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Malleolar Fracture after Total Ankle Arthroplasty

A Comparison of Two Designs

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There has been a resurgence in the treatment of end-stage tibiotalar arthritis with prosthetic replacement. This procedure has highlighted numerous complications including malleolar fracture. We wanted to determine the clinical relevance of malleolar fracture with the two most commonly used implants in the United States. We retrospectively compared the first 20 STAR with the first 25 Agility total ankle arthroplasties done by two surgeons. We examined the fracture rate, the timing, location, and treatment of the fracture, and the outcome in each group. In the Agility group, five fractures occurred, all intraoperatively. Four involved the medial malleolus and one involved the lateral malleolus. All fractures were fixed as implant stability was compromised. In the STAR group, there were four fractures. Two lateral malleoli fractured intraoperatively and were fixed. Two medial malleoli fractures occurred postoperatively and were treated nonoperatively. There was one medial malleolar nonunion in each group. The incidence of malleolar fracture was 20% in each group, comparable to results reported in relevant literature. We highlight some of the causes of malleolar fracture and describe our technique of prophylactic malleolar pinning to prevent this complication. Malleolar fracture is clinically relevant with the Agility and STAR implants and should be anticipated and prevented.

Treatment of painful ankle arthritis by prosthetic replacement originally was proposed in the late 1960s. The initial designs, however, were fraught with difficulties, and outcomes were unpredictable with high complication rates.[1,3,4,7–9] As science and technology have allowed for advances in design and improvement in prosthetic longevity, there has been a resurgence in the popularity of treating end-stage tibiotalar arthritis by arthroplasty.[3,5–7]

Even the newer designs, however, have technical learning curves and complications have selectively been disclosed.[3,5,6] One such commonly recognized complication is malleolar fracture. This can range from clinical insignificance to incapacitation and may be design-dependent.

Malleolar fractures can occur variably throughout the perioperative period. In our experience, they may occur during or immediately after surgery, or any time in the convalescent period.

Historically, rates of fracture have ranged from 12–22% and have variable clinical significance.[1,2,4–6,10–12] No uniform treatment plan has been recommended to date because of the heterogeneity of design and length of followup.

We wished to determine the clinical relevance of malleolar fracture involving the two most commonly implanted prostheses in patients in the United States today, using the STAR and the Agility total ankle replacements. We examined the rate of fracture, the timing of recognition of fracture, and the stability of the implant after fracture to determine a rationale for treatment of this seemingly common problem.

MATERIALS AND METHODS

We retrospectively compared the first 25 Agility (DePuy, Warsaw, IN) total ankle replacements with the first 20 STAR total ankle replacement (Waldemar Link, Hamburg, Germany), done by two surgeons, respectively. Ethics approval was obtained from our institution according to US regulations regarding human research.

Data were collected regarding the incidence of fracture occurrence, the location of fracture (medial versus lateral malleolus), time to recognition of the fracture, and treatment implemented. The treatment chosen was based on the stability of the implant. If the stability of the prosthesis was compromised, the fracture was reduced and fixed but if the fracture did not affect the stability of the prosthesis, it was treated nonoperatively. Principles were extrapolated from those applied to the treatment of periprosthetic fractures in other regions of the body: fixation of the implant, overall alignment, likelihood of healing, and ability to do ROM exercises and participate in rehabilitation while the fracture heals.

