Biodegradable fixation of ankle fractures

A roentgen stereophotogrammetric study of 32 cases

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We performed a prospective randomized study comparing fixation with biodegradable polyglycolic acid (PGA) rods (n 15) or screws (n 17) in 32 selected displaced supination-eversion fractures. Immediate postoperative weight bearing in a walking cast was encouraged. An exact reconstruction of the ankle mortise was achieved in 26/32 ankles. Roentgen stereophotogrammetric analysis (RSA) revealed rather small movements in the ankle mortise during fracture healing. A better stability was achieved by using screws. After 6 months the clinical results did not differ. One case of sinus formation and one with local effusion occurred; both healed without impairing the clinical result.

To compare the results with a nondegradable osteosynthesis technique, a reference group of supination-eversion fractures previously operated on with cerclage-wires, staples and pins was used. RSA showed better fracture stability with nondegradable fixation. The clinical results, however, did not differ.

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Absorbable implants have the obvious clinical advantage of not having to be removed. Biodegradable rods and screws made of polyglycolide (PGA) have been used clinically for fixation of ankle fractures since the middle of the 1980s (Rokkanen et al. 1985, Böstman et al. 1987, Hirvensalo 1989, Frökjaer and Möller 1992).

We evaluated the postoperative fracture stability achieved by biodegradable rods versus screws, and compared the biodegradable osteosynthesis technique with a technique using metal wires, staples and pins.

Patients and methods

This prospective, randomized study included a selected series of 32 patients with an operated supination-eversion injury (Table 3).

Exclusion criteria were: patients who preferred not to participate, age under 18 and over 75 years, open fractures, other injuries interfering with the rehabilitation program, and patients unable to cooperate, e.g., alcoholics and drug addicts. One patient was excluded after randomization, as the postoperative radiographic examination revealed a more severe, pilon type of fracture. Included were supination-eversion fractures displaced more than 2 mm, and suitable for fixation with biodegradable osteosynthesis devices, i.e., no comminution of the fragments and not too osteoporotic bone.

The study was approved by the Ethics Committee of Karolinska Hospital.

At the beginning of the operation the fractures were randomly allocated to fixation either with biodegradable rods (n 15) or with biodegradable screws (n 17) (Noncolored PGA; Biofix; Bioscience Ltd, Tampere, Finland). Postoperatively, a walking cast was used for 7 weeks and full weight bearing was allowed.

The fractures were classified according to Lauge-Hansen (1942; Table 1). 8 SE IV patients had sustained an injury to the lig. deltoideum instead of a medial malleolar fracture. Thus, only 13 SE IV fractures were operated on at the medial malleolus, 6 of them with a rod and 7 with a screw. There were 14 fractures of the posterior tibial margin. As none of them included more than one-third of the articular surface, they were not operated on.

Postoperative residual displacement (Table 2) was classified according to Cedell (1967). All operations were performed by the authors. The lateral and medial malleoli were fixated by a rod or a screw with diameters of 3.2 mm and 4.5/3.2 mm, respectively, length 40–70 mm. Reduction was maintained by a clamp or a cerclage-wire during drilling and insertion of the screw or the rod. On the lateral side, when a rod was used, a channel was drilled proximally from the tip of the lateral malleolus, crossing the fracture surfaces, and perforating the medial cortex of the distal fibular shaft. When using a screw, the drill channel passed from the ventral cortex of the proximal fibular shaft,

Table 1. Fracture classification according to Lauge-Hansen (1942). Ankles stereophotogrammetrically analyzed are given within brackets

	Lateral malleolar			Bimalleolar		
	Rod	Screw	Nondegr.[a]	Rod	Screw	Nondegr.[a]
Supination -eversion						
II	2 (2)	7 (7)	9 (6)			
III	1 (1)	1 (1)	6 (3)			
IV	6 (6)	2 (1)	2 (1)	6 (6)	7 (7)	13 (7)
Total	9 (9)	10 (9)	17 (10)	6 (6)	7 (7)	13 (7)

[a] Ahl et al. 1986, 1987.

Table 2. Residual displacement after operative treatment of ankle fractures. Cedell classification (1967)

		Rod (n 15)	Screw (n 17)	Nondegr.[a] (n 30)
Lateral malleolus	anatomic	12	16	28
	good	3	1	1
	poor	0	0	1
Medial malleolus	anatomic	3	6	12
	good	3	1	1
	poor	0	0	0
Tibialis posterior	anatomic	3	2	7
	good	3	4	8
	poor	1	1	3

[a] Ahl et al. 1986, 1987.

