Title: Longer term outcomes following high tibial osteotomy for osteoarthritis; a prospective, multi-centre observational study comparing Tomofix and OPTY-LINE devices.

Running title: OPTY-LINE for high tibial osteotomy

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Declarations

Conflicts of interest/Competing interests

Financial interests: MD previously received historic consultancy remuneration and has received research support (in the form of medical devices and a research grant) from Nuvasive, ending in 2018. The other authors have no financial conflict of interest to declare**.**

Non-financial interests: none.

Funding

This study was funded by by Nuvasive Specialized Orthopedics, Inc, 7475 Lusk Blvd, San Diego, CA 92121 USA.

Availability of data and material (data transparency)

Anonymised data is available from the corresponding author upon request.

Code availability (software application or custom code)

Not applicable

Authors' contributions

All authors contributed to the study conception and design. LJ prepared the study protocol for ethics application, conducted data analysis and drafted the manuscript; LB and MM identified and consented patients, collated clinical outcome measures, and prepared and interpreted study data; JM was co-investigator, identified and consented patients, and collated clinical outcome measures; MD was principal investigator, conceived the idea, and critically appraised and reviewed the draft manuscript. All authors read and approved the final version of the manuscript.

Ethical approval and ethical standards

Ethics approval was obtained from the UK's National Research Ethics Service, North-West Lancaster Committee, reference 16/NW/0017; in addition, Health Research Authority and local National Health Service Trust approvals were obtained prior to commencing the study. Written informed consent was obtained from all participants

Acknowledgements

We are grateful to Ms Zoe Saunders and Ms Katherine Davidson, research practitioners, North Cumbria Integrated Care NHS Foundation Trust, for project delivery support.

Title: Longer term outcomes following high tibial osteotomy for osteoarthritis; a prospective, multi-centre observational study comparing Tomofix and OPTY-LINE devices.

Abstract

Purpose Assessing surgical accuracy and patient recorded outcome measures for patients fitted with either the OPTY-LINE intramedullary realignment system or the Tomofix plate for medial opening wedge high tibial osteotomy (HTO).

Patients & Methods Two matched case series of patients with symptomatic medial compartment osteoarthritis without other significant knee pathology. One group comprised of 19 patients receiving the Tomofix plate, whereas another comprised of 12 patients receiving the OPTY-LINE intramedullary nail. Patella-centred long leg alignment radiographs were assessed to calculate surgical accuracy in all cases. Patients completed knee injury osteoarthritis outcome scores (KOOS) and osteotomy surgery patient satisfaction questionnaires pre-operatively and at 24 months post-surgery.

Results Absolute surgical accuracy at 2 years post-surgery was a mean 4.2 [standard deviation 3.7] for OPTY-LINE versus 9.2 [SD 7.8] for Tomofix ($p = 0.11$, Mann-Whitney U-test). On average, patients in either the OPTY-LINE and Tomofix cohort reported at least a minimal perceptible clinical improvement – minimum average improvement of 15 - for all five KOOS themes. No significant difference in change of KOOS scores over time or patient satisfaction levels were observed between the two cohorts.

Conclusion The OPTY-LINE device for HTO performs to a similar level as the Tomofix device. Surgical accuracy data is promising for OPTY-LINE, but does not seem to readily translate into difference in patient-reported outcomes compared to Tomofix. Even longer follow-up periods, to measure survival rates, and true randomised trials on larger samples can elucidate if there is a benefit for using one device over the other.

Keywords: osteoarthritis, high tibial osteotomy, intramedullary device, KOOS score, surgical accuracy.

Introduction

Open-wedge high tibial osteotomy (HTO) is an accepted treatment for osteoarthritis of the knee especially in the young and active patient. The current gold standard osteotomy implant is the angle stable titanium locking plate which permits early weight-bearing and functional return [1]. Despite the undoubted material strength of this implant and its many variants, the results of surgical accuracy achieved in osteotomy surgery vary significantly [2,3]. Much of this variability may result from inadequate surgical planning, variable surgical technique, failure to consider intra-articular deformity and unanticipated events such as hinge fractures [4]. Previous papers have shown a correlation between the surgical outcome, in terms of achieved correction angle in HTO, with clinical outcome [5,6]. In some patients full correction is not achieved whereas in others there is an overcorrection [7].

