Original Article

Minimally Invasive Screw Cement Augmentation in Pedicle Technique (MIS CAPT) for Spine Fixation in Osteoporosis Fragility Fracture and Non-Fracture Patient: Surgical Technique, Indication and 1-year Outcome Evaluation.

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Abstract

OBJECTIVES: The aim of this study is to describe novo technique of cemented augmentation with percutaneous pedicle screws called "Minimally Invasive Screw Cement Augmentation in Pedicle Technique (MIS CAPT)" which can be used with ordinary percutaneous screws in both fracture and non-fracture osteoporotic fragile bone patients.

MATERIALS AND METHODS: Twenty-four patients were enrolled and data of perioperative and early postoperative through 1-year were recorded.

RESULTS: The patients were divided into the non-fracture group (n = 12) and the fracture group (n = 12). Mean ages of patient were over 70 years old. Mean estimated blood loss and the operative time were lower in the fracture group than those of the non-fracture group (107.5 vs. 758.3 ml and 174.7 vs. 405.5 min., respectively). All patients in the fracture group were discharged from intensive care unit within 24 hours, while 25% of the non-fracture were unable. The mean time to start ambulation in the fracture and the non-fracture group was 17.5 and 48.5 hours, respectively. The hospital stay was approximately 7–9 days in both groups. All patients had no postoperative neurological complications or infections. Minor cement leakage (9.4%) was found in the fracture group without any effect on health or outcome. Within 1-year follow-up, no loosening was found in all MIS CAPT screws and in the fracture group, only 2.8-degree loss of kyphosis reduction was presented in the fracture group.

CONCLUSION: It is concluded that MIS CAPT is an effective-versatile minimally invasive spinal fixation technique in osteoporotic or fragility bone conditions. The outcome is excellent in terms of successful operation, minimal complications, and rigid fixation in both fracture and non-fracture elderly fragility bone patients.

Keywords: cement augmentation, fragility fracture, minimally invasive, MIS CAPT, osteoporosis

Osteoporosis is a metabolic bone disease characterized by a reduction in bone mass, alteration of bone microarchitecture, and increased skeletal fragility, which leads to a higher risk of fragility fractures.[1,2] With the growing elderly population worldwide, the management of osteoporotic fragility vertebral fractures has become an interesting and challenging issue.[3] The latest recommendation from Spine Section of the German Society for Orthopaedics and Trauma (DGOU) for the management of osteoporotic vertebral fractures suggests an increasing trend towards spinal fixation in osteoporotic patients.[4] The success of this surgery relies on achieving a solid construction between bone and spinal fixation implant. However, the prevalent complication in the osteoporotic population is the loosening of the bone-screw interface, as the holding power of screws decreases with decreasing bone mineral density (BMD). To minimize this problem, polymethyl methacrylate (PMMA) is commonly used to augment fixation strength by interdigitating with the surrounding trabecular bone and firmly anchoring the screw, resulting in more than twofold increase in pull-out strength. [5–13]

The introduction of cement augmentation pedicular screw fixation was initially designed in 2000 for conventional open surgery. The perioperative and postoperative complications of conventional open surgery in the osteoporotic population, especially in older age groups and individuals with underlying diseases were significantly high.[3,14–17] Therefore, there has been a growing interest in surgical techniques that aim to reduce morbidity associated with open instrumented surgery. Minimally invasive spine (MIS) surgery, along with percutaneous pedicle screw fixation, was introduced and showed less soft tissue trauma, lower postoperative pain, lower blood loss, lower wound infection rates, and faster recovery and ambulation than the previous technique.[18–23] Unfortunately, elderly osteoporosis patients who need percutaneous pedicular screw fixation along with cement augmentation mostly require conventional open surgery.

The MIS technique for cement augmentation with specially designed fenestrated pedicle screws was previously demonstrated to have some advantages in terms of reduced perioperative and postoperative complications and increased pull-out strength in osteoporotic bone. This technique was not only used in osteoporosis fragility fractures but also in other spinal degenerative diseases. However, these screws are not widely available, particularly in Thailand, where they are not currently accessible. [24–34] Therefore, a novo technique called MIS CAPT using available and cost-effective cannulated pedicle screws has been modified for MIS spine surgery.

