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Posterolateral lumbar fusion using facet joint fixation with biodegradable rods: a pilot study

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Introduction

Biodegradable rods have been used during the last decade for fixation of smaller fractures in the extremities [2], but the fixation method has never been employed in spine surgery. Uninstrumented posterolateral lumbosacral fusion is associated with few and minor complications, but the risk for nonunion varies between 10% and 40% [1, 4, 5, 12, 14].

A pilot study was designed to see whether transarticular biodegradable rods crossing the denuded facet joints can affect the kinematics and the healing rate of uninstrumented posterolateral fusions performed for disc/facet joint degeneration in the lower lumbar spine. The study was ac-

Abstract Roentgen stereophotogrammetric analysis (RSA) was used to assess whether there is a potential for biodegradable rods crossing the denuded facet joints to increase the stability and healing rate of lumbar posterolateral fusions. Eleven consecutive patients with lumbosacral disc/facet joint degeneration had a posterolateral fusion augmented with 2- or 3.2-mm biodegradable rods passing perpendicularly through the center of the denuded facet joints. The patients were followed-up with RSA in supine and erect positions monthly from the 2nd to the 6th postoperative month, and again 1 year postoperatively. All seven L5-S1 fusions healed. Four cases were stable as defined by RSA within 3 months, two within 6 months, and one within 1 year. One L4-S1 fusion could not be evaluated by RSA.

None of the remaining three L4-S1 fusions fully healed. In all three cases 1- to 3-mm intervertebral translations remained at 1 year. None of the 11 fusions showed any radiographic signs of osteolysis around the biodegradable rods. The promising results of this pilot study indicate that posterolateral L5-S1 fusion augmented with transarticular biodegradable rods crossing the denuded facet joints may yield rapid intervertebral stabilization and a high healing rate without any adverse rod effects. This may be due to enhanced initial fusion stabilization and/or increased ossification induced by the rods.

Key words Biodegradable rod · Facet joint · Lumbar spine · Posterolateral fusion · Stereophotogrammetry

complished by using roentgen stereophotogrammetric analysis (RSA) [10], which is highly suitable for three-dimensional studies of lumbar intervertebral mobility [7].

Materials and methods

Patients

Eleven consecutive patients without prior low back surgery (age range 39–59 years, mean 46 years) underwent an uninstrumented posterolateral fusion in situ augmented with biodegradable rods, between L5 and S1 in seven patients and between L4 and S1 in four (Table 1). No laminectomy was performed. The indication for surgery was intractable low back pain, refractory to nonsurgical measures, judged originating from disc/facet joint degeneration in

 Table 1
 Patient characteristics

Case	Sex	Age at surgery (years)	Fusion level	Radiographic fusion			
1	М	41	L5-S1	Convincing			
2	F	42	L4-S1	Partial			
3	М	39	L5-S1	Convincing			
4	М	59	L4-S1	Partial			
5	F	39	L5-S1	Convincing			
6	Μ	41	L5-S1	Convincing			
7	М	58	L5-S1	Convincing			
8	Μ	42	L4-S1	Partial			
9	F	47	L5-S1	Convincing			
10	М	50	L4-S1	Partial			
11	F	40	L5-S1	Convincing			

the levels designated for fusion. The patients were instructed to keep their trunk straight for 5 months following surgery and were given a soft lumbosacral corset with dorsal rigid reinforcement, mainly as a regimen reminder [6].

Methods

Biodegradable rods

The rods (Biofix, Bioscience, Tampere) consist of self-reinforced polyglycolic acid composite material [2]. The rod length used was 3 cm and the diameter 2 or 3.2 mm (Fig. 1). Each rod has an initial shear strength of 180-200 MPa and a bending strength of 300-350 MPa, values exceeding at least 20 times the strength of cancellous bone. Postoperatively, the rods degrade; the major part of their mechanical strength is lost in 30-40 days, and they are completely digested in 6-12 months.

