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Clinical Curative Effect of the Combined Use of Cortical Bone Trajectory Screws and Pedicle Screws for Internal Fixation in the Treatment of Senile Osteoporosis and Lumbar Degenerative Diseases

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Abstract

Objective: This study aims to explore the clinical curative effect of internal fixation and bone graft using cortical bone trajectory screws (CBT) combined with pedicle screws (PS) to decompress the lumbar posterior during the treatment of osteoporosis and lumbar degenerative diseases.

Method: From February 2014 to August 2015, the researcher chose 40 patients with osteoporosis and lumbar degenerative diseases, for whom former conservative treatment proved invalid, and operated internal fixation and bone graft to decompress the lumbar posterior. Pedicle screw fixation was performed on 27 cases in Group A, while the technique of cortical bone screws combined with pedicle screws was adopted for 13 cases in Group B.

The two groups of patients were observed with respect to the operative duration, intraoperative blood loss, and VAS scores before and after the surgery, JOA score, and improvement rate.

Results: The symptoms of all the 40 patients were improved. Postoperative JOA and VAS scores significantly increased. In regard of operative duration, blood loss, JOA and VAS scores of the two groups, there was no difference of statistical significance. Bilateral pedicle screw placement failed for two cases in Group A and unilateral fixation was used instead. The rest of the patients succeeded with the screw placement. As to Group B patients, there was not a single case of placement failure due to the inadequate adhesive force, or any fracture of the cortical bone screw trajectory. The placement process inflicted no vascular or nervous damage upon any of the patients. Postoperative radiographic follow-up showed no screw loosening, fall-off, or collapse. The screws, connecting rods, fusion devices were well located at good positions. No adverse events happened to any patient.

Conclusion: There are several advantages of jointly using cortical bone trajectory screws and pedicle screws for internal fixation in the treatment of senile osteoporosis and lumbar degenerative diseases: small injuries in the muscles and soft tissues, strong adhesive force, and satisfactory early effects.

Keywords: Cortical bone trajectory; Osteoporosis; Lumbar fusion; Lumbar degeneration

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Materials and Methods

Using pedicle screws for the internal fixation and bone graft to decompress the lumbar posterior is effective in treating lumbar degenerative diseases. When taking this approach for patients with osteoporosis and lumbar degenerative diseases, however, such risks will occur as insufficient adhesive force of the pedicle screw, unstable fixation, screw pullout, or even pedicle fracture or rupture due to the screw cutting the sclerotin [1].Therefore, how to enhance the adhesive force of screws has become a hot research topic.

Santoni "et al." [2] put forward a new method of screw placement–cortical bone trajectory (CBT): place into the pedicle the screw from end to head at the sagittal position, and from center to side at the axis, so as to increase the contact area between the screw and cortical bone in the pedicle. In this screw trajectory, the trabecula density is higher than that of the traditional pedicle screw trajectory. Thus, the adhesive force of the screw to the bone structure can be enhanced. Meanwhile, the cortical bone trajectory (CBT) features a slightly inward entry point, which can avoid excessive stripping of the outer flank of the articular process during exposure of the incision. This can reduce

Table 1: General data of Group B patients.