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TABLE 1. Comparison of the Fracture Characteristics of Each Group

Prosthesis	Number of Fractures	Location	Timing	Treatment	Outcome
Agility	5	4 medial malleolus	Intraoperative	3–screws	1 nonunion
				1–K wires	3 united
		1 lateral malleolus	Intraoperative	Plate and screws	United
STAR	4	2 medial mallcolus	2 months	Nonoperative	Nonunion
			1 year	Nonoperative	United
		2 lateral malleolus	Intraoperative	Intramedullary screws	2 united

RESULTS

The first surgeon did 25 Agility total ankle arthroplasties and recognized five fractures (Table 1). All fractures occurred intraoperatively. Four involved the medial malleolus and one involved the lateral malleolus. All fractures created an unstable situation because the Agility relies on compression between the malleoli for stability of the tibial tray. Each fracture required some form of fixation to provide stability and then all were stable to manipulation and joint ROM. Three of the medial malleolar fractures were fixed with cancellous screws (Fig 1) and one was fixed with K wires. The one lateral malleolar fracture was treated with plating as part of the syndesmotic fusion. At followup, there were no differences between patients with fractures and patients without fractures in all except one patient, who had a nonunion of a medial malleolus. Notably, this individual was a known heavy smoker (Fig 2).

The second surgeon did 20 STAR total ankle arthroplasties and four fractures were recognized (Table 1). Interestingly, only two were seen intraoperatively and both occurred in the fibula. These were thought to be stable on direct examination of the implant, but there was a fear of propagation of the fracture leading to loss of containment of the PE component and lateral subluxation of the talus in the mortise. Therefore these each were fixed with one intramedullary screw (Fig 3), both without complications.

Two medial malleolar fractures occurred after weightbearing was begun, one at 2 months and one at 1 year postoperatively. Neither was thought to threaten the stability of the implant, as assessed by stress fluoroscopy. These were treated with cast immobilization. The fracture that occurred 1 year postoperatively healed in 3 months without incident (Fig 4A, B). The other fracture is a radiographic nonunion, but is asymptomatic and the patient has refused operative repair (Fig 5). It was thought that the patient's failure to comply with the nonweightbearing status was a major detractor in the ability of the fracture to heal.

The rate of fracture in our series was 20% in each group. Two thirds of the fractures were on the medial side and ⅓ were on the lateral side. In the Agility group 80% were medial but in the STAR group only 50% were medial. Statistical analysis revealed that the rates of malleolar fracture in our two series are the same with either design. However, considerable differences exist in the pathogenesis, presentation, and location of the fractures.

DISCUSSION

Total ankle replacement is having a resurgence in popularity because of the development of second-generation prostheses.[3,8,9] Our experience was that malleolar fracture was a considerable complication, and we wanted to deter-

TABLE 2. Comparison of the Fracture Rate of Various Studies

Authors	Prosthesis	Cases	Number of Fractures	Fracture Rate
Bolton-Maggs et al[1]	ICLH Ankle	62	3	5%
Buechal et al[2]	New Jersey LCS	23	1	4%
Kitaoka and Patzer[4]	Mayo	160	4	3%
Myerson and Mroczek[6]	Agility	A 25	6	24%
		B 25	2	8%
Stauffer[10]	Mayo	102	5	5%
Wood et al[11]	TPR	7	0	0%
	STAR	7	1	14%
Wynn and Wilde[12]	Beck-Steffee	36	8	22%

TABLE 3. Comparison of the Location and Treatment of Fractures

Authors	Number of Fractures	Location	Treatment
Bolton-Maggs et al[1]	3	2 medial, 1 lateral	Unspecified
Buechel et al[2]	1	1 medial	Unspecified
Kitaoka and Patzer[4]	4	Unspecified	ORIF
Myerson and Mroczek[6]	6	4 medial, 2 lateral	Medial-Nonoperative Lateral-ORIF
	2	2 medial	Nonoperative
Stauffer[10]	5	5 medial	Unspecified
Wood et al[11]	0		
	1	1 medial	Nonoperative
Wynn and Wilde[12]	8	Unspecified	Nonoperative

mine the clinical relevance of malleolar fracture with the Agility and STAR prostheses.

Our study is limited in that it is retrospective and the number of cases in each group is small; however, it is comparable in size to other studies[5,6] and was done during the FDA approval process on the use of the STAR ankle prothesis, which restricted the number of cases designated units could do. Surgery also was done at a specialist foot and ankle unit, and fracture rates might be lower than in the general population.