OPTY-LINE is a novel intramedullary realignment system. A magnetically-driven distraction and compression mechanism is precisely activated via an external remote control device operated by the patient [8,9]. The system is predicated on the successful nail implant used in limb lengthening surgery [9]. Whilst the HTO nail implant's structural properties contrast significantly with the angle locking plate, the most important difference between the two systems is the functionality of the intra-medullary magnetised device which permits gradual post-operative correction to a more consistent and precise intended target point than the plate technique - as measured on surveillance long leg radiography. The opening wedge is gradually opened post-operatively in small increments of 0.5 -1mm per day after a latent period of several days. Once the desired correction has been achieved (which may include reversal in direction of the mechanism if there has been small overcorrection), the distraction is concluded [8]. Initial short-term follow-up outcome data for OPTY-LINE patients suggests that higher surgical accuracy can potentially be achieved with this system and that initial patient satisfaction with the procedure may be comparable to patients who undergo an HTO with Tomofix. Furthermore, bone regeneration in the osteotomy gap appears speedier with post-operative correction in comparison with a plate technique [8].

There is a lack of data on the long-term outcomes for the OPTY-LINE nail system. The objectives of this present study were to determine what levels of surgical accuracy are achieved in the longer term and if long-term patient knee functionality and overall satisfaction differ between those patients treated with OPTY-LINE or Tomofix devices respectively.

Patients & Methods

Sample and study setup

Between December 2015 (date of first patient operation) and February 2020, patients were identified at two different hospitals, by two different surgeons who performed all the operations at their respective sites. Patients were recruited without randomisation and this therefore concerned a prospective, two cohort, multi-centre comparative study. Patients had an HTO procedure and one of two devices was used: OPTY-LINE system (Nuvasive Inc) or Tomofix plate (DePuy Systhes, West Chester, USA). For the OPTY-LINE cohort, patients were identified prospectively and consecutively from surgical and clinic lists – an exception were those patients who had already participated in an initial short-term follow-up study [8]. For the Tomofix cohort, patients were identified retrospectively from surgery lists (though they were approached consecutively commencing with patients operated on from December 2015 onwards), i.e. they had already undergone their HTO procedure. As with the OPTY-LINE cohort, some patients who consented to taking part in this present study had also participated in the initial short-term follow-up study. National Research Ethics approval was obtained (reference 16/NW/0017), as well as Health Research Authority and local National Health Service Trust approvals prior to commencing the study. Inclusion criteria were HTO using Tomofix device or OPTY-LINE device for symptomatic medial compartmental osteoarthritis, and mental capacity. Exclusion criteria were patient age under 18 years, and a lack of competence in English. Further clinical parameters were applied and these are listed in the paper concerning initial comparison of the two medical devices [8]. Patients gave written informed consent, in line with the Declaration of Helsinki concerning Good Clinical Practice.

Surgical procedures & Rehabilitation

Tomofix plate surgery.

The opening wedge HTO procedure was performed as reported previously [10,11].

OPTY-LINE nail surgery.

The OPTY-LINE device surgical procedure is described in the short-term outcome study report [8]. Pre-operative planning guided the post-operative correction with the external magnet device to extend the nail.

Post-operative rehabilitation

All patients were administered a calf pump and prescribed enoxaparin sodium (Clexane®) whilst hospitalised; upon discharge from hospital, rivaroxaban was prescribed for two weeks. Patients were encouraged to achieve full mobility by advising the following activities: toe touch weight-bearing in first two weeks; partial to full weight bearing as comfort allowed after 2 weeks; full weight bearing was allowed from 4 weeks onwards, followed by full weight bearing 2 weeks later.

Correction planning and accuracy assessments

An identical approach to planning was taken for both devices in terms of establishing the intended knee joint correction, and this was performed as described previously [10].The absolute value for the weight-bearing axis crossing the proximal tibial joint line (% Mikulicz

point) was utilised to calculate accuracy (meaning a value of zero is deemed a perfect correction) [12,13].

