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Biodegradable implants in the treatment of scaphoid nonunions

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Abstract We reviewed 12 male patients with scaphoid nonunions treated by open reduction, bone grafting, and internal fixation with biodegradable implants made of self-reinforced poly-L-lactic acid. Mean patient age was 22.5 (20–25) years. Ten patients had type D2 scaphoid nonunions with a fracture line in the middle one third, one patient had type D2 nonunion with a fracture line in the proximal one third, and one patient had type D1 distal one-third fibrous union. The mean wrist score (modified Mayo wrist score) was 20.8 (10–40) preoperatively and improved after 22–80 months (55–90). All nonunions healed, and the mean solid union time was 4.5 (3.5–7) months. We obtained excellent results in five patients, good results in four, fair results in two, and a poor result in one. The results of this study offer a valid alternative in the fixation of scaphoid nonunions. The major advantage of biodegradable materials is to eliminate the requirement for the removal of the fixation material.

Résumé Nous avons examiné douze malades de sexe masculin avec une non-consolidation du scaphoïde traitée par réduction ouverte, greffe osseuse et fixation interne avec des implants biodégradables faits d'acide poly-L-lactique auto-renforcé (SR-PLLA). L'âge moyen des malades était de 22.5 ans (20–25). Dix malades avaient une non-consolidation de type D2 avec le trait de fracture dans le tiers central, un malade avait le type D2 avec un trait de fracture dans le tiers proximal et un malade avait le

type distal D1 avec union fibreuse. Le score moyen du poignet (Mayo wrist score modifié) était 20.8 (10–40) en préopératoire et amélioré après 22 mois à 80 (55–90). Toutes les nonunions ont consolidées dans un temps moyen de 4.5 mois (3.5–7). Nous avons obtenu d'excellents résultats chez cinq malades, de bons résultats chez quatre, des résultats médiocres chez deux et un résultat mauvais pour une. Les résultats de cette étude offrent une alternative valide pour la fixation des non-consolidations du scaphoïde. L'avantage majeur des matières biodégradables est d'éliminer l'exigence d'ablation du matériel d'ostéosynthèse.

Introduction

Biodegradable implants have been used for 25 years. They were first used by maxillofacial surgeons in 1971 [1] and later for malleolar fractures in 1985 [15]. Scaphoid fractures are the most common carpal bone injuries [10]. We report on 12 patients with scaphoid nonunions treated by biodegradable screws and pins made of self-reinforced poly-L-lactic acid (SR-PLLA) (Bionx Implants Ltd, Tampere, Finland).

Material and methods

Between April 1993 and February 1997, 12 patients with scaphoid nonunions were treated by open reduction, bone grafting, and internal fixation with biodegradable screws or pins. All patients were male with an average age of 22.5 (20–25) years. The right and left wrist was equally involved. Nine patients had a fall on outstretched hand, two patients injured the hand in a motor vehicle accident, and one patient was struck by a heavy object. The average time between fracture and surgery was 9.8 (3–20) months. In nine patients, the fracture was undiagnosed at the first visit, and three patients were treated unsuccessfully with a short spica cast. According to Herbert's classification [7] ten patients had type D2 scaphoid pseudoarthrosis with

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fracture line through the middle one third, one had type D2 scaphoid pseudoarthrosis with fracture line in the proximal one third, and one patient had type D1 scaphoid distal one third fibrous union (Table 1).

For evaluation of the clinical complaints, we used the modified Mayo Clinic wrist scoring system (MMWSS) [16]. Seven patients had pain at rest, while five had moderate pain with daily activities. The average flexion, extension, radial, and ulnar deviation of the affected wrist was 44.5°, 41.6°, 10.4°, and 10.8°, respectively. Grip strengths were obtained before and after surgery by the Jamar dynamometer with the elbow at 90° flexion and forearm in neutral position. Average grip strengths of injured and uninjured hands were 19.1 kg and 34.4 kg, respectively. The average MMWSS was 20.8 (Table 1). Antero-posterior radiographs were taken with the wrist in neutral and in ulnar and radial deviations, and stress radiographs with clenched hand and lateral radiographs were also taken in various positions. Our criteria for osseous union were trabeculation across the fracture line on anteroposterior, lateral, and full-ulnar deviation radiographs [14]. The nonunions were all judged to be stable.

