Foot and Ankle Surgery 28 (2022) 418–423

Contents lists available at ScienceDirect

Foot and Ankle Surgery

journal homepage: www.elsevier.com/locate/fas

Fiber-reinforced fixation implant for proximal interphalangeal joint arthrodesis shows implant bio-integration at 1-year follow-up

Jurij Štalc[a,*], Luke D. Cicchinelli[b,c], Stuart Miller[d], Martinus Richter[e]

[a] Valdoltra Orthopedic Hospital, Ankaran, Slovenia
[b] Clínica Cándido Guillén, Vigo, Spain
[c] Clínica Pereira, Vigo, Spain
[d] Department of Orthopaedic Surgery, MedStar Union Memorial Hospital, Baltimore, MD, USA
[e] Department for Foot and Ankle Surgery, Rummelsberg and Nuremberg, Germany

ARTICLE INFO

Article history:
Received 23 April 2021
Received in revised form 8 June 2021
Accepted 20 June 2021

Keywords:
Arthrodesis
Fusion
Continuous mineral fibers
Hammertoe
Degradation
Bio-integration

ABSTRACT

Background: A new bio-integrative fiber-reinforced implant (OSSIOfiber® Hammertoe Fixation Implant, OSSIO Ltd., Caesarea, Israel) was developed for proximal interphalangeal joint (PIPJ) correction-arthrodesis. The main purpose of this clinical study was to assess implant bio-integration at 1-year follow-up.

Methods: Twenty-four patients, previously treated for a Hammertoe deformity using the bio-integrative, fiber-reinforced implant, were enrolled in this follow-up study. One-year follow-up included clinical examination, patient reported outcomes, radiographs, Magnetic Resonance Imaging (MRI) and bio-integration scoring.

Results: Proximal interphalangeal joint (PIPJ) radiographic fusion rate was 92% (n = 22). MRI was analyzed for 24 (100%) patients. In 100% of patients (n = 24), the border between implant and surrounding tissue was scored as partially visible. There were no cyst formation or fluid accumulation findings. Mild bone edema was detected in 29% (n = 7) and is attributed to the chronic distribution of forces due to chronic abnormal gait and pasture. None of the edema findings were considered as adverse implant-related finding. The mean bio-integration score was 7.71 ± 0.46.

Conclusions: This study demonstrates safe bio-integration of the newly developed fiber-reinforced implant at 1-year follow-up without negative side effects.

1. Introduction

Kirschner wire (K-wire) fixation is considered the standard method for proximal interphalangeal joint (PIPJ) correction arthrodesis for correction of hammertoe deformity [1–4]. K-wire fixation has several limitations, such as lack of rotational stability (as usually only one wire is used), K-wire site infection, wire migration, breakage, non-union, malunion and necessity for K-wire removal [1,2,4–6]. A variety of intramedullary internal fixation devices, which do not require removal, have been developed to overcome these limitations and improve PIPJ correction arthrodesis outcomes. These devices are made of a variety of resorbable and permanent materials [1,3,7–21]. Specifically, implant resorption is considered a beneficial factor as it eliminates the need for hardware removal procedures [19,8–21]. However, the resorption process can be associated with an inflammatory response [4,19,8–21]. For this reason, integration or better bio-integration with the surrounding tissue, without adverse inflammatory reaction, is an important goal for the ongoing development and wider acceptance of non-permanent orthopedic devices. A bio-integrative material composed of continuous reinforcing mineral fibers, bound together by a degradable polymer [poly (L-lactide-co- D,L-lactide), PLDLA] matrix was used to develop a PIPJ fixation implant (OSSIOfiber® Hammertoe Fixation Implant, OSSIO Ltd., Caesarea, Israel, Fig. 1a and b) [4,22,23]. This novel implant demonstrated favorable PIPJ fusion rates without complications in a previous prospective, multicenter, clinical trial [4]. This first-in-human study was focused on joint fusion and safety with longest follow-up of 26 weeks [4], and bio-integration effect was not primarily assessed. The main purpose of this follow-up study was to analyze the bio-integration process at 1-year follow-up with inclusion of Magnetic Resonance Imaging (MRI) and a newly introduced bio-integration score.