Study schedule

At baseline, subject demographics and pre-surgery clinical parameters (including radiological imaging) were recorded as part of standard clinical care; radiograph diagnostics at 12 months post-surgery was also part of standard care. Therefore, relevant data could be retrieved for patients who had already undergone surgery within the last two years. At 24 months post-surgery (-4/+8 months), a prospective study visit took place where the following data was collected: patient-reported outcome measures (PROMs), Knee injury and Osteoarthritis Outcome Score (KOOS) survey [14] as well as an post-surgery patient satisfaction questionnaire (design based on earlier versions) [15,16,17]. Possible answers to the survey were 'Very dissatisfied' (score = 1), 'Dissatisfied' (2), 'Neutral' (3), 'Satisfied' (4), 'Very satisfied' (5). Participants also attended the radiology department for two additional X-rays, one long leg anterior-posterior and one lateral knee image. In addition to this, OPTY-LINE patients attended out-patient clinic for the correction visits described in [8].

Statistical analysis

Microsoft Excel was used for entering data and analyses were performed with SPSS v20 (IBM), whereas an a-priori power calculation was conducted with GPower 3.1 freeware. The change in KOOS – for each sub-category - between baseline and 24 months post-operation (KOOS delta) was used to determine the required sample size a priori. Based on our previous observations [8],

a KOOS mean delta difference of 10 between the two cohorts (with standard deviation of ±10, significance p-value of 0.05, and power of 80%) necessitated a sample size of 28 with a distribution between the two cohorts of 1:1 where possible. The minimal perceptible clinical improvement (MPCI) is used to ascertain if a certain improvement in a patient-related outcome measure is clinically relevant [14]. This was therefore used a guide when determining the sample size for this study. The MPCI of approximately 10 obtained has been applied to KOOS in power analyses and when determining cut-offs for improvement and deterioration [14, 18]. Statistical significant differences were determined with two-sided Mann-Whitney test and Chi-square test respectively.

Results

A total of 31 patients were recruited, of which for 19 cases the Tomofix plate fixation was used and for 12 cases the Nuvasive OPTY-LINE nailing system was deployed. None of the cases required revision surgery within the study timeframe. All patients met the eligibility criteria outlined in the methods section 2.1. Table 1 shows an overview of distribution of demographics and comparison between the two cohorts. No significant difference between cohorts was noted for any of the recorded demographic variables, including age or body mass index. Table 2 summarises the surgical accuracy per case, as well as the average accuracy achieved per cohort and how it compares with the other device. In terms of absolute accuracy, OPTY-LINE performed better on average but not to a statistically significant level (p-value 0.11). Absolute accuracy within 10 degrees of the planned Mikulicz was achieved in 11 out of 12 OPTY-LINE cases (92%), whereas this was the case for 11 out of 19 Tomofix cases (58%; p-value 0.10, Fisher exact test).

Minimal perceptible clinical improvement (MPCI) - an increase in score of at least 15 points - were observed for both the OPTY-LINE and Tomofix patients for each of the KOOS sub-scales. All KOOS subcategory scores increased significantly between baseline and two years post-surgery in both cohorts (p-value <0.05, Wilcoxon test). However, no significant difference in difference over time (Δ) was observed for OPTY-LINE versus Tomofix as summarised in Table 3.

Functional outcomes associated with the HTO procedure were also assessed through a patient satisfaction survey; Figure 1 displays the distribution of answers given to the four survey questions. For the question 'At this moment in time, how satisfied are you with the results of surgery for improving your ability to do recreational activities (including sports)?', there was no significant difference in median score between the OPTY-LINE and Tomofix cohorts (3.5 [inter-quartile range 2.3-4.8] vs 4.0 [2.0 vs 5.0], p-value 1.00, Mann-Whitney U-test). Likewise, no significant difference was observed when the survey question was related to: doing home, garden or office work (4.0 [4.0-5.0] vs 4.0 [3.0-5.0], p-value 0.75); improvement of pain (4.5 [3.3-5.0] vs 4.0 [3.0-5.0], p-value 0.26); and overall satisfaction after surgery (4.5 [4.0-5.0] vs 4.0 [3.0-5.0], p-value 0.48).

