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Comparison of polylactide screw and expansion bolt in bioabsorbable fixation with patellar tendon bone graft for anterior cruciate ligament rupture of the knee

A preliminary study

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Abstract In a preliminary study, 24 patients with rupture of the anterior cruciate ligament (ACL) were operated on using implants made of self-reinforced poly-L-lactide (SR-PLLA). The operation method was outside-in bone-tendon-bone reconstruction. In 10 patients the fixation was made with an SR-PLLA screw with a diameter of 6.3 mm, in 12 with an SR-PLLA expansion plug with a diameter of 6.0 mm, and in two cases both implants were used, but these cases were excluded from comparison. The purpose of the study was to evaluate and compare the use and fixation results of these two implants. The follow-up time averaged 3.2 years. Twenty patients attended follow-up. On subjective evaluations, seven of the eight patients following SR-PLLA screw fixation and six of the ten after expansion plug fixation regarded their knee as normal or nearly normal. Arthrometric testing showed the side-to-side difference to average 2.9 mm following SR-PLLA screw fixation and 2.6 mm after expansion plug fixation (NS). Six of the patients had giving-way symptoms (two after screw fixation and four after plug fixation). The pivot shift test was slightly positive in two patients and positive in one patient after SR-PLLA screw fixation, and in three knees slightly positive and in another three knees positive following expansion plug fixation. Radiography showed variation in the location and orientation of the bone channels. Magnetic resonance imaging was performed in seven cases, and in two cases an edema was found in the tendon of the anterior cruciate ligament graft and in six cases the implants were visible. No statistical difference in results between the SR-PLLA screw and SR-PLLA expansion bolt was noted. Fixation with expansion plug seems technically more challenging, with a tendency to inferior results compared to screw fixation. In the absorbable fixation of a bone-tendon-bone graft there are no metallic artifacts on magnetic resonance imaging and no need to remove the fixation material regarding the revision surgery.

Key words Bioabsorbable · Anterior cruciate ligament reconstruction · Polylactide · Self-reinforced poly-L-lactide screw · Expansion plug

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Introduction

Bone-tendon-bone (BTB) autograft has gained substantial popularity in treating anterior cruciate ligament (ACL) rupture of the knee [1, 2]. The Kurosaka interference screw has proved to have greater fixation strength than other metallic fixation methods [3, 4]. In surgery, the dimensions of the bone tunnel relative to the dimensions of the bone block of the graft and of the interference screw affect the fixation strength, and the intra-articular location of the bone tunnels is also critical for a good outcome [5–13]. It has been shown that the enlargement of the bone tunnels seen with an allograft patellar tendon bone graft and achilles tendon graft does not affect the clinical outcome [14]. The formation of femoral bone cysts with certain allograft patellar tendon bone grafts in metallic fixation has been reported [15].

In recent years bioabsorbable implants have become accepted in clinical use [16, 17]. Rods [18], screws [19], and plugs [20] made of self-reinforced poly-L-lactide (SR-PLLA) and self-reinforced polyglycolide have been successfully used in the fixation of cancellous bone fractures and osteotomies. A tissue response that is sometimes associated with the use of polyglycolide implants is not seen with implants made of self-reinforced polylactide [20]. Larger screws, 6.3 mm in diameter, made of SR-PLLA have been developed to be used in patellar tendon graft fixation. Previously, expansion plugs of 4.5 mm in diameter were used, with favorable results [21, 22], and presently a larger plug has also been developed. The fixation strength of the SR-PLLA screw [23, 24] and the SR-PLLA expansion plug [24] in the patellar tendon bone graft has been studied with the bovine cadaver knee and compared to the fixation strength of the Kurosaka screw [23] and AO screw [24]. The fixation strength of the SR-PLLA expansion plug in femoral insertion was 1379 ± 328 N and that of the SR-PLLA screw 1454 ± 230 N [24]. These screws and plugs are absorbed over a few years. The implants do not produce artifacts in magnetic resonance imaging (MRI); however, to avoid this a magnetically negative drill bit and a tap should be used. At present a meniscal arrow made of SR-PLLA can also be used in the arthroscopic technique in treating the meniscal rupture commonly associated with ACL ruptures [25].

