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박사학위논문

경골 간부 골절에서 골수내 정과 최소침습적 강판 고정술의 임상적, 방사선학적 비교

제주대학교 대학원

의학과

강 현 성

2019년 8월

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Clinical and radiological outcomes between Locking intramedullary nail and Minimally invasive plate osteosynthesis in tibia shaft fractures

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A thesis submitted in partial fulfillment of the requirement for the degree of Doctor of Medicine

2019. 08.

This thesis has been examined and approved.

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목차

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ABSTRACT

Background: Meta-diaphyseal tibia fracture is a challenging fracture to treat for orthopaedic surgeons, and there is still no consensus in the literature on the standard treatment for meta-diaphyseal tibia fracture. The following study compares the efficacy and indications of minimally invasive plate osteosynthesis (MIPO) to those of intramedullary (IM) nailing for the treatment of meta-diaphyseal tibia fracture.

Methods: Eighty-five patients with a tibia shaft fracture in the proximal or distal 1/3 of the tibia who had undergone IM nailing or MIPO were enrolled in this study. Group I included 42 patients who had undergone IM nailing, and Group M consisted of 43 patients who had been treated by MIPO. The following clinical outcomes were assessed: time of callus formation, bone union, and complications of malunion, nonunion, angulation, and shortening. Each patient was followed up at least 1 year postoperatively.

Results: There was no significant difference ($P>0.05$) in hospital stay, time to radiographic union and the incidence of union status among the two groups. The mean callus formation and mean union periods for Group I were 10.1 weeks and 17.2 weeks, respectively, and those for Group M were 10.7 weeks and 19.81 weeks, respectively. In regards to postoperative complications, there were two cases of nonunion, two cases of delayed unions and four cases of malunion in group I, whereas only one case of delayed union was observed in group M. There was no difference in functional evaluation between the two methods after operation ($P>0.05$).

Conclusion: We consider that the minimally invasive plate osteosynthesis and locking intramedullary nail stabilization are all efficient methods for treating proximal or distal tibia shaft fractures. However, when the fracture is associated with the meta-diaphyseal junction,

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IMN with combination techniques as additional polar screws or small plate can help prevent secondary collapse of the fracture.

Key Words: Tibial shaft fracture, Intramedullary nailing, Minimally Invasive Plate Osteosynthesis

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초록

목적: 경골 간부 골절은 그 위치나 생리학적인 요인들로 인해 치료가 어려운 골절 중의 하나이다. 현재까지 비수술, 고식적 금속판 고정술, 외고정술, 골수강 내 정 고정술 등 여러 치료 방법이 제시되고 발전되어 왔으나, 아직 확실히 정립된 표준 치료 방법은 없다. 경골 간부 골절에서 치료 방법이 변화하고 있으며, 각각의 합병증과 단점을 보완하기 위해 수많은 임상적 연구와 시도를 거쳐 덜 침습적이면서도 고정력을 얻을 수 있는 수술 방법들이 발명되고 있다. 그 중 가장 대표적인 술식이 골수강 내 정 고정술과 최소 침습적 강판 고정술이다. 따라서 이 연구는 경골 간부 골절에서 골수강 내 정 고정술과 최소 침습적 강판 고정술을 이용한 치료 결과를 분석하여 어떠한 방법이 치료에 더 효과적이고 적응증이 될 수 있는지 확인하고자 하였다.

방법: 2003년 5월부터 3013년 12월까지 경골 간부 골절에서 골수강 내 정 고정술이나 최소 침습적 강판 고정술을 받은 85명의 환자를 대상으로 하였다. 골수내 정 고정술을 받은 42명의 대상자를 그룹 I으로, 최소 침습적 강판 고정술을 받은 43명의 대상자를 그룹 M으로 하였다. 수술 이후 지속적인 경과 관찰을 통해 가골 형성시기, 골유합 시기를 확인하고, 부정유합이나 불유합, 각형성, 단축 등의 합병증이 발생하는지 조사하였다. 모든 환자들을 수술 후

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최소 1년 이상 추적 관찰하였다.