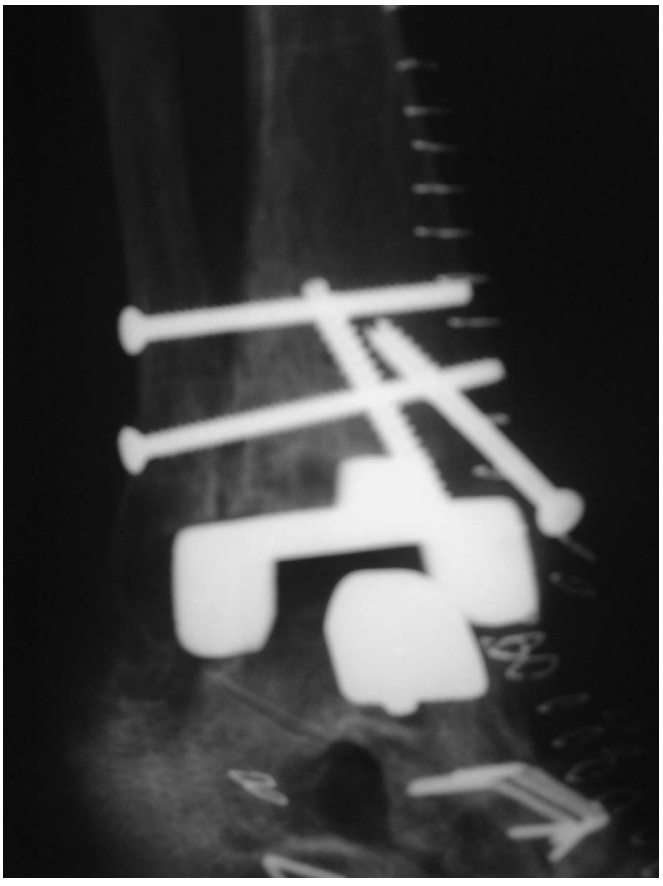

Fig 1. The radiograph shows a patient with rheumatoid arthritis and an Agility implant after repair of an intraoperative medial malleolar fracture.

The rate of malleolar fracture in our study was independent of prosthesis design but the etiology, presentation, location, and treatment were design-dependent. This can be attributed to a different surgical technique for each prosthesis and to morphologic features of the implants. Additionally, the treatment of these fractures is disparate and highly dependent on implant design.

The sources of fractures varied, and multiple factors were involved in the genesis of each injury. Saw-blade excursion and lack of care near the periphery of the jigs will create bony defects leading to stress risers.[3,6,8] Oversizing of the tibial component or malposition of the tibial tray can lead to fractures as can repeated trial implantation or multiple reduction attempts.[3,6] Overdistraction of the joint site and early hardware removal before final implantation (specifically the external fixator) are unique to the Agility total ankle replacement and are potential causes of fracture because this can create sudden episodic bending moments about the malleoli.[2,3,6] This also can lead to abnormal stress risers and create the potential for a fatigue fracture. Unloading of the malleoli leading to disuse osteoporosis is theoretical but logical, and makes sense especially in the context of the delayed presentation of some fractures, as we have seen.

Presentation of fractures uniformly occurred intraoperatively with the Agility prosthesis but only with the lateral malleolus in the STAR prosthesis. Typically, these are recognized easily because they affect implant stability. Immediate fixation is recommended to reduce the risk of displacement and also to lower the potential risk of morbidity of having to return for subsequent procedures. Those recognized immediately postoperatively usually are missed intraoperative fractures and not insufficiency fractures. Those occurring after weightbearing begins have an

