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Outcomes of Angular Stable Locking System in Femoral Diaphyseal Fractures of Elderly Patients: A Multicenter Comparative Study

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Background: The angular stable locking system (ASLS) was developed to provide additional stability to the distal interlocking screw of the intramedullary (IM) nail. Effects of ASLS on the treatment of femoral diaphyseal fractures in the elderly remain unknown. The aim of this study was to compare radiological outcomes of IM nailing using ASLS screws to IM nails with conventional interlocking screws in elderly patients with femoral shaft fractures.

Methods: A multicenter retrospective review of 129 patients (average age, 73.5 years; 98 women and 31 men) aged 65 years or older who underwent IM nail fixation for femoral diaphyseal fractures (AO/Orthopaedic Trauma Association [OTA] classification 32) was conducted. Demographic information of patients, fracture site (subtrochanteric or shaft), fracture type (traumatic or atypical), and AO/OTA fracture classification were investigated. Reduction status was evaluated by postoperative plain radiography. Presence of union and time to union were evaluated through serial plain radiograph follow-up. Reoperation due to nonunion or implant failure was also evaluated.

Results: ASLS was used in 65 patients (50.3%). A total of 118 patients (91.5%) achieved union without additional surgery and the mean union time was 31.8 ± 13.0 weeks. In terms of reduction status, angulation was greater in the group using ASLS. There were no statistically significant differences of union rate, time to union, and reoperation rate according to the use of ASLS ($p > 0.05$). There was no difference in the outcomes according to the use of ASLS even when the analysis was divided in terms of fracture site or fracture type ($p > 0.05$). In further subgroup analysis, only the traumatic subtrochanteric area group showed statistically significantly shorter time to union when ASLS was used ($p = 0.038$).

Conclusions: In geriatric patients with femoral diaphyseal fractures, the use of ASLS was not considered to have a significant effect on fracture healing. Fracture healing seemed to be more affected by surgical techniques such as minimizing the gap and fracture characteristics such as atypical femoral fractures, rather than implants.

Keywords: *Femoral shaft, Traumatic fracture, Atypical fracture, Angular stable locking system, Intramedullary nail*

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Femoral shaft fractures are mostly caused by high-energy injuries such as motor vehicle collisions in young patients and low-energy injuries such as ground level falls in elderly osteoporotic patients.[1] Intramedullary (IM) nailing is the most widely used treatment method for femoral shaft fractures, and the use of IM nailing showed comparable results in elderly patients.[2] After IM nailing, union-related problems such as nonunion and delayed union have been reported as major postoperative complications, and the reported complication rates range up to 13%.[3]

It has been reported that delayed union after IM nailing is often caused by the use of bisphosphate (BP) and osteoporosis in the elderly patients.[4,5] There are many elderly populations taking BP for osteoporosis, and its use has been reported to be a risk factor of atypical femoral fractures (AFFs).[6] Furthermore, in geriatric women, postmenopausal osteoporosis is prevalent and bone remodeling accompanied by the expansion of medullary canal and cortical thinning proceeds.[7] It has been reported that osteoporotic bone fractures have more comminuted and complex patterns.[8] For these reasons, it is difficult to achieve stable fixation in the elderly, and fixation failure frequently occurs.[9] When using IM nailing in the long bone in elderly patients, the distal cortical bone may be brittle and thin, making purchasing force of the distal interlocking screw weaker and resulting in screw loosening or rotational instability.

Angular stable locking system (ASLS) was developed to provide additional stability to the distal interlocking screw of the IM nail.[10] ASLS works as a biodegradable sleeve mounted into an interlocking screw. The sleeve fills the gap between the screw and the nail, thereby increasing the angular stability of the nail-screw construct. ASLS has been mainly studied in tibial fractures, and both biomechanical and clinical studies reported good results.[11-13] However, studies of ASLS in osteoporotic bone or the elderly patients are limited. Also, to the best of our knowledge, studies on the effects of ASLS on the treatment of femoral shaft fractures are lacking. The aim of this study was to compare radiological outcomes of IM nailing using ASLS screws to IM nailing with conventional interlocking screws in elderly patients in a multicenter retrospective review.

