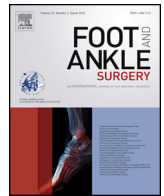




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The Endolog technique for moderate to severe hallux valgus treatment: Clinical and radiographic analysis of 194 patients

Federico Bertolo^{a,*}, Andrea Pautasso^a, Claudio Cuocolo^b, Daniela Invernizzi^b,
Francesco Atzori^b

^a University of Turin, Via Gianfranco Zuretti 29, Turin, 10126, Italy

^b Orthopaedic Department, Piccola Casa Della Divina Provvidenza, Via San Giuseppe Benedetto Cottolengo, Turin, 10152, Italy

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ABSTRACT

Background: Endolog is an intra-medullary titanium device used for a minimally-invasive hallux valgus correction. The aim of this study was to evaluate clinical and radiographic outcomes of this device.

Methods: A retrospective study with a prospective data collection was conducted. Patients underwent to Endolog procedures from September 2009 to April 2017 were enrolled. Mild HV deformity ($HVA \leq 19^\circ$ and $IMA \leq 13^\circ$) or associated procedure to Endolog technique were excluded. The radiological (HVA, IMA and PASA) and clinical (AOFAS score) pre and post-operative data were compared through Wilcoxon Signed-Rank test.

Results: 194 feet (144 moderate and 50 severe HV) underwent HV correction respecting study's criteria. AOFAS scores significantly improved from 31.0 ± 12.7 points preoperatively to 88.5 ± 8.0 at 24 months. Even all radiographic measurements significantly improved during 2 years' follow-up. Only 6 patients experienced complications: 4 cases of HV recurrence and 2 cases of intolerance device-related pain.

Conclusions: Endolog technique proved to be a valid option in the moderate-to-severe hallux valgus treatment, comparable to other surgical techniques described in literature.

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1. Introduction

Hallux valgus (HV) is a common and progressive deformity affecting forefoot, that can lead to severe pain and functional deterioration. It is often an inherited disorder and mainly affects women between forty to sixty years old living in both industrialized and developing countries [1–3]. Hallux valgus has a multifactorial pathogenesis, which is a mixture of individual and acquired factors, such as a constitutional imbalance between abductor and adductor muscles, or a habitual use of tight-fitting and high-heeled shoes [4]. Clinical findings in HV disease are: subluxation of the first metatarsophalangeal joint (MTPJ) with lateral displacement of proximal phalanx and pronation of big toe, medial exostosis of metatarsal head, first tarsal-metatarsal joint (TMTJ) instability, metatarsus varus and other related clinical signs such as callus, bursitis over the bony prominence and lesser toe deformities [5]. The consequence of all these forefoot structural alterations are an incorrect weight-bearing

transmission during the gait and an increase of pain and pressure at the head of other metatarsal bones [6]. Several surgical procedures have been described in literature for the correction of this deformity such as distal, proximal and double metatarsal osteotomies; proximal phalanx osteotomies; tarsal-metatarsal arthrodesis, soft tissues procedures etc. [7–15], but there is no single procedure that has definitely shown its superiority in comparison to others [16].

Recently, “Endolog” device has been proposed for the treatment of mild, moderate and severe hallux valgus forms. It is a titanium implant formed by a proximal curvilinear part, inserted into the medullary canal, and a distal flat-holed portion. It ensures stability to sub-capitated metatarsal osteotomy by fixing the metatarsal head with an angular stability screw distally and attaching to the metatarsal cortex on the intramedullary side proximally, with three distinct contact points. The literature is very lacking as regards the HV correction through Endolog device. In fact, to our knowledge only 5 studies [17–21] are connected with the term “Endolog” by searching on the “PubMed” database systems.

The aim of this study was to investigate the potential of the Endolog technique in terms of moderate and severe hallux valgus forms correction, by evaluating patient's clinical satisfaction and objective radiographic parameters after 2 years' follow-up.

* Corresponding author.

