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ARTICLE

Intramedullary fixation with bioabsorbable and osteoconductive hydroxyapatite/poly-L-lactide threaded pin in digital replantation

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ABSTRACT
In digital replantation, Kirschner wire (K-wire) fixation has commonly been used for osteosynthesis. On the other hand, K-wires are often obtrusive because of protrusion from the replanted digit. We describe a case series treated using hydroxyapatite/poly-L-lactide (HPLLA) threaded pins, which are not only bioabsorbable, but also osteoconductive, for osteosynthesis in crushed amputation or comminuted fracture, including distal phalanx amputation. Using an HPLLA threaded pin, 10 digital replantations were performed between July 2016 and April 2018. The precisely cut pin is manually pushed into the fracture site as an intramedullary nail. The pin is first pushed into the distal site, and then into the proximal site, after drilling with a K-wire of the same diameter as the pin. All amputations were crush type, and levels of amputations were Tamai zone I in three cases, zone II in two and zone III in five. Eight of the 10 digits survived. The two digits that did not survive showed venous insufficiency. Bone union of the eight digits was successfully obtained after 9–19 weeks (median 12 weeks). No adverse events occurred such as distortion of the pin, infection or foreign body reaction. The HPLLA threaded pin may be an adequate device to fix fractures in digital replantation.

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Intramedullary fixation; digital replantation; comminuted fracture; hydroxyapatite/poly-L-lactide; threaded pin

Introduction

The Kirschner wire (K-wire) is widely used for bone fixation in digital replantation, but has drawbacks such as protrusion and risks of loosening and wire tract infection. These situations affect range-of-motion exercises and activities of daily living. Internal fixation such as soft wire banding or plate fixation may solve such problems, but those techniques are complicated and often impinge on neurovascular bundles and other soft tissues [1,2].

Intramedullary fixation using a bioabsorbable rod offers advantages in terms of bone fixation, due to the technical simplicity and the lack of any need for removal of foreign materials. Bioabsorbable poly-L-lactide (PLLA) rod has revealed good results in digital replantation, but has not been used for distal phalanx amputations besides comminuted fracture [3,4]. Moreover, PLLA has been reported to cause foreign body reactions during the degradation process [5,6].

Hydroxyapatite/poly-L-lactide (HPLLA) is also bioabsorbable, comprising hydroxyapatite and PLLA, and is already widely used in procedures such as craniofacial, hand and joint surgeries [7,8]. HPLLA is osteoconductive and homogeneously degradable. Homogeneous degradation is an essential condition to minimize foreign body reactions [8]. These properties are also advantageous in the bone union process, providing comparable results to PLLA.

We therefore considered that HPLLA could be applied to distal phalanx or crushed amputations. Bone union can be difficult to obtain in both types because of the comminuted or reduced blood supply. The purpose of this study was to provide a clinical recommendation regarding the use of an HPLLA pin with threaded surface as an intramedullary nail for bone fixation in digital replantation after crushed-type or distal phalanx digital amputation.

Patients and methods

From July 2016 to April 2018, HPLLA threaded pins were applied for intramedullary bone fixation in 10 digital replantations. The HPLLA threaded pins used were 40 mm in length with two standard diameters of 1.5 and 2.0 mm. All patients were male, ranging in age from 21 to 74 years (median 49 years). Injured digits were three thumbs, and two index, three middle, one ring and one little finger. The level of amputation was Tamai zone I in three cases, zone II in two and zone III in five [9]. Injuries were either locally crushed around the amputated site only, or diffusely crushed defined as showing damage to the entire amputated digit (Table 1).

First, the bone stump was trimmed with a bone rongeur and then washed with saline. Both edges of the amputated bone were centrally drilled from the stump with a K-wire of the same diameter as the HPLLA threaded pin (super FIXSORB-MX, known as OSTEOTRANS-MX overseas; Teijin Medical Technologies, Osaka, Japan) (Figure 1(A)). The drilled cavity was made as deep as possible without penetrating the joint or fingertip. The pin was then manually inserted into the cavity of the amputated digit (Figure 1(B,C)). The depth of the cavity in the proximal bone was

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Table 1. Demographics of patients, results of survival and time to bone union.

