T. Juutilainen · E. Hirvensalo · E. K. Partio
H. Päätiälä · P. Törmälä · P. Rokkanen

Complications in the first 1043 operations where self-reinforced poly-L-lactide implants were used solely for tissue fixation in orthopaedics and traumatology

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Abstract This is an analysis from one hospital of the first 1043 operations where pure self-reinforced poly-L-lactide (SR-PLLA) implants have been used alone. The operations were performed between 1988 and 1999 and included 407 orthopaedic patients and 636 trauma patients. There was a total of 107 complications. There were 21 infections but no sinus formation. Failure of fixation was seen in 46 patients. In 936 operations the healing was uneventful.

Résumé C'est une analyse, au sein d'un même hôpital des 1043 premières opérations où des implants de poly-L-lactide auto-renforcé pur (SR-PLLA) ont été utilisés de façon isolée. Les opérations ont été faites entre 1988 et 1999 et ont inclus 407 malades orthopédiques et 636 malades traumatisés. Il y avait un total de 107 complications. Il y avait 21 infections mais aucune fistulisation. L'échec de fixation a été noté chez 46 malades. Dans 936 opérations la guérison était obtenue sans incident.

Introduction

Bioabsorbable fixation devices have been used clinically in bone fixation for 17 years. Presently, bioabsorbable

implants are used with several indications in orthopaedics, sports medicine, and trauma surgery. This study is an analysis of the first 1043 operations where pure poly-L-lactide (SR-PLLA) implants have been used alone without any other implants. The study aims to clear up possible difficulties related to the use of bioabsorbable fixation devices in orthopaedics and traumatology.

Material and methods

All operations were performed at the Department of Orthopaedics and Traumatology, Helsinki University Central Hospital, during the years 1988–1999. The indication for operation was orthopaedic disorder (e.g. arthrodesis in rheumatoid arthritis, hallux valgus, and instability of the shoulder) in 407 patients, and trauma (mainly fractures and ligament ruptures) in 636 patients. The mean age was 43 years for orthopaedic patients and 37.7 years for trauma patients. In the orthopaedic series there were 294 women (72.2%) and in the trauma series 278 women (43.7%). All complications were counted, as were small variations from normal without any need for special treatment. Each complication was signed up separately, e.g. failure of fixation causing infection and further non-union were counted as three complications.

Results

The results are summarised in Table 1. The average operation time in the orthopaedic series was 63 min and in the trauma series 48 min. A total of 55 complications (13.5%) was seen in the orthopaedic series (Table 2) and 52 (8.2%) in the trauma series (Table 3). The overall complication rate was 107/1043 (10.3%). Infection was seen in 13 orthopaedic and eight trauma patients (2%). Failure of fixation was found in 20 (4.9%) patients in the orthopaedic series and 26 (4.1%) in the trauma series. There were no sinus formations. No fluid accumulation was seen in orthopaedic patients whereas three trauma patients (0.5%) had fluid accumulation. Deep venous thrombosis was present in eight patients – three in the orthopaedic series and five in the trauma series. The postoperative healing was uneventful in 936 (89.7%)

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T. Juutilainen (✉) · H. Päätiälä
Department of Orthopaedics and Rheumaorthopaedics,
Surgical Hospital, Helsinki University Central Hospital,
PO Box 263 (Kasarminkatu 11–13), 00029 HUS, Finland
e-mail: timo.juutilainen@hus.fi
Tel.: +358-9-47160570, Fax.: +358-9-47187487

E. Hirvensalo · E.K. Partio · P. Rokkanen
Department of Orthopaedics and Traumatology,
Helsinki University Central Hospital,
PO Box 266 (Topeliuksenkatu 5), Fin-00029 HUS, Finland

P. Törmälä
Institute of Biomaterials, Tampere University Of Technology,
PO Box 589, 33101 Tampere, Finland

Table 1 Summary of all results after operations with self-reinforced poly-L-lactide implants

	Orthopaedics total	Trauma total	All total
Number of operations	407	636	1043
Age (mean years)	43	37.7	39.8
Sex (female/male)	294/113	278/358	572/471
Operation time (mean min)	63	48.4	54.1
Hospital stay (mean days)	3.8	3.4	3.5
Sick leave (mean days)	67.6	56.1	60.3
Postoperative complications ^a	55 (13.5%)	52 (8.2%)	107 (10.3%)
Infections	13	8	21
New fracture	0	4	4
Failure of fixation	20	26	46
Fixation not perfect	3	2	5
Non-union of fracture	16	4	20
Deep venous thrombosis	3	5	8
Small fluid accumulation	0	2	2
Fluid accumulation	0	1	1
Sinus formation	0	0	0
No complications	352 (86.5%)	584 (91.8%)	936 (89.7%)

^a Each complication was signed up separately

patients – 352 (37.6%) were orthopaedic and 584 (62.4%) trauma. The operations resulted in uneventful healing in 352 cases (86.5%) in the orthopaedic series and 584 (91.8%) in the trauma series.