E-mail addresses: federico.bertolo@hotmail.com (F. Bertolo), andrea009@alice.it (A. Pautasso), claudio.cuocolo@icloud.com (C. Cuocolo), dr.danielainvernizzi@gmail.com (D. Invernizzi), f_atz@libero.it (F. Atzori).

2. Materials and methods

A retrospective study of a prospectively collected database was conducted. Inclusion criteria were patients with a moderate or severe HV deformity, undergoing Endolog device implantation, from September 2009 to April 2017 at Piccola Casa della Divina Provvidenza Cottolengo Hospital (Turin). Only patients with a complete 2-year follow-up, as established in our clinical practice, were included. Exclusion criteria were mild HV forms; all the patients undergoing Endolog device implantation with associated other surgical procedures on other toes or proximal phalanx of the big toe; finally, patients with an incomplete follow-up. During the period considered, the indications for surgical treatment were preserved the same: both dorsomedial and plantar MTPJ pain; intolerance to tight shoes and restricted gait autonomy; the presence of painful bunion at the first metatarsal head in addition to the cosmetic aspects. As established by our ordinary clinical protocol, feet X-rays in weight-bearing position were acquired both dorsoplantar and lateral projections preoperatively, 30 days after surgery, at 12 months and 24 months after surgery. In case of worsening of the patient's symptoms, further clinical and/or radiographic controls were planned over 2 years after surgery. Not-weight-bearing feet X-rays acquired postoperatively were not included for the radiographic evaluation, because for the presence of functional bandage. Radiological analysis (Fig. 1) was carried out using Radiant DICOM Viewer[®] software by which were measured hallux valgus angle (HVA), the intermetatarsal angle (IMA) and proximal articular set angle (PASA), according to the Ad Hoc Committee of the American Orthopaedic Foot & Ankle Society recommendations [22]. Moreover, these angles with sesamoid subluxation and joint congruity are the common radiological predictors that have been studied in literature [23–26]. Hallux valgus angle (normal value $<15^\circ$) is the angle between longitudinal axes of the first metatarsal bone and proximal phalanx; IMA (normal value $<10^\circ$) is the angle between longitudinal axes of the first and the second metatarsal bones; PASA (normal value $<6^\circ$) is the angle between longitudinal axes of the first metatarsal bone and the perpendicular to the line passing through the ends of the cartilaginous surface of the metatarsal head. According to the literature hallux valgus deformity was then classified as mild (HVA $\leq 19^\circ$ and IMA $\leq 13^\circ$), moderate (HVA 20° – 40° and IMA 14° – 20°) and severe (HVA $> 40^\circ$ and IMA $> 20^\circ$) [1,27,28].

Clinical outcome, in terms of pain, function and alignment in patient underwent HV correction, was investigated through the administration of the American Orthopaedic Foot and Ankle Society (AOFAS) hallux-metatarsophalangeal-interphalangeal scale [29] preoperatively, at 30 days and 24 months after surgery.

All clinical and radiographic analysis were performed by the same surgeon while surgical procedures were executed with the same technique by different surgeons.

The surgical procedure (Fig. 2) started with a 3-cm dorsal-medial longitudinal skin incision, centered to the first metatarsal head. Care was taken to avoid the neurovascular bundle and then capsulotomy, in line with skin incision, was performed. Exposure of the medial surface of the head of the first metatarsal bone and of exostosis was completed by detaching the capsular and ligamentous tissues from the bone. After that, tenotomy of conjoined tendon of abductor hallucis muscle was executed. Then a wedge-shaped exostosectomy was performed in a distal to proximal way with an oscillating micro-saw. It is crucial to achieve a flat surface of cancellous bone in order to the correct placing of Endolog device, which must adhere to bone with its holed plate perfectly. When a pronation of the big toe was found, a dorsal-plantar oblique exostosectomy was performed in order to obtain a derotation of the metatarsal head on the frontal section. Subsequently a linear or oblique (if lengthening or shortening was necessary) sub-capitated osteotomy of the first metatarsal was performed and the head was shifted laterally by manual traction. Finally, a right sized Endolog device was implanted (following trial device insertion under fluoroscopic imaging guidance) and fixed to the metatarsal head with angular stability screw, paying attention to the plantar position of the head and the correct pairing of the plate to the bone. Incision was closed with a 2-0 non-absorbable suture after a subtraction capsuloplasty, in which a wedge of capsular tissue from the plantar flap was removed and the subsequent capsulorrhaphy with a 0-absorbable suture consented to have an extra adduction of the big toe. At the end of surgical procedure, a functional bandage was packed.