Case	Age	Gender	Symptoms	Affected segments	Fusion mode	Internal fixation method
1	55	Female	20-plus years of lumbago aggravating with numbness and pain in lower limbs for 2 years.	L5/S1	PLIF	PS and CBT for both sides of L5 and S1 respectively.
2	57	Female	5-plus years of lumbago aggravating with intermittent claudication for 2 years.	L3/4, L4/5	Inter-transverse	PS for the right side and CBT for the left.
3	61	Female	3-plus years of lumbago aggravating with numbness in left leg for 2 weeks.	L4/5, L5/S1	PLIF	CBT for both sides of L4 and L5; PS for both sides of S1.
4	59	Male	Lumbago with pain in left leg for 3-plus months.	L4/5	TLIF	CBT for the left side of L4 and L5; PS for the right side.
5	67	Female	5-plus years of lumbago aggravating with numbness in lower limbs for 3-plus months.	L4/5, L5/S1	TLIF	CBT for the left side of L4, L5, and S1; PS for the right side.
6	63	Female	Numbness and pain in lower limbs for 2-plus years.	L4/5, L5/S2	TLIF	CBT for the left side of L4, 5, L5 and S1; PS for the right side.
7	58	Male	3-plus years of lumbago, aggravating with intermittent claudication for over half a year.	L4/5	TLIF	CBT for the right side of L4 and L5; PS for the left side.
8	70	Female	Pain in lower limbs for more than half a year, aggravating over the past month.	L3/4, L4/5	Intertransverse	CBT for the left side of L3, L4 and L5; PS for the right side.
9	66	Male	Numbness and pain in right leg for 5-plus months.	L5/S1	TLIF	CBT for the right side of L5 and S1; PS for the left side.
10	53	Male	Pain in left leg for 10-plus years, aggravating over the past three months.	L4/5	TLIF	CBT for the left side of L4 and L5; PS for the right side.
11	73	Female	Lumbago and intermittent claudication for 8-plus months.	L4/6	PLIF	CBT for both sides of L4; PS for both sides of L5.
12	63	Male	Pain in left leg for over one year.	L5/S1	TLIF	CBT for the left side of L5 and S1; PS for the right side.
13	67	Male	Pain in left leg for half a year after taking an operation on the lumbar vertebra.	L4/5	TLIF	PS for the left side and CBT for the right side.

CBT: Cortical bone trajectory; PS: Pedicle screw.

Table 2: Postoperative outcomes.

Cases No.	Surgical segment (s)	Operative duration (hour)	Intraoperative blood loss (ml)	Preoperative JOA	Postoperative JOA	JOA improvement rate	Preoperative VAS	Postoperative VAS	Complications
1	1	1.5	150	13	22	56.25	5	2	None
2	2	2	350	12	23	64.7	5	3	None
3	2	2.5	400	8	23	71.42	6	1	None
4	1	1.5	200	10	25	78.94	5	2	None
5	2	2	350	9	24	75	5	1	None
6	2	2.5	380	11	21	55.55	7	2	None
7	1	2	220	6	25	82.6	8	3	None
8	2	3	430	15	26	78.57	5	1	None
9	1	1.5	120	14	25	73.33	4	1	None
10	1	1.5	180	8	20	57.14	5	1	None
11	1	2	200	12	25	76.47	4	2	None
12	1	1.5	150	17	27	83.33	3	1	None
13	1	1.5	150	12	25	76.47	5	1	None

the intraoperative blood loss, shorten operative duration, and realize a minimally invasive surgery to some extent. Many patients, however, show anatomic variations on some segments to the extent that the CBT screw entry point cannot be determined or the entry point is damaged by amplified decompression force, making it impossible to place the CBT screw. Under such circumstances, the traditional pedicle screw technique can come into use for internal fixation. Besides, the two screw placement methods are mutually supplementary: if one fails, the other can be adopted.

Therefore, this paper proposes a combination of CBT and the pedicle screw techniques to treat senile osteoporosis and lumbar degenerative disease. This can achieve a satisfactory curative effect by enhancing the adhesive force of screws, improving the pre-fusion lumbar stability, and reducing the damages inflicted upon patients during surgical exposure.

Data collection and methodology

General Data: From February 2014 to April 2015, Shang Hai Chang Zheng Hospital received 40 patients with osteoporosis and lumbar degenerative diseases, including 18 males and 22 females, aged from 52 to 76, averaging 63.4 years old. Inclusion criteria: First, the patient suffered from lumbago of various degrees, radiating pain in the lower limbs, or intermittent claudication, which seriously affected his or her daily life and work. Second, the patient received over three months of systematic conservative treatment but to no avail. Third, before the operation, the patient underwent detailed history-taking, physical examination, bone density inspection, X-ray radiographing, CT scanning, and MRI examination. Two doctors with senior positions had discussions and determined that it was necessary to perform surgeries on less than three segments. Exclusion criteria: First, preoperative data were incomplete or postoperative follow-up failed. Second, there were other pathogenic factors like trauma, tumor, and infection. Third, the patient had system diseases considered contraindications. The internal fixation and bone graft decompressing the lumbar posterior was performed on all the patients. The 27 cases in Group A received internal fixation via the pedicle screw, while the 13 cases in Group B received CBT in combination with PS. The specific method adopted depended on patient conditions. See Table 1 for the general data of Group B patients (Table 1).

