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Original Article

Percutaneous vertebral augmentation in special Genant IV osteoporotic vertebral compression fractures

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ABSTRACT

Background: Percutaneous vertebral augmentation is widely used for treating osteoporotic vertebral compression fractures (OVCFs). Bony encroachment in the spinal canal can be detected in some severe cases, increasing the difficulty of operation and risks of perioperative complications.

Purpose: A special type of OVCF has been introduced, and the clinical efficacy of vertebral augmentation has been evaluated in treating this special OVCF.

Materials and methods: The medical history of patients with OVCF treated with vertebral augmentation was reviewed. The vertebral body height and local kyphotic angle were measured and calculated on the lateral plain radiographs. The visual analogue scale and Oswestry Disability Index were assessed preoperatively, two days after operation, and at final follow-up periods. Complications such as cement leakage and recurrent vertebral fractures were also recorded and followed up.

Results: Twenty-nine patients with special Genant IV OVCF accepted vertebral augmentation, and 28 of them were followed up. The mean follow-up duration was 21.9 months, ranging from 17 to 34 months. The lateral plain radiographs revealed significant restoration of vertebral body height and local kyphotic angle. Both visual analogue scale and Oswestry Disability Index scores showed improvement 2 days after surgery and at final follow-up. Four patients experienced asymptomatic cement leakage, and 6 patients suffered OVCF recurrence in other segments.

Conclusion: Despite a great challenge, vertebral augmentation can be considered as a safe and effective option for treating special the Genant IV OVCF, showing significant restoration of vertebral body height, local kyphotic angle, and daily life function.

The translational potential of this article: Vertebral augmentation has been proven a safe and effect surgery method for special Genant IV OVCF. While surgery complications related to the commercially available filling material – polymethyl methacrylate (PMMA) is common and inevitable. Hence, this article is aimed to provide practical surgical techniques and suggestions to the modification of PMMA and fabrication of newly developed bone cements.

Introduction

Osteoporotic vertebral compression fracture (OVCF) is the most common type of osteoporotic fractures observed in the elderly, causing intractable back pain, spine deformity, and other systematic complications. The estimated annual incidence of symptomatic OVCF is approximately half a million in Europe, affecting 1.1% women and 0.6% men in the age ranging 50–79 years [1]. In China, the number of patients with OVCF reached to 30 million and is growing by 1.81 million every year, resulting in medical expenses of 9.45 billion yuan.

Based on fracture morphology and collapse degree, Genant et al. [2] and Nieuwenhuijse et al. [3] have semiquantitatively classified OVCF as mild (grade 1, 20–25% height reduction), moderate (grade 2, 26–40% height reduction), severe (grade 3, 41–67% height reduction), and very severe (>67% height reduction). Hence, very severe OVCF was defined as Genant IV OVCF in accordance with the traditional Genant semiquantitative grades. In many cases of Genant IV OVCF, bony fragments that protrude into the spinal canal during imaging examination were detected, making it a special type of Genant IV OVCF. In brief, the special Genant IV OVCF refers to very severe OVCF (with a vertebral body height

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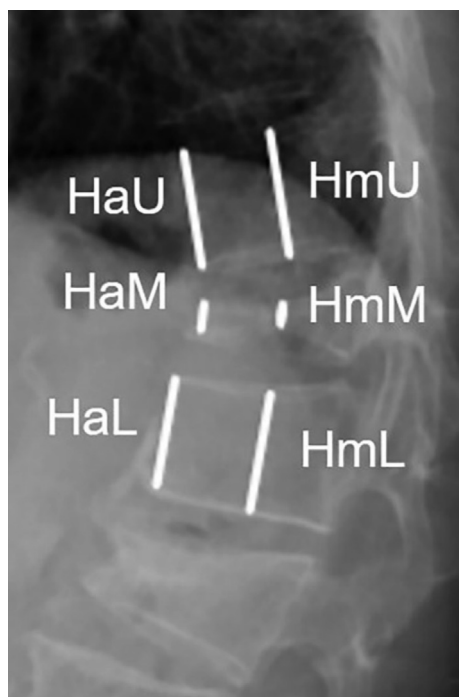


Figure 1. The measurement of body height. H = vertebral body height; M = the fracture vertebra; U = upper segment; L = lower segment; a = anterior part of the vertebra; m = middle part of the vertebra.

reduction of >67%), with bony fragments protruding into the spinal canal.

