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TECHNICAL REPORT

Short-term results of minimally invasive surgery using a 3D-printed guide for the treatment of hallux valgus

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Abstract

Introduction Minimally invasive surgery (MIS) is often used to treat hallux valgus deformities, as it is associated with few wound complications and shorter recovery times. Minimally invasive chevron osteotomy and Akin osteotomy (MICA) is a common minimally invasive treatment for HV. However, effective correction of hallux valgus and precise screw placement during MIS are difficult. The aim of this study was to introduce and evaluate the clinical and radiographic effectiveness of a novel MIS technique involving the use of a 3D-printed guide for hallux valgus.

Materials and methods We retrospectively studied the results of MIS with a 3D-printed guide plate for symptomatic hallux valgus from May 2022 to December 2023. The preoperative and postoperative hallux valgus angle (HVA), intermetatarsal angle (IMA), distal metatarsal articular angle (DMAA), first metatarsal pronation angle (M1PA), tibial sesamoid position (TSP), forefoot width, visual analogue scale (VAS) score, AOFAS Hallux MTP-IP score, and the number of intraoperative fluoroscopy were measured.

Results A total of 22 feet in 19 patients were included in the study. There were 15 women and 4 men with an average age of 38.0 y (range 16–61). The preoperative HVA, IMA, DMAA and M1PA were 30.3 ± 10.7°, 13.9 ± 2.8°, 8.3 ± 2.9° and 16.3 ± 6.5°, respectively. The postoperative HVA, IMA, DMAA and M1PA were 10.7 ± 4.1°, 5.7 ± 1.8°, 2.3 ± 1.7° and 3.5 ± 2.1°, respectively. The forefoot width decreased from 92.1 ± 5.5 mm to 85.6 ± 5.4 mm on average. The VAS and TSP ranged from 4.4 ± 0.9 and 4.9 ± 0.8 to 0.3 ± 0.6 and 2.0 ± 1.1, respectively. The AOFAS Hallux MTP-IP scores improved from 59.1 ± 10.7 to 94.8 ± 5.7 on average. The average number of fluoroscopy shots during operation were 34 times (range 30 to 38).

Conclusions A 3D printed guide technique can be beneficial for precise positioning of the first metatarsal head, enhancing the accuracy of screw placement, and reducing radiation exposure.

Keywords Hallux valgus · Minimally invasive · Operative technique · Three-dimensional correction · 3D printing

Introduction

The global estimated pooled prevalence and incidence of hallux valgus (HV) is 19%, and HV usually causes forefoot pain and limited mobility [1]. For symptomatic hallux valgus deformities, surgery is always performed after failed correction with orthotics. Although more than 150 procedures have been introduced for surgical correction of HV deformities, no single technique has been found to be clearly superior [2]. A recent systematic review of open techniques for HV correction revealed that the mean rate of patient dissatisfaction was 10.6%, and the incidence of deformity recurrence was 4.9% [3]. In recent years, minimally invasive surgery (MIS) has become increasingly popular due to its association with less surgical trauma, less extensive soft tissue dissection, less postoperative pain, less scarring,

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and earlier functional recovery [4]. Multiple types of MIS have been described over the last 3 decades. First-generation techniques mainly involve postoperative bandaging instead of internal fixators to maintain the fixed position. Second-generation techniques involve K-wires for stability. Third-generation techniques such as minimally invasive chevron and Akin osteotomy (MICA) have been widely used in the treatment of HV, as they are known to increase stability, enable early weightbearing and improve range of motion [5]. MICA has a flat learning curve and requires specific training and intensive practice [6]. Recent research has revealed that, compared with traditional surgery, MICA for correcting HV deformities is more time consuming and involves a considerable amount of radiation [7]. Moreover, MICA is limited in correcting multidirectional deformities because of the osteotomy design and limited amount of space for instrument manipulation. A fourth-generation technique, namely, minimally invasive extra-articular transverse and akin osteotomy (META), which involves transverse osteotomy instead of chevron osteotomy at the first metatarsal neck, was developed to address the limitations of MICA [8]. Therefore, the method by which to accurately correct and maintain the three-dimensional position of the metatarsal head during the operation remains unclear and warrants further study.