* Corresponding author at: Valdoltra Orthopedic Hospital, Jadranska cesta 31, Ankaran, 6280, Slovenia.
E-mail address: jurij.stalc@ob-valdoltra.si (J. Štalc).

https://doi.org/10.1016/j.fas.2021.06.004

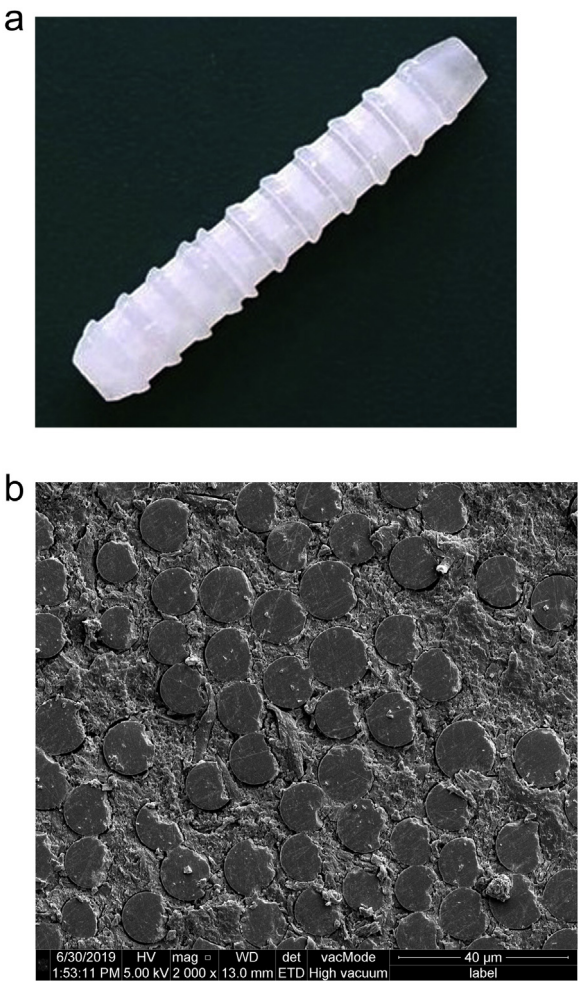

Fig. 1. a and b. a shows the 2.9 mm bio-integrative, fiber-reinforced hammertoe fixation implant (OSSIO*fiber*® Hammertoe Fixation Implant, OSSIO Ltd., Caesarea, Israel) used in this study. b shows an electron microscope cross-section scan demonstrating continuous mineral fibers surrounded by polymeric material.

2. Material and methods

2.1. Study design

This multicenter, prospective, single-arm, open-label study was conducted at an orthopaedic hospital in Slovenia and two foot and ankle surgery centers in Spain between December 2019 and November 2020. Patients aged 18–75 years who required PIPJ arthrodesis and participated in the previous study assessing the safety and performance of the bio-integrative implant for correction of hammertoe deformity and were able to provide written, informed consent were eligible for inclusion in this follow-up study. Further inclusion and exclusion criteria are shown in Table 1. Recruitment was set at a minimum of 75% from original study cohort of 25 patients. This study adhered to the Declaration of Helsinki and was approved by the local ethics committee at each institution.

During the screening visit, the patient demographic data, medical history, medication information and clinical assessment of the operated foot were recorded. Foot and toe assessment as well as pain score (0–10), Foot and Ankle Ability Measure Activities of Daily Living Subscale (FAAM-ADL, 0–100) and percentage level of functioning (0–100) were performed ("Baseline") [4,24]. Radiographs were taken and evaluated and computed tomography (CT) scans were ordered at the surgeon's discretion [4].

2.2. Implant

The bio-integrative hammertoe fixation implant (OSSIO*fiber*® Hammertoe Fixation Implant, OSSIO Ltd., Caesarea, Israel) is comprised of continuous, reinforcing mineral fibers (SiO_2, Na_2O, CaO, MgO, B_2O_3, and P_2O_5; approximately 50%w/w), which have been shown both *in vitro* and *in vivo* to support bone growth and regeneration and are bound together with PLDLA polymer resin (approximately 50% w/w) [23]. Controlled and gradual bio-integration into the surrounding bone without adverse inflammatory response, has been previously shown [22]. The implant used in this study has a hexagonal cross-section with a nominal dimension of 2.9 mm diameter and 19 mm length (Fig. 1a). The ribbed design allows for implant fixation in the phalangeal canal of the toe. The internal structure of the implant consists of layers of oriented continuous fibers (Fig. 1b) that should provide mechanical strength through the bone healing process.

