

Surgical treatment of the osteoporotic spine with bone cement-injectable cannulated pedicle screw fixation: technical description and preliminary application in 43 patients

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OBJECTIVES: To describe a new approach for the application of polymethylmethacrylate augmentation of bone cement-injectable cannulated pedicle screws.

METHODS: Between June 2010 and February 2013, 43 patients with degenerative spinal disease and osteoporosis (T-score <-2.5) underwent lumbar fusion using cement-injectable cannulated pedicle screws. Clinical outcomes were evaluated using a Visual Analog Scale and the Oswestry Disability Index. Patients were given radiographic follow-up examinations after 3, 6, and 12 months and once per year thereafter.

RESULTS: All patients were followed for a mean of 15.7 ± 5.6 months (range, 6 to 35 months). The Visual Analog Scale and Oswestry Disability Index scores showed a significant reduction in back pain ($p=0.018$) and an improvement in lower extremity function ($p=0.025$) in patients who underwent lumbar fusion using the novel screw. Intraoperative cement leakage occurred in four patients, but no neurological complications were observed. Radiological observation indicated no loosening or pulling out of the novel screw, and bone fusion was excellent.

CONCLUSIONS: The described polymethylmethacrylate augmentation technique using bone cement-injectable cannulated pedicle screws can reduce pain and improve spinal dysfunction in osteoporotic patients undergoing osteoporotic spine surgery.

KEYWORDS: PMMA; Pedicle Screw; Osteoporosis; Lumbar Stenosis; Degenerative Lumbar Surgery.

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INTRODUCTION

The elderly population is rapidly increasing worldwide, accompanied by increases in instances of degenerative spinal diseases that accompany osteoporosis, such as spondylolisthesis, intervertebral disk protrusion, spinal canal stenosis and vertebral compression fractures. These diseases reduce bone quality and the stability of the spine and ultimately lead to pronounced lower back pain or radiating pain in the lower limbs and activity limitations.

Many methods are used for posterior internal fixation, including Harrington rods, Luque rods and Cotrel-Dubousset instrumentation. Pedicle screw instrumentation is the most widely used method for the posterior fixation of patients' vertebrae (1). However, when pedicle screws are used in the osteoporotic spine, the internal fixation strength of the pedicle screws decreases significantly due to low bone mineral density (BMD) (2,3), which results in an increased risk of the screws loosening and pulling out. Enhancing the screw fixation strength in patients with osteoporosis is currently a challenge for spinal surgeons.

Various methods have been suggested to increase screw fixation strength in osteoporotic patients, including improving the design of the screw-rod (4-7), increasing the diameter or length of the pedicle screw (8-11) and using a cannulated pedicle screw for polymethylmethacrylate (PMMA) augmentation (12-16). All of these strategies have potential disadvantages, such as the screw loosening or

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pulling out, vascular or visceral injury and complications associated with PMMA leakage (17). Thus, new techniques are needed to improve the effectiveness and safety of procedures for osteoporotic patients. However, hardened PMMA is very strong and PMMA-augmented cannulated screw fixation is still considered the most efficient method in this field.

This study reports our clinical experience using an improved cannulated screw and novel bone cement design in patients with spinal diseases and osteoporosis who underwent posterior internal fixation. The main differences between this screw and other products are the new screw's special side holes and screw head design. The screw's three side holes can more broadly distribute the PMMA and the multi-axis/single-axis screw head can decrease the difficulty of using a screw in surgical procedures, especially in patients undergoing surgery for spondylolisthesis and degenerative scoliosis.

The purpose of this paper is to describe and recommend a new surgical approach using a PMMA-augmented cannulated screw and to investigate the occurrence of pain and spinal disability after using this approach in patients with osteoporosis and coexisting degenerative spinal diseases.

