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Radiographic and complication evaluation of 2 different bioresorbable pins in hallux valgus corrective surgery

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Osteotomies to correct hallux valgus are usually secured using metal implants. Their main disadvantage is the need for a repeat surgery for removal of implanted material. Bioresorbable implants would make it possible to overcome this complication. Few studies analyse the results of using bioresorbable pins. The primary objective of this study is to compare hallux valgus correction radiographic results with the use of two types of bioresorbable pins. The secondary objectives are to screen for possible complications related to the use of these bioresorbable pins.

This is a descriptive, retrospective, single-centre study carried out between May 2018 and May 2022 in the orthopaedic surgery department of the Centre Chirurgical Emile Gallé at the CHRU in Nancy (France). The study involved 105 hallux valgus (98 patients) operated on by open double metatarsal and phalangeal osteotomy. Osteotomies were stabilised with resorbable polylactic acid (PLLA) pins (Arthrex® TRIM-IT® drill pin) in 57 cases (53 patients), and with resorbable polylactic acid-polyglycolic acid copolymer (PGLA) pins (Bioretec® ActivaPins®) in 48 cases (45 patients). The efficacy of hallux valgus correction was analysed in terms of changes in preoperative and postoperative radiographic parameters at 1 and 6 months on a weight-bearing foot. Descriptive statistics were used to describe the demographic and radiological parameters of each group.

The mean age was 59.7 years (range 25-81 years) in the PLLA group and 56 years (range 23-78 years) in the PGLA group. The mean preoperative HVA was 30° (range 15-63°) in the PLLA group and 30.8° (range 15-57°) in the PGLA group. The mean preoperative IMA was 14.4° (range 7-30°) in the PLLA group and 13.8° (range 7-20°) in the PGLA group. There was a statistically significant correction of hallux valgus in the PLLA ($p=5.24 \times 10^{-15}$) and PGLA ($p=3.56 \times 10^{-13}$) groups. The mean correction for the hallux valgus angle was 13° in the PLLA group and 12° in the PGLA group. There was no statistically significant difference in hallux valgus correction between the PLLA and PGLA groups, particularly in terms of hallux valgus severity. There was no radiological or clinical complication in the groups related to bioresorbable pins.

The use of bioresorbable pins allows effective stabilisation of osteotomies to correct hallux valgus. There was no significant difference in correction between PLLA and PGLA implants, regardless of the severity of the hallux valgus. We did not observe any obvious clinical or radiological complications related to their use. The use of bioresorbable osteosynthesis material in forefoot surgery seems to offer interesting advantages, providing patients with safer and less invasive treatment solutions.

Keywords: hallux valgus, resorbable pins, PGLA, PLLA, basal metatarsal.

INTRODUCTION

Hallux valgus is one of the most common pathologies of the forefoot in adults. It results from a progressive medial deviation of the first metatarsal Osteotomies to correct hallux valgus are usually secured using metal implants. Their main disadvantage is the need for a repeat surgery for removal of implanted material. Bioresorbable implants would make it possible to overcome this complication. Few studies analyse the results of using bioresorbable pins. The primary objective of this study is to compare hallux valgus correction radiographic results with the use of two types of bioresorbable pins. The secondary objectives are to screen for possible complications related to the use of these bioresorbable pins.

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The use of bioresorbable pins allows effective stabilisation of osteotomies to correct hallux valgus. There was no significant difference in correction between PLLA and PGLA implants, regardless of the severity of the hallux valgus. We did not observe any obvious clinical or radiological complications related to their use. The use of bioresorbable osteosynthesis material in forefoot surgery seems to offer interesting advantages, providing patients with safer and less invasive treatment solutions.. When the initial medical treatment becomes insufficient, surgical correction is indicated with osteotomies to realign the first ray. A large number of surgical procedures have been described with various osteotomy fixation systems, generally metallic[2].

However, metal implants may be associated with specific complications. If they are prominent, they can cause pain, skin irritation or even local infections. These complications can lead to a repeat surgery for the removal of material that has become problematic in 2 to 15% of cases[3,4]. Similarly, hypersensitivity to metals can have local or systemic consequences[5,6].

