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ORIGINAL ARTICLE

Results of Bioabsorbable Screws for the Fixation of Chevron Osteotomy in the Treatment of Hallux Valgus Deformities

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Background: This study aimed to investigate the safety and reliability of using bioabsorbable screws for the fixation of chevron osteotomy in the treatment of hallux valgus (HV) deformity.

Methods: Clinical cases of chevron osteotomy in the treatment of HV deformities in our hospital between December 2018 and August 2022 were retrospectively summarised to compare preoperative imaging indices with those at the final follow-up session, including the hallux

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valgus angle (HVA), intermetatarsal angle (IMA) and tibial sesamoid position (TSP). The American Orthopaedic Foot and Ankle Society (AOFAS) hallux metatarsophalangeal-interphalangeal scale, short-form health survey questionnaire (SF-36) and European Foot and Ankle Society (EFAS) scale were used to assess therapeutic efficacy. The visual analogue scale (VAS) was used to assess pain relief. Moreover, complications were recorded.

Results: Twenty-six patients (39 feet) were included, and the mean follow-up period was 24.0 months. No infection, delayed healing or non-healing was recorded. The osteotomy ends healed well without non-union or delayed union. Four cases of recurrence (HVA ≥20°), two of numbness in the distal toe, one of necrosis of the first metatarsal head and one of osteoarthritis of the first metatarsophalangeal joint occurred. No patients underwent secondary surgery. The HVA, IMA and TSP significantly reduced at the final follow-up session compared with their preoperative values, and significant improvement was seen in clinical scores.

Conclusion: The use of bioabsorbable screws for the fixation of chevron osteotomy is safe and effective in the treatment of HV deformities.

Level of Evidence: Ⅳ

Keywords: Bioabsorbable， Hallux Valgus， Chevron Osteotomy， complication

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1. **Introduction**

Hallux valgus (HV) is the most common deformity in foot and ankle with an extremely high prevalence and often needs surgery. Specifically, chevron osteotomy is one of the widely performed procedures and has obtained favourable results【1】. After osteotomy a metal headless compression hollow screw is usually used for fixation. The osteotomy end may be well fixed using metal screws. However, like other metal implants, metal screws are associated with issues such as stress shielding and delayed foreign body reaction, which often requires secondary surgery to remove , increasing the physical, psychological and economic burden of the patient.

In recent years, development has been seen in bioabsorbable materials, which have been increasingly utilized in surgery to treat HV deformities. Bioabsorbable screws have an elastic modulus similar to that of cancellous bones and can be proved to prevent stress shielding and bone atrophy caused by metal screws. Moreover, these screws are more biocompatible, can be naturally absorbed by the body through decomposition and metabolism, have a higher safety profile and do not require removal by secondary surgery【2-4】. However, the reliability of the fixation by bioabsorbable screws remains controversial because they have lower strength than metal screws. Our previous biomechanical study revealed that bioabsorbable screws exhibited compression strengths comparable to those of titanium–titanium alloy hollow screws and 60%–

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90% of the stiffness of these hollow screws. Moreover, polylactic acid (PLA) bioabsorbable screws retained their strength and stiffness after as many as 240,000 compression cycles while avoiding stress shielding【5】.

Thus, this study aimed to investigate the efficacy and safety of using bioabsorbable screws in the fixation of chevron osteotomy for the treatment of HV deformities by retrospectively comparing and analysing preoperative and postoperative clinical scores and imaging indices of patients with HV deformity.

2. Material and Methods

2.1 Research ethics

This study strictly adhered to the *Declaration of Helsinki* and passed the review by the institutional review board of the hospital.

2.2 Patient screening

This study retrospectively analysed clinical cases in which bioabsorbable screws were used for the fixation of chevron osteotomy in the treatment of HV deformities in the study hospital between December 2018 and August 2022. The inclusion criteria were as follows: (1) patients with HV and observable clinical symptoms, (2) patients who underwent chevron osteotomy, (3) patients who underwent fixation of osteotomy using bioabsorbable screws, (4) patients aged ≥18 years and (5) patients with a follow-up period ≥12 months. The exclusion criteria were as

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follows: (1) patients who underwent other operative procedures, (2) use of internal fixation materials other than bioabsorbable screws, (3) follow-up period <12 months or loss to follow-up and (4) comorbidities with infectious joint diseases such as rheumatoid arthritis.

