A Modified Spinal Reconstruction Method Reduces Instrumentation Failure in Total En Bloc Spondylectomy for Spinal Tumors

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Abstract:

Introduction: Long-term spinal stability after total en bloc spondylectomy (TES) is challenging. The aim of this study was to examine whether the new method could reduce the incidence of instrumentation failure (IF).

Methods: We retrospectively compared 116 patients with spinal tumors who underwent TES between 2010 and 2019 and were followed up for >1 year. IF, cage subsidence, and complications were evaluated. Propensity score matching between conventional and new method groups was performed for age, sex, body mass index, preoperative radiotherapy, number of resected vertebrae, number of instrumented vertebrae, tumor level, and follow-up period. There were 25 cases each in the conventional and new method groups. The conventional method used a titanium mesh cage for anterior reconstruction and 5.5-mm-diameter titanium alloy rods for posterior fixation. The new method used a more robust cage for anterior reconstruction, bone grafting was performed around the cage, and 6.0-mm-diameter cobalt chromium rods were used for posterior fixation. We compared the incidence of IF and cage subsidence after TES between the conventional and new method groups.

Results: While 5 out of 25 patients (20.0%) in the conventional method group experienced IF, none from the new method group experienced IF. Three-year implant survival rates were 87.3% in the conventional and 100% in the new method groups. The new method group had a significantly higher implant survival rate ($p<0.01$). Cage subsidence was observed in 11 of 25 (44/0%) patients in the conventional method and 1 of 25 (4.0%; significantly lower, $p<0.05$) in the new method group.

Conclusions: The new reconstruction method significantly reduced IF incidence in patients with TES.

Keywords:

Total en bloc spondylectomy, instrumentation failure, cobalt chromium, bone fusion, liquid nitrogen

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Introduction

Total en bloc spondylectomy (TES) is designed to achieve complete oncological resection of spinal tumors[1,2)]. Several studies have reported better local control and prognosis with this technique compared with piecemeal resection of spinal tumors[3-8)]. Furthermore, with continuing advances in cancer treatment, even patients with malignant spinal tumors can now expect long-term survival[9,10)]. It is therefore important to maintain their long-term spinal stability after TES. However, the spinal column is completely discontinuous due to resection of the vertebral body and posterior spinal element, including ligaments. Therefore, spinal reconstruction in this surgery is a challenge. After resection of the affected vertebrae, robust instrumentation and bone grafting are necessary, along with anterior column support, to restore spinal stability.

Since 2010, instead of harvesting autografts from the ilium or fibula, we have mainly used liquid nitrogen-treated bone from the resected, tumor-affected vertebra as grafted bone, while parts without tumor contamination, such as partially resected adjacent vertebra, have been used as fresh autografts, without liquid nitrogen treatment, at our institution. This technique has the following benefits: no pain at

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Table 1. Differences between the Conventional Method and the New Method.

	Conventional method	New method
Rod	φ 5.5 mm, titanium alloy	φ 6.0 mm, cobalt chromium
Cage	Titanium mesh cage with a thickness of 1.0 mm	More robust cage (with a thickness of 1.5 mm) with end caps
Bone grafting	Inside the cage	Inside and around the cage

φ, diameter

the bone harvest site, shortened operating time, decreased blood loss, and additional antitumor immune response[11]. Liquid nitrogen-treated bone has been reported to delay bone healing compared with fresh autograft[12]; further, the rate of instrumentation failure (IF; 42.6%) is high in TES using liquid nitrogen-treated bone[13].

Since 2015, a modified reconstruction method has been developed and performed to improve initial fixation and promote bone healing to prevent IF, even when using liquid nitrogen-treated bone. The purpose of this study was to investigate whether the new reconstruction method could reduce the rate of IF.

Materials and Methods

Study population

This retrospective study was approved by our institutional review board, and all participants provided written informed consent. Between 2010 and 2019, 158 patients with primary or metastatic spinal tumors underwent TES at our institute. Of these, 14 patients died, and 28 patients were lost to follow-up within 1 year. Finally, 116 patients (73.4%) who were followed up for >1 year after TES were included in this study. There were 60 men and 56 women, with an average age of 52.1 years (range: 14-75 years). Of the 116 patients, 78 underwent TES using the conventional method and 38 underwent TES using the new method. Propensity score matching was implemented between the conventional and new methods for age, sex, body mass index (BMI), preoperative radiotherapy, number of resected vertebrae, tumor level, number of rods, number of instrumented vertebrae, and follow-up period; this technique allows researchers to minimize potential confounding factors or selection bias arising from imbalances in baseline characteristics across groups. After matching, there were 25 patients in the propensity score matched (PSM) conventional group and 25 patients in the PSM new method group. Comparisons were made between these two groups.