The purpose of this preliminary study was to compare and evaluate the use of an SR-PLLA screw and plug in the BTB reconstruction of an ACL rupture. Radiographic findings were also evaluated.

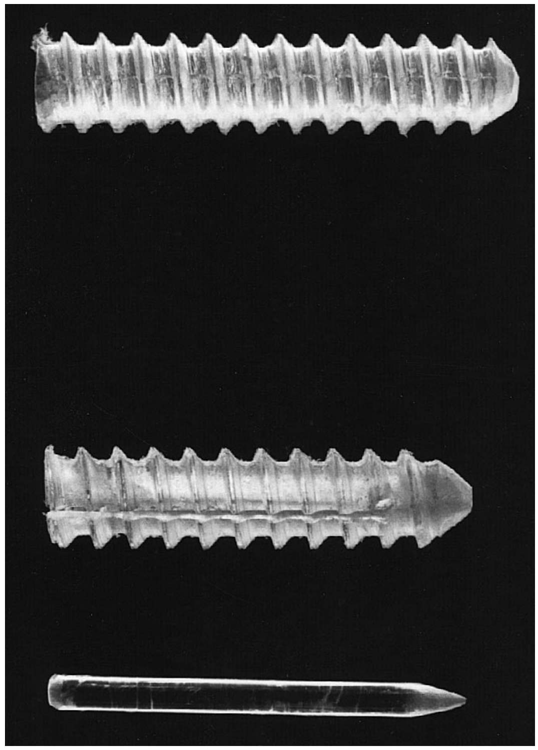

Fig. 1 SR-PLLA screw (*above*) and SR-PLLA expansion plug (*below*) and the 2-mm rod which is hammered to the plug when the plug is in its additional drill hole

Material and methods

Twenty-four patients (mean age 27 years, range 16–43; 15 men, 9 women) with an ACL rupture were operated on in 1990–1994 with BTB graft reconstruction. The implant was inserted into the bone channels from outside of the knee (outside-in technique). The injury type was contact sports in 11 knees, noncontact sports in 6, casual accident in 5, and traffic accident in 2. The mean time from injury to operation was 3 years. Twelve patients were operated on within a year after the injury. In ten knees there was a rupture of the meniscus which was treated with resection of the rupture (one in the screw fixation group at follow-up, six in the plug fixation group at follow-up). In three knees there was a medial collateral ligament rupture which was also operated on (each of these patients attended the follow-up; in all cases the graft was fixed with screws).

A straight vertical incision (5–7 cm) was made to remove the BTB graft and to approach the tibia. Hoffa's fat pad was removed to expose intra-articular structures. A small additional lateral incision was made to drill the femoral bone channel. In ten of the patients an SR-PLLA screw (6.3 mm in diameter) was used to fix the bone block in the bone tunnel (Fig. 1). First, a cannulated drill diameter of 7–10 mm depending on the size of the bone block of the graft was used. After that the BTB graft was pulled to its right place. A special tap was used before insertion of the SR-PLLA screws. The screws were inserted. In 12 patients an SR-PLLA expansion plug of 6.0 mm in diameter was used. After the graft was in its place, additional drilling (diameter 5 mm) was carried out for the expansion plug to the side of the bone channel (parallel) so that the drill takes bone from the bone block and from the host bone. The expansion plug (diameter 6 mm) was introduced to this additional bone channel and a rod 2 mm in diameter was then hammered to the plug, which enlarged it up to 8 mm in diameter and at the same time compressed the bone block to the cancellous host bone. In one patient with screw fixation an additional expansion plug was used in both insertions, and in one patient plug fixation was loose also due to too small bone block, and the fixation was strengthened with an SR-PLLA screw. Postoperatively a cast was used in six patients for 2–4 weeks (three in screw fixation group at follow-up and one in the plug fixation group), and an orthosis was used in 18 of the patients for 2–4 weeks. No thromboembolic prophylactic was used.