Case	Sex	Age (years)	Injured digit	Level of amputation	Type of amputation	Replant survival	Time to bone union	TAM (°)[a]
1	Male	63	Right thumb	Zone III	Locally crushed	Survived	11 weeks	100 (55%)
2	Male	49	Left thumb	Zone III	Locally crushed	Survived	13 weeks	112 (62%)
3	Male	21	Left ring finger	Zone III	Locally crushed	Survived	9 weeks	186 (72%)
4	Male	54	Right middle finger	Zone II	Locally crushed	Survived	12 weeks	198 (76%)
5	Male	74	Left middle finger	Zone II	Locally crushed	Lost	Not observed	Not observed
6	Male	49	Right little finger	Zone I	Locally crushed	Survived	12 weeks	222 (85%)
7	Male	29	Left index finger	Zone III	Locally crushed	Survived	10 weeks	180 (69%)
8	Male	49	Left index finger	Zone III	Diffusely crushed	Survived	16 weeks	132 (51%)
9	Male	42	Right middle finger	Zone I	Locally crushed	Survived	19 weeks	244 (92%)
10	Male	56	Left thumb	Zone I	Diffusely crushed	Lost	Not observed	Not observed

[a]Total active motion (TAM) was measured at 6 months after replantation. Percentages compared to normal side are provided in parentheses.

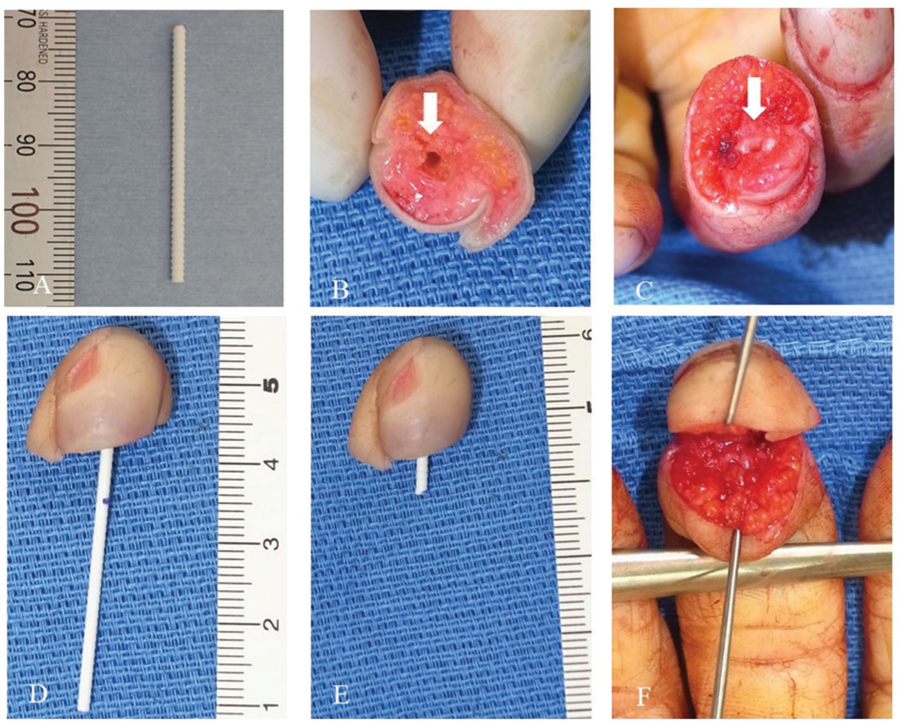

Figure 1. (A) A hydroxyapatite/poly-L-lactide threaded pin, 2.0 mm in diameter and 40 mm in length. (B) Cavity of the distal site (white arrow). (C) Cavity of the proximal site (white arrow). (D) The HPLLA pin is inserted into the amputated digit. (E) The pin is precisely cut to fit the proximal cavity. (F) After osteosynthesis using the HPLLA pin.

measured with a depth gauge. The excess HPLLA threaded pin was cut using Cooper scissors to fit the depth of the proximal cavity. Next, the pin inserted into the amputated digit was pushed into the intramedullary cavity of the proximal bone (Figure 1(D–F)). During this insertion, although slight resistance was sometimes felt, settlement was completed by gently pushing and twisting the pin. Forced pushing was prohibited to avoid distortion of the pin. If the fracture was comminuted in the amputated digit, the bone pieces were gathered around the pin as closely as possible.