Surgical procedures

TES consisted of en bloc laminectomy after transpedicular osteotomy, subsequent en bloc corpectomy, and spinal reconstruction[1,2,14]. Both the conventional and new methods used the same technique for resection of the tumor-affected vertebra, with the only difference being in the reconstruction method. In both methods, after en bloc laminectomy, two-above and two-below segmental fixations were performed. In principle, two rods were used. In some cases, such as those involving the lower lumbar spine, four rods were used as needed. Titanium (Ti) alloy rods of 5.5-mm diameter were used in the conventional method, while in the new method, cobalt chromium (CoCr) rods of 6.0-mm diameter were used. After posterior instrumentation using the conventional method, anterior reconstruction was performed using a Ti mesh cage with a thickness of 1.0 mm (MOSS-Miami; DePuy Motech, Warsaw, IN, USA) filled mainly with frozen autografts treated with liquid nitrogen. In the new method, a more robust cage (with a thickness of 1.5 mm) with end caps (VBOSS cage; Stryker, Allendale, NJ, USA or PYRAMESH; Medtronic Sofamor Danek, Memphis, TN, USA) was used for anterior reconstruction. It was mainly filled with frozen autografts treated with liquid nitrogen. Bones that were not affected by the tumor, such as ribs and vertebral arches adjacent to the tumor vertebra, were not treated with liquid nitrogen but were mixed with liquid nitrogen-treated bone and used as bone grafts. Additional bone grafting using frozen autografts treated with liquid nitrogen was performed around the cage to bridge the upper and lower vertebrae in the new method group only.

To increase spinal stability, the posterior instrumentation was adjusted to slightly compress the inserted vertebral cage in both methods. Finally, at least two transverse connectors were used. Patients were required to wear a rigid spinal brace for 3 months postoperatively, followed by a soft brace for another 3 months.

The differences between the conventional method and the new method are presented in Table 1.

Evaluation

The occurrence of IF was determined using plain radiographs at 1, 3, and 6 months postoperatively, and then approximately every 6 months thereafter. Computed tomography (CT) was performed to determine the details of the IF, which was defined as rod fracture, screw breakage, cage breakage, and screw back-out. We compared the incidence of IF between the conventional and new method groups using Kaplan-Meier survivorship analysis with the log-rank test. The incidence of cage subsidence (≥3 mm), surgical time, intraoperative blood loss, and postoperative complications that required reoperation were also compared between the two groups using the student's t-test or a chi-squared test. Cage subsidence was determined according to the findings of the CT scan 1 month after surgery. We also evalu-

Table 2. Demographic Data.

	Conventional method group	New method group	p*
Sex (M:F)	11:14	13:12	0.571
Age	57.5±11.6	54.2±8.6	0.250
BMI	21.9±2.8	23.1±4.7	0.283
Preoperative radiotherapy	9 (36.0%)	6 (36.0%)	0.355
Tumor histology (primary)	5 (20.0%)	6 (24.0%)	0.733
Numbers of resected vertebrae	1.34±0.59	1.2±0.577	0.401
Tumor level (lumbar)	4 (16.0%)	6 (24.0%)	0.480
No. of rods (>2)	0 (0%)	1 (4.0%)	0.500
Numbers of instrumented vertebrae (>2)	0 (0%)	0 (0%)	1
Follow-up period (months)	39.2±26.4	38.7±16.7	0.929