Table 3. Patient data and clinical results 3 and 6 months after surgery. Mean values

	Lateral malleolar			Bimalleolar		
	Rod	Screw	Nondegr.[a]	Rod	Screw	Nondegr.[a]
Age	48	36	45	49	45	58
range	(28–69)	(21–50)	(16–78)	(40–57)	(25–70)	(39–86)
Men/women	8/1	5/5	8/9	4/2	3/4	7/6
Score (max 100)						
3 months	63	67	76	43[b]	74[b]	61
6 months	89	96	91	73	86	75
Loaded dorsal flexion (percent)						
3 months	58	65	76	52	58	57
6 months	83	89	87	77	80	79
Loaded plantar flexion (percent)						
3 months	75	83	78	72	70	80
6 months	85	95	90	86	91	87

[a] Ahl et al. 1986, 1987
[b] Significant results ($P < 0.05$) comparing rods and screws.
No significant differences comparing rods/screws and nondegradable devices.

across the fracture surfaces and through the dorsal cortex of the distal malleolar fragment. The anterior syndesmosis ligaments were secured by Maxon osteosutures. On the medial side, the rod or the screw was inserted from the tip of the medial malleolus, across the fracture surfaces, into the tibial metaphysis.

Roentgen stereophotogrammetric analysis (RSA; Selvik 1974, 1989, Kärrholm 1989) was performed in all patients. Tantalum markers, diameter 0.8 mm, were inserted into the distal tibia, the lateral and medial malleoli, and the fibula, proximal to the fracture site. Due to an insufficient number of stable markers, 1 patient could not be examined stereophotogrammetrically. Radiographic examinations (n 32), including RSA (n 31), were performed postoperatively, at 7 weeks, and after 6 months.

Clinical follow-ups were undertaken at 3 and 6 months. Loaded dorsal/plantar ankle flexion, expressed as a percentage of the uninjured ankle (Lindsjö 1981), and a scoring system (Olerud and Molander 1984) were used.

Due to psychiatric illness, 1 patient could not participate at the clinical follow-up at 6 months. We have earlier reported the clinical results and the postoperative fracture stability for lateral malleolar (Ahl et al. 1986) and bimalleolar (Ahl et al. 1987) fractures, operated on with metal cerclage-wires, staples and pins. The supination-eversion injuries in these studies were used as a reference group in the present study in order to compare biodegradable and nondegradable osteosynthesis techniques. To be able to compare postoperative fracture stability, the fractures operated on with biodegradable fixation have been divided into lateral malleolar fractures (n 19)—i.e., fractures operated on only at the lateral malleolus, and bimalleolar fractures (n 13)—i.e., fractures operated on both at the lateral and medial malleoli (Tables 1–3).

Table 4. Roentgen stereophotogrammetric analysis at 6 months compared with the postoperative analysis. Mean values in mm (widening, translation, compression) or degrees *SD*

	Lateral malleolar		Bimalleolar	
	Rod (n 9)	Screw (n 9)	Rod (n 6)	Screw (n 7)
Movements of the lateral malleolus in relation to the tibia				
Widening of the ankle mortise	0.4 *1.1*	0.0 *0.5*	–0.5 *0.7*	0.1 *0.6*
Proximal translation	0.8 *0.6*	0.7 *0.9*	1.3 *1.3*	0.3 *0.4*
Dorsal translation	–0.2 0.5	0.1 *0.8*	–0.6 *1.3*	–0.1 *1.2*
Varus angulation	0.1 *1.0*	–0.1 *1.4*	1.8 *1.2*	0.3 *1.8*
Dorsal angulation	1.3 *2.0*	1.2 *1.2*	1.5 *1.6*	0.7 *0.9*
Outward rotation	1.0 *0.7*	2.1 *1.4*	2.8 *3.7*	1.5 *3.6*
Movements of the medial malleolus in relation to the tibia				
Medial translation			0.3 *0.5*	0.1 *0.3*
Proximal translation			0.4 *0.6*	0.3 *0.3*
Ventral translation			0.2 *0.4*	0.2 *0.3*
Movements of the lateral malleolus in relation to the proximal fibula				
Compression of the lateral malleolar fracture	1.5 *0.9*	1.0 *0.9*	1.5 *0.9*[a]	0.6 *0.5*[a]

[a]Significant ($P < 0.05$) results.

The Student's *t*-test and the Mann-Whitney U-test were used. $P < 0.05$ was considered significant.

Results

All fractures healed. No deep infection occurred and no reoperation was performed. A local skin irritation or a superficial wound infection occurred in 3 patients. In 2 of them and in 1 other patient local eczema developed around the scar. A fluctuant swelling at the implant site occurred in 2 patients. One resolved spontaneously, while the other developed a sterile sinus formation that resolved uneventfully after removal of a small sequester of the degrading implant. Postoperative residual displacement of the lateral (4/32) or medial (4/13) malleolus was found in 6/32 ankles, 5 in the bimalleolar and 1 in the lateral malleolar group (Table 2). In all cases the displacement was minimal, not exceeding 1 mm. No redislocation occurred.