METHODS

Patient Selection

The study protocol was approved by the Institutional Review Board at each participating institution (No. 2018-09-019-013). Patient consent was waived because of the retrospective nature of the study. The retrospective comparative study was conducted from January 1, 2012, to January 1, 2017. After a post-hoc analysis, to ensure a sufficient number of patients, patients were recruited from four institutes. The inclusion criteria were patients aged 65 years or older who underwent IM nailing for femoral diaphyseal fractures. In this study, the fracture site corresponding to AO/Orthopaedic Trauma Association (OTA) classification 32 was included.[14] To reduce surgery-related bias, only IM nailing cases with proximal cephalomedullary fixation and distal two interlocking screws were included. Each patient's fracture site and fracture type were investigated. The fracture site was categorized into a subtrochanteric area and a shaft area, and fracture types were classified as a traumatic fracture and an AFF. The subtrochanteric area was defined as the area 5 cm distal to the lesser trochanter, and the shaft area as from 5 cm distal to the lesser trochanter to the distal diaphysis. AFFs were diagnosed based on injury mechanisms and plain radiographs according to the diagnostic criteria of the American Society for Bone and Mineral Research.[6] Fractures that did not meet the diagnostic criteria of the AFF were defined as traumatic fractures. The exclusion criteria were multiple fractures, open fractures, associated nerve or vessel injuries at initial visit, use of blocking screws, bilateral AFFs requiring prophylactic IM nailing of the contralateral femur, follow-up loss before bone union or at least 1 year. Finally, a total of 129 femurs of 129 patients were included (Fig. 1).

Surgical Procedure and Rehabilitation Protocol

All patients underwent surgery using IM nails and four orthopedic trauma surgeons (KCP, CWO, OJS, and JWK) performed the operation at four trauma centers. Surgery

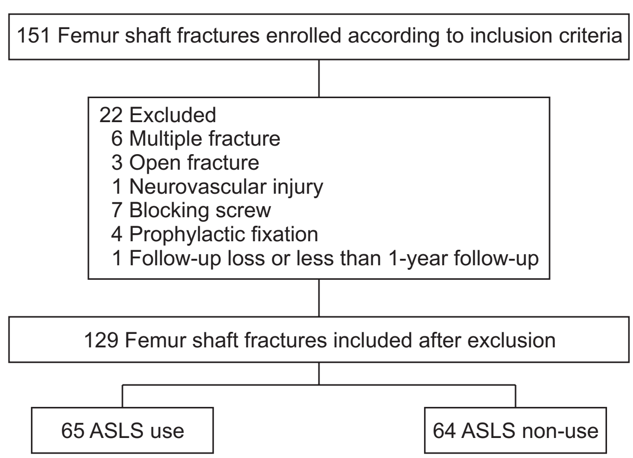

Fig. 1. Flow diagram of patient enrollment. ASLS: angular stable locking system.

was performed in each surgeon's familiar position, fracture table with lithotomy position or lateral position. The implants used for IM nail fixation were the Expert Asian Femoral Nail (A2FN, Synthes) and long-proximal femoral nail antirotation II (Long-PFNA II, Synthes). Both A2FN and Long-PFNA II can use conventional screws and ASLS as distal interlocking options. In A2FN, two reconstruction type screws were used for proximal cephalomedullary fixation. In Long-PFNA II, one helical blade was used. In all patients, single distal interlocking option was used, either conventional screws or ASLS. In 2012, when the study was initiated, ASLS was not available in all four institutions, and all femoral shaft fractures in elderly patients were treated with IM nail fixation using conventional distal interlocking screws. ASLS has been used since 2013. The four institutions agreed on the indications to use ASLS in cases of atypical fractures, newly diagnosed osteoporosis, and a history of osteoporosis. If there was a history of osteoporosis, ASLS was used even if the T-score was higher than –2.5 in a bone mineral density (BMD) test within 1 year. The diameter, length, and neck-shaft angle of the nail was determined by measurement of the contralateral anteroposterior (AP) and lateral images before surgery. After obtaining appropriate reduction considering length, axis, and rotation, screw fixation was done. Before distal interlocking screw fixation, the surgeons used the forward-striking technique to minimize the gap by loosening the traction of the affected lower extremity and compressing the fracture site manually.