The aims of this study were to present the new method of minimally invasive spinal fixation technique for elderly osteoporosis and fragility bone patient by using the ordinary percutaneous pedicle screws with cement augmentation, called "MIS CAPT" and evaluate perioperative and 1-year postoperative outcomes in the fracture and non-fracture patients.

Materials and methods

This study received approval from the medical ethics committee of Bangkok Hospital (BHQ-IRB 2023-02-07). A retrospective analysis was conducted on 24 patients of both sexes aged between 50 to 92 years old with osteoporosis and fragile bone who underwent MIS CAPT with and without interbody fusion at Bangkok Hospital between December 2015 and June 2022. A total of 190 screws were implanted, with a minimum of 4 and a maximum of 12 screws per patient.

The indication for cement augmentation in pedicle screw hole was consensus by spine specialist under meta-analysis and evidence from previous studies.[4,35,36] This agreement was the guidance to prevent adverse event of screws loosening, instrument failure leading to reoperation for the patients who had been operated on in our centre.

The patients were divided into two groups by the categories of disease. The first group was patients who had spinal fixation for spinal degenerative disease (non-fracture group), and the second group was patients who underwent the operation to stabilize a fragility spinal fracture with or without osteoporosis (fracture group).

The inclusion criteria were as follows:

For thoracolumbar and lumbosacral fixation (non-fracture group) which has at least 2 of the following.

1. Age more than 70 years old.
2. Severe osteoporosis (BMD < -3.0)
3. History of fragility fracture
4. Kyphotic correction > 15 degrees
5. Degenerative scoliosis correction
6. Reduction of slippage > grade 1
7. At the end vertebra of long fusion from thoracolumbar to lumbosacral junction.
8. Conjunction with anterior reconstruction, lumbar interbody fusion.
9. Revision of loosening pedicle screws.
10. Metastatic spine fixation.
11. Patients considering risk of screw loosening: morbid obesity (Body Mass Index: BMI >35), chronic steroid use, Parkinson disease, seizure, uncontrollable movement, chronic kidney disease, metabolic bone disease that affects bone strength, poor compliance, not following post-operative recommendations.

For osteoporotic and fragility vertebral fracture (OVF) type 3 or above [4] which has at least 1 of the following (fracture group).

1. Age more than 70 years old.
2. Severe osteoporosis (BMD < -3.0)
3. History of other fragility fracture
4. Kyphotic correction > 10 degrees.
5. Non-union with spinal cord compression
6. Unable to restore the anterior column at the fracture site.
7. Multilevel fracture which needs long-construct fixation.
8. Patients considering risk of screw loosening: morbid obesity (BMI >35), chronic steroid use, Parkinson disease, seizure, uncontrollable movement, chronic kidney disease, metabolic bone disease that affects bone strength, poor compliance, not following post-operative recommendations.

The exclusion criteria were as follows:

1. Patients with a follow-up period of less than 1 year postoperatively.
2. Patients with fragility spinal fractures or other spinal diseases who can be treated effectively using non-operative treatment.

Surgical techniques

1. Patient positioning

Patient is positioned with proper support for the chest and pelvis to ensure that the operating table is radiolucent in both planes. Additionally, the operating table should facilitate unrestricted movement of the C-arm over the surgical site in both planes.

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2. Identifying and preparing the perfect pedicle screw placement by navigation system

The navigated antenna was placed on the patient's spine, and the intraoperative O-arm (Medtronic) was used to capture a three-dimensional (3D) image of the spinal column. Using the navigated ball-tip-probe, the ideal entry points for the pedicles were estimated with a marking pen, and the incision plans were aligned in a straight line.

Stab incision, screws hole preparation and guide wire insertion

A small stab incision was made for the initial pedicle screw entry point. Blunt dissection of the soft tissue and paraspinal muscles was performed deeply to pedicle entrance. The navigated awl-tip tap was utilized to create the pedicle screw tunnel, and the estimated plane of the pedicle screws was saved in the navigation system. Subsequently, a navigated cannulated Jamshidi's needle was inserted into the same pedicle tunnel followed by the guide wire according to the previously saved plane. After removing the cannulated Jamshidi needle, the guide wire was left in place. These steps were repeated for all the involved pedicles.