In recent years, 3D technology, namely 3D printing, has been increasingly applied in the planning of orthopedic procedures [9]. For example, 3D technology has been used in the creation of surgical guides specifically tailored to individual patients [10]. These guides embody the unique anatomical features of each patient and are beneficial for surgical planning and performing each preplanned step in the actual surgery [11]. To achieve three-dimensional correction, accurate osteotomy and screw placement, reduce radiation exposure, we present MIS using a 3D-printed patient-specific surgical guide after preoperative planning on the basis of 3D CT reconstruction.

The objective of this study was to propose a novel technique for three-dimensional correction of HV deformities and prove its effectiveness and safety via short-term follow-up data.

Methods

Inclusion/exclusion criteria and data collection

We retrospectively reviewed surgical cases from a single center. An experienced foot and ankle specialist performed all the procedures. The inclusion criteria for this study were as follows: (1) need for surgery because of a symptomatic HV deformity. The HV angle (HVA) was measured on weight-bearing anteroposterior (AP) X-rays, and an HV deformity was classified as mild (15° ≤ HVA < 20°); moderate (20° ≤ HVA ≤ 40°); or severe (HVA > 40°); (2) no previous surgical treatment for a hallux valgus deformity; (3) aged 16 years or older; and (4) a follow-up duration of 6 months or longer. The exclusion criteria were as follows: (1) a history of foot trauma or surgery; (2) TMT joint instability or a diagnosis of generalized hypermobility; and (3) rheumatic diseases, foot neuropathy, or vascular insufficiency.

Weight-bearing radiographs (AP and lateral) and CT scans were obtained. The HVA, intermetatarsal angle (IMA), distal metatarsal articular angle (DMAA), first metatarsal pronation angle (M1PA), tibial sesamoid position (TSP) defined by Hardy and Clapham [12], AOFAS Hallux MTP-IP score [13] and visual analogue scale (VAS) score were assessed. The number of intraoperative fluoroscopy were measured.

The study was approved by our institutional ethics committee, and all patients signed the consent form and agreed to be included in the study (No. KY2023003).

3D planning

A 3D model of the foot was reconstructed using CT (Siemens, Germany) scans of the foot, which were formatted in Digital Imaging and Communications in Medicine (DICOM). The data were subsequently imported into Mimics software (Materialise, Belgium), and then a 3D model of the affected foot was constructed and saved as a stereolithography (STL) file. The 3D reconstruction saved as an STL file was then imported into 3-matic software (Materialise, Belgium) to simulate MICA. Surgical guides are designed on the basis of the planned osteotomy design, deformity correction, and screw placement. There are six positioning holes on the surgical guide. The first hole is used to insert a Kirschner wire, which serves as a guide pin to assist in the insertion of the proximal screw. According to MICA technology, the Kirschner wire is passed through the first hole of the guide, inserted at the medial base of the first metatarsal and advanced to the lateral cortex, 1 cm proximal to the metatarsal osteotomy. The second and third holes are used to insert Kirschner wires as a reference for observing the rotation angle of the metatarsal head. The fourth hole is used for the insertion of a Kirschner wire to locate the metatarsal osteotomy site. The osteotomy site is located at the metatarsal head-neck junction, and the direction of the osteotomy is perpendicular to the second metatarsal bone. The fifth hole is used for the insertion of a guide pin, which indicates metatarsal pronation. The guide pin passing through the 5th hole of the surgical guide is inserted from the inside to the outside of the metatarsal head, forming an angle with the guide pin passing through the 2nd or 3rd hole of the surgical guide, in the coronal plane, and making this angle equal to the M1PA. The sixth hole is used for the insertion of the guide pin, which locates the Akin osteotomy site. This guide pin is coming from the middle to distal third of the medial cortex and aiming to the proximal lateral edge of the proximal phalanx. The surgical guides are manufactured using biocompatible resin and an stereo lithography apparatus (SLA) 3D printer.