The patients were followed up at regular intervals (3 weeks, 6 weeks, 3 months, 6 months, 1 year, 2 years. etc.). Twenty of the patients attended the follow-up check. In eight the fixation was carried out with SR-PLLA screws and in ten with SR-PLLA expansion plugs. The two patients who received both kinds of implants (screw and plug) were excluded from the comparison. Outcome was assessed with a questionnaire (according to the International Knee Documentation Committee with questions concerning the knee function (A, normal; B, nearly normal; C, abnormal; D, severely

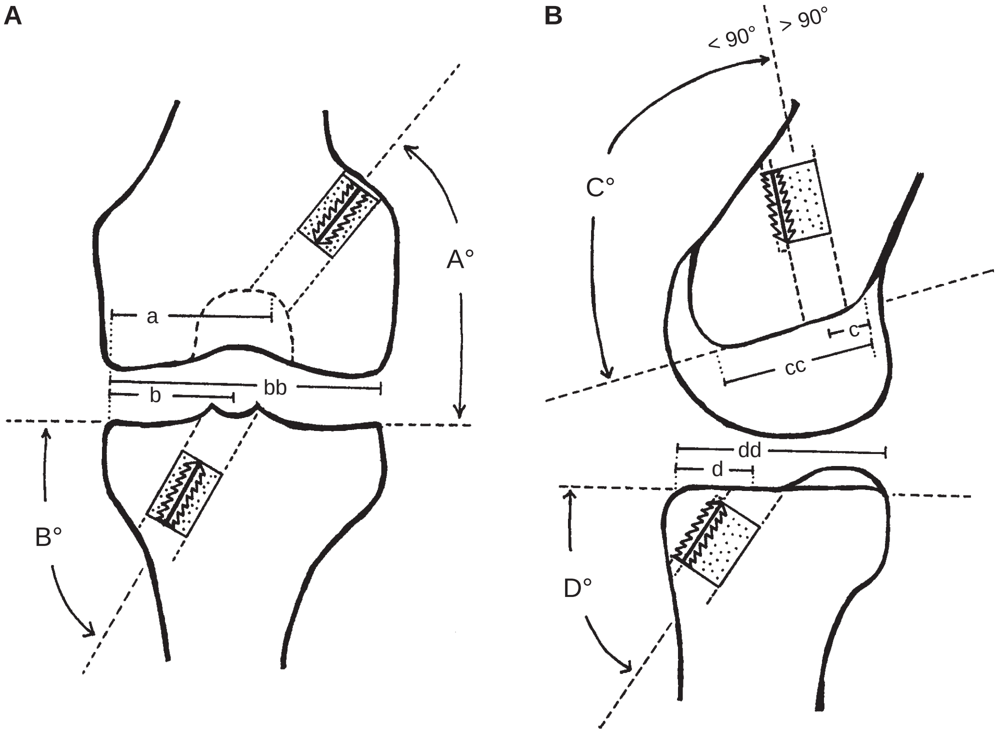

Fig. 2 A, B Fixation with SR-PLLA plug and measurement of the bone channel locations and orientations (see Table 3). In plug fixation, after the bone block is in place in the bone tunnel, another drill channel is made parallel to it and the plug is inserted. After that the rod is hammered into the plug. **A** Anteroposterior view. **B** Side view

abnormal), effect of the present condition of the knee on activity (0–3, 0 = no limitation, 3 = severe limitation), and symptoms according to the activity level (pain, effusion, giving way). The composite scheme for evaluating symptoms was:

- A: No pain, effusion, or giving-way on activity level I (contact sports, sports with loaded rotation, e.g., soccer)
- B: No pain, effusion, or giving-way on activity level II: (noncontact sports with pivoting movements, e.g., tennis, skiing, heavy labor)
- C: No pain, effusion, or giving-way on activity level III (sports without pivoting movements, e.g., jogging and light labor)
- D: No pain, effusion or giving-way on activity level IV (no sports activity, walking)

Range of movement was categorized as follows:

- A: Lack of extension < 3° or lack of flexion 0°–5°
- B: Lack of extension 3°–5° or lack of flexion 6°–15°
- C: Lack of extension 6°–10° or lack of flexion 16°–25°
- D: Lack of extension > 10° or lack of flexion > 25°

Stability was evaluated manually (pivot shift, Lachman, varus rotation, valgus rotation) [26]:

- A: Lachman 1–2 mm or medial or lateral joint opening 0–2 mm, pivot shift –
- B: Lachman 3–5 mm or medial or lateral joint opening 3–5 mm, pivot shift +
- C: Lachman or medial or lateral joint opening 6–10 mm, pivot shift ++
- D: Lachman or medial or lateral joint opening over 10 mm or pivot shift +++

In addition, an arthrometer was used with 20 lb. and maximum posteroanterior manual force with the knee in 20° flexion to measure anteroposterior laxity. The activity level was assessed before injury, after injury, and at follow-up. On radiography the bone tunnel locations were measured from the anteroposterior and side view as a proportion to eliminate differences in the radiography magnification, and the orientation of the bone tunnels was measured in degrees (Fig. 2). The incorporation of the bone plug to the host bone was noted on radiography. Statistical significance was calculated using Student's *t* test, the Mann-Whitney *U* test, and the χ^2 test.

