

Clinical application of a pedicle nail system with polymethylmethacrylate for osteoporotic vertebral fracture

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Abstract The instrumentation of the osteoporotic spine may sometimes result in failure due to the loosening or pullout of the conventional pedicle screw. Moreover, augmentation of screws with polymethylmethacrylate (PMMA) has risks of complications. We developed a new and original pedicle nail system with PMMA for osteoporotic vertebral fractures. A clinical evaluation of this novel pedicle nail system utilized in patients with an osteoporotic vertebral collapse was performed to determine the effectiveness and safety of this technique. Thirty-four elderly patients who suffered from osteoporotic compression fractures were treated by posterolateral fusion using the pedicle nail system. The mean follow-up period was 37 months. Of the 25 patients with neurological symptoms, two patients improved two stages at the Frankel level. Fifteen patients improved one stage at the Frankel level, and eight other patients improved, however, their improvement did not exceed a Frankel level. Nine cases with neuralgia symptoms improved from 4.4 to 2.2 points on average on the Denis pain scale ($p < 0.01$). The fusion rate was 94% as determined by X-rays of flexion and extension, and the correction of the compression fracture site was maintained well. A pedicle nail system stabilizes the spinal column with osteoporosis and reduces the

instrumentation failure. The technique for the insertion of the pedicle nail reduces complication from cement augmentation. The authors speculate that the strategy using the pedicle nail system for osteoporotic spine may be effective and safe when the surgery is performed through a posterior approach.

Keywords Osteoporosis · Pedicle screw · Compression fracture · PMMA · Spinal fusion

Introduction

Osteoporotic spinal compression fractures have been described as stable fractures and they are usually well managed with no operative treatment [18]. However, vertebral collapse and delayed union might occur, and paraplegia and persistent pain are caused by the abnormal movement of the fractured part or displaced bone fragments into the spinal canal [12, 13, 24]. Several treatment options have been reported for these patients, such as the anterior procedure [11, 19], posterior procedure [15], and a combined anterior and posterior procedure [22]. Loosening and pullout of the conventional pedicle screw may occur in the posterior decompression and fusion because the fixation strength of the pedicle screw is inadequate [6, 20, 26].

Augmentation of the screw with bone cement is one method to solve this problem [26]. There are potential problems, such as a risk of cement leakage outside the vertebral body and a difficulty of removing the fixed screw if there are complications after the initial surgery.

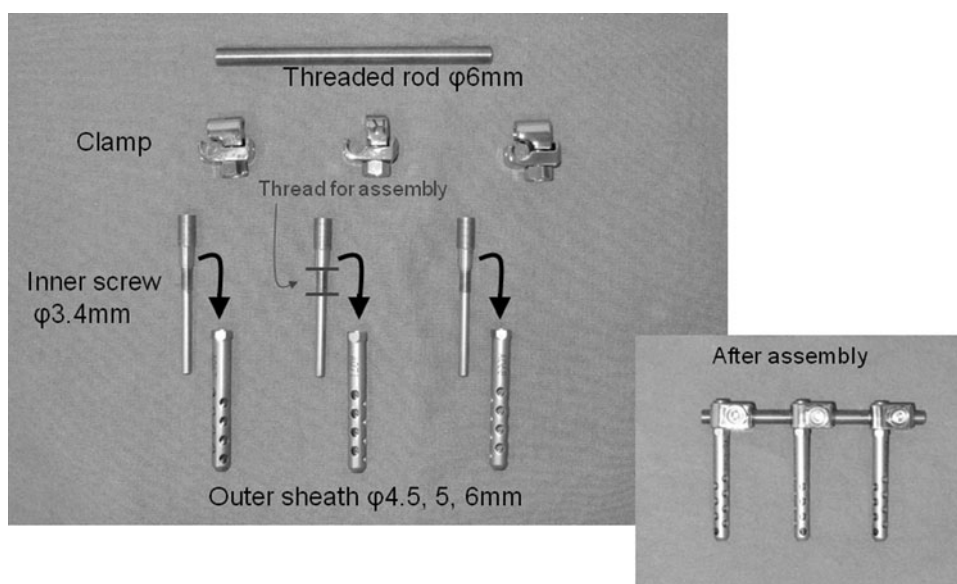
We developed a new and original pedicle nail system (Japan Patent No. 3846698, Pedicle Nail System, Nakashima Medical, Okayama, Japan) to solve the risk of cement leakage and the difficulty of removing the fixed nails. The pedicle nail system (Fig. 1) consists of the