Surgical procedure

1. Patients were positioned supine on the operation table under general anesthesia, and no tourniquet was used.
2. The 3D-printed guide was fixed on the foot. The guide was used to identify the osteotomy site of the first metatarsal neck and the proximal phalanx (Akin osteotomy), the locations for screw placement and correction of the metatarsal pronation deformity.
3. Six 2.0-mm Kirschner wires were inserted through the holes of the guide, after which the guide was removed. The fourth Kirschner wire was removed, and transverse osteotomy was performed as described according to the direction of the Kirschner wire.
4. A 3.0-mm Steinmann pin was inserted into the shaft of the metatarsal to translate the metatarsal head, maintaining the correction of the pronation of the first metatarsal. The metatarsal head was rotated, and the 5th Kirschner wire was aligned parallel to the 2nd or 3rd Kirschner wire to correct metatarsal pronation.
5. The first Kirschner wire was exchanged with a hollow screw guide wire, and the 4.0-mm fully threaded screw (Double Medical Technology Inc., Xiamen, CHINA) was inserted along the guide wire. Another screw was inserted parallel to the first screw.
6. Akin osteotomy was performed along the direction of the 6th guide pin. The Akin osteotomy represents a medial closing wedge osteotomy of the proximal phalanx. After the osteotomy was completed, a 3.0-mm fully threaded screw was inserted.
7. Finally, the medial triangle of the metatarsal cortex, which was located to the medial and distal to the second screw, was excised [14].

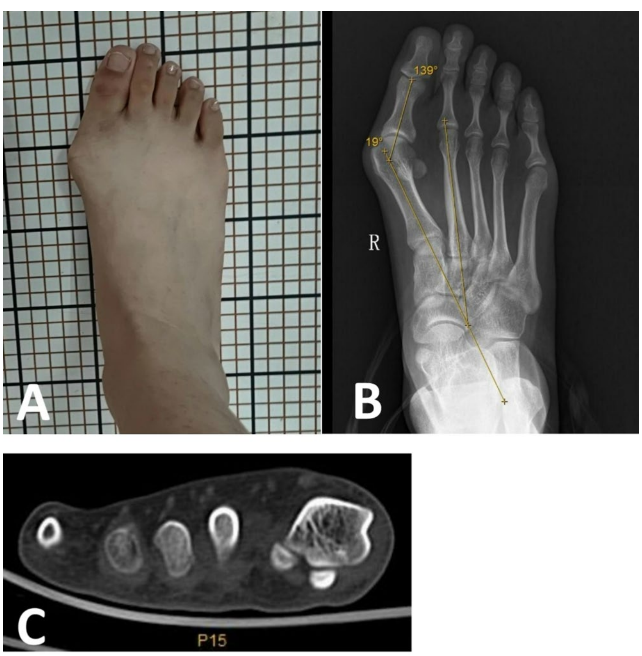

Fig. 1 A 18-year-old female patient with a severe HV deformity. **A** Preoperative appearance of the right foot. **B** Preoperative weight-bearing X-ray image showing a severe hallux valgus deformity of the right foot. The HVA was 41°, the IMA was 19°, and the TSP was 4. **C** CT image showing pronation of the first metatarsal

Postoperative protocol and evaluation

After the operation, patients were allowed to perform a few weight-bearing activities with the assistance of forefoot decompression shoes for 4–6 weeks. After 2 weeks, the sutures are removed. Then, rehabilitation exercises, including active and passive exercises involving the toes, were performed three times a day. Within a few days after surgery, a CT scan was used to measure the M1PA and observe the fixing position of the screws. If the proximal screw's fixation position achieves 3-point fixation (medial cortex, lateral cortex, and the lateral half of the 1st metatarsal head), it is considered qualified. Weight-bearing X-rays of each foot were obtained at routine time points following surgery (6 weeks, 3 months, 6 months, and 12 months), during which the IMA, HVA, DMMA and TSP were documented. The AOFAS and VAS scores were calculated at the final follow-up appointment (Figs. 1, 2, 3 and 4).

Statistical analysis

Statistical analysis was performed with SPSS (version 23.0; SPSS Inc., USA). All measurements (IMA, HVA, DMMA and M1PA) are expressed as means and standard deviations. Preoperative and postoperative scores and radiologic angle measurements were compared using paired sample t tests. A p value less than 0.05 indicated statistical significance.