3. Placement of vertebroplasty trocar to right depth, preparing for cement injection under real-time fluoroscopy.

To obtain a lateral view of the vertebral column, the fluoroscope was brought to the operative field under the table. The side-opening vertebroplasty needle assembly (Vertecem V+ system, DePuy-Synthes, USA) which consists of outer-middle-inner pieces was used for cement injection. The outer sleeve assembled with the middle sleeve (trocar) was inserted over the guide wires. The needle's tip was advanced until it reached the anterior half of the vertebral body (Figure 1A,1B), and then all the guide wires were removed. Note: all pedicle screws must be prepared for immediate placement after cement injection. 3D intraoperative computerized tomography (CT) images may be obtained before cement injection to ensure all vertebroplasty needles are not outside each pedicle.

4. Cement injection 360 degrees in the screw hole under real-time fluoroscopy

The cement was mixed to ensure that the consistency of the cement was suitable for injection. The cement was transferred into 1-2 ml syringes and filled into a side-opening inner needle (cement injector) (Figure 2A). The middle sleeve (trocar) was removed from the spine. The cement injector (inner needle) was inserted into the outer sleeve and positioned correctly to allow for the perpendicular flow of cement through the needle assembly. The cement was carefully injected while the real-time fluoroscope was monitored during cement delivery to ensure no cement leakage to dangerous areas. The needle was continuously rotated 360-degrees to achieve a symmetrical ball-like shape of the cement mantle (resembling a growing cloud shape) to get an optimal cement mantle all around the screw hole. If the cement flowed into a dangerous direction, the injection force was promptly stopped. Note: the average amount of cement typically ranges from 1 ml to 1.5 ml for each pedicle.

5. Repositioning of guide wire and pedicle screw insertion

After completing the cement injection process in each pedicle, the inner sleeve (cement injector) was removed, and the guidewire was reinserted into the vertebral body over the outer sleeve to ensure the most accurate and it was an efficient method for pedicle screw placement. Thereafter the outer sleeve was removed while the guidewire was left within the pedicle. The prepared cannulated pedicle screw was inserted over the guidewire under fluoroscopic or navigated control to get the best position. The guidewire was removed after the pedicle screw was placed. (Figure 2B). Note: This technique was compatible with all designs of MIS percutaneous cannulated pedicle screws.

