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Mixed reality–guided vertebroplasty versus traditional fluoroscopy group in the treatment of osteoporotic vertebral compression fracture

A randomized controlled trial

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Abstract

Background: Osteoporotic vertebral compression fractures (OVCFs) are common among the elderly, and percutaneous vertebroplasty (PVP) is the standard minimally invasive procedure for treating OVCF, but previous PVP mainly uses X-ray fluoroscopy, which poses additional radiation and complication risks to patients.

Objective: To explore the clinical efficacy of PVP for treating OVCFs with the assistance of mixed reality (MR) navigation technology.

Methods: Forty OVCF patients were tested in the prospective, randomized, and controlled study and were randomly grouped into MR-guided group and conventional fluoroscopy group with 20 patients, respectively. The indicators such as surgery duration, number of fluoroscopy, pain scores, and surgical complications between both groups were evaluated.

Results: The comparison between the MR-guided group and the control group in terms of surgical duration, number of fluoroscopy, bone cement dosage, and bone cement leakage showed that the MR-guided group (26.00 minutes [26.00–27.75]) had a significantly shorter surgical duration than that of the control group (29.00 minutes [27.25–34.25]) ($p < 0.001$). The MR-guided group (26.00 times [25.25–32.75]) had a fewer number of total fluoroscopy than that of the control group (35.00 times [31.00–41.00]) ($p < 0.05$), a higher bone cement dosage than that of the control group ($p < 0.05$), and the bone cement leakage rate is lower in the MR-guided group (10.00%) compared with the control group (30.00%); however, there was no statistically significant difference ($p > 0.05$). Pain relief and vertebral height restoration postoperative and during follow-up were comparable between the 2 groups ($p > 0.05$).

Conclusions: MR-guided PVP surgery for the treatment of OVCF can significantly reduce surgical duration, the number of punctures, the number of fluoroscopy, radiation exposure to both patients and medical staff, and the risk of surgery-related complications and featured as a safe, precise, and efficient auxiliary technology that merits wider application in minimally invasive spinal surgery.

Keywords: mixed reality, osteoporotic vertebral compression fracture, safety, surgical navigation, vertebroplasty

1. Introduction

Osteoporotic vertebral compression fracture (OVCF) is prone to occur in the elderly, especially in the context of population aging, which has exacerbated the trend of its incidence rate.[1] OVCF can cause severe pain, spinal deformities, and limited mobility, posing adverse effects on patients' quality of life.[2,3] Statistical data show that the adverse effects on patients' quality of life due to OVCF are comparable to chronic diseases such as chronic obstructive pulmonary disease and rheumatoid arthritis.[4]

Currently, percutaneous vertebroplasty (PVP) is the mainstream minimally invasive surgical method for treating OVCF. Since its inception in 1987 in France by Galibert et al.,[5] PVP has become a standard treatment for OVCF, featuring its advantages in minimally invasive, precise efficacy, and fewer complications. PVP technology can inject bone cement into the fracture site through

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percutaneous puncture, which can advance the rehabilitation process, relieve pain, and restore a certain vertebral height and spinal stability. A meta-analysis results confirmed that compared with conservative treatment methods, PVP technology can significantly improve pain alleviation and functional recovery of the fracture site in patients with OVCF and their quality of life.[6]

However, previous PVP mainly relied on X-ray fluoroscopy to guide the puncture process and bone cement injection, which posed a risk of radiation damage to patients and surgeons. The study results of Synowitz and Kiwit[7] showed that without using protective measures at the time of PVP, the surgeon's right hand is exposed to a mean intraoperative radiation dose of 0.62 ± 0.55 mSv, far higher than that in other orthopedic surgeries. Therefore, long-term low-dose radiation can increase the risk of surgeons suffering from diseases such as radiation cataracts and thyroid cancer.[8,9] Additionally, previous PVP with X-ray fluoroscopy cannot accurately confirm the puncture angle and depth. The most common complication of PVP is bone cement leakage, and a meta-analysis involving 4187 vertebral bodies from 2872 patients in 22 studies showed that the incidence of bone cement leakage after PVP surgery was 54.7%.[10] Bone cement leakage can compress the spinal cord or nerve roots, resulting in an adverse outcomes such as paraplegia and nerve damage.[11,12] Therefore, surgeons urgently need a new surgical navigation technology with reasonable radiation dosage and greater precision and accuracy to achieve a safer and accurate therapy.

In recent years, the rapid advancement of computer technology and medical imaging technology has captured widespread attention on new surgical navigation technologies featured by augmented reality (AR) and mixed reality (MR) in orthopedic disease treatment.[13,14] Compared with conventional optical and electromagnetic navigation methods, MR-guided PVP surgery can visualize the surgical process based on real-time image feedback information for detection and is flexible and convenient to operate.[15,16] Compared with O-arm navigation, intraoperative computed tomography (CT) navigation, and robot-assisted PVP technology, this MR navigation has the advantages of being easy to operate, having lower costs, and not requiring intraoperative scanning of 3D CT, which would otherwise increase the radiation dose for both medical staff and patients.[17]