In our initial two cases, we added a single oblique K-wire fixation due to concern about rotation of the replanted digit. After osteosynthesis, the process of digital replantation was performed with microsurgical techniques in all cases. In the process of replantation, the flexor tendon was directly repaired by end-to-end suture in Tamai zones II and III. The combination of an early active motion protocol [10] and a passive motion protocol in a dorsal splint [11] was started by postoperative day 7, regardless of the presence or absence of tendon repair. The dorsal splint was placed for three weeks after replantation. At the same time, patients were permitted limited use of the injured hand without the dorsal splint, including the injured digit, in daily life when engaged in activities such as washing the face or hands and putting on clothes. Total active motion (TAM) of affected digits was measured after 6 months postoperatively (Table 1).

Results

The replanted digit did not survive in two cases, due to venous insufficiency. One was a Tamai zone II, locally crushed-type amputation of the left middle finger, and the other was a Tamai zone I, diffusely crushed-type amputation of the left thumb. The other eight replanted digits all survived.

Bone union was followed in the surviving eight cases, and was confirmed according to the presence of osseous bridging callus or trabecular connections on radiographs. Bone union was achieved within 9–19 weeks (median 12 weeks). No cases showed any adverse events such as infection, foreign body reaction, distortion or rotation of the pin.

Figure 2. Case 1. (A) Anteroposterior X-ray view before replantation. (B) Anteroposterior X-ray view after operation. A single oblique K-wire fixation to avoid finger rotation is seen. (C) Anteroposterior X-ray view at 11 weeks after replantation. Complete bone union has been obtained.

Case reports

Case 1

A 63-year-old man sustained a Tamai zone III locally crushed amputation of the right thumb in an accident involving an electric saw (Table 1). An HPLLA threaded pin (diameter 2.0 mm; length 40 mm) was applied for intramedullary fixation of the crushed proximal phalanx of the right thumb. The excess pin was cut to fit the depth of the cavity made by a 2.0-mm K-wire. The pin settled in the amputated digit was pushed into the cavity of the proximal bone with gentle twisting. Oblique K-wire fixation was added because of concern about rotation of the digit, but this was removed after 1 week to allow combined early active and passive mobilization in a dorsal splint of the injured hand. Bone union was radiographically observed 11 weeks after replantation (Figure 2).

Case 9

A 42-year-old male worker sustained a locally crushed Tamai zone I amputation of the right middle finger in an accident involving an industrial press (Table 1). An HPLLA threaded pin (diameter 1.5 mm; length 40 mm) was applied to fix the comminuted fracture in the distal phalanx. Amputated bone was drilled 5 mm in length with a K-wire of 1.5 mm in diameter. The pin was first inserted into the distal bone, then the proximal bone was drilled while avoiding penetration of the distal interphalangeal joint. The pin inserted into the distal bone was precisely cut to fit the drilled cavity. After reduction, a gap of about 1.5 mm was seen, but the amputated site was sufficiently stable to allow early mobilization of the finger. The replanted digit survived and combined early active and passive mobilization in a dorsal splint was started 7 days postoperatively. Bone union was observed 19 weeks after replantation (Figure 3).

Discussion

The HPLLA threaded pin is bioabsorbable and osteoconductive due to the constituent hydroxyapatite. The pin contains 30 weight percent hydroxyapatite particles, reinforced by the original forging process. The bending strength remained at over 200 MPa for up to 24 weeks, providing sufficient time for full bony union, so the HPLLA threaded pin was considered to satisfy the requirements for initial mechanical strength of an intramedullary nail [12]. In addition, HPLLA is gradually and homogenously degraded and absorbed due to the inclusion of hydroxyapatite. In contrast, PLLA is not a composite, and so degrades faster than HPLLA, but the degradate of PLLA tends to remain *in situ* because of the irregularly sized particles and can cause foreign body reactions [13].

In terms of the efficacy of the hydroxyapatite component of HPLLA, a study involving rat femurs found the cavity and drill hole were completely replaced by bone tissue with no adverse events after 5 years [14]. Such consistent replacement represents one of the key advantages of bioabsorbable devices.