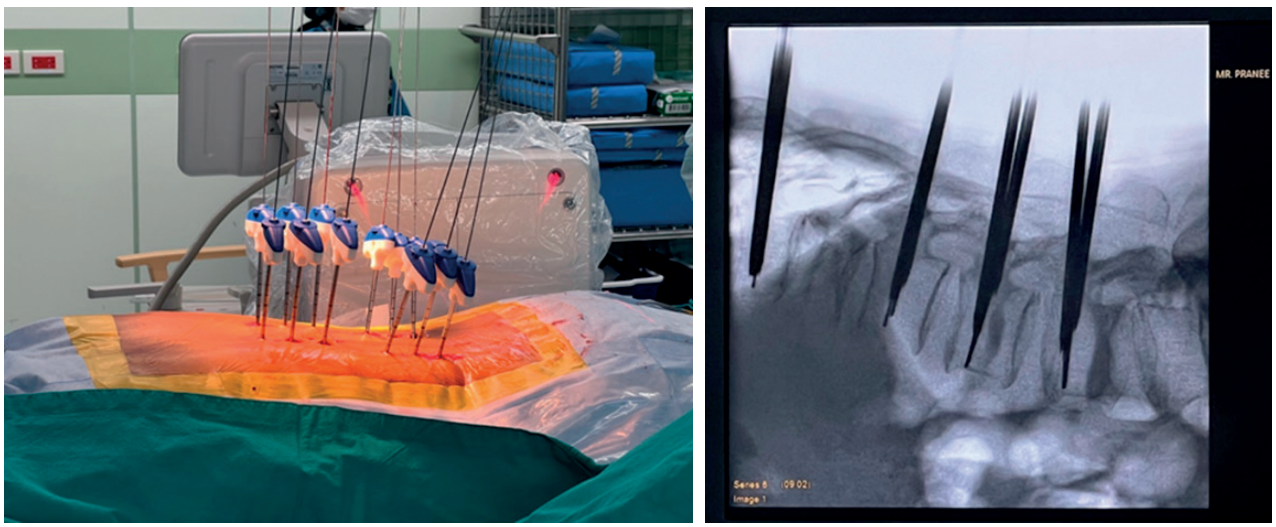

Figure 1: Multiple vertebroplasty needles were inserted over guide wire (1A). Intraoperative fluoroscopy shows the direction and depth of the vertebroplasty needle over the guide wire in the vertebral body (1B).

6. Finalized and complete screws construction

After all pedicle screws were placed, intraoperative CT images (O-Arm, Medtronic, USA) were taken to ensure that the screws and cement were in the correct positions. After confirming the positions of the screws and waiting until the cement was hardened, Screw towers' alignment was adjusted, and a rod measuring device was used to determine the appropriate rod length. Then the contoured spinal rods were inserted percutaneously from cephalad to caudad. Gentle reduction force may be applied to achieve optimal spinal alignment and vertebral height. Finally, the instruments were in complete assembly. All screws, towers, and rods holder were removed. Bleeding was checked and the skin incision was closed. Note: In osteoporotic or fragility vertebral fracture cases, the cement injection into the fracture vertebral body (vertebroplasty procedure) without screws may be done in the latest step for immediate stabilization of the fracture site.

After the surgery was finished, all patients underwent an x-ray of the affected spine in anteroposterior (AP) and lateral views compared to the previous x-ray before surgery (Figures 3A, 3B).

Perioperative data

The estimated blood loss, operating time, and complications were monitored throughout the procedure. Any instances of PMMA leakage during the injection process if present were documented. The x-ray was monitored for 1 year after operation in each patient to evaluate the screws loosening and spinal alignment.

Clinical outcomes

Clinical evaluations were conducted by reviewing in-patient records, which included data on first-time ambulation, intensive care unit (ICU) stays, hospital stays, neurological complications, wound infections, and reoperations.

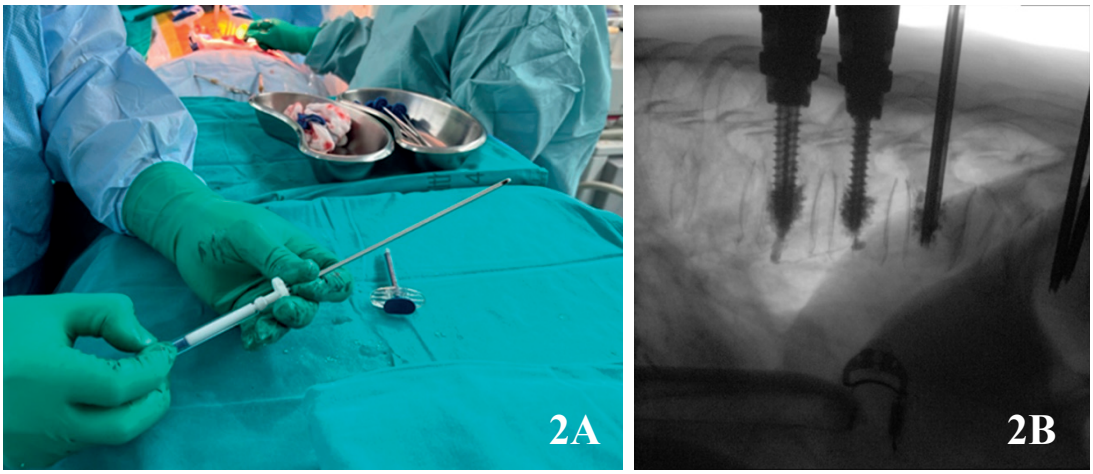

Figure 2: The side-opening inner sleeve (cement injector) allows flow of cement in 360-degree perpendicular direction (2A). Cement was injected into the vertebral body under continuous fluoroscopic control. Guide wires were replaced, and screws were inserted (2B).