2.3 Surgical methods

Nerve block and local infiltration anaesthesia were performed in all patients. As shown in Figure 1, the patient was placed in the supine position, and a rubber tourniquet was tied around the proximal end of the ankle joint on the operative side. All patients were initially subjected to lateral soft tissue release. A 1-cm longitudinal incision was made in the web space between the first and second toes of the foot to separate the metatarsophalangeal (MPT) joint capsule, cut off the adductor hallucis muscle, and release the sesamoid ligaments and lateral joint capsule. Then a longitudinal incision of approximately 3 cm was made on the anteromedial aspect of the distal end of the first metatarsal to expose the first metatarsal head. After removing hyperplasia exostosis, a V-shaped osteotomy (chevron osteotomy) of 60°–90° was made, with the centre of the metatarsal head as the apex. After pushing the distal end of the osteotomy outward by 6–8 mm depending on the severity of the HV deformity, a 2.7-mm bioabsorbable screw (SinoBiom, Changchun, China) was used for the fixation from the proximal aspect . Then, the tightening of the medial joint capsule was simulated, and a closed wedge osteotomy (Akin osteotomy) of the proximal phalanx may be performed if the surgeon was not satisfied with the foot's appearance. After a visual inspection of the foot alignment, the procedure was completed with layer-by-layer suturing.

Wound dressing was changed, and anti-inflammatory therapy was provided postoperatively. The medical staff also assisted the patient in performing active and passive movements of the first metatarsophalangeal joint. The patient may walk off the floor in a forefoot decompression shoe 1 week postoperatively. The patient resumed normal weight-bearing walking 6 weeks postoperatively.

2.4 Observation items and methods

2.4.1 Radiological assessment

The anteroposterior and lateral views of the weight-bearing X-ray images of the affected foot were taken before surgery and at the final postoperative follow-up to measure the HV angle (HVA) and 1-2intermetatarsal angle (IMA) and assessed the tibial sesamoid position (TSP).

2.4.2 Functional assessment

The AOFAS hallux metatarsophalangeal-interphalangeal scale was used to assess therapeutic efficacy, with 100 as the total score (90–100 points indicating excellent; 75–89, good; 50–74, fair; and <50, poor. A short-form health questionnaire (SF-36) and the European Foot and Ankle Society (EFAS) scale were also used to assess therapeutic efficacy. The visual

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analogue scale (VAS) was used to assess the degree of pain relief, and complications were recorded.

2.5 Statistical methods

Data were analysed using IBM SPSS Statistics for Windows version 27.0 (IBM Corp., Armonk, NY, USA), and measurement data were expressed as (x ± s). The paired t-test was used to compare preoperative and postoperative measurement data, and the independent samples t-test was used to compare the results between groups. A $P < 0.05$ indicated a statistically significant difference.

3. Results

3.1 Clinical outcomes

A total of 26 patients (39 feet) were included in this study, including 23 female and 3 male patients, with 8, 5, and 5 cases involving the left, right, and bilateral feet, respectively. The mean patient age was 39.3 years, which ranged from 20–63 years. The mean follow-up period was 24.0 months, which ranged from 12–57 months. Distal osteotomy of the first metatarsal (chevron osteotomy) was performed in all 39 feet. Akin osteotomy was additionally performed on 7 feet, distal chevron osteotomy of the fifth metatarsal on 2 feet, Weil osteotomy of the second metatarsal on 1 foot, second interphalangeal joint fusion on 1 foot, and Morton neuroma excision on 1 foot. No infection, delayed healing or non-healing was seen, and osteotomy ends healed well without non-union or delayed union. Regarding complications, four cases of recurrence (HVA ≥ 20°), two of distal toe numbness, one of necrosis of the first metatarsal head and one of osteoarthritis of the first metatarsophalangeal joint occurred, and none required secondary surgery.(Table 1)