Active range-of-motion exercises were started from the day after surgery. Partial weight-bearing was initiated with crutches within 2 weeks after surgery. For patients who were unable or unsuitable for partial weight-bearing using crutches, walker or wheelchair ambulation was performed. Partial weight-bearing was gradually increased within the patient's tolerable pain range. If the patient was judged to be able to walk independently, the walking aid was removed, and full weight-bearing was performed.

Radiologic Assessment

Simple radiographs were taken initially, immediately after operation, at 2 weeks, 6 weeks, 3 months, 6 months, and then every 3 months after operation. After complete bone union, patients were followed up twice a year unless they had complications. All radiographs were converted to Digital Imaging and Communications in Medicine files. The radiologic data were checked twice by two orthopedic surgeons who did not participate in the surgery (KTH and IK). Based on the initial plain radiographs, fracture types were classified into 32-A, 32-B, and 32-C according to the AO/OTA classification[14] and the fracture sites were divided into the subtrochanteric area and shaft area.

The reduction status of the fracture was evaluated by measuring the alignment and displacement on the immediate postoperative radiographs.[15,16] Coronal alignment was measured between the midline of the proximal segment and the midline of the distal segment in the femoral AP images. Sagittal alignment was measured between the anterior cortex of proximal and distal segments in femoral lateral images. In the case of subtrochanteric fractures, coronal alignment was measured using the midline of the neck and distal fragment shaft and compared with the contralateral neck shaft angle. Coronal displacement was measured as the maximal distance between both cortices of proximal and distal segments in the AP images. Similarly, sagittal displacement was measured as the maximal distance between both cortices of proximal and distal segments in lateral images.

Assessment of Outcomes

Patient demographics included age, sex, body mass index (BMI), smoking, alcohol history, history of glucocorticoid use, relevant medical comorbidities, BMD, follow-up period, mechanism of injury (high/low), and preoperative BP use. BMD was defined as the lowest T-score value among hip and spine in dual-energy X-ray absorptiometry. BMD results were verified in all patients. For patients with a history of osteoporosis, BMD test results within 1 year were verified. If there was no BMD result within 1 year, BMD test was performed after admission. Falls of less than 1 m in height or ground level fall were classified as low-energy injuries, and other injuries were classified as high-energy injuries. Surgical records included procedure and type of implant (A2FN/Long-PFNA) and distal screw (ASLS/standard interlocking screw). Bone union was defined as the formation of cortical continuity in more than 3 cortices among 4 cortices in AP and lateral images. Presence of union and time to union were evaluated through serial plain radiograph follow-up. Delayed union was defined as no fracture healing after 6 months. Fractures without increased callus formation with pain on follow-up radiographs after 9 months or those with implant failure were defined as nonunion.[17] Failure was defined as all cases requiring secondary surgery due to delayed union/nonunion or metal failure.

Statistical Analysis

IBM SPSS statistics ver. 20.0 (IBM Corp.) was used for statistical analysis. The intraobserver reliability and interobserver agreement of the fracture reduction status and bone union were calculated with intraclass correlation coefficients (ICCs) and Cohen's kappa (κ) coefficients of agreement. The normality test was carried out through the Kolmogorov-Smirnov test and the Shapiro-Wilk test. An independent t-test was performed when normality was satisfied for a continuous variable. If normality was not satisfied, the Mann-Whitney U-test was performed. For categorical variables, the chi-square test or Fisher's exact test was performed. A $p < 0.05$ was considered statistically significant.

RESULTS

A total of 129 patients were included in the study. Their mean age was 73.5 years (range, 65–87 years) and 98 patients (75.9%) were women. The mean follow-up period was 23.5 months (range, 12–73 months). Osteoporosis was diagnosed in 88 cases (68.2%) and AFF in 75 cases (58.1%). The average T-score was –2.3 (range, 0.7 to –4.7). Low-energy injury was predominant (96 cases, 70.6%).