Percutaneous vertebral augmentation, including percutaneous vertebroplasty and balloon kyphoplasty, has become a routine surgical procedure for treating OVCF and has gained wide satisfactory efficacy results [4]. Owing to its difficulty in puncturing and high risk of bone cement leakage, the procedure remained more challenging when it comes to the special Genant IV OVCF. Balloon expansion and cement injection might aggravate the protrusion of bony fragments, thus causing encroachment of the spinal canal and resulting in traumatic neurological deficit. Thus, the special Genant IV OVCF was considered a contraindication for vertebral augmentation [5].

With the development of several surgical techniques, two bone cement infusion techniques, the graded infusion technique [6–8] and the incremental temperature cement delivery system [9–11], are used to avoid the risk of cement leakage. As far as we know, there have been only few studies published regarding the efficacy of vertebral augmentation on this special Genant IV OVCF. This study aimed to analyze the follow-up data of patients with special Genant IV OVCF and explore the technical tips of vertebral augmentation to obtain greater clinical efficacy and lower the incidence of complications.

Materials and methods

The history of patients with OVCF treated with vertebral augmentation from January 2016 to June 2017 was reviewed. A total of 29 patients met our inclusion criteria, which were as follows: [1] acute OVCF was confirmed by medical history, physical examination, and imaging examination; [2] collapse degree of vertebral body height (anterior or middle part) was more than 2/3; [3] bony fragments protruded into the spinal canal without any neurological symptoms; [4] persistent back pain sustained for days or months and little pain relief was achieved after conservative treatment; and [5] there were no traumatic, pathological vertebral fractures or other serious systematic diseases.

Preoperative imaging examination including plain radiography, computed tomography (CT), and magnetic resonance (MR) scanning was



Figure 2. Measurement of the local kyphotic angle (LKA).

performed for each patient. Fracture morphology was analyzed based on the analysis of preoperative lateral radiographs. The predicted height was calculated as the mean value of adjacent superior and inferior non-fractured vertebra. The vertebral body height variation was presented as follows: (fractured vertebral body height/predicted vertebral body height) * 100%. The local kyphotic angle was measured as the angle formed by two lines that are respectively parallel to the superior end plate of the cephalad vertebra and the inferior end plate of the caudal vertebra (Figures 1 and 2). MR was performed again to confirm the fractured vertebra and determine if the fracture was fresh. CT scanning revealed the integrity of vertebral walls and any existence of the intra-vertebral cleft sign.

The patients were placed in a prone position and treated under general anaesthesia. After localizing the fractured vertebra, two longitudinal incisions were made, and the guide wires were penetrated to the fractured vertebra (at 2 and 10 o'clock) by the bilateral transpedicular approach. Successively larger cannulas were then used to enlarge and deepen the puncture hole. Bone biopsy was performed before injecting the bone cement to confirm the diagnosis of the osteoporotic fracture. In kyphoplasty, two balloon tamps were carefully inserted with the guidance of the C-arm machine into the anterior one-fourth part of the vertebral body. The balloon tamps were inflated to restore the body height and create a void in which the bone cement was injected. After that, the inflation was stopped when the pressure reached 200 psi or when the tamps reached the end plate. Once the inflation was achieved, the balloon tamps were deflated and removed, and the bone cement polymethyl methacrylate (PMMA) was then injected into the cavity. While in vertebroplasty, the bone cement was directly injected into the vertebral body without balloon tamp expansion. The injection process of bone cement was monitored by fluoroscopy in the lateral view and was stopped if any cement leakage was detected in the fluoroscopic image. The amount of cement injected was recorded, and the wounds were closed with nonabsorbable sutures. Early activity was encouraged within 24 h after the surgery, and antiosteoporotic treatment was routinely the preferred choice for outpatients.

Clinical efficacy was evaluated by the visual analogue scale (VAS) and Oswestry Disability Index (ODI) score. The VAS ranged from 0 (no pain) to 10 (the worst experienced) and was used for measuring back pain. Daily life function was estimated by the ODI score.

