscopy to check the bone cement distribution.

Table I: Comperative Demographic and Surgical Data of Both Groups

	Group A	Group B	p-value
Age (years)	57.1 ± 9.2	60.4 ± 10.3	p>0.05
Male/Female (n)	6/16	5/17	p>0.05
BMI (kg/m^2)	26.9 ± 5.2	25.6 ± 4.8	p>0.05
Preoperative VAS	8.3 ± 1.4	8.2 ± 1.3	p>0.05
TARD (mGy)	2.6±0.4	6.1±1.9	**p<0.05**
TST (min)	12.4 ± 2.6	20.2 ± 3.2	**p<0.05**
Postoperative VAS	2.3 ± 0.6	2.4 ± 0.7	p>0.05

***BMI:** Body mass index, **TARD:** Total absorbed radiation dose, **VAS:** Visual analog scale, **TST:** Total surgery time.*

9.2 years (range 51–77) and a mean BMI of 26.9 5.2 kg/m^2 (6 males and 16 females). Group B included twenty-two patients (5 males and 17 females) with an average age of 60.4 10.3 (49–76) and a mean BMI of 25.6 4.8 kg/m^2 (Table I). There was no statistically significant difference between the groups (p > 0.05) in terms of mean patient age, male/female ratio, or mean BMI.

TARD (2.60.4 mGy vs. 6.11.9 mGy, p 0.05) and TST (12.4 2.6 min vs. 20.2 3.2 min, p 0.05) were statistically different between groups A and B. However, there was no statistically significant difference between the patient groups in preoperative and postoperative VAS values (p>0.05) (Table I). Before surgery, all patients received a single antibiotic dose. There were no infections or neurological problems in either group, and no patients required additional surgery.

Imaging Data

The patients' postoperative CT scans were evaluated. In comparison to group B (6/22, 27.3%), cement leakage was lower in group A (3/22, 13.6%) (p>0.05). There were no neurological symptoms in any of the cement leak patients, and they were all asymptomatic.

DISCUSSION

Evolving 3D printing technologies enable preoperative planning and template creation. It has been observed that pre-surgical planning reduces operation time due to the surgical templates created with the assistance of 3D printers (10). The decrease in the use of fluoroscopy during the procedure protects both the patient and the surgeons from the harmful effects of radiation. This study looked at the clinical and radiological impact of patient-specific templates created using 3D printing for unilateral PKP application.

PVP, according to Andrei et al., and Zhu et al., can relieve pain caused by OVCFs faster than conservative treatment and improve patients' quality of life (2,17). According to the literature, when unilateral PKP is compared to bilateral PKP, there is a shorter operation time and less radiation exposure in unilateral PKP cases (5,14). Unilateral PKP techniques frequently require a greater tilt angle to achieve adequate cement distribution in the vertebral body, which increases the risk of pedicle invasion, nerve damage, and cement leakage (15). The results of the unilateral PKP technique in patients with OVCF were investigated in our study using the 3D printing method. Our research is the first of its kind in the field.

In our study, patients in group A had shorter total surgery times (TST) and total radiation doses (TARD) than patients in group B, which was statistically significant (p<0.05). According to the literature, 3D printing guide template-supported bilateral PVP cases had shorter operation fluoroscopy shot time, radiation dose, and operation time than conventional C-arm fluoroscopy-assisted bilateral PVP cases (10). Furthermore, patients in this study who underwent the 3D printing guide template-supported bilateral PVP technique had longer operating times and higher total radiation doses (4.9 0.9 mGy) than patients who underwent the 3D printing guide template-supported unilateral PVP technique.

One of the most common PKP side effects is cement leakage into neighboring tissues (12,13). There were no serious complications in our study's patients, and no patient required reoperation. Using the proper entrance sites, the likelihood of cement leakage can be reduced. In our study, we discovered that group A (3/22, 13.6%) had significantly lower cement leakage than group B (6/22, 27.3%). Although there was no statistically significant difference between the two groups, we believe that as the number of cases in the study increases, there may be statistically significant differences in the frequency of cement leakage.

According to the findings, using a personalized 3D printed guide model has made traditional unilateral PKP a more effective surgical procedure for patients and a safer surgical procedure for surgeons and anaesthesiologists. Surgeons have mastered vertebral anatomy through successful preoperative planning with the help of personalized 3D printing guide model. The guide template established the proper location and angle for transpedicular intervention. As a result, using these guide templates, it was possible to reach the point where the cement in the vertebral corpus would be given from the skin in fewer fluoroscopy times and in less time than standard PKP applications. At the same time, the operation was shortened, and the radiation dose received was reduced.

Transpedicular intervention in PKP applications is a difficult technique to learn for young surgeons. This method can help younger surgeons learn PKP faster and identify puncture sites that require further examination.

Our research has some limitations. Preoperative guide templates and printing increased patient costs and surgeon workload. Furthermore, one of our study's limitations was the lack of multiple-level OVCF patients with advanced kyphosis or scoliosis.

CONCLUSION

Unilateral percutaneous kyphoplasty, which is aided by a 3D printed guide template, is a more delicate procedure than the standard method. Reducing operation time, radiation time, and radiation exposure has made surgery safer for surgeons and anaesthesiologists while also improving patient outcomes. This surgical technique can be used to train young surgeons who will be performing PKP surgery in the future. Furthermore, our research will pave the way for preoperative planning for PKP applications in complex OVCF patients (multiple fractures, kyphosis, scoliosis, etc.).

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AUTHORSHIP CONTRIBUTION

Study conception and design: IDC, IK, GG
Data collection: IDC, HT, IU, MCS
Analysis and interpretation of results: IK, MA, MCS
Draft manuscript preparation: IDC, SO, GG
Critical revision of the article: IK, MA
Other (study supervision, fundings, materials, etc...): IU, SO, HT
All authors (IDC, GG, MA, IU, MCS, SO, HT, IK) reviewed the results and approved the final version of the manuscript.

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