■ MATERIAL AND METHODS

Screw design

The novel bone cement-injectable cannulated pedicle screw (CICPS) (Kanghui Medical Devices Co., Ltd., Jiangsu, China) is barrel-shaped, with a 3-mm pitch and various outer diameter and length specifications (screws 6.5 mm in diameter and 45 mm in length were used in this study) (Figure 1 A). The pedicle screw has a cannulation diameter of 2.2 mm and the multi-axis or single-axis screw head is designed to make the surgical process easier. Three side holes (round, 2 mm diameter; oval, 3 mm long and 2 mm wide; and U-shape, 4 mm long and 2 mm wide) are arranged from the smallest to the largest at the distal end of the screw (Figure 1 B). After CICPS insertion, the PMMA is

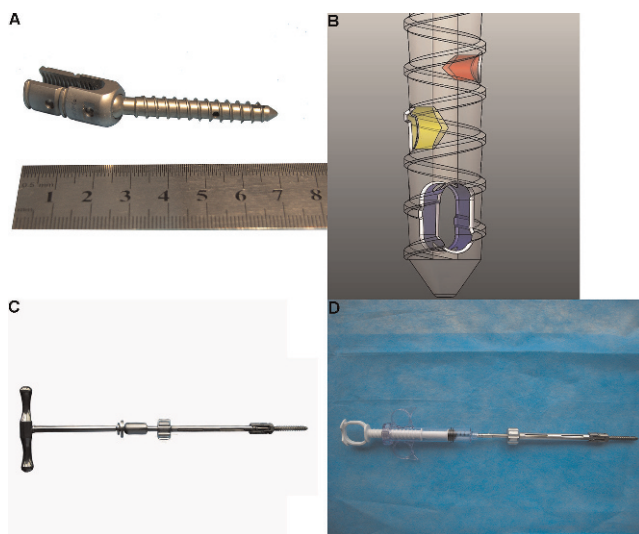


Figure 1 - A: The CICPS. B: Three side holes were arranged from smallest to largest at the distal end of the screw. C and D: The CICPS connects to the T-shaped handle and the specially designed bone cement syringe through an adapter.

injected using a specially designed syringe and adapter and it distributes into the trabeculae of the surrounding bone through the three side holes (Figures 1 C and D). The new syringe is designed with fine gradations so that the proper amount of PMMA can be injected effectively. PMMA injection can be discontinued when leakage is observed using intraoperative imaging.

Clinical Series

Patients. Between June 2010 and February 2013, 43 consecutive patients with osteoporosis and a degenerative spinal disease such as degenerative lumbar spondylolisthesis, lumbar disc herniation/lumbar spinal stenosis, compression fractures and ankylosing spondylitis, or osteoporosis were selected from our inpatient population and enrolled in this study. Osteoporosis was diagnosed according to the World Health Organization's diagnostic criteria for osteoporosis, in which a patient's T-score is less than or equal to -2.5 (T-score ≤ -2.5) (18). All patients had lower back pain and varying degrees of neurogenic issues such as radiating pain, numbness, or muscle weakness in the lower limbs. Each patient had previously undergone at least six months of conservative treatment before surgery. Exclusion criteria included having a blood coagulation disorder, an allergy to any element of the implants and/or a normal BMD. The study was approved by the Southwest Hospital ethics committee. Surgery was performed on those who chose to undergo CICPS for their lumbar fusion and patients were observed for a minimum of 6 months after surgery. All patients provided informed consent before surgery and they were followed up through periodic clinical and radiologic examinations.

Surgical techniques

Prone positioning during general anesthesia was required for all patients who underwent posterior internal fixation. The lesion was approached using a posterior midline incision and total laminectomy and posterolateral fusion was performed based on the lesion characteristics. After confirming the complete decompression of the compromised nerve roots, the transpedicular screw placement site was tapped using a tapper. A 3-mm needle was inserted into the vertebrae through the prepared pedicle screw tract to confirm that there was no cortical bone rupture. To provide a broader space for PMMA distribution, the screw insertion angle was made slightly larger than that of a conventional pedicle screw (Figure 2 A). In addition, the length of the screw should be approximately 80% to 90% that of the vertebra (Figure 2 B).

After injecting the pedicle screw, the adapter was used to connect the screw and the specially designed syringe. PMMA (1 to 2 ml) was injected into each cannulated screw for augmentation. We suggest that the optimal amount of PMMA is 1.5 ml and the optimal injection time is during the sticky stage. To keep the neural canal protected from cement leakage, X-ray imaging was undertaken during all steps of the procedure. If cement leakage to the posterior part of the screw was observed using a lateral X-ray view, the injection of PMMA was stopped.

