Malleolar fractures in alcoholics treated with biodegradable internal fixation

6/16 reoperations in a randomized study

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29 alcohol abusers with displaced malleolar fractures were randomized to treatment with biodegradable self-reinforced polyglycolide screws or metallic implants. During an average follow-up time of 7 (0–15) months, 8 patients out of 16 treated with biodegradable fixation had postoperative redisplacement of the fracture and 6 were reoperated. 1 fracture in 13 patients with metallic fixation had a slight displacement postoperatively which did not require reoperation.

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Fracture treatment in alcohol abusers is complicated because of lack of co-operation, liability to further trauma and osteoporosis (Karlström and Olerud 1974). Malleolar fractures in particular are related to alcohol abuse (Antti-Poika and Karaharju 1988). In a Swedish study of lower limb fractures 25% of men and 4% of women were considered alcoholics. The incidence of alcoholic abuse was 37% in the subgroup of 30–50-year-old men with malleolar fractures (Johnell et al. 1985). Moreover, the high incidence of postoperative complications after operative treatment of malleolar fractures in alcoholics has been documented (Tønnesen et al. 1991). So far there have been no prospective studies concerning operative treatment of malleolar fractures in alcoholics. In the earlier studies of biodegradable fixation of malleolar fractures, alcohol abusers had been excluded (Böstman et al. 1987, 1989, Hirvensalo 1989, Partio et al. 1992). The results of these studies indicated that biodegradable fixation is a reliable method for treatment of malleolar fractures in adults. Our purpose in this prospective, randomized study was to find out whether this method can be used in malleolar fractures of alcoholics.

Patients and methods

Between 1991 and 1993, 29 patients with closed displaced malleolar fractures associated with verified alcohol abuse were studied prospectively (Tables 1 and 2). The following criteria had to be fulfilled for inclusion in the study:

1. Fracture displacement more than 2 mm. The fracture of the lateral malleolus was not allowed to be comminuted in the preoperative radiographs. Suprasyndesmotic fractures (Weber type C) were excluded.

2. No associated injuries of clinical significance.

3. No medical contraindications to anesthesia or operation, and no diabetes requiring insulin treatment.

The study was approved by the Ethics Committee, Department of Orthopedics and Traumatology, Helsinki University Central Hospital. The random-

Table 1. The inclusion criteria for the diagnosis of alcoholism

The patient has to have at least one of the following symptoms:

1. Physical dependence: The patient has abstinence syndrome such as gross tremor, hallucinosis, withdrawal seizures or delirium tremens caused by alcoholic abuse.
2. Evidence of tolerance to the effects of alcohol: A blood alcohol level of more than 150 mg/100 mL without gross evidence of intoxication, or a blood alcohol level of more than 300 mg/100 mL (measured with a breath analyzer device).
3. Major alcohol-associated illness: The patient suffers from alcoholic hepatitis, alcoholic pancreatitis or alcoholic cerebellar degeneration.
4. Psychosocial dependence: Drinking despite strong medical or social contraindication known to patient (job or home loss or marriage disruption because of drinking, driving repeatedly while intoxicated).

Modified from the Criteria for the Diagnosis of Alcoholism, Criteria Committee, National Council on Alcoholism, New York (1972).

Table 2. Clinical data of the patients

A	B	C	D	E	F	G	H	I	J	K	L	M	N	O
1	40	m	L	G	–	–	–	+	–	–	–		20	100
2	52	m	B	M	–	–	–	–	–	–	–	+	49	90
3	46	m	L	M	–	–	–	–	–	–	–	+	54	100
4	29	m	L	G	–	–	–	–	–	–	–		40	95
5	37	m	T	G	+	+	–	–	–	–	–		0	
6	56	m	T	M	–	–	–	–	–	–	–	–	57	95
7	50	m	L	L	–	–	–	–	–	–	–		50	100
8	32	m	B	G	–	–	–	–	–	–	–		6	
9	60	f	T	G	+	–	–	+	–	+	+	–	14	
10	49	m	T	G	–	–	+	+	–	+	+		9	
11	30	f	L	G	–	–	–	–	–	–	–		54	100
12	39	m	B	M	–	–	–	–	–	–	–	–	6	
13	62	m	P	G	–	–	–	–	–	+	+	–	63	100
14	47	m	B	G	–	–	–	–	–	–	–		50	100
15	37	m	L	M	–	–	–	–	–	–	–	–	9	
16	49	m	T	M	–	+	–	–	–	–	–	+	52	100
17	68	m	T	G	–	–	+	–	–	+	–		18	
18	52	m	B	G	–	–	+	–	–	+	+	+	60	
19	31	f	T	M	–	–	–	–	–	–	–	+	57	100
20	41	m	B	M	–	–	–	–	–	–	–	+	45	85
21	62	m	T	M	–	–	–	–	–	–	–	+	57	100
22	41	f	L	M	–	–	–	–	–	–	–	–	5	
23	45	m	B	M	–	–	–	–	–	–	–	+	51	90
24	44	f	T	G	+	–	–	–	–	–	–		5	
25	48	f	T	M	+	–	–	–	+	–	–	–	51	100
26	36	m	T	G	+	–	–	–	–	+	–		5	
27	48	f	B	G	–	–	+	–	–	+	+	–	11	
28	49	m	B	M	–	–	–	–	–	–	–		26	100
29	47	f	L	G	–	–	+	–	–	+	+	–	11	

