Joint Diseases and Related Surgery

InSafeLOCK® humeral nailing for humeral nonunions: Clinical and radiological results

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Humeral fractures account for 5 to 8% of all fractures.[1] The main treatment modality for humeral fractures is conservative treatment. In rare cases, nonunion may occur with an incidence of 15% due to mistakes made during conservative treatment or deformities due to muscle pulls.[2] The mistakes made during conservative treatment are that patients are not frequently checked radiologically and clinically, particularly in the first month. Nonunion is defined as the presence of pathological movement and pain clinically and the absence of union findings within 9 to 12 months radiologically. There are additional risk factors for nonunion including smoking, alcohol abuse, diabetes, age, open fractures, vascular injury, and infection. Furthermore, nonunion risk varies according to the fracture's location and is found in the highest proximal humeral fractures.[1,2]

According to the sign of life at the fragments' ends, Judet, Miller, Weber, and Cech divided the nonunions into two types: the first type is those that

ABSTRACT

Objectives: This study aims to evaluate the clinical and functional results of patients treated with InSafeLOCK® humeral nail and iliac crest autograft for humeral nonunion.

Patients and methods: A total of 15 patients (11 males, 4 females; mean age: 52.1±15.3 years; range, 31 to 78 years) who were followed conservatively for humeral fractures and operated with the InSafeLOCK® humeral nail and iliac bone graft in our center between June 2018 and January 2020 were retrospectively analyzed. Data including demographic and clinical characteristics of the patients, operative data, and pre- and postoperative Visual Analog Scale (VAS), Disabilities of the Arm, Shoulder, and Hand (DASH), and Constant-Murley Scores (CMS) were recorded.

Results: The mean time from injury to nonunion treatment was 10.9±1.6 months. Five patients had atrophic, eight patients had oligotrophic, and two patients had hypertrophic nonunion. Preoperatively, the mean DASH was 37.7±9.1, the mean CMS was 69.7±6.3, and the mean VAS was 3.8±0.7. In all patients, union was achieved. The mean operation time was 59.0±16.2 min. The mean postoperative DASH score was 16.1±8.7, CMS 87.4±3.4, and VAS score 0.8±0.7. Regarding the shoulder joint, the mean abduction was 164.7±11.3 degrees, the mean internal rotation was 82.0±6.8 degrees, the mean external rotation was 81.3±8.3 degrees, and the mean flexion was 162.0±12.1 degrees. During follow-up, complications such as vascular-nerve injury, reflex sympathetic dystrophy, screw migration or loosening, implant failure, and loss of reduction did not occur in any of our patients.

Conclusion: Considering the satisfactory functional and radiological results, the InSafeLOCK® humeral nail can be used safely in humeral nonunions.

Keywords: Humeral fracture, intramedullary nailing, nonunion, InSafeLOCK® humeral nail.

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are biologically active and vascular (hypertrophic); the second type is those that are not biologically active and avascular (atrophic).[3] The general problem in the hypertrophic union is related to mechanical balance. The general problem with the atrophic union is biological. In atrophic nonunions, the classical plating method, which aims at compression at the ends of the fractures, is preferred, and the

fracture ends are supported with grafts. In cases of hypertrophic nonunions, fixation with the bridged plating technique is preferred.[4] In the literature, the use of grafts in hypertrophic nonunions is found.[5,6]

There are different treatment methods including plate, intramedullary nailing, autografting with vascularized or non-vascularized fibular graft, external fixators, and their combinations in humeral nonunion. However, due to the mechanism of trauma, comorbidities, inadequate bone quality, and defects, a surgically complicated and challenging process is expected.[1,7-9]

On one hand, in the fixation of humeral fractures with standard intramedullary nails, an additional incision is made for distal locking screws, and this may cause neurovascular injury. Furthermore, it increases the duration of surgery and fluoroscopy. In the postoperative period, complications such as infection and screw loosening can occur.[10] On the other hand, the InSafeLOCK® (TST Tibbi Aletler San. ve Tic. Ltd. Sti., Istanbul, Turkey) humeral nail does not need an additional distal incision and reduces the need for fluoroscopy.

