

Effectiveness of cannulated screw fixation for femoral neck fracture assisted by three-dimensional printing navigation template in middle-aged and elderly patients

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Abstract. – OBJECTIVE: We sought to explore the effectiveness of cannulated screw fixation for femoral neck fractures in middle-aged and elderly patients assisted by a three-dimensional printing navigation template.

PATIENTS AND METHODS: A total of 98 middle-aged and elderly patients who underwent cannulated screw fixation for femoral neck fractures were retrospectively analyzed. They were allocated into two groups, each comprising 49 patients. Surgical indexes, hip function, and pain levels were compared between the two groups.

RESULTS: The study group, assisted by the three-dimensional printing navigation template, exhibited significantly reduced nail insertion, fewer instances of C-arm fluoroscopy, shorter operation time, quicker time to bone union, earlier initiation of walking exercise, shorter time to weight-bearing walking, and reduced hospital stay than those in the control group (all $p < 0.001$). However, the study group also experienced higher blood loss compared to the control group ($p < 0.001$). Postoperatively, at 3 months and 12 months, the study group demonstrated significantly higher scores compared to the control group (both $p < 0.001$) and reported significantly lower pain scores than that in the other group at 1 week and 12 months post-surgery (both $p < 0.001$). Furthermore, the study group experienced significantly fewer postoperative complications than the control group ($p = 0.029$).

CONCLUSIONS: Cannulated screw fixation for femoral neck fractures assisted by a 3D printing navigation template is more effective and safer than traditional fixation methods. This approach represents a promising alternative for surgical management.

Key Words:

Three-dimension printing, Template, Cannulated screw fixation, Femoral neck fracture, Elderly patients, Prognosis.

Introduction

Hip fractures constitute a significant global health concern, with an estimated 2.6 million people projected to experience them by 2025, with femoral neck fractures accounting for 50% of these cases¹. In China, the number of patients with hip fractures is expected to increase from 0.7 million in 2013 to 4.5 million by 2050, with a predominant portion being elderly individuals². Femoral neck fractures typically result from severe trauma, often leading to ischemia necrosis, non-union of bone, and a high disability rate, significantly impacting the daily lives and mobility of affected patients. Achieving anatomical reduction and stable fixation is essential for these patients to regain joint function and improve their prognosis³.

At present, various surgical methods, such as internal fixation and artificial hip replacement, are employed in clinical practice for treating femoral neck fractures. However, the anatomical complexity of the femoral neck, characterized by anteversion and neck-shaft angles, poses a surgical challenge⁴. Regardless of the chosen surgical approach, femoral head necrosis, non-union of the fracture, and postoperative complications remain significant challenges in the management of femoral neck fractures. In particular, middle-aged and elderly patients with femoral neck fractures often present with significant displacement of fracture ends to high-energy trauma, which can damage the blood supply to the femoral head and increase the incidence of complications. Meanwhile, determining the optimal screw insertion position is challenging due to factors such as surgeon experience, visual disparities, and unstable operations, even after

repeated C-arm fluoroscopy. Multiple X-ray fluoroscopies also raise concerns about radiation exposure, making the choice of hollow screw insertion a topic of debate⁵. With the advent of three-dimension (3D) printing technology, it has been implemented in the surgical treatment of femoral neck fractures to facilitate precise hollow screw insertion. Nonetheless, concerns have been raised in literature about the fact that the modeling, design, and template printing process might prolong surgery and complicate fracture reduction. However, these concerns have been based on limited sample sizes, constrained reliability, and inconclusive results, primarily in elderly patients.

Therefore, this study aimed to explore the effectiveness of hollow screw fixation for femoral neck fracture assisted by a 3D printing navigation template in middle-aged and elderly patients.

Patients and Methods

Participants

A total of 98 middle-aged and elderly patients who underwent surgery for femoral neck fractures from August 2020 to August 2021 were included in this retrospective analysis. The patients were divided into the study group (3D printing navigation template-assisted hollow screw fixation) and the control group (traditional hollow screw fixation). This study was approved by the Ethics Committee of The Second Affiliated Hospital of Shandong First Medical University (No. 2021-096), and informed consents for publication were received from all participants.