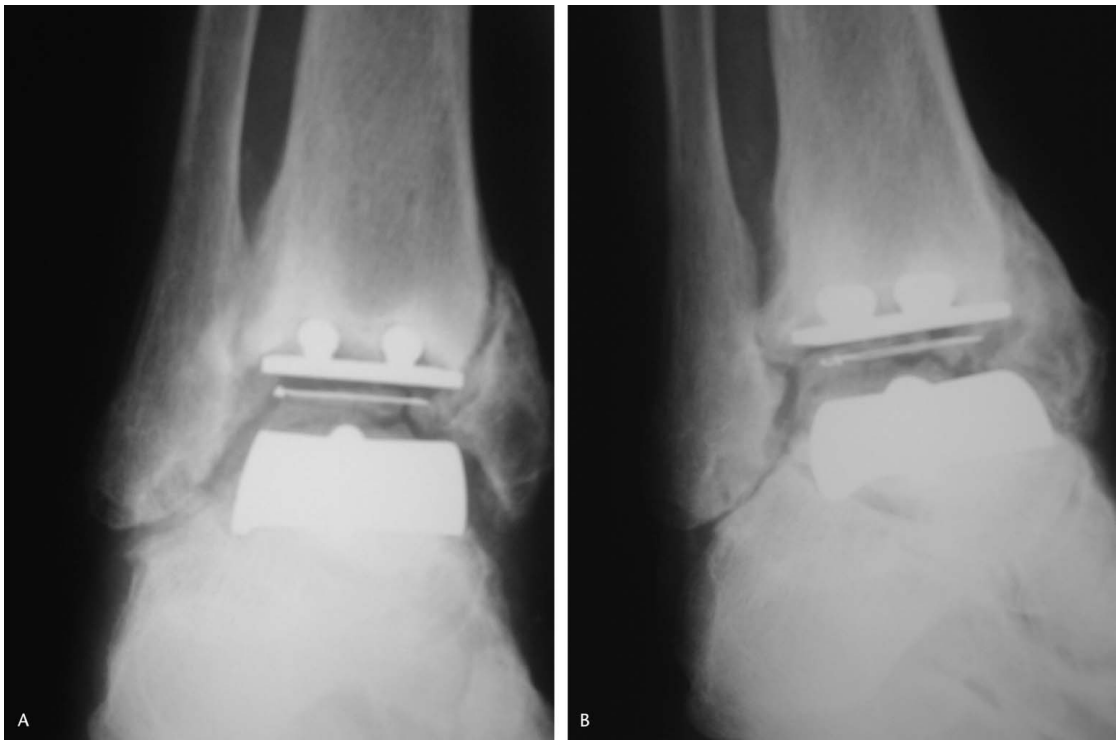

Fig 2A–B. (A) The radiograph shows a patient with a chronic postoperative medial malleolar fracture that occurred approximately 1 year after a STAR ankle replacement. (B) This patient's fracture united with cast immobilization for approximately 3 months.

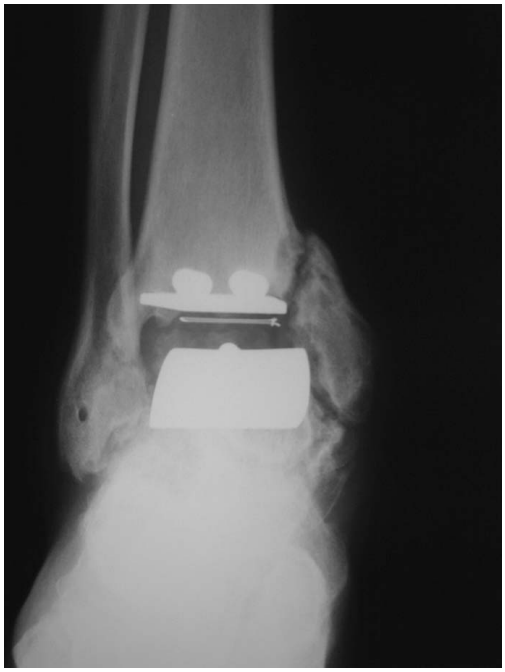

Fig 3. This patient had a subacute medial malleolar fracture develop 2 months after surgery that has not united; however, the patient states he is asymptomatic and does not want additional treatment.

indolent course of vague pain or follow a separate incident of a traumatic event. In our experience, these are unique to the STAR prosthesis, because of insufficiency, either caused by careless saw cuts or disuse osteopenia from malleolar unloading combined with the subsequent stress of resumed weightbearing.