2.3. Surgical procedures [4]

Two foot and ankle surgeons performed all surgeries at three different sites. Each surgery took place within 30 days of enrollment or pre-screening radiographs (Fig. 2a and b). On the day of the surgery, patient eligibility was confirmed, medications information was recorded, and a foot and toe assessment was performed. For the surgery, local and/or regional anesthesia was administered. Following the site standard of care, some patients received prophylactic antibiotic. During the surgery, fluoroscopy imaging was used. A straight longitudinal midline approach over the PIPJ was used. Resection of both joint surfaces followed. The proximal phalanx diaphyseal canal and the middle phalanx diaphyseal canal were drilled with 2.9 mm diameter to the appropriate depth (Fig. 3a). Using the implant holder, the proximal end of the fiber-reinforced hammertoe fixation implant was introduced into the proximal phalanx, parallel to the long axis of the drill hole to prevent bending (Fig. 3b). The middle phalanx was manually reduced over the distal end of the implant while applying slow, steady pressure until bone-to-bone contact was reached (Fig. 3c). After confirming that the implant was properly fitted and

Table 1
Study inclusion and exclusion criteria.

Inclusion criteria	Exclusion criteria
Subject successfully enrolled in original 26 weeks follow-up study (i.e. treated with OSSIOfiber™ Hammertoe Fixation Implant)	Subject is unable to attend the scheduled follow up visits
Subject completed all required visits under protocol for original 26 weeks follow-up study	Women who are pregnant or who intend to become pregnant during the course of the study.
Subject did not require any revision surgery of the treated toe	Any condition which in the view of the principle investigator makes it unsafe for the subject to participate in this study.
Subject has given voluntary, written informed consent.	
Subject is able to understand the clinical investigation and is able and willing to perform all study follow-up visits and procedures.	