MR technology is a newly born human–computer interaction technology that seamlessly integrates real-world information and virtual information to generate a new visual environment and perform real-time interaction. MR technology utilizes multisource sensors to collect real-time environmental data and matches and renders with computer-generated virtual information, enabling users to switch the modes between real-world perception and virtual content.[18–20] The MR system consists of core components such as a computing platform, environmental perception devices, display devices, and interactive devices,[21] and head-mounted display is currently used as the mainstream display form in MR systems[22] (Fig. 1). The device integrates multiple optical sensors, inertial measurement units, depth cameras, environmental interpretation cameras, and holographic lenses. By using HoloLens, the system can collect spatial data and modeling, and then combine multichannel information rendering, such as visual, auditory, and somatosensory, to create a real-world environment (Fig. 2). Additionally, HoloLens supports multiple human–computer interaction methods, such as voice, gaze, and gestures, making it easy to operate.[19,23]

As a new direction in the development of digital healthcare, MR navigation technology serves as a surgical assistant tool, providing high-precision, intelligent, and personalized treatment outcomes for surgical procedures. However, its application in the field of minimally invasive spinal surgeries, such as PVP and PKP, has been relatively limited. This article aims to evaluate the clinical efficacy and safety of MR-guided PVP surgery and compare its differences with a control group for the treatment of OVCF through a prospective, randomized, and controlled trial to provide evidence-based medicine proofs and experience reference for the clinical promotion and application of this technology in minimally invasive spinal surgery.

2. Methods

2.1. Study design

This study is a single center, prospective, randomized and controlled clinical trial, with the data collected from patients who underwent PVP surgery in the General Hospital of Northern Theater Command from September 2022 to December 2023, and the study protocol was approved by the Ethics Committee of General Hospital of Northern Theater Command (No. LSY(2021)025), and all the patients agreed and signed a surgical informed consent before starting the clinical trial.

2.2. Selection criteria for the patients

2.2.1. Inclusion criteria for patients. Patients aged ≥ 60 years; the imaging (X-ray, CT, or magnetic resonance imaging) examination results indicates a single segment of OVCF, and the fracture duration is less than 1 month; accompanied by severe back pain (VAS score ≥ 7), lasting for more than 2 weeks with a poor conservative efficacy; and bone density T value ≤ –2.5 SD, meeting the diagnostic criteria for osteoporosis.

2.2.2. Exclusion criteria for patients. Pathological fractures, including metastatic tumors and myeloma; posterior fracture of the vertebral body accompanied by spinal cord or nerve root compression; patients with coagulation disorders or other contraindications to surgery, who are not able to tolerate surgical procedures; the degree of vertebral compression fracture exceeds 75% of the vertebral height; and cognitive impairment and inability to complete surgical procedures.

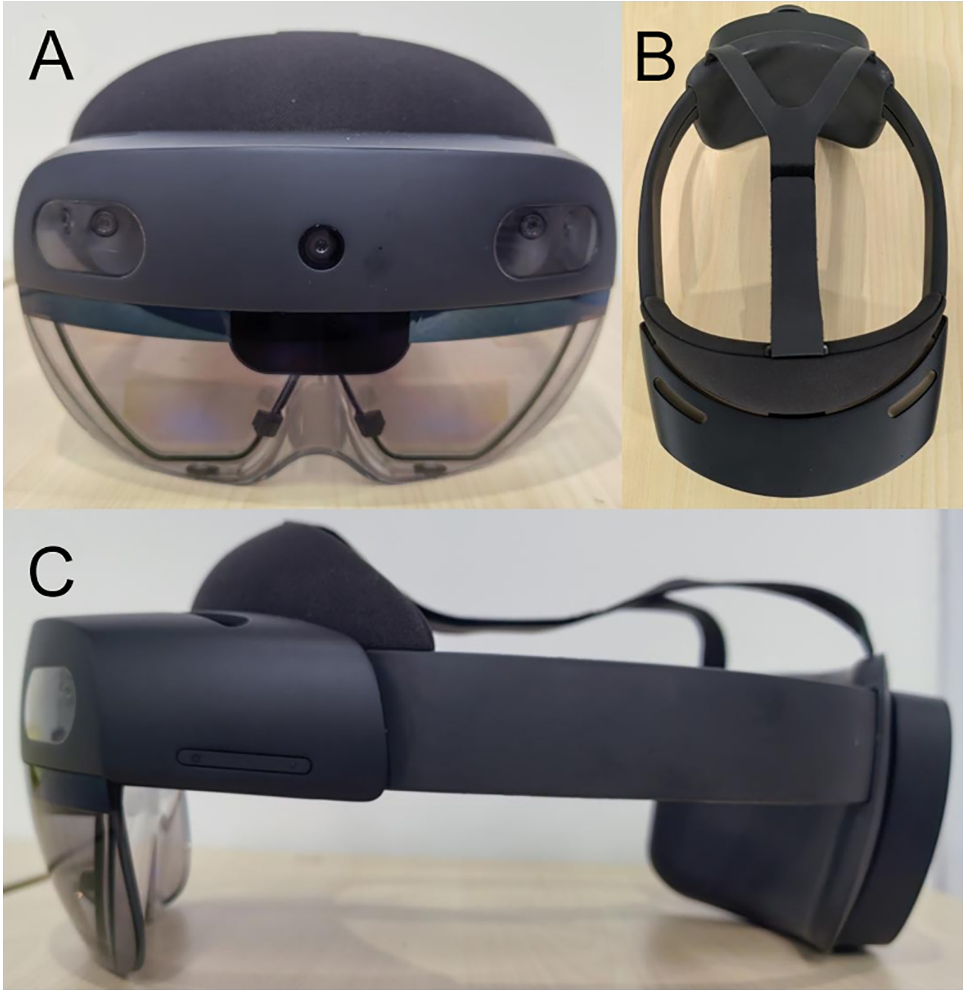

Figure 1. Different angle views of the MR navigation head-mounted display device (HoloLens 2 generation). (A) HoloLens 2 generation front. (B) HoloLens 2 generation side. (C) HoloLens 2 generation planform. MR = mixed reality.