Inclusion and Exclusion Criteria

Inclusion criteria: (I) Less than 72 hours from fracture to admission; (II) Unilateral closed femoral neck fracture; (III) Absence of injury to other organs, nerves, and blood vessels; (IV) Recommendation and suitability for surgical treatment; (V) Normal hip function before injury; (VI) Written informed consent obtained.

Exclusion criteria: (I) Severe infection; (II) Pathological fracture; (III) Open fracture. (IV) Coexisting fractures in other sites; (V) Rheumatoid arthritis, a disease affecting other vital organs or malignancies; (VI) Compartment syndromes; (VII) Cognitive impairment, language barriers, or affective disorders; (VII) Pregnancy or breastfeeding.

Surgical Methods

Patients in the control group underwent conventional hollow screw internal fixation. After being administered anesthesia, patients were positioned supine with the ipsilateral hip of the injured limb elevated. Fracture reduction was achieved through traction on an orthopedic surgery traction bed (HE-F04, Howell Ltd, Haerbin, China). The reduction of the fracture was monitored using C-arm fluoroscopy (OEC 9900, GE Ltd, USA), and once a satisfactory reduction was achieved, the patients were sterilized. Then, three guide pins (Shanghai Kangding Medical Equipment Co., LTD, Shanghai, China) were inserted in an inverted equilateral triangle pattern along the long axis of the femoral neck, positioned approximately 3 cm below the greater trochanter of the femur. C-arm fluoroscopy was applied to confirm the guide pin positions. Next, the guide pins served as the standard for measuring depth and drilling holes. Three cannulated screws (Beijing Libel Institute of Biological Engineering Co., LTD, Beijing, China) were inserted into the corresponding nail channels, and the screws were secured while releasing the traction frame. Repeated C-arm fluoroscopy was performed to visualize and fine-tune the position of the cannulated screws. After irrigating the surgical site with normal saline (Merck KGaA, Darmstadt, Germany), inspecting the surgical instruments, and closing the surgical incision layer by layer, the wound was dressed with sterile materials.

Patients in the study group underwent hollow screw internal fixation assisted by a 3D printing navigation template. This approach involved performing a hip joint computer tomography (CT) scan and 3D reconstruction. The CT scan image data were saved in DICOM format. Minics medical software (version 14.11, Materialise Ltd, Belgium) was used to review and analyze the image data, create a 3D model of the femoral neck fracture, and conduct multi-angle 3D data measurements. A 5-millimeter margin was reserved to account for reduction error, and an inverted equilateral triangle pattern was designed as the optimal nail channel and the sequence for hollow screw insertion. The software facilitated the establishment of the optimal vertex and angle for the hollow screw within the proximal femur, enabling the prediction of the screw's diameter, length, and position. Anatomical data concerning the patient's bone surface shape were extracted, and a reverse template was gen-

erated within the software to fit the optimal top placement channel. This process also involved virtual reduction of the femoral neck and surgical drilling. The customized 3D-guided template was produced using a new biological material (polylactic acid) at a 1:1 ratio and sterilized for surgical use.

The anesthesia and reduction methods in the study group mirrored those used in the control group. The femoral trochanter was designated as the reference point for the placement of the 3D-printed navigation template. The template was adjusted as necessary to ensure a secure fit. The extension lines of Kirschner pins (Dongguan Yue Linsen metal Technology Co., LTD, Dongguan, China), intended for insertion into the template's guided holes, were positioned within the femoral neck using C-arm fluoroscopy. Subsequently, the pins were inserted along the defined paths in accordance with the position and depth of the virtual insertion points. Once the appropriate positions and depths of the pins were confirmed, three cannulated screws with the correct specifications were threaded into the corresponding nail channels. The screws were secured while simultaneously releasing the traction frame. Repeated C-arm fluoroscopy was performed to visualize and fine-tune

the position of the cannulated screws. Following this, the surgical site was rinsed with normal saline, the surgical instruments were inspected, the surgical incision was closed layer by layer, and sterile dressings were applied. Preoperative and postoperative images aided by the 3D navigation template are shown in Figure 1. Intraoperative images and postoperative imaging data of patients in the study group are shown in Figure 2.