Since their first uses in ankle traumatology in 1984[7], the use of bioresorbable materials has significantly developed[8-10] and their composition has evolved[8]. They are thought to give good results for osteosynthesis of hallux valgus correction osteotomies[11-15]. Some authors report complications specific to these bioresorbable implant[13,16-18]. However, there are few studies comparing the results of using resorbable pins with different compositions.

Our hypothesis is that the use of absorbable pins for surgical correction of hallux valgus is reliable and free of associated complications. The primary objective of this study is to compare hallux valgus correction radiographic results with the use of two types of bioresorbable pins. The secondary objectives are to screen for possible complications related to the use of these bioresorbable pins.

PATIENTS AND METHODS

Study design

This is a descriptive, retrospective, single-centre study carried out between May 2018 and May 2022 in the orthopaedic surgery department of the Centre Chirurgical Emile Gallé at the CHRU in Nancy (France).

We analysed 205 hallux valgus records (181 patients) over the timeframe in question that were treated by a single senior operator for corrective surgery by double metatarsal and phalangeal osteotomy. The technique used was an external subtraction valgisation basal-metatarsal osteotomy associated with an Akin type phalangeal osteotomy[19]. The inclusion criteria were: adult patients operated on for primary correction by open double metatarsal and phalangeal osteotomy. The exclusion criteria were: paediatric patients, history of prior corrective surgery of hallux valgus on the same foot, corrective surgery by percutaneous technique, absence of associated Akin osteotomy, patients lost to follow-up before 6 months.

Over the period considered, 6 records (4 patients) were excluded because it was a second surgical treatment of hallux valgus, 43 records (34 patients) because the procedure was performed percutaneously, 24 feet (22 patients) because an Akin osteotomy had not been performed, and 27 feet (23 patients) because they were lost to follow-up before the 6th month postoperatively.

The study involved 105 feet (98 patients). 57 feet (53 patients) were stabilised with resorbable polylactic acid (PLLA) pins (Arthrex® TRIM-IT® drill pin), and 48 feet (45 patients) with resorbable polylactic acid-

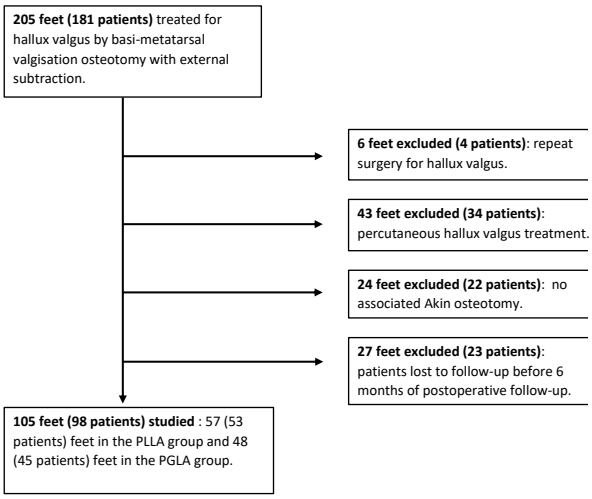

Figure 1. — Flowchart of the study inclusion and exclusion criteria.

Figure 2. — Radiological measurements of the hallux valgus A) Hallux valgus angle (HVA) and inter-metatarsal angle (IMA) measurements. B) Sesamoid position

Sesamoid position	Lateral sesamoid (LS) or medial sesamoid (MS) position in relation to the lateral border of the first metatarsal (M1)
0	LS within the lateral border of M1
1	LS cuts the lateral border of M1
2	LS crosses the lateral border of M1
3	MS cuts the lateral border of M1

polyglycolic acid copolymer (PGLA) pins (Bioretec ® ActivaPins ®) (Figure 1).