2.3. Grouping and randomization

A total of 40 patients who met the inclusion and exclusion criteria were included in this study. They were randomly assigned to the MR-guided group (20 patients received MR-guided PVP surgery) and the control group (20 patients received conventional X-ray fluoroscopy-guided PVP) using a random number table method, with allocation concealment. The surgeries in both groups were performed by the same experienced spinal surgeon who had undergone training in the MR navigation system.

2.4. Surgical methods

2.4.1. MR-guided group. The surface of the HoloLens headset was disinfected with ultraviolet light before the surgery. The patients were placed in a prone position and received routine disinfection and draping. The surgeon

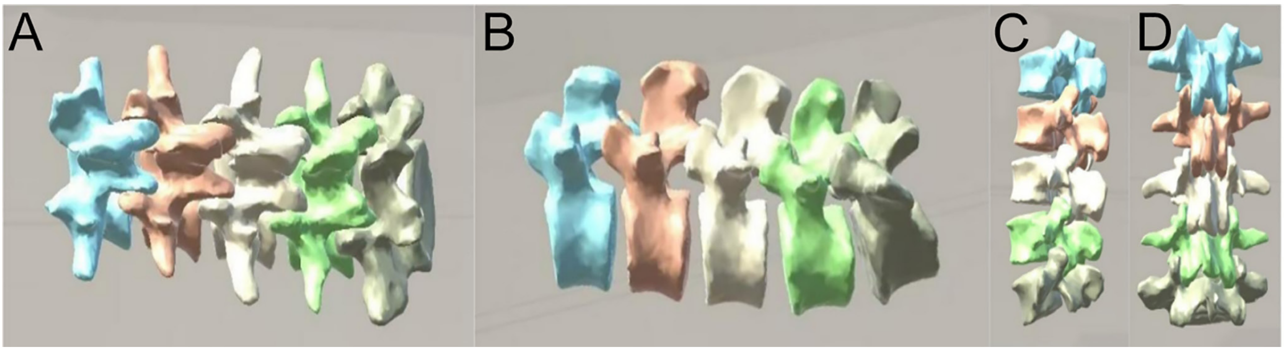

Figure 2. Acquisition and modelling of the spatial position of the spine in patients via the HoloLens 2 generation. (A, D) The coronal plane of the spine. (B, C) The sagittal plane of the spine.

wears the HoloLens headset, which superimposes the patient's preoperative 3D CT images onto the surgical field in real time. During the surgery, the entry point for the needle on the skin is marked under "visualized" conditions. The drug ratio for local anesthesia is 20 mL lidocaine (0.1%) + 10 mL ropivacaine + 20 mL saline. A 1-mL hypodermic needle was first used for local infiltration of anesthesia on the skin surface, subcutaneous tissue, and deep fascia. Then, a 7-gauge hypodermic needle was applied to locally anesthetize the periosteal tissues of the articular process. After real-time visualization and operation under the guidance of MR-guide technology, a 3.2-mm length percutaneous needle for bone puncture was gradually advanced along the anesthesia position, and the puncture angle and depth were visualized for adjustment in real time until the tip of the puncture needle was positioned on the medial edge of the pedicle on the puncture side in the anteroposterior view and on the posterior edge of the vertebral body in the lateral view. Subsequently, an anteroposterior and lateral fluoroscopy was performed to verify its accuracy. After confirming its safety and accuracy, the puncture needle was advanced further into the anterior one-third region of the vertebral body. After that, remove the needle core, inject the bone cement, controlling the injection rate and dosage, withdraw the puncture needle, and suture the incision.

2.4.2. Control group.

The patients were placed in a prone position and received routine disinfection and draping. First, 2 Kirschner wires were used to cross-fix the fracture site, and the "9 o'clock" (left) or "3 o'clock" (right) position on the surface projection of the vertebral arch of the fractured vertebra was preliminarily selected as the skin entry hole with anteroposterior fluoroscopy. The drug ratio for local anesthesia is 20 mL lidocaine (0.1%) + 10 mL ropivacaine + 20 mL saline. The surgeon used a 1-mL hypodermic needle to locally anesthetize the skin surface, subcutaneous tissue, and deep fascia along the injection point, and then used a 7-gauge percutaneous needle to anesthetize the surface of the articular process. The surgeon incised the skin and soft tissue, and inserted a 3.2-mm length percutaneous needle to position the puncture site with anteroposterior fluoroscopy, adjusted the puncture angle and depth with fluoroscopy to make the needle tip located at the "9 o'clock" or "3 o'clock" position for projection on the surface of the pedicle. Incise the skin and soft tissue, insert a percutaneous needle and adjust the puncture angle and depth with lateral fluoroscopy until the needle tip is located at the anterior site in one-third length of the vertebral body, remove the needle core, and inject bone cement through a cannula until the bone cement dosage meets the predetermined filling target. Then, pull out the percutaneous needle and suture the incision.

2.5. Efficacy evaluation

A surgeon other than the study should be responsible for evaluating the surgery efficacy and safety of patients in both groups.

Two surgeons who had never been exposed to MR navigation technology but had extensive experience in spinal surgery, together with 1 senior radiologist, independently conducted postoperative imaging assessments in a double-blind manner. All differences were resolved through discussion and reached a consensus.