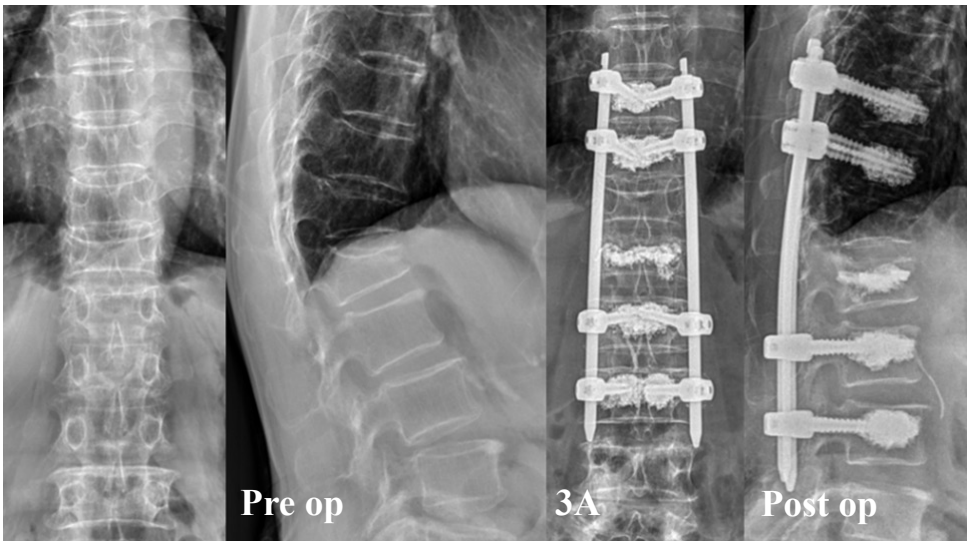

Figure 3: The spinal x-ray of a patient before (3A) and after (3B) the MIS CAPT operation.

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Radiologic assessment

Radiological images were acquired preoperatively, postoperatively, and at 6 and 12 months after surgery. The radiographic evaluation involved the use of x-rays and CT scans to assess screw loosening and the progression of kyphosis in fixation level. Screw loosening was defined as the presence of a radiolucent line around the screws of at least 1 mm or noted screw migration at the 12-month follow-up.

Statistical analysis

Statistical calculations were conducted using STATA version 15. Categorical data, including screw loosening, cement leakage, neurological complications, infections, and reoperation, were expressed as percentages or prevalence. Continuous data, such as estimated blood loss, operative time, time of start ambulation, hospital stays, and degree of kyphosis reduction loss were expressed as mean or median.

Results

The demographic results are presented in Table 1. A total of 24 patients were subjected to spinal fixation with MIS CAPT from 2015 to 2021. Demographic data show mean ages were over seventy years old, while the non-fracture group and the fracture group were 73.0 and 74.8 years old, respectively. All patients consisted of 18 females and 6 males, with more females than males in both groups. Majority of the fracture group had a BMI lower than 25 but in the non-fracture groups patients had a body mass index both lower and above 25 within the same distribution. Elderly people were operated on in both groups, therefore, both also had several concurrent diseases that were not directly affected by our operation.

For patients who were operated on for fracture reasons, the mean BMD; T-score is -3.3. In 12 patients of the fracture group, 9 of them had a BMD of less than -2.5 (osteoporosis) and 3 of them had a BMD between -1.0 and -2.5 (osteopenia). In the non-fracture group, not all patients had BMD measurements before surgery. Nevertheless, the data show none of the patients have normal BMD measurements. (Table 1)