Surgical Method: After general anesthesia, the patient lay prone on a W-shaped cushion to hung the abdomen in the air. After the operative segments were pinpointed, routine disinfection was performed and the patients draped. A median incision was made on the lumbar vertebra posterior segment. The layers were cut open to expose the spinous process. Subperiosteal dissection was done on the paravertebral muscle groups on both sides of the spinous process.

A choice was made between traditional CBT and PS according to the preoperative plan and intraoperative actuality (Table 2). If PS was adopted, the lambdoidal crest at the juncture of the lateral border of the articular process and transverse process should be exposed, whereas if CBT was adopted, only the outer flank of the vertebral plate and the articular process medial border should be exposed at the segment to be nailed.

With the exposure completed, vertebral plate resection, expansion and decompression of the pedicle, and posterior lumbar interbody fusion (or transforaminal lumbar interbody fusion) were performed on the surgical segments. Then internal fixation of lumbar vertebra was carried out. The pedicle screw was placed in this way: with the apex of the “lambdoidal” crest as the entry point, the coronal position was inclined outside-in by 5° to 15° (the degree depending on the segment, the same direction as the pedicle); the sagittal head was inclined by 0° to 30°(parallel to the end plate). The screw, 6.0 mm - 7.0 mm long in diameter, should outreach the vertebral midline but not go beyond the vertebral body. As for CBT, the method was as follows: the entry point was on the vertebral plates 2 mm below the inferior margin of the upper articular process or 2 mm inward. Abrasive drilling was done prior to the insertion of the screw, which was inclined inside-out by 5° to 15°, the end at the sagittal position tilting by 30° to 10°. The screw, 3.5 mm - 5.0 mm long in diameter, would suffice with its front end penetrating the pedicle. After the C-arm X-ray machine confirmed the screw was in good position, a titanium rod of appropriate length was selected, pre-bent, and placed together with a nut for fixation. Depending on whether or not the screw was solidly fixed, a horizontal linkage unit can be used to enhance the internal fixation. The wound surface was rinsed and stanched; the endorhachis was covered with gelatin sponge; an effective negative-pressure drainage device was placed. The wound was sutured layer by layer to the cutis, marking the end of the operation. For all the patients in Group A, the internal fixation was performed by means of PS, whereas CBT combined with PS was adopted for Group B patients.

Postoperative Treatment: The vital signs, limb movement, and feelings of the patients were closely observed within three days after the operation. Anti-inflammatory, hormonal, and dehydration drugs were used for three to five days. The negative pressure drainage tube was pulled out within 48 hours after the operation. The patients were reminded to exercise their lumbodorsal muscles and waistlines, obtain protection when out of the bed, and gradually take more activities to restore the capacity of doing normal activities within 3 months after operation. Meanwhile, anti-osteoporosis treatment was enhanced.

Methods of Postoperative Observation and Evaluation: After operation, the patients were followed up for six to 15 months (11.2 months on average). Follow-up visits were made one week and three months after the operation. These data were collected and analyzed: 1. Relevant variables in the perioperative period: operative duration, intraoperative blood loss, postoperative complications (if any); 2. Clinical symptoms, physical signs, and neural functional recovery. The lumbago and neural functions were evaluated before the operation as well as three months and six months after it according to the rating scale of Japanese Orthopaedic Association (JOA, 1986). The improvement rate was calculated. The visual analogue scale (VAS) was applied to assess the change of the pain felt by patients. 3. Image evaluation: radiographs were taken and CT scanning was conducted of the true lateral position of the lumbar vertebra promptly after operation, three months later, and during the final follow-up visit, so as to find out if the internal fixer loosened, fell off, broke, shifted, or if there was any intervertebral altitude loss.

