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Original article

Distal interphalangeal joint arthrodesis with the intramedullary Lync® implant: Prospective study of 22 cases

Arthrodèse interphalangienne distale par implant centromédullaire Lync® : série prospective de 22 arthrodèses

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ABSTRACT

Several techniques have been described for fusion of the distal interphalangeal joint. The intramedullary Lync® implant (Novastep™) may be superior to other options as it is available in straight or bent configurations, does not need to be removed and does not require fingertip incisions. The objective of our prospective study was to determine the effectiveness of finger distal interphalangeal (DIP) arthrodesis with Lync® implants. Between February 2016 and June 2017, we performed 22 cases of DIP arthrodesis with this implant. Pain was assessed with a visual analog scale, the joint range of motion was measured using a digital goniometer, the pulp to palm distance was measured using a ruler, and the QuickDASH Questionnaire was filled out. AP and lateral X-rays were used to look for secondary displacement at 3 weeks and joint fusion at 6 weeks, 3 months, 6 months and 12 months. The primary endpoint was clinical and radiological union defined as the presence of trabecular bone bridges across the arthrodesis site. The patients' mean age was 57.8 years ± 9.9 (36–73). The mean follow up was 10 months ± 4.9 (3–15). The pre-operative pain level was 6/10 ± 2.4 (0–10) and it was 1.3/10 ± 1.7 (0–6) at 3 months post-operative ($P < 0.0001$). The mean pre-operative DASH Score was 64/100 ± 16 (15.9–86.3) and it was 19/100 ± 14 (2.3–45.4) at 3 months post-operative ($P < 0.0001$). At the end of the study, 20 DIP joints were fused (91%); 18 joints had fused at the 3 month follow-up visit (82%). Three cases required reoperation. DIP arthrodesis with the Lync® implant resulted in DIP fusion in 91% of cases. When fusion was achieved, it provided pain relief and improved function. The Lync® implant is less bulky than other arthrodesis devices and does not need to be removed.

Mots clés :
Articulation interphalangienne distale
Main
Arthrodèse

RÉSUMÉ

De nombreux moyens d'ostéosynthèses ont été décrits pour fixer les arthrodèses interphalangiennes distales (IPD). Nous avons voulu évaluer l'efficacité d'un nouvel implant intra-osseux qui aurait pour intérêt de pouvoir varier l'angulation dans le foyer d'arthrodèse, de ne pas nécessiter d'ablation de matériel et d'éviter les contre-incisions pulpaires. L'objectif de l'étude était de déterminer l'efficacité de l'arthrodèse des IPD digitales par les implants intra-osseux Lync® (Novastep™, OrangeBurg, NY, USA). Nous avons suivi 22 arthrodèses IPD réalisées entre février 2016 et juin 2017. La douleur était évaluée par l'échelle visuelle analogique (EVA), les amplitudes articulaires étaient mesurées en degrés au goniomètre (Goniomètre digital Erler Zimmer), la distance pulpe-paume était mesurée à l'aide d'une règle en millimètres, un score de qualité de vie QuickDASH était réalisé. Des radiographies de face et de profil cherchaient un éventuel déplacement secondaire à 3 semaines et les signes de consolidation à 6 semaines, 3 mois, 6 mois et 12 mois. Le critère de jugement principal était la consolidation clinique et

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radiologique définie par la présence d'un pont osseux interfragmentaire. L'âge moyen des patients était de 57,8 ans ± 9,9 (36–73). Le suivi moyen était de 10 mois ± 4,9 (3–15). L'EVA pré-opératoire de la douleur était de 6/10 ± 2,38 (0–10) et à 3 mois 1,3/10 ± 1,7 (0 6) ($p < 0{,}0001$). Le score Quick DASH moyen préopératoire était de 64/100 ± 16 (15,91–86,36) et à 3 mois 19/100 +/ 14 (2,27–45,45) ($p < 0{,}0001$). À la fin de l'étude, 20 arthrodèses étaient consolidées soit 91%, 18 arthrodèses l'étaient déjà au recul de 3 mois soit 82%. Trois arthrodèses ont nécessité une reprise chirurgicale et une pseudarthrodèse a été notée mais le doigt était asymptomatique. L'arthrodèse IPD par implant intra-osseux Lync® a permis l'arthrodèse IPD dans 91% des cas. En cas de fusion, il a amené l'indolence et amélioré les scores fonctionnels. Il permet d'éviter l'encombrement du matériel d'ostéosynthèse et son ablation.