BMI, body mass index
*Student's t-test or Chi-squared test

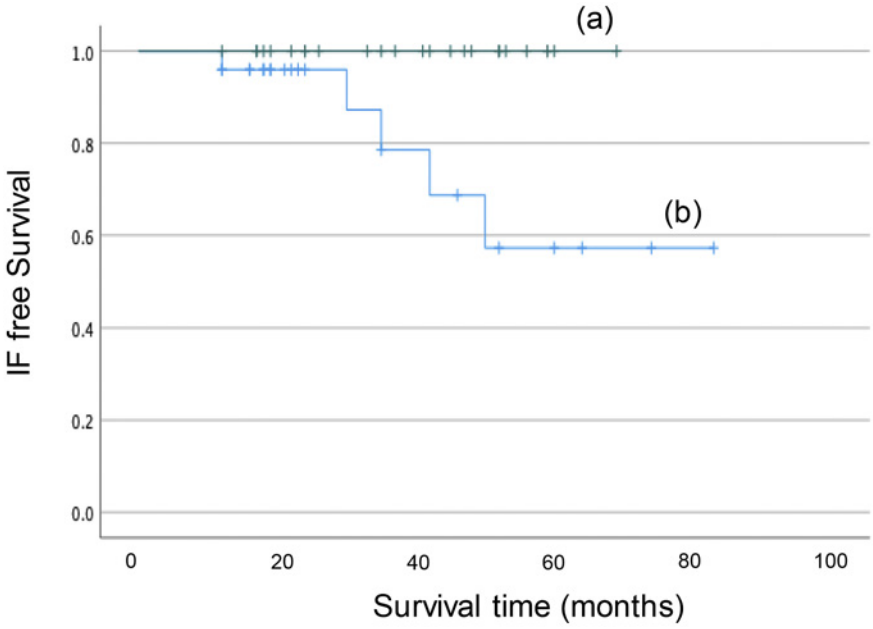

Figure 1. Kaplan-Meier survivorship curve showing IF-free survival probability for patients in the new method (a) and conventional method (b) groups. The three-year implant survival rate was 87.3% in the conventional method group and 100% in the new method group. The log-rank test showed that patients with the new method had a lower incidence of IF than those with the old method (log-rank test: p<0.01).

ated whether the grafted bone around the anterior cage had formed bridging bone in patients who underwent CT scans >1 year after surgery. Bridging bone evaluation was conducted by modification of Lechner et al.'s grading[15]. All data were analyzed with SPSS 23.0 (SPSS Inc, Chicago, IL, USA). All p-values of <0.05 were considered significant.

Results

Demographic data

No statistically significant differences were found in sex, age, BMI, preoperative radiotherapy, tumor histology, number of resected vertebrae, tumor level, number of rods, number of instrumented vertebrae, or follow-up period between the two cohorts after PSM. In the new method groups, there was one patient with lower lumbar spine involvement who underwent TES with more than two rods (4 rods) (Table 2).

Instrumentation failure

In the conventional method group, 5 of 25 patients (20.0%) experienced IF at a median of 34.0 months (range, 12-50 months) after TES. There were 4 patients with rod fracture and one patient with screw back-out. In the new method group, none of the 25 patients (0%) experienced IF. According to the Kaplan-Meier survivorship analysis, 3-year implant survival rates were 87.3% in the conventional method group and 100% in the new method group. The log-rank test showed that patients in the new method group had a lower incidence of IF (log-rank test, p<0.01) (Fig. 1).

Table 3. Operation and Complications.

	Conventional method group	New method group	p*
Operative time	477.9±161.7 min	475.0±164.2 min	0.479
Intraoperative blood loss	684.8±666.3 ml	390.4±290.2 ml	<0.05
Cage subsidence (≥3 mm)	11 cases (44.0%)	1 cases (4.0%)	<0.01
Complications	4 cases (16.0%)	4 cases (16.0%)	0.649
SSI	1 cases (4.0%)	2 cases (8.0%)	0.5
Wound dehiscence	0 cases (0%)	0 cases (0%)	1
Local recurrence	4 cases (16.0%)	2 cases (4.0%)	0.334

SSI, surgical site infection

*Chi-squared test

Table 4. Computed Tomography Evaluation of Bridging Bone Formation around the Cage.

Bridging bone grade		n (%)
Grade	Criteria	
3	BB ≥50%	12 (34.3%)
2	BB <50%	11 (31.4%)
1	Indeterminate BB	9 (25.7%)
0	No BB	3 (8.6%)

BB, bridging bone

Cage subsidence

At the 1-month follow-up, cage subsidence of ≥3 mm was observed in 11 of 25 patients (44.0%) in the conventional method group and 1 of 25 (4.0%) in the new method group (Table 3). The incidence of cage subsidence was significantly higher in the conventional method group ($p<0.05$).