Neurologic and Radiographic Evaluation

One week after surgery, all patients in this study were encouraged to attempt ambulation wearing a customized lumbosacral orthosis, which they wore for 3 months. Each

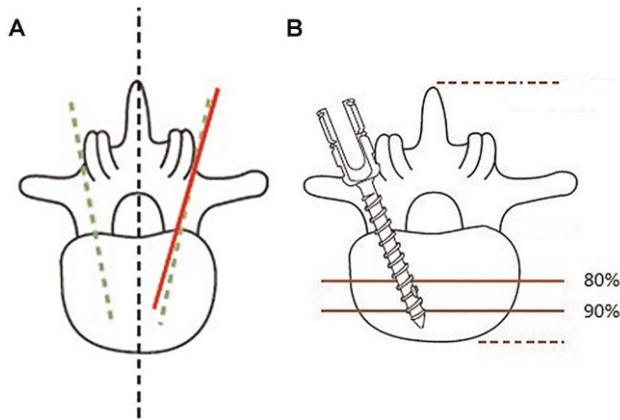


Figure 2 – A: The screw insertion angle is made slightly larger than that of a conventional pedicle screw (shown with a solid red line). B: When determining the proper screw length, a circular side hole in the anterior 80% to 90% of the vertebral body is appropriate.

patient’s recovery and neurologic situation determined whether the patient was allowed to participate in positive activity or go to work. Patients with wound infections, apparent pain, preoperative symptom aggravation, or other untoward reactions did not undertake positive activity or work. The patients’ clinical outcomes and their abilities to function were assessed using the Visual Analog Scale (VAS) and the Oswestry Disability Index (ODI) scoring system pre- and post-operation, respectively, at 3, 6 and 12 months after surgery and once per year after the first year. The data were analyzed using the self-control method.

Complications, including cement leakage, blood clots and infection, were also evaluated. X-ray and CT imaging evaluations were performed pre- and post-operatively and at each outpatient follow-up interval. Anteroposterior, lateral and flexion-extension lumbosacral X-ray planes were obtained to evaluate pedicle screw loosening or pullout. CT scans, including two- and three-dimensional reconstructions, were performed on each patient to determine cement leakage and interbody fusion at 6 and 12 months after surgery. A solid fusion was evaluated on the follow-up films at 12 months after surgery and successful fusion was assessed according to Sapkas’ and Christiansen’s methods (19,20). Screw loosening was defined as a radiolucency of one millimeter (mm) or wider at the bone/screw interface (12).

The data are presented as the mean \pm standard deviation (SD) and were analyzed using SPSS for Windows ver. 13.0 (SPSS Inc., Chicago, IL). The paired t-test was performed to compare continuous variables, including preoperative and final VAS and ODI scores. A *p*-value of less than 0.05 was considered significant.

RESULTS

The patients enrolled in this study were preoperatively diagnosed with degenerative spondylolisthesis (17 patients, including one patient whose surgery was repeated because of common screw loosening after the first surgery), lumbar disc herniation/lumbar spinal stenosis (15 patients), compression fractures (7 patients) and ankylosing spondylitis (4 patients). The patients’ baseline clinical characteristics are listed in Table 1.

The overall operation time was 235.6 ± 70.0 min (range, 62 to 430 min) and the average blood loss was 591.9 ± 706.6 ml (range, 200 to 4000 ml). There were no serious hemorrhage complications when using the self/allogeneic blood transfer methods during the operation. In addition, no complications arose during the procedure or related to the surgery and there was no nerve, blood vessel, or internal organ injury. When injecting the PMMA, there was no cement leakage from the junctions in the device. Thus, operative site contamination did not occur during any of the operative procedures.

For this study, a CICPS was used for degenerative spondylolisthesis, lumbar disc herniation/lumbar spinal stenosis, compression fractures and ankylosing spondylitis. Typical images of a patient with ankylosing spondylitis and degenerative spondylolisthesis are presented in Figure 3 and Figure 4, respectively.