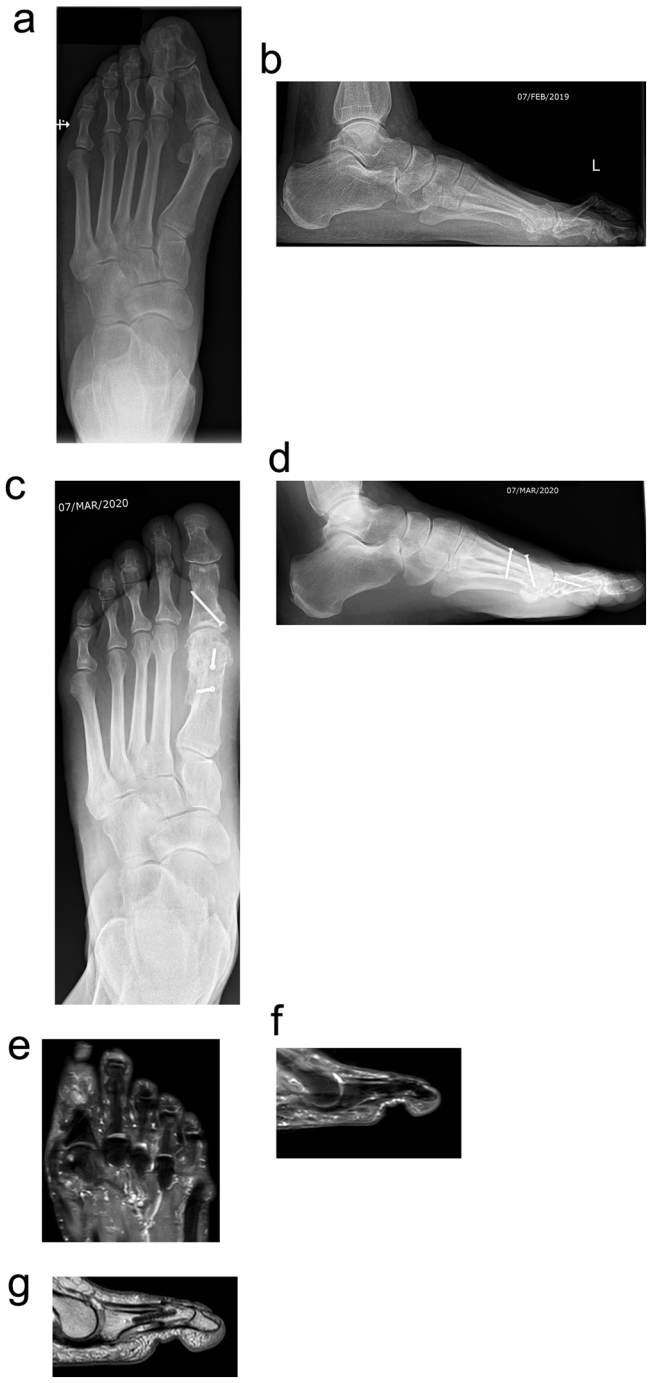

Fig. 2. a–g. Study case. A 64-year-old female with forefoot deformity including Hallux valgus and hammertoe at the 2nd ray without relevant overlength of the metatarsal at the left foot. a shows the dorsoplantar preoperative radiograph with full weight bearing. b shows the lateral preoperative radiograph with partial weight bearing following the local standard showing the plantarflexed subluxation of the 2nd PIPJ. In study part 1, 75% PIPJ fusion was registered at 12 weeks and 100% at 26 weeks postoperatively [4]. c shows the dorsoplantar radiograph with full weight bearing at 1 year follow-up confirming complete fusion of the 2nd PIPJ. The correction of the first ray is not part of this study and was no exclusion criteria. d shows the lateral radiograph with partial weightbearing with the typical superimposition of the toes. e shows an axial MRI reformation without edema or cystic change, T1/PD-weighted, resolution/slice thickness 3.0 mm at 1-year follow-up. f shows a parasagittal reformation T1/PD-weighted, resolution/slice thickness 2.8 mm also without edema or cystic change and imperceptible implant. g shows a parasagittal reformation T2-weighted, resolution/slice thickness 1.2 mm with blurred margins about the implant in the process of bio-integration. The bio-integration score calculates as follows, Border between implant and bone, partially visible, 2 points; bone edema, none, 2 points; cyst formation, no, 2 points; fluid accumulation, no, 2 points; total score, 8 points.

fixated to the bone, the surgeon completed the procedure using routine soft tissue closure.

2.4. Aftertreatment [4]

Dorsoplantar, lateral and lateral oblique radiographs were taken immediately following the procedure. All patients were fitted with a protective shoe for six weeks. Patients were advised to elevate the foot for the early postoperative days. At one week post-operatively patients returned to clinic for a dressing change and wound evaluation.

2.5. Follow-up

Post-operative follow-up to 26 weeks was performed and analyzed in the previous study of same cohort [4]. The one-year follow-up included clinical examination, radiographs, pain score, FAAM-ADL and MRI assessment (minimum resolution 1.2 mm, Table 2). A MRI based bio-integration score was developed for this study (Table 3). MRI images were reviewed and analyzed by a certified, independent reviewer; each assessment was performed twice for intra-observer reliability.

2.6. Statistics

Excel Version 1809 (Microsoft, Redmont, WA, USA) was used for the statistical evaluation of intra-observer reliability of MRI assessment (paired t-test, heteroscedatic).

3. Results

3.1. Patients

From a potential cohort of 25 patients, 24 were screened and enrolled in this follow-up study, including 23 female (96%) and 1 male (4%). The mean age of the cohort was 64.9 ± 7.3 (range, 50–75) years. Mean preoperative scores were as follows: pain 5.3 ± 2.5, FAAM-ADL 73.8 ± 19.4 and percentage level of functioning 69.4 ± 16.9.

3.2. Procedures

The hammertoe deformity affected the second toe in 23 patients (96%), and the third toe in one patient (4%). Nineteen patients (76%) underwent concomitant procedures for first ray deformities, including corrective osteotomies and first MTP joint fusion. Fig. 2a–g shows radiographs and MRI of one representative case.

3.3. Follow-up

All 24 patients (100%) completed the 1-year follow-up. Pain scores improved to 0.3 ± 1.08, FAAM-ADL to 96.3 ± 6.6 and percentage level of functioning to 96.0 ± 5.9. 100% of subjects were either very satisfied (19/24) or satisfied (5/24) with the procedure outcomes. Radiographs confirmed fusion in 92% (n = 22) PIPJ at 1-year follow-up. Table 4 shows the results of the MRI assessment for the 24 patients (100%). The implant was visible in all patients. In 100% of patients (n = 24), the border between implant and surrounding tissue was scored partially visible. There were no cyst formation or fluid accumulation findings. Mild bone edema was detected in 29% (n = 7). None of the edema findings were considered as implant related. The mean bio-integration score was 7.71 ± 0.46 (Table 3). The intraobserver reliability (test–re-test) was sufficient (each $p > 0.16$).