The InSafeLOCK® humeral nail is a newly designed nail. Clinical studies on anatomical, biomechanical, and primary traumas have been reported on this nail.[11-13] To the best of our knowledge, there are no clinical studies on using the InSafeLOCK® nail to treat nonunion of humeral shaft fractures. In the present study, we hypothesized that InSafeLOCK® humeral nails could be used safely in cases of nonunion. We, therefore, aimed to evaluate the functional and radiological results of the new generation distal locking humeral nails in humeral fracture nonunions.

PATIENTS AND METHODS

This retrospective study was conducted at Haydarpaşa Numune Training and Research Hospital, Department of Orthopedics and Traumatology between June 2018 and January 2020. Data collection was performed prospectively. After an X-ray examination, the diagnosis of humeral nonunion was made with the presence of pathological movement and nonunion. Inclusion criteria were as follows: having a diagnosis of nonunion in the humerus (no radiological or clinical evidence of union in the bone tissue after a minimum of nine months); having a minimum of 12-month follow-up postoperatively; and undergoing operation with a new generation distal locking humeral intramedullary nail and iliac crest autograft for surgery. The decision to use this surgical technique was the surgeon's preference.

Exclusion criteria were as follows: having nonunion of extra-articular fractures in the distal 5 cm of the humerus; undergoing revision surgery for humeral shaft fractures, undergoing surgery with only intramedullary nails, and having a follow-up period of shorter than 12 months. A total of 15 patients (11 males and 4 females; mean age 52.1±15.3 years; range, 31 to 78 years) in whom the new generation distal locking InSafeLOCK® humeral intramedullary nail and iliac bone graft were used due to nonunion of the humeral shaft fractures were included in the study. A written informed consent was obtained from each patient. The study protocol was approved by the Ağrı Training and Research Hospital Ethics Committee (No: 19, Date: 23.11.2020). The study was conducted in accordance with the principles of the Declaration of Helsinki.

The data including the patients' age and sex, affected side, operation time, length of stay in the hospital, nonunion types, the time between trauma and surgery, and pre- and postoperative Visual Analog Scale (VAS) scores,[14] Disabilities of the Arm, Shoulder, and Hand (DASH) scores,[15] and Constant-Murley Score (CMS)[16] of the patients were recorded. At the time of hospitalization of the patients, the preoperative VAS, DASH, and CMS questionnaires were performed. Postoperative shoulder joint movements of the affected and unaffected sides were recorded.

Surgical technique

Under general anesthesia, the patient was transferred to the operating table in the beach chair position. An anterolateral incision was made over the fracture line. In all cases, the radial nerve was explored and protected. The fracture site was debrided, until the fresh bleeding bone was obtained and the scar tissue was removed. A 4- or 5-cm longitudinal incision was made in front of the acromion. By passing through the deltoid and supraspinatus fibers, the humeral head was reached. Under fluoroscopy control, the Kirschner wire (K-wire) was delivered, and the entrance was carved over the K-wire. Then, a guidewire was placed and advanced up to the olecranon fossa. In all patients, the humeri were reamed. After the height was measured, an InSafeLOCK® humeral nail of the appropriate size and diameter was placed with the distal arch of the nail facing forward. Through the nail with a 3×400-mm K-wire, the distal posterior cortex of the humerus was punctured. The InSafeLOCK® humeral nail was placed to the distal posterior cortex of the humerus by delivering the endopin through the nail. Additionally, by placing the endopin to the bone and squeezing the nail forward with the endopin,

distal locking was achieved. Then, proximal locking screws of the humeral nail were delivered.

Iliac crest exposure was obtained through a 3 to 6-cm transverse incision at least 3 cm dorsal to the anterior superior iliac spine (ASIS) and 2 cm inferior to the crest prominence. Subperiosteal muscle detachment generated bone exposure 1 to 2 cm in-depth, with minimal manipulation of the iliacus muscle. A graft was obtained with an osteotome, preserving 2 to 3 cm of the ventral crest. The gluteal fascia was reattached to the periosteum, and a Vicryl suture was used to close the wound. Nylon sutures were used to close the skin. Drains were not used.

In all patients, iliac bone graft was used and placed in the pseudoarthrosis site. Then, the supraspinatus tendon was sutured and the tissues were closed. Surgery was terminated (Figures 1 and 2).

Postoperative follow-up

The patients started active and passive shoulder and elbow exercises on the first postoperative day. Only four patients who could not achieve full joint movements at four weeks were referred to the physical therapy and rehabilitation center in our hospital. A 1-hour rehabilitation program was applied five days a week, until the patients reached the normal range of motion. The physical therapy of these four patients was completed within three months in total.