SPSS 22.0 (SPSS Inc., Chicago, IL, USA) was used for data analysis, and continuous variables were presented as the mean ± standard deviation. Statistical data of radiographic and clinical outcomes in different periods were compared by the paired t test, and $p < 0.05$ was considered statistically significant.

Table 1
Demographic data of patients.

Item	Data
Total number (patients/vertebrae)	29/31
Age (years)	74.21 (±9.27)
Gender	Male 6 (17.86%) Female 23 (82.14%)
Fractured level	T7–T10 3 (9.68%) T11–L2 26 (83.87%) L3–L5 2 (6.45%)
Operation time (mins)	62.43 (±45.09)
Cement volume (mL)	6.48 (±2.10)
Complications	Cement leakage 4 (12.90%) OVCF recurrence 6 (20%)

One male patient with T11 OVCF died, and thus, the recurrence was calculated as 6 of the 30 vertebrae.

OVCF = osteoporotic vertebral compression fracture.

Table 2
Radiological results of vertebral augmentation.

Radiological results	Preoperative	Postoperative	Final follow-up
Body height (anterior) (%)	43.33 ± 0.10	63.90 ± 0.18 ^a	58.62 ± 0.18 ^a
Body height (middle) (%)	34.94 ± 0.08	61.56 ± 0.23 ^a	57.65 ± 0.21 ^a
Local kyphotic angle (°)	19.13 ± 10.40	15.20 ± 9.87 ^a	16.83 ± 10.07 ^a

^a $p < 0.05$ compared with the preoperative value.

Results

General information

One patient died during the follow-up period owing to failed cardiac and pulmonary function. The remaining 28 patients (5 men and 23 women) with 30 fractured vertebrae differing from T7 to L5 accepted vertebral augmentation and completed the follow-up. The mean age of the patients was 74.21 years, and the mean follow-up duration was 21.9 months (Table 1).

Surgical information

All vertebrae were punctured bilaterally and expanded by using balloon tamp. The mean operation time was 62.43 min, and the mean volume of bone cement required for each vertebra was 6.48 mL. No intraoperative complication such as an anaesthesia accident, wrong operating segment, or instrument breakage occurred.

Radiographic results

The radiographic results are presented in Table 2. Vertebral body height and local kyphotic angle showed significant recovery 2 days after surgery, and both showed slight changes during the follow-up period (Figure 3).