All five fractures in the Agility group were created and recognized intraoperatively, whereas only half of the fractures in the STAR group (only those on the lateral side) were identified in the operating room. Medial fractures were more common overall (six of nine ankles) and involved the medial side in 80% of the Agility group. Lateral fractures showed a predilection with the STAR group (two of four ankles). Myerson and Mroczek[6] had a similar distribution of fractures in their series with the Agility. The importance is unknown.

Treatment is implant-dependent. Because the Agility prosthesis relies on three-sided ingrowth and in particular, syndesmotic compression of the malleoli, any structural defect in the system requires immediate repair on recognition. Any failure to create a rigid mortise may lead to failure of ingrowth and early loosening.

The unique design of the STAR prosthesis does not directly rely on either malleolus for stability. As with normal ankle mechanics, fibular stability may be crucial to

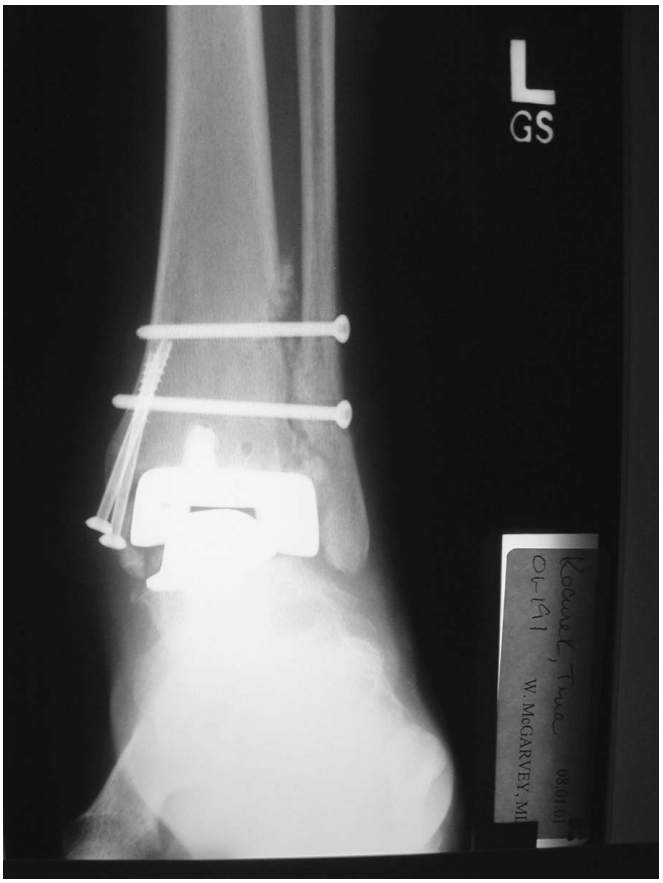

Fig 4. The radiograph shows a medial malleolar nonunion after an Agility ankle replacement in a patient who smokes.