A Case
B Age (years)
C Sex
D Type of fracture
  T trimalleolar
  B bimalleolar
  P lateral malleolus and posterior tibial margin
  L lateral malleolus
E Fixation material
  G SR-PGA
  L SR-PLLA
  M metallic
F Syndesmosis transfixation
G Posterior tibial margin fixed
H Wound infection
I Transient fluid accumulation
J Minimal redisplacement
K Failed fixation
L Reoperation
M Removal of metallic implants
N Follow-up time (weeks)
O Functional score (points)

ization was done by drawing closed envelopes. The patients who refused to participate in this study were not included—nor were their data recorded—and they were treated with metallic implants. 29 patients who fulfilled the criteria were randomly allocated to treatment with self-reinforced dyeless polyglycolide (PGA) screws (Biofix®), 16 cases, or metallic AO-implants, 13 cases (Table 3).

On admission to the emergency department, a dislocated ankle was reduced and a splint was applied before the first radiographic examination. Standard anteroposterior, lateral and mortise radiographs were taken preoperatively, immediately after the operation and at regular intervals during the follow-up. The amount of displacement of the lateral malleolus on the primary radiographs was, on average, 4.7 (0–12) mm in the PGA group and 4.5 (1–11) mm in the metallic group on anteroposterior view and 5.9 (1–20) mm and 5.4 (0–10) mm on lateral view. There were 21 right and 8 left ankle fractures. One bimalleolar fracture treated with metallic implants was Weber type A, all the other fractures were Weber type B (Lindsjö 1985).

Table 3. Summary of malleolar fracture patients treated with absorbable self-reinforced polyglycolide or metallic implants

	SR-PGA implants	Metallic implants
Number of patients	16 [a]	13
Male/Female	11/5	10/3
Age	46 (29–68)	46 (31–62)
Weight (kg)	76 (51–110)	78 (60–110)
Expiration alcohol content (prom.)	2.3 (0.9–3.6)	2.2 (1.6–3.2)
Trimalleolar	6	5
Bimalleolar	4	5
Lateral malleolar and posterior tibial margin	1	
Lateral malleolar	5	3

[a] One patient with lateral malleolar fracture had a self-reinforced poly-L-lactide screw inserted because no suitable SR-PGA implant was availabe at the time of operation.

The operations were carried out, on average, 16 (4–30) hours (PGA fixation) and 11 (6–19) hours (metallic fixation) after the accident, except in 2 cases; one patient came to the hospital 8 days after the trauma and for the other patient the operation was postponed 4 days because of massive swelling of the ankle on admission. Standard longitudinal incisions were used. The fracture reduction, temporary and final fixations were performed by the technique previously reported for PGA screws (Partio et al. 1992) or AO metallic implants. A posterior tibial margin fracture, exceeding one fourth of the articular surface, required fixation in one patient in both groups. The distal tibiofibular syndesmosis was torn and transfixed in 5 patients, 4 in the PGA group and 1 in the metallic group. Disrupted deltoid ligaments were not sutured (Baird and Jackson 1987). The lateral malleolus was fixed with a one-third tubular plate in 10 cases and with interfragmentary screws in 3 cases in the metallic group, according to the surgeon's preference. Bloodless field and spinal anesthesia were used, except in 2 patients who had general anesthesia. The operating time was on an average 48 (15–135) minutes in the PGA group and 53 (25–105) minutes in the metallic group. A below-the-knee plaster cast was applied postoperatively and maintained for 6 weeks. The first 3 weeks were non-weight bearing, 2 partial and the last week fully weight bearing. At 3 weeks, the stitches were removed and the plaster cast was changed. The metallic transsyndesmotic screw was removed 9 weeks after operation. Other metallic implants were intended to be removed 1 year after operation.