The 10 cases we reported were all crushed-type amputations, but the HPLLA threaded pin allowed successful fixation, even for comminuted fractures. Maintaining the alignment of the bone pieces to increase the adhesive surface between the HPLLA pin and bone pieces is important for achieving fixation of the comminuted fracture. Hydroxyapatite on the surface of the HPLLA threaded pin adheres to the bone tissue around the pin. The bone tissue can then gradually enter spaces where the HPLLA has decomposed. Finally, the HPLLA threaded pin is thought to be entirely replaced by bone tissue [15]. To apply the HPLLA threaded pin, a distance of at least 5 mm from the articular surface or end of the distal phalanx is needed. We use the HPLLA threaded pins, applying the 1.5-mm-diameter pins for distal phalanges, and the 2.0-mm-diameter pins for middle or proximal phalanges.

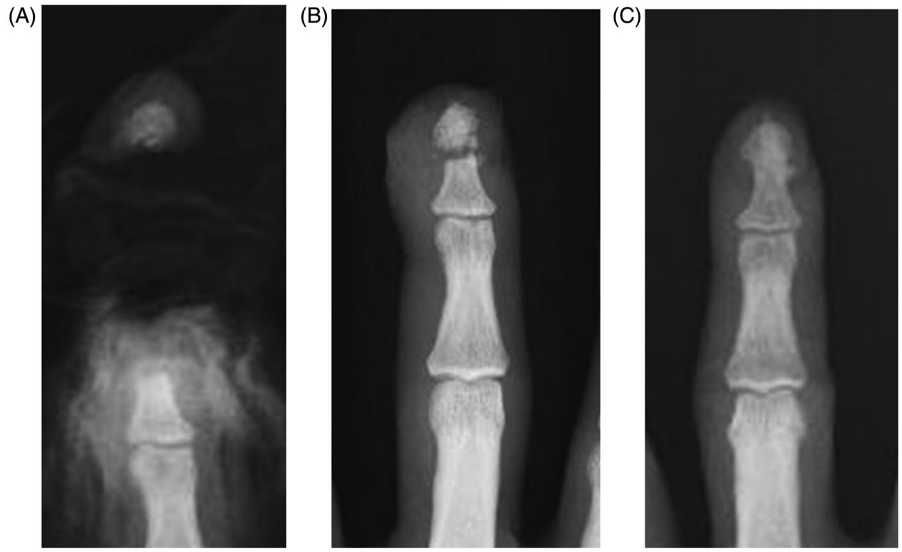

Figure 3. Case 9. (A) Anteroposterior X-ray view before replantation. (B) Anteroposterior X-ray view after replantation. (C) Anteroposterior X-ray view at 19 weeks after replantation. Complete bone union has been obtained.

In repairing the flexor tendon, if end-to-end suture is impossible, especially in Tamai zone II, anchor devices could prove helpful. However, pull-out wiring is not recommendable because of the potential for interference with the pin. Our initial two cases underwent fixation with an additional K-wire because of concerns about digit rotation (Figure 2). Alternatively, bone fixation with two parallel HPLLA pins may be an option to avoid finger rotation, especially of the middle or proximal phalanges. However, in general, the stability of just one HPLLA pin in the replanted digit appears to provide sufficient stability for early active and passive mobilization.

Two key limitations need to be considered when interpreting the results described in this report. One was that the longest follow-up was only 2 years. We were therefore unable to confirm complete absorption and replacement of the HPLLA threaded pin. Foreign body reactions to deposits of HPLLA could potentially occur up until complete absorption. The other was that this small dataset did not demonstrate the specific efficacy of this fixation compared to controls. The risk of rotational instability could not be definitively determined despite our eight cases showing good fixation. Additional oblique K-wire fixation should thus be considered if rotation risk remains even after skin stitches.

An HPLLA threaded pin will not be able to be removed if severe infection spreads within the replanted digit or if an additional operation is needed owing to nonunion. While infection following intramedullary fixation with a bioabsorbable device has not been reported to date, indications for unsanitary injuries or in a compromised host should be considered with caution.

Conclusion

Intramedullary fixation with an HPLLA threaded pin is a simple and useful technique in digital replantation.

Disclosure statement

No potential conflict of interest was reported by the author(s).

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