Radiographic evaluation considered the following parameters:

- A_0: angle between tibial plateau and femoral bone tunnel axis (anteroposterior view)
- B_0: angle between tibial plateau and tibial bone tunnel axis (anteroposterior view)
- C_0: angle between Blumensaat's line and femoral tunnel axis (side view)
- D_0: angle between tibial plateau and tibial tunnel axis in side view
- A_d: distance of the femoral bone tunnel orifice from the tibial plateau medial point divided by tibial plateau width (percentage)
- B_d: distance of the tibial bone tunnel orifice from the medial point of the tibial plateau divided by the tibial plateau width (percentage)
- C_d: distance of the femoral bone tunnel orifice from the posterior cortex in Blumensaat's line divided by the length of the Blumensaat's line (percentage)
- D_d: distance of the tibial tunnel orifice from the tibial plateau anterior point in the side view divided by the width of the tibial plateau in the side view (percentage)

Results

Comparison of the SR-PLLA screw and SR-PLLA expansion plug fixations

Mean follow-up time was 3.2 ± 1.3 years. Mean operation time was 74 ± 18 min, and there was no difference in this between the screw and plug fixation groups. Sick leave was

Table 1 Comparison of SR-PLLA screw and plug fixation (the follow-up patients)

	SR-PLLA screw (n = 8)	SR-PLLA plug (n = 10)
Males, females	7, 1	2, 8
Age (years)	27	27
Follow-up (years)	3.6	2.7
Subjective evaluation[a] (n)		
A	3	0
B	4	6
C	1	2
D	0	2
Symptoms (n)		
A	3	2
B	0	1
C	4	4
D	1	3
Range of movement (n)		
A	5	7
B	3	2
C	0	0
D	0	1
Stability (n)		
A	4	3
B	3	3
C	0	1
D	1	3
Return to preinjury activity level (n)	6	3
Preoperative level I (n)	5	5
Giving way symptoms (n)	2	4
Arthrometry (mm)	7.5 ± 2.2 (5–11)	6.4 ± 2.6 (3–11)
Arthrometry, difference between the knees (mm)	2.9 ± 3.0 (0–8)	2.6 ± 1.6 (0–5)

[a] "How does your knee function?"

108 ± 68 days. There were two deep venous thromboses (immobilization with brace) and one transient femoral nerve lesion resulting from the cuff. No synovitis, sinus formation, or infections occurred.

On subjective evaluation, three patients regarded the knee as normal after screw fixation (Table 1). Most of the patients after screw and plug fixation regarded their knee as nearly normal. There was no pain, effusion, or giving-way symptoms in level I activities in five patients, in three following screw fixation, and two after plug fixation. In one patient following plug fixation the range of movement remained restricted to 0°–75° due to patellofemoral arthrosis; the range of movement of the other patients was normal or nearly normal. Knee stability was normal or nearly normal in eight patients following screw fixation and in six following plug fixation. There was no correlation between the length of time between injury and operation and the clinical outcome.

Table 2 Activity level of the follow-up patients preinjury, preoperatively, and at follow-up (n)

Activity level group	Preinjury	Preoperative	Follow-up
I. Contact sports	11	1	6
II. Noncontact sports with loaded rotation	5	1	4
III. Noncontact sports without loaded rotation	2	10	6
IV. No sports activity	0	6	2

I + II vs. III + IV, preinjury–follow-up: $P = 0.06$; I + II vs. III + IV, preoperative–follow-up: $P = 0.01$

In present activity level two patients experienced some giving-way symptoms following screw fixation and four patients after plug fixation. Ten of the examined 18 patients could return to their preinjury activity level after the operation (six fixed with screw, four fixed with plug). In one of these patients the pivot shift sign was positive and in two slightly positive. In these ten patients the average difference between the operated knee and the uninjured knee (side-to-side difference) in arthrometric testing was 1.8 mm (0–6 mm). The postoperative activity level at the follow-up of the I-II and III-IV activity groups was significantly higher than the activity level preoperatively ($P = 0.01$; Table 2). All but one patient (who used a sports orthosis) returned to the activity level I and had a negative pivot shift sign.