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Fig. 1 Construction of pedicle nail system. The pedicle nail consists of an outer sheath and an inner screw. The outer sheath has a cylinder shape with some holes which act as an anchor for the PMMA. Its shape enables the nail to be easily inserted, and the layer of the PMMA thus becomes like the stem of a total hip replacement system. The inner screw is an internal component which has a thread; therefore, it is possible to remove the inner screw easily



pedicle nail,¹ which has an inner screw and outer sheath, clamps and rods.

Surgical technique of the pedicle nail system (Fig. 2)

The patient is situated in a prone position. The surgical procedure is performed using a paraspinous approach or a posterior approach. The pedicle nail procedure is conducted as follows: Under a fluoroscopic guide, a hole for the nail is made in the pedicle by a probe. A drill or shape tool should not be utilized to affect this expansion. The hole is expanded little by little with the special 4.5–6.5-mm probes in such a way that the cortex of the pedicle not be damaged. Once the nail hole is completed, a sounder is utilized to confirm whether or not the cortex of the pedicle was damaged during the procedure. A plug is then inserted to stop the bleeding. After all the holes are made, about 2 ml of prepared polymethylmethacrylate (PMMA) bone cement (CEMEX, TECRES, Verina, Italy) is injected into the vertebral holes using an injection cannula. Thereafter, the pedicle nails, the inner screw and outer sheath combined, are inserted into the holes pressing the PMMA. Subsequently, a posterolateral bone graft is made with autogenous iliac bone. Then, the rods and clamps are assembled. When the patient has a vertebral cleft, vertebroplasty is performed with hydroxyapatite sticks prior to the insertion of the pedicle nails with PMMA.

All surgical treatment using the pedicle nail system were performed after informed consent was obtained from the patients and their families.

¹ The pedicle nail has been called novel pedicle screw (NPS) in other research [23]. We are using pedicle nail in this report to alleviate any confusion between the pedicle nail or NPS and conventional pedicle screws.

Postoperative management

The patient is allowed to turn in bed on the first day after the operation. On the third day, the patient is allowed to stand with aid of a tilt table. The patients are encouraged to stand and walk with a TLSO (corset) on the seventh postoperative day. The patient is to wear the TLSO for 3 months as prescribed.