Surgical technique

Using pneumatic tourniquet, operations were performed from the dorsolateral side of the wrist. By protecting the sensorial branch of the radial nerve, the extensor pollicis tendon was retracted dorsally and the extensor pollicis brevis tendon ventrally. While exposing the joint capsule, the radial artery and its dorsal carpal branch were protected. The joint capsule was incised parallel to the long axis of the scaphoid. The nonunion site was located, and the sclerotic and cystic tissue was drilled. Cancellous graft harvested from the radial styloid was interposed in the nonunion site. After temporarily holding and compressing the fragments with a bone clamp, fixation was performed using one biodegradable lag screw or two biodegradable pins. After suture, a short arm splint with the thumb included was applied.

A single SR-PLLA lag screw was used in six patients and two SR-PLLA pins in the rest. Antibiotic prophylaxis was given using first generation cephalosporin administered 12 h preoperatively and 48 h postoperatively. The sutures were removed 15 days after surgery, and a spica cast including the thumb was applied. The patients were followed with clinical examinations and radiographs at 1-month intervals until union and thereafter with 3-month intervals. When bony union was found, the cast was removed and range of motion exercises initiated. The average duration of immobilization was 9 (5–10) weeks.

Results

Mean follow-up was 25 (22–35) months, and union was obtained in all patients. Average union time was 4.5 (3.5–7) months. In four cases, we observed sterile discharge

postoperatively, which later stopped. No sinus was seen, and no bacterial wound infection was encountered. Two patients suffered from Sudeck's atrophy. They were treated with alpha-receptor blockers and physical rehabilitation. Pain subsided completely in eight patients. Eight patients were very satisfied, and four patients rated their satisfaction as fair (Table 2).

Postoperative average movement of the wrist is listed in Table 2. In comparison with preoperative motion, wrist flexion improved 58%, extension 58%, radial deviation 37%, and ulnar deviation 32%. Average postoperative grip strength was 31.5 (25–38) kg. Patients were evaluated using MMWSS 22 months postoperatively. Average score was 80 (range 55–90), and results in five patients was considered excellent, in four good, in two fair, and in one poor.

Discussion

There are advantages and disadvantages of biodegradable implants. The most important advantage is that removal after union is not required [3]. While metallic implants cause stress shielding in the underlying bone and eventually this phenomenon results in bone weakness, biodegradable materials that have a bending modulus close to bone gradually dissolve and transfer stress to the bone [16]. On the other hand, since it is sufficient to drill the implant site and there is no obligation to remove the biodegradable implants, revision surgery is simpler than in the case of metallic implants. The major disadvantage of biodegradable implants is their cost, as they are more expensive than metallic implants.

It has been reported that biodegradable implants can cause graft versus host reaction in some patients within the first 3 months. However, this reaction did not affect bone healing, and there was no adverse effect in the latter [5]. In our patients, four had minimal discharge, but this did not affect clinical results. Only one patient was graded as fair according to the MMWSS. It has also been reported with early biodegradable implants that osteolysis around the implants can be seen after 3 months in half of the adult patients [2]. Osteolysis was found in 82% of patients with graft versus host reaction and in 40% of the other patients. Osteolysis is seen less frequently in children and does not affect the function of the epiphyseal plate [2]. Bostman reported sinus formation with inflammatory reaction in nine of 516 patients after implantation of biodegradable material [5]. The biodegradable material is not visible on radiographs, but it is possible to locate the implant's bony canal silhouette. Short shelf life is another disadvantage.