Discussion

This study assesses the performance of the OPTY-LINE nail in HTO with greater than 6 month follow-up, and builds on an initial short-term outcome comparison between these two devices [8]. The results of this comparative matched case series indicate that OPTY-LINE is

non-inferior to the well-established Tomofix device in terms of long-term surgical accuracy and patient-reported outcomes. In conventional osteotomy surgery – using a fixed plate device like Tomofix - the surgeon depends on pre-operative imaging, careful planning and meticulous intra-operative judgement in order to achieve as accurate a correction as possible. Post-operative rehabilitation has to follow appropriate guidance in order to protect the fixation where appropriate. The gradual distraction and contraction of the fixation with OPTY-LINE allows for fine tuning of the mechanical axis or MiKulicz point in order to place it as close to the desired pre-operatively measured point. The respective average accuracy achieved with OPTY-LINE versus Tomofix in this study supports the ability for fine tuning with the former device; good outcomes are achieved with OPTY-LINE both in terms of average absolute accuracy within each cohort and the proportion of cases for which accuracy falls within 10 degrees of the target Mikulicz value (though a larger sample size would be required to demonstrate a statistically significant difference between the two cohorts). Previous research has reported similar surgical accuracy figures for Tomofix when used for HTO [12]. Despite OPTY-LINE being a device that is not fixed to bones, no marked change in correction was observed 2 years after surgery. This follows initial promising surgical accuracy and HTO healing results observed at 3 and 6 months post-surgery involving a smaller cohort of patients [8]. It is not inconceivable, albeit not proven through experimentation, that the early regeneration of bone observed in HTO cases using OPTY-LINE may aid in maintaining a correction. In the Tomofix cases some more accuracy variance was observed; possibly due to the plate being fixed, this device does not appear to be prone to loss of correction despite healing of the bone within the tibial wedge taking up to a year [19,20, 21].

We recognise this study has some limitations. Medical device allocation to OPTY-LINE or Tomofix was not random – this is partly because the study was an extension of the initial comparative study performed with some of the participants [8]. Nonetheless, as shown in Tables 1 and 3, baseline variables were well matched between the two case series. Apart from the risk of recruitment bias, reporting bias was also present because radiological measurements were conducted by clinical staff who knew the treatment allocation for the patient; this was unavoidable because the Tomofix and Ellipse devices show up differently on a radiograph. On a positive note, radiographs were obtained at two years after surgery, and none of the participants withdrew or were lost to follow-up, and radiographs.

The results of the KOOS scores and patient satisfaction scores at two years post-surgery match each other in that, on average, all patients' knee function improves significantly after HTO. OPTY-LINE and Tomofix match each other in terms of KOOS score improvements for the sub-themes too. As summarised in Figure 1, patients' opinion of OPTY-LINE may be more marked instead of the gradual distribution for Tomofix. For example, for work-related and overall satisfaction those in the OPTY-LINE cohort tend to be either very satisfied or very dissatisfied about the results of their HTO. The KOOS results extend the positive outcomes achieved with OPTY-LINE (and Tomofix) in the initial proof-of-concept study with the device, whereas the patient satisfaction scores have improved from a mere neutral at six months post-surgery to an average 'satisfied' score in this present study [8]. Of note is the strong improvement in sport & recreation scores recorded by both OPTY-LINE and Tomofix patients. In the initial short-term follow-up study of OPTY-LINE this could not be appraised, since patients tend to wait a number of months before returning to more strenuous activities such as sports [22, 23]. However, since HTO patients can

be younger than knee replacement patients and are usually still physically active, both OPTY-LINE and Tomofix are suitable candidate medical devices to treat osteoarthritis of the knee. Importantly, the satisfaction rates observed for both OPTY-LINE and Tomofix cohorts are comparable to those reported for knee replacement. Overall, the percentage of dissatisfied patients in our study is 17% whereas Bourne and colleagues reported that 19% of patients are dissatisfied after total knee arthroplasty (TKA) [16]. Another comparative study between TKA and HTO could not establish differences in patient related outcome measures [24].

Conclusions

In addition to the angle stable titanium locking plate, such as Tomofix, the OPTY-LINE medical intramedullary realignment system provides an alternative for achieving angle correction in HTO. The results of this comparative case series with longer term follow-up show that from a patient perspective there is no marked difference in change in knee function and overall post-surgery satisfaction between OPTY-LINE and Tomofix. In this study, the potential increased surgical accuracy achieved with OPTY-LINE did not translate into improved patient-reported outcomes. Comparative performance of OPTY-LINE versus locking plate systems like Tomofix, through a prospective randomised controlled trial design with a survival element built in, should be conducted to investigate if improved surgical accuracy can indeed be achieved with OPTY-LINE and if it translates into differences in patient-reported outcome measures related to knee function and overall post-surgery satisfaction.