3.2 Imaging assessment

Radiological assessment parameters, including HVA, IMA and TSP grading, significantly improved at the final follow-up compared with their preoperative levels. As seen in table 2, the postoperative and preoperative HVAs were 12.7° ± 5.1° and 33.4° ± 6.7°, the postoperative and preoperative IMAs were 5.8° ± 1.7° and 14.6° ± 2.9°, and the postoperative and preoperative TSP grades were 2.9 ± 0.9 and 6.0 ± 0.7, respectively. Compared with preoperative scores, postoperative clinical scores including the AOFAS, SF-36, EFAS and VAS scale scores were significantly improved. The postoperative and preoperative AOFAS scale scores were 94.3 ± 6.1 and 64.2 ± 11.0, the postoperative and preoperative VAS scale scores were 0.6 ± 0.7 and 4.4 ± 1.6, the postoperative and preoperative EFAS scale scores were 20.5 ± 3.5 and 9.6 ± 4.1, the postoperative and preoperative SF-36 scores were 96.4 ± 3.4 (physical component score, PCS) and 82.7 ± 16.4 (mental component score, MCS) and 81.1 ± 7.5 (PCS) and 73.2 ± 13.6 (MCS), respectively (Table 2).

3.3 Reduction of the TSP and therapeutic efficacy

To assess the effect of TSP reduction on the therapeutic efficacy, study cases were divided into two groups, namely, the TSP reduction group (n = 29) and the TSP non-reduction group (n = 10). The results of the comparative analysis of the postoperative imaging parameters as well as pain and functional scores showed no significant difference in HVA, IMA, , VAS scale scores, and AOFAS scale scores between the two groups.

4. Discussion

The use of bioabsorbable materials for the treatment of HV deformities was first reported in 1995 when Small et al【6】 used bioabsorbable polydioxanone pins to fix chevron osteotomy for the treatment of HV deformities. The patients were followed up for 1 year, and the results showed no complications or infections, no fractures or displacements and no need for pin removal, which appeared to be a significant benefit compared with fixation using metals. Since then, a few studies have reported favourable outcomes【7-9】.

In the present study, the HVA, IMA, and TSP grade were significantly improved at the final follow-up compared with preoperative levels, with a mean follow-up period of 24 months. Moreover, postoperative AOFAS, SF36, EFAS and VAS scale scores were also significantly improved. These findings were similar to those of previous reports, and the therapeutic efficacy

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of bioabsorbable screws were comparable to that of metal screws reported during the same period【10-12】, which indicated the favourable clinical efficacy of bioabsorbable screws. Moreover, secondary surgery was not required to remove the implants, which reduced the physical and psychological burden on the patients, resulting in high acceptance and satisfaction with the surgery.

Mechanical strength is a major concern when using bioabsorbable materials for the fixation of fracture or osteotomy. However, it is relatively safe when used in chevron osteotomy because of the following reasons. Firstly, chevron osteotomy is a V-shaped and embedded osteotomy, where the upper and lower osteotomy surfaces are compressed against each other, resulting in relatively higher stability when bearing load and thus requiring relatively lower strength for the implants material【13】. Secondly, unlike most of the previous studies that have mainly used materials such as PLA or its copolymers, the novel material used in the present study incorporated hydroxyapatite, which increased the flexural and tensile strengths of the material【14】. Meanwhile, owing to the presence of threads, the screws gained a stronger grip and resistance to pulling out unlike the previously used pins, which increased the stability of the fixation. Our previous biomechanical study revealed that bioabsorbable screws exhibited compression strengths comparable to those of titanium–titanium alloy hollow screws and 60%–90% of the stiffness of these hollow screws. Moreover, PLA bioabsorbable screws retained their

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strength and stiffness after as many as 240,000 compression cycles while avoiding stress shielding. From the above experimental analyses, despite the huge difference in the mechanical properties between the two materials, the fixation outcomes are compatable when they are used for fixation as implants in chevron osteotomy. The most significant difference between the two materials is that at low load levels (not more than 300 N), the mean angular deformation of PLA is approximately 2.3 times higher than that of Titanium, indicating micromotion is more likely to occur when using PLA screws for fixation【5】. Numerous clinical studies have revealed that bone healing begins with a certain degree of mobility and fracture width and that the adaptability to deformation at the fracture healing sites is quite astonishing. Therefore, appropriate physical stimulation is a key factor in promoting fracture healing【15-17】. We believe that the stiffness of PLA screws lower than those of metal screws should not be considered a disadvantage but an advantage in promoting fracture healing following osteotomy.