Results

After taking the surgery of internal fixation and bone graft to decompress the lumbar posterior, the 40 patients witnessed symptom improvement of different extents. Internal fixation by pedicle screw was applied to the 27 cases of Group A with an operative duration of 1.5 hours - 3.5 hours (1.75 h on average) and with a blood loss averaging 160 ml at a single segment or 315 ml at double segments. The preoperative JOA score averaged 11.9 (5-17), the postoperative one being 23.85 (19-26), and the improvement rate averaged 70.31%. The preoperative VAS scored 4.95 on average, while the postoperative one was 1.8. There were two cases suffered a failure of pedicle screw placement into S1, so this side was not fixed. Six patients acutely find the inadequacy of the adhesive force by using of the pedicle screw, but no adverse events like pullout and cutting occurred. The above mentioned eight patients were instructed to rest in bed for six weeks, strengthening functional exercise and anti-osteoporosis treatment. Follow-up of one year, the eight patients were fixed position in place with no screw loosening, fracture, intervertebral space collapse and other adverse events.

For the 13 cases in Group B, internal fixation was done by joint efforts of traditional pedicle screw and CBT techniques. Operative duration ranged from 1.5 hours to 3 hours, averaging 1.958 hours. Blood loss averaged 174 ml at a single segment and 330ml at double segments. The preoperative JOA scored 11.25 (6-17) on average, while the postoperative one was 23.83 (20-27), with an improvement rate of 71.11%. The preoperative VAS score averaged 5.17, the postoperative one being 1.67. During operation, no screw placement failure occurred due to poor adhesive force, and no cortical bone screw trajectory fractured. A totality of 60 screws were placed in the 13 patients, with no blood vessel or nerve damaged. Postoperative radiographic follow-up showed no sign of screw loosening, falloff, or collapse. The screws, connecting rod, and the fusion apparatus were all well-positioned. No adverse events happened. No statistically significant difference was found between the two groups in terms of the operative duration, blood loss, JOA and VAS scores (Table 2 and Figure 1and 2).

Discussion

The pedicle screw placement technique has been applied for over 50 years to the surgical treatment of various diseases and injuries of

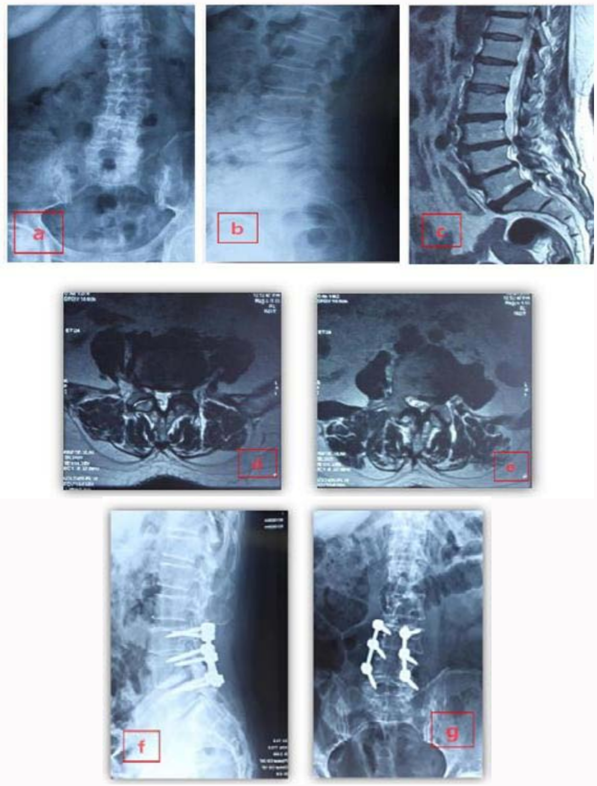

Figure 1: Case 1: A 57-year-old female patient with L3/4 and L4/5 lumbar spinal stenosis.
A and B: preoperative X-ray films.
C-E: preoperative MRI sagittal position, L3/4 transverse section, L4/5 transverse section.
F and G: postoperative X-ray films (CBT used for the the right side and PS for the left side).