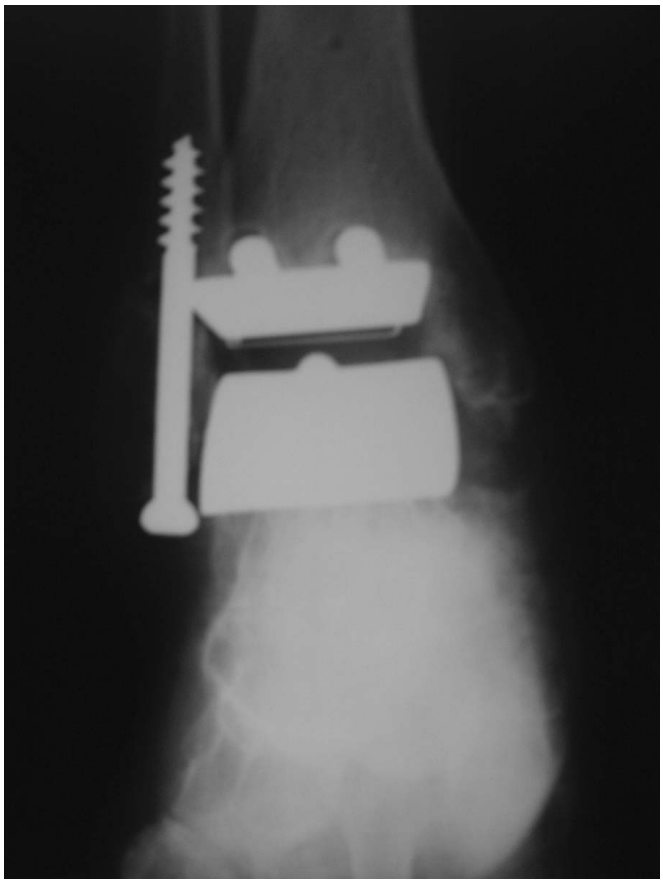

Fig 5. The radiograph shows a repaired lateral malleolar fracture after a STAR ankle replacement. This fracture occurred and was recognized intraoperatively.

maintaining talar position within the mortise. Malleolar fracture, if recognized at the time of surgery, may be fixed and most likely will do well as long as the implant has ingrowth on its tibial surface and the PE component is not able to subluxate. Our patient with the medial malleolar nonunion shows this. Therefore, if a fracture is recognized late, conservative care is reasonable and appropriate.

One suggestion to avoid intraoperative fracture, to prevent overexcursion of the saw blade, and to reduce repetitive stress on the medial malleolus is to place guide pins into the malleoli before beginning the saw cuts (Fig 6). This mainly applies to the Agility prosthesis, but carries some relative benefit for the STAR prosthesis. These pins are left in place throughout the procedure. This offers the advantage of added stability, and if a fracture should occur, the pins may be used as fixation or replaced with screws. These are removed before closure, once all the hardware is in place.

Results suggest that since we began doing this, no intraoperative or postoperative fractures have been seen. This can be done with minimal time expenditure during the case and at negligible cost to the patient. Numerous surgeons, to avoid sawing through or fracturing the medial malleolus, have begun placing the tibial component farther from the medial cortex. This can be successful regarding fracture prevention; however, it may lead to overtightening of the deltoid ligament, which in turn, can result, depending on the amount of lateral displacement, in a varus moment about the ankle. When doing the Agility total ankle replacement, once the fixator is removed, the talar component immediately tips into a varus position that often is not corrected even with aggressive attempts at ligament balancing or release. Therefore, it is critical that the position of the tibial component be appropriately medialized. The provisional K wire technique allows for this without compromise to the thin medial cortex.

Total ankle arthroplasty has a steep technical learning curve. Malleolar fracture is a common complication, regardless of the type of prosthesis chosen, and our results are comparable with results of other studies.[1,2,4,6,10–12] Surgeons doing total ankle replacement must be cognizant