Materials and methods

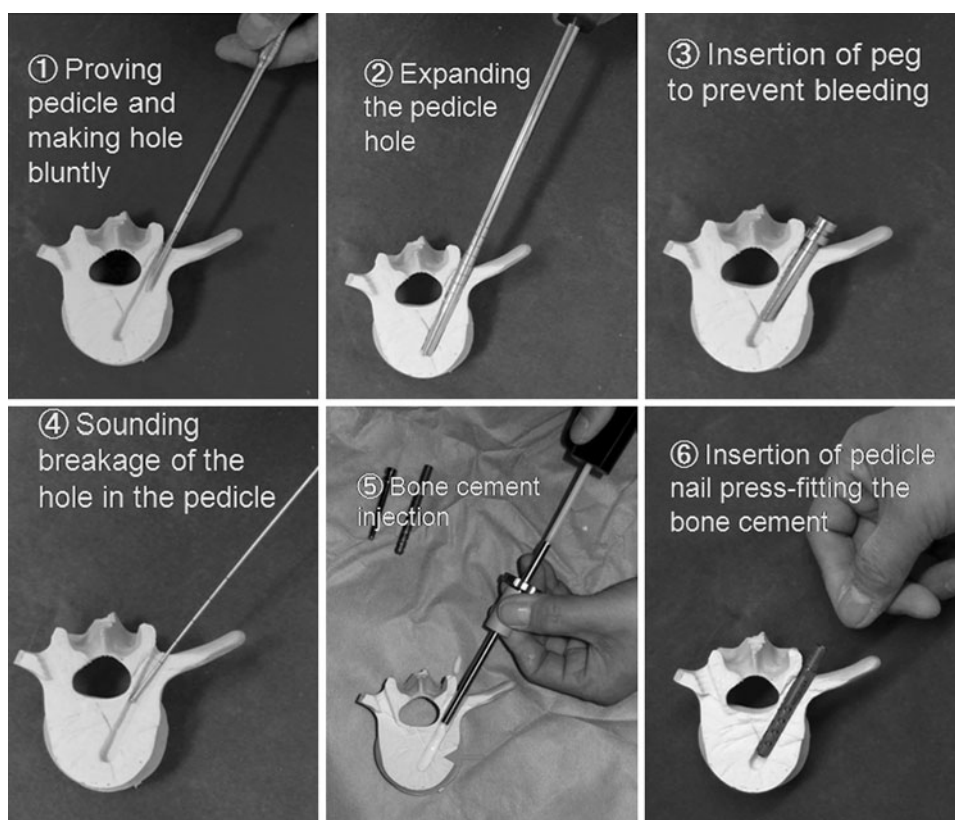
From 2000 to 2008, a total of 34 patients who suffered from paraplegia and/or persistent pain from osteoporotic compression fractures were treated by posterolateral fusion using the pedicle nail system. The patients consisted of 10 males and 24 females with an average age of 77 years (range 67–89 years). The mean follow-up period was 37 months (range 12–69 months). The level of fracture was Th9 in three patients, Th10 in two patients, Th11 in two patients, Th12 in 12 patients, L1 in eight patients, L2 in one patient, L3 in five patients and L4 in five patients. Three patients in this study had more than one level of fracture.

Ten patients were diagnosed with severe wedge fractures. Twenty-four patients were diagnosed with delayed union with neural deficits and an intervertebral cleft in the fracture site. Twenty-four patients were injured by a fall, two patients were hit by a bicycle, one patient fell down the stairs and one patient was injured by lifting something. Six patients had no trauma about the compression fracture.

Clinical evaluation

The neurological status of each patient was assessed using the Frankel classification. They were evaluated prior to the

Fig. 2 Surgical technique of the pedicle nail system



operation and again during the 12 months after the operation. Patients' pain was evaluated with the Denis pain scale [4].

Radiographic evaluation

The fusion was judged with X-rays of flexion and extension positions at 6 months after the operation. Fusion was evaluated as a success when a difference of the angle between the images was within 5° as determined by overlapping the flexion and extension X-rays. Any loosening of the pedicle nail was judged with a CT or X-rays at 6 months after the operation. Loosening was judged by the presence of any clear zones in a nail's surroundings. Any pullout of the nails and additional compression fractures of adjacent vertebrae were checked utilizing X-rays at all follow-up examinations.

Statistical analysis

The preoperative and postoperative pain score was analyzed with paired *t* test using Stat View statistical software (Version 4.02, ABACUS Concepts, Berkeley). Statistical significance level was defined as $p < 0.01$.

Results

The clinical results are summarized in Table 1. The fusion levels observed were one in 3 patients, two in 26 patients, 3

in 3 patients and 5 in 2 patients. Nine patients were treated by posterolateral fusion using the pedicle nail system, 8 patients had previously undergone vertebroplasty by PMMA, and 16 patients had undergone augmentation with hydroxyapatite sticks and posterolateral fusion by the pedicle nail system.

Clinical evaluation

Of the 25 patients with neurological symptoms, two patients improved two stages at the Frankel level. Fifteen patients improved one stage at the Frankel level. There was also improvement in eight patients; however, their improvement did not exceed a level at the Frankel level. There were no patients who deteriorated further after the procedure. Nine cases composed of neuralgia symptoms improved from 4.4 preoperative to 2.2 points postoperative on average using the Denis pain scale ($p < 0.01$).