In contrast to metal implants, biodegradable materials do not produce an artefact on MRI and thereby offer an opportunity to expand the evaluation of scaphoid non-union and osteonecrosis with MRI. Scandinavian surgeons reported synovitis after internal fixation of intraarticular knee fractures with PLA and PGA implants [4]. The more recent generations of self-reinforced biodegradable im-

Table 1 Preoperative findings

Patients	Age/ gender	Trauma	Left/ right	Herbert type of the nonunion	The interval between fracture and surgery (months)	Initial treatment	Unaffected side			Affected side			The ratio of		Hand grip	The ratio of the		Pain	Mod.
							Flex/	Rad/	Flex/	ext	uln dev	total	movement of		strength	grip strength of			
							ext	dev	ext				affected side		affected/ normal	the affected			
													versus normal			side to the			
													side (%)			normal side (%)			
1	25/M	Fall on the hand	Right	Type D2 mid 1/3 pseudo.	10	None	90°/90°	30°/45°	30°/25°	15°/10°		31			16kg/30kg	53	Not satis- fied, can- not work	Pain at rest	15
2	22/M	Fall on the hand	Left	Type D2 proximal 1/3 pseu- do	12	None	90°/90°	30°/50°	50°/45°	15°/15°		48			25kg/28kg	89	Not satis- fied but can work	Moderate pain during daily activ- ities	35
3	23/M	Heavy load crush injury	Right	Type D2 mid 1/3 pseudo.	11	None	85°/90°	30°/45°	50°/50°	10°/10°		48			15kg/32kg	46	Not satis- fied, can- not work	Pain at rest	10
4	20/M	Fall on the hand	Right	Type D2 mid 1/3 pseudo.	12	None	85°/10- 0°	35°/45°	45°/45°	10°/10°		41			20kg/35kg	57	Not satis- fied, can- not work	Pain at rest	15
5	25/M	Fall on the hand	Left	Type D2 mid 1/3 pseudo.	7	Cast immobili- zation (2 months)	90°/90°	30°/45°	45°/30°	10°/10°		37			22kg/38kg	57	Not satis- fied, can- not work	Pain at rest	15
6	25/M	Motor vehicle acci- dent	Left	Type D2 mid 1/3 pseudo.	12	Cast immobili- zation (6 weeks)	90°/10- 0°	30°/55°	35°/15°	10°/10°		25			15kg/42kg	35	Not satis- fied, can- not work	Moderate pain during daily activ- ities	15
7	20/M	Fall on the hand	Right	Type D2 mid 1/3 pseudo.	3	Cast immobili- zation (6 weeks)	85°/10- 0°	30°/45°	50°/55°	20°/20°		55			20kg/35kg	57	Not satis- fied but can work	Moderate pain during daily activ- ities	35

Table 1 (continued)

Patients	Age/ gender	Trauma	Left/ right	Herbert type of the nonunion	The interval between fracture and surgery (months)	Initial treatment	Unaffected side		Affected side		The ratio of total movement of affected side versus normal side (%)	Hand grip strength affected/ normal	The ratio of the grip strength of the affected side to the normal side (%)	Pain	Mod. Mayo wrist scores
							Flex/ext	Rad/uln dev	Flex/ ext	Rad/ uln dev					
8	22/M	Fall on the hand	Left	Type D2 mid 1/3 pseudo.	13	None	90°/90°	30°/45°	45°/45°	5°/10°	41	20kg/40kg	50	Not satis- fied, can- not rest	15
9	21/M	Fall on the hand	Right	Type D1 distal 1/3 fibrous union	4	None	85°/90°	30°/50°	40°/35°	5°/5°	33	15kg/35kg	52	Not satis- fied, can- not rest	15
10	22/M	Fall on the hand	Left	Type D2 mid 1/3 pseudo.	20	None	90°/90°	30°/45°	40°/45°	10°/10°	45	18kg/38kg	47	Not satis- fied but can work	25
11	24/M	Fall on the hand	Right	Type D2 mid 1/3 pseudo.	8	None	90°/10- 0°	35°/45°	45°/40°	5°/10°	37	20kg/30kg	66	Not satis- fied, can- not work	15
12	21/M	Motor vehicle acci- dent	Left	Type D2 mid 1/3 pseudo.	6	None	90°/90°	30°/45°	60°/70°	10°/10°	58	24kg/30kg	80	Not satis- fied but can work	40

