Fixation with poly-L-lactic acid screws in hip osteotomy

68 hips followed for 18–46 months

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ABSTRACT – This study evaluated 68 consecutive hip osteotomies in 61 patients using absorbable poly-L-lactic acid screws for fixation. 47 hips underwent a rotational acetabular osteotomy, 17 hips Chiari's pelvic osteotomy, and 4 hips transtrochanteric rotational osteotomy. Cortical screws were used to transfix the osteotomized acetabulum, and cancellous screws to reattach the intraoperatively osteotomized greater trochanter. The average age at surgery was 35 (12–49) years. The mean duration of follow-up was 32 (18–46) months. All the osteotomized acetabulums united well, but 4 of 54 trochanteric osteotomies failed to unite.

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Matsusue and Yamamuro (1992) reported that poly-L-lactic acid rods maintained a bending strength exceeding that of human cortical bone (120–210 MPa, Swanson 1971) in the medullary canal for 8 weeks and they found no significant differences between the results in in vitro and in vivo environments. The mechanical bending strength of the poly-L-lactic acid screw remained at about 200–240 MPa 3–6 weeks after insertion, not unlike that of 280 MPa in the most popular stainless steel implant (SUS316L) (Matsusue and Yamamuro 1992). The poly-L-lactic acid screws began to weaken 8–10 weeks after insertion along with water-added dissociation.

The use of poly-L-lactic acid screws for hip osteotomy (both acetabular and proximal femoral) is tempting because in later total hip replacement surgery, metal screws tend to cause irritation. We report our results with poly-L-lactic acid screws in fixation of hip osteotomies.

Patients and methods

Between April 1997 and July 1999, 68 consecutive hip osteotomies were performed in 61 patients (54 women) using absorbable poly-L-lactic acid screws to fix bony fragments. Rotational periacetabular osteotomy or a shelf procedure for treatment of subluxation or osteoarthrosis of the hip secondary to congenital dislocation, subluxation, or dysplasia was used in patients with a spherical femoral head, an intact joint space and good congruity between the acetabulum and the femoral head (47 hips). Chiari pelvic osteotomy was done in patients with an irregular femoral head or with incongruity between the acetabulum and the femoral head (17 hips). Osteonecrosis of the femoral head was treated with varus intertrochanteric osteotomy or transtrochanteric rotational osteotomy in patients with at least 90° hip flexion, 25° abduction, and radiographic prediction of a postoperative lateral head index exceeding 25% (Masuda et al. 1988) (4 hips). The average age at the time of surgery was 35 (12–49) years, average height 156 (140–178) cm, and average weight 54 (39–88) kg. The mean duration of follow-up was 32 (18–46) months. No patientwas lost to follow-up.

Surgical procedures

Rotational acetabular osteotomy was performed through a transtrochanteric approach with intraoperative incision and reattachment of the greater trochanter. Poly-L-lactic acid screws were used to transfix the osteotomized acetabulum to the pelvis. Reattachment of the greater trochanter was done

Figure 1. Preoperative radiographs of a 45-year-old woman with dysplasia and arthrosis of the left hip.

Rotational acetabular osteotomy. 3 poly-L-lactic acid cortical screws fix the osteotomized acetabulum. Metallic cancellous screws were used to reattach the greater trochanter. This case was one of the first 14 hips in which poly-L-lactic acid screws were not used to fix the greater trochanter.

42 months later, solid bone union and sclerosis can be seen around the screw channels. The clinical result was good with no hip pain. No focal reaction occurred around the hip.

with metallic cancellous screws in the first 14 hips, and poly-L-lactic acid screws in the last 33 hips treated since February 1998. Chiari's pelvic osteotomy and transtrochanteric rotational osteotomy were also performed through a transtrochanteric approach, using poly-L-lactic acid screws to fix the greater trochanter. Therefore, 54 consecutive osteotomized greater trochanters were reattached with poly-L-lactic acid screws. All absorbable poly-L-lactic acid screws were Fixsorb (Takiron Co, Osaka, Japan).