The postoperative protocol was: full weight bearing using a heel-bearing shoe until 30 days after surgery, clinical evaluation and renewal of functional bandage at week 1, sutures and bandage removal at week 2 after surgery.

The authors considered HV recurrence when symptoms reappeared after surgical treatment and a significant radiological correction loosening was detected.

The statistical analysis was conducted using IBM SPSS[®] (Data Analysis and Statistical Software): a Kolmogorov–Smirnov test was used to study the values distribution in all data series, then Wilcoxon Signed-Rank test was applied to compare preoperative and follow-up AOFAS scores, HVA, IMA and PASA groups of values. A p value of < 0.05 was considered statistically significant.

3. Results

During the nine years considered, 872 various procedures for HV correction were performed in our institution. Five-hundred seventy-two mild HV forms were excluded from the analysis, according to inclusion and exclusion criteria adopted. About the remaining 300 moderate and severe HV forms treated with Endolog device, 94 were associated to other surgical procedures on



Fig. 1. Radiological analysis: (a) hallux valgus angle (HVA); (b) the intermetatarsal angle (IMA); (c) proximal articular set angle (PASA).

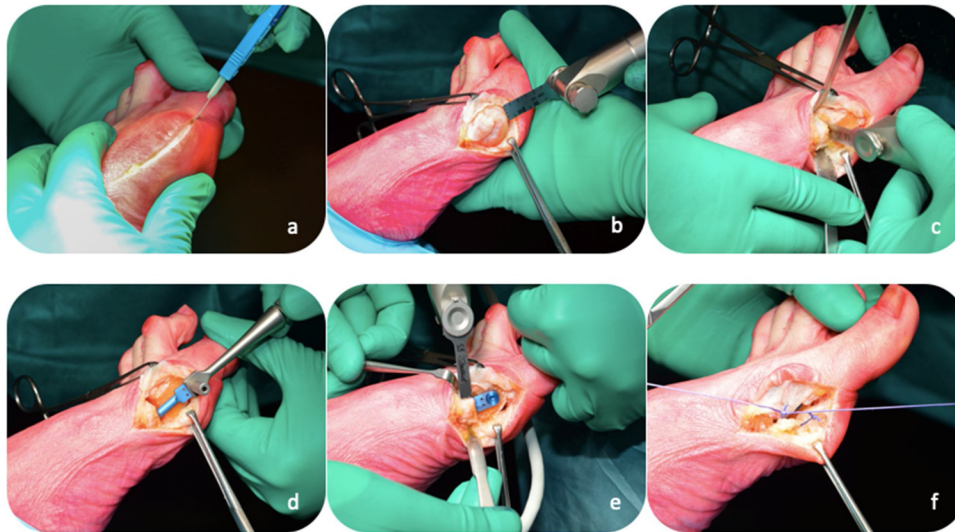


Fig. 2. The surgical procedure: (a) 3-cm dorsal-medial longitudinal skin incision, centered to the first metatarsal head; (b) Exostosectomy; (c) Sub-capitated osteotomy of the first metatarsal; (d) Intramedullary Endolog implantation; (e) Smoothing of medial cortical surface of metatarsus; (f) Subtraction capsuloplasty.