Postoperative Treatment

In both groups, patients received routine postoperative antibiotics within 24 hours, and measures to prevent stress ulcers were taken. Subcutaneous abdominal injections of heparin (5,000 UI) were administered 12 hours after the operation and then once daily for 4-7 days. Coagulation function and complete blood counts were monitored regularly (1-2 times per week) during heparin administration and immediately discontinued in the presence of abnormal coagulation. Patients were instructed to perform quadriceps function exercises, including hip, knee, and ankle movements if appropriate while avoiding straight leg lifts and premature weight-bearing activities.

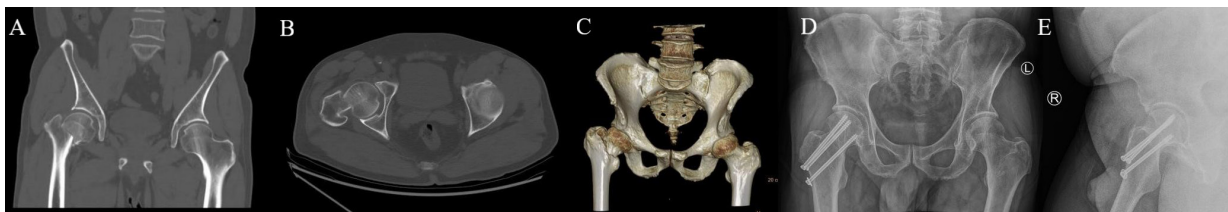


Figure 1. Right femoral neck fracture in the study group. **A**, Coronal image of the right hip fracture before surgery. **B**, Horizontal image of the right hip fracture before surgery. **C**, 3D reconstruction of the right hip fracture. **D**, Intraoperative insertion of hollow screw. **E**, Post-operative image of hip fracture union. 3D: 3D printing.

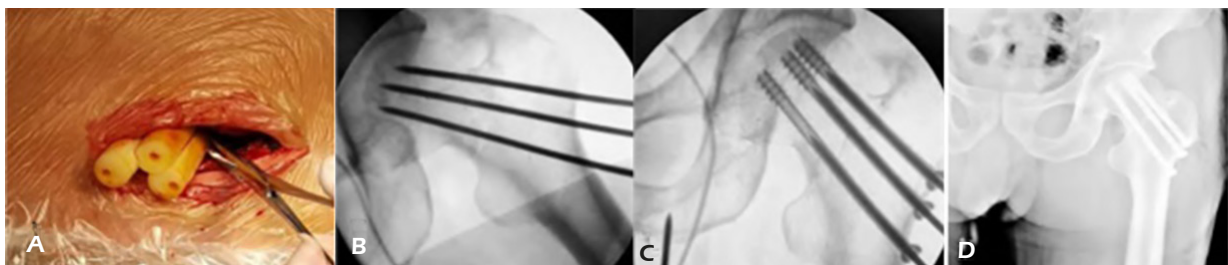


Figure 2. Intraoperative images and postoperative imaging data of patients in the study group. **A**, Intraoperative application of 3D printing navigation templates. **B**, Intraoperative fluoroscopic observation of guide needle positioning position. **C**, Three hollow screws were screwed in and pressurized during the operation, and the nails were placed satisfactorily. **D**, X-ray reexamination after surgery showed that the fracture was well reduced.

Observation Indexes

Blood loss, the number of nail insertions, the number of C-arm fluoroscopy sessions, operation duration, time from surgery to fracture union, time from surgery to the initiation of walking exercises, time from surgery to full weight-bearing walking, and duration of hospital stay were all considered to be surgery-related indicators.

Harris scores were used to assess hip function before the operation, at 3 months and 12 months post-operation⁶. These scores are comprised of function (47 points), joint activity (5 points), pain (44 points), and deformity (4 points), with a maximum score of 100. A higher score indicates better hip function of the injured limb.

Pain scores were recorded before the operation and at 1 week and 3 months after the operation *via* the visual analog scale (VAS)⁷, which has a range of 0-10 points. A higher score reflects a greater level of pain.

Follow-Up

After the surgery, patients underwent a 1-year follow-up period. We conducted regular follow-ups using WeChat or telephone communication on a monthly basis, and patients were seen in the outpatient department every 3 months. During this follow-up period, we documented any cases of bone non-union, femoral neck necrosis, and fixation failure.

Statistical Analysis

All the data collected in this study were subjected to rigorous analysis using SPSS 21.0 software (IBM Corp., Armonk, NY, USA). Normally

distributed measurement data were expressed as mean±standard deviation (SD), and the comparisons were evaluated using the Student's *t*-test. Categorical data were expressed as n (%), and differences between the two groups were examined through Chi-square analysis or Fisher's exact test. A significant level of $p < 0.05$ was applied to identify statistically significant differences.