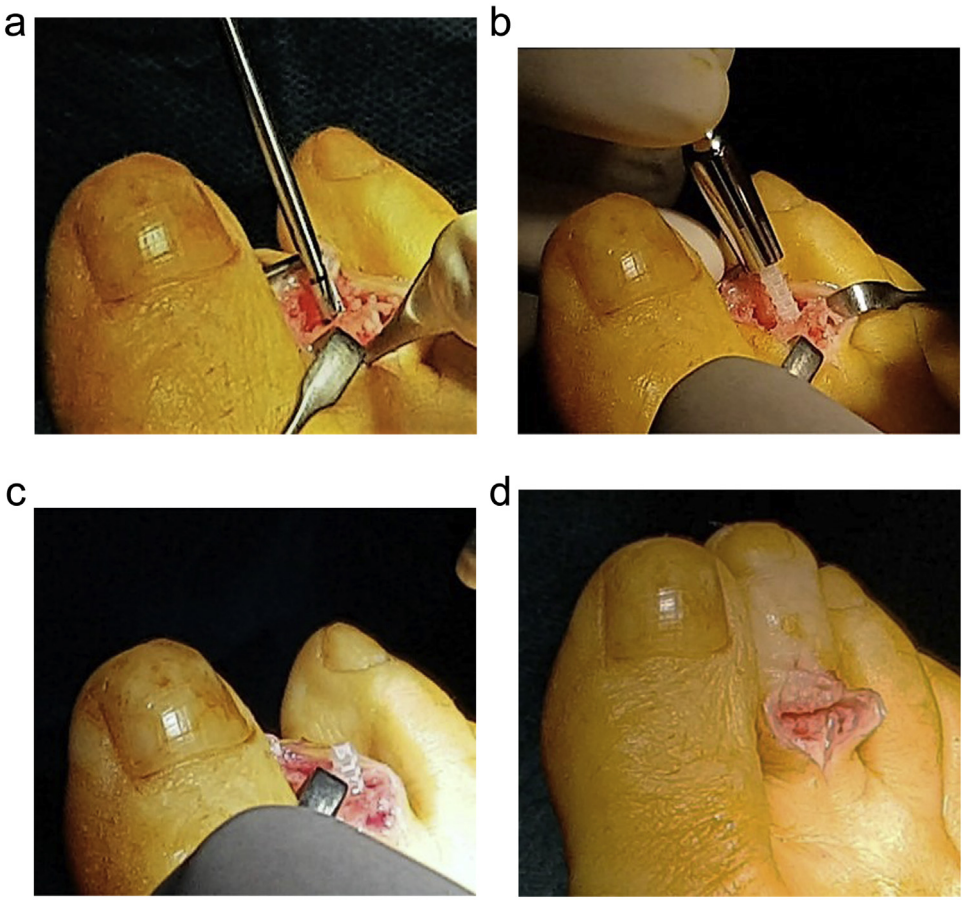

Fig. 3. a–d. Intraoperative situs. A 2.9 mm diameter, marked drill to create tunnel in the proximal phalanx (a). Implant insertion with inserter retrograde into proximal phalanx (b). Implant distal side visible following insertion into the proximal phalanx (c). After mounting the middle phalanx onto implant gradual pressure is applied until bone to bone contact is achieved (d).

Table 2
MRI protocol.