The efficacy of hallux valgus correction was analysed in terms of changes in preoperative and postoperative radiographic parameters at 1 and 6 months on a weight-bearing foot. All radiological measurements were carried out by an operator on frontal weight-bearing X-rays taken pre-operatively and at 1 and 6 months post-operatively. The intermetatarsal angle (IMA), the hallux valgus angle (HVA) and the position of the lateral sesamoid or the medial sesamoid in relation to the lateral border of the first metatarsal were compared between the 2 groups. The IMA is the angle between the longitudinal axes of the first and second metatarsals. The HVA is the angle between the longitudinal axes of the first metatarsal and the first phalanx of the hallux (Figure 2). The radiological severity of hallux valgus was assessed by HVA. Hallux valgus was mild if the HVA was less than 20 degrees. It was moderate if HVA was between 20 and 40 degrees. It was severe if the HVA was greater than 40 degrees. Bone consolidation was considered achieved if at least 2 out of 4 cortical bones were in continuity on the front and profile radiographs. The radiographic correction of hallux valgus was assessed by the HVA correction delta between preoperative and postoperative at 1 and 6 months (Δ (HVA °m0-HVA °m1 and Δ(HVA °m1-HVA °m6)). The existence of a secondary displacement was considered significant if the HVA correction delta between the first month postoperatively and the postoperative period at 6 months was greater than 5°. Complications were screened for using radiographs at 6 months post-operative (radiological pseudoarthrosis, osteolysis, resorption granuloma) and by the study of the medical record transcribing the clinical follow-up (scar disunion, osteoarticular infection, complex regional pain syndrome, pin's pain, surgical reintervention, hematoma) (Table I).

Surgical technique

The surgical technique used was the same in both groups except for the implants used. The patients were placed in the dorsal decubitus position, under loco-regional anaesthesia or general anaesthesia. A sterile, single-use calf tourniquet was inflated to 250mmHg. An internal approach from P1 to the base of M1 was performed via arthrotomy. A first exostosectomy of the metatarsal head was performed, followed by release and recentring of the sesamoid strap. An external subtraction valgisation basal-metatarsal osteotomy was then performed, stabilised by 2 retrograde convergent

Table I. — Comparison between the PLLA and PGLA groups in radiological and clinical complication (Fischer test p=1).

Complication		*Total*	PLLA	PGLA
Radiological	Resorption granuloma	0		
	Pseudoarthrosis	0		
	Osteolysis	0		
Clinical	Scar disunion	1	1	
	Osteoarticular infection	0		
	Hematoma	0		
	Pin's pain	0		
	Complex regional pain syndrome	3	1	2
	Surgical reintervention	2	1	1

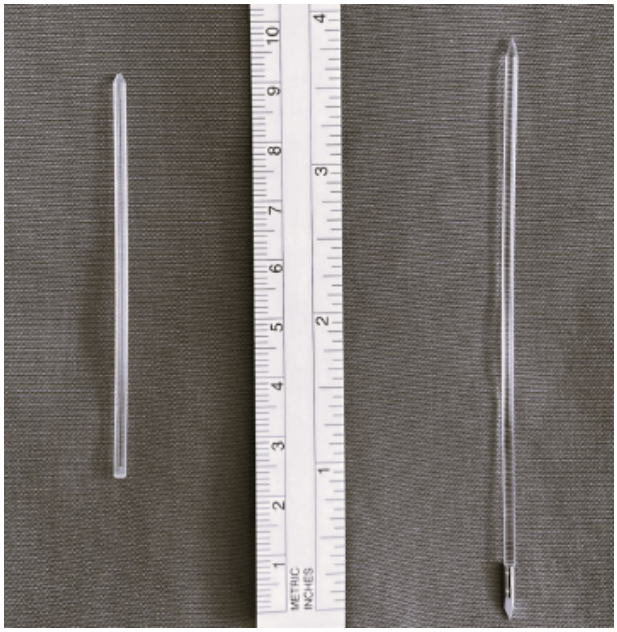

Figure 3. — Resorbable polylactic acid-polyglycolic acid copolymer (PGLA) pins (Bioretec ® ActivaPins ®) on the left. Resorbable polylactic acid (PLLA) pins (Arthrex® TRIM-IT® drill pin) on the right.

bioresorbable pins measuring 2 mm in diameter (Figure 3). Akin varus osteotomy of the first phalanx of the hallux was then performed, stabilised with a 10mm wide nitinol shape memory staple in the PLLA group or a 1.5 mm diameter PGLA pin in the PGLA group. A suture of the sesamoid strap was performed, with closure of the arthrotomy using a transosseous resorbable suture. Finally, subcutaneous and cutaneous sutures were performed using interrupted resorbable sutures. A slightly compressive dressing was put on for the first 12 hours as well as local cryotherapy using a refrigerant boot. Full weight-bearing was authorised for 1 month in a weight-relieving shoe. The patients were then seen in consultation at 1, 3 and 6 months post-operatively for a clinical and radiographic check of the weight-bearing frontal and lateral views (Figure 4*)*.