Radiographic evaluation

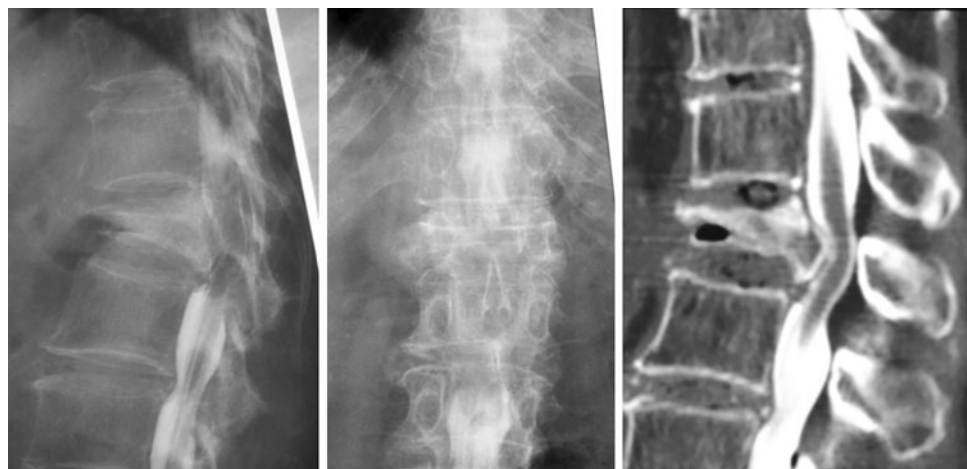
The fusion rate was 94% (32 cases) as determined by X-rays of flexion and extension, and the correction of the compression fracture site was maintained well. No pullout or cutout of any pedicle nails occurred. Clear zones around nails were found in only 6 nails (4%) of the 179 total nails inserted. A compression fracture of adjacent vertebrae was

Table 1 Clinical data for patients undergoing pedicle nail system

Patient no.	Age	Sex	Mechanism of injury	Chief complaint	Frankel grading/PreOP–PostOP	Danis pain scale/PreOP–PostOP	Fixation level	Bone union	Vertebroplasty	Posterior decompression	Complication
1	77	M	No trauma	Paraplegia	C–C		L2–L4	(+)	PMMA/Pre OP		
2	79	F	Fall	Paraplegia	C–C		T8–T10	<–>	HA	–	Late collapse of implanted caudal vertebra
3	76	F	Fall	Paraplegia	C–C		T7–T11	(+)	(–)		
4	84	F	Fall	Paraplegia	C–D		T11–L1	(+)	PMMA/Pre OP		
5	73	F	Fall	Paraplegia	C–D		L3–L5	(+)	(–)	–	
6	78	M	No trauma	Paraplegia	C–D		T11–L4	<–>	HA		Loosening of the pedicle nail
7	85	F	No trauma	Paraplegia	C–D		T10–T12	(+)	HA		
8	73	F	Fall	Paraplegia	C–D		T11–L1	(+)	PMMA/Pre OP		
9	74	F	Fall	Paraplegia	C–D		T10–T12	(+)	(–)		
10	79	F	Fall	Paraplegia	C–D		T11–TL1	(+)	HA		
11	73	M	Fall	Paraplegia	C–D		T12–L2	(+)	HA		
12	82	F	Fall	Paraplegia	C–D		T8–T10	(+)	(–)	–	
13	78	M	Fall	Paraplegia	C–D		T11–L1	(+)	HA		
14	85	F	No trauma	Paraplegia	C–D		T12–L2	(+)	HA		
15	89	F	Fall	Paraplegia	C–E		T11–L1	(+)	HA		
16	73	F	Fall	Paraplegia	D–D		T11–L1	(+)	HA		
17	79	M	No trauma	Paraplegia	D–D		L2–L4	(+)	HA		
18	70	F	Fall	Paraplegia	D–D		T11–L1	(+)	PMMA/Pre OP		
19	74	M	Fall	Paraplegia	D–D		T12–L2	(+)	HA		
20	67	M	Fall	Paraplegia	D–D		T12–L5	(+)	(–)		Failure of clamp
21	80	F	Fall	Paraplegia	D–D		T12–L2	(+)	(–)		
22	78	M	Fall	Paraplegia	D–E		L3–L5	(+)	HA		
23	76	M	Lift up	Paraplegia	D–E		T12–L2	(+)	HA	–	
24	72	F	TA by bicycle	Paraplegia	D–E		L4–L5	(+)	(–)	–	
25	80	F	No trauma	Paraplegia	D–E		T11–L1	(+)	PMMA/Pre OP		
26	78	F	TA by bicycle	LBP	E–E	5–2	T12–L2	(+)	HA		
27	77	F	Fall	LBP	E–E		T9–T12	(+)	PMMA/Pre OP		
28	69	F	Fall	LBP	E–E	4–2	T11–L1	(+)	PMMA/Pre OP		
29	79	F	Fall	LBP	E–E	4–2	L3–L5	(+)	PMMA/Pre OP		
30	77	F	Fall	LBP	E–E	4–2	L1–L3	(+)	HA		Cement leakage
31	73	M	Fall off	LBP	E–E	5–2	L3–L5	(+)	HA		
32	88	F	Fall	LBP	E–E	5–3	T11–L1	(+)	(–)		
33	72	F	Fall	LBP	E–E	4–2	T12–L1	(+)	(–)		
34	70	F	Fall	LBP	E–E	4–2	T12–L2	(+)	(–)		