Although we can not assess dynamic changes in bioabsorbable screws in the fixation for chevron osteotomy to determine transient stability, as patients' immediate postoperative X-ray images were non-weight-bearing and any loss of displacement distance could not be measured accurately, the osteotomy of all patients healed by primary intention, without non-union or delayed union, which indirectly confirmed the stability of the fixation of osteotomy.

Regarding complications, four cases of recurrence, two of distal toe numbness, one of

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necrosis of the first metatarsal head, and one of osteoarthritis of the first metatarsophalangeal joint occurred, none of which required secondary surgery. All these were common procedure-related complications rather than material-related complications【18】. The most common complications of the use of bioabsorbable materials include foreign body reactions, osteolysis, and bone cysts. Bostman et al【19】reported clinically significant local inflammation and sterile tissue reactions in 108 (4.3%) of 2528 patients who underwent surgery with pins, rods, bolts, and screws made of polyglycolic acid (PGA) or PLA. In patients experiencing severe reactions, extensive osteolytic lesions were seen along the implant track, which histopathologically manifested as non-specific foreign body reactions. Pavlovich et al【20】 reported a case of a cystic lesion on magnetic resonance imaging after fixation of chevron osteotomy with bioabsorbable material in the treatment of HV deformities. After surgical excision, the lesion was identified as a giant cell granuloma. None of the above complications were recorded in this study, and the probable reason was that most of the bioabsorbable materials used in previous studies were monomers of PGA or PLA, which would be resorbed rapidly within a short time, eliciting extensive immune response with a large increase in macrophages and cavity formation. On the contrary, the novel material used in the present study consisted of a mixture of PLA and hydroxyapatite, which would be slowly resorbed over a long time, eliciting a much weaker immune response. Meanwhile, the addition of hydroxyapatite can provide a weak alkaline local

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environment to promote osteogenesis in the surrounding tissues, making the material more biocompatible【21】. In this study, at 2 years postoperatively, most of the screws had not been completely resorbed, maintaining a favourable mass effect, which made it safer. (Figure 2)

In the treatment of HV deformities, whether the position of the sesamoid bone should be reducted has been controversial. Some studies have suggested that poor TSP reduction may lead to poorer clinical outcomes and higher recurrence rates postoperatively【22,23】, whereas others have shown no significant relationship between postoperative TSP reduction and clinical outcomes【24,25】. In the subgroup analyses in the present study, the relationship between TSP reduction and prognostic imaging and functional pain scores was explored, and the results showed no significant differences in imaging parameters between the TSP reduction group and the TSP non-reduction group. Regarding clinical pain and functional scores, although the TSP non-reduction group had poorer scores than the TSP reduction group, the results were not statistically significant. (Table 3)

This study has some limitations. Firstly, retrospective analyses without a control group were performed. In this study, analogous clinical efficacy was obtained when compared with similar studies. Secondly, the follow-up period was short and may be categorised as a short-term follow-up. The follow-up period has not yet reached the time required for the complete resorption of bioabsorbable screws. Thus, future studies should have a longer follow-up period.

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Lastly, the number of cases analysed was low; thus, more cases are needed to support our findings.

5. Conclusion

The fixation of chevron osteotomy with bioabsorbable screws is safe and effective for the treatment of HV deformities.

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Declarations Competing interests

The authors declare no competing interests.

