Fracture fixation with biodegradable rods

Forty-one cases of severe ankle fractures

Eero Hirvensalo

In a prospective study of 41 patients, severe ankle fractures of Lauge-Hansen types SE III–IV, PA III, and PE III–IV were treated by open reduction and internal fixation using biodegradable self-reinforced polglycolide cylinder-shaped rods. Disruption of the distal tibiofibular syndesmosis and/or fracture of the posterior tibial margin requiring reduction and fixation were the inclusion criteria for the study. The mean follow-up time after operation was 16 (12–32) months. Two failures of fixation necessitated reoperation. A secondary displacement of 1–2 mm of the lateral malleolus occurred in 3 cases. Transient accumulation of soluble polyglycolide mass complicated the course in 3 cases, but did not influence the radiographic or the functional result. Function became good in 30 patients. The advantage of the biodegradable implants is that they do not need to be removed at secondary operations.

After healing of internally fixed ankle fractures, removal of the metallic plates and screws is recommended by the Association for the Study of Internal Fixation (Müller et al. 1979). Such a second operation always causes inconvenience to the patient.

Biodegradable implants for fixation of fractures and osteotomies have been successfully used in animals (Greve and Holste 1985, Claes et al. 1986, Vainionpää et al. 1986, Eitenmüller et al. 1987, Leenslag et al. 1987, Vihtonen 1988), and promising clinical results have been obtained in simple displaced unimalleolar and bimalleolar fractures (Rokkanen et al. 1985, Böstman et al. 1987, 1989).

I report a prospective study of 41 patients with severe ankle fractures treated with polyglycolide rods.

Patients and methods

From March 1986 to December 1987, all the adult patients admitted to the my department for a severe ankle fracture entered the study if the following criteria were fulfilled: (1) Fracture types according to Lauge-Hansen (1942, 1954), the progressive severity being presented by Roman numerals from I to IV: supination-eversion (SE) III–IV, pronation-abduction (PA) III, and pronation-eversion (PE) III–IV; only those cases were included that had suprasyndesmotic fibular fractures combined with total disruption of the syndesmosis and/or those with a large posterior tibial fragment (over 25 per cent) necessitating operative fixation. (2) Age of the patient between 16 and 70 years. (3) No concomitant injuries of clinical significance. (4) Patient willing to enter the study and compliance not disturbed by mental disorder or alcoholism. (5) Good quality of bone excluding severe comminution of fragments and osteoporosis.

The study included 41 patients, 24 women and 17 men. The mean age was 41 (16–66) years, the women being somewhat older (mean 43 years) than the men (mean 38 years). There were 15 SE IV fractures, 10 PE IV fractures, 8 SE III fractures, 5 PA III fractures, and 3 PE III fractures (Table 1). The biodegradable rods (Biofix C) were manufactured in Tampere, Finland (Bioscience Ltd.), of self-reinforced polyglycolide (SR-PGA) composite material. A thin polydioxanone (PDS) layer was applied to cover the implant in order to lengthen the hydrolyzation time within bone tissue (Törmälä et al. 1988, Vasenius et al. 1989).

At operation, standard channels of 2.0 mm, 3.2 mm, or 4.5 mm for the installation of the rods were drilled. In SE and PA fractures, the reduced fibular fracture was fixed either with a 3. 2- or 4.5-mm by 70-mm rod

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Table 1. Severe ankle fractures of 41 patients treated with biodegradable rods