In five knees the pivot shift sign was negative, in two slightly positive, and in one positive following SR-PLLA screw fixation. The side-to-side difference was 2 mm or less in five knees, 2–4 mm in one, and more than 4 mm in two. The average the side-to-side difference was 2.9 mm (0–8 mm). In patients with SR-PLLA expansion plug fixation there were four negative pivot shift knees. In three knees the pivot shift was slightly positive and in three knees positive. The side-to-side difference was 2 mm or less in four knees, 2–4 mm in three, and more than 4 mm in two. One patient refused testing. The average side-to-side difference was 2.6 mm (0–5 mm; NS). In both groups the patients who had a positive or slightly positive pivot shift sign showed an average difference between the knees in arthrometric testing of 4.5 mm (3–8 mm), which was significantly higher than in patients with a negative pivot shift, whose average was 1.0 mm (0 mm-2 mm; $P = 0.0002$, t test). There were no statistical differences between those receiving screw fixation and those receiving plug fixation (Table 1).

Three patients showed no symptoms (tenderness, irritation, numbness) at the graft donor site following screw fixation, two had slight symptoms, and three had moderate symptoms. After plug fixation there were slight symptoms in four patients and moderate symptoms in six.

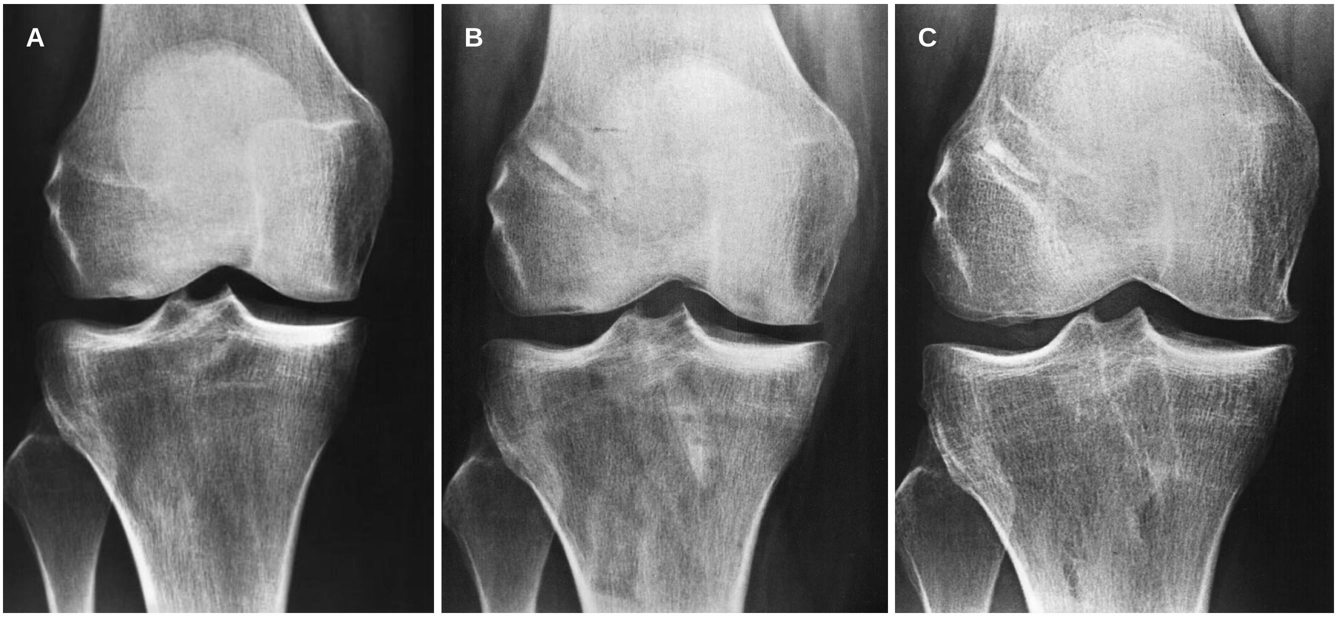

Fig. 3 A–C Radiograph of the knee with SR-PLLA expansion plug used in fixation. Tibial and femoral drill channels were 9 mm in diameter and the drill channel for the plug 6 mm in diameter. **A** Preoperative radiography. **B** Postoperative radiography. **C** At 3-year follow-up, bone plugs are incorporated, and there is sclerosis at the bone channel margins