All 43 patients were diagnosed with severe osteoporosis and had decreased BMD (T-score ≤ -2.5). A total of 125 CICPSs were surgically implanted in patients during this study (Table 1) and 1.0 to 2.0 ml PMMA was injected into each screw. All patients were followed up for 6 to 35 months (average of 15.7 ± 5.6 months). The preoperative ODI and VAS scores were $54.02 \pm 18\%$ and 7.46 ± 1.67 mm, respectively. At the last follow-up, the ODI and VAS scores were $23.58 \pm 11.65\%$ and 1.83 ± 0.82 mm, respectively. The scores at the last follow-up were significantly improved compared to preoperative scores (ODI, *p* = 0.025; VAS, *p* = 0.018).

The pain and nerve compression symptoms in all patients were relieved to various degrees post-operatively and some patients’ symptoms disappeared. Good corrective effects on

Table 1 - Baseline demographic and clinical characteristics of 43 patients with cement-augmented bone cement-injectable cannulated pedicle screws in the osteoporotic spine.

Variable	Value
Mean age, years; mean \pm SD (range)	60.4 \pm 11.6 (46 to 82)
Gender (n; M:F)	13:30
Mean follow-up duration, months; mean \pm SD (range)	15.7 \pm 5.6 (6-35)
Mean BMD, T-score; mean \pm SD (range)	-3.13 \pm 0.62 (-2.5 to -4.7)
Preoperative diagnosis, n (%) / the number of CICPS, n	
Lumbar spondylolisthesis	17* (49.0%) / 49
Lumbar disc herniation/lumbar spinal stenosis	15 (34.9%) / 38
Vertebral fracture	7 (16.3%) / 20
Ankylosing spondylitis	4 (9.3%) / 18
Total	43 (100%) / 125

CICPS: bone cement-injectable cannulated pedicle screw.

*: one patient had a solid screw that loosened after the first operation; the second operation used a CICPS.

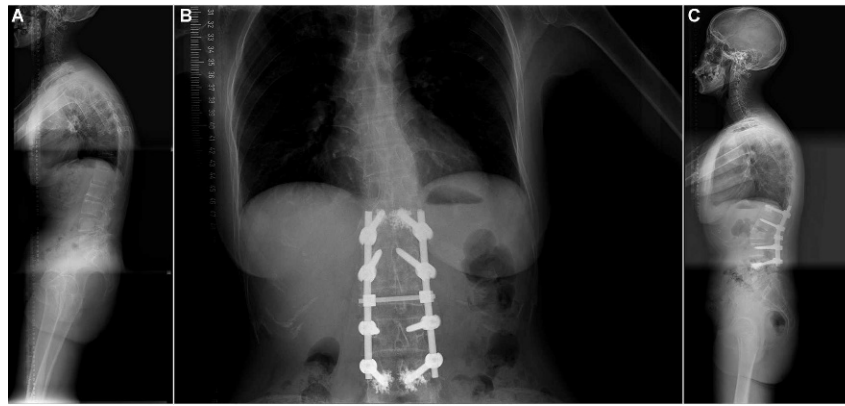


Figure 3 - A: A 43-year-old female patient who had a 10-year history of lower back pain and kyphosis. The pain had been worsening for 1 year and she was diagnosed with ankylosing spondylitis and kyphosis. B and C: The patient underwent a partial osteotomy of the key vertebrae without intervertebral fusion. CICPS augmentation with PMMA was used at the top and bottom of the internal fixation instrument. X-ray images showed good spinal correction 6 months after the surgery.

spinal deformity were observed and there were no instances of screw loosening, screw pullout, or fracture of the CICPS. PMMA leakage into the vertebral body venous plexus was observed in four patients, but this leakage was not clinically relevant. CT scan results 6 to 12 months after surgery showed that bone healing had occurred within the vertebrae and around the screws. None of the patients involved required revision surgery for screw loosening or failed fusion after CICPS implantation using PMMA. Pulmonary emboli or wound infections were not observed after surgery.

DISCUSSION

The optimum method for enhancing pedicle screw fixation strength has been investigated (17), but no conclusive determination of the optimum method has been made. In the osteoporotic spine, the use of various absorbable or nonabsorbable cements to strengthen pedicle screws is considered the most effective method to stabilize and support the degenerating spinal column (21-23). Traditionally, PMMA use involves three main steps: 1) drill a pilot hole; 2) inject the PMMA; and 3) insert the pedicle screw. Using this traditional method, PMMA distribution cannot be controlled during the screw injection process, which leads to a high risk of PMMA leakage into the spinal

canal, neural foramina, and vertebral venous plexus. PMMA leakage can damage the spinal cord, nerve root and other vital organs. Another complication is the exothermic reaction that occurs as the PMMA hardens which, especially when it occurs in close proximity to neural elements (24,25), could damage these neural elements. In more serious cases, pulmonary embolism (26), paraplegia (27), or death (28) can occur as a result of PMMA leakage.