Union was defined as the disappearance of pain in the nonunion area and radiological tricortical bridging at the postoperative follow-up period.
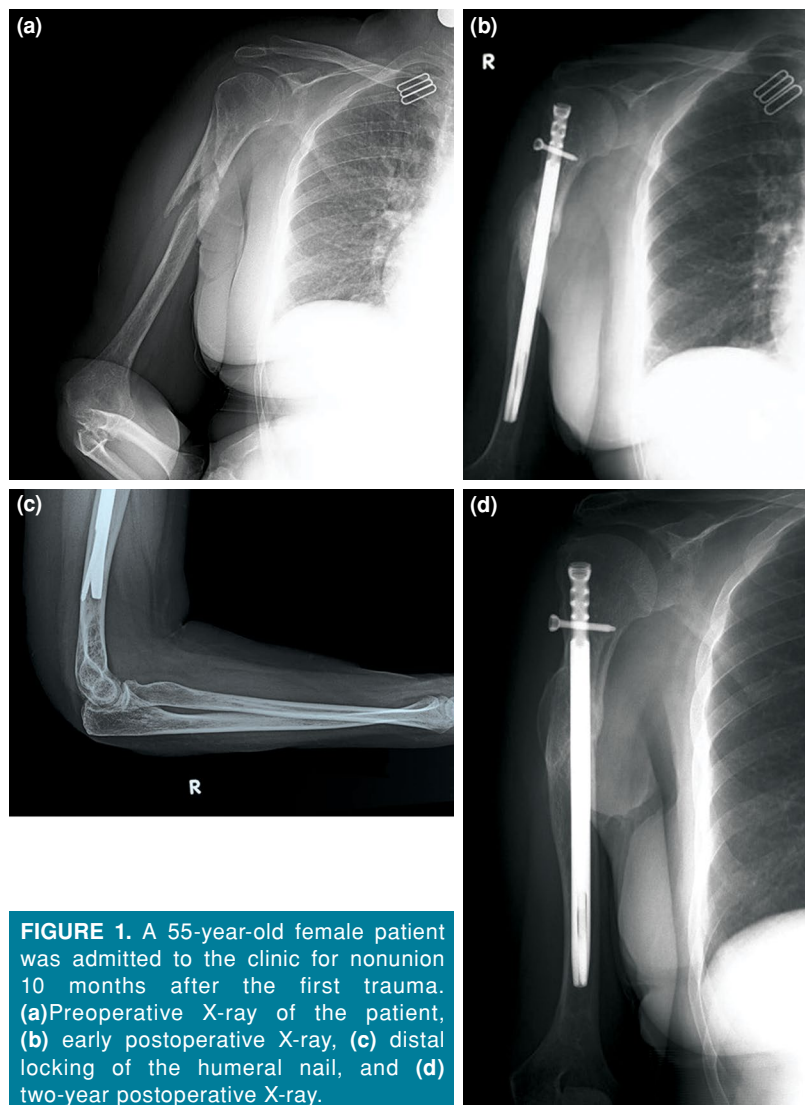
FIGURE 1. A 55-year-old female patient was admitted to the clinic for nonunion 10 months after the first trauma. **(a)** Preoperative X-ray of the patient, **(b)** early postoperative X-ray, **(c)** distal locking of the humeral nail, and **(d)** two-year postoperative X-ray.

Statistical analysis

Statistical analysis was performed using the IBM SPSS for Windows version 23.0 software (IBM Corp., Armonk, NY, USA). Descriptive data were expressed in mean ± standard deviation (SD), median (min-max) or number and frequency, where applicable. Independent samples t-test was used to compare the groups, and Pearson correlation test was used to analyze the relationship of functional scores. A *p* value <0.05 was considered statistically significant.

RESULTS

Of the patients, two were heavy smokers, and one had diabetes mellitus. The remaining 12 patients had no known medical history of predisposing factors.

The mean time from injury to the treatment of nonunion was 10.9±1.6 (range, 9 to 14) months. The mean operation time was 59.0±16.2 (range, 40 to 90) min. The mean time to union was 20.7±5.3 (range, 12 to 30) weeks. The mean follow-up was 21.7±6.0 (range, 12 to 30) months (Table I).