Coil	8ch. foot/ankle coil/16 ch flex coil
Position	–
Landmark	–
Series I	Axial FSE TR 3400 /TE 4000 msec; BW 31 kHz; ETL 7–9; NEX 2; FOV 10 cm; SL 3–3.5 mm; matrix 512 × 320
Series II	Coronal STIR TR 4000 /TE 17 msec; TI 150(1.5 T) 190(3 T) ; BW 31 kHz; ETL 7–9; NEX 2; FOV 16 cm; SL 3 mm; matrix 256 × 192
Series III	Sagittal thin Oblique FSE angled to the operated toe metatarsal shaft TR 4000/TE 34 msec; BW 31.2 kHz; ETL 7–10; NEX 2; FOV 15 cm; SL 1.2 mm; matrix 512 × 384
Series IV	Sagittal Oblique FSE 2nd through 5th MT shafts TR 4000/TE 34 msec; BW 31.2 kHz; ETL 7–10; NEX 2; FOV 15 cm; SL 2–2.5 mm; matrix 512 × 320–384
Series V	Coronal FSE TR 4000/TE 34 msec; BW 31.2 kHz; ETL 7–10; NEX 2; FOV 12 cm; SL 1.2–2 mm; matrix 512 × 320–352
Series VI	Sagittal STIR TR 4000 /TE 17 msec; TI 150(1.5 T) 190(3 T) ; BW 31 kHz; ETL 7–9; NEX 2; FOV 15 cm; SL 2.5–2.8 mm; matrix 256 × 192

BW — bandwidth.
ETL — echo train length.
SL— slice thickness.
NEX — number of excitations.

4. Discussion

This is the first study analyzing bio-integration of an implant for osteosynthesis. Many implants are classified as “resorbable”, “absorbable” or "degradable" [25–29]. Even Magnesium-alloys and Polyvinyl implants are considered as degradable which is theoretical, yet extremely unlikely, as these materials are unable to degrade during a human’s lifetime [27,30]. When considering an orthopaedic fixation device, surgeons are looking for safe and effective methods. The ideal implant should integrate with the surrounding tissue without any negative side effects. In this study, we could prove bio-integration of the newly developed implant at 1-year follow-up without negative side effects. This observation is the main finding of the study and suggests that further, and up-to-complete bio-integration will occur at a later stage.

Table 3
Bio-integration score.

Parameter	Points
Border between implant and bone	
Not visible	4
Partially visible	2
Clearly visible	0
Bone edema	
None	2
Mild	1
Moderate/massive	0
Cyst formation	
No	2
Yes	0
Fluid accumulation	
No	2
Yes	0
In total	Minimum 0 = no bio-integration, maximum 10 = complete bio-integration.

Table 4
Bio-integration Score Results.

Parameter	Points (mean ± std)
Border between implant and bone (0–4)	2.0 ± 0
Bone edema (0–2)	1.71 ± 0.46
Cyst formation (0–2)	2 ± 0
Fluid accumulation (0–2)	2.0 ± 0
Total score (0–10)	7.71 ± 0.46

std, standard deviation.

4.1. Assessment of bio-integration

Different options for the assessment of bio-integration were discussed including CT and MRI. CT has a clear advantage of a much higher resolution (down to 0.1 mm), whereas the typical resolution of MRI is 3 mm which would not allow for an adequate assessment of an implant with a nominal dimension of 2.9 mm (Fig. 2a) [31]. The whole implant could theoretically be missed between two slices, as all other relevant structures and findings including cyst formation, bone edema, and fluid.; the potential advantage of MRI in relation to CT is the better detection of these relevant findings. Based on a special scanning protocol, we could achieve a resolution/slice thickness of 1.2 mm which we considered as adequate and lessens the potential risk of missing important data (Fig. 2g).

4.2. Development of a degradation score

We were not aware of a scoring system for implant degradation or bio-integration; therefore, we created a system for this study (Table 3). We considered optimal bio-integration as a non-visible border between implant and bone, and lack of fluid, implant-related bone edema or cyst formation. This finding results in a maximum bio-integration score of 10 points. In contrast, clearly visible border between bone and implant, with evidence of cyst formation, implant-related bone edema and fluid result in a minimum bio-integration score of 0 points. The average bio-integration score in our study was 7.71 ± 0.46. We consider this a very favorable result even though we cannot compare this with the literature based on missing comparable data. However, the implant was still visible at one year in all cases which was an expected finding, as full degradation was not expected at the 1-year timepoint. The intra-observer reliability of the bio-integration score was sufficient to consider this score a reproducible measure. Mild bone edema was detected in 7 of 24 subjects – this finding is very common in older patients and in post-orthopaedic procedures of the foot; it is often attributed to the chronic distribution of forces due to abnormal gait and posture or foot malalignment [32]. None of the edema findings were considered as adverse implant related event.