1. Introduction

Arthrodesis is the preferred treatment for addressing symptomatic degeneration of finger distal interphalangeal (DIP) joints. It is often indicated for primary or post traumatic osteoarthritis, locked dislocations, sequelae of mallet finger or lacerations of the flexor digitorum profundus (FDP) tendon. The arthrodesis is typically performed by decortication of the joint surfaces and then bone fixation. However some surgeons perform this procedure percutaneously without decortication when the joint space is completely gone [1,2], or use arthroscopy to decorticate the subchondral bone [3]. Several bone fixation methods can be used: K wires [4], cannulated screws [5], cerclage wire [6], absorbable pin [7], plate [8]. Double threaded screws, whether cannulated or not, help to compress the fusion site. Use of a screw implies a straight fusion, as it is nearly impossible to achieve fusion in slight flexion. If the screw head is not buried, its presence in the subungual area can cause discomfort, often leading to its removal.

Intramedullary implants for small joint arthrodesis have been introduced more recently [9,10]. Advantages of these devices are that they are less bulky in the distal phalanx, allow the arthrodesis site to be fixed in flexion and do not need to be removed. The same type of device is used in toe interphalangeal joints [11,12]. Very good outcomes have been reported in terms of bone fusion [13–16] (Table 1). Among these implants, the titanium Lync® implant (Novastep, Orangeburg, NY, USA) is unique in that the phalangeal bone anchoring is established through controlled mechanical deformation, instead of shape memory like most intramedullary implants. This makes it easier to compress the phalangeal segments being fused. Its dimensions are amenable to the size of distal phalanges, which was confirmed in morphometric studies of the proximal interphalangeal (PIP) and DIP joints of the fingers [17,18].

Table 1
Outcomes in published studies of toe PIP fusion Fusion rate in published studies of toe PIP arthrodesis.

Implants and materials	Authors	Numbers of patients	Fusion rate
Smart Toe® (Stryker) Nitinol	Sandhu 2013	35	93.8%
	Khan 2014	82	96.3%
	Obrador 2018	94	96.8%
Pro Toe® (Wright Medical) Stainless Steel	Scott 2013	63	93.6%
	Basile 2015	60	85.0%
Toegrip® (Synchro Medical) Polyketone	Averous 2015	142	83.0%
Ipp On® (Integra) Stainless Steel	Coillard 2014	117	83.8%
TenFuse® (Solana Surgical) Bone graft	Obrador 2018	27	96.3%

The aim of our study was to determine the reliability of finger DIP joint fusion performed with Lync® implants. The secondary objectives were to determine the main complications of this technique and compare our findings with published results of DIP arthrodesis.

2. Patients and methods

2.1. Study population

We carried out a prospective study of 22 DIP arthrodesis cases performed between February 2016 and June 2017 in 19 patients. There were 17 women and 2 men. Two patients were left handed and 17 were right handed. The mean patient age was 57.8 years ± 9.9 (36–73). Eleven patients were retired, and none performed manual labor. Six patients were smokers. Twelve of the 17 women and both men wanted their finger fused in flexion.

The patients were operated at two hospitals by three different senior surgeons. Bone fixation was accomplished with an intramedullary Lync® implant (Novastep, Orangeburg, NY, USA), which is available straight (0°) or bent (10°).