결과: 두 군간의 재원기간이나 골유합 시기에 유의한 차이는 없었고 (P>0.05), 가골 형성시기는 그룹 I에서 10.1주, 그룹 M에서 10.7주였고, 골유합 시기는 그룹 I에서 17.2주, 그룹 M에서 19.8주였다. 그룹 I에서 불유합 2례, 지연유합 2례, 부정유합 4례가 있었으며, 그룹 M에서는 지연유합이 1례 있었다. 수술 후 두 군간의 기능적, 임상적 차이는 없었다.

결론: 경골 간부 골절에서 골수강 내 정 고정술과 최소 침습적 강판 고정술 모두 안정적인 고정을 얻을 수 있었다. 하지만 경골 간부와 골간단부 연결부위에서는 골수강 내 정 고정술만으로는 고정이 견고하지 않기 때문에 각형성이나 부정유합이 발생할 가능성이 있다. 따라서, 블로킹 나사나 소형고정판을 이용한 골수강 내 고정술이나 최소 침습적 강판 고정술이 골절부위 지지를 통하여 2차적인 골절부 소실을 예방할 수 있을 것이다.

색인단어: 경골 간부 골절, 골수강 내 고정술, 최소 침습적 강판 고정술

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INTRODUCTION

Interlocking intramedullary (IM) nailing is the mainstream treatment for tibia shaft fracture due to the minimal soft tissue dissection, good bone union rate, and early return to daily living associated with this procedure. The IM nailing procedure has greatly improved overtime resulting in these promising outcomes, and thus, its indications have been extended to fractures closer to joints.(1) There is an abundance of published studies on the other outstanding surgical technique for the treatment of tibia shaft fracture, minimally invasive plate osteosynthesis (MIPO), and MIPO enables successful bony union of the tibia shaft fracture without the development of soft tissue infection or malunion.(2-4) The purposes of this study were to compare the clinical outcomes of these two surgical techniques for the treatment of meta-diaphyseal fracture, IM nailing and MIPO, and to deduce the effectiveness and indications of these techniques.

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MATERIALS AND METHODS

From May 2003 to December 2013, of 208 patients who had sustained a tibia shaft fracture (AO classification type 42), 85 patients with proximal or distal metaphyseal and proximal or distal diaphyseal tibia shaft fractures who had undergone intramedullary nailing or minimally invasive plate osteosynthesis were enrolled in this study. Group I consisted of 42 patients who underwent intramedullary nailing, and group M consisted of 43 patients who underwent MIPO. The outpatient clinic records and radiologic evaluations in both databases were studied retrospectively. The tibia fractures in group I were categorized by a fracture line located close to the proximal or distal 1/3 of the tibia and were relatively less comminuted than in group M. The subjects in group M had unstable tibia fractures in the proximal or distal 1/3 of the tibia that were not suitable for treatment with intramedullary nailing. For group I, the mean age was 45.82 years (range: 23~75 years), and the mean follow-up period was 22 months (range: 15~50 months). The sex ratio (M : F) of group I was 31:11. For group M, the mean age of 56.64 years (range: 29~83 years), and the mean follow-up period was 20 months (range: 12~46 months). Group M consisted of 30 males and 13 females (Table 1). Fracture patterns were classified according to the AO/ATA classification system (Table 2). Time to operation was determined based on the presence or absence of an open fracture

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and/or collateral injury and the general condition of the patient. For group I, after excluding one patient who had undergone 2nd stage delayed intramedullary nailing, the mean time from injury to surgery was 5.0 days (range: 1~17 days). For group M, after excluding three patients who underwent delayed MIPO, the mean time from injury to surgery was 7.2 days (range: 2~19 days). In group I, 29 and 13 patients underwent IM nailing with a Cannulated Tibial Nail (Synthes®, USA) and a M/DN Tibial Nail (Zimmer®, USA), respectively. For group M, all patients were treated with a locking compression plate (LCP) (Synthes®, USA), except for one patient who was treated with an anatomical plate (12-hole). Fibula fracture was present in 32 cases in group I and 27 cases in group M. Plate fixation of the fibula was performed in 7 patients in group I and 13 patients in group M. Rush pin fixation of the fibula was performed in three patients and two patients from the I and M groups, respectively. One patient from group I underwent inter-fragment screw fixation of the fibula fracture. For 21 patients in group I and 3 patients in group M, no intervention was performed.