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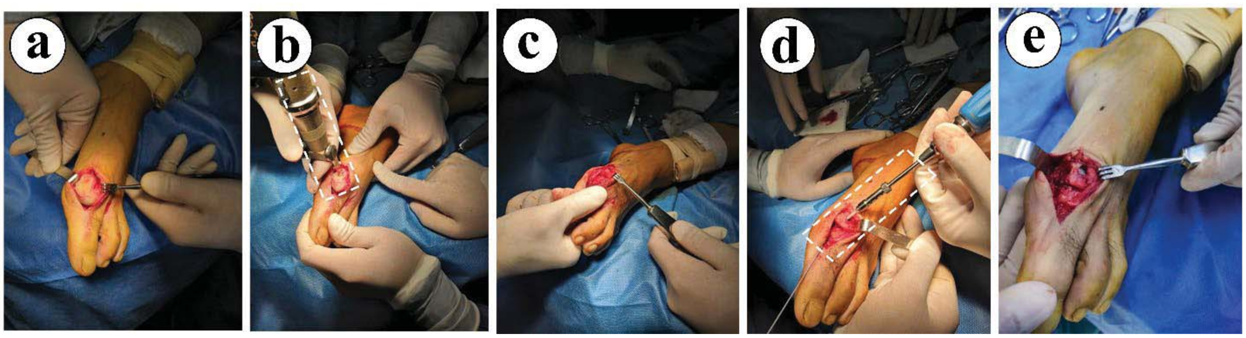
Figure 1. Surgical Procedure. a. Dorsal-medial incision expose the 1st metatarsal head; b. "V"-sharp osteotomy with the angle of 60°-90°; c. Lateral displace 6-8mm; d. Bioabsorbable screws (2.7mm) implantation ; e. Remove the excess prominence



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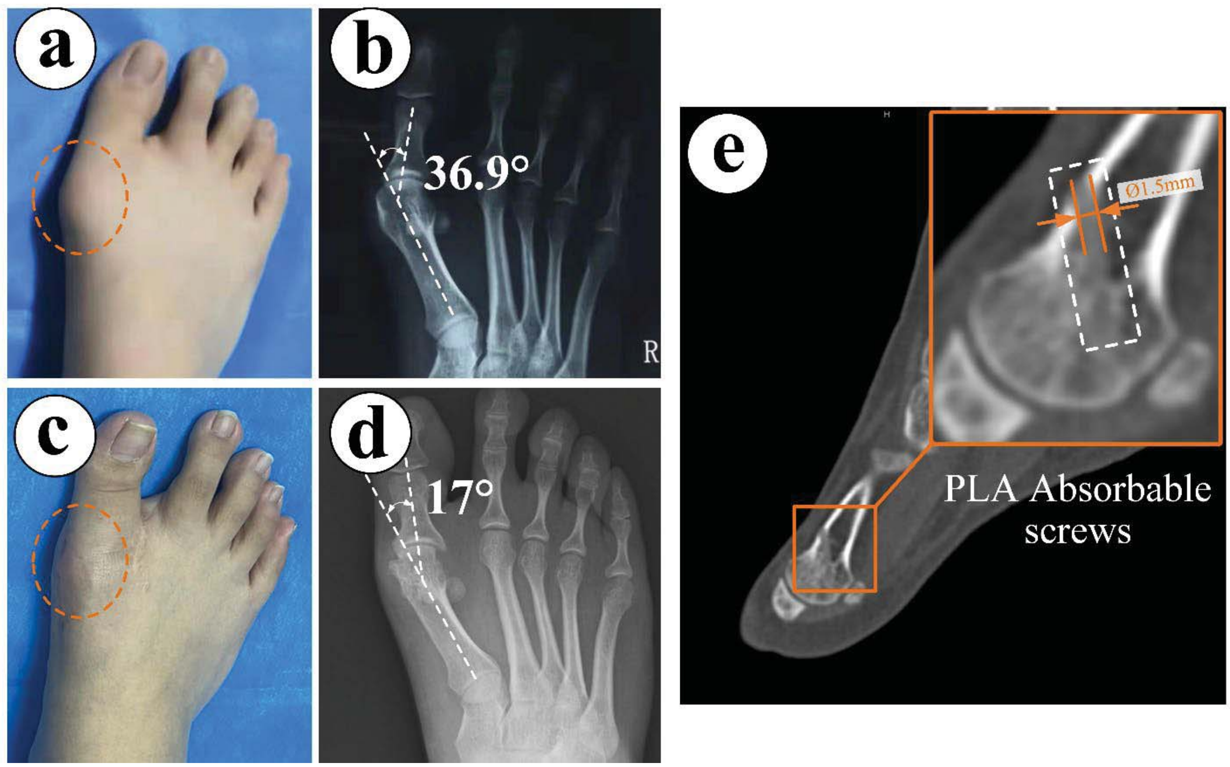