The clinical course of each patient was recorded. The patients were discharged after, on average, 5.6 (2–17) and 3.8 (2–11) days, respectively. Visiting times at the outpatient department were arranged at 3 and 6 weeks, and at 3, 6 and 12 months after operation. The functional result was scored on a scale of 100, using the method of Olerud and Molander (1984) both at 6 and 12 months. The final assessment was intended to be made at 1 year.

Results

Postoperative radiographs showed exact reduction and fixation in all 16 patients treated with PGA implants and in 9/13 patients with metallic implants. In the metallic group, a 2 mm displacement in the dorsal cortex of the fibula was seen in the lateral view (case 6). In case 15, the interfragmentary screw was 6 mm too long. In case 20, there was a 2 mm displacement of the medial malleolus and the lateral malleolus was split at the screw site. In case 25, there were displacements of both malleoli, 1 mm on the medial and 2 mm on the lateral side.

Failed fixations

There were redisplacements in 8 patients treated with PGA, 6 of which were reoperated. These patients did not follow the after-treatment instructions and had their plaster casts broken or softened because of uncontrolled weight bearing. However, the same problem concerned almost every patient in this study. Case 17 refused to have the suggested reoperation. The displacements, which included 2 mm widening of the distal tibiofibular syndesmosis after breakage of the SR-PGA-transfixation screw at 3 weeks, were considered acceptable in case 26. The failures were noticed mainly at the 3 or 6 weeks' control visits and the reoperations were carried out as soon as the condition of the skin permitted.

Of the fractures with failed fixation, 4 were trimalleolar, 2 bimalleolar, 1 lateral malleolar with a fracture of the posterior tibial margin, and 1 lateral malleolar only. The pattern of the redisplacement as well as the condition of the screws found at reoperation varied. In 1 bimalleolar and 2 trimalleolar fractures, one side had redisplacement while 3 other redisplacements were bilateral. The screws were broken in 4 malleoli and intact in 2, where the bone had failed. In case 13, the threads of the broken screw had dissolved and the core was hard. The other broken screws still had hard threads. In case 10, there were no signs of the screws, but considerable aseptic fluid accumulations, which were suspected of being infectious at the reoperation and reosteosynthesis was therefore not done. However, bacterial cultures were negative.

One patient (case 25) in the metallic group operated without a plate had a 3 mm displacement at 3 weeks in the lateral malleolus. The fracture healed in this position and caused no complaints during the 12-month follow-up.

The difference in redisplacements between the groups (8/16 versus 1/13) is significant (p 0.04, Fischer's test) and the difference is even more convincing when we compare the patients who would have needed reoperation (7/16 versus 0/13) (p 0.01).

Other complications

Transient tissue reactions due to polyglycolide were observed in 3 patients, 2 of whom were among those reoperated. 4 patients had a superficial wound infection and 1 deep (case 18), all in the PGA-group with redisplacement. 3 of these infections including the deep one, occurred after the reoperation. In case 17, Acinetobacter was found. In other infections, there

were staphylococci or the cultures were not significant.

Case 4 had severe postoperative pain and numbness of the leg and he could not dorsiflex his ankle. Because of lack of co-operation, the diagnosis of compartment syndrome remained uncertain, but fasciotomy was carried out 8 days after the primary operation. The muscles were found to be vital.

Case 19 had a deep venous thrombosis at 3 weeks, treated with anticoagulant therapy.

Implant removals

The metallic transsyndesmotic screw was removed at 9 weeks. Other metallic implants were removed in those patients who participated in the follow-up long enough and agreed to the suggested removal operation. In the metallic group, the implants were removed in 7 patients after 10 (8–12) months on an average. 2 patients refused to undergo this procedure and 4 were lost to follow-up. Among the reoperated patients, 1 patient had the procedure in another hospital because of infection, one refused the removal and the remaining 3 were lost to follow-up.

Function

11 patients in the PGA group and 6 in the metallic group were lost to follow-up, of these 10 and 3 before 6 months, respectively. Thus, function could be recorded in 6 patients in the PGA group and 10 in the metallic group with follow-up times of 12 (9–15) months and 12 (6–13) months, respectively.

The average score was 99 (95–100) in the PGA group and 96 (85–100) in the metallic group. These results can be considered excellent. All the patients in the PGA group were subjectively satisfied, although there still was limited motion in one ankle at 40 weeks. In the metallic group, 2 patients were dissatisfied, case 2 because of pain, limited motion and swelling at 49 weeks, and case 20 because of pain and limited motion. In addition, case 23 had limited motion at 1 year, but he was satisfied.