the spine and spinal cord. During the treatment of senile patients with osteoporosis and lumbar degenerative diseases, some problems are likely to occur, such as poor adhesive force of the PS, screw loosening, falloff, and even pedicle breakage or fracture due to the screw cutting the bone tunnel. The fractured fragments may press nerves, resulting in corresponding symptoms and surgical failures. Therefore, the force of the screw adhering to the bone structure is crucial for success of the operation.

Halvorson "et al." [3] observed that in a group with a normal bone density, the average axial pullout force reached 1540±361N. By contrast, it was 206±159N in a group with osteoporosis. Okuyama "et al." [4] believed that with the BMD reduced by 10 mg/ml, the screw pullout force could decrease by 60 N. These studies indicated that the axial pullout force of the internal fixer was positively correlated with lumbar BMD. Kumano "et al." [5] considered it unsuitable to apply pedicle screw fixation to patients whose osteoporosis was so severe that the axial pullout force dropped below 100 N, arguing the screw was prone to loosening and falloff.

Therefore, researchers should focus on how to enhance the adhesive force of the internal fixer to better serve decompression and fusion surgeries on senile patients with severe osteoporosis and lumbar degenerative diseases who are in urgent need of surgical treatment. Nowadays, frequently-used methods of enhancing the adhesive force include: enlarging the contact area between the screw and the bone structure, increasing screw diameter and length, and changing the distance between screw threads [6-7]. Researches conducted by Brantley "et al." [8] showed that when the placement depth accounted for 80% of the distance between the screw entry point and the intersection of the pedicle axis and vertebral anterior margin, the fixation strength was sufficient to the extent that deeper placement would exert no apparent effect on it. Some researchers suggested the screw should outreach the cortical bone at the vertebral anterior margin for better stability. This proposal, however, is apt to damage the issues, blood vessels, and nerves at the anterior margin and thus cause relevant complications [9]. Brantley "et al." [8] also indicated that the best ration of the pedicle screw diameter to the pedicle cross-sectional area was 70-90% because that ensured adequate fixation strength. Further increase of the diameter would not significantly strengthen the fixation but only incur cracks and fractures of the pedicle. Therefore, increasing the diameter and length of the screw has a limited role in actual operation. Moreover, for some patients, the screw diameter and length cannot be increased because of their bone structures.

Additionally, many researchers attempted to apply bone cement and calcium phosphate to enhance the fixation. Choma "et al." [10] prepared drill ways on osteoporosis patients, applied a certain amount of bone cement, and then placed the screws, so as to realize reliable and stable fixation by enhancing the axial pullout force for the screw. This method, however, is likely to cause bone cement spillover and embolism, which has attracted increasing academic attention [11]. All of the above mentioned methods are based on the traditional pedicle screw placement trajectory. It was Santoni "et al." who first put forward the placement method of pedicle cortical bone screw trajectory [2], indicating that by changing the direction of the screw trajectory, the screw could maximize the contact area between it and the cortical bone to increase the adhesive force. This method