Statistical analysis

Descriptive statistics were used to describe the demographic and radiological parameters of each group (mean, standard deviation, minimum, maximum). The comparability of the groups was assessed using the Student test for continuous variables, and a Chi-2 test for discontinuous variables. A Student test was carried out to assess:

– The correction of hallux valgus, and therefore a significant change in radiological measurements between preoperative and the 6th month postoperatively in each group.

– The difference in postoperative radiological measurements, particularly in terms of hallux valgus severity, between the PLLA and PGLA groups.

– The significant occurrence of complications in one of the two groups.

A Fisher test was carried out to assess the significant occurrence of secondary displacement at 6 months postoperatively, particularly in terms of hallux valgus severity, between the PLLA and PGLA groups.

The threshold of statistical significance was determined for a p value of less than 0.05 for all analyses.

RESULTS

The PLLA group included 57 feet (53 patients) of which 47 were women and 10 were men. The PGLA

Figure 4. — 59-year-old patient with moderate symptomatic right hallux valgus treated with basi-metatarsal valgisation osteotomy with external subtraction stabilised by 2 bioresorbable PGLA pins. Frontal x-rays of the right foot with weight bearing: a) pre-operatively, b) at 1 month post-operatively, c) at 6 months post-operatively.

Table II. — Comparison between the PLLA and PGLA groups in terms of demographic and radiographic parameters

		PLLA (57 feet)	**PGLA** (48 feet)	**Statistical test**	**p-value**
Demographic parameters	**Age**	58.7±12.8 years	55.7±13.4 years	Student test	p=0.24
	Gender Male: Female	10:47	15:33	Chi2 test	p=0.15
	Laterality Right: Left	28 :29	28 :20	Chi2 test	p=0.45
	Risk factor: cigarette smoking	8	9	Chi2 test	P=0.69
Radiological parameters	**Mild hallux valgus**	4	10	Student test	p=0.14
	Moderate hallux valgus	45	28	Student test	p=0.03
	Severe hallux valgus	8	10	Student test	p=0.43

group included 48 feet (45 patients) of which 33 were women and 15 were men. The mean age was 59.7 years (range 25-81 years) in the PLLA group and 56 years (range 23-78 years) in the PGLA group.

The mean preoperative HVA was 30° (range 15-63°) in the PLLA group and 30.8° (range 15-57°) in the PGLA group. The mean preoperative IMA was 14.4° (range 7-30°) in the PLLA group and 13.8° (range 7-20°) in the PGLA group.

The preoperative position of the sesamoids under the head of the first metatarsal was on average at stage 2 (interval 1-3) in the PLLA and PGLA groups.

There was no statistically significant demographic difference between the PLLA group and the PGLA group (Tables II and III). The two groups were comparable.

There was a statistically significant correction of hallux valgus in the PLLA ($p=5.24 \times 10^{-15}$) and PGLA ($p=3.56 \times 10^{-13}$) groups. Indeed, in each group, there was a statistically significant difference between preoperative and postoperative radiographic measurements at 6 months of IMA, HVA and sesamoid position. The delta correction (Δ) of the AHV is 13° (range -12-42°) ($p=5.24 \times 10^{-15}$) on average in the PLLA group and 12° (range -4-30 °) ($p=3.56 \times 10^{-13}$) on average in the PGLA group. The delta correction (Δ) of the IMA was 3.4° (range -7-16°) ($p=2.65 \times 10^{-9}$) on average in the PLLA group and 3.4° (range -3-10°)

Table III. — Preoperative, 1-month and 6-month post-operative radiographic parameters. Comparison between the PLLA and PGLA groups of hallux valgus radiographic correction *(Δ (AHV°m0- AHV°m6)) (Student test)*