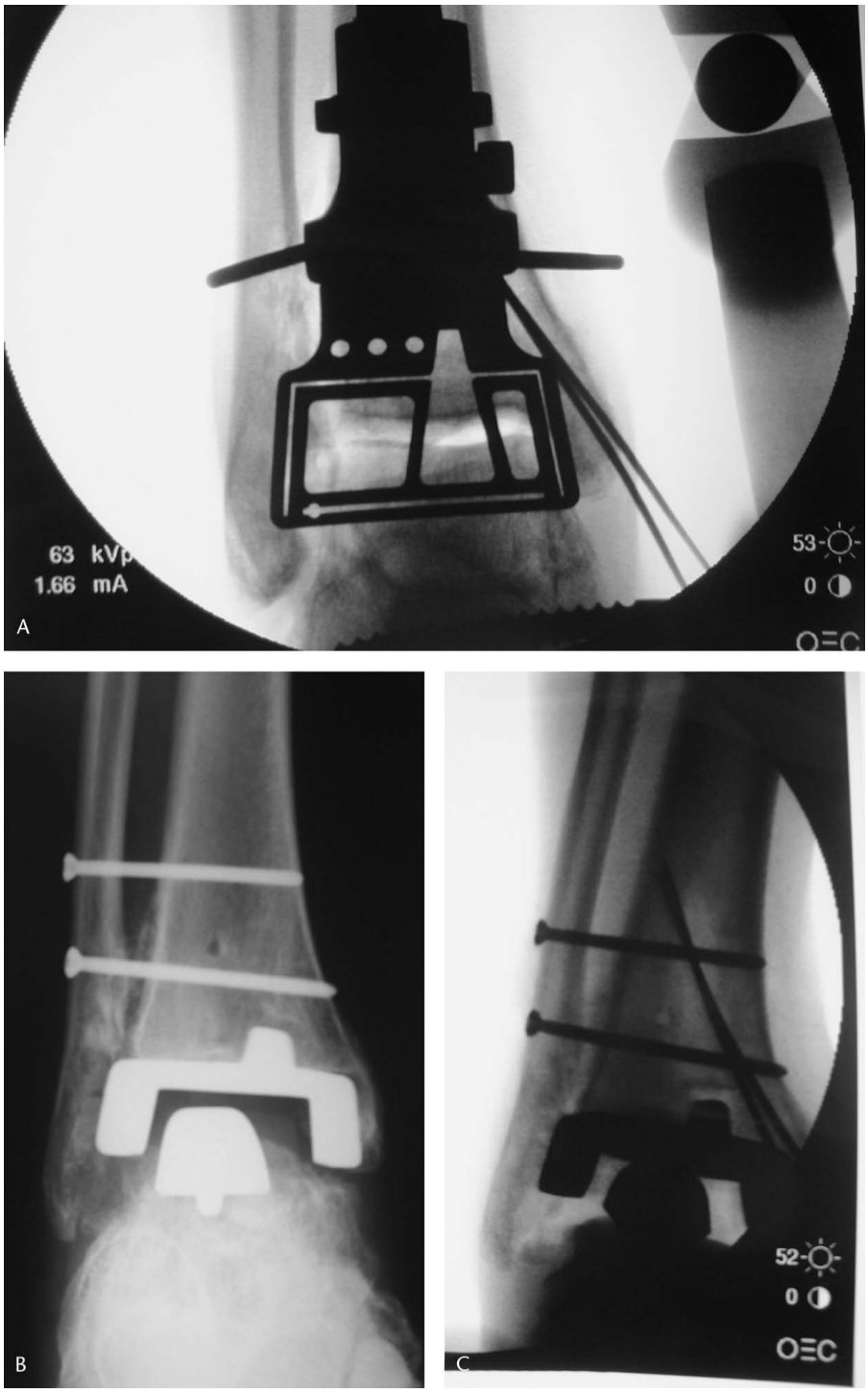

Fig 6A–C. (A) The radiograph shows the technique of malleolar pinning to avoid malleolar fracture intraoperatively. (B) The pins are thought to provide resistance to excessive saw blade excursion and (C) to provide extra stability against torque forces imparted to the malleolus during insertion of the implants.

of this complication and actively prevent it (or at least search for it) before completion of the procedure. Treatment should be instituted based on the inherent stability of the design style. Measures, such as attention to saw blade excursion, careful preoperative templating, infrequent implant manipulations, and, as we have suggested, prophylactic pinning may significantly reduce the incidence of this potentially disastrous problem.

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