other toes or proximal phalanx of the big toe, hence they were excluded. Of 206 eligible patients for the study, 12 did not completed follow-up checks correctly. A total of 194 feet (111 left sided, 83 right sided) of consecutive 194 patients, 181 women and 13 men, average age 66 ± 117 (37–93) years were considered. One-hundred forty-four moderate HV deformity and fifty severe HV deformity was treated through implantation of Endolog device. The mean total AOFAS score was 31 ± 12.7 (0–53) points preoperatively; a significantly improvement ($p < 0.05$) at 30 days with 80.8 ± 11.2 (60–100) points and at 24 months after surgery with 88.5 ± 8 (41–100) points was detected. Regarding radiological measurements, the mean preoperative HVA was $34^\circ \pm 8.3^\circ$ (19.1° – 57.5°) and significantly improved ($p < 0.05$) with a mean value of $13.9^\circ \pm 6^\circ$ (4° – 33.9°) at 24 months' follow up. The mean preoperative IMA was $14.6^\circ \pm 4.2^\circ$ (5.1° – 31.1°) with a significant correction ($p < 0.05$) at 24 months after surgery (mean value of $7.4^\circ \pm 3.1^\circ$ (2.4° – 15.6°)). The mean preoperative PASA was $26.4^\circ \pm 10.3^\circ$ (range 2.5° – 49.4°) and significant improved ($p < 0.05$) at 24 months after surgery with a mean value of $10.3^\circ \pm 6.8^\circ$ (range 0.5° – 28°). All the results are reported in Table 1. Fig. 3 shows a clinical case of HV correction with Endolog device and its radiological controls during follow-up.

Only 6 patients experienced complications during the period considered: 4 cases of HV recurrence and 2 cases of irritative device-related pain, which led to implant removal. No cases of wound or bone infection, hypertrophic scar, avascular necrosis of the first metatarsal head, defects of bone consolidation (malunion, delayed union, non-union) and lesser transfer metatarsalgia were encountered.

4. Discussion

Hallux valgus is a widespread disease and its early diagnosis associated with a correct treatment can improve the quality of life to affected patients. The supremacy of a surgical technique over another one has not yet been demonstrated in the literature, although several procedures were described [30–35].

This study showed good clinical and radiographic results as well as patient satisfaction, as demonstrated by other authors describing Endolog surgical technique. Regarding clinical outcomes, we obtained a mean increase of 57.5 points on AOFAS scale after a 2 years' follow-up; Di Giorgio et al. [21] obtained a mean increase of 66.1 points after the same period, while Biz et al. [19] an average increase of 65.3 points after 4 years' follow-up. Our results are in line with literature (Table 2), but the less mean increase found in our series, could be probably explained by the bigger cohort considered.

Radiographic outcome demonstrated similar trend during follow-up related to other studies about Endolog (Table 2), but some differences were found out. In fact, the mean HVA correction was 20.1° from the preoperatively period to 2 years after surgery. This value was higher than those found in other studies probably due to a higher number of patients considered in this study, thus a higher number of severe HV corrected.

Regarding IMA, we obtained a good correction at 2 years after surgery with this technique; in our opinion, this is remarkable also considering the higher maximum preoperative values detected than in the other works [21,19,18]. As proposed by Condon et al. [36] severe IMA preoperative values ($> 16^\circ$) should be treated with

Table 1
Clinical and radiographic results of the 194 feet studied.

Parameters	Follow up (Mean \pm sSD (Min–Max))			Δ Difference (Pre-op – 2 years)
	Preoperative	Month 1	Month 24	
HVA	$34.0^\circ \pm 8.3^\circ$ (19.1° – 57.5°)	$8.9^\circ \pm 5.4^\circ$ (3.1° – 32.1°)	$13.9^\circ \pm 6.0^\circ$ (4.0° – 33.9°)	20.1°
IMA	$14.6^\circ \pm 4.2^\circ$ (5.1° – 31.1°)	$6.4^\circ \pm 2.4^\circ$ (2.2° – 14.8°)	$7.4^\circ \pm 3.1^\circ$ (2.4° – 15.6°)	7.2°
PASA	$26.4^\circ \pm 10.3^\circ$ (2.5° – 49.4°)	$6.7^\circ \pm 5.0^\circ$ (0.1° – 23.7°)	$10.3^\circ \pm 6.8^\circ$ (0.5° – 28.0°)	16.1°
AOFAS scale (Total)	31.0 ± 12.7 (0–53)	80.8 ± 11.2 (60–100)	88.5 ± 8.0 (41–100)	57.5