The following inclusion criteria were used:

- symptomatic DIP joint destruction or
- symptomatic chronic DIP instability.
- The following exclusion criteria were applied:
- history of surgical treatment at the DIP joint
- history of musculoskeletal infection at the DIP joint
- history of surgical treatment at the PIP joint or the metacarpophalangeal joint
- diabetes or immunosuppression

2.2. Surgical technique

The surgical procedure was performed on an outpatient basis under regional anesthesia with an arm tourniquet inflated to 250 mm Hg. A dorsal "H" incision was made, and the terminal slip of the extensor mechanism was cut transversely. Any marginal osteophytes were resected with bone nibblers. The bone cuts at the base of the distal phalanx (P3) and the head of the middle phalanx (P2) were done with an oscillating saw, orthogonal and perpendicular to the P2 and P3 axis. The intramedullary cavity of the P2 head and P3 base were prepared using dedicated instrumentation (Fig. 1). The Lync® implant is available in a single size with two different offsets: 0° and 10°. The offset was chosen based on the patients' functional or esthetic requirements. Once the implant is inserted, its primary stability is achieved by controlled mechanical deformation using the instrumentation provided by the manufacturer to spread the arms of the implant, which rest against the phalangeal cortical bone. Compression of the fusion site was

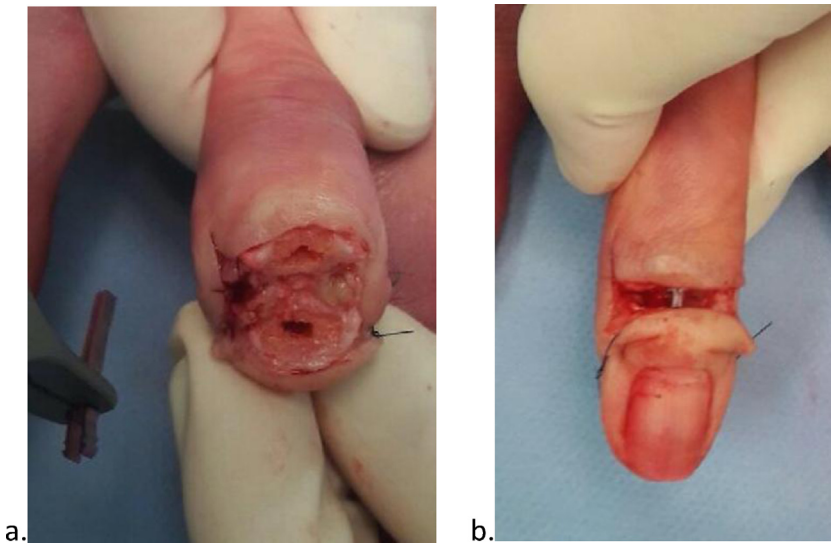

Fig. 1. Preparation of intramedullary cavities (a). Implant in place before compression is applied (b).

accomplished by external maneuvers that brought together and compressed P3 on P2. Fluoroscopy was used to verify the positioning of the intramedullary implant. The skin was closed with simple interrupted non absorbable sutures. Standard AP and lateral X-rays views were taken immediately post-operative. The wrist was immobilized for 3 weeks using a volar splint.

2.3. Follow-up

The patients were reviewed in our offices at 3 weeks, 6 weeks, 3 months, 6 months and 12 months post-operative by an independent examiner (PA) who was not involved in the surgical procedures. Pain was evaluated on a visual analog scale (VAS) as being between 0 (no pain) and 10 (worst imaginable pain); joint range of motion was measured in degrees using a digital goniometer (Erler Zimmer); pulp to palm distance was measured using a ruler with millimeter increments between the tip of the operated finger and the distal palmar crease; the QuickDASH [19] Score was calculated to assess quality of life. AP and lateral X-rays were taken to look for secondary displacement at 3 weeks and evidence of fusion at 6 weeks, 3 months, 6 months and 12 months. The radiological sagittal fusion angle was measured in degrees on a strict lateral view as the angle between the central axis in the middle and distal phalanx. For each surgery, we recorded the duration of the procedure and the offset of the implant used. The primary endpoint was clinical and radiological fusion defined as regression of pain and presence of a bone bridge between fragments.