Discussion

In the present series with bioabsorbable SR-PLLA implants the mean complication rate was acceptable (10.4%), and the fixation failed only in 46 cases (4.4%). Fixation of proximal femoral fractures was not exact in 9/49 cases (18.4%). Forty patients with femoral neck fractures were treated by internal fixation using three SR-PLLA lag screws of 6.3 mm in diameter and 38 patients using three metallic screws of 7 mm in diameter [6]. In this study it was observed that SR-PLLA lag screws can be used safely to fix subcapital femoral neck fractures in Garden Stage I and II fractures and in younger patients in Garden III fractures. Six femoral head fractures associated with a traumatic posterior dislocation of the hip were treated by open reduction and internal fixation using SR-PGA and SR-PLLA (one case) and SR-PLLA (all other cases) rods and screws [5]. In three patients the end results were excellent and in one patient the result was fair. In the Bristow-Latarjet operation for recurrent anterior dislocation of the shoulder the failure rate was 5/37 (13.5%) using a PLLA expansion block for fixation of the coracoid process. Infection was the main single complication after talocrural arthrodesis without rheumatoid arthritis. There were four infections in 11 patients. The groups were, however, small, but it seems that bioabsorbable fixation may not be a good choice with these indications, although the learning curve of the surgeons may also influence the results.

A series of 51 patients with displaced fractures of the ankle were treated by open reduction and internal fixation with bioabsorbable screws [1]. A mild, transient, subcutaneous foreign body reaction occurred in one patient 22 months after fixation. This shows that the incidence

of foreign body reaction to SR-PLLA screws in the ankle is low and indicates that the implant may not have been fully introduced in the bone. The observation was confirmed in our combined analysis of 1043 operations where fluid accumulations were noticed in 3/1043 cases (0.29%).

In trauma patients, bioabsorbable implants have been used mainly for periarticular fixation of trauma lesions. In children, diaphyseal fractures have also been fixed with bioabsorbable rods. Five children with forearm fractures were treated using bioabsorbable intramedullary rods, and all fractures healed uneventfully within 6 weeks.

When wound infections associated with bioabsorbable devices used in the fixation of fractures, arthrodeses, and osteotomies were studied, the infection rate was only 0.7% when SR-PLLA implants only were used [7]. A comparison between metallic (2073 patients) and bioabsorbable (1012 patients) fracture fixation devices in displaced ankle fractures yielded infection rates of 4.1% and 3.2% respectively. There was no difference in the rates of deep infection (0.4%) [8]. The higher infection rate (2%) in our combined series of 1043 SR-PLLA operations is explained mainly by the infections after talocrural arthrodesis (4/11).

Twenty-five patients with an ankle fracture were treated with bioabsorbable plates and screws of high-molecular-weight injection-moulded polylactide [2]. All patients showed an uneventful bone healing, and there was no secondary redislocation. The problem was fixation of the bone causing late fluid accumulation. Favourable results were observed in our series where 125 ankle fractures were operated on using bioabsorbable SR-PLLA screws only.

Bone mineral density (BMD) was measured after operative ankle fracture treatment with bioabsorbable SR-PLLA or metallic screws [3]. The average BMD value in the distal tibia was 18% lower after metallic screw fixation compared to the non-operated ankle as early as after 1.4 years; after SR-PLLA screw fixation the BMD

Table 2 Details of orthopaedic operations where self-reinforced poly-L-lactide implants were used solely in the fixation of bones and joints. (RA rheumatoid arthritis)

Issue	Operation											
	Bristow-Latarjet	Fixation of osteo-chondritis dissecans	Anterior cruciate ligament rupture	Subtalar arthrodesis (no RA)	Talocrural arthrodesis (no RA)	Wrist arthrodesis (RA)	Other (RA)	Metatarsal osteotomy for hallux valgus	Chevron osteotomy	Other operations for osteoarthritis	Other operations for orthopaedics	Total
Number of operations	37	13	23	10	11	60	20	12	132	20	60	407
Age (mean-years)	29.4	26.5	27.2	54.3	50.8	48.9	53.8	46.3	44.8	47.2	41	43
Sex (female/male)	14/23	7/6	8/15	3/7	5/6	48/12	20/0	11/1	126/6	9/11	38/22	294/113
Operation time (mean-min)	113.1	53.5	71	72.4	105.5	87.6	64.5	39.9	35	59.5	61.1	63
Hospital stay (mean-days)	3.5	3.4	4.3	6.7	5.9	4.5	3.4	2.3	2	5.3	5.5	3.8
Sick leave (mean-days)	69	76.8	113.6	157.8	76.8	60.8	49.7	72.8	45.8	129.3	71	67.6
Postoperative complications	6 (16.2%)	0	4 (17.4%)	1 (10%)	7 (63.6%)	5 (8.3%)	1 (5%)	1 (8.3%)	7 (5.3%)	5 (25%)	18 (30%)	55 (13.5%)
Infections	0	0	0	0	4	2	0	1	1	1	4	13
New fracture	0	0	0	0	0	0	0	0	0	0	0	0
Failure of fixation	5	0	2	0	1	1	0	0	4	1	6	20
Fixation not perfect	0	0	0	0	0	0	0	0	2	0	1	3
Non-union	1	0	0	1	2	2	1	0	0	2	7	16
Deep venous thrombosis	0	0	2	0	0	0	0	0	0	1	0	3
Small fluid accumulation	0	0	0	0	0	0	0	0	0	0	0	0
Fluid accumulation	0	0	0	0	0	0	0	0	0	0	0	0
Sinus formation	0	0	0	0	0	0	0	0	0	0	0	0
No complications	31 (83.8%)	13 (100%)	19 (82.6%)	9 (90%)	4 (36.4%)	55 (91.7%)	19 (95%)	11 (91.7%)	125 (94.7%)	15 (75%)	41 (73.2%)	352 (86.5%)