Of 15 patients, five (33.3%) had right humeral nonunion and 10 (66.7%) had left humeral nonunion. The affected humerus of eight (53.3%) patients was on the dominant side, and the nondominant sides of seven (46.7%) patients were affected. Eleven nonunion fractures (73.3%) were in the midshaft of the humerus, and four nonunion fractures (26.7%) had proximal extensions. Atrophic nonunion was present in five (33.3%) patients. Oligotrophic nonunion was recognized in eight (53.3%) patients, and hypertrophic
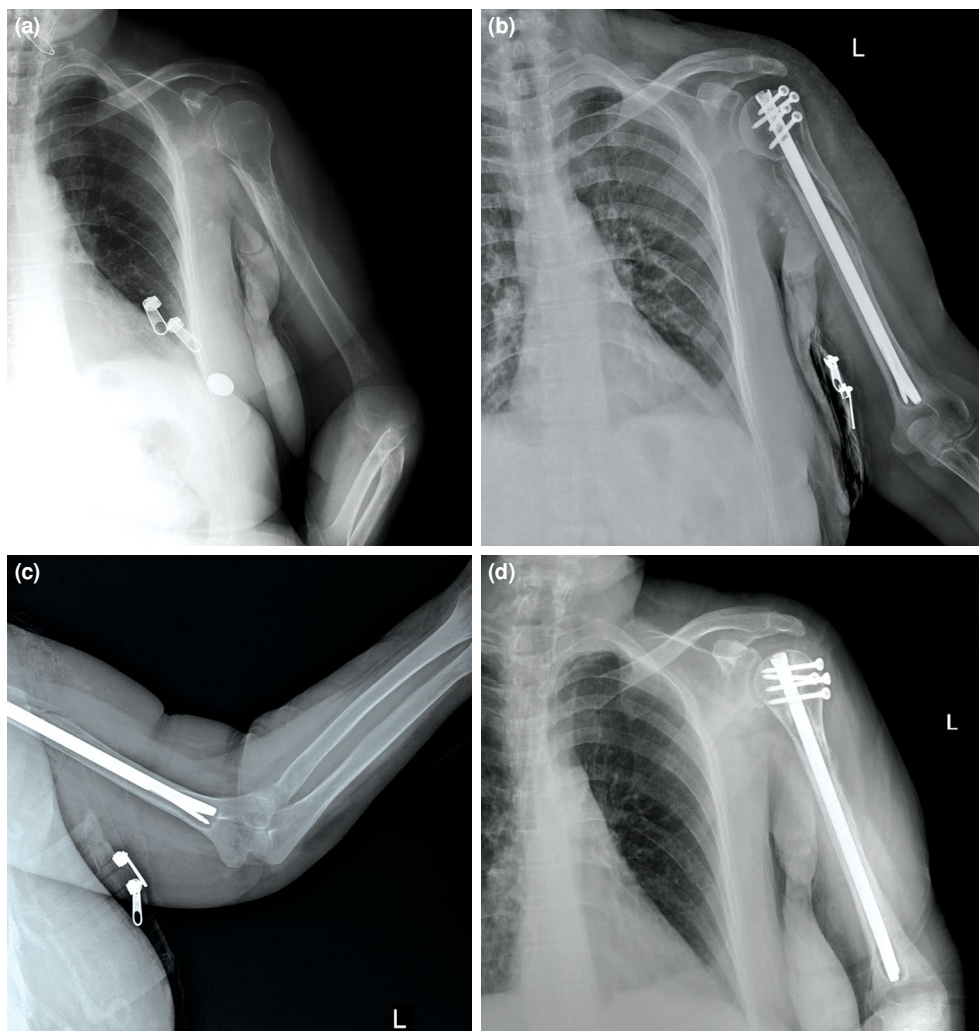
FIGURE 2. A 63-year-old female patient was admitted to the clinic for nonunion 12 months after the first trauma. **(a)** Preoperative X-ray of the patient, **(b)** early postoperative X-ray, **(c)** distal locking of the humeral nail, and **(d)** one-year postoperative X-ray.