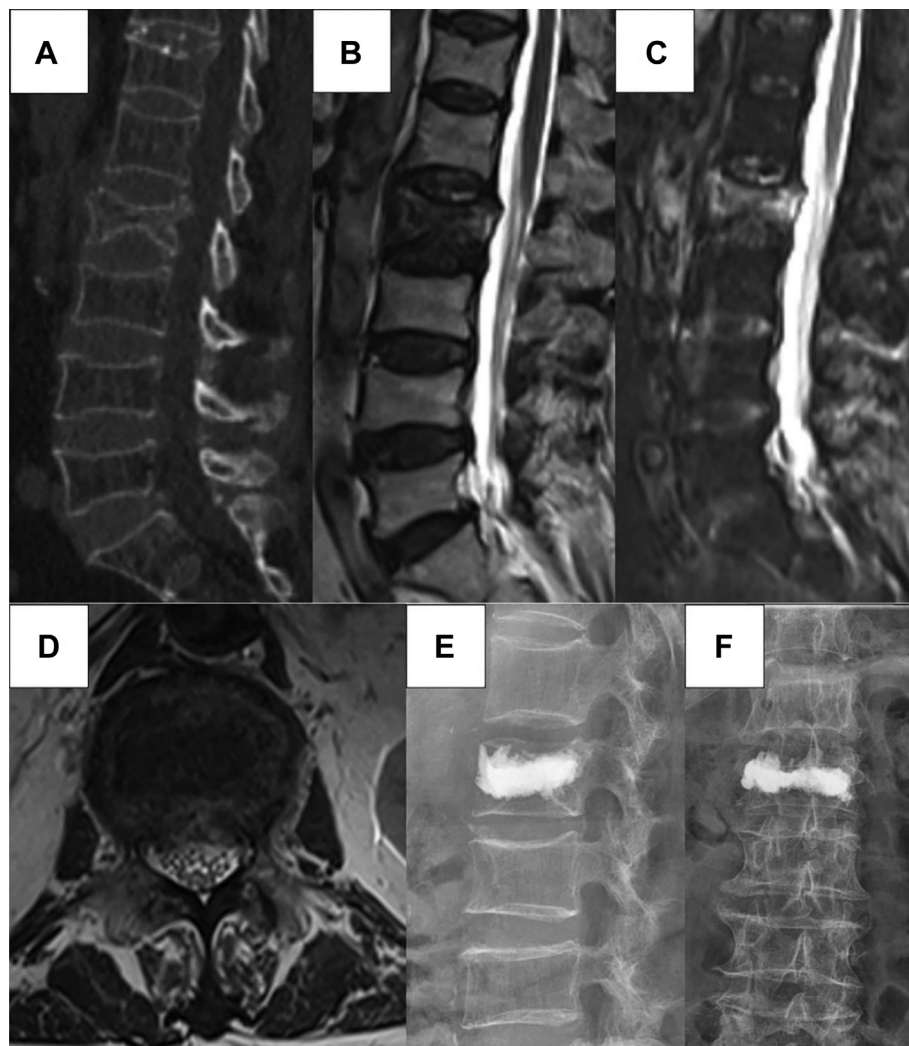


Figure 3. An 88-year-old woman with the special Genant IV OVCF was treated with kyphoplasty. (A) Preoperative sagittal CT reconstruction showed V-shaped OVCF at L2. (B–D) The preoperative MR revealed bone marrow oedema and spinal canal encroachment. (E–F) The postoperative radiograph displayed great recovery of the vertebral body height and LKA without cement leakage. CT = computed tomography; LKA = local kyphotic angle; OVCF = osteoporotic vertebral compression fracture.

Table 3

Clinical outcomes of vertebral augmentation.

Clinical outcomes	Preoperative	Postoperative	Final follow-up
VAS	6.68 ± 1.25	2.18 ± 0.61 ^a	2.34 ± 1.10 ^a
ODI (%)	69.57 ± 9.73	24.93 ± 6.96 ^a	26.00 ± 6.86 ^a

ODI = Oswestry Disability Index; VAS = visual analogue scale.

^a $p < 0.05$ compared with the preoperative value.

Clinical outcomes

The VAS score was 6.68 ± 1.25 before surgery, which was decreased to 2.18 ± 0.61 two days after surgery, and the score was 2.34 ± 1.10 during the final follow-up period. On the other hand, the ODI score implied that the patients' daily life function showed improvement during the follow-up period (Table 3).

No serious complications occurred in any patient. Four vertebrae demonstrated asymptomatic cement leakage by radiological imaging, and the prevalence of leakage was 12.90% (4/31). Among them, two cases had intervertebral leakage, and the other two had paravertebral leakage. During the follow-up period, 6 patients experienced OVCF recurrence, with 4 being adjacent to the former vertebrae. All patients with recurrence underwent another vertebral augmentation, and symptoms such as low back pain were relieved (Figures 4 and 5).

According to the CT and MR imaging results, 8 patients had nonunion. Of these, 3 had experienced OVCF recurrence, and one had asymptomatic cement leakage. The remaining patients did not suffer any complications after surgery.

Discussion

Nowadays, percutaneous vertebral augmentation has been widely applied for osteoporotic fractures, but controversy still remains owing to its uncertain efficacy and complications. According to us, vertebral augmentation is considered an effective treatment option for acute painful OVCFs. A number of high-quality meta-analyses and randomized controlled trials (RCTs) studies have also supported our opinion [12–15]. Patients with OVCF could recover from back pain and disability quickly after undergoing surgery with little trauma and in short operation time.

However, the special Genant IV OVCF does not share a similarity with the ordinary OVCF, and this might be due to the bony fragments that cause neurological deficit. Vertebral augmentation for the special Genant IV OVCF may encounter a variety of challenges. First, injection of bone

cement could aggravate the protrusion of fragments, thus compressing the spinal cord or nerve roots and causing neurological deficits. Second, the walls of the vertebral body are not intact in most of the cases. Therefore, the risk of cement leakage is much higher in the special Genant IV OVCF. Third, owing to the severity of collapse, it is very hard to restore the vertebral body height and kyphotic angle. What is more, the elderly patients with special Genant IV OVCF lack bone mass and thus are in high risk of OVCF recurrence after vertebral augmentation.