2.5.1. Main efficacy indicators.

Surgical duration refers to the time (measured in minutes) from disinfection and draping of sterile surgical sheets to the completion of suturing. Number of total fluoroscopy refers to the number of times C-arm X-ray machines are used for fluoroscopy during surgery. Bone cement injection dosage (mL) refers to the total amount of bone cement injected during surgery. Mean of preoperative and postoperative height of fractured vertebral body (HFV) is the average height of the anterior and posterior edges of the vertebral body calculated in neutral position (cm). Number of fluoroscopy times to reach the target location refers to intraoperative anteroposterior fluoroscopy with a C-arm indicates that the tip of the puncture needle is located in the middle area between the medial edge of the pedicle and the spinous process, while lateral fluoroscopy shows that the tip of the puncture needle has reached the anterior one-third region of the fractured vertebral body.

2.5.2. Secondary efficacy indicators.

It refers to the use of VAS scores to evaluate postoperative pain relief on the preoperative and puncturing to the target location, 1st day, and at the 3rd, 6th, and 12th months, respectively. On the preoperation and 1st day postoperative and 6th and 12th months, Oswestry disability index (ODI) scores were used to evaluate the improvement of functional impairment. On the 1st postoperative day, X-ray and 3D CT examinations were performed to measure the mean height recovery of preoperative and postoperative height of the fractured vertebral body, as well as bone cement diffusion and bone cement leakage. Follow-up was done at the 3rd, 6th, and 12th months to evaluate the recovery of the height of the fractured vertebrae and therapeutic effect.

2.5.3. Safety evaluation.

Record the complications that occur during the perioperative period, including bone cement leakage (intraspinal, paraspinal, and intervertebral).

2.6. Postoperative

The patient should rest in bed for 3 hours after surgery, and the physician should closely monitor the patient's vital signs and limb activity and regularly provide antiosteoporosis treatment.

2.7. Statistical analysis

The researcher used SPSS 26.0 software to process and analyze the data. Metric data that followed a normal distribution were presented as mean ± standard deviation, and *t*-tests were used to compare the differences between the groups. Non-normally distributed quantitative data

Table 1

Analysis of preoperative baseline data for patients in both groups.

Variable	Level	MR-guided group	Control group	χ^2/Z	*p* value
Gender (%)	Male	6 (30.00)	7 (35.00)	0.114	0.736
	Female	14 (70.00)	13 (65.00)		
Age, median (P25–P75)		71 (68.30 to 74.50)	69 (68.00 to 76.00)	–0.014	0.989
Weight, median (P25–P75)		62.00 (58.30 to 66.00)	63.00 (60.00 to 67.00)	–0.393	0.694
Smoking status (%)	T	9 (45.00)	10 (50.00)	0.1	0.752
	F	11 (55.00)	10 (50.00)		
Diabetes complication (%)	T	8 (40.00)	9 (45.00)	0.102	0.749
	F	12 (60.00)	11 (55.00)		
Hypertension complication (%)	T	13 (65.00)	12 (60.00)	0.107	0.744
	F	7 (35.00)	8 (40.00)		
Coronary heart disease complication (%)	T	7 (35.00)	6 (30.00)	0.114	0.736
	F	13 (65.00)	14 (70.00)		
Preoperative bone density *T* value, median (P25–P75)		–2.80 (–3.00 to –2.60)	–2.80 (–3.00 to –2.60)	–0.302	0.763
Preoperative VAS score, median (P25–P75)		8.00 (7.00 to 9.00)	8.00 (7.00 to 8.00)	0.000	1.000
Total points		20	20		

F = false, MR = mixed reality, T = true, VAS = visual analogue scale.

were presented as median (quartiles) (M [P25–P75]), and intergroup differences were analyzed using the Wilcoxon rank sum test. Categorical data were expressed as percentages (%) using the chi-squared test or Fisher exact test, with $p < 0.05$ indicating statistically significant differences.

3. Results

3.1. General information

This study included a total of 40 patients with OVCF, including 20 in the MR-guided group (MR-guided PVP surgery) and 20 in the control group (conventional X-ray fluoroscopy-guided PVP). Both groups of patients were followed up. There was no statistically significant difference in baseline data, such as gender, age, body weight, smoking status, complications, preoperative bone density *T* value, and preoperative VAS score between the patients in both groups with comparability ($p > 0.05$) (Table 1).

3.2. Surgical overview

Table 2 shows the comparison between the MR-guided group and the control group in surgical duration, bone cement dosage, and bone cement leakage rate. The surgical duration of the MR-guided group (26.00 minutes [26.00–27.75]) was significantly shorter than that of the control group (29.00 minutes [27.25–34.25]) ($p < 0.001$), and the bone cement dosage in MR-guided group (6.05 ± 1.93 mL) was also higher than that of control group (4.50 ± 1.96 mL) ($p < 0.05$). The MR navigation group was lower than the conventional group in terms of cement leakage rate (10.00% vs 30.00%), but not significant ($p > 0.05$).

3.3. Pain relief

The results showed that there was no significant difference in preoperative VAS scores between the 2 groups ($p > 0.05$) (Table 3). The VAS scores for puncturing to the target location in the MR-guided group were lower than those in the control group, and the difference was statistically significant ($p < 0.05$). On the 1st day, 3rd month, and 6th month postoperative and the last follow-up, the pain relief level of the MR-guided group was comparable to that of the control group, and there was no significant statistical difference between the groups ($p > 0.05$).