		PLLA	PGLA
Mean **preoperative** (range)	**HVA°**	30 (range 15-63)	30.8 (range 15-57)
	IMA°	14.4 (range 7-30)	13.8 (range 7-20)
	Sesamoid position	2 (range 1-3)	2 (range 1-3)
Mean **1-month post-operative** (range)	**HVA°**	17.6 (range 4-35)	18.5 (range 4-35)
	IMA°	9.3 (range 4-20)	9.1 (range 5-15)
	Sesamoid position	1 (range 0-2)	1 (range 0-2)
Mean **6-month post-operative** (range)	**HVA°**	17 (range 0-60)	18.9 (range 5-36)
	IMA°	10.9 (range 1-25)	10.5 (range 5-17)
	Sesamoid position	1 (range 0-3)	1 (range 0-2)
Hallux valgus correction *Δ (HVA °m0- HVA °m6)* mean (range) *p-value*	**Δ HVA°**	13 (range -12-42) $p=5.24 X 10^{-15}$	12 (range -4-30) $p=3.56 X 10^{-13}$
IMA correction ° *Δ (IMA°m0- IMA°m6)* mean (range) *p-value*	**Δ IMA°**	3.4 (range -7-16) $p=1.94 X 10^{-7}$	3.4 (range -3-10) $p=2.65 X 10^{-9}$
Sesamoid position correction *Δ (stage m0- stage m6)* mean (range) *p-value*	**Δ Sesamoid position**	1 (range 0-2) $p=3.49 X 10^{-18}$	1 (range 0-2) $p=7.3 X 10^{-17}$

Table IV. — Comparison between the PLLA and PGLA groups in the correction of hallux valgus radiographic parameters *(Δ m0- m6)* according to the severity of preoperative hallux valgus *(Student test)*

Δ Radiographic measurements *(m0-m6)*	**Mild hallux valgus** *p-value*	**Moderate hallux valgus** *p-value*	**Severe hallux valgus** *p-value*
Δ IMA°	P=0.97	P=0.65	P=0.09
Δ HVA°	P=0.2	P=0.11	P=0.88
Δ Sesamoid position	P=0.59	P=0.29	P=0.65

(p=$1.94 X 10^{-7}$) on average in the PGLA group (Table IV). The sesamoids were recentred under the head of the first metatarsal by one stage on average for the PLLA group ($p=3.49 X 10^{-18}$) and PGLA (p=7.3 X 10^{-17}) (Table III).

There was no statistically significant difference in hallux valgus radiographic correction between the PLLA and PGLA groups. The comparisons of deltas (Δ) between preoperative and postoperative radiographic measurements at 1 and 6 months of the IMA (p= 0.28), HVA (p= 0.54) and sesamoid position (p= 0.53) were not statistically significant between the PLLA and PGLA groups.

Similarly, there was no statistically significant difference in hallux valgus radiological correction between the PLLA and PGLA groups in terms of hallux valgus severity (Table IV).

There was 1 significant secondary displacement (of more than 5°) of the osteosynthesis in each group.

Complications

We did not observe any statistically significant radiological and/or clinical complication in either group (p=1) (Table I).

The osteotomies all consolidated in each group. We did not observe any osteolysis or radiological granuloma across the course of the bioresorbable pins. No patient experienced pain related to the implants and no patient underwent a new procedure for the removal of the implants.

Two patients experienced a secondary displacement of the metatarsal osteotomy (>5°) but none of these patients underwent a new procedure because they were asymptomatic.

We observed three complex regional pain syndromes (2 in the PGLA group and 1 in the PLLA group) in the recovery period, observed objectively on a bone scan. They gradually resolved with symptomatic medical treatment.

One case of superficial scar disunion was observed in the PLLA group. Healing was achieved with local care without the need for repeat surgery. No infection was observed in our case series.

Two patients underwent post-operative revision surgery. The first in the PGLA group due to a hallux erectus related to retraction of the extensor. It was corrected by an osteotomy of the first phalanx and tendon elongation. The second, in the PLLA group, presented with pain on a hallomegaly of the 2nd ray without dysharmony of the metatarsal pad. It was corrected by a shortening osteotomy of the first phalanx of the 2nd ray.