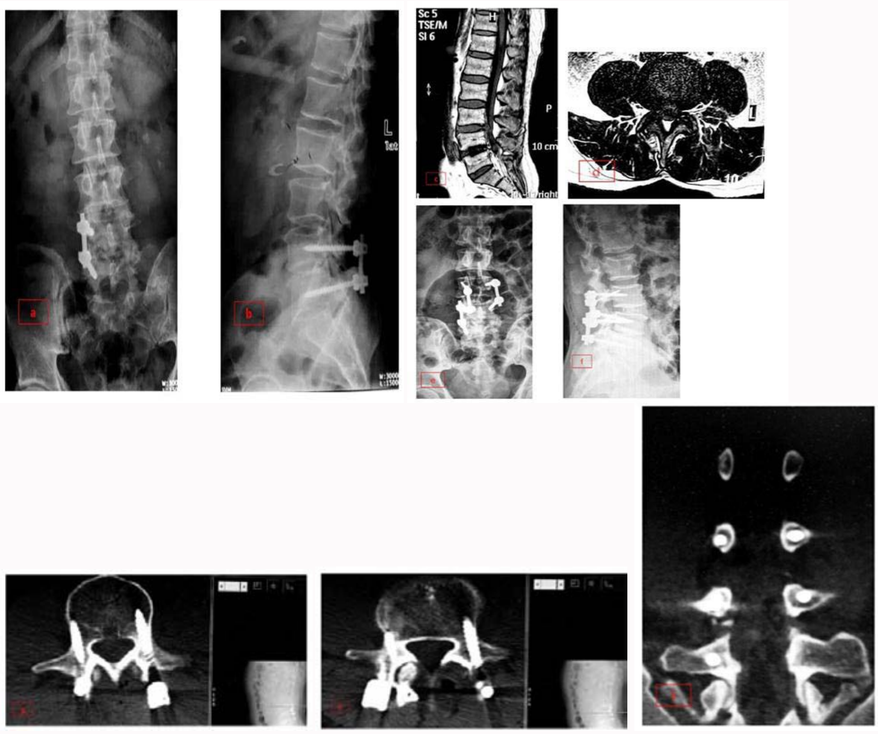

Figure 2: Case 2: A 61-year-old female patient with L4/5 and L5/S1 lumbar spinal stenosis.
A and B: preoperative X-ray films.
C and D: preoperative MRI.
E and F: postoperative X-ray films (CBT used for the both sides of L4/5 and PS for the both sides of S1).
G-I: postoperative CT imaging of bilateral CBT screw fixation.

was called “CBT screw fixation technique”. Relevant tests showed that compared to traditional pedicle screw, the axial pullout force for the CBT screw could increase by 30%. In a test simulating the stress on the vertebral body conditioned by the complex movements of human body, however, the pullout forces of CBT screw and pedicle screw were basically the same. The CBT technique could firmly fix the screw via four spots contacting the cortical bone: the cortical bone at the back of the entry point, the inner lateral wall in the rear of the pedicle, the outer lateral wall of the anterior part of the pedicle, as well as the anterolater wall of vertebral body [12-13]. In-vitro tests carried out by Inceoglu “et al.”[14] also showed that the pullout force for the CBT screw was higher than that for the traditional screw. In a fatigue test, after 5000 rounds of continuous rotation at a frequency of 3Hz with a force moment of 4Nm, the pullout force for CBT screw was still higher than that for the traditional screw, demonstrating better long-term stability of CBT.

Relevant studies revealed that in patients with severe osteoporosis, cancellous bone BMD significantly decreased while the cortical bone BMD did not. By CT scanning, Santoni “et al.”[2] found that the CBT screw was surrounded by a large amount of high-density sclerotin and that there was no significant correlation between the pullout force and the cancellous bone BMD. For senile patients with osteoporosis, the pedicle cortex was still strong enough.

The CBT technique could increase the contact area with cortical bone to obtain a reliable adhesive force. Therefore, the CBT technique offers spinal surgeons a new method of treating such patients. Furthermore, CTB has another advantage over the traditional pedicle screw placement technique [13] in that it is safer to place the CBT screw. The CBT screw, placed head ward and outward, can avoid damages of the nerve roots, dural sacs, and other important tissues. With an inward entry point, it can do without extensive muscle peeling and tissue excision and thus realize the ideal of “small injury and fast recovery”. Especially for the obese and those whose lumbodorsal muscles are overdeveloped, the outward-inclined entry trajectory makes it more convenient to place the screw. Besides, the inward entry point of CBT can avoid damages upon the medial branch nerves (MBN), which stem from a dorsal branch of spinal nerves and pass by the articular process. The traditional pedicle screw placement method required peel-off of this area and thus inflict damages upon the nerves, causing corresponding symptoms. On account of the advantages mentioned above, a mastery of the CBT screw placement method can, for senile patients in particular, remarkably shorten the operative duration, lessen blood loss in the peeling of soft tissues, and thus lower the risk of anesthesia.