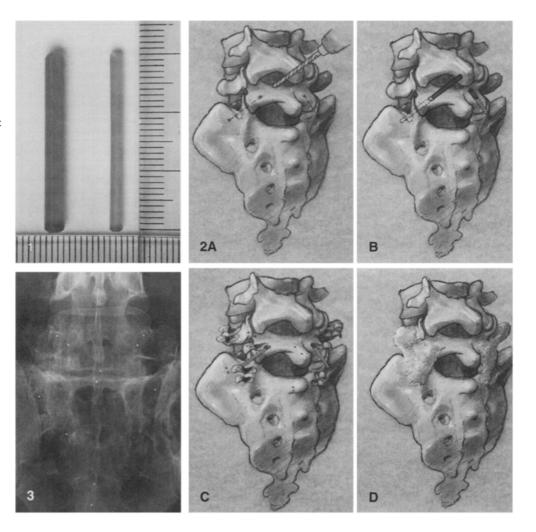
Surgical procedure

The posterolateral surfaces of the lumbosacral spine were exposed through a central skin and muscle incision. The facet joints were cleaned of cartilage and subcondral cortex. A canal appropriate for a biodegradable rod of 2 or 3.2 mm diameter was drilled perpendicular to the joint line through the center of each facet joint, i.e. two facet joints in the L5–S1 fusions and four facet joints in the L4-S1 fusions (Fig. 2a). The choice of rod diameter was determined by the size of the facet joint. In each predrilled canal a rod was inserted (Fig. 2b). By absorbing fluid the rods expanded slightly within a few minutes and became fixed in the canals. The

Fig. 1 Biodegradable rods (Biofix, Bioscience, Tampere) with a length of 3 cm and diameters of 2 and 3.2 mm

Fig. 2A-D Posterolateral L5-S1 fusion augmented with transarticular biodegradable rods crossing the denuded facet joints. A Canal appropriate for a biodegradable rod of 2 or 3.2 mm diameter drilled perpendicular to the joint line through the center of each denuded facet joint. B Biodegradable rod inserted in each predrilled canal. C Decorticated posterolateral surfaces with 0.8-mm tantalum balls implanted in a standardized pattern into the sacrum and the most proximal vertebra intended for fusion. D Denuded facet joints filled with cancellous bone graft and decorticated surfaces covered with the same

Fig.3 Bilateral osseous L5-S1 fusion with bridging trabecular bone



posterolateral surfaces were decorticated in the usual way. To enable follow-up RSA, 0.8-mm tantalum balls were implanted in the sacrum and the most proximal vertebra included in the fusion at standardized predetermined locations (Fig. 2c) [7]. The denuded facet joints were filled with cancellous bone graft and the decorticated posterolateral surfaces were covered with the same (Fig. 2d). The bone graft was harvested through the same incision from the dorsal part of one or both iliac crests, depending on the amount of cancellous bone in each individual crest.

RSA

One woman (the second patient) had to be excluded from RSA follow-up because of incorrect placement of the tantalum balls. Each of the remaining ten patients was examined with RSA [7, 10] monthly from the 2nd to the 6th month postoperatively, and again 1 year after surgery. The RSA was performed as described before [7] in a radiographic set-up with two 40° angulated roentgen tubes with simultaneous exposures. A combined reference plate and calibration device with 0.8-mm tantalum balls at known positions was placed in front of the film plane, enabling simultaneous calibration and patient examination. At each RSA the patients were examined in supine and erect positions without corset. The translatory movements along the transverse, vertical, and sagittal axes, induced by the change in position of the 0.8-mm tantalum balls implanted into the fused vertebrae, were calculated by computed data processing. These translations visualized the movements of the most proximal vertebra of the fusion in relation to the sacrum. To conform with the instruction to keep the spine straight for 5 months postoperatively and to standardize the examination, no active movements of the spine were performed.