A	B	C	D	E	F	G	H	I	K	L	M	N	O	P
1	29,f	PE IV	+	+	+	+	–	–	–	+	13	–	–	100
2	57,f	PE III	–	–	+	+	–	–	–	–	13	–	–	100
3	38,f	SE IV	–	+	–	+	–	–	–	–	13	–	–	100
4	36,f	SE III	–	–	+	+	–	–	–	–	29	–	–	87
5	57,m	PE IV	+	–	+	–	–	–	–	–	28	+	–	100
6	48,f	SE IV	–	+	+	+	–	–	–	–	12	–	–	90
7	40,m	PA III	+	+	+	+	–	–	–	+	12	–	–	95
8	66,f	SE IV	–	+	–	–	–	–	–	–	12	+	–	100
9	21,m	SE IV	–	–	+	+	–	–	–	–	27	–	–	96
10	53,f	PA III	+	–	+	+	–	+	–	–	32	+	–	59
11	44,m	PE III	–	–	+	+	–	–	–	–	26	–	–	100
12	50,m	PE IV	+	–	+	+	–	–	+	–	18	–	+	71
13	53,f	PA III	+	+	–	+	–	–	–	–	13	–	–	97
14	36,m	SE IV	+	–	+	+	–	–	–	–	22	–	+	86
15	35,m	SE III	–	–	+	+	–	–	–	–	18	–	–	89
16	26,m	PE III	–	–	+	+	–	–	–	–	25	–	–	100
17	47,m	PE IV	+	+	+	+	–	–	–	–	12	–	–	97
18	41,m	PE IV	–	–	+	+	–	–	–	–	13	–	–	86
19	41,m	SE III	–	–	+	+	–	–	–	–	14	–	–	90
20	21,f	SE IV	–	+	+	+	–	–	–	–	12	–	–	100
21	28,m	SE III	–	–	+	+	–	–	–	–	13	–	–	100
22	38,m	SE III	–	–	+	+	+	–	–	–	18	+	–	90
23	57,f	SE III	–	–	+	+	+	–	–	–	13	+	–	100
24	25,f	PE IV	+	–	+	+	–	–	–	–	13	–	–	90
25	24,f	SE III	–	–	+	+	–	–	–	–	12	–	–	100
26	26,f	PA III	+	–	+	+	–	–	+	–	12	–	–	100
27	46,f	SE IV	+	–	+	+	–	–	–	–	13	–	–	100
28	48,f	PA III	+	+	+	–	–	–	–	+	12	+	–	63
29	35,f	SE IV	+	–	+	–	–	–	–	–	13	+	–	75
30	45,f	PE IV	+	–	+	+	–	–	–	–	16	–	–	80
31	54,m	SE IV	–	–	+	+	+	–	–	–	12	+	–	90
32	49,f	SE IV	+	–	+	+	–	–	–	–	12	–	–	90
33	49,f	SE IV	–	–	+	+	–	–	–	–	15	–	–	100
34	16,m	SE IV	–	–	+	+	–	–	–	–	24	–	–	100
35	56,f	PE IV	+	+	+	+	–	–	–	–	12	–	–	95
36	40,f	SE IV	+	–	+	+	–	–	–	–	13	–	–	100
37	23,m	SE IV	–	–	+	+	–	+	–	–	13	+	–	96
38	45,m	SE III	–	–	+	+	–	–	–	–	13	–	–	100
39	42,f	PE IV	+	–	+	+	–	–	–	–	13	–	–	96
40	57,f	SE IV	–	+	+	+	–	–	–	–	12	–	+	86
41	40,f	PE IV	–	–	+	+	–	–	–	–	12	–	–	89

A case
B age and sex
C type of fracture after Lauge-Hansen:
SE supination-eversion
PA pronation-abduction
PE pronation-eversion
D fracture of medial malleolus
E fracture of the posterior tibial margin with operative treatment
F disruption of syndesmosis
G accurate reduction
H minimal redisplacement
I failed fixation and reoperation
K superficial bacterial infection
L symptomatic transient fluid accumulation
M follow-up time (months)
N radiographic end-result: incongruity
O narrowing of the joint space
P functional score (points)

from the tip of the lateral malleolus, 19 cases (Böstman et al. 1987, 1989), or, when a more proximal fracture, with one 2-mm by 20–30-mm rod nearly perpendicular to the fracture, 9 cases (Figure 1). In PE fractures the proximal fibular fracture was left without fixation, 13 cases.

The medial malleolar fragment, 18 cases, was fixed using one or two 3.2-mm by 50-mm rods. The posterior tibial fragment was exposed posteromedially and fixed with equal rods directed from the front backward and distalwards to the posterior rim, 11 cases (Figure 1).

In syndesmotic disruptions, 38 cases, one 3.2-mm or 4.5-mm rod was inserted juxta-syndesmotically from the lateral side through all four cortices in a proximal and medial direction (Figure 1). The anterior tibiofibular ligament was sutured with absorbable sutures.

All the patients wore a plaster cast for 6 weeks.