3.4. ODI measurements

Table 4 summarizes the comparison of ODI scores between patients in both groups at different time points.

Table 2

Comparison of surgery duration, bone cement dosage, and bone cement leakage between the MR-guided group and the control group.

Group	Number of cases	Surgery duration (min), median (P25–P75)	Bone cement dosage (mL), mean ± SD	Bone cement leakage, case (%)
MR-guided group	20	26.00 (26.00–27.75)	6.05 ± 1.93	2/20 (10.00%)
Control group	20	29.00 (27.25–34.25)	4.50 ± 1.96	6/20 (30.00%)
$Z/t/\chi^2$	—	–3.631	2.518	—
p value	—	<0.001	0.016	0.235*

MR = mixed reality.*Used Fisher exact test.

Table 3

Comparison of the VAS scores between the MR-guided group and the control group at different time points.

Item	MR-guided group, median (P25–P75)	Control group, median (P25–P75)	*Z*	*p* value
Preoperation	8.00 (7.00–9.00)	8.00 (7.00–8.00)	0.000	1.000
Puncture to the target location	7.00 (6.00–7.75)	7.50 (7.00–8.00)	−2.318	0.020
1st day postoperation	2.00 (1.00–3.00)	2.00 (1.25–3.00)	−0.403	0.687
3rd month postoperation	2.00 (1.00–3.00)	2.00 (1.20–3.00)	−0.221	0.796
6th month postoperation	2.00 (1.00–2.00)	2.00 (1.05–2.00)	−0.302	0.761
12th month postoperation	1.00 (1.00–2.00)	1.50 (1.00–2.00)	−0.313	0.755

MR = mixed reality.

Table 4

Comparison of the ODI scores between the MR-guided group and the control group at different time points.

Group	Preoperation	1st day postoperation	6th month postoperation	12th month postoperation
MR-guided group, median (P25–P75)	71.55 (62–80.75.00)	23.50 (20.00–29.00)	17.50 (13.25–19.00)	12.00 (11.00–16.00)
Control group, median (P25–P75)	68.00 (62.30–82.80)	23.50 (21.00–29.00)	16.00 (13.30–19.00)	12.00 (11.25–16.10)
Z	−0.245	−0.626	−0.122	−0.078
p value	0.806	0.531	0.903	0.902

MR = mixed reality.

There was no significant difference in preoperative ODI scores between the groups ($p > 0.05$), while the postoperative ODI scores of the MR-guided group and the control group decreased significantly compared with preoperative scores, respectively. The ODI scores of the MR-guided group were comparable to those of the control group at the 1st day, 6th month, and 12th month postoperative, with a nonsignificant statistical difference between the groups ($p > 0.05$).

3.5. Imaging examination

Table 5 presents the recovery of the mean vertebral height (HFV) at various time points. There was no significant difference in preoperative HFV between the 2 groups ($p > 0.05$), and both groups demonstrated better postoperative HFV recovery than preoperative HFV. The recovery of HFV in the MR navigation group was comparable to that in the traditional PVP group, with no statistically significant differences observed ($p > 0.05$). At the at the 6-month and 12-month follow-up, the vertebral height in the MR navigation group improved but remained comparable to that in the traditional PVP group, with no significant difference ($p > 0.05$).

3.6. Comparison of the number of intraoperative fluoroscopies

Table 6 summarizes the comparison of intraoperative puncture and fluoroscopy between the MR-guided group and the control group. The results showed that the MR-guided group had lower numbers of puncture, fluoroscopy times to reach the target location, and total fluoroscopy compared with those of the control group, and the differences are statistically significant ($p < 0.05$).

3.7. Typical case

The patient, an 83-year-old female, was admitted to the hospital in May 2023 because of “sprained back pain for 3 days.” Before treatment, magnetic resonance imaging revealed a thoracic 12 vertebral compression fracture (Fig. 3). She underwent MR navigation-assisted PVP (Fig. 4). Postoperative CT images, including coronal,

Table 5

Mean height of the fractured vertebral body (HFV) on the preoperative, the 1st day, the 6th postoperative month, and the last follow-up.

Group	Preoperation	1st day postoperation	6th month postoperation	12th month postoperation
MR-guided group (cm), median (P25–P75)	3.05 (2.80–3.40)	3.30 (3.10–3.60)	3.23 (3.00–3.50)	3.15 (2.90–3.40)
Control group (cm), median (P25–P75)	3.20 (2.93–3.30)	3.30 (3.10–3.40)	3.22 (3.00–3.38)	3.21 (3.00–3.43)
Z	−0.354	−0.409	−0.305	−0.221
p value	0.723	0.683	0.704	0.872

MR = mixed reality.

Table 6

Comparison of intraoperative puncture and fluoroscopy between the MR-guided group and the control group.

Group	MR-guided group, median (P25–P75)	Control group, median (P25–P75)	*Z*	*p* value
Number of punctures	2.00 (1.00–4.50)	4.50 (4.00–6.00)	−3.344	0.001
Number of fluoroscopy times to reach the target location	6.00 (6.00–7.00)	12.50 (10.00–16.00)	−5.113	<0.001
Number of total fluoroscopy	26.00 (25.25–32.75)	35.00 (31.00–41.00)	−3.001	0.003
n	20	20		

MR = mixed reality.

sagittal, and axial views, demonstrated uniform cement distribution with no leakage (Fig. 5). At the 1-year follow-up, the patient reported complete relief from lower back pain and had resumed normal daily activities.