LBP low back pain, PMMA/Pre OP polymethylmethacrylate/preoperation, HA hydroxyapatite

Fig. 3 Myelography and CT of an 85-year-old woman with L1 fracture. Myelography (*left*) shows both a vertebral collapse and severe neural compression by the posterior wall of the L1 vertebra. Computed tomography (*right*), which was taken after myelography shows severe neural compression



observed in two patients. An outflow of bone cement outside the vertebral body occurred in one patient but fortunately no adverse symptoms occurred. A nail and clamp came off in one patient. There were no cases of pulmonary infarction or rapid decrease in blood pressure due to complications involving the bone cement that was utilized.

Case report

The patient was an 85-year-old woman who experienced back pain without any event. She had suffered from the back pain and weakness of her lower legs for 3 months. At initial presentation, she could not walk or sit due to the pain. She had grade 2 muscle weakness in her lower extremities as measured by a manual muscle test and sensory disturbance below the level of L1. Radiographs and computed tomography that were taken after myelography (Fig. 3) and an MRI (Fig. 4) showed vertebral collapse with a vertebral cleft and severe neural compression by fragments of L1.

We performed a Th12–L2 posterior fusion using the pedicle nail system, and we also performed a transpedicular vertebroplasty of L1 with hydroxyapatite sticks. She could walk without a cane at 8 months after surgery. Thirteen months after surgery, bone union was evident in A–P and lateral radiographs (Fig. 5) (upper middle and left) without pedicle nail loosening. Postoperative CT (Fig. 5) (upper right and lower) shows no bone cement leakage. At that time, the fusion had been completed as determined in the radiographs and computed tomographs.

Discussion

Surgical treatment of the osteoporotic spine is difficult and the osteoporotic spine is associated with a high rate of screw pullout due to poor bone quality [6, 20]. Therefore,