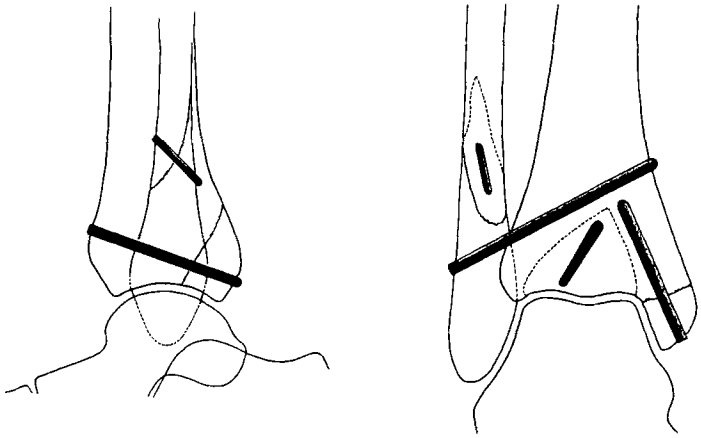

Figure 1. Fixation of a trimalleolar fracture of the ankle. Schematic views showing the positions of the polyglycolide rods in their channels after fixation of the fragments and transfixation of the syndesmosis.

Table 2. Functional scoring scale modified* after Phillips et al. (1985)

SUBJECTIVE (maximum 80 points)	Points	OBJECTIVE (maximum 20 points)	Points
Pain (54 points)		Gait (6 points)	
Always after any activity	0	Antalgic limp	0
Prolonged after mild activity	10	External rotation gait	3
Transient after mild activity	20	Normal gait	6
Prolonged after heavy activity	35		
Transient after heavy activity	40		
None	50		
Requires medication	0		
Requires no medication	4		
Function (26 points)		Range of movement (14 points)**	
Climbs using normal foot first	0	Dorsiflexion	
Requires aid of banister	2	Difference > 10 degrees	0
Climbs normally	3	Difference < 10 degrees	2
		No difference	7
Descends using normal foot first	0		
Requires aid of banister	2	Plantar flexion	
Descends normally	3	Difference > 20 degrees	0
		Difference < 20 degrees	2
Walks < 100 m	0	No difference	3
Walks < 1000 m	3		
Walks unlimited distances	6	Supination	
		Difference > 0 degrees	0
Recreational activities limited	0	No difference	2
No activities limited	3		
		Pronation	
Requires crutches	0	Difference > 0 degrees	0
Requires cane	4	No difference	2
Requires no aid	8		
Dissatisfied	0		
Moderately satisfied	2		
Very satisfied	3		

* Shortened without any essential changes in the scale.
** Difference from the normal side.

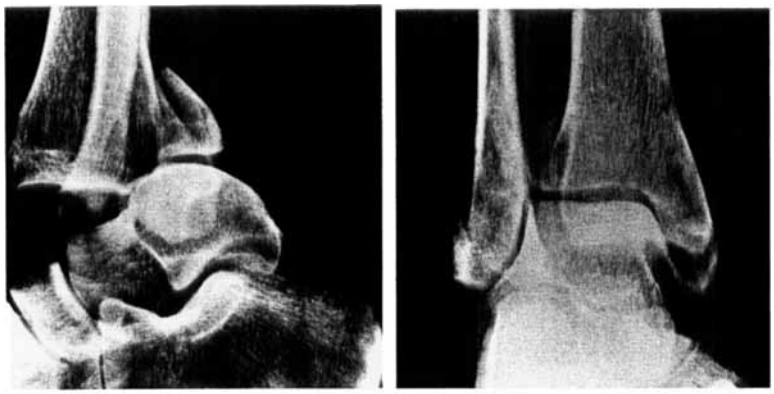

Figure 2. Case 28 with a displaced trimalleolar PA III fracture.

On admission. The operative technique followed the principles presented in Figure 1.

Result after 12 months showing an anatomic ankle mortise, except for an 1 mm displacement at the posterior tibial fragment, which was judged to be acceptable at the operation.

Figure 3. Case 37 with a partly ligamentous SE IV fracture. On admission (to the left). Initially an anatomic position of fixation was achieved. A redisplacement of the syndesmosis was observed at the 3 weeks' check-up. The oblique drill channel for the positional rod, 3.2 mm in diameter, is partly visible and indicates breakage of the rod (to the right).