The accuracy, i.e., the measurement error, of this RSA set-up has previously been found to be 0.3 mm for the transverse axis, 0.6 mm for the vertical axis, and 0.7 mm for the sagittal axis [7]. Induced intervertebral translations were not considered significant unless they exceeded these values.

Radiography

Conventional radiographs with anteroposterior and lateral views were obtained 6 months and 1 year after surgery.

Results

All seven cases with L5-S1 fusion healed and became rigid (Fig. 3) as defined by RSA, i.e., no intervertebral translations exceeded the accuracy of the RSA set-up used (Table 2) and radiography (Table 1). Three fusions were stable within 2 months according to RSA, one within 3 months, two within 5 months and one within 1 year. Before fusion stabilization the sagittal translation of the most proximal vertebra of the fusion in relation to the sacrum was less than 2 mm and directed anteriorly in all cases. When present, the transverse translations were directed either to the right or to the left and the vertical translations caudally, but these translations were mostly nonexistent.

None of the four cases with L4-S1 fusion fully healed. In the three cases available for RSA, 1- to 3-mm sagittal translations remained at the 1-year follow-up (Table 2). The transverse and vertical translations were mostly less than 1 mm. The directions of the translations were similar to the directions of the translations before rigid fusion in the healed cases described above, except at three examinations. There was a cranially directed vertical translation at 3 and 4 months in case 8, and a posteriorly directed sagittal translation at 5 months in case 10. Partial osseous fusion was noted on the radiographs in all four cases (Table 1).

No nerve root impairment or other intraoperative complications occurred. None of the 11 cases showed any radiographic signs of osteolysis around the biodegradable rods.

Discussion

Uninstrumented posterolateral lumbosacral fusion yields a healing rate of 60%–90% [1, 4, 5, 12, 14]. Since the ad-

Table 2 Roentgen stereophotogrammetric analysis (RSA) intervertebral translations 2–12 months after surgery. Translations exceeding the accuracy^a of the RSA set-up appear in bold (m months, • inadequate or missed measurement)

Case	Transverse translation (mm)						Vertical translation (mm)					Sagittal translation (mm)						
	2 m	3 m	4 m	5 m	6 m	12 m	2 m	3 m	4 m	5 m	6 m	12 m	2 m	3 m	4 m	5 m	6 m	12 m
1	0.0	0.0	0.0	0.1	0.0	•	0.0	0.0	0.2	0.1	0.1	•	0.0	0.1	0.2	0.3	0.3	•
2	•	•	•	•	•	•	•	•	•	•	•	•	•	•	٠	•	•	•
3	0.0	0.0	0.0	0.0	0.0	0.1	0.4	0.2	0.2	0.1	0.1	0.0	0.2	0.0	0.2	0.2	0.1	0.1
4	0.1	0.6	0.4	0.6	0.2	0.6	0.8	0.6	1.0	0.2	0.7	0.8	2.7	3.7	5.5	0.4	3.0	3.0
5	0.3	0.5	0.1	0.4	0.1	0.2	0.1	0.2	0.2	0.0	1.2	0.2	1.4	1.0	0.8	0.0	0.2	0.1
6	0.0	0.1	0.1	0.1	0.0	0.1	0.0	0.1	0.2	0.1	0.2	0.3	1.0	0.4	0.8	0.4	0.5	0.6
7	0.1	0.4	0.2	0.0	0.0	0.0	0.1	0.1	0.1	0.0	0.3	0.2	0.5	1.2	0.8	0.0	0.6	0.1
8	1.3	1.3	1.2	0.8	1.0	0.9	0.5	0.8	1.0	0.4	0.3	0.2	2.1	4.6	4.5	3.7	3.4	2.7
9	0.0	0.2	0.1	0.1	0.1	0.1	0.1	0.0	0.1	0.0	0.0	0.0	0.9	0.2	0.1	0.0	0.1	0.2
10	0.3	0.3	0.6	0.3	0.1	0.7	0.4	0.5	0.6	0.2	0.3	0.2	0.2	0.5	0.3	0.8	0.2	0.9
11	0.1	0.1	0.0	0.1	0.2	0.2	0.1	0.2	0.0	0.1	0.2	0.0	0.3	0.5	0.4	0.0	0.1	0.2