Cortical screws were used to fix the osteotomized acetabulum. A 3.3 mm drill bit was used to make the screw hole, then the entire length of the drill hole was tapped using a 4.7 mm tap, followed by insertion with a screwdriver which allowed sufficient torque. The screws had a threaded diameter of 4.5 mm, a core diameter of 3.2 mm, and a length of 40–65 mm; 2 screws were used in 2 hips, 3 in 41 hips, and 4 in 4 hips. Cancellous screws were used to reattach the greater trochanter. A 4.2-mm drill bit was used to penetrate the medial calcar cortex of the femur, and the entire length of the drill hole was tapped with a 6.6 mm tap. The screw was inserted using a screwdriver with a washer placed to penetrate the medial cortex and allow sufficient torque for interfragmental compression. The cancellous screws had a threaded diameter of 6.5 mm, a core diameter of 4.0 mm, an unthreaded diameter of 4.0 mm, and a length of 45–70 mm, all of which were inserted with a washer; 2 screws in 27 hips, and 3 screws in 27 hips. None of the screws broke during insertion.

Postoperative treatment

All patients with pelvic osteotomies and trochanteric osteotomies began straight leg-lifting exercises from the day after surgery and used wheel chairs for 2 weeks. Partial weight-bearing using 2 crutches and abductor muscle exercises were started after 6–8 weeks and full weight-bearing was usually allowed 8–10 weeks postoperatively. The average hospitalization was 3 months. The patients were encouraged to use 2 crutches to prevent injury 3–4 months postoperatively.

Evaluation

Clinical and radiographic follow-ups were done at 1, 2, 3, 4, 6, 8 weeks, and then after 3, 4, 6 and 12 months, and thereafter every half year postoperatively. Serial anteroposterior and lateral radiographs were used to assess bone union and radiolucent zones of the screw. The appearance of bridging bony trabeculation without sclerosis was defined as bone union. Reactions to foreign material were evaluated on anteroposterior radiographs and according to the local clinical-physical findings.

The bending strength of 2 broken and 2 new screws was measured (Figure 2). Statistical analysis of data concerning the rate of bone union was done using Fisher's exact probability test. Probability values less than 0.05 were considered significant.

Figure 2. A 25-year-old man with steroid-induced osteonecrosis of the left hip.

Transtrochanteric rotational osteotomy was done using 2 poly-L-lactic acid cancellous screws to fix the greater trochanter.

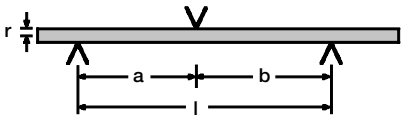
2 weeks after surgery, considerable proximal migration of the greater trochanter occurred.

The patient was reoperated on to fix the displaced greater trochanter fragment 15 days after the primary surgery.

The 2 broken screws after retrieval. Both breakages occurred at the border between the threaded part and the smooth shaft.

Results

In pelvic osteotomies, good bone union was obtained in all cases within 6 months of surgery. There was no pain or tenderness around the hip. Serial radiographs showed no displacement of the osteotomized acetabulum in any of the 47 hips (Figure 1). The lucencies of implant channels or osteosclerosis around the implants could be seen on 34/47 radiographs taken at the last follow-up examination. In trochanteric osteotomies, bone union occurred in 50/54 within 3 months of surgery.



$$\delta_{max} = \frac{Mr}{I} \qquad M = \frac{abW_{max}}{l} \qquad I = \frac{\pi(2r)^4}{64}$$

δ_{max} = maximum bending strength (MPa)
M = maximum bending moment
I = cross sectional moment
W_{max} = maximum strain (kgf)
l = span length (mm)
a, b = distance between the point where force was applied and the point of action (mm)
r = radius of the specimen (mm)

Diagram of the 3-point bending method. 5 days after reoperation, the bending strength of the retrieved screw shaft was measured with the 3-point bending method using the universal testing instrument model 1130 (Instron Co, Kawasaki, Japan). The retrieved screw was stored in room air at 18 °C and 45% relative humidity. The span length, distance between the point where force was applied and the point of action, and radius of the specimen were 20.0 mm, 12.0 mm, 8.0 mm, 2.25 mm, respectively. The cross-head speed was 2.0 mm per minute, and the temperature 18 °C. The maximal strain indicated 6.4 kgf, therefore, the maximum bending strength was calculated as 34 MPa. The other screw was stored in room air for 4 weeks after reoperation. The screw was soft on palpation and easily broken with bare hands when examined by an orthopedic surgeon. As a control study, the bending strength of 2 new poly-L-lactic acid cancellous screws of the same diameter was measured. The span length, distance between the point where force was applied and the point of action, and radius of the specimen were 20.0 mm, 10.0 mm, 10.0 mm, 2.25 mm, respectively. The cross-head speed and temperature were the same, as described above. The maximal strain of the 2 screws was 35 kgf, therefore, the maximal bending strength was calculated as 196 MPa.