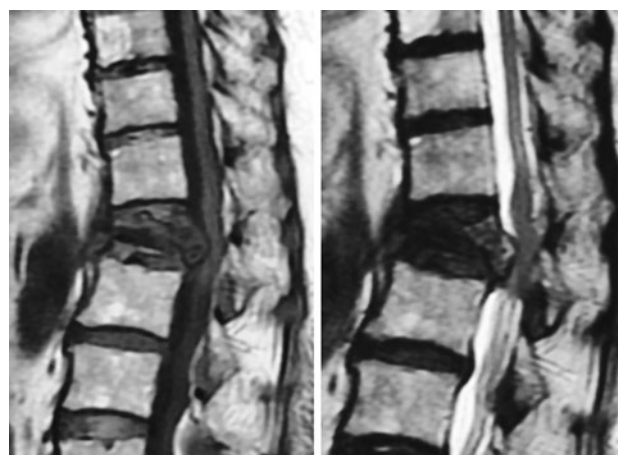
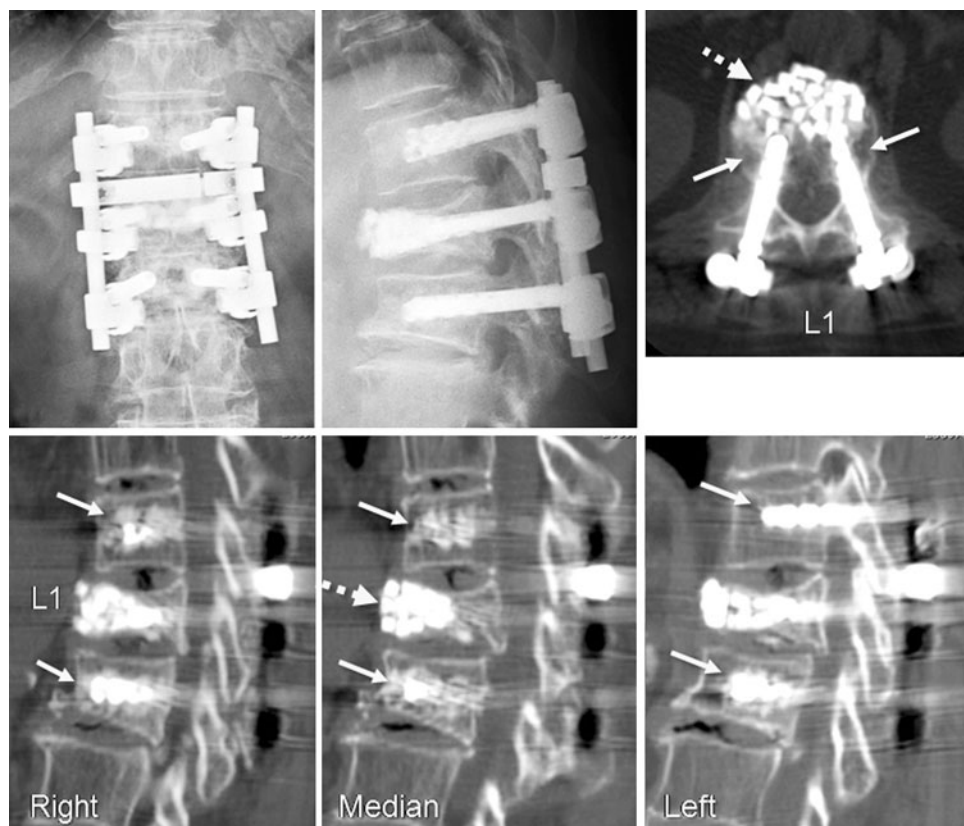


Fig. 4 Preoperative MRI. T1-weighted (*left*) and T2-weighted (*right*) MRIs also show severe neural compression

cement augmentation of pedicle screws could be used in patients with a severely osteoporotic spine [26]. This augmentation by injecting bone cement shows increasing fixation in the osteoporotic spine [2, 5, 7]. However, screws have their problems.

Takigawa et al. [23] reported significant findings in laboratory pull-out and cyclic loading tests for the pedicle nail and control screw in 18 specimens. The pull-out test indicated a mean maximum pull-out force of 346 N for the control screw without cement and a mean pull-out force of 760 N for the pedicle nail with cement. In addition, the results of the cyclic loading test revealed that a loosening of 50% of the implants occurred after 17,000 cycles for the pedicle nail but only after 30 cycles for the control screw. Sugimoto et al. [21] reported the efficacy of this system applied to patients with multiple myeloma. This system enables surgeons to successfully treat patients with osteoporotic vertebral fractures by using a short fusion procedure due to twice the pullout strength of the nail.

Fig. 5 Radiograph and CT 13 months after surgery; bone union is evident in A–P and lateral radiographs (*upper middle and left*) without pedicle nail loosening. The bone cement around the nail is shown by axial view (*upper right*) and sagittal view (*lower*) of CT and there is no cement leakage (*broken arrows show hydroxyapatite sticks and cement; solid arrows show bone cement around the nail*)



Furthermore, the use of cement in a pedicle screw augmentation and in vertebroplasty must be done with caution because of a number of potential serious complications that may occur with the intraosseous injection of bone cement [6]. The risk of PMMA extravasations ranged between 27 and 74% [3, 8, 10, 16, 17], with resultant neurological deficits, such as radiculopathy, which occurs in 3.7% of cases and cord compression, which occurs in 0.5% of cases [1]. However, the increased fixation strength could outweigh the risks in patients with compromised bone quality.