4.3. Shortcomings of the study

Shortcomings of this study are low case number, missing control group, and the relatively short follow-up time. The case number was calculated with a focus on safety and implant performance. A missing control group is a methodological shortcoming as in many other studies that we cannot invalidate. A follow-up time of 1 year does not meet some international scientific standards for clinical studies with a minimum of 2 years. However, this follow-up study did not primarily focus on clinical outcome but on bio-integration. The results demonstrate that substantial bio-integration has occurred at one year, even though not complete. Another potential limitation is the assessment method of bio-integration as discussed above. The use of a non-validated degradation score is also a potential shortcoming, but a validated score does not yet exist.

In conclusion, this is the first study analyzing bio-integration of an implant for osteosynthesis. We could prove the bio-integration of the newly developed fiber-reinforced implant at 1-year follow-up without negative side effects. The implants were partially bio-integrated at the 1-year timepoint. An ongoing study project is desired to follow these patients at best until complete bio-integration is reached.

Conflict of interest

Luke D. Cichinelli, Martinus Richter and Stuart Miller are consultants of Ossio. Martinus Richter is consultant of Curvebeam, Geistlich, Intercus, and Implants International, proprietor of R-Innovation, and shareholder of Curvebeam. The study was funded in part by Ossio Ltd., Caesarea, Israel.

Acknowledgements

The authors thank Carolyn M. Sofka, MD, FACR, Department for Radiology and Imaging, Hospital for Special Surgery, New York, NY, USA, for evaluation of MRI images and revisions of the corresponding text.

References

[1] Sullivan JP, Churchill CL. Digital arthrodesis of the lesser toes. Clin Podiatr Med Surg 2017;34(3):289–300.
[2] Kramer WC, Parman M, Marks RM. Hammertoe correction with k-wire fixation. Foot Ankle Int 2015;36(5):494–502.
[3] Guelfi M, Pantalone A, Cambiaso Daniel J, Vanni D, Guelfi MG, Salini V. Arthrodesis of proximal inter-phalangeal joint for hammertoe: intramedullary device options. J Orthop Traumatol 2015;16(4):269–73.
[4] Cicchinelli LD, Stalc J, Richter M, Miller S. Prospective, multicenter, clinical and radiographic evaluation of a bio-integrative, fiber-reinforced implant for proximal interphalangeal joint arthrodesis. Foot Ankle Orthop 2020;5(4):1–10.
[5] Zingas C, Katcherian DA, Wu KK. Kirschner wire breakage after surgery of the lesser toes. Foot Ankle Int 1995;16(8):504–9.
[6] Klammer G, Baumann G, Moor BK, Farshad M, Espinosa N. Early complications and recurrence rates after Kirschner wire transfixion in lesser toe surgery: a prospective randomized study. Foot Ankle Int 2012;33(2):105–12.
[7] Caterini R, Farsetti P, Tarantino U, Potenza V, Ippolito E. Arthrodesis of the toe joints with an intramedullary cannulated screw for correction of hammertoe deformity. Foot Ankle Int 2004;25(4):256–61.