Results

Baseline Characteristics

Each group comprised 49 patients, with 28 male and 21 female patients in the study group and 29 male and 20 female patients in the control group. The mean age was 62.83±11.82 (range: 45-74) years in the study group and 62.76±12.16 (range: 45-76) years in the control group.

There were no significant differences in age, gender, injured sites, time from surgery to admission, Garden classification, or cause of injury between the two groups ($p > 0.05$) (Table I).

Surgical Indexes

In the study group compared to the control group, the insertion of nails (11.23±2.12 *vs.* 23.17±2.76 times), the number of C-arm fluoroscopy sessions (19.87±2.54 *vs.* 40.76±2.62 times), the operation time (47.65±4.54 *vs.* 63.29±5.38 minutes), the time to bone union (3.68±0.65 *vs.* 4.96±0.68 months), the time to walking exercise (29.46±3.21 *vs.* 60.92±3.32 days), the time to weight-bearing walking (4.51±1.02 *vs.* 5.93±1.09 months), and hospital stay (9.76±1.87

Table I. Baseline characteristics of the two groups (n, mean ± SD).

Variables	Study group (n=49)	Control group (n=49)	<i>p</i> -value
Age (years)	62.76 ± 12.16	62.83 ± 11.82	0.977
Gender (male/female)	29 (59.18%)/20 (40.82%)	28 (57.14%)/21 (42.86%)	0.838
Laterality			0.675
Left	19 (38.78%)	17 (34.69%)	
Right	30 (61.22%)	32 (65.31%)	
Time from injury to admission	7.32 ± 0.43	7.27 ± 0.45	0.575
Garden classification			0.786
I	7 (14.29%)	9 (18.37%)	
II	13 (26.53%)	16 (32.65%)	
III	20 (40.81%)	16 (32.65%)	
IV	9 (18.37%)	8 (16.33%)	
Cause of injury			0.875
Traffic accident	11 (22.45%)	9 (18.37%)	
Fall	29 (59.18%)	31 (63.26%)	
Drop	9 (18.37%)	9 (18.37%)	

SD: standard deviation.

vs. 11.89±1.93 days) were all significantly lower in study group (all $p<0.001$). However, the blood loss in the study group was significantly higher than that in the control group (98.13±8.96 vs. 78.87±9.09 ml, $p<0.001$) (Table II).

Hip Function

There were no significant differences in hip function scores between the two groups before surgery (37.38±4.39 vs. 37.43±4.42, $p=0.955$). However, the scores were significantly higher in the study group than in the control group at 3 months (46.47±4.43 vs. 40.28±4.56, $p<0.001$) and 12 months (79.98±7.63 vs. 68.93±7.72, $p<0.001$) after surgery, respectively (Table III).

Pain Score

No significant differences in pain scores were found between the two groups before surgery (5.87±1.23 vs. 5.81±1.32, $p=0.816$). However, the pain scores in the study group were markedly

lower than those in the control group at both 1 week (2.34±0.43 vs. 3.57±0.48, $p<0.001$) and 12 months (1.01±0.32 vs. 1.16±0.37, $p<0.001$) after surgery (Table IV).

Outcomes During Follow-Up

Patients were followed up for an average of 13.28±1.32 (range: 12-15) months. Postoperative complications were significantly less frequent in the study group compared to the control group (2.04% vs. 14.29%, $p=0.029$) (Table V).

Discussion

Currently, the standard treatment for middle-aged and elderly femoral neck fractures often involves closed reduction and cannulated screw internal fixation, which has shown satisfactory surgical outcomes. Following biomechanical principles, this method provides reli-

Table II. Comparison of surgical indexes between two groups (mean ± SD).