To prevent the serious complications mentioned above, a cannulated pedicle screw may be used (12-14,29,30). This type of pedicle screw allows the injection of PMMA through holes in the sides of the screw after screw insertion. When leakage into the spinal canal is observed using x-ray monitoring, PMMA injection into the vertebra can be immediately stopped. Based on previous experience using CICPS, the authors recommend using intraoperative x-ray monitoring during the PMMA injection procedure. The surgeon must also be an experienced spinal surgeon and the PMMA injection step should be completed under the guidance of a doctor who has PVP/PKP (percutaneous vertebroplasty/percutaneous kyphoplasty) surgical experience. Thus, neurological symptoms can be reduced substantially. Four patients in our study had PMMA vertebral venous plexus leakage. The injection process was stopped immediately when the surgeon observed this situation. The

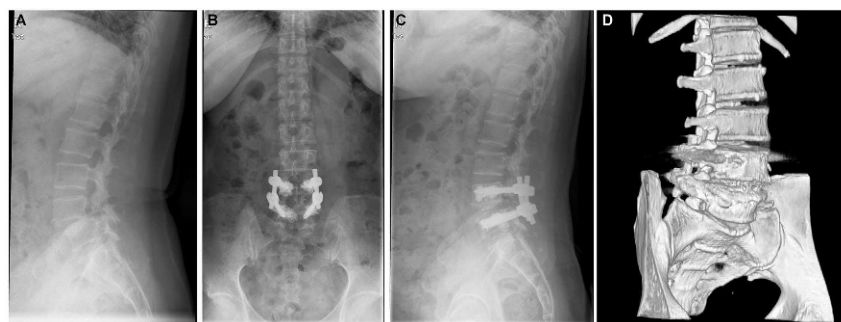


Figure 4 - A: A 54-year-old female patient who had a history of back pain for more than five years. The pain was exacerbated after a trauma four months before presentation and she was diagnosed with L4 spondylolisthesis. B and C: The patient underwent internal fixation and transforaminal lumbar interbody fusion. All screws used for augmentation were CICPS. Eight months after surgery, x-ray images showed that the spine reduction was sustained. No screws were loosened or pulled out. Three-dimensional CT images showed that bone fusion had already been achieved (D).



Table 2 - Suggestions for bone cement-injectable cannulated pedicle screw applications in different diseases.

Disease	Augmentation approach
Lumbar spondylolisthesis	1) all screws use CICPS augmentation; 2) intervertebral fusion
Lumbar disc herniation/lumbar spinal stenosis	1) CICPS augmentation on one side, a conventional screw used on the other side; 2) intervertebral fusion
Vertebral fracture	1) fixation at the adjacent vertebral bodies, but no screw implanted in the fractured vertebral body; 2) PVP/PKP performed on the fractured vertebral body; 3) CICPS augmentation on one side and a conventional screw on the other side;
Ankylosing Spondylitis	4) no intervertebral fusion 1) partial osteotomy for the key vertebra; 2) four screws at the top and bottom using CICPS augmentation; 3) no intervertebral fusion

PVP: percutaneous vertebroplasty.
PKP: percutaneous kyphoplasty.

leaks did not result in any neurological symptoms during postoperative observation and follow-up.

The main difference between CICPS and other cannulated screws is the design of the PMMA outflow channels. PMMA distribution using cannulated screws with different numbers of side holes was evaluated (31) and 1) a large amount of PMMA flowed out from the oppositely arranged proximal side holes, whereas almost no PMMA was observed in the distal holes; and 2) the nearer the proximal side hole was to the screw head, the higher the axial force pulling it out and the greater the risk of cement leakage. Our results are consistent with these conclusions. Based on the above results, the three CICPS side holes were arranged by size from smallest to largest at two-fifths of the length from the distal end of the screw and the central hollow tract was closed at the screw tip. Imaging results showed that the CICPS design increased the amount of cement flowing to the distal end of the screw. PMMA was uniformly distributed around the distal half of screw and almost no distribution was observed at the proximal half. The distribution pattern was significantly improved compared to other existing types of cannulated screw systems (12-14,29). This type of cement distribution effectively avoided complications related to cement leakage in clinical applications.