[8] Coillard JY, Petri GJ, van Damme G, Deprez P, Laffenêtre O. Stabilization of proximal interphalangeal joint in lesser toe deformities with an angulated intramedullary implant. Foot Ankle Int 2014;35(4):401–7.
[9] Ellington JK, Anderson RB, Davis WH, Cohen BE, Jones CP. Radiographic analysis of proximal interphalangeal joint arthrodesis with an intramedullary fusion device for lesser toe deformities. Foot Ankle Int 2010;31(5):372–6.
[10] Fazal MA, James L, Williams RL. StayFuse for proximal interphalangeal joint fusion. Foot Ankle Int 2013;34(9):1274–8.
[11] Jay RM, Malay DS, Landsman AS, Jennato N, Huish J, Younger M. Dual-component intramedullary implant versus kirschner wire for proximal interphalangeal joint fusion: a randomized controlled clinical trial. J Foot Ankle Surg 2016;55(4):697–708.
[12] Averous C, Leider F, Rocher H, Determe P, Guillo S, Cermolacce C, et al. Interphalangeal arthrodesis of the toe with a new radiolucent intramedullary implant (Toegrip). Foot Ankle Spec 2015;8(6):520–4.
[13] Obrador C, Losa-Iglesias M, Becerro-de-Bengoa-Vallejo R, Kabbash CA. Comparative study of intramedullary hammertoe fixation. Foot Ankle Int 2018;39(4):415–25.
[14] Gill LH. Principles of joint arthroplasty as applied to the ankle. Instr Course Lect 2002;51:117–28.
[15] Kominsky SJ, Bermudez R, Bannerjee A. Using a bone allograft to fixate proximal interphalangeal joint arthrodesis. Foot Ankle Spec 2013;6(2):132–6.
[16] Doty JF, Fogleman JA. Treatment of rigid hammer-toe deformity: permanent versus removable implant selection. Foot Ankle Clin 2018;23(1):91–101.
[17] Frey-Ollivier S, Catena F, Hélix-Giordanino M, Piclet-Legré B. Treatment of flexible lesser toe deformities. Foot Ankle Clin 2018;23(1):69–90.
[18] Nielson DL, Young NJ, Zelen CM. Absorbable fixation in forefoot surgery: a viable alternative to metallic hardware. Clin Podiatr Med Surg 2013;30 (3):283–93.
[19] Wendelstein JA, Goger P, Bock P, Schuh R, Doz P, Trnka HJ. Bioabsorbable fixation screw for proximal interphalangeal arthrodesis of lesser toe deformities. Foot Ankle Int 2017;38(9):1020–5.
[20] Konkel KF, Menger AG, Retzlaff SA. Hammer toe correction using an absorbable intramedullary pin. Foot Ankle Int 2007;28(8):916–20.
[21] Konkel KF, Sover ER, Menger AG, Halberg JM. Hammer toe correction using an absorbable pin. Foot Ankle Int 2011;32(10):973–8.
[22] Berlet GC, Nyska M, Jackson ND. The bio-integration and bone fixation performance of continuous mineral fiber-reinforced implants. Orthop Res Soc Trans 2020;334:.
[23] Preiss-Bloom O, Poreh D, Merchav-Feuermen R, Lindner T. OSSIOfiber(TM) intelligent bone regeneration technology overview. OSSIO vol DOC000625. Woburn, MA: OSSIO Inc; 2019 2019.
[24] Martin RL, Irrgang JJ, Burdett RG, Conti SF, Van Swearingen JM. Evidence of validity for the Foot and Ankle Ability Measure (FAAM). Foot Ankle Int 2005;26 (11):968–83.
[25] Könneker S, Krockenberger K, Pieh C, von Falck C, Brandewiede B, Vogt PM, et al. Comparison of SCAphoid fracture osteosynthesis by MAGnesium-based headless Herbert screws with titanium Herbert screws: protocol for the randomized controlled SCAMAG clinical trial. BMC Musculoskelet Disord 2019;20(1):357.
[26] Yang Y, Zhou X, Zhang M, Zhou Y, Wang B, Yuan C. Lateral wall osteotomy combined with embedded biodegradable implants for displaced intra-articular calcaneal fractures. J Orthop Surg Res 2019;14(1):74.
[27] Windhagen H, Radtke K, Weizbauer A, Diekmann J, Noll Y, Kreimeyer U, et al. Biodegradable magnesium-based screw clinically equivalent to titanium screw in hallux valgus surgery: short term results of the first prospective, randomized, controlled clinical pilot study. Biomed Eng Online 2013;12:62.
[28] Liu JN, Ong HS, Wang MY, Wan K, Qu XZ, Zhang CP. Randomized control trial comparing the titanium osteosynthesis and the biodegradable osteosynthesis in mandibulotomy access. Head Neck 2019;41(4):915–23.
[29] Fink C, Benedetto KP, Hackl W, Hoser C, Freund MC, Rieger M. Bioabsorbable polyglyconate interference screw fixation in anterior cruciate ligament reconstruction: a prospective computed tomography-controlled study. Arthroscopy 2000;16(5):491–8.
[30] Glazebrook M, Blundell CM, O'Dowd D, Singh D, de Vries G, Le ILD, et al. Midterm outcomes of a synthetic cartilage implant for the first metatarso-phalangeal joint in advanced hallux rigidus. Foot Ankle Int 2019;40(4):374–83.
[31] Richter M, Zech S. Matrix-associated stem cell transplantation (MAST) in chondral lesions at the ankle as part of a complex surgical approach- 5-year-follow-up in 100 patients. Foot Ankle Surg 2019;25(3):264–71.
[32] Szaro P, Geijer M, Solidakis N. Traumatic and non-traumatic bone marrow edema in ankle MRI: a pictorial essay. Insights Imaging 2020;11(1):97.