TABLE I				
Demographic data of patients				
	n	%	Mean±SD	Min-Max
Age (year)			52.1±15.3	31-78
The time between trauma and surgery (month)			10.9±1.6	9-14
Operation time (min)			59.0±16.2	40-90
Follow-up period (month)			21.7±6.0	12-30
Union time (week)			20.7±5.3	12-30
Sex				
Male	11	73.3		
Female	4	26.7		
Side				
Right	5	33.3		
Left	10	66.7		
Dominance				
Dominant side	8	53.3		
Nondominant side	7	46.7		
Nonunion type				
Atrophic	5	33.3		
Oligotrophic	8	53.3		
Hypertrophic	2	13.3		
SD: Standard deviation; min: Minute.				

nonunions were detected in two (13.3%) patients (Table I).

The mean fracture union time was 21.6±6.7 (range, 14 to 30) weeks in atrophic nonunions, 20.0±5.1 (range, 12 to 28) weeks in oligotrophic nonunions, and 21.0± 4.2 (range, 18 to 24) weeks in hypertrophic nonunions.

There was a statistically significant difference in the pre- and postoperative DASH score, CMS, and VAS scores of the patients (p<0.001) (Table II). In the

TABLE II		
Clinical results of the patients		
	Preoperative	Postoperative	
	Mean±SD	Mean±SD	p
DASH	37.7±9.1	16.1±8.7	<0.001
CMS	69.7±6.3	87.4±3.4	<0.001
VAS	3.8±0.7	0.8±0.7	<0.001
DASH: Disabilities of the Arm, Shoulder, and Hand; CMS: Constant-Murley Scores; VAS: Visual Analog Scale.			

TABLE III		
Shoulder range of motion of the patients		
	Surgery side	Contralateral side	
	Mean±SD	Mean±SD	p
Abduction (deg)	164.7±11.3	170.7±8.0	0.189
Internal rotation (deg)	82.0±6.8	86.7±4.9	0.089
External rotation (deg)	81.3±8.3	92.0±5.6	0.005
Flexion (deg)	162.0±12.1	174.0±7.4	<0.001
SD: Standard deviation; deg: Degree.			

postoperative physical examination of the patients, there was no statistically significant difference between the abduction angle of the normal arm and the abduction angle of the operated arm (p=0.189). In addition, there was no statistically significant difference between the internal rotation angles of the normal arm and the internal rotation of the operated arm of the patients (p=0.089) (Table III).

During the follow-up period of at least 12 months, complications such as vascular-nerve injury, reflex sympathetic dystrophy, screw migration or loosening, implant failure, and loss of reduction did not occur in any of our patients. Implant removal was not performed in any patient. Union was achieved in all patients.

DISCUSSION

In the present study, patients who were followed conservatively and developed nonunion due to humeral fractures were analyzed. These patients were operated on using a new generation distal locking humeral nail and iliac crest autogenous graft. In all patients, union was achieved. Thanks to the new generation humeral nail's internal distal locking feature, we did not need to make an additional incision. Also, there was no need to use fluoroscopy or targeting guides. Thus, it would be possible to avoid complications that may occur during distal locking in traditional intramedullary nailing.

There are different surgical techniques used to treat humeral nonunion.[1,8,13,17-20] These surgical techniques have been proposed to ensure the functional performance of upper extremity movements and bone union. Many authors have suggested the plate fixation method as the gold-standard treatment owing to its compression properties and maximum rotational stability.[7,19,21,22] Some studies have shown that intramedullary nailing has similar results.[8,23] Due to certain reasons such as fragmentation of the fracture line, soft tissue adhesion, and osteopenia, the expected compression in plate fixation is obstructed. High complication rates are also observed in plate fixation.[24] Therefore, locked intramedullary humeral nails are preferred instead of plate fixation.[8,19]

In a study including 41 patients with delayed union or nonunion, Lin et al.[8] reported that 21 of the patients had humeral midshaft fractures. They used bone grafts on 39 of the 41 patients. A total of 39 patients achieved a successful humeral union. Singh et al.[25] treated 20 patients with humeral diaphyseal nonunion using humeral nails and autogenous grafts. They achieved union

in 19 patients. Ilyas et al.[26] treated 27 cases of humeral shaft fractures previously operated using humeral nails and autogenous grafts. Although they achieved union in 15 patients, they found nonunion in 12 patients. In our study, 11 patients had humeral midshaft fractures, and four patients had proximal extensions. The iliac bone graft was used in every patient. The complete union was achieved in all 15 patients.