Table 1: Demographic data of 24 patients

Variables	Non-fracture (n = 12), (n(%))	Fracture (n = 12), (n(%))
Age		
Mean	73.0	74.8
Median (min - max)	76 (52 – 80)	74.5 (61 – 92)
Gender		
Female	10 (83.3)	8 (66.7)
Male	2 (16.6)	4 (33.3)
Body Mass Index		
≤25	6 (50.0)	8 (66.7)
>25	6 (50.0)	4 (33.3)
Mean	25.1	23.7
Median (min - max)	23.9 (17.1 – 29.5)	23.8 (17.1 - 31.7)
Concurrent Diseases (note: many patients have more than one disease)		
Hypertension	5	10
Diabetes Mellitus	3	3
Dyslipidemia	3	7
Parkinson	1	0
Obstructive sleep apnea	1	0
Dilated Descending Aorta	1	0
Non Hodgkin Lymphoma	1	1
Coronary heart disease	0	1
Chronic Kidney disease	0	1
Normal pressure hydrocephalus	0	1
Hypothyroidism	0	2
Bone mineral density (BMD)		
Mean	N/A	-3.3
Median (min - max)	N/A	-3.7 (-1.2 to -5.6)
Normal BMD	0	0
Osteopenia -1.0 to -2.5	3 (25.0)	3 (25.0)
Osteoporosis <-2.5	4 (33.3)	9 (75.0)
No data	5 (41.7)	0

N/A = not available

Table 2 shows the parameter outcome in total patients, including all categories that underwent MIS-CAPT (Table 2). In the non-fracture group, the estimated blood loss and operative time varied due to the complex technique required to correct degenerative spine surgery. However, in the fracture group, the estimated blood loss and operative time were slightly consistent and low, with approximately 100 ml and 3 hours, respectively. The same as the time needed in the ICU, 75% of the non-fracture patients were discharged from the ICU within 24 hours, compared to 100% of the fracture group. This procedure is minimally invasive so the first-time ambulation when patients were able to sit on bed was short, especially in the fracture group, with an average of only 17.5 hours after surgery. The mean hospital stay was about 1 week in most patients (2 patients were admitted longer than usual due to other health reasons). No neurological complications or infections were found in either group of patients.

No cement leakage was noticed in the non-fracture group, but nine of the ninety-six screws in the fracture group minimal cement leakage outside the vertebral body was noticed, which did not need correction and did not result in any serious complications. In the fracture group, none of the patients underwent reoperation within a 1-year period, but one of the non-fracture patients needed re-operation on his spine at different levels of the operation site. The efficacy of bone-cement-metal stability can be estimated by the number of screws loosening and the degree of kyphosis reduction loss at the fixation level. Among the 190 screws performed by MIS CAPT technique, there were no instances of screw loosening observed during the 1-year follow-up period and only 2.8 degrees' kyphosis reduction loss at the 1-year follow-up in fracture patients was found.

Table 2: Perioperative and postoperative parameters outcome

Variables	Non-fracture (n = 12), (n(%))	Fracture (n = 12), (n(%))
Total screws	94	96
Estimated blood loss (ml)		
Mean	758.3	107.5
Median (min - max)	815 (180 – 1500)	85 (20 – 300)
Operative time (min)		
Mean	405.5	174.7
Median (min - max)	443 (172 – 660)	172.5 (135 – 215)
Discharge ICU		
Within 24 hours	9 (75.0)	12 (100)
Longer than 24 hours	3 (25.0)	0
Time of start ambulation (hours)		
Mean	48.5	17.5
Median (min - max)	50.9 (21.2-72)	19.8 (9.1-41.3)
Hospital stays (days)		
Mean	8.8	6.9
Median (min - max)	6 (2 – 30)	7.0 (2 – 32)
Cement leakage screws		
No	94/94 (100)	87/96 (90.6)
Minor cement leakage	0	9/96 (9.4)
Major cement leakage	0	0
Neurological complications		
No	12 (100)	12 (100)
Yes	0	0
Infections		
No	12 (100)	12 (100)
Yes	0	0
Re-operation		
No	11 (91.6)	12 (100)
Yes	1 (8.4)	0
Screw loosening at 1 year		
No	94/94 (100)	96/96 (100)
Yes	0	0
Degree kyphosis reduction loss		
Mean	N/A	2.8
Median (min - max)	N/A	2.4 (8.0-0.6)