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Table 1, demographics and baseline characteristics of study subjects

Parameter	OPTY-LINE (n = 12)	Tomofix (n = 19)	p-value
Age, mean in yrs (SD)[#]	52 (11)	54 (8)	0.82
Sex, n (male / female)[@]	10/2	12/7	0.23
Weight, mean in kg (SD)[#]	87 (15)	88 (15)	0.75
Height, mean in cm (SD)[#]	175 (8)	173 (10)	0.48
Body Mass Index, mean in kg/m^2 (SD)[#]	28 (4)	29 (4)	0.72
Leg affected, n (left/right)[@]	5 / 7	12 / 7	0.24
Length of stay, median in days (IQR)[#]	1 (1-1.75)	1 (1-2)	0.94

 # Mann-Whitney U-test, two-sided; @ Chi-squared test

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Table 2, Analysis of achieved versus intended Mikulicz at follow-up

Device	Patient no.	Planned Mikulicz value	Achieved Mikulicz value at 2 yrs	Surgical accuracy targeting error at 2yrs	Surgical accuracy, absolute value at 2 yrs*
OPTY-LINE	OL1	55	55.9	0.9	0.9
	OL2	57.5	52.7	-4.8	4.8
	OL3	55	52.8	-2.2	2.2
	OL4	55	51	-4	4
	OL5	55	57.7	2.7	2.7
	OL6	55	47	-8	8
	OL7	55	56.1	1.1	1.1
	OL8	55	62.1	7.1	7.1
	OL9	55	55	0	0
	OL10	51	49	-2	2
	OL11	59	72	13	13
	OL12	62	57	-5	5
	Mean (SD)	55.8 (2.7)	55.7 (6.6)	-0.1 (5.8)	4.2 (3.7)
Tomofix	TF1	50	67.5	17.5	17.5
	TF2	55	59.7	4.7	4.7
	TF3	55	49.9	-5.1	5.1
	TF4	55	72.3	17.3	17.3
	TF5	65	41.2	-23.8	23.8
	TF6	55	61	6	6
	TF7	65	53	-12	12
	TF8	55	53	-2	2
	TF9	55	49	-6	6
	TF10	55	67	12	12
	TF11	55	79	24	24
	TF12	55	54	-1	1
	TF13	55	74	19	19
	TF14	55	56.25	1.25	1.25
	TF15	55	55	0	0
	TF16	55	64	9	9
	TF17	55	45	-10	10
	TF18	65	67	2	2
	TF19	58	56	-2	2
	Mean [SD]	56.5 (4.0)	59.2 (10.2)	2.7 (12.0)	9.2 (7.8)
p-value[#] (OPTY-LINE vs Tomofix)				0.44	0.11

** A value of 0 equates to accuracy of 100% (achieved Mikulicz – intended Mikulicz [Elson, 2017]).*

[#]Mann-Whitney U-test, two-sided; p-value < 0.05 considered statistically significant.

Table 3, KOOS scores for knee functionality at various time points

KOOS sub-category	OPTY-LINE, median (IQR), n=12	Tomofix, median (IQR), n=19	p-value*
Pain - baseline	50 (40-67)	44 (33-56)	
Pain - 2yrs	79 (71-98)	78 (61-81)	
Pain – Δ	29 (18-49)	22 (8-39)	0.36
Symptoms – baseline	54 (37-63)	43 (29-64)	
Symptoms – 2 yrs	75 (65-86)	61 (54-82)	
Symptoms – Δ	24 (16-41)	15 (0-43)	0.43
Activities daily living – baseline	68 (51-79)	53 (37-71)	
Activities daily living – 2 yrs	92 (79-100)	81 (65-94)	
Activities daily living – Δ	22 (10-41)	25 (12-31)	0.95
Sport/recreation – baseline	20 (0-39)	20 (5-40)	
Sport/recreation – 2 yrs	60 (46-74)	55 (40-75)	
Sport/recreation – Δ	35 (25-60)	35 (10-45)	0.33
Quality of life – baseline	28 (15-43)	19 (6-31)	
Quality of life – 2 yrs	63 (44-93)	50 (13-75)	
Quality of life – Δ	18 (8-35)	25 (9-40)	0.60

**Mann-Whitney U-test; IQR, interquartile range*

Figure 1, Patient satisfaction at 2 years post-surgery – distribution of answers to four survey questions (degree of satisfaction related to sport/leisure activities, work, pain and overall)