4. Discussion

This prospective, randomized, and controlled study aims to evaluate the clinical application value of MR navigation technology in PVP surgery for OVCF. The findings of this research revealed that MR-guided PVP surgery exhibited benefits over control surgery in aspects such as operation time, bone cement dosage, VAS scores at the time of puncture reaching the target location, the number of punctures, and fluoroscopy frequency. MR navigation facilitates precise puncture guidance, increases the amount of bone cement used while maximizing the reduction of complications such as bone cement leakage, and enhances the effectiveness of vertebral height restoration. This technology increases surgical precision and safety. During the long-term follow-up, the therapeutic effects of the 2 groups of patients were comparable. These findings are consistent with the application significance of MR navigation technology in orthopedic surgery published in previous literature.[24–26]

The medical field is one of the important application directions of MR technology, which introduces medical imaging data into the MR system for 3D reconstruction, and then matches it with the patients' anatomical structure in real time, enabling surgeons to accurately plan

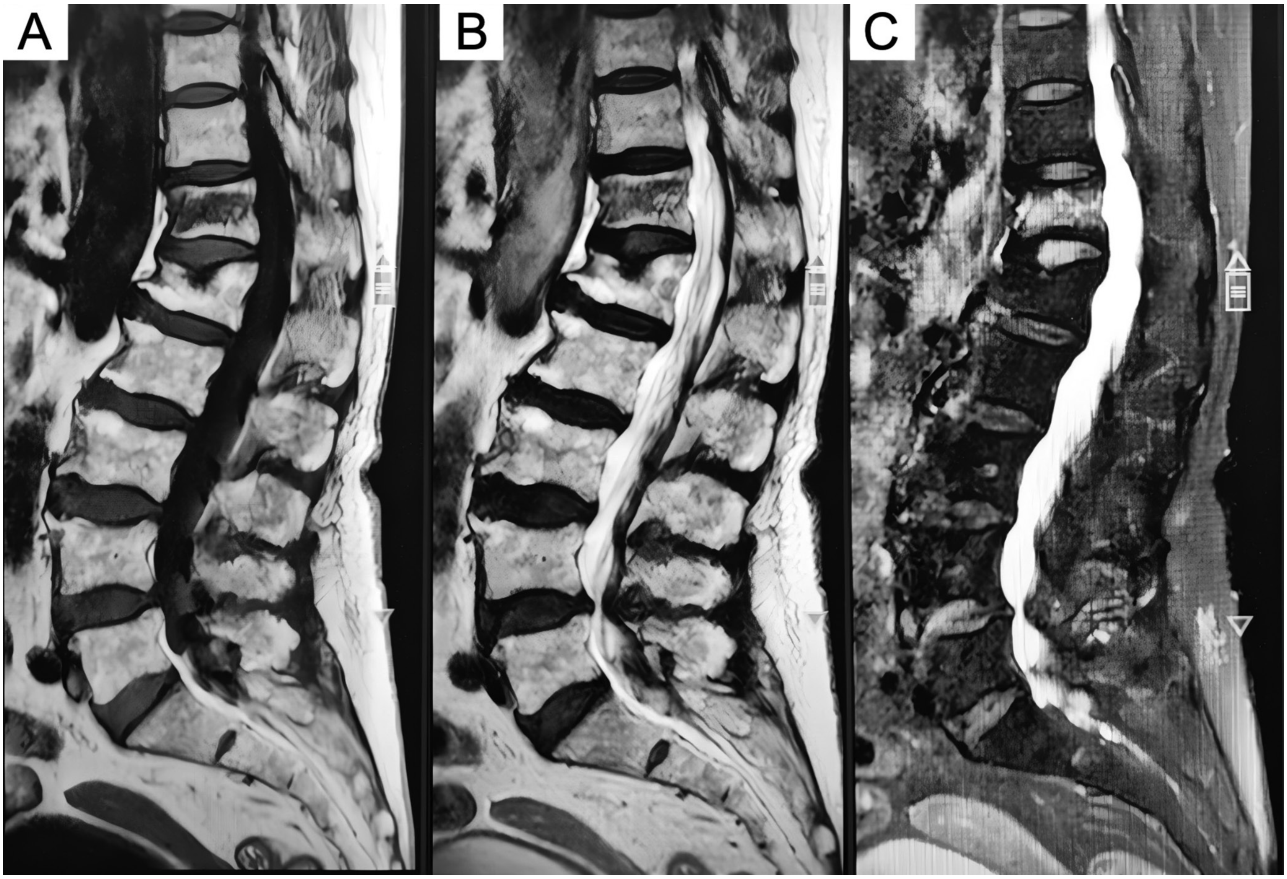

Figure 3. Typical case: preoperative lumbar magnetic resonance imaging. T1 (A) and T2 (B) sequences indicate a compression fracture of the thoracic vertebra 12, an intravertebral bar fracture signal shadow, and a high signal shadow indicative of an evident fracture of pressure fat (C), suggesting vertebral intramedullary edema and confirming a fresh T12 fracture.