Pedicle screw loosening and pullout were the main reasons that internal fixation failed, with the failure incidence ranging from 0.6% to 11% (32). In our study, however, no screw loosening or pullout was observed. We speculated that this was a result of the cement distribution from the side holes into the cancellous bone, which led to the formation of a new cement/bone complex structure where the cement was located. The complex produced an anchoring effect to increase the screw stability of the CICPS. Consistently, only a small amount of PMMA was needed to secure the screw, which suggests a large benefit to using CICPSs. Along with improving fixation stability, the small amount of PMMA required could reduce the risk of leakage.

Several clinical reports have shown that screw breakage results in pedicle screw fixation failure (6,9,21,33). Breakage can occur as a result of cancellous bone compression along the shaft due to the repetitive motion of inserting the screw. When the pedicle screw is loaded at the screw head, the pedicle isthmus acts as a fulcrum around which the screw rotates, causing compression and resulting in a "butterfly-shaped" void (33). Repetitive loading creating a "three-point

bending" effect may eventually cause a fatigue fracture. Palmer et al. reported two cases of screw breakage and another report indicated a screw breakage rate of 5% (5/37) (6). However, in the present study, no screw breakage was observed. The application of a multi-axis/single-axis screw head design, which can swing to resist fatigue load, might explain why no screw breakage occurred. More importantly, a multi-axis/single-axis screw head could improve the ease of connecting the rod and may also reduce operation time.

Stable internal fixation created excellent conditions for bone fusion. In the present study, patients were followed-up for more than 6 months and all patients achieved bone fusion, with a fusion rate of 100% (43/43). This 100% fusion rate may have several explanations. First, all of the inferior and superior endplate cortical bone was surgically removed at the fusion level before the bone graft and the bone grains were firmly compacted during surgery to avoid bone absorption caused by bone deficiency. Second, different CICPS augmentation approaches were used according to the required mechanical intensity for each patient's spinal degeneration disease. If the required mechanical strength was higher, more CICPSs were used. Suggestions for the application of CICPS to other diseases are presented in Table 2. Third, patients in this study were encouraged to undertake early ambulation one week after surgery using a customized lumbosacral orthosis, but positive activity and work were not allowed until three months later. Controlling postoperative motion effectively prevented movement in the area of fusion. This led to rapid bone growth. Finally, the stable fixation effect prevented fusion failure, which had a higher incidence in other studies (89-95%) (12) and which commonly occurs in patients with poor spinal stability, such as patients with lumbar spondylolisthesis (34). Thus, the stable fixation effect of CICPS might also promote and play an important role in bone fusion.

Although CICPS showed excellent preliminary results in the osteoporotic spine, it has several limitations. For the clinical application of CICPS, screw removal is very difficult because of the extreme hardness of cured PMMA. If the screw loosens, as it may because of infection, the revision surgery is challenging. Thus, the use of CICPS with PMMA is not suitable for all patients with osteoporosis and the indications for surgery must be carefully considered. The long-term clinical efficacy in patients treated with CICPS with PMMA requires further evaluation with a larger number of patients and a longer follow-up period.



We describe and recommend a new surgical approach for the application of PMMA augmentation to CICPS. This augmentation technique can improve the fixation stability and reduce the risk of complications. Our results indicate that CICPS is an excellent method for use in the osteoporotic spine, but the safety and efficacy of using this technique in the osteoporotic population needs to be confirmed in a larger series with a longer follow-up period.

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AUTHOR CONTRIBUTIONS

Dai F and Liu Y drafted study concepts, designed the study, performed experimental studies, acquired and analyzed the data, drafted the manuscript, they also contributed equally to this work. Zhang F, Sun D, Luo F and Zhang Z performed literature research, statistical analyses and experimental studies. Xu J is a guarantor of the integrity of the entire study, is responsible for experimental guidance and quality supervision, participated in coordination and helped drafting the manuscript. All authors read and approved the final version of the manuscript.

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