Partial weight bearing was started at 3 weeks and full weight bearing at 5 weeks. Clinical and radiographic check-ups were arranged at 3 weeks, 6 weeks, 3 months, 6 months, and 1 year postoperatively.

The functional outcome was assessed using a scoring system, slightly simplified from that presented by Phillips et al. (1985); (Table 2). Accurate postoperative reduction implied anatomic position of the fragments, normal medial clear space, and normal tibiofibular clear space, no shortening or rotatory malposition of the fibula, normal talocrural angle, and talar tilting less than 2 mm (Lauge-Hansen 1954, Pettrone et al. 1983). The mean follow-up time was 16 (12–32) months.

Results

The achieved reduction and initial position of fixation was anatomic in 37 cases (Table 1). Four cases had a nearly anatomic reduction: in one fibular fracture (Case 5), in one fracture of the medial malleolus (Case 29), and in two fractures of the posterior tibial fragment (Cases 8 and 28; Figure 2). These positions were accepted and were unchanged until union.

Cases 22, 23, and 31 with initially anatomic reduction had a 1 to 2 mm lateral redisplacement of the lateral malleolus at one of the later check-ups. No reoperations were considered necessary in these cases either.

In Cases 10 and 37 an opening of the syndesmotic clear space was noticed 3 weeks postoperatively, and a reoperation with metallic implants was undertaken in both (Figure 3).

An anatomic ankle mortise was seen at the final radiographic evaluation in 29 of the 41 cases. In 9 cases there was a slight incongruity of the ankle joint, and in 3 cases some narrowing of the ankle joint space. Neither synostoses nor ligamentous calcifications occurred in this material. No evidence of delayed union or nonunion was encountered.

Two superficial wound infections caused by *Staphylococcus epidermidis* were seen. In 6 cases a transient accumulation of a soluble polyglycolide mass occurred beneath the primarily uneventfully healed scar, on an average 3 months after the operation. In 3 cases this was asymptomatic and did not require any treatment. In Case 28, it resulted in a spontaneous sinus formation at 17 weeks; and in Cases 1 and 7, the fluid was evacuated by a 5-mm incision. No positive bacterial cultures were encountered, and the healing was completed within 1–2 months without any further complications.

The mean function score was 92 points (maximum 100 points). Thirty of the 41 patients had a submaximal to maximal (90–100 points) score, i.e., they were satisfied with the result, the ankle was painless, and none or only slight objective restriction of movement was noticed.

Discussion

In the present study, special attention was paid to the totally torn syndesmosis in suprasyndesmotic fibular fractures and on large posterior tibial fragments. The fixation of the posterior tibial fragment, as well as the medial malleolus, was successful in all the cases. The application of the rod did not evoke problems. Neither diastasis nor torsional displacement between the fragments occurred.

The radiographic results with an anatomic ankle mortise in two thirds and the good functional recovery were not inferior to the results of ASIF instrumentation (Lindsjö 1985, Phillips et al. 1985) or nonrigid fixation with staples, pins, and cerclage wires (Cedell 1967, Olerud and Molander 1986, Ahl et al. 1987). However, the two failures of transfixation of the syndesmosis showed that a breakage or bending of the rod is possible. It is worth noticing that a decrease of the bending strength of the used implants in vivo is more rapid than that of shear strength (Vasenius et al. 1989). Therefore the fixation properties of the rod are not ideal when a soft-tissue gap, as that between tibia and fibula, allows bending of the rod. Consequently the transfixation channel should be drilled more distally, in the vicinity of the syndesmosis. Because of the risk of syndesmodesis, this has not been recommended for metallic positional screws (Müller et al. 1979). However, like in previous studies of biodegradable fracture fixation (Böstman et al. 1987, 1989), no extraosseous calcification occurred in the present study.

The transient accumulation of fluid in 6 cases was not unexpected, since similar observations have been made in previous studies using polyglycolide (Dexon®) or lactide-glycolide copolymer (Vicryl®) (Gammelgaard and Jensen 1983, Lange et al. 1988, Böstman et al. 1987, 1989). This phenomenon did not influence the union of the fracture or the functional outcome in the present study.

The conclusion of this study is that the use of polyglycolide rods may be extended also to severe ankle fractures.

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