Surgical technique

In group I, patients were placed in the supine position under spinal / general anaesthesia,

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and the nail was inserted into the closed marrow cavity after reduction of the fracture under C-arm guidance. For fractures within the proximal 1/3 of the tibia, the operator meticulously determined the best marrow nail insertion site by examining both the coronal and sagittal plane under C-arm guidance. The insertion site was selected more proximally. The fracture was reduced using reduction forceps. For segmental fractures in the proximal 1/3 of the tibia, maintaining the reduction of the fracture was difficult; therefore, reduction was performed after temporary fixation of the fracture with reduction forceps. A marrow nail was inserted with the knee joint in a semi-extended position. For proximal fractures, when possible, horizontal and oblique interlocking screws were inserted together. For distal fractures, when two horizontal interlocking screws were not sufficient to achieve stability, an additional screw was inserted so that it perpendicularly crossed the other screws. In group M, patients were placed in the supine position under spinal / general anaesthesia. Prior to surgery, a wire was inserted in the calcaneus or distal tibia, and sufficient traction was obtained with a traction device. The tibia was corrected, the fracture was loosely controlled, and then the fracture was reduced using the joy-stick technique with the inserted wire. Then, percutaneous fixation with the inserted wire or reduction forceps was performed. Upon confirmation of the location of the metal plate and the reduction status, each bony fragment was fixated with more than three nails.

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Additionally, when the bone was not severely comminuted, nail fixation was performed using the non-locking hole of the LCP rather than the bridge-plating technique. Conventional lag screws were inserted in the proximal and distal sides of the fracture to pull each side of the fracture to the metal plate and achieve alignment. Distal fibular fractures located within 5 cm from the tibio-fibular syndesmosis or fibular fractures with external instabilities when valgus or varus force was applied under C-arm guidance necessitated surgical procedures. The fibula fracture was fixated before the tibia fracture to achieve lateral stability of the ankle joint and stability of the overall length of the lower extremity. Metal plate fixation was considered the first-line therapy, but when epidermal defects were present, rush pin fixation was used. Surgical procedures were not performed for fractures without lateral instabilities located more than 10 cm above the distal fibula.

Follow-up & Evaluation

Postoperative complications, joint pain, and range of motion were accessed by reviewing admission and outpatient medical records retrospectively, and time to bony union and callus formation were also evaluated via periodic radiologic studies. Functional outcomes were

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evaluated using the JeJu National University Hospital lower extremity trauma scale system. Bony union was defined as a lack of tenderness over the fracture site, ambulation without the aid of orthosis, and the observation of a bridge callus by radiologic evaluation. Malunion was defined as valgus / varus mal-alignment and rotational deformity of more than 5 degrees, anterior / posterior angulations of more than 10 degrees and shortened length of the tibia of more than 2 cm. Nonunion was defined as the presence of a fracture at a minimum of 9 months after the original injury that had not healed and had not shown radiographic progression for at least 3 months.

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RESULTS

Operative management of distal or proximal tibia fracture required mean total operation times of 119.4 minutes (45 ~ 145 minutes) and 126.7 minutes (49 ~ 153 minutes) with the use of intramedullary nailing and MIPO techniques, respectively. As for average hospital stay, Group I was 22.1 days (range 9~101days) and Group M was 22.6 days (range 7~95days) with no statistical significance. (P = 0.822). The incidence of reoperation, including conversion of external fixator to definitive fixation and revision due to nonunion, in each Group I and M were 12 cases and 14 cases respectively. (P = 0.69) For group I, after excluding two cases each of nonunion and delayed union, the average callus formation period was 10.1 weeks, and the mean union period was 17.2 weeks. For group M, the mean callus formation period was 10.7 weeks, and the mean bone union period was 19.8 weeks. One case of delayed union and no cases of nonunion were observed in group M (Table. 3). Coronal and sagittal angulations were assessed on 1-year postoperative radiographs. Patients from group I showed average coronal and sagittal angulations of 1.32 and 1.91 degrees, respectively, while group M showed average coronal and sagittal angulations of 2.01 and 2.26 degrees, respectively (Table 4). In regards to postoperative complications, in group I, there were 2 cases of nonunion, 2 cases of delayed union, and 4 cases of malunion, whereas