2.4. Statistics

Continuous quantitative variables were summarized by their mean and standard deviation, while qualitative variables were summarized by their counts and percentages. The normality of the distributions was evaluated on histograms and with the Shapiro–Wilk test. Comparisons of clinical numerical data over time were done using the Wilcoxon non-parametric test.

3. Results

3.1. Population

The mean follow up was 10 ± 4.9 months (3–15). The surgical indication was made for primary osteoarthritis in 14 cases, post traumatic osteoarthritis in 1 case, locked dislocation in 2 cases, sequelae of FDP tendon laceration in 2 cases and sequelae of mallet finger in 2 cases. One procedure was done on the thumb, 7 on the index, 5 on the middle finger, 7 on the ring finger and 3 on the little finger. The mean tourniquet time was 24.8 min ± 8.53 (10–40). Two patients were excluded because they had a history of DIP arthritis and one other patient was excluded because he had undergone PIP arthroplasty. The characteristics of the study population are given in Table 2.

The pre-operative VAS for pain was 6/10 ± 2.38 (0–10) and at 3 months it was 1.3/10 ± 1.7 (0–6) ($P < 0.0001$). The mean pre-operative QuickDASH was 64/100 ± 16 (15.91–86.36) and at 3 months it was 19/100 ± 14 (2.27–45.45) ($P < 0.0001$). The mean post-operative pulp to palm distance was 10.88 ± 15.23 mm (0–50); 11 patients had a pulp to palm distance of 0 (Fig. 2). The mean pulp to palm distance was 12 mm (0–50) for fusion cases with the 0° implant and 10.4 mm (0–30) for fusion cases with the 10° implant.

3.2. Fusion

At 15 months' follow up, 20 of the cases had achieved fusion, or 91%. At 3 months' follow up, 18 of the cases had achieved fusion, or 82%, while 4 cases had a non-union. Of the 22 implants inserted, 16 had a 10° offset and 6 were straight. The mean post-operative fusion angle on lateral X-rays was 9.3° (−3 to 19). In fingers with a 10° offset implant, the post-operative fusion angle was 10.68° (0–19°); it was 5.66° (−3 to 11°) with the straight implants.

3.3. Complications

There were four cases of delayed fusion. Three patients were re-operated because of pain and signs of osteolysis around the implant, without clinical signs of sepsis. A new round of bone fixation was carried out with K wires and autograft bone (Fig. 3).

One female patient underwent revision at 6 weeks post-operative because of the appearance of bone resorption around the implant. Microbiology samples were positive for *Staphylococcus epidermidis* and *Staphylococcus aureus*; treatment for non-union combined with appropriate antibiotics resulted in healing.

A second female patient, smoker, underwent revision at 12 weeks because of pain; cortical perforation of the implant was discovered on X-rays. At 16 weeks post-operative, her finger was no longer painful, but no signs of interfragmentary bone bridging were visible on x rays.

Table 2
Characteristics of the patients in our study. FDP: flexor digitorum profundus.

Age	Sex	Follow up (months)	Finger/Side	Indication	Fusion at 3 months on radiographs	VAS pain	Surgical revision
36	F	15	4R	locked dislocation	YES	0	NO
51	F	15	3R	osteoarthritis osteoarthritis	NO	6	YES
			4R		YES	0	NO
62	M	14	4L	FPD laceration	YES	0	NO
55	F	10	2L	osteoarthritis	YES	0	NO
57	F	11	2L	osteoarthritis	NO	0	YES
61	F	10	3R	osteoarthritis osteoarthritis	YES	0	NO
			4L		YES	4	NO
52	F	11	4L	osteoarthritis	YES	0	NO
59	F	12	2R	osteoarthritis	YES	0	NO
54	M	6	2L	FPD laceration	YES	0	NO
64	F	11	3R	osteoarthritis	YES	0	NO
62	F	15	3R	osteoarthritis osteoarthritis	YES	1	NO
			4R		YES	1	NO
73	F	14	5R	sequelae mallet finger	YES	0	NO
64	F	16	2R	osteoarthritis	NO	2	NO
66	F	13	5L	osteoarthritis	YES	4	NO
65	F	5	2R	osteoarthritis	NO	4	YES
39	F	4	1R	FPD laceration	YES	3	NO
73	F	3	3R	osteoarthritis	YES	1	NO
65	F	3	2R	locked dislocation	YES	0	NO
40	F	4	4R	sequelae mallet finger	YES	0	NO

Fig. 2. AP (a) and lateral (b) radiographs of distal interphalangeal fusion with a bent Lync® implant in the middle finger. Clinical outcome in extension (c) and flexion (d).