Two patients from each groups failed to attend follow-up. Two of these (one from each group) had symptomatic instability of the knee, and revision surgery of ACL has been performed. The two patients in whom additional fixation was needed with another implant attended follow-up. The side-to-side difference in one patient was 0 mm, and the knee was stable and nearly normal. The other patient had a 3-mm side-to-side difference, a slightly positive pivot shift and a nearly normal knee.

Radiological analysis

Postoperatively the bone block of the graft was visible on radiography in 13 of 20 cases in both the femur and the tibia, but in four cases only the femoral block was visible (Fig. 3) One year postoperatively the femoral bone block in nine patients and the tibial block in eight patients was incorporated at its place and was not visible, and in eight femoral and five tibial cases the plug was incorporated and could be identified as rounded. In a few cases the incorporation resulted in a funnel-shaped bone channel especially on the tibial side and after plug fixation. Sclerosis was seen 1 year postoperatively at the bone tunnel margins in all cases on the tibial side and in four of five on the femoral side. In the screw and plug fixation groups there was no difference in these findings, but in one patient in the plug fixation group the femoral bone block was loose and was seen to migrate distally. Also in another patient (not at follow-up) following plug fixation the femoral bone block was loose, resulting later in revision surgery.

The tibial tunnel margins were visualized in 14 patients and the femoral tunnel margins in 13 patients in both postoperative and 1-year follow-up radiography. The margin of the tibial tunnel was seen most clearly in the side view and that of the femoral tunnel in the anteroposterior view. The maximum width of the tunnels was measured. In eight patients there was widening of the tibial tunnel (1–8 mm). The overall average change in the width of the tibial tunnel (postoperatively to 1 year) was 2.2 mm (–4 mm to +6 mm). In ten patients there was widening of the femoral tunnel (+1 mm to +7 mm). The overall the difference (postoperatively to 1 year) was 2.5 mm (0 mm to +7 mm).

Of the eight patients with a widened tibial channel, five were operated on using an SR-PLLA plug, which requires another drill channel to the side of the bone tunnel. Of the ten patients with a widened femoral tunnel, six were operated on with a plug.

The orientation of the bone channels were measured in all cases (Fig. 2, Table 3). On anteroposterior radiography the angle from the femoral tunnel (A_0) to the tibial plateau was 27° (0°–85°). In the knees with positive pivot shift the angle seemed to be more transverse (15°) than in the stable knees (38°), but statistically there was no difference (P = 0.25). In the side view the average angle of the femoral tunnel (C_0) was 82° (40°–122°). The angle in the knees with positive pivot shift was steep towards the tendon (67.3°) while that in the knees with negative pivot shift was smoother (97°; P = 0.001). There was no statistical difference in the bone tunnel orientation or location between the SR-PLLA screw and expansion plug groups.

It was also noted that in all knees in which the pivot shift sign was positive the A_0 angle was rather transversal

Table 3 Orientation and location of the bone channels in patients with positive and negative pivot shift sign (see Fig. 2)

	Orientation (°)				Location (%)			
	A_0	B_0	C_0	D_0	A_d	B_d	C_d	D_d
Pivot shift negative	38.0	73.7	96.5	67.0	57.8	44.4	42.7	35.2
Pivot shift positive	15.2	75.4	67.3	68.5	57.5	46.8	30.2	39.9
P[a]	0.25	–	0.001	–	–	–	0.06	0.08

[a] Mann-Whitney *U* test

(< 35°), and that the C_0 angle was steep (< 90°). In only one knee with negative pivot shift was the A_0 angle less than 90° and the C_0 angle less than 35°. In the knees with negative pivot shift the A_0 angle was less than 35° in only five cases ($P = 0.025$), and the C_0 angle was less than 90° in only two ($P < 0.001$).