Operation and complications

No statistically significant differences were found in the operation time between the two groups. The mean blood loss was 684.8±666.3 mL in the conventional method group and 390.4±290.2 mL in the new method group. Intraoperative blood loss was significantly lower in the new method group ($p<0.01$).

Four patients (16.0%) in the conventional method group and four patients (16.0%) in the new method group required reoperation due to complications other than IF. In the conventional method group, there was one case of surgical site infection (SSI) with wound dehiscence, one case of SSI, and four cases of local recurrence; while in the new method group, there were two cases of SSI and two cases of local recurrence. There were no significant differences in the complication rate between the two groups (Table 3).

Bridging bone formation around the cage

Among patients who underwent TES with the new reconstruction method, 35 of 38 (92.1%) underwent CT scans >1 year after TES: the grade of bridging bone was 3 in 12 patients (34.4%), 2 in 11 patients (31.4%), 1 in 9 patients (25.7%), and 0 in 3 patients (8.6%) (Table 4). CT images from a patient with grade 3 bridging bone formation are shown in Fig. 2.

Discussion

The new reconstruction method was designed to prevent IF by increasing the fixation force and rate of bone fusion in the anterior reconstructed column. The new method is based on three key factors: changing the rod to CoCr of 6.0-mm diameter, changing the cage to a more robust cage with end caps, and bone grafting around the cage. In this comparative study, the incidence of IF and cage subsidence was significantly lower after TES using the new reconstruction method compared with the conventional method. In addition, most cases that underwent TES using the new reconstruction method showed bridging bone formation at the grafted bone area around the cage.

IF is not a rare complication in TES, even when the fresh autogenous bone is used. There are several reports of IF after TES using the fresh autogenous bone. Yoshioka et al. evaluated 32 patients who underwent TES and survived for >1 year; IF was observed in eight patients (17.0%)[16]. Park et al. evaluated 32 patients who underwent TES and survived for >2 years; IF was observed in 12 patients (37.5%)[17]. In TES, the affected vertebral body and its surrounding supporting tissues, such as muscles and ligaments, are completely removed, making it prone to instability and creating challenging conditions for bone fusion. In addition, the frequency of IF is reported to be higher in TES using liquid nitrogen-treated bone than that using fresh autogenous bone. Shinmura et al. reported that IF occurred in 26 of 61 patients (42.6%) after TES using liquid nitrogen-treated bone; the reason for this is that frozen autogenous bone tends to delay bone formation compared with fresh autogenous bone[13]. In this study, the incidence of IF in the new method group was 0% despite the use of liquid nitrogen-treated bone, while it was 20.0% in the conventional method group. Thus, the new reconstruction method is useful in preventing IF.

Matsumoto et al. reported that cage subsidence leads to the failure of load sharing in the anterior column, resulting in an increased load imposed on the posterior instrumenta-