Proximal displacement of the greater trochanter fragment was found in 4 hips 2–4 weeks postoperatively. 1 displacement took place 2 weeks after Sugioka's transtrochanteric rotational osteotomy (Figure 2), 2 occurred 2 and 3 weeks after rotational acetabular osteotomy, and another 4 weeks after Chiari's pelvic osteotomy. 2 cancellous screws were used in 3 hips, and 3 cancellous screws in 1. There was nothing unusual about the initial fixation, radiographs, and postoperative activity levels in patients whose trochanters became displaced. All 4 displacements were severe, therefore, reoperation to fix the greater trochanter fragment was done using the Dall-Miles cable system. At reoperation, all poly-L-lactic acid screws were macroscopically broken in the middle of the screw shaft. The threaded part of the screws was tightly fixed in the medial cortex of the femur. Therefore, the displacement of the fragments was due to weakness of the poly-L-lactic acid screw shaft. We found no signs of infection, and no focal tissue reactions suggesting an inflammatory response to the poly-L-lactic acid screws macroscopically. In one of these cases, reoperated 15 days after the primary operation, we measured the strength of the screws (Figure 2). After revision, radiographic bony union of the fragment had occurred in all 4 of these cases. Serial radiographs showed no displacement of the osteotomized greater trochanter in the other 50 hips. The lucencies of implant channels or osteosclerosis around the implants could be seen on 35/50 radiographs taken at the last follow-up examination. There was no statistically significant difference between the rate of radiographic bone union in pelvic osteotomies and in trochanteric osteotomies ($p = 0.08$).

Abnormal radiographic findings other than lucencies and osteosclerosis, such as osteolytic reaction or bone atrophy, were not seen in any hips. We found no infections or focal reactions, such as redness or swelling around the hip. None of the screws had to be removed except for the 4 fractured ones.

Discussion

Matsusue et al. (1997) reported good long-term clinical results in orthopedic surgery treated with poly-L-lactic acid implants. Clinical studies to date show a relatively low rate of mechanical failure necessitating reoperation (Böstman 1991). According to the manufacturer, the initial bending strength is 250 MPa and the initial shear strength 95 MPa in the cortical and cancellous screws. The initial strength is reported to be maintained for 10–15 weeks in vitro. We measured an initial bending stress of 196 MPa in 2 new cancellous screws. However, the bending stress of 34 MPa that we measured in the fractured screw 20 days after the index operation was less than that stated by the manufacturer.

Hardly any clinical experience is available on the reliability of absorbable screws in hip surgery. Although a poly-L-lactic acid screw has been considered to be strong enough to fix the osteoto-

mized acetabulum in rotational acetabular osteotomy (Nakamura et al. 1993), trochanteric osteotomy is inherently unstable and requires greater mechanical strength for secure fixation. Ninomiya and Tagawa (1984) reported that all 45 osteotomized acetabulums in rotational acetabular osteotomy healed with 2 metallic Kirschner wires. Trousdale et al. (1995) had 2 nonunions at the pubic osteotomy site and 0 at the iliac osteotomy site using metallic 4.5 mm cortical screws in 42 patients who underwent periacetabular osteotomy. The incidence of nonunion or displacement at the site of trochanteric osteotomy fixed with metallic implants reportedly ranges from 0 to 29% (Charnley 1972, Amstutz and Maki 1978, Bray et al. 1987, Anwar et al. 1993, Dall et al. 1993, Sullivan et al. 1994, Sochart and Porter 1997). The rate of nonunion in our study using bioabsorbable implants was 4/54, which is similar to the rates reported in studies using metallic implants. All the poly-L-lactic acid screws in these 4 hips were macroscopically broken in the middle of the screw shaft, and the threaded part of the screws was tightly fixed in the medial cortex of the femur. The screws may therefore have begun to fall during their usual degradation process. Chu and Campbell (1982) reported that degradation starts in the weakest parts of the structure, where surface cracks start to form. A small manufacturing flaw in the screw may also have been present which became worse during insertion, or else the initial strength of the poly-L-lactic acid screws was not uniform and that of the broken screws was less. Rapid degradation of a poly-L-lactic acid screw because of the relatively highly vascular intertrochanteric region may be another reason (Hollinger and Battistone 1986). We conclude that poly-L-lactic acid screws are best for transfixing an osteotomized acetabulum in rotational acetabular osteotomy. However, they may break when used in femoral trochanteric osteotomy and are probably not suitable for reattaching the intraoperatively osteotomized greater trochanter.

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