^a Accuracy = minimum significant measurement: transverse translation > 0.3 mm, vertical translation > 0.6 mm, sagittal translation > 0.7 mm

147

vent of osteosynthetic spinal stabilization, the optimal choice between uninstrumented and instrumented techniques in lumbar fusion has been debated. Adjunctive spinal instrumentation seems to enhance fusion rates in degenerative disorders [13], although the risk of intraoperative and postoperative complications is somewhat increased for instrumentation [9].

Semirigid fixation systems such as the Graf technique [11] have been presented as alternative to rigid hardware spine fixation, but no biodegradable material has yet been tried. Following promising animal experiments, biodegradable polyglycolic acid rods (Biofix) have been used for the past decade for fixation of smaller fractures in the extremities, with healing results equalling those of conventional metallic osteosynthetic devices [2]. The elasticity and strength of polyglycolic acid rods is similar to bone during the 1sth month after surgery, followed by gradual decline of the physical properties during the biodegradation.

It is difficult to assess fusion solidity by any radiographic method [3]. RSA, however, visualizes the stabilizing effect of fusions with high accuracy by measuring intervertebral movements, which can be followed over time, thus enabling us to establish time schedules for different surgical techniques and postoperative regimens [7, 8].

One-level uninstrumented posterolateral lumbosacral fusions seem to heal more frequently than two-level procedures [1, 4, 5]. This healing pattern seems to be confirmed in our pilot study of disc/facet joint degeneration treated by posterolateral fusion augmented with transarticular biodegradable rods crossing the denuded facet joints. Fast fusion stabilization as defined by RSA was achieved in all one-level cases, whereas none of the twolevel fusions were successful. Eighty percent of the onelevel fusions became stable within 5 months as compared to the 20% of conventional uninstrumented posterolateral lumbosacral fusions that eventually healed in a prior RSA study [8]. The rapid elimination of intervertebral movements in several of the one-level fusions may be due to enhanced initial stabilization of the facet joints and/or increased ossification induced by the rods, whereas the more deranged biomechanical situation after the vaster soft tissue cleaning including facet joint denudation in the

two-level cases might counteract these possible fusionpromoting effects. Although all the one-level fusions were performed between L5-S1, it is possible that this onelevel technique would lead to a similar promising healing rate at other levels in the lumbar spine, despite the intrinsic biomechanical differences between the lumbar levels.

Complications induced by biodegradable rods can be categorized as either general or specific. The general complications are the same as for all types of implants, i.e., infection and implant insufficiency/breakage. There was no overt general complication in our study, although the integrity of the rods was impossible to evaluate. The specific complication of biodegradable rods is delayed inflammatory foreign-body reaction as a response to chemical irritation from the degradation debris [2]. This late inflammatory reaction can be asymptomatic and subclinical as well as clinically manifest with symptomatic soft tissue swelling and/or radiographically verified osteolysis. Neither clinical manifestation occurred in our study.

Conclusions

The promising results of the current pilot study indicate that posterolateral L5-S1 fusion augmented with transarticular biodegradable rods crossing the denuded facet joints might yield rapid intervertebral stabilization and a high healing rate without any adverse rod effects. This may be due to enhanced initial fusion stabilization and/or increased ossification induced by the rods. The technique reduces the potential early and late implant-related problems of instrumented fusions, and may be a good surgical option in one-level lumbar fusions. The pilot series presented is kinematically well documented, but small, which makes it imperative to validate the findings in larger materials comparing biodegradable rod fusions with conventional fusions, preferably in randomized studies.

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