Results

Between May 2022 and December 2023, a total of 22 feet in 19 patients were included in the study. There were 15 females and 4 males, with an average age of 38.0 years (range 16–61). There were 5 feet with mild, 12 with moderate

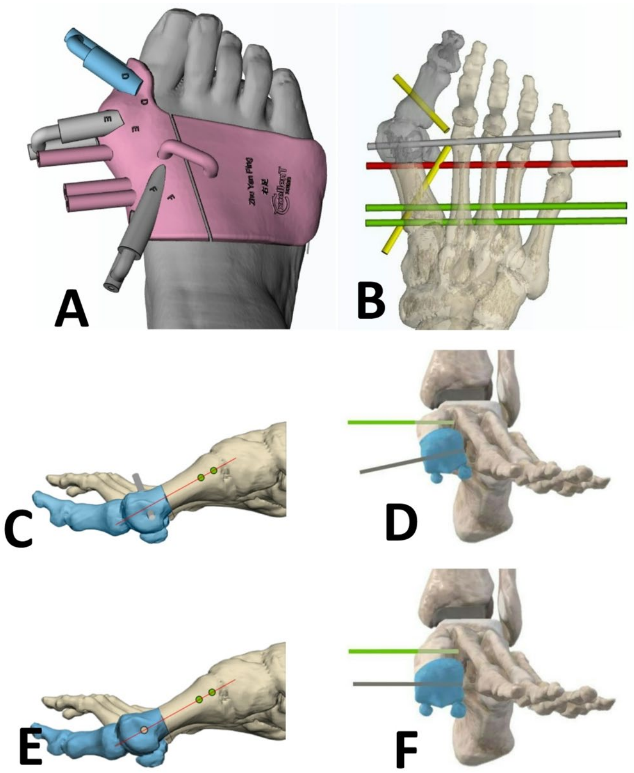

Fig. 2 A 3D model of the foot and guide. **A** The 3D-printed guide features six positioning holes for the insertion of Kirschner wires as guide pins. **B** Schematic diagram of the position and orientation of the 6 guide pins inserted through this 3D-printed guide. The first guide pin aids in the insertion of the proximal screw. The second and third guide pins act as references for observing the rotation angle of the metatarsal head. The fourth guide pin is utilized to locate the metatarsal osteotomy site. The fifth guide pin is used to indicate metatarsal rotation. The sixth guide pin is used to locate the Akin osteotomy site. **C**–**D** The guide pin, inserted into the metatarsal head and proximal metatarsal, forms an angle on the coronal plane, which is equal to the M1PA. **E**–**F** After completing the osteotomy, rotate the metatarsal head until the metatarsal head guide pin is parallel to the proximal metatarsal guide pin to correct the metatarsal head pronation deformity

and 5 with severe HV deformities in this study. The average follow-up time was 9.6 ± 2.1 months, and the shortest and longest follow-up times were 6 months and 13 months, respectively (Table 1). The average number of fluoroscopy shots during operation were 34 times (range 30 to 38). The preoperative HVA, IMA, DMAA and M1PA were 30.3 ± 10.7°, 13.9 ± 2.8°, 8.3 ± 2.9° and 16.3 ± 6.5°, respectively. The postoperative HVA, IMA, DMAA and M1PA were 10.7 ± 4.1°, 5.7 ± 1.8°, 2.3 ± 1.7° and 3.5 ± 2.1°, respectively. The forefoot width decreased from 92.1 ± 5.5 mm to 85.6 ± 5.4 mm on average. The VAS and TSP ranged from 4.4 ± 0.9 and 4.9 ± 0.8 to 0.3 ± 0.6 and 2.0 ± 1.1, respectively, on average. The AOFAS Hallux MTP-IP scores improved from 59.1 ± 10.7 to 94.8 ± 5.7 on average (Table 2). All cases have achieved 3-point fixation of the proximal screw fixation position.