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in group M there was only 1 case of delayed union (Table 5). For cases of malunion, 1 patient in group I presented with 5 degrees of valgus angulation immediately after surgery. Another patient from group I showed 5 degrees of anterior angulation postoperatively, and the angle was increased to 14 degrees after the performance of weight-bearing exercise. The postoperative complications of a 10 degree anterior angulation and a 2 cm-shortened tibia were noted in one patient undergoing weight bearing rehabilitation each. One patient from group I had an open fracture (Gustilo and Anderson classification type IIIB) and was treated with external fixation to achieve soft tissue recovery followed by intramedullary nailing to achieve bone union without any complications. In group M, two patients had an open fracture (Gustilo and Anderson classification type IIIA). One of them was treated with the combination of external fixation and MIPO; in that patient, superficial soft tissue infection was subsequently discovered and was successfully managed with intravenous antibiotics without plate removal. The other patient underwent MIPO alone, and in that patient, although bone union was accomplished within 17 weeks of the operation, the patient sustained temporary sensory loss over the deep peroneal nerve territory and post-traumatic arthritis in the traumatized ankle, which necessitated ankle fusion 3 years after the initial operation. This was not considered to be a postoperative complication but, rather, a consequence of the trauma that caused the fracture.

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The functional outcomes of each group were evaluated using the Jeju National University Hospital lower extremities trauma scale (JNUHLETS) at 2 year postoperatively, and the functional outcomes were excellent in both groups (Table 6)

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DISCUSSION

Mechanical stability without impairment of callus formation is requisite for successful surgical treatment of proximal and distal tibia fracture. Intramedullary nailing and minimally invasive plate osteosynthesis are currently the most extensively used closed reduction techniques for the treatment of fractures due to their abilities to preserve blood circulation and prevent soft tissue infection, rotational deformities and shortened length of the tibia.(4-6)

Intramedullary nailing for the treatment of unstable and malaligned tibia shaft fractures is widely known for its high rate of achieving bone union and excellent functional results and clinical outcomes. However, intramedullary nailing does not provide sufficient fixation force in the treatment of proximal and distal tibia fractures, which may lead to malunion, nonunion and even failure of the nail.(7)

Freedman and Johnson et al.(8) retrospectively reviewed 133 fractures of the tibia treated with intramedullary nailing and revealed a significantly higher rate of tibial malalignment, up to 8%, for fractures of the proximal third of the tibia compared to fractures of the middle shaft or distal third of the tibia. Additionally, Freedman and Johnson et al. found that tibia shaft fractures with an extended fracture line to the proximal or distal metaphysis showed a higher rate of malunion after treatment with the intramedullary nailing technique compared

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to fractures with a shorter fracture line.

Gorczyca at el(9) performed an in vitro biomechanical experiment using fresh-frozen cadaveric tibias osteotomed at 4 and 5 cm above the tibiotalar articular surface using an intramedullary nail, and the osteotomed tibias were evaluated for their resistance against compression and torsion forces. There was no difference in the resistance of the tibias osteotomed at 4 and 5 cm above the tibiotalar articular surface to either force when they were applied separately. However, application of compression–torsion force resulted in intramedullary nail loosening in the tibias osteotomed at 4 cm above the tibiotalar articular surface. Thus, Gorczyca at el claimed that patients with distal tibia fractures treated with intramedullary nailing must follow weight-bearing restrictions until significant fracture healing occurs to prevent coronal plane malalignment of the fracture. In three patients with malunion in our study, alignment and stability of the fracture site was achieved postoperatively; however, in those patients, follow-up radiography revealed signs of malunion with weight bearing exercise initiation. Therefore, patients with complex fracture patterns must delay weight bearing exercise until bone union is radiological confirmed.