Clinical follow-up at 3 and 6 months

When comparing biodegradable screws with rods, a tendency in favor of the screws was seen, but this was significant only regarding the ankle score at 3 months for bimalleolar fractures (Table 3). When comparing biodegradable with nondegradable fixation, the clinical results did not differ.

Roentgen stereophotogrammetric analysis

RSA revealed small movements in the ankle mortise during fracture healing (Table 4). However, a tendency towards better fracture stability with screws was found in the bimalleolar group and this difference was significant for the compression of the fibular fracture (Table 4). When comparing the RSA results at 7 weeks and 6 months, no differences were found.

As only minor differences were found between the fractures operated on with rods or screws, these groups are presented together when they are compared with the reference groups operated on with nondegradable devices. An increased fracture mobility in the biodegradable groups was revealed only regarding proximal translation and compression of the lateral malleolar fracture (Table 5).

Discussion

We found osteosynthesis with biodegradable rods and screws a rather demanding technique. Pre-drilling must be precise and carefully performed not to break the bone fragments or to widen the canal for the rod that must fit snuggly to give good stability. The screws, on the other hand, could not be used as compression-screws and could only maintain the compression and the stability achieved by the clamp or the cerclage-wire, when placed in position.

Table 5. Roentgen stereophotogrammetric analysis after fracture healing compared with the postoperative analysis. Mean values in mm or degrees *SD*

	Lateral malleolar				Bimalleolar			
	Biodegradable (n 18)		Nondegr.[a] (n 10)		Biodegradable (n 13)		Nondegr.[a] (n 7)	
Movements of the lateral malleolus in relation to the tibia								
Widening of the ankle mortise	0.2	*0.8*	0.2	*0.3*	–0.2	*0.7*	0.1	*0.3*
Proximal translation	0.7	*0.7*[b]	–0.1	*0.4*[b]	0.7	*1.0*[b]	–0.3	*0.3*[b]
Dorsal translation	0.0	*0.7*	0.2	*0.3*	–0.4	*1.2*	0.2	*0.4*
Varus angulation	0.0	*1.2*	0.4	*0.6*	1.0	*1.7*	0.3	*0.9*
Dorsal angulation	1.3	*1.5*	0.2	*0.4*	1.0	*1.3*	0.4	*0.7*
Outward rotation	1.6	*1.2*	0.6	*1.0*	2.1	*3.6*	0.4	*0.8*
Movements of the medial malleolus in relation to the tibia								
Medial translation					0.2	*0.4*	0.1	*0.1*
Proximal translation					0.3	*0.5*	0.0	*0.1*
Ventral translation					0.2	*0.4*	0.1	*0.1*
Movements of the lateral malleolus in relation to the proximal fibula								
Compression of the lateral malleolar fracture	1.3	*0.9*[b]	–0.2	*0.3*[b]	1.0	*0.8*[b]	0.0	*0.1*[b]

[a] Ahl et al. 1986, 1987
[b] Significant ($P < 0.05$) results.

A fluctuant swelling and sinus formation occurred in 2 patients. Both eventually healed and did not influence the final results. Similar inflammatory foreign-body reactions have earlier been reported by Hirvensalo (1989) and Böstman et al. (1990, 1992), with an incidence of 7–15 percent.

With conventional radiography it is difficult to detect small redisplacements that might be of clinical importance (Ramsey and Hamilton 1976, Olerud and Molander 1986, Curtis et al. 1992). RSA makes it possible to detect such small movements between fracture fragments. We are not aware of any publication where RSA has been used to analyze fracture stability after operations with biodegradable devices.

RSA was performed in only 17 ankles in the reference groups, as only fractures where early postoperative weight bearing was performed were included. In our previous studies, however, no differences between early and late weight bearing were found, and when including all supination injuries, regardless of whether early or late weight bearing was performed (n 31), the results are comparable (Ahl et al. 1989).

The selected patients operated on with biodegradable fixation had less osteoporosis and less communition of the fracture fragments than the reference groups. Thus, those operated on with biodegradable fixation were younger and more often males. In spite of this selection, biodegradable fixated fractures were less stable. However, except for a rather pronounced shortening of the fibula and increased outward rotation of the lateral malleolus, only small movements occurred during fracture healing. Nor did the increased instability seem to influence the clinical results. Comparing biodegradable rods and screws, the screws gave a slightly better fracture stability and should be preferred.

Nondegradable fixation is easier to handle, gives better fracture stability, can be used in more severe fractures and is thus in our opinion still the best treatment.

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