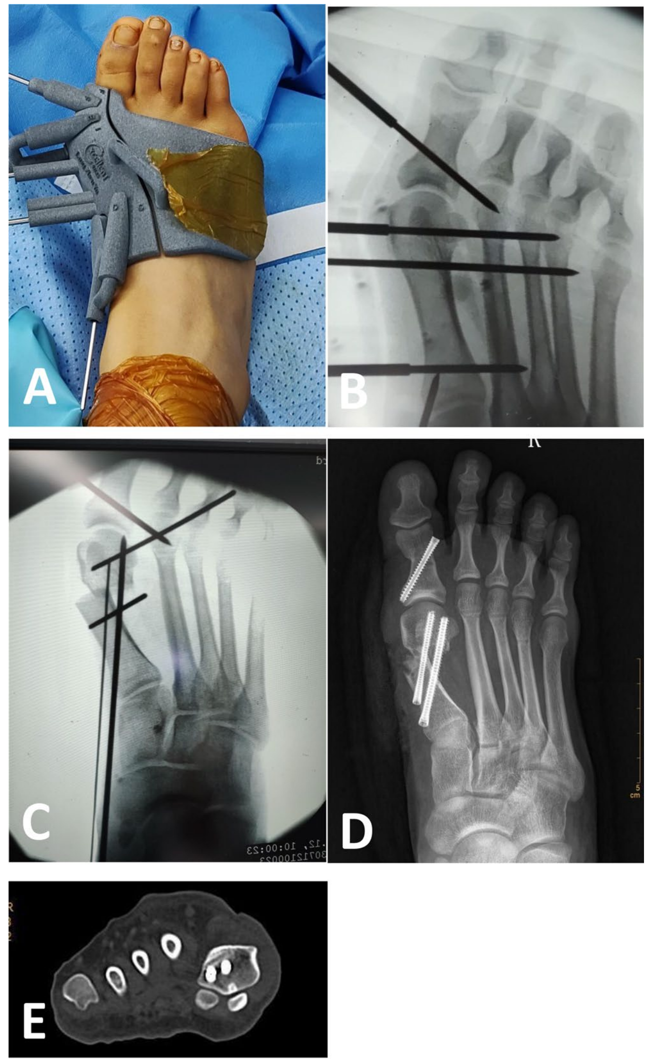

Fig. 3 Surgical steps. **A** The guide was fixed on the foot. **B** A Kirschner wire was inserted through the guide, and then osteotomy was performed, followed by hallux valgus deformity correction, which was confirmed by C-arm fluoroscopy. **C** After correction, the Kirschner wire was inserted to assist final screw insertion. **D** and **E** Postoperative radiographic and CT scans of the foot showing that the HVA, IMA, and M1PA had returned to normal

Discussion

Several MIS techniques are considered third-generation techniques. MICA is a third-generation technique that has been proven to be equally as or even more effective than open chevron or scarf osteotomy [14–16]. However, mastering the MICA technique can be difficult [17, 18]. Moreover, another disadvantage is that, compared with open surgery, MIS involves a relatively larger amount of radiation [19]. Toepfer and Strässle [6] concluded that surgical efficiency improved as the surgeon approach proficiency, leading decreases in radiation exposure after 40 procedures. In our surgical practice, an average of 34 fluoroscopies were

Fig. 4 Six-month postoperative follow-up data. **A** and **B** Postoperative radiographic parameters of the foot. **C** Postoperative appearance of the foot

Table 1 Patient demographics

Variable	Overall
Patients (n)	19
Feet (n)	22
Sex (n)	
Male	4
Female	15
Age (years)	38.0 ± 15.2
HV grading (n)	
Mild	5
Moderate	12
Severe	5
Mean follow-up (months)	9.6 ± 2.1

required when 3D-printed guides were used, which was significantly lower than the average of 126.6 reported in the literature [20].

Numerous studies have shown that first metatarsal pronation is an important factor in hallux valgus deformity correction, particularly in terms of recurrence [21]. Adequate correction of pronation has been associated with lower recurrence rates after hallux valgus surgery [22]. Ferreira et al. utilised the percutaneous chevron and Akin (PECA) technique to treat hallux valgus, reported that the PECA technique can correct pronation of the first metatarsal [23]. However, controlling the degree of metatarsal rotation is difficult with manual correction. In our series, with the

Table 2 Comparison of preoperative and postoperative scores and radiologic angle measurements for 22 feet with hallux valgus deformities

Outcome	Preoperative Mean ± SD	Postoperative Mean ± SD	Preoperative and postoperative difference	*P* Value
HVA (°)	30.3 ± 10.7	10.7 ± 4.1	19.6	<0.001
IMA (°)	13.9 ± 2.8	5.7 ± 1.8	8.2	<0.001
DMAA (°)	8.3 ± 2.9	2.3 ± 1.7	6.0	<0.001
M1PA (°)	16.3 ± 6.5	3.5 ± 2.1	12.8	<0.001
TSP	4.9 ± 0.8	2.0 ± 1.1	2.9	<0.001
Forefoot width (mm)	92.1 ± 5.5	85.6 ± 5.4	6.5	<0.001
VAS	4.4 ± 0.9	0.3 ± 0.6	4.1	<0.001
AOFAS score	59.1 ± 10.7	94.8 ± 5.7	35.7	<0.001

assistance of 3D-printed guides, all metatarsal pronation were easily corrected, and the MIPA was corrected from an average of 16.3° preoperatively to 3.5° postoperatively.