DISCUSSION

External subtraction valgisation basal-metatarsal osteotomy was described in our department in 1990[19]. It allows for the correction of significant metatarsus varus. The osteosynthesis initially proposed consisted of convergent double pinning using metal pins. It gave good results in correcting deformity. However, it frequently caused discomfort due to the migration of metal pins, leading to repeat operations to remove the material. For this reason, they have been replaced with resorbable pins. The bioresorbable pins stabilise the osteotomy. There is then a gradual transfer of forces from the resorbable pins to the cortical bone as the bone consolidates and the pins degrade. Their fixation in the bone results in an increase in the volume of the pin of 1 to 3% after its insertion into the bone[10]. Their biomechanical properties are close to those of the cortical bone[8]. Conversely, the biomechanical properties of metal implants are different from those of cortical bone and bioresorbable implants. Their resistance and Young's modulus of elasticity are higher. The force transfers between the two are therefore uneven and can cause stress shielding reactions[20,21].

However, bioresorbable implants have disadvantages that are specific to them. First-generation biodegradable polymers such as polyglycolic acid (PGA) or poly-lactic acids such as poly-L-lactic acid (PLLA) were responsible for local inflammatory reactions during implant resorption, causing osteolysis and bone granulomas. Several authors have highlighted these complications associated with implants used to fix osteotomies for the correction of hallux valgu[22,23]. In a series of 94 chevron osteotomies fixed with PGA pins, Pelto-Vasenius *et al.*[18] reported 21 cases (22%) of osteolysis. However, they found no link between osteolysis and the development of infection, avascular necrosis of the metatarsal head, loss of correction of hallux valgus or osteoarthritis. For other teams, the overall incidence of complications due to these first-generation bioresorbable implants is of the order of 5.3%[17]. Furthermore, not all bioresorbable implants are equal in terms of complication rates. There appear to be fewer complications associated with the use of poly-p-dioxanone (PDS) pins, which are close to PGA, compared with PGA pins (3% compared with 55% respectively)[22]. Similarly, there are fewer complications associated with the use of PLLA rather than PGA[17,24]. Finally, larger implants give rise to more resorption granulomas than smaller ones[15].

These side effects led to the development of implants made of poly-lactide-co-glycolic acid copolymer (PGLA). These PLGA implants generate little local inflammation during their degradation[25]. They hydrolyse more slowly and are eliminated from bone tissue after several years[26,27]. As a result, they remain stable for longer in the osteosynthesis process. Several studies have reported the successful use of PLGA implants, notably in paediatric bone surgery[9] and foot surgery[12,13]. The current literature reports rare cases of resorption granulomas and osteolysis with these implants[13,14,16].

In our study, we did not find any osteolysis or radiological resorption granulomas with the use of bioresorbable pins. We did not observe any other complications that could be related to the use of these materials. They offer sufficient mechanical stability to maintain correction until bone consolidation is obtained. Finally, no pin removal was necessary.

Standard radiological images of the foot in front-loading position have all been taken at our center by the same team. However, the accuracy of angular radiological measurements can vary depending on the incidence of the ray[28]. Recent studies on the use of weightbearing conebeam computed tomography seem to show an interest in increasing the precision of angular measurements[29-32]. It also seems to offer advantages in the search for more precision and detailed signs of osteolysis and bone non-union. Our center is not currently equipped to perform this type of imaging.

The main strength of this study lies in the population studied. This was a single-centre, single-operator study with a reproducible operating technique. Our two groups were homogeneous and comparable with large numbers compared to other existing studies. Indeed,

there are few studies comparing the results of different bioresorbable materials in first ray surgery, especially with PLLA and PGLA implants[27,30].

The limits of our study lie in its structure. This is a retrospective descriptive study whose data is derived from patients' medical records. It is deliberately based on a radiographic analysis of the corrections to the deformity, the main objective being to check the reliability of fixation using different absorbable pins.

CONCLUSION

The use of bioresorbable pins seems allows effective stabilisation of osteotomies to correct hallux valgus. We did not observe any obvious clinical or radiological complications related to their use. It would be interesting to carry out new studies including a larger number of patients with radiological follow-up by weightbearing conebeam computed tomography and clinical follow-up by standardized scores. The use of bioresorbable osteosynthesis material in forefoot surgery seems to offer interesting advantages, providing patients with safer and less invasive treatment solutions.

Conflicts of interest: None to report

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