A2FN with two reconstruction screws was used in 110 patients (85.3%), and Long-PFNA was used in 19 patients (14.7%). On the postoperative reduction status, mean AP and lateral angulation were 2.7° ± 9.3° and 3.5° ± 10.5°, respectively. There were 4.6 ± 11.5 mm and 5.8 ± 15.2 mm of mean AP and lateral displacement, respectively. On the bone union, 118 patients (91.5%) achieved union without additional surgery and the mean union time was 31.8 weeks (range, 20–72 weeks) (Fig. 2). Delayed union occurred in 42 patients (32.6%), and nonunion was noted in 11 cases (8.5%). There were 13 failure cases: plate augmentation in 8 cases, exchange nailing in 2 cases, dynamization in 1 case, bone graft in 1 case, and exchange nailing with plate augmentation in 1 case (Fig. 3). Complete bone union was achieved after reoperation in all

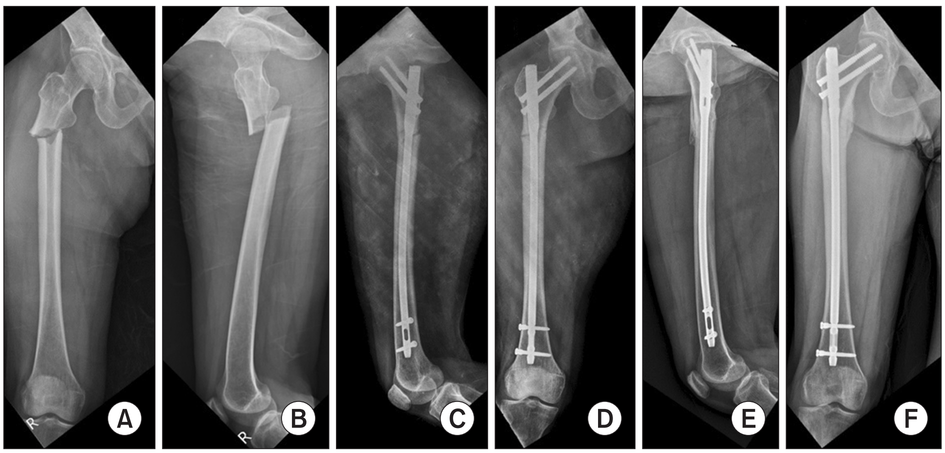

Fig. 2. Preoperative anteroposterior (A) and lateral (B) radiographs of a 73-year-old female patient, showing an atypical femoral fracture in the subtrochanteric area. Immediate postoperative anteroposterior (C) and lateral (D) radiographs showing the fracture fixed with antegrade femoral nails with reconstruction type proximal screws and two distal angular stable locking system screws. Follow-up anteroposterior (E) and lateral (F) radiographs at 28 weeks after operation show union was obtained without complications.