The location of the tibial tunnel from the anterior edge of the tibia in the side view (D_d) did not differ significantly between the knees with positive or negative pivot shift. It was close to the recommended 40% [10].

In two patients MRI showed edema of the graft. In one case the fixation material could not be seen (3 years after the operation), in two cases the bolts and screws were clearly seen, and in four cases only remnants of the bolts and screws were noted. In one man with fixation with two bolts on the tibial side MRI revealed a lesion close to the proximal tibial bone channel which on radiology seemed to be a granulomatous area. The patient experienced no pain, the clinical outcome was good, and the knee was stable.

Discussion

Metallic fixation of BTB grafts sometimes encounter problems. In femoral fixation the metallic thread can lacerate the tendon when the screw is inserted. It is difficult to find the tibial or femoral screw when a removal is indicated. In revision surgery the metallic screws may cause problems, the screws can be difficult to remove, and they may leave a hole in the bone which must be repaired if the bone tunnel is misplaced. An absorbable fixation method strong enough for early rehabilitation is ideal.

This preliminary study evaluated two new implants. The group receiving plug fixation included more women, but in our opinion this did not affect the results. Cast and orthosis are not currently used postoperatively. Of our 18 patients 13 (72%) considered their knee to be normal or nearly normal. In 12 there were no giving-way symptoms. In nine knees the side-to-side difference was less than 2 mm in arthrometric testing. The overall result was acceptable, the activity level at the follow-up being significantly higher than preoperatively. Arthrometric testing showed no statistical difference between the groups. The pivot shift sign was negative in five of eight patients following screw fixation and in four of ten following plug fixation. The fact that more meniscal resections were performed in the plug fixation group may, at least partly, affect the result. Medial collateral ligament surgery was performed on three patients in the screw fixation group. Follow-up radiography showed the femoral bone block to have migrated distally on the femoral side in two SR-PLLA plug fixations. Fixation with a plug thus seems inferior to that with a screw.

There were technical difficulties in some of the fixations. In one case the screw broke during insertion. Two cases required additional fixation for a stable graft because of the bone block being too small. Fixation with an expansion plug is more challenging than that with a screw, as an additional drill hole is needed and a rod to be inserted into the plug. However, a bovine cadaver study has demonstrated that the fixation strength of the patellar tendon bone graft is more than required both in screw and plug fixations [24]. Technical variation was involved in this series: the angle of the femoral channel varied from 0° to 85° in the anteroposterior view. On anteroposterior radiography the femoral bone tunnel seemed to be more transverse in the knees with a positive pivot shift sign than in stable knees. Graf et al. [13] have demonstrated experimentally that transverse femoral channels produced with the outside-in technique are associated with graft failure in a wear-related damage mechanism [13]. An angle that is too steep may result in graft damage or loosening in the femoral fixation site, and this could be one of the reasons for instability of knees under these circumstances.

Some widening of the bone tunnels was noted in radiography. Plug fixation requires another drill channel parallel to the original channel to the side of it. Neither of these two channels was visible postoperatively on radiography, but they become visible when sclerosis occurs at the bone tunnel margins, which partly explains the noted widening of the bone channels. Possibly the plug should be inserted without a drill channel but using a special instrument.

No synovitis or sinus formation was encountered. In one man radiology revealed a clinically insignificant granulomatous area on the tibial side, representing an inflammatory reaction. In this patient two plugs had been used in graft fixation on the tibial side, and the high dose may have been responsible for the lesion.

Bone channel widening without clinical significance and femoral bone cysts with poor results have been reported in allograft fixation. The causes of these phenomena are thought to be different. Bone channel widening also occurs in autograft patellar tendon bone grafts [14]. The bone tunnels and the bone block were clearly visible in most cases on the postoperative radiography, and the ossification of the bone plug was easy to follow, especially on the tibial side. When the bone plug is incorporated with the host bone, the channel often becomes funnel-shaped, especially on the tibial side.

Follow-up of the graft is easy with both radiography and MRI when absorbable fixation of a BTB graft is used. Although no statistical differences in outcome were noted in the present series between the SR-PLLA screw and the SR-PLLA expansion plug for fixation of the patellar tendon bone graft, there was a tendency to better results with the former.

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