Martinez et al.[23] in their study fixed the humeral fractures of 24 patients with bone grafts and humeral locking nails. They reported that 18 patients had humeral midshaft nonunion and applied the nail application as retrograde and unreamed. Excellent and good results were obtained in 23 (95.9%) patients concerning the shoulder joint range of motion. In our study, there was no significant difference in terms of shoulder abduction and internal rotation movements of the patients concerning the shoulder range of motion results, compared to the contralateral side. There were significant differences in the external rotation and flexion movements of the operated side and the contralateral shoulder joint, which can be explained by the fact that we used antegrade nails in our study.

In their study, Sügün et al.[19] used locked retrograde intramedullary nails in 13 patients for humeral nonunion. The dominant side of nine patients and the non-dominant side of four patients were affected. Ten of the patients had fractures of the humeral midshaft and 10 patients had atrophic nonunion and three patients had hypertrophic nonunion. The authors obtained the mean shoulder abduction range of motion as 140.9°, the mean shoulder flexion range of motion as 170°, the mean shoulder internal rotation range as 62.7°, and the mean shoulder external rotation range as 91.5°. They recorded the average CMS as 88.1 and the average DASH-T score as 11.7. In our study, in eight (53.3%) patients, the dominant side was affected, and in seven (46.7%) patients, the non-dominant side was involved. Moreover, atrophic nonunions were detected in five (33.3%), oligotrophic nonunions in eight (53.3%), and hypertrophic nonunions in two (13.3%) patients. The mean shoulder abduction range of motion of our patients was 164.67°, the average shoulder internal rotation range of motion was 82°, the mean shoulder external rotation range of motion was 81.33°, and the average shoulder flexion range of motion was 162°. In our study, the mean of the postoperative CMS results obtained from 15 patients was 87.40, and the average of the postoperative DASH score results was 16.07. These results are consistent with the literature.

In another study, Martinez et al.[23] reported that the mean time between fracture and surgery was 9.1 (range, 6-11) months. Sügün et al.[19] reported this time period as 17.8 (range, 6-84) months, while Singh et al.[24] as 18.2±4.2 months. In our study, the mean time between fracture and surgery was 10.9±1.6 months.

Furthermore, Lin et al.[8] found the average operation time to be 101 (range, 72-138) min, while Sügün et al.[19] to be 245 (range, 85-450) min. In our study, the mean operation time was 59.0±16.2 min. The reasons that shortened our operation time were the internal distal locking feature of the humeral nail and the fact that our patients did not undergo a previous surgery.

The mean duration of union was reported as 5.6 (range, 3-9) months in the Lin et al.'s[8] study and 4.2 (range, 3-7) months in the Sügün et al.'s[19] study in nonunion cases treated with humeral nails. In our study, the mean time to union was 20.7±5.3 weeks.

In a study, Ilyas et al.[25] reported that one patient had an iatrogenic humeral fracture, two patients had transient radial nerve damage, one patient had ulnar nerve injury, and one patient had an iatrogenic radial nerve injury. Sügün et al.[19] reported that three patients had radial nerve injury after surgery. In the study of Singh et al.,[24] two patients had infections and one patient had nonunion. In our study, the patients did not undergo surgery before, and there was no iatrogenic nerve damage after the treatment.

In their biomechanical study, Erden et al.[12] compared two different intramedullary humeral nails. The two humeral intramedullary nails were stable against axial and rotational loads and the authors reported that the newly developed InSafeLOCK® humeral nail did not require fluoroscopic control and an additional incision for the distal locking screw. Similarly, we also achieved sufficient stabilization with the nail during the surgery. Therefore, we encouraged the patients to take active and passive movements in the early postoperative period. In the postoperative period, we did not encounter any problems or complications related to the stabilization or early motion. Based on these findings, we believe that distal locking provides adequate stabilization.

There are several limitations to this study. It has a retrospective design with a relatively small sample size. Also, the number of proximal screws in this study was not standardized. To reach more detailed results, further multi-center, large-scale, prospective studies are required.

In conclusion, the InSafeLOCK® humeral nail can be easily applied without damaging the vessels, nerves, or other soft tissues around the elbow owing to its distal locking feature. The InSafeLOCK® humeral nail may be an alternative for humeral nonunion with satisfactory functional and radiological results.

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