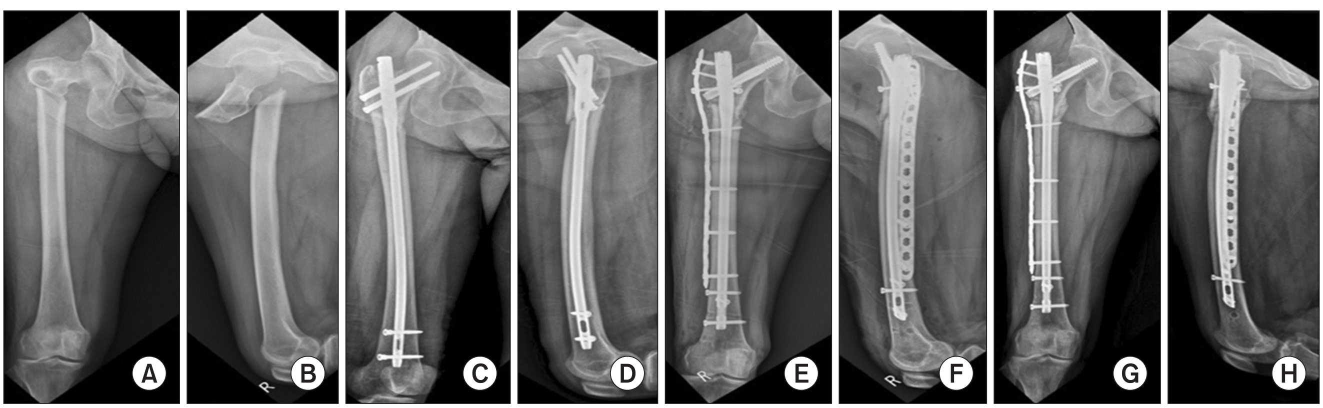

Fig. 3. Preoperative anteroposterior (A) and lateral (B) radiographs of a 72-year-old female patient, showing a subtrochanteric atypical femoral fracture by slip down. Immediate postoperative anteroposterior (C) and lateral (D) radiographs showing the fracture fixed with antegrade femoral nails with two distal angular stable locking system screws. Nonunion was diagnosed at 9 months after operation. Immediate postoperative anteroposterior (E) and lateral (F) radiographs showing reoperation of exchange nailing with plate augmentation was performed. Follow-up anteroposterior (G) and lateral (H) radiographs at 6 months after reoperation show bone union was obtained.

failure cases.

On the comparison between the ASLS and non-ASLS groups, sex, injury mechanism, BP use, and AO/OTA fracture classification were statistically significantly different between the two groups (Table 1). Age, BMI, smoking, alcohol, glucocorticoid use, DM, BMD, mean follow-up period, proportion of atypical fractures, and fracture site were not statistically significantly different between the two groups. There was no statistical difference in the type of IM nails used (Table 1).

On the comparison of the reduction status between the two groups, AP and lateral angulation were significantly greater in the ASLS group ($p = 0.002$ and $p = 0.048$, respectively) (Table 2). There was no significant difference in AP and lateral displacement between the two groups ($p = 0.518$ and $p = 0.829$, respectively) (Table 2). On the postoperative reduction status, the ICC for intraobserver reliability and interobserver agreement was 0.789 (95% confidence interval [CI], 0.76–0.82) and 0.723 (95% CI, 0.69–0.75), respectively. On the bone union status, intraobserver reliability and interobserver agreement shown by Cohen's kappa (κ) coefficient of agreement was 0.826 (95% CI, 0.77–0.87) and 0.745 (95% CI, 0.59–0.88), respectively.

The average union time was 31.2 ± 13.1 weeks in

Table 1. Patient Demographic Data

Variable	All patients (n = 129)	ASLS use (n = 65)	ASLS non-use (n = 64)	*p*-value
Sex (male : female)	31 : 98	7 : 58	24 : 40	< 0.001
Age (yr)	73.5 ± 5.9	74.2 ± 5.7	72.8 ± 6.1	0.130
BMI (kg/m^2)	23.2 ± 3.4	23.0 ± 2.9	23.3 ± 3.8	0.672
Smoking (%)	9 (7.0)	2 (3.1)	7 (10.9)	0.096
Alcohol (%)	11 (8.5)	4 (6.2)	7 (10.9)	0.511
Glucocorticoid use (%)	13 (10.1)	6 (9.2)	7 (10.9)	0.976
DM (%)	21 (16.3)	8 (12.3)	13 (20.3)	0.321
BMD (T-score)	–2.3 ± 1.2	–2.4 ± 1.0	–2.2 ± 1.3	0.415
Follow-up period (mo)	23.5 ± 14.6	22.2 ± 13.4	24.7 ± 15.7	0.624
Low-energy injury (%)	94 (72.9)	58 (89.2)	36 (56.3)	< 0.001
Fracture site (%)				0.666
Subtrochanteric	51 (39.5)	24 (36.9)	27 (42.2)	
Shaft	78 (60.5)	41 (63.1)	37 (57.8)	
Atypical fracture (%)	75 (58.1)	43 (66.2)	32 (50.0)	0.093
Preoperative BP use (%)	62 (48.1)	40 (61.5)	22 (34.4)	0.004
Preoperative BP duration (mo)	42.2 ± 30.7	34.1 ± 17.4	56.9 ± 42.6	0.014
AO/OTA classification (%)				0.025
32-A	101 (78.3)	57 (87.7)	44 (68.8)	
32-B	23 (17.8)	7 (10.8)	16 (25.0)	
32-C	5 (3.9)	1 (1.5)	4 (6.3)	
Type of IM nail (%)				0.594
A2FN	110 (85.3)	57 (87.7)	53 (82.8)	
Long-PFNA II	19 (14.7)	8 (12.3)	11 (17.2)	