Therefore, it is proposed that the CBT technique be adopted for the patients of this group to increase the adhesive force of lumbar internal fixer and avoid screw loosening, falloff, and other complications. In actual operation, however, since the CBT screw entry point is inside and below the upper articular process, some of the patients may require destruction of the screw entry reference point in case of intervertebral space stenosis or severe hyperplasia at the articular process, which require TLIF fusion and expansion of the decompression scope.

That may possibly lead to a failure of the screw placement. In patients with severe scoliosis or slippage, the screw entry point has already been deviated. If it is taken as the reference point, the spinal canal and nerve roots may be damaged. For such patients, the traditional pedicle screw placement method can be adopted for the segment with CBT screw placed into other segments. Takata "et al."[15] performed posterior fixation on a patient with single-segment slipped disk by placing CBT screw into the L4 segment and traditional screw into L5, the ends of the two screws drawing close in a lambdoidal pattern. The incision was made at the apex of it to ensure a small operative scope.

Different from this case, patients in this group suffered from slipped disk as multiple segments. The connecting rod could not be installed by this means because the tails of the CBT screws and traditional PS were not in line with each other. Therefore, it was necessary to devise a suitable method of screw placement.

The operative scheme and principles are as follows. First, for the side with the severer slipped disk and spinal canal stenosis, unilateral TLIF fusion should be used because the bigger compression scope of this side is likely to damage the CBT screw entry point. Thus, the conventional pedicle screw placement technique was used here, while CBT method was adopted for the other side characterized by the smaller decompression scope. Second, the CBT technique should be applied to the proximal end of the to-be-nailed segment, so as to reduce the incision length and exposure scope for minimal invasion. Third, the PS placement spot at the S1 segment was closer to the outer flank. Exposure was difficult due to the hindrance of ilium and muscles. For this segment, therefore, the screw could be placed inside-out so that fewer soft tissues would be peeled off. Fourth, for senile patients with osteoporosis, if the screw is not properly placed with one method, or repeated attempts of screw placement have damaged the screw trajectory, then the alternative method can be adopted as a remedy. Fifth, for patients who have undergone several surgeries, the CBT screw should be placed into the same pedicle without removing and exposing the original internal fixer, so long as the pedicle is considered spacious enough. This can effectively shorten the operative duration, reduce blood loss, and narrow the scope of resection (Figure 2).

Hence, for this group of patients, CBT was adopted in combination with the traditional pedicle screw. The two mutually supplementary methods, if combined in a flexible way, can effectively shorten the operative duration, reduce intraoperative blood loss, and realize feasibly minimal invasion. Patients with severe osteoporosis who received this treatment did not suffer any intraoperative placement failure, postoperative screw loosening, falloff, or other complications. Their postoperative JOA and VAS scores significantly improved in comparison with the preoperative ones.

Conclusion

For surgery-requiring senile patients with severe osteoporosis and lumbar degenerative diseases in need of surgery, this paper, considering both decompression and intervertebral fusion, proposes a method of individualized and combined internal fixation. The CBT screw placement technique can enhance the adhesive force of the internal fixation screw to bone structures and avoid screw loosening, falloff, and other complications. During operation, the two methods of screw placement can be combined in accordance with the actual situation to reduce intraoperative blood loss, shorten operative duration, and provide supplementary treatment for the patients whose screw trajectory has been damaged by a failure of placing pedicle screws in the traditional way. Observation of the postoperative short-term curative effects showed no screw loosening, falloff, or other complications. All patients were satisfied with the curative effect. Despite the small number of samples, this study offers a new clinical insight into the use of internal fixers for surgery-requiring senile patients with severe osteoporosis and lumbar degenerative diseases. In this respect, it is taking the lead both at home and abroad.

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