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Discussion

The present study showed that most of the patients underwent MIS CAPT were old and had a risk of poor bone quality. Mean ages were more than 70 years old in both groups and complied to the need of a special technique of bone fixation for preventing screw loosening and for undergoing minimally invasive technique to reduce complications from open surgery. Many patients decide not to undergo surgery but rather to use medication and rehabilitation. However, they may face poor quality of life and mental health issues due to chronic pain. Bone problems affected more females than males. This is in accordance with the fact that women suffer more from osteoporosis and fragility fractures than men.37 Half of our operated patients need spinal fixation for degenerative spinal disease, which comes from many causes, such as spondylolisthesis, scoliosis, and revision back surgery. Most patients had concurrent diseases such as hypertension, diabetes mellitus, and dyslipidemia. The success rate of the operation, however, seems not to be related to any of these diseases. The BMD for the fracture group was an average of -3.3, and patients in both groups did not have normal BMD, which indicated that many patients in our study suffered from severe osteoporosis.

All patients in our study had indications to perform spinal fixation with pedicle screws for both fracture and non-fracture reasons. Even though in many cases of osteoporosis fracture can be treated conservatively, some certain types of fragility fracture can be predicted to have the poor outcome without surgery. The surgical intervention in fragility spinal fracture was proven to prevent chronic pain, deformity, and debilitated condition in elderly patients. Given that most of the patients were in the old age group with osteoporosis or fragility bone, there was greater risk of complications from operations. The special technique for minimizing soft tissue trauma as minimally invasive surgery and for making rigid bone fixation to prevent screws loosening was therefore designed.

In our study, we present a novel surgical technique for minimally invasive percutaneous pedicle screw fixation with cement augmentation, utilizing conventional non-fenestrated percutaneous pedicle screws. This technique is compatible with any cannulated pedicle screw system in our country and can be performed using C-arm fluoroscopy with or without O-Arm navigation guidance. The screw used in this procedure was a conventional MIS cannulated pedicle screw, which is available nationwide. This procedure was different from previous studies in which fenestrated pedicle screws, expandable screws, hydroxyapatite augmented screws and transdiscal pedicle screws fixation were used.[38–41] The injection of cement along with the pedicle screw made the strength of fixation between the bone-screw-cement interface much better. Previous biomechanics data of open cement augmentation in pedicle screws hole showed that the pull-out strength was higher, up to 348%.[42] Our technique, did not measure in mechanical strength, yet had zero loosening of screws within a year, indicating that the strength must be high.

This technique shows many advantages since it causes minimal complications after surgery and the patients are kept for a short duration in the hospital after surgery. Previous data showed that using conventional open fixation techniques in elderly patients led to more complications, such as post-operative infection, a long hospital stay, and a slow recovery.[43] Additionally, risks for elderly patients from prolonged anesthesia, bleeding, and soft tissue damage were high leading to patient weakness. Our technique shares short operation time, minimal bleeding, and minimally invasive strategies that have a positive effect on the patient's overall health status. All these benefits make rapid recovery for elderly patients, especially those with fragility fractures or spinal disease. Moreover, the patient's pain score was rapidly reduced within a few hours, corresponding to a short time of first ambulation. One of the major advantages of our technique is that all poor bone patients had zero screws loosening after a 1-year follow-up period. The rigid bone-cement-screws interface has a direct effect on maintaining the spinal alignment, which shows a small increasing degree of kyphotic angle in a one-year follow-up.

There is a consideration that only a single orthopedic surgeon performed the operation in this study. Thus, the outcome was minimally variable due to surgical procedure, technique, and skill.

Conclusion

The modified cementation technique for MIS percutaneous pedicle screw fixation called Minimally Invasive Screw Cement Augmentation in Pedicle Technique (MIS CAPT) is a safe and effective approach with minimal complications, especially in elderly osteoporotic or poor bone quality patients with and without fracture who need rigid spinal fixation within the minimally invasive strategy. The utilization of conventional, non-fenestrated MIS pedicle screws makes this technique versatile nationwide. The risk associated with PMMA leakage was acceptable and cannot be overcome by the several beneficial aspects of this procedure, especially in elderly patients who have osteoporosis and fragile bones.

Conflict of interest

The authors declare no conflict of interest.

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