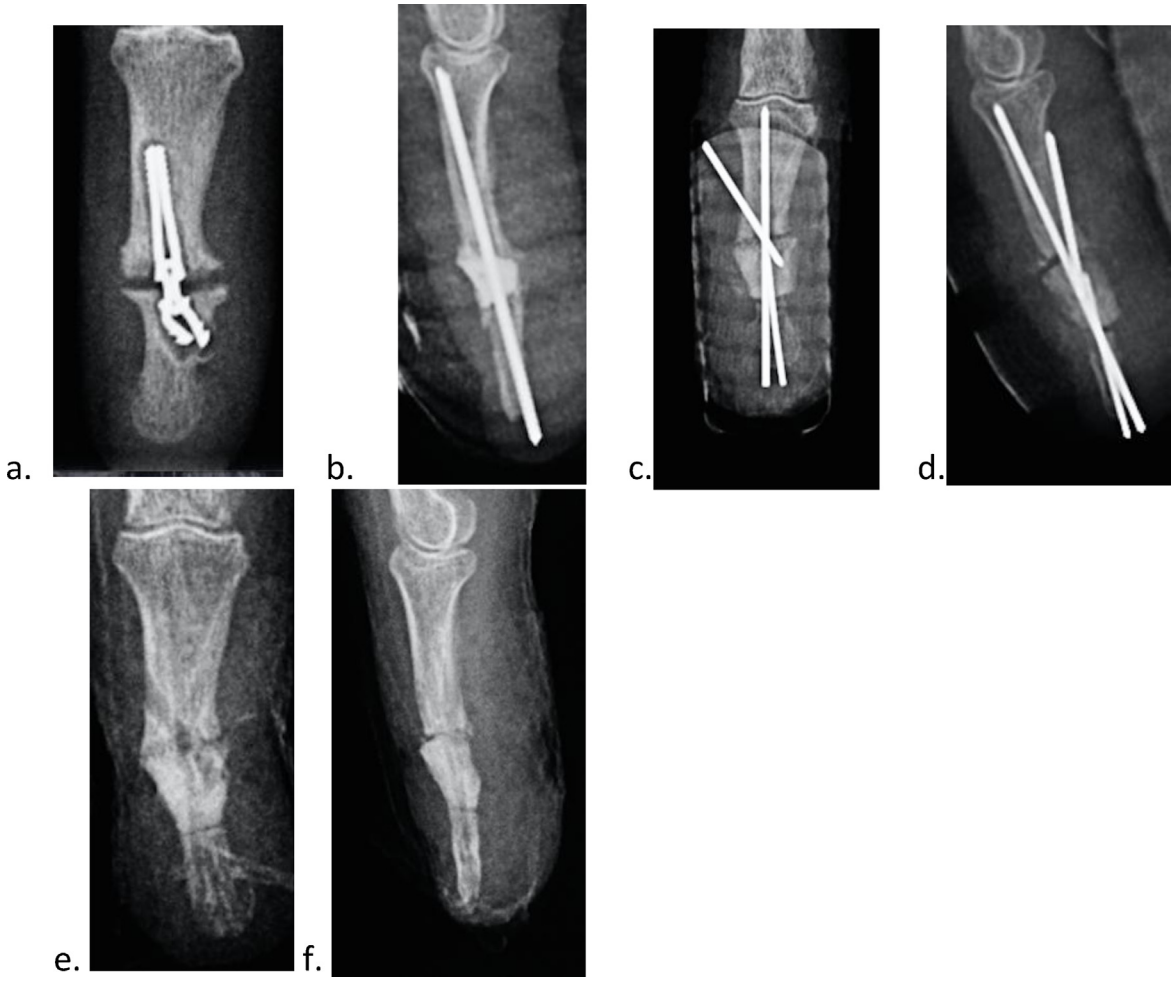

Fig. 3. Delayed fusion in a 51 year old female patient (a). Revision procedure in which the implant was removed, and a cement spacer inserted (b). Surgical revision with K wire fixation and iliac crest autograft (c,d). AP and lateral radiographs at the 15 month follow up visit; the patient no longer had pain in her finger (e, f).

Lastly, a third female patient was reoperated at 10 weeks post-operative because of pain and cortical perforation visible on X-rays. Treatment for non-union was carried out; microbiology samples were positive for *Staphylococcus epidermidis* and *Staphylococcus lugdunensis*. She required an extended course of antibiotics until the arthrodesis site fused.

One additional patient had delayed fusion that was asymptomatic, thus she did not require surgical revision.

4. Discussion

4.1. Clinical outcomes

In our study, arthrodesis using an intramedullary implant significantly reduced pain and improved the functional scores, similar to other fixation methods. Jakubek et al. reported the QuickDASH improved from 37 to 14.5 after 1 year with nitinol implants (X Fuse®, Stryker) [20]. Spies et al. reported a mean QuickDASH Score of 27 after fusion with retrograde screw fixation [21]. In our study, the mean post-operative pulp to palm distance was 10.88 ± 15.23 mm (0–50). Eleven patients had a pulp to palm distance of 0. Three patients were operated for sequelae of FDP tendon lacerations and one had PIP related pre-operative stiffness that was not resolved after DIP fusion. Some patients also had associated PIP osteoarthritis.

4.2. Fusion rate

Kocak et al. reported an 89% fusion rate at 3 months in 64 cases of arthrodesis with cannulated Herbert screw [22], Matsumoto et al. reported 97% fusion with a retrograde screw [23], Arata et al. reported 100% fusion with an absorbable pin at 8 weeks [7], and Iwamoto et al. reported a 96% fusion rate at 3 months [24] (Table 3). In a meta analysis, Dickson et al. reported a 96.1% fusion rate out of 492 arthrodesis cases performed with a screw and a 91.6% fusion rate for the 346 cases performed with K wires [5]. The fusion rate with the intramedullary Lync® implant appears to be equal to that with other fixation methods.