We developed a new pedicle nail system which requires the nails to be reinforced with bone cement, and also developed an improved surgical technique to help prevent the complications mentioned above.

First of all, a pedicle nail has a cylinder shape without a thread. The nail also has some holes in the cylinder which act as anchor holes for the PMMA. When the bone cement is used, a thread is unnecessary—like the stem of an artificial joint.

Tapping into the pedicle correctly and checking for damage to the pedicle wall is essential to prevent PMMA outflow from the pedicle. A pedicle hole for inserting the pedicle nail is gradually widened using blunt probes to prevent damage to the pedicle wall and the widened hole is easily checked for damage by a sounder (Fig. 2).

The viscosity of the PMMA influences the possibility of PMMA extravasations and pulmonary embolism [14]. In other instruments for augmentation utilizing PMMA, the augmentation into the pedicle through the cannulated portion uses a low viscosity PMMA and high pressure needs to be used for the injection of the PMMA. Owing to the pressure used to inject the PMMA, it could easily flow into the vein or not extend to the vertebrae uniformly. With a pedicle nail, the cement is injected into vertebral holes using an injection cannula with low pressure, and the pedicle nail is inserted into the holes pressing the bone cement, which enters into the trabecular bone of the vertebra uniformly. The amount of bone cement is about 2 ml which is enough to reinforce fixation strength of the nail [2, 6]. Therefore, the possibility of leakage upon insertion of the pedicle nail, thus resulting in pulmonary embolism, is reduced.

Finally, the pedicle nail is divided into two parts, the inner screw and the outer sheath. As a result, the inner screw can be easily removed, and instruments other than the outer sheath can be removed easily. With conventional pedicle screws, there is a difficulty in removal in the event of complications such as infection and skin irritation due to the prominence of the instrument. However, after removing the clamps, rods and inner screw of the pedicle nail system with the outer sheath remaining, the height of the

instrument becomes markedly lower. Therefore, irrigation is easy when infection occurs and skin irritation by the instrument is minimized. There are some reports regarding vertebral body fractures after removing conventional screws in an osteoporotic spine [25]. However, with the pedicle nail system, the outer sheaths remain after removing the instrument, thus preventing postoperative fractures.

There have been three major approaches used in the treatment of patients with thoracolumbar fractures. The posterior approach is simple to perform and less traumatic for the patient. However, it has a high rate of instrument failure and a loosening or pullout of pedicle screws in patients with an osteoporotic spine [9, 15, 20]. Therefore, long segment fixation is recommended. The negative aspect of this is that additional compression fractures may occur in the terminal vertebra or adjacent vertebrae of the long fusion. Also, the surgical time is longer and the surgical trauma is more invasive.

In patients with a vertebral cleft, a vertebral body reconstruction from the posterior approach is essential to reduce instrument failure and the loss of the kyphosis correction. We performed vertebroplasty on a pedicle with PMMA or hydroxyapatite sticks. Pedicle nails can also be inserted in the vertebral body that was stabilized by vertebroplasty.

In summary, we use the pedicle nail system augmented with PMMA which provides about two times the fixation strength of a conventional pedicle screw. Using this system allows for final fixation of the spinal column which is strong enough even in an osteoporotic spine. A fusion rate of 94% is a result of the high fixation of the pedicle nail system.

Conclusion

Pedicle nails augmented by PMMA stabilizes the spinal column and reduces the likelihood of instrument loosening and/or pulling out in patients with osteoporosis. The technique for the insertion of the pedicle nail reduces complication from cement augmentation. For osteoporotic vertebral fractures, the strategy using PMMA augmentation may be effective and safe when the surgery is performed through a posterior approach.

Conflict of interest statement None.

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