Values are presented as mean ± standard deviation or number (%).
ASLS: angular stable locking system, BMI: body mass index, DM: diabetes mellitus, BMD: bone mineral density, BP: bisphosphonate, OTA: Orthopaedic Trauma Association, IM: intramedullary, A2FN: Expert Asian Femoral Nail (Synthes), PFNA II: Proximal Femoral Nail Antirotation II (Synthes).

Table 2. Postoperative Reduction Status, Final Radiologic Outcomes, and Failure Requiring Reoperations

Variable	All patients (n = 129)	ASLS use (n = 65)	ASLS non-use (n = 64)	*p*-value
Reduction status				
AP angulation (°)	2.7 ± 9.3	4.4 ± 11.5	1.4 ± 6.8	0.002
Lateral angulation (°)	3.5 ± 10.5	5.0 ±13.7	1.8 ± 5.3	0.048
AP displacement (mm)	4.6 ± 11.5	4.7 ±12.1	4.4 ± 10.9	0.518
Lateral displacement (mm)	5.8 ± 15.2	5.9 ±16.8	5.4 ± 13.6	0.829
Radiologic outcome				
Union time (wk)	31.8 ± 13.0	31.7 ± 11.8	31.8 ± 14.2	0.791
Healed	76 (58.9)	40 (61.5)	36 (56.3)	0.594
Delayed union	42 (32.6)	17 (26.2)	25 (39.1)	0.135
Nonunion	11 (8.5)	8 (12.3)	3 (4.7)	0.206
Failure (reoperation)	13 (10.1)	9 (13.8)	4 (6.3)	0.254

Values are presented as mean ± standard deviation or number (%).
ASLS: angular stable locking system, AP: anteroposterior.

the ASLS group and 30.8 ± 14.3 weeks in the non-ASLS group, and there was no statistically significant difference between the two groups (Table 2). There were no statistically significant differences in delayed union, nonunion, and reoperation rates between the two groups (Table 2).

Further analysis was performed according to the use of ASLS. Groups were divided in terms of fracture type (AFF or traumatic) and fracture location (subtrochanteric or shaft). In the AFF group, there was no statistically significant difference in union time, union rate, delayed or nonunion, and reoperation rate according to the use of ASLS. In the traumatic group, radiologic outcomes and reoperation rate were not statistically significantly different according to the use of ASLS. In the subtrochanteric group, the radiologic outcome and reoperation rate were not statistically different according to the use of ASLS. Furthermore, there was no statistically significant difference in radiologic outcome and reoperation rate according to the use of ASLS in the shaft group.

More specific subgroup analysis regarding both fracture type and site was performed (AFF-subtrochanteric group [n = 30], AFF-shaft group [n = 45], traumatic subtrochanteric group [n = 21], and traumatic shaft group [n = 33]). In this subgroup analysis, only traumatic subtrochanteric group showed a statistically significantly shorter union time when ASLS was used (ASLS [n = 12]: 26.7 ± 10.3 weeks, non-ASLS [n = 9]: 39.3 ± 12.2 weeks, p = 0.038). There was no statistical difference in other radiological results (union rate, delayed union rate, or nonunion rate) and reoperation rates. In the other subgroups, there was no statistical difference in all radiological results and reoperation rates according to the use of ASLS.

DISCUSSION

This study is a retrospective, multicenter study to investigate whether the use of ASLS for IM nailing affects the radiological outcome and reoperation rate in elderly patients with femoral diaphyseal fractures (AO/OTA classification 32). A total of 129 femoral fractures were included based on our inclusion and exclusion criteria. Current data of this study demonstrated that there were no differences in union time, union rate, delayed union, nonunion, and reoperation rate according to the use of ASLS in elderly patients with femoral diaphyseal fractures. Same results were shown in the subgroup analysis; only traumatic subtrochanteric fracture group (n = 21) showed a statistically significantly shorter union time when ASLS was used (p = 0.038).