Group I contained two proximal tibial fracture cases that experienced nonunion. Both of the unstable fractures were caused by high-energy force and contained butterfly fragments (AO - 42 B2). For these fractures, it was difficult to acquire sufficient fixation with an

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intramedullary nail alone, and a bone defect developed at the fracture site. One of these cases presented with instability immediately after the operation, and it was thought to be due to a technical error of misselection of the diameter of the intramedullary nail and the insertion site and the absence of an additional plate or locking screw. The diameter of the intramedullary nail was not sufficiently thick to create enough fixation force. This issue was resolved with bone grafting and replacement of the original intramedullary nail with a thicker intramedullary nail.

MIPO achieves effective bone union by preserving sufficient blood flow over the fracture site and generating lower risks of infection, malunion, and re-fracture than intramedullary nailing.(2, 10) All but one of the subjects treated with MIPO obtained primary bone union. In this study, distal tibia fracture treated with 2nd staged MIPO resulted in an excellent clinical outcome, despite the presence of severe soft tissue injury and an open fracture. In this study, one patient with an open fracture (Gustilo and Anderson classification IIIa) developed superficial soft tissue infection after 2nd staged MIPO; it was alleviated by conservative treatment, and effective bone union was accomplished without any complications.

Helfet and Suk et al(4) insist that for distal tibia fracture cases that also contain a fibula fracture, fixation of the fibula fracture is crucial. In 17 of the 37 cases of proximal / distal

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tibia fracture with fibula fracture, open reduction and internal fixation of the fibula was performed to establish lateral stability. Fibular fixation, especially for fractures that are severely comminuted, allows for an accurate estimate of the length of the fibula and, thus, allows for easier and firmer reduction of the tibia fracture. Five cases with distal fibular fracture were treated with rush-pin fixation and one was treated with inter-fragment screw fixation due to catastrophic soft tissue damage. The other 20 cases were conservatively treated because the fracture line was located more than 10 cm above the distal 1/3 of the fibula and did not show instability. The distal fibular fracture case that was treated with plate fixation for fibula stabilization resulted in successful bone union; in contrast, among the 5 distal fibular fracture cases treated with rush pin fixation, one experienced malunion and one experienced delayed union. Therefore, we hypothesize that rush pin fixation does not achieve lateral stability due to its vulnerability to rotational force.

Both IM nailing and MIPO generated excellent clinical outcomes in the bone union period. Among the 42 patients treated with intramedullary nailing, 4 cases of malunion were observed, all of which presented with butterfly fragments (AO - 42 B2) and comminuted fractures caused by high-energy trauma (AO - 42-C2, 42-C3). Fracture site location was different in the 4 cases of malunion, with three proximal tibia fractures and one distal meta-diaphyseal tibia fracture. One case that presented with anterior angulation after surgery and

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developed mild anterior angulation immediately after surgery, which worsened to 14 degrees when weight bearing exercise was initiated.

For proximal and distal metaphyseal fractures, firm fixation is difficult to achieve using intramedullary nailing alone, particularly in cases with butterfly fragments or severe comminution because the diameter of the fracture site is larger than the diameter of the nail.(11)

If a fracture is unstable after intramedullary nail fixation, peripheral insertion of blocking screws or additional peripheral fixation using a minimally invasive miniplate can help secure the fracture site. It is requisite to perform extra fixation when treating proximal tibia fracture by intramedullary nailing because the closeness of the fracture site to the metaphysis is positively correlated with the diameter of the fracture site.(12)

A 85-year old male with severe osteoporosis who had sustained a proximal tibia fracture (AO - 42 B2) experienced shortening of tibial length by 2 cm due to the loosening of interlocking screws caused by weight bearing exercise. Immediately after the surgery, anterior angulation of 5 degrees and valgus deformity of 5 degrees developed. When treating proximal tibia fracture, the nail insertion site should be accurately selected and the intramedullary nail should be introduced with the knee joint in the semi-extended position to avoid the high occurrence rate of anterior and valgus deformities.(12-14)

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In the above studies, the patients with meta-diaphyseal tibia fractures who underwent intramedullary nail insertion without additional miniplate or blocking screw fixation had a high incidence of malunion and nonunion. As proposed by Shahulhameed A et al.(15), intramedullary nailing for the treatment of proximal tibia fracture should include additional fixation in order to accomplish sturdy fixation.