It is crucial not only to properly correct the first metatarsal pronation but also to utilize a safe and effective technique to guarantee the precision and safety of screw insertion. The importance of MICA technology dictates that the optimal fixation criteria are 3-point fixation (medial cortex, lateral cortex, and the lateral half of the 1st metatarsal head) for the proximal screws and 2-point fixation (medial cortex and central position in the 1st metatarsal head) for the distal ones. A particularly significant concern is that the screw is inserted at the base of the first metatarsal and advanced to the lateral cortex, 1 cm proximal to the metatarsal osteotomy. Importantly, the distal exit point of the screw must achieve this exact position. Further distal placement of the screw could result in a fracture extending into the osteotomy site, leading to insufficient fixation stability. If it is too proximal, then it will not be able to hold in the MT head. A computer navigation system was once regarded as an acceptable supplementary technology for screw placement. Nonetheless, the use of a navigation system in foot and ankle surgeries is limited by its cumbersome operation, complex registration processes, and excessive costs. In order to accurately insert the 3-point fixation screw, some guided trajectory system have been utilized [24]. A recent study by Ferreira et al. revealed that the utilization of a 3D-printed guide in minimally invasive HV correction can enhance precision in screw placement [25]. In our study, with the assistance of 3D printing guide, we have achieved precise insertion of these two screws in all cases.

3D printing technology is increasingly used in orthopedic surgeries. This technology is beneficial for optimizing preoperative planning and realizing personalized, precise treatments. It increases the precision of complex surgical procedures and can significantly reduce both the operative duration and radiation exposure. A recent scoping review with a pooled total of 932 participants revealed that 3D printing reduces operating times, blood loss volumes, fluoroscopy times, bone union times and postoperative pain while improving surgical accuracy and indirectly accelerating functional recovery [26]. Mounsef et al. identified and analyzed 3299 articles and reported significant reductions in operative time, blood loss volume, and radiation exposure with three-dimensional printing [27]. Ferreira et al. believed that the advantages of his novel 3D-printed patient-specific instrumentation guides in minimally invasive HV correction not only enhance precision in screw placement but also reduce surgical time, decrease radiation exposure, improve procedural safety, and expedite learning curves [25]. evaluating the effectiveness of surgical correction.

Although weight-bearing radiographs are generally sufficient for assessing the efficacy of corrective surgeries, X-rays cannot accurately measure metatarsal rotation. We use CT scanning to more accurately assess the outcomes of deformity correction, thus providing a more objective evaluation of this innovative technology. In recent years, the radiation levels from modern CT equipment, particularly when used for extremities, have been continuously decreasing. Furthermore, the use of 3D-printed guide plates has resulted in a reduction of radiation exposure during surgeries. Consequently, the use of CT scanning does not result in significant additional radiation exposure.

The outstanding feature of our novel 3D-printed guide is its precise correction of first metatarsal pronation deformities. Furthermore, this 3D-printed guide facilitates the insertion of screws. Significant improvements in the scores of various scales used confirmed the successful correction of HV deformities at the 6-month follow-up visit, thus confirming the effectiveness, safety, and feasibility of using a 3D-printed guide.

The study has certain limitations, including a small sample size and the absence of a comparative analysis with alternative surgical procedures. In addition, the follow-up duration was not long enough to prove the long-term efficacy of using a 3D-printed patient-specific guide. Additional high-quality clinical trials are needed to validate these results on a larger scale.

Conclusions

In summary, the utilization of novel 3D-printed patient-specific guides in minimally invasive HV deformity correction is potentially beneficial for precise positioning of the first metatarsal head, improving the precision of screw placement, decreasing radiation exposure.

Author contributions All authors contributed to the design, execution, and analysis of this study. Wang. designed this study, conducted surgeries, and drafted the manuscript. Bai. participant study designed. Zhu. Zheng. and Liu. contributed the performance of surgeries, the data collection and analyses. He. contributed to data collection.All authors commented on previous versions of the manuscript and approved the final manuscript.

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Data availability No datasets were generated or analysed during the current study.

Declarations

Competing interests The authors declare no competing interests.

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