4.3. Other intramedullary implants

Three studies have looked at the intramedullary X Fuse® implant for finger DIP fusion: Seitz et al. reported a 96% fusion rate in 32 cases [10], Jakubek et al. reported a 95% fusion rate at 14 months in 24 patients [20] and Ameline et al. reported a 89% fusion rate at 3 months and 95% at 11 months in 32 patients. The fusion rate with the Lync® implant in our study appears equal to that of the X Fuse® implant. However, all of these studies included only a small number of cases, thus larger randomized studies are needed to validate the best fixation method.

Table 3
Outcomes of various published DIP fusion techniques. IM: intramedullary.

Fixation method	Author/year	Number of patients	Fusion rate	Complication rate
X fuse IM implant	Seitz et al. 2013	21	96%	4% non-union
Cannulated screw	Kosak et al. 2011	64	95%	5% non-union 6% delayed union 8% hardware removal
K wires	Stern et al. 1992	111	88%	13% non-union 4.5% infection 4% secondary displacement 3% dorsal skin necrosis
Oblique screw	Iwamoto et al. 2013	28	96%	3% fracture 3% infection
Retrograde screw	Matsumoto et al. 2013	89	97%	3% non-union 9% additional K wire fixation 1% screw protrusion
Absorbable pin	Arata et al. 2003	22	100%	0%
Plate	Mantovani et al. 2008	15	100%	13% plate removal

4.4. Fusion position

The different offsets of the Lync® implant (0° or 10°) allowed us to set the arthrodesis in slight flexion when requested by the patient. In our study, the post-operative radiological fusion angle averaged 9.3° with 16 offset implants and 6 straight implants. Ameline et al. reported a 8.7° change in the fusion angle in the sagittal plane between the immediate post-operative X-rays and the final fusion position with 0°, 15° and 25° X Fuse® implants, which casts doubt on the primary stability of shape memory implants [25]. Anchoring by controlled mechanical deformation may improve the primary stability of the arthrodesis relative to shape memory implants.