IM nails are commonly used as a treatment of choice for femoral shaft fractures, and favorable results have been reported.[18,19] Interlocking screws are used to enhance rotational and angular stability in IM nailing. It has been reported that using a conventional interlocking screw can cause screw-to-nail toggle, which can cause excessive interfragmentary movement.[11,20,21] It has been reported that excessive interfragmentary movement creates a gap at the fracture site causing secondary displacement, delayed healing, and delayed union or nonunion.[21,22)]

Angle-stable nails were developed to reduce screw-to-nail toggles and to enhance construct stability. ASLS is an angle-stable nail system where a screw is mounted into a biodegradable sleeve to obtain strong angular stability and torsional stiffness. Favorable results have been reported in biomechanical and clinical studies.[11-13)] According to biomechanical studies using ASLS in distal tibial fractures, the group using ASLS had less interfragmentary movement and higher torsional stiffness than the group using conventional interlocking screws.[12,23)] ASLS showed strong torsional stiffness in a fracture at the meta-diaphyseal junction area, where cortical bone support is limited, causing decreased construct stability.[12,13)] It has been suggested that the use of ASLS can reduce complications such as reduction loss, nonunion, and delayed union.[12)] In elderly patients, the femoral cortex becomes thinner and canal expansion occurs, and the bowing of the femur progresses.[7,24)] These changes make it impossible to sufficiently fill the inside of the canal with the diameter of the nail, or a mismatch between the canal and the nail may result in weakening of mechanical stability.[24,25)] In addition, in elderly osteoporotic fractures, the cortex is thin, which makes fixation failure and peri-implant fractures more frequently occur.[9)] Due to these characteristics, it was thought that the use of ASLS for IM nailing in elderly patients with femoral diaphyseal fractures would be helpful in fracture healing.

The ASLS screw did not show a significant effect on femoral diaphysis fracture in elderly patients, and it may be due to the characteristics of elderly patients. Elderly patients have physical and mental deterioration, such as sarcopenia and muscle weakness, decreased coordination during exercise, risk of falls, and difficulty in using crutches, and cognitive disorder.[26-29)] Under these circumstances, weight-bearing can be relatively delayed even if early range of motion exercise is performed. In our study, full weight-bearing was performed if it was judged that the patient could walk independently during outpatient follow-up. The criteria for judgment were radiologically confirmed callus formation and clinically tolerable pain at the surgical site in full weight-bearing. Even after meeting these criteria, elderly patients often had insufficient muscle strength or had a high risk of falling, so they continued to use a walking aid. Elmi et al.[30)] reported that the ambulation level was decreased after femoral shaft fractures in elderly patients, which is consistent with the reason why full weight-bearing was delayed in our study.

Previous biomechanical studies were conducted under the assumption of a weight-bearing situation. ASLS screws are inserted after being mounted into a biodegradable sleeve, and the sleeve provides strong fixation for initial 12 weeks. The results of our study suggest that the elderly patient's tendency to start weight-bearing slowly might preclude the initial 12-week advantages of high angular stability and torsional stiffness of ASLS. In addition, while there is a biomechanical study conducted with porcine or sheep bones that have a higher bone density than human bone, experiments on atypical fracture models or osteoporosis models were not performed. Boyer et al.[13)] reported a 94% union rate without additional surgery within 6 months after surgery when using ASLS in human distal tibial fractures. This study was conducted in a group with an average age of 45 years and 28 out of 41 were men. Direct comparison with this study is limited because there was no control group such as elderly or osteoporotic patients. However, considering the age and gender distribution, achieving bone union using ASLS without additional surgery in 86.3% of traumatic fractures (19/22) in the current study might be comparable to the results reported by Boyer et al.[13)]

When ASLS was used in the traumatic subtrochanteric group (n = 21), the union time was statistically significantly shorter ($p = 0.038$). This seems to be due to the difference in the injury mechanism between the ASLS and non-ASLS groups. All 9 cases of the non-ASLS group were high-energy injuries, and only 3 out of 12 cases of the ASLS group had high energy injuries in the traumatic subtrochanteric fracture group. High energy injury accompanies more severe soft-tissue damage and shows a more comminuted fracture pattern rather than a simple fracture pattern. Comminuted fractures are difficult to reduce and may cause additional soft-tissue damage during reduction, which may impair healing of the fracture.