In our study, the patients recovered greatly from low back pain and disability after vertebral augmentation. To obtain a safe and effective treatment option for the special Genant IV OVCF, much attention should be paid to the perioperative details, and we share our experiences accordingly. During surgery, the working cannula should be placed in the anterior part of the vertebra to avoid worsening bony fragment protrusion. For cases with nonunion fractures, surgeons should place the tip of the cannula in the cleft so that different parts of the vertebral body are adhered together by cement. Attention must be paid not to inject too little bone cement as the filling would harden spontaneously without adhesion to the vertebra, thus failing to fix the broken vertebra. Finally, intraoperative fluoroscopy ought to be taken frequently when injecting bone cement for monitoring the movement of the posterior bony fragment and any bone cement leakage during the procedure.

The graded infusion technique and the incremental temperature cement delivery system are essential to prevent complications. First, the thick bone cement was injected to build the barrier of vertebral walls, and the thinner cement was then injected after the barrier was hardened. During the surgery, the room temperature was adjusted to 20 °C to form a temperature gradient between the environment and the human body (37 °C). As a result, bone cement injected into the vertebra hardens, while the cement in the working cannula is still in the injectable phase. These two techniques decrease the risk of cement leakage and allow infusion of even filling.

The incidence of cement leakage, a common complication in vertebral augmentation, ranges from 18.1% to 41.1% [16]. Most of the leakage occurs in the spinal canal, intervertebral and paravertebral spaces, and vessels. Cement leakage into the spinal canal or foramen compresses the spinal cord and nerve root, increasing the risk of neurological symptoms. Although most of the vessel leakage is asymptomatic, pulmonary artery embolism caused by bone cement can be lethal. Injection of cement should be stopped immediately if any leakage was observed during fluoroscopy. Another common complication is fracture recurrence. The osteoporotic elderly, who often have poor bone mineral density and have

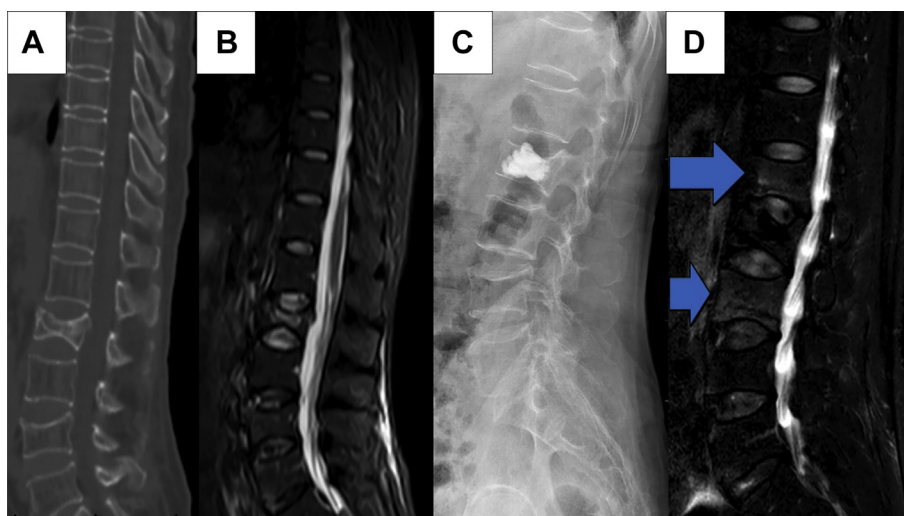


Figure 4. (A) CT scanning showed a special Genant IV OVCF in L2. (B) MR imaging showed bone marrow oedema in L2 and compression of dura. (C) Postoperative X-rays indicated intervertebral leakage. (D) Eight months later, MR imaging showed bone marrow oedema in L1 and L3 (blue arrows), suggesting OVCF recurrence. CT = computed tomography; MR = magnetic resonance; OVCF = osteoporotic vertebral compression fracture.