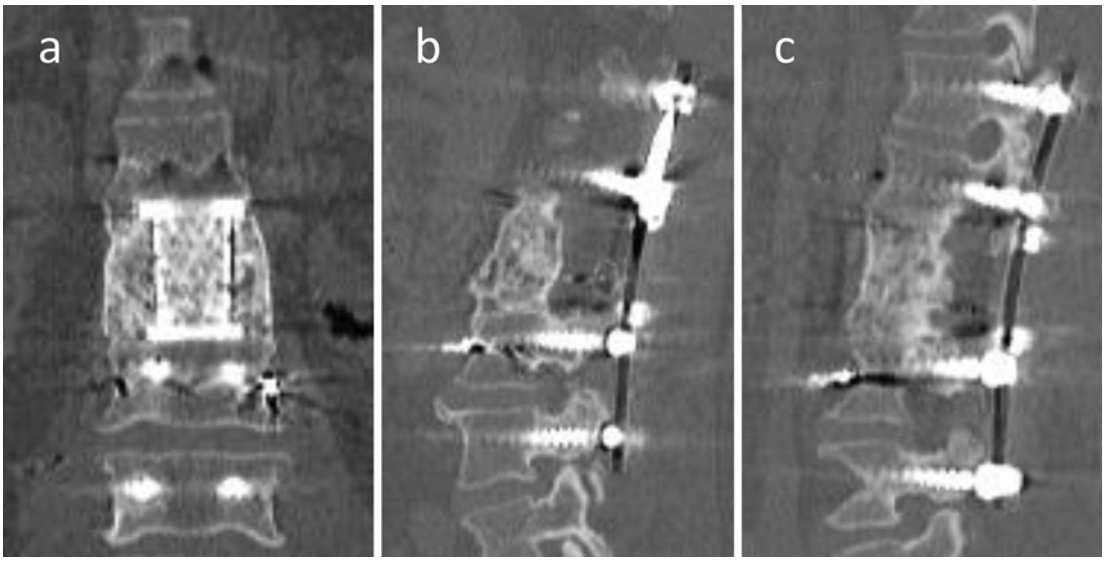

Figure 2. A 48-year-old man who underwent TES for metastasis of renal cell carcinoma at L2. Coronal (a), sagittal (b), and (c) computed tomography images 36 months after TES, showing good bridging bone formation.

tion, and cage subsidence is a risk factor for IF[18]. Cage subsidence is not a rare complication after TES; it has a reported incidence of 40%-64%[16,18]. Thus, reducing cage subsidence is one of the most important aspects of IF prevention.

In recent years, IF has also become a problem in corrective fixation for adult spinal deformity, and many studies have shown that IF is reduced by changing the rods from Ti to CoCr[19,20]. CoCr has a higher Young's modulus, bending stiffness, and fatigue life in the dynamic test than Ti[21,22], and it reinforces the solidity of the construct in spinal fusion surgery[19]. Furthermore, the new reconstruction method used a thicker rod with a diameter of 6.0 mm. We believe that changing the rods to CoCr of 6.0-mm diameter prevented both fatigue failure of the rods and cage subsidence by increasing the rigidity of the spinal structure after TES.

Biomechanically, cage subsidence stems from a mismatch between the intrinsic bone strength and the strain applied to the vertebral endplate by the interbody device[23].

One effective means of preventing subsidence is to maximize the end cap size of the implanted interbody[24], which decreases the focal stress on the bony endplates. This may help to keep the pressure applied by the end cap below the Young's modulus of the apposed endplates, preventing endplate failure and implant subsidence[25]. The VBOSS and PYRAMESH cages have specialized end caps, and the use of these cages was believed to be effective in preventing cage subsidence. Moreover, we believe that the strength of these cages also contributed to the prevention of cage breakage.

Even if cage subsidence can be prevented, if the anterior reconstructed column does not fuse, the rod and cage will continue to be loaded and fatigue breakage of the instrumentation will occur. Bone fusion is essential in patients who are expected to have long-term survival after TES.

In the new method, bone grafting was performed around the cage to increase the contact area between the grafted bone and the endplate with the aim of fusing the anterior reconstruction column, even when using liquid nitrogen-treated bone. As a result, bridging bone formation around the cage was observed in >65% of cases. We believe that bone grafting around the cage has the advantage of increasing the rate of bone fusion and preventing IF. The increase in fixation force due to the change in rod and cage may also have contributed to bone healing.

The fact that there was no significant difference in operative time and complications between the two groups in this study indicates that the new surgical method is not technically demanding. The lower blood loss with the new technique was thought to be due to the surgeon's improved performance of the TES technique over time, rather than the contribution of the new technique.

The limitations of this study were that it was a retrospective study and the follow-up period was relatively short. In previous reports, IF occurred at an average of 28-32 months (range, 6-93 months) after TES[13,17,18]. Since the mean follow-up periods in the conventional and new method groups were 39.2±26.4 and 38.7±16.7 months (range, 12-69 months), respectively, IF could still occur in the future. Despite these limitations, this study with a relatively large number of patients showed that the new method significantly reduces the incidence of IF in the short term. The results of this study will contribute to future reconstruction strategies for TES.

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Author Contributions: Research conception and design:

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Drafting of manuscript: Shinmura K.

Manuscript review: Kato S, Demura S, Murakami H, Tsuchiya H.

Study supervision: Murakami H, Tsuchiya H.

Approval of the final manuscript: all the above listed authors.

Ethical Approval: All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards. The study was approved by the Ethics Committee of the Graduate School of Medical Sciences, Kanazawa University.

Informed Consent: All participants provided written informed consent.

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