Table 3 Details of trauma operations where self-reinforced poly-L-lactide implants solely were used in the fixation of bones and joints

Issue	Fixation of											
	Radial head and neck fracture	Distal humerus fracture	Fractures in the hand	Collateral ligament rupture	Talus fracture	Late fixation of ankle fracture	Proximal femur fracture	Patellar fracture	Meniscal rupture	Ankle fracture	Others ^a	Total
Number of operations	51	10	40	218	22	9	49	22	34	116	65	636
Age (mean-years)	39.2	23.3	33.2	36.1	30.8	39.8	65.9	33.3	29.3	35.7	36.8	37.7
Sex (female/male)	29/22	8/2	9/31	81/137	2/20	6/3	36/13	13/9	10/24	64/52	21/44	278/358
Operation time (mean min)	68.2	53.6	44	28.1	109.5	26.6	76.7	61.5	65.1	35.2	75	48.4
Hospital stay (mean days)	3.5	1.5	2	1.6	8.6	2.1	9.9	4.3	2	2.6	5.8	3.4
Sick leave (mean days)	53.5	50.6	37.1	38.3	95.2	56.5	149.5	69.9	50.5	60.9	56.1	56.1
Postoperative complications ^b	7 (13.7%)	0	5 (12.5%)	4 (1.8%)	2 (9.1%)	0	11 (22.4%)	1 (4.5%)	4 (11.8%)	7 (6.0%)	11 (16.9%)	52 (8.2%)
Infections	1	0	1	1	0	0	1	0	0	1	3	8
New fracture	1	0	0	0	1	0	0	0	2	0	0	4
Failure of fixation	3	0	2	2	0	0	9	1	2	0	7	26
Fixation not perfect	0	0	2	0	0	0	0	0	0	0	0	2
Non-union of fracture	2	0	0	0	0	0	1	0	0	0	1	4
Deep venous thrombosis	0	0	0	0	1	0	0	0	0	4	0	5
Small fluid accumulation	0	0	0	1	0	0	0	0	0	1	0	2
Fluid accumulation	0	0	0	0	0	0	0	0	0	1	0	1
Sinus formation	0	0	0	0	0	0	0	0	0	0	0	0
No complications	44 (86.3%)	10 (100%)	35 (87.5%)	214 (98.2%)	20 (90.9%)	9 (100%)	38 (77.6%)	21 (95.5%)	30 (88.2%)	109 (93.9)	54 (83.1%)	854 (91.8%)

^a Different indications^b Each complication was signed up separately

value was only 6.4% lower than in the non-operated ankle after 3.9 years. These results indicate that SR-PLLA fixation seems to have a positive influence on BMD.

In our series of 1043 SR-PLLA operations the complication rate was high after talocrural arthrodesis, after fixation of fracture of the olecranon, and after radial head or neck fracture fixation. In talocrural arthrodesis the main complication was infection (four cases). This confirms that talocrural arthrodesis is a very demanding operation, and complications cannot be avoided. The selection of implants for internal fixation may not necessarily influence the end results. Also, radial head or neck fractures are prone to postoperative complications. In our series there were seven complications in 51 operations (13.7%). Three were failures of fixation, two non-unions, one infection, and one new fracture. This confirms that radial head or neck fractures can be troublesome to treat operatively, and the results may not be different using metallic fixation devices.

The use of bioabsorbable fixation devices is growing. New indications and devices are under development, and, different medications and hormones have been mixed with bioabsorbable implants. Preliminary results with these new devices are encouraging, but further studies are still needed. By now bioabsorbable fixation devices provide a good alternative to metallic devices in many indications. As bioabsorbable implants degrade gradually there is no need to remove the implants. Moreover, the economic impact of bioabsorbable fixation devices seems to be more favourable than that of metallic implants in the operative treatment of ankle fractures when all expenses are considered [4].

The results of the present series show that SR-PLLA implants are very suitable devices for different kinds of

operations in orthopaedics, sports medicine, and trauma. Complications are not related to the implants but are general responses when surgical procedures are used in bone surgery. We have also seen that the rate of complications diminishes when more operative technical experience is gained.

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