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CONCLUSION

We consider that the minimally invasive plate osteosynthesis, locking intramedullary nail stabilization are all efficient methods for treating proximal or distal tibia shaft fractures. Intramedullary nailing yields promising results when fractures are near the mid-shaft of the tibia. However, when the fracture is associated with the dia-metaphyseal junction, intramedullary nailing alone tends to result in malunion and angular deformity. Application of additional blocking screws or a miniplate to guide the nail or the use of the minimally invasive plate osteosynthesis technique can help prevent secondary collapse of the fracture.

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TABLES & FIGURES

Table 1.Demographic information.

	Group I	Group M	Total
Male	31	30	61
Female	11	13	24
			Average
Mean age	45.8	56.6	51.2
Mean F/U period (Months)	22	20	21

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Table 2. Distribution of cases on the AO/ATO classification.

AO / ATO classification	A1	A2	A3	B1	B2	B3	C1	C2	C3	total
Group I (IM)*	19	8	1	4	6	1	0	3	0	42
Group M(MIPO)†	8	8	3	1	3	3	6	4	7	43

*IM nail: Intramedullary nail, †MIPO: Minimally invasive plate osteosynthesis

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Table 3.Comparison of Intramedullary nail and MIPO on clinical outcome.

	Group I (IM)*	Group M(MIPO)†
Op. time (Minutes)	119.4 (45 ~ 145)	126.7 (49 ~ 153)
Callus formation (weeks)	10.1 (5.7 ~17.2)	10.7 (6.5 ~14.5)
Mean union period (weeks)	17.2 (8.7 ~ 25.2)	19.81 (11.5 ~ 26.5)
Nonunion/Malunion (Case)	6	0

*IM nail: Intramedullary nail, †MIPO: Minimally invasive plate osteosynthesis

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Table 4. Average coronal and sagittal angulation of Group I and M.

	Group I	Group M
Coronal angulation	1.32(0.32 ~ 2.58)	2.02(0.38 ~ 4.25)
Sagittal angulation	1.91(0.21 ~ 4.88)	2.76(0.11 ~ 4.65)

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Table 5.Data of complication cases.

No	Age/Sex	Location/Distance*	AO classification	Group	Fibular fracture Y/N	Location	Fixation	Complication
1	33/M	Proximal / 12cm	42- B2	I	Y	Proximal	x	Nonunion
2	69/M	Proximal / 10cm	42- B2	I	N	X	x	Nonunion
3	41/M	Distal / 5cm	42- C1	M	Y	Distal	rush pin	Delayed union
4	43/M	Distal / 6cm	42- A2	I	Y	Proximal	x	Delayed union
5	52/M	Distal / 6cm	42- A2	I	Y	Mid 1/3	x	Delayed union
6	56/F	Proximal / 9cm	42- C2	I	Y	Mid 1/3	x	14' anterior angulation
7	50/M	Proximal / 12cm	42 - B2	I	Y	Mid 1/3	x	5' valgus angulation
8	67/M	Distal / 10cm	42 - B1	I	Y	Distal	rush pin	10' valgus angulation
9	85/M	Proximal / 9cm	42 - B2	I	Y	Mid 1/3	x	2cm shortening
10	53/M	Proximal / 12cm	42 - C3	M	Y	Mid 1/3	x	Temporary peroneal nerve neuropathy
11	68/M	proximal / 10cm	42 - C1	I	Y	Distal	x	Soft tissue infection

*Distance: Distance between the adjacent joint (a knee joint or a ankle joint) line and the main fracture line (cm).

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Table 6. Fucntional outcomes evaluated by Jeju National University lower extremity trauma scale

Subject	Range	Group I	Group M
I. PAIN : VAS SCORE	0~1	25	29
	2~3	16	12
	4~5	1	2
	6~7	0	0
	8~9	0	0
	10	0	0
II. Activity Score	Running	13	15
	Climbing stairs (no difficulty on stairs, hills)	15	14
	Outdoor walking (no difficulty on irregular floors, steeps)	8	9
	Indoor walking (no difficulty on regular floors)	5	4
	Walking with aid (cane, crutches, walker)	1	1
	Unable to walk	0	0

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