Variables	Study group (n=49)	Control group (n=49)	p-value
Intraoperative blood loss (milliliters)	98.13 ± 8.96	78.87 ± 9.09	< 0.001
Number of nail insertions	11.23 ± 2.12	23.17 ± 2.76	< 0.001
C-arm perspective frequency	19.87 ± 2.54	40.76 ± 2.62	< 0.001
Operation duration (minutes)	47.65 ± 4.54	63.29 ± 5.38	< 0.001
Time to fracture union (months)	3.68 ± 0.65	4.96 ± 0.68	< 0.001
Time to walking exercises (days)	29.46 ± 3.21	60.92 ± 3.32	< 0.001
Time to weight-bearing walking (months)	4.51 ± 1.02	5.93 ± 1.09	< 0.001
Hospital-stay (days)	9.76 ± 1.87	11.89 ± 1.93	< 0.001

SD: standard deviation.

Table III. Comparison of hip function test between the two groups (mean ± SD, points)

Variables	Study group (n=49)	Control group (n=49)	p-value
Before surgery	37.38 ± 4.39	37.43 ± 4.42	0.955
3 months after surgery	46.47 ± 4.43	40.28 ± 4.56	< 0.001
12 months after surgery	79.98 ± 7.63	68.93 ± 7.72	< 0.001

SD: standard deviation.

Table IV. Comparison of self-pain report between the two groups (mean ± SD, points).

Variables	Study group (n=49)	Control group (n=49)	p-value
Before surgery	5.87 ± 1.23	5.81 ± 1.32	0.816
3 months after surgery	2.34 ± 0.43	3.57 ± 0.48	< 0.001
12 months after surgery	1.01 ± 0.32	1.16 ± 0.37	< 0.001

SD: standard deviation.

Table V. Comparison of long-term outcomes between the two group (n).

Variables	Study group (n=49)	Control group (n=49)	p-value
Nonunion	1 (2.04%)	3 (6.12%)	
Osteonecrosis of the femoral head	0 (0.00%)	1 (2.04%)	
Failure of fixation			
Fracture of nail	0 (0.00%)	1 (2.04%)	
Retreat of nail	0 (0.00%)	1 (2.04%)	
Dissection of femur head	0 (0.00%)	1 (2.04%)	
Total	1 (2.04%)	7 (14.29%)	0.029

able shear resistance, bending resistance, and rotation resistance on both the tension and pressure sides of the fracture. It effectively stabilizes and supports the fractured bone ends without significantly compromising the local blood supply, which is conducive to fracture healing and surgical success⁸. However, this procedure requires a surgeon with considerable experience and skill to ensure accurate nail insertion, making it challenging to achieve the optimal nail position and depth, often requiring multiple fluoroscopy scans and thereby increasing radiation exposure. Meanwhile, repeated adjustments to the guide pin's position can impact bone quality and the stability of cannulated screw fixation. Therefore, it is imperative to explore a safe and accurate method for ensuring the proper insertion of cannulated screws. In recent years, 3D printing technology has made great progress in the field of medical surgery and received extensive attention from clinicians^{9,10}.

CT scans and 3D reconstructions of the injured limb conducted before the operation are imported into the Mimics software. This software allows us to create a precise, 1:1 anatomical structure and navigation template of the human body, greatly aiding in surgical positioning, and is expected to offer solutions to a wider range of clinical issues¹¹. In this study, a 3D CT-printed navigation template for the injured limb was produced after CT scanning and hip reconstruction before the operation. This pre-planning process facilitated the delineation of the operation area and procedure, as well as the reduction process, nail channel direction, and the position and depth of the hollow screw. During the operation, the hollow screw could be inserted successfully, guided by the template. This approach addresses the issue where surgical accuracy primarily relies on the surgeon's experience and the tactile sensation of screw insertion. As a result, it improves the operation's success rate and reduces

postoperative complications. The results of this study showed that the number of nail insertions, the frequency of C-arm fluoroscopy sessions, operation time, time to fracture union, time to walking exercise, time to weight-bearing walking, and hospital stay were all significantly reduced in the study group compared to the control group. However, blood loss was notably higher in the study group ($p < 0.05$). It underscores the potential benefits of 3D printing navigation templates in shortening the operation time, accelerating fracture union, expediting postoperative mobility, reducing the need for needle path adjustments under repeated fluoroscopy, diminishing the risk of radiation exposure, minimizing bone injury during reverse repositioning, shortening hospital stay, and improving patient prognosis. However, this study also revealed that blood loss in the study group was higher ($p < 0.05$), likely due to the need for the 3D-printed navigation template to be in close proximity to the bone tissue for effective guidance, which required additional soft tissue dissection and contributed to the increases blood loss¹².