Figure 2. A 21-year-old female with right foot HV deformity. a. Preoperative image ; b. Preoperative anteroposterior X-ray; c. Image at 24 months after surgery; d. Anteroposterior X-ray at 24 months after surgery; e. CT scan at 24 months after surgery showed that the diameter of bioaborbable screw was about 1.5mm

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Table 1. Patient Information

	Number	Ratio %
Age（year）	39.3（20-63）	NA
Sex	n =26	
Female	23	88.5%
Male	3	11.5%
Operate side	n =26	
Left	8	30.8%
Right	5	19.2%
Bilateral	13	50.0%
Deformity Severity	n =39	
Mild（HVA＜30）	12	30.8%
Moderate （HVA30-40）	22	56.4%
Severe （HVA＞40）	5	12.8%
Accesory Surgery	n=39	
Akin	7	17.9%
Distal osteotomy of 5th metartarsal	2	5.1%
Weil osteotomy of 2nd metartarsal	1	2.6%
The second interphalangeal joint fusion	1	2.6%
Morton neuroma excision	1	2.6%
Function Rating Postoperation	n=39	
Excellent	34	87.2%
Good	5	12.8%
Fair	0	0
Poor	0	0
Complication	n =39	
Recurrence	4	10.3%
Numbness	2	5.1%
Necrosis of 1st metartarsal head	1	2.6%
Arthritis of 1st Metartarsophalangeal jiont	1	2.6%

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Mean follow-up（month）	21.0 （12-57）	NA

Table 2. Comparison of radiological and clinical fuction results preoperative and postoperative

Index	Pre-op	Post-op	P-value
HVA（°）	33.4± 6.7	12.7± 5.1	＜0.001
IMA（°）	14.6 ±2.9	5.8± 1.7	＜0.001
TSP	6.0 ±0.7	2.9 ±0.9	＜0.001
VAS Score	4.4 ±1.6	0.6± 0.7	＜0.001
AOFAS Score	64.2± 11.0	94.3± 6.1	＜0.001
EFAS Score	9.6 ± 4.1	20.5± 3.5	＜0.001
SF-36(PCS)	81.1 ± 7.5	96.4 ± 3.4	＜0.001
SF-36(MCS)	73.2 ± 13.6	82.7 ± 16.4	＜0.001

Note: HVA:hallux valgus angle; IMA:intermetatarsal angle;TSP:tibial sesamoid position; VAS:visual analogue scale ;AOFAS: American Orthopaedic Foot and Ankle Society ; EFAS:European Foot and Ankle Society ;SF-36:short-form health survey questionnaire; PCS:Physical Component Score; MCS:Mental Component Score

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Table 3. Comparison of radiological and clinical fuction results between sesamoid reduction and non-reduction

Index	Sesamoid Reduction（n=29）	Sesamoid Non-reduction（n=10）	P-value
HVA(°)	12.7± 5.5	13.2± 3.5	.788
IMA(°)	5.8 ±1.8	5.9 ±1.2	.883
TSP	2.5± 0.5	4.2± 0.4	＜0.001
VAS Score	0.4± 0.6	0.9± 0.9	.112
AOFAS Score	95.0 ±6.0	92.4 ±6.4	.274
EFAS Score	21.2 ±2.7	20.2 ±3.0	.693
SF-36(PCS)	96.6 ±2.5	95.8± 1.9	.862
SF-36(MCS)	80.8 ±4.5	81.2± 3.1	.792