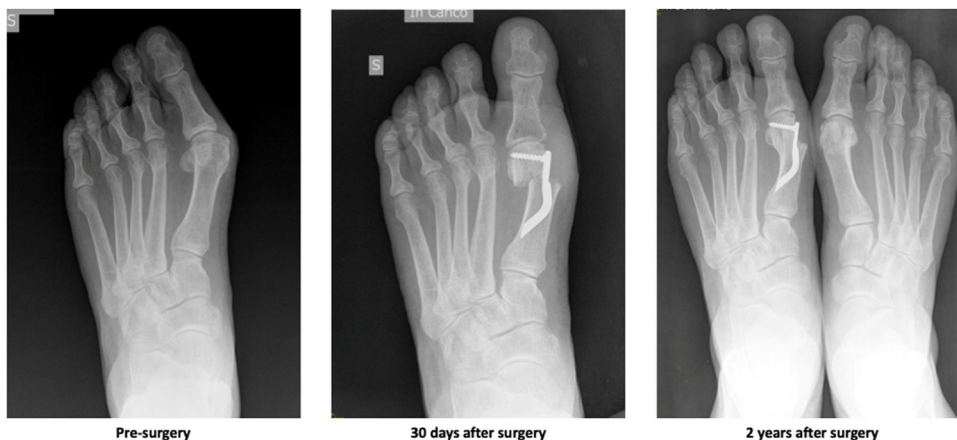


Fig. 3. Clinical case of HV correction with Endolog device. Feet X-rays in weight-bearing position were acquired pre-operative, 30 days and 2 years after surgery. The radiological images show a good hallux valgus correction with an excellent healing 2 years after surgery.

Table 2
Clinical and radiological results of other endolog studies.

Study	Parameters	Follow up (Mean ± sSD (Min–Max))		Δ Difference (Pre-op – 2 years)
		Preoperative	Month 24	
Di Giorgio et Al. (2013) – 25 feet (21)	HAV	36.6° ± 8.1° (20.0°–53.0°)	22.7° ± 6.7° (8.0°–32°)	13.9°
	IMA	16.0° ± 1.9° (14.0°–19.9°)	6.1° ± 2.9° (3.0°–11.0°)	9.9°
	PASA	13.4° ± 3.7° (4.0°–22.0°)	6.9° ± 4.9° (1.0°–10.0°)	6.5°
	AOFAS scale (Total)	22.1 ± 11.1 (0–34)	88.2 ± 6.1 (85–100)	66.1
Biz et Al. (2015) – 30 feet (19)	HAV	33.4° ± 10.7° (17.8°–66.6°)	16.6° ± 5.4° (7.2°–25.2°)	16.8°
	IMA	12.3° ± 3.1° (7.1°–18.5°)	6.4° ± 1.4° (7.7°–15.0°)	5.9°
	PASA	21.9° ± 9.8° (8.1°–43.2°)	11.2° ± 4.8° (3.8°–22.1°)	10.7°
	AOFAS scale (Total)	28.7 (19–42)	94.0	65.3
Di Giorgio et Al. (2016) – 20 feet (18)	HAV	27.5° ± 7.2°	13.4° ± 4.4°	14.1°
	IMA	15.9° ± 3°	8.2° ± 1.9°	7.7°
	PASA			
	AOFAS scale (Total)	32.4	89.2	56.8

a proximal osteotomy or a tarsal-metatarsal arthrodesis. Although high preoperative IMA values were often found in our series, the Endolog device resulted very effective in correction of this radiographic parameter.

Concerning PASA, the mean correction was 16.1° after 2 years' follow-up; it is a quite high value if compared with the other Endolog' studies, of course related to a higher number of patients considered. In addition, according to the authors, this finding is related to a peculiar feature of Endolog device such the easy management of triplanarity and quick fixation of metatarsal head during the surgical operative time. In fact, this technique not only allowed a medial to lateral shift of the first metatarsal head, paying attention to its plantar position, but also its rotation on dorsal-plantar and frontal planes (whether a hallux pronation was detected). This led Endolog device to be particularly effective in correction of MTPJ subluxation and of high preoperative PASA values detected in our series.