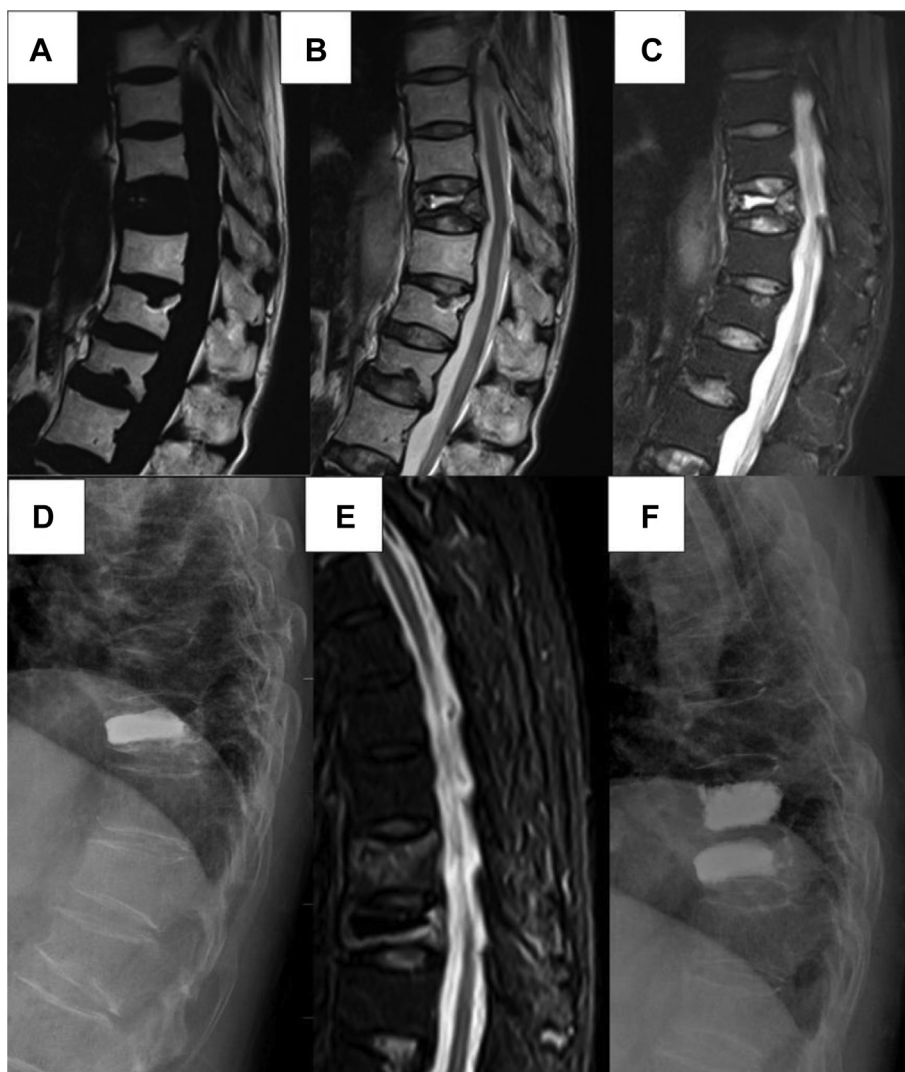


Figure 5. (A–C) Preoperative MR imaging showed low signal intensity in the T1-weighted image and high signal intensity in the T2-weighted image in T10, which is a classical sign of intravertebral fluid. (D) Postoperative X-ray showed a solid fixation of the fracture. (E) Five months later, MR imaging showed bone marrow oedema in T9, and the patient underwent another vertebral augmentation. (F) Postoperative X-ray image of the second surgery. MR = magnetic resonance.

low activity before and after surgery, aggravating osteoporosis condition and leading to the cause of another fracture. Hence, antiosteoporotic therapy is recommended as a routine method to prevent the OVCF and its recurrence. The mismatch of biomechanical properties of PMMA (high stiffness and compressive strength) and the vertebral body is deemed to be another cause of recurrence. Thus, the development of new filling with appropriate mechanical properties is imperative.

In conclusion, percutaneous vertebral augmentation can be very challenging, especially with the special Genant IV OVCFs, which is associated with the protrusion of bony fragments into the spinal canal. But the technique can still achieve great clinical outcomes and lower the complications if special attention and particular tips are applied.

Ethical approval statement

This retrospective article was approved by local ethical committee and informed consent was also achieved.

Conflict of interest

The authors have no conflicts of interest to disclose in relation to this article.

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