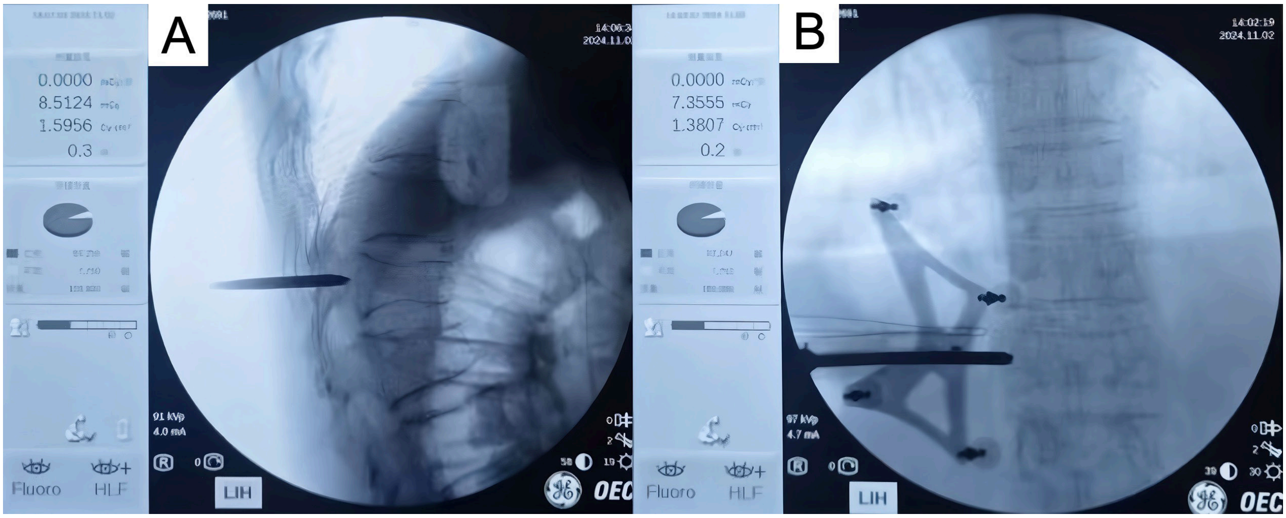

Figure 4. Typical case 1: intraoperative X-ray perspective validation image. (A) Lateral. (B) Anterior–posterior.

surgical plans and simulate training in an intuitive 3D environment and to obtain clear intraoperative navigation information in real time.[27] Currently, MR navigation technology is applied in multiple surgical fields with good development prospects. For the application in neurosurgery, the prospective clinical study performed by Incekara et al.[28] provided a proof of concept for the clinical feasibility of using HoloLens in surgical plans for brain tumors in the operating room. In the field of urology, the study results of Bertolo et al.[29] showed that applying MR technology to robot-guided radical prostatectomy through preoperative MR modeling and real-time intraoperative overlay, and surgeons can also use MR technology to perform urological-related surgeries. With the deepening application of MR technology in surgical procedures, its role in the field of orthopedics, especially in spinal surgery, is gradually being valued.[30–33] Kong et al.[34] utilized AR technology to significantly improve the safety and precision and accuracy of screw insertion. The study results showed that the screw insertion precision and accuracy of the AR navigation group was 97.5%, while that of the free-hand group was 77.5%. Additionally, the linear and angular deviations of the AR navigation group were significantly lower than those of the free-hand group. Edström et al.[35] found that using the MR-guided system can improve surgical accuracy, reduce the risk of complications and revision surgeries, and minimize the amount of radiation to surgeons. Patel et al.[36] applied MR technology to complex spinal deformity corrective surgery, implementing personalized corrective plans through real-time tracking and feedback, and effectively reduced the risk of complications.

In this study, the surgical duration of the MR-guided group (26.00 minutes [26.00–27.75]) is obviously lower than that of the control group (29.00 minutes [27.25–34.25]) ($p < 0.001$). The total number of fluoroscopy of the MR-guided group (26.00 times [25.25–32.75]) is also lower than that of the control group (35.00 times [31.00–41.00]) ($p < 0.05$), and both have statistically significant differences. First, MR navigation headsets can

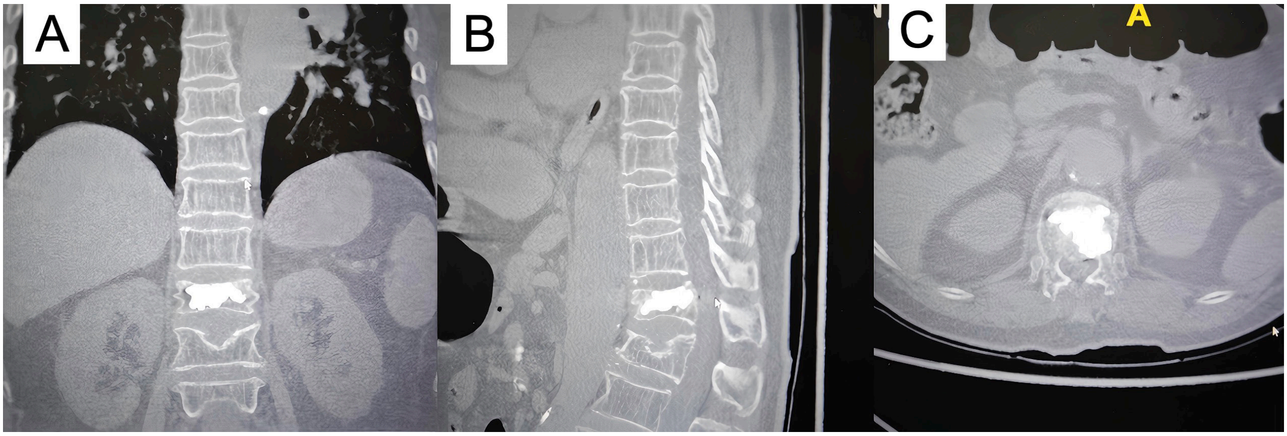

Figure 5. Typical case 1: postoperative CT image of the thoracic spine. (A) Coronal, (B) sagittal, and (C) axial views of postoperative CT images obtained via MR navigation assistance for the PVP of T12 compression fractures. Postoperative CT revealed uniform cement distribution and no leakage. CT = computed tomography; MR = mixed reality; PVP = percutaneous vertebroplasty.