When comparing the postoperative reduction status between the two groups, AP and lateral angulation were greater in the ASLS group. This could be explained by the fact that more AFF patients were included in the ASLS group. AFF patients have more severe femoral bowing.[6)] So, the mismatch between femoral bowing and IM nail curvature in the ASLS group would have been greater, which resulted in greater postoperative angulation. On the other hand, there was no significant difference in postoperative displacement (gap) between the two groups. It is thought that this is because all surgeons minimized the fracture site gap through forward-striking before inserting distal interlocking screws. It has been reported that the residual fracture site gap after IM nail fixation interferes with bone union.[21,22)] The reason why there was no difference in radiologic outcomes such as union rate between the two groups may be because gap reduction was performed consistently throughout all surgeries.

Based on the results of our study, the use of ASLS in elderly patients with femoral shaft fractures can be considered to have relatively little benefit of having high stiffness in the first 12 weeks, and radiologic outcomes appear to be more influenced by surgical techniques such as minimizing fracture site gaps and fracture characteristics such as atypical fracture.

This study has some limitations. It is a retrospective study, and there was no unified surgical method and postoperative rehabilitation protocol as it was performed by different surgeons. Although the prospective study design has advantages, there is a risk that the prospective study may raise ethical issues in a situation where the effect of ASLS on femoral shaft fractures in the elderly has not been sufficiently studied. Therefore, we conducted a retrospective study and set the study period from 2012, when ASLS was not used. In this way, we were able to compare the outcomes according to the use of ASLS without ethical issues. This is an advantage that only a retrospective study can have. However, patient's mobility level before and after surgery, pain, and the other complications rather than union-related reoperation were not investigated. It is a limitation of a retrospective study.

Although there was no unified surgical method in our study, the surgical technique for IM nail fixation for femoral shaft fractures is well established, and all surgeons performed IM nail fixation according to the established surgical technique. For example, all surgeons reduced the fracture site gap through the forward-striking technique before inserting distal interlocking screws. In addition, in our study, the surgical instruments and the number of distal interlocking screws were unified, cephalomedullary fixation was performed in all cases, and the indications for using ASLS were unified to minimize surgery-related bias. Taken together, this study in which four trauma specialists participated is not expected to have a significant confounding effect.

The use of ASLS may be effective when the diameter of the canal increases in the femoral distal 1/3 area and fitting is not possible with IM nails. In our study, the study participants were elderly patients, and the frequency of atypical femoral fractures was high. Femoral shaft fractures in elderly patients occur frequently in the subtrochanteric area and midshaft area due to the effects of femoral bowing and osteoporosis, and the incidence is low in the distal 1/3 area. The number of femoral shaft fractures in the distal 1/3 area in elderly patients was too small to be classified separately.

In our study, patients were recruited from four institutions by performing post-hoc analysis to obtain a sufficient sample size. We could obtain a relatively large sample size of 129 including 75 atypical fractures. However, when subgroup analysis was performed according to fracture type and fracture location, the sample size per subgroup was relatively small. There is a possibility that the subgroup analysis might have been underpowered. Therefore, a prospective study involving a larger sample size and more specifically subdividing the fracture site and type is needed to evaluate the effectiveness of ASLS in IM nailing in elderly patients with femoral shaft fractures, especially in the distal 1/3 area. Biomechanical studies of ASLS in osteoporotic femoral shaft fractures are also needed.

In conclusion, the use of ASLS is not considered to have a significant effect on fracture healing in geriatric patients with femoral diaphyseal fractures. Fracture healing seems to be more affected by surgical techniques such as minimizing the gap and fracture characteristics such as atypical femoral fractures, rather than implants.

CONFLICT OF INTEREST

No potential conflict of interest relevant to this article was reported.

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