Table 2 Postoperative results

Patient	Type of fixation	Postoperative early complication	Union time (months)	Postoperative grip strength (kg)	The ratio of the postoperative grip strength of the affected side to the normal side (%)	Postoperative pain	Postoperative flex/ext ratio	Postoperative radial/ulnar deviation ratio	The ratio of total movement of affected side versus normal side (%)	Follow-up time (month)	Postoperative late complication	Satisfaction	Mod. Mayo wrist score	Result
1	Two pins	–	4.5	30	100	Only cold-weather-related pain	50° /45°	20° /20°	52	29	None	Excellent	80	Good
2	Two pins	Minimal discharge at the wound site	4	28	100	No pain	90° /80°	35° /30°	90	12	None	Excellent	90	Excellent
3	Screw	–	4	32	100	No pain	80° /75°	30° /30°	86	24	None	Excellent	90	Excellent
4	Screw	Minimal discharge at the wound site	4.5	30	85	Mild pain after heavy work	60° /55°	20° /20°	58	30	None	Fair	65	Fair
5	Screw	–	3.5	38	100	No pain	90° /80°	30° /40°	94	22	None	Excellent	90	Excellent
6	Two pins	Sudeck atrophy	7	36	85	Moderate pain after heavy work	60° /30°	15° /2 5°	47	35	Radioscaphoid mild arthrosis	Fair	55	Poor
7	Two pins	Minimal discharge at the wound site	6	25	71	Only cold-weather-related pain	70° /85°	30° /30°	82	29	None	Fair	65	Fair
8	Screw	Sudeck atrophy	4.5	34	90	No pain	90° /90°	30° /45°	100	22	None	Fair	85	Good
9	Screw	Minimal discharge at the wound site	4.5	30	85	No pain	85° /80°	30° /35°	90	24	None	Excellent	80	Good
10	Two pins	–	4	35	92	No pain	90° /90°	30° /35°	96	24	None	Excellent	80	Good
11	Two pins	–	4	30	100	No pain	80° /80°	30° /40°	85	25	None	Excellent	90	Excellent
12	Screw	–	4	30	100	No pain	70° /70°	30° /45°	84	24	None	Excellent	90	Excellent

plants, such as SR-PLLA, are believed to have a reduced risk of adverse tissue reactions [9].

Hope reported the outcome in children with displaced elbow fractures, and in 11 patients, Kirschner wires were used for internal fixation and in 13 patients PGA pins. All children had full function 6 months after surgery [8]. Although it has been reported that scaphoid nonunion fixed with polyglycolide pins resulted in a union rate of 64% as against 60% when Herbert screws were used [13], we found a union rate of 100%. Bocholts et al. used polylactide screws in 100 ankle fractures and metallic screws in 55 [6]. There were no radiographic and functional difference between the two groups at an average of 37 months after surgery. Partio et al. reported successful results in 11 of 12 patients using SR-PGA and SR-PLLA screws in talocrural arthrodesis. The average union time was 9 weeks [11]. Partio also treated seven patients with severe hind foot valgus deformity due to spastic neuromuscular disease by subtalar arthrodesis [12]. On one side the arthrodesis was performed with SR-PLLA screws and on the other side with AO screws at the same time. Radiographically, the results were better in the feet treated with SR-PLLA screws.

The use of biodegradable implants increases gradually as orthopedic surgery also increases gradually, and the results are equally successful as with metallic materials [4, 7, 11]. Although the number of cases in our study was small, the preliminary results were promising.

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