match the patients' 3D CT imaging with the surgical field in real time, without using conventional methods to judge for the fracture morphology and puncture depth under a 2D perspective, enabling surgeons to have a visual and comprehensive understanding of the fractured vertebral body.[37] Second, MR navigation technology can guide the percutaneous needle according to MR-guided visualization and adjust the needle insertion point and angle in real time, without the need for repeated fluoroscopy positioning during surgery, which improves the success rate of the first puncture, reduces the duration of surgery and the number of fluoroscopic exposures, and minimizes radiation exposure for both medical staff and patients.[38]

The results of this study indicated that the VAS scores of the MR-guided group were lower than those of the control group when puncturing to the target location, and the difference was statistically significant. This may be attributed to the fact that the MR navigation-assisted group reduced the pain and discomfort caused to patients by repeated adjustments of the needle position and multiple fluoroscopic exposures. It also decreased the number of times the periosteum surface and muscles were stimulated during the surgery and minimized the damage to soft tissues.[39] The results showed that the ODI scores of patients in both groups were significantly improved postoperatively compared with preoperatively. However, there was no significant difference during the follow-up period ($p > 0.05$). This indicates that the MR-guided technique had good clinical therapeutic effects and application value, and its long-term efficacy was comparable to that of traditional methods. The comparison of postoperative HFV between the 2 groups in this study indicates that the recovery of vertebral height in the MR-guided group is superior to that in the control group; however, there was no statistically significant difference ($p > 0.05$). Wei et al.[40] retrospectively analyzed the clinical efficacy of MR navigation technology and control group surgery and found that the former has certain advantages in improving spinal kyphosis deformity.

Bone cement leakage is a common complication after PVP surgery, and a meta-analysis showed that the bone cement leakage rate after PVP surgery was 54.7%.[10] Although most cases of bone cement leakage were without clinical symptoms, bone cement injected into the spinal canal or nerve roots can lead to catastrophic consequences such as paraplegia.[41] Therefore, reducing the risk of bone cement leakage is crucial for improving the safety of PVP surgery. The results of this study showed that the bone cement dosage in the MR-guided group (6.05 ± 1.93 mL) was higher than that in the control group (4.50 ± 1.96 mL) ($p < 0.05$); however, the MR-guided group (10.00%) had a lower rate of bone cement leakage than the control group (30.00%). It was mild paravertebral leakage in the MR-guided group. The reason for this is that MR navigation technology can improve the precision and accuracy of percutaneous needle positioning and puncture depth control, especially when inserting the needle into the center-edge of the vertebral body with anteroposterior fluoroscopy, and can avoid damage to the upper endplate and can reduce the risk of bone cement leakage due to injured pedicle wall and vertebral body caused by puncture.[42,43]

MR navigation technology shows great potential for development in spinal surgery, but its further application in minimally invasive surgeries, such as PVP, still faces certain challenges and issues. First of all, it is necessary to deal with the complex spinal anatomy, significant tissue deformation, and wide range of motion, while also ensuring the real-time registration and tracking stability during the surgical process.[44] Second, the surgery requires high-standard hardware facilities and a sterile operating environment, which poses high demands on the hospital's software and hardware capabilities.[33] Finally, surgeons need to undergo systematic training to master its application proficiently.[28,45] In addition, the surgery has not yet been clinically validated through large-sample studies with long-term follow-up. Its long-term efficacy and potential risks still need to be further assessed and confirmed. With breakthroughs in computer graphics, artificial intelligence, and other fields, MR navigation technology is expected to be widely used in minimally invasive spinal surgeries in the future.[46] Advances in information technology and intelligent devices have also created conditions for the remote collaboration and large-scale application of MR-guided surgical systems.[47] In the future, with the upgrading of hardware and software, optimization of indications, and accumulation of evidence-based medical evidence, MR navigation technology is expected to become a routine auxiliary tool for kyphoplasty and even more minimally invasive spinal surgeries. It will surely benefit more patients with spinal diseases.

5. Conclusions

MR-guided PVP surgery treatment for OVCF has improvement in terms of surgical duration, the number of punctures, the number of fluoroscopy, the bone cement leakage rate, and pain relief. MR navigation technology can accurately guide puncture operations, improve surgical safety and effectiveness, featuring as a safe, accurate, and minimally invasive innovative technology, and is expected to shorten the learning time for less experienced surgeons to master the PVP surgery technology.

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Ethical statement

This study was performed in line with the principles of the declaration of Helsinki and the approval was granted by the Ethics Committee of General Hospital of Northern Theater Command (No. LSY(2021)025).

Conflicts of interest

The authors have no conflicts of interest to disclose.

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Data availability statement

Data collected and analyzed for the study are available from the corresponding authors upon reasonable request.

Author contributions

YL and AX contributed equally to this study and were responsible for data processing and analysis, work summarization, and the final drafting of articles. YX and HY were responsible for performing the surgery and final review and proofreading. YW and ZW were responsible for reviewing the data and references. LX and HG were responsible for image collection. All authors reviewed the manuscript.

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