Di Giorgio et al. in a recent work, compared Endolog system with Reverdin-Isham technique for the treatment of moderate hallux valgus: no difference between the two techniques in terms of clinical and radiologic outcome were found, but PASA was not included in the

radiographic evaluation [18]. HVA has been often considered as the single most important factor predicting outcomes after hallux valgus surgery [37], but according to Easley and Trnka [38], there is no evidence about absolute radiographic measurements in HV disease.

Endolog device is considered a mini-invasive procedure characterized by little skin incision and soft tissues sparing, as described before. In the last decades, several authors proposed different minimally invasive techniques for the HV treatment. Giannini et al., describing the "S.E.R.I." technique for the correction of mild-to-moderate hallux valgus in 896 feet, showed a mean increase of 42.2 points on AOFAS score and a similar radiographic measurements improvement after a minimum of 5-year follow-up [39,8]. Iannò et al. reported a series of 85 feet treated with a corrective minimally invasive distal metatarsal osteotomy (MIDMO) with a modified Bösch technique. At a mean follow-up of 73.3 months, AOFAS score had a mean increase of 39.7 points and radiographic angles had similar trends than in our study [40]. Another multicenter study by Bauer et al. reported a series of 179 feet with mild-to-moderate HV deformities underwent to percutaneous Reverdin-Isham distal osteotomy. At a mean of 13 months of follow-up, AOFAS score had a mean increase of 41 points and the mean radiographic values were similar to ours [41].

Regarding complications, only 4 cases of HV recurrence were detected during 2-years' follow-up. These patients belonged both to the moderate (2 cases) than severe (2 cases) HV groups and all of them presented a pronation of the big toe preoperatively. The incorrect exostosectomy resulted probably crucial in determining the recurrence of the deformity according to the authors, as patients with similar clinical presentation and radiographic preoperative angles did not experience recurrence. Whether surgical procedures were performed by different surgeons, probably played a substantial role in determining this finding.

Moreover, 2 cases of irritative device-related pain occurred during our follow-up. These 2 patients did not present bunion preoperatively and a small exostosis with very thin capsular flaps were encountered during surgical dissection, besides a thin skin layer. According to the authors, this led to an insufficient soft tissue cover of the Endolog device in addition to a repeated contact between the shoe and the surgical site during postoperative period, resulting in a device's intolerance. In agreement with other works [19,21], no other complications during our ordinary follow-up period were found.

This study had several limitations. The average age was 66 years old, and the results may not be replicable in younger and active populations. Although a higher number of patients considered than other studies about Endolog, we reported a short-term follow-up (2 years) as established in our common practice. This probably led to underestimate the real frequency of recurrence of the disease using this technique. Only one study about Endolog reports cases with a midterm follow-up (4 years (19)). For this reason, we consider the formulation of studies with a long-term follow-up as fundamental in the future, in order to assess effectiveness of this technique more precisely. Furthermore, a control group lacked, making hard to compare Endolog technique to other surgical procedures for HV correction. At the end, while all clinical and radiographic analysis were performed by the same surgeon, surgical procedures were executed by different surgeons leading to a less standardized technique.

5. Conclusions

The Endolog technique proved to be reliable in correcting moderate-to-severe hallux valgus with good resolution of the clinical and radiographic outcomes, with good pain compensation and excellent patient tolerance.

Despite, long-term follow-up studies will be necessary to define the real potential of Endolog device in correction of HV deformity, the authors believe that this work could add important data to the literature, regarding this little-known surgical technique. Furthermore, thanks to its low learning curve, easy reproducibility and apparent low complication and recurrence rate, Endolog could certainly find space in HV surgery, especially in centers where few foot surgeries are performed annually.

Informed consent

Informed consent was obtained from all the patients included in our study.

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Disclaimer

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All Authors certify they not have signed any agreement with a commercial interest related to this study, which would in any way limit publication of any data generated for the study or to delay publication for any reason.

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