Discussion

The significantly higher rate of failures in the PGA group noted during the study caused us to discontinue it. In the metallic group, there was only one minimal redisplacement postoperatively and no reoperations. There was no difference between the patient groups concerning the difficulty in treating the fractures or in the background of the patients.

Comparing the function between the groups is meaningless because of the high rate of loss to follow-up. However, this was expected and verifies the inclusion criteria concerning serious chronic alcohol abuse.

Transient tissue reactions were detected in at least 3 patients. This rate with current dyeless screws is higher than in earlier reports (Böstman et al. 1990, 1992), but because of the small number of patients alcoholism cannot be considered as a risk factor of a tissue reaction. In this particular patient group, the difference from an infection often remains uncertain.

Moreover, elderly people have osteoporosis and have difficulties in following the postoperative instructions about restricted weight-bearing, but they at least try to co-operate. Nevertheless, there was no difference in the stability of fixation between PGA-treated and metallic-treated malleolar fractures in a prospective, randomized study of 37 patients over 65 years old, using the same implant materials as in this study (Kankare et al., submitted). Thus the reason for the poor results in alcoholics can be assumed to be their unwillingness to co-operate.

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References

Antti-Poika I, Karaharju E. Heavy drinking and accidents—a prospective study among men of working age. Injury 1988; 19 (3): 198-200.

Baird R A, Jackson S T. Fractures of the distal part of the fibula with associated disruption of the deltoid ligament. Treatment without repair of the deltoid ligament. J Bone Joint Surg (Am) 1987; 69 (9): 1346-52.

Böstman O, Vainionpää S, Hirvensalo E, Mäkelä A, Vihtonen K, Törmälä P, Rokkanen P. Biodegradable internal fixation for malleolar fractures. A prospective randomised trial. J Bone Joint Surg (Br) 1987; 69 (4): 615-9.

Böstman O, Hirvensalo E, Vainionpää S, Mäkelä A, Vihtonen K, Törmälä P, Rokkanen P. Ankle fractures treated using biodegradable internal fixation. Clin Orthop 1989; 238: 195-203.

Böstman O, Hirvensalo E, Mäkinen J, Rokkanen P. Foreign-body reactions to fracture fixation implants of biodegradable synthetic polymers. J Bone Joint Surg (Br) 1990; 72 (4): 592-6.

Böstman O, Partio E, Hirvensalo E, Rokkanen P. Foreign-body reactions to polyglycolide screws. Observations in 24/216 malleolar fracture cases. Acta Orthop Scand 1992; 63 (2):173-6.

Criteria Committee, National Council on Alcoholism. Criteria for the diagnosis of alcoholism. Ann Int Med 1972; 77 (2): 249-58.

Hirvensalo E. Fracture fixation with biodegradable rods. Forty-one cases of severe ankle fractures. Acta Orthop Scand 1989; 60 (5): 601-6.

Johnell O, Kristenson H, Redlund-Johnell I. Lower limb fractures and registration for alcoholism. Scand J Soc Med 1985; 13 (3): 95-7.

Kankare J, Partio E K, Hirvensalo E, Böstman O, Rokkanen P. Biodegradable self-reinforced polyglycolide screws and rods in the fixation of displaced malleolar fractures in the elderly. Ann Chir Gyn. Submitted for publication.

Karlström G, Olerud S. The management of tibial fractures in alcoholics and mentally disturbed patients. J Bone Joint Surg (Br) 1974; 56 (4): 730-4.

Lindsjö U. Classification of ankle fractures: the Lauge-Hansen or AO system? Clin Orthop 1985; 199: 12-6.

Olerud C, Molander H. A scoring scale for symptom evaluation after ankle fracture. Arch Orthop Trauma Surg 1984; 103 (3): 190-4.

Partio E K, Böstman O, Hirvensalo E, Vainionpää S, Vihtonen K, Pätiälä H, Törmälä P, Rokkanen P. Self-reinforced absorbable screws in the fixation of displaced ankle fractures: a prospective clinical study of 152 patients. J Orthop Trauma 1992; 6 (2): 209-15.

Tønnesen H, Pedersen A, Jensen M R, Møller A, Madsen J C. Ankle fractures and alcoholism. The influence of alcoholism on morbidity after malleolar fractures. J Bone Joint Surg (Br) 1991; 73 (3): 511-3.