Hip function serves as the primary index for assessing the effectiveness of femoral neck fracture treatment, offering valuable insights into patient prognosis¹³. Previous studies by Hao et al¹⁴ and Wan et al¹⁵ highlighted the benefits of 3D printing navigation templates, showcasing reduced operation time and fewer X-ray fluoroscopy scans during femoral neck fracture internal fixation. Such advancements facilitate improved hip function recovery in patients. The results of the current study are consistent with these findings, as it demonstrates that hollow screw internal fixation assisted by 3D printing navigation templates effectively restores hip function in middle-aged and elderly patients with femoral neck fractures. Notably, the hip function of the study group was superior to that of the control group at 3 months and 12 months after surgery ($p < 0.05$).

Pain management is another critical aspect affecting postoperative recovery in femoral neck fracture patients. Those experiencing severe pain exhibit heightened inflammatory and stress reactions, potentially impeding incision healing. Additionally, severe pain can hinder patient compliance with postoperative functional training, leading to delayed hip function recovery⁷. Ding et al¹⁶ showed that personalized 3D printing templates could reduce guide pin insertions, shorten operation times, reduce blood loss, and alleviate limb pain. In this study, the pain levels in the study group were better than those in the control group at 1 week and 3 months after surgery ($p < 0.05$), suggesting that hollow screw internal fixation assisted by 3D printing navigation templates effectively relieves pain in middle-aged and elderly patients with femoral neck fractures. Besides, this approach contributes to improved surgical safety and a reduction in postoperative complications¹⁶. This study revealed a significantly lower incidence of postoperative complications in the study group compared to the control group ($p < 0.05$), indicating the effectiveness of hollow screw internal fixation assisted by 3D printing navigation templates in reducing postoperative complications in middle-aged and elderly patients with femoral neck fractures. It is important to note that one case of bone non-union occurred in the study group, possibly resulting from multiple adjustments of guide pins and screws during the operation. Such adjustments may have damaged the integrity of the lateral cortex of the femoral neck, reduced femoral neck strength, compromised blood supply to the femoral head, and reduced the stability and fixation strength of the hollow screw. To address this, several considerations should be taken into account: (1) All navigation tools should be sterilized, the camera lens should be cleaned, and the sterilization reflection ball used for navigation should be checked. The field of view between the camera lens and the sterilization reflection ball on the reference frame should remain unobstructed during navigation. (2) The stability of the frame should be maintained during the operation, and the guide pins and screws should be placed gently to avoid displacement of the injured limb. In case of displacement, recalibration of the computer navigation system is necessary, as displacement can lead to the deviation of the navigation system. (3) The 3D-printed navigation template is only an aid and should not serve as the sole reliance during surgery. The surgeon must still

plan and adjust hollow screw placement based on anatomical knowledge, clinical experience, and surgical expertise. (4) When inserting the guide pins, ensure they are sharp and free from bending, avoiding potential deviations in pin placement due to elastic deformation caused by the hard bone barrier during the operation.

Limitations

There were several limitations in the present study. Firstly, it is essential to recognize the inherent biases due to the retrospective nature of this study. Secondly, the study represents a single-center analysis with a relatively small sample size. Thirdly, the analysis did not delve into the distribution and length of screws, factors that are also important for surgery. Thus, all results in this study should be interpreted with caution, and prospective studies with larger sample sizes are warranted.

Conclusions

In conclusion, the use of 3D printing navigation templates to assist in hollow screw fixation for femoral neck fractures offers enhanced effectiveness and safety compared to traditional fixation methods. This innovative approach presents a promising avenue for improving patient outcomes.

Ethics Approval

The study was in accordance with the Declaration of Helsinki and was approved by the Ethics Committee of The Second Affiliated Hospital of Shandong First Medical University (No. 22-78).

Informed Consent

All participants provided informed consent for publication.

Availability of Data and Materials

The datasets generated and analyzed during the current study are available from the corresponding author on reasonable request.

Conflict of Interest

The authors declare that they have no competing interests.

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No funding was received for this study.

Authors' Contributions

Yang Gao and Yao Lv contributed to the conception and design of the study; Deqian Kong and Bo Li performed the experiments, collected and analyzed data; Yang Gao and Yao Lv wrote the manuscript. All authors reviewed and approved the final version of the manuscript.

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