4.5. Delayed fusion

There were four cases of delayed fusion in our study: three required surgical revision with autologous bone graft and K wire fixation. One cases did not require revision since the patient was asymptomatic. Jakubek et al. described 2 cases of failed fusion in 24 patients treated with a nitinol implant [20]; Ameline et al. described one case of non-union and one of fixation failure [25].

Analysis of our fusion failures reveals two cases of intra*operative cortical breach – one proximal in P2 and one distal in the radial side of P3 – leading to non-union and surgical revision. The intramedullary technique has additional steps to prepare the recess for the Lync® implant. We suspect there is a learning curve with the instrumentation, especially that these two cases occurred early in our series (2nd and 5th cases) and did not happen again later on. Despite the implant's compatibility with the size of distal phalanges, the fact this implant and its instrumentation were initially developed for foot applications may have contributed to these cortical breaches.

4.6. Infection related complications

Brutus el al. reported 4 infections out of 27 cases with the Acutrak® screw (Acumed™) [26]. Stern and Fulton reported a 4.5% infection rate after arthrodesis with K wires [27]. In our study, when two cases of delayed fusion were revised, microbiology samples were positive, and the patients were treated with appropriate antibiotics. These two patients underwent non-union treatment in which autologous iliac crest bone graft was stabilized with K wires. Radiological fusion was observed in one of the two cases of iliac crest grafting at 3 months, while the other was asymptomatic in tight non-union.

4.7. Other complications

Dickson et al. reported a 1.6% and 1.8% rate of skin necrosis after arthrodesis with cannulated screw and K wires, 1.6% fracture rate with screw fixation and 1.8% dysesthesia rate [5]. In our study, we found no signs of fingernail deformity, skin complications or fracture. Using a single dorsal incision that does not extend into the fingertip may help to prevent dysesthesia.

4.8. Bulkiness of fixation devices

Several authors reported the fixation devices perforated the cortex: 1% for Matsumoto et al. [23], 8% for Kocak et al. [22], 7% for Stern [27], 10% for Lister et al. [28]. In their meta-analysis, Dickson et al. reported a 2.2% rate of hardware protrusion and that 5% of patients required removal out of 326 arthrodesis cases with screw fixation [5].

In addition, two anatomical studies of distal and middle phalanges have shown that certain compression screws are not well suited to the dimensions of P3 [22,23]. Fixation of intramedullary implants in the P3 base helps to avoid transfixation of the phalangeal tuberosity and would be less bulky for the distal phalanx. In our study, none of the implants had to be removed because of device related discomfort; the only cases in which the implant was removed were due to delayed fusion.

5. Conclusion

DIP arthrodesis with the intramedullary Lync® implant leads to good outcomes in terms of pain, functional scores and bone union. The fusion rate was 91% in our study. This method gets around certain complications encountered with other fusion techniques: implant bulkiness, need to remove implant, skin problems, fingertip dysesthesia. The phalanges must be prepared meticulously to avoid cortex penetration and risk of non-union. While our findings are encouraging, randomized studies are needed to validate the superiority of a certain fixation method relative to others.

Disclosure of interest

CF – Clinical trials: co-investigator, non-primary researcher, study collaborator for Hospital & Healthcare Consulting Conferences: invited speaker by Allergan, Baxter, IPSEN, MERZ
GS – Consultant for Novastep Inc.
ML – Consultant for Exatech
AA – Consultant for KeriMedical and Newclip Technics
The other authors declare that they have no competing interest.

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