Title: OPTY-LINE remote-controlled adjustable intramedullary device implantation in opening wedge high tibial osteotomy; prospective proof-of-concept pilot and comparison with Tomofix fixed plate device method.

Abstract [250 words max; currently 239 words]

Purpose The objective was to evaluate the degree of bone regeneration achieved after opening wedge high tibial osteotomy (HTO), comparing case series treated with OPTY-LINE and Tomofix fixed-plate device respectively. Furthermore, surgical and patient-reported outcomes were assessed for each modality.

Patients & Methods Males with symptomatic medial compartmental osteoarthritis and no serious (co-morbid) knee pathology were followed-up, five Tomofix and six OPTY-LINE patients. Patients underwent CT assessment and completed KOOS and osteotomy surgery patient satisfaction questionnaires, 3 and 6 months post-surgery. A radiologist impression score and a quantitative digital density analysis were performed by two independent radiologists.

Results At six months post-surgery, for Tomofix the median healing impression score was 'progressive healing' – equivalent to a mean bone healing quotient of 1.30 [standard deviation 1.74]. For OPTY-LINE the median score was 'union virtually complete', p = 0.041, whereas the bone healing quotient was 1.78 [SD 1.58], p = 0.089. The post-operative absolute surgical accuracy was a mean 4.1 [2.3] for OPTY-line versus 12 [7.5] for Tomofix (p = 0.052). At baseline, however, Tomofix patients had more knee symptoms, as determined by KOOS symptom sub-score, when compared to the OPTY-LINE cohort (p = 0.009).

Conclusion Patients implanted with the OPTY-LINE device for HTO exhibit significantly accelerated post-surgical bone regeneration and higher surgical accuracy compared to Tomofix

patients. Large-scale controlled studies with longer follow-up are indicated to further evaluate the clinical and patient-related outcome performance of OPTY-LINE to confirm these initial findings.

Keywords: bone regeneration, bone healing, computerized tomography, high tibial osteotomy, intramedullary device, KOOS score.

Introduction

Angle stable plates are the current implants of choice in opening-wedge high tibial osteotomy (HTO) offering increased stability and earlier post-operative weight-bearing than their predecessors.[1,2] Some authors have described full-weight bearing as early as two weeks post-surgery without negative impact.[3] Tomofix patients tend to resume normal activities of living soon after surgery with work-related physical activities introduced at 3 to 4 months and sports after approximately 6-12 months.[6,7] One reservation for allowing patients to fully weight bear early on is the perceived risk of loss of correction of the angle, although in practice this effect appears to be a rare occurrence.[1,8,9] Histologically, there is variability in the degree of healing and indeed maturation of bone regeneration achieved in the open wedge. With current fixed plate devices, even 18 months post-procedure, a minor subset of patients will not have significant signs of regeneration in the gap.[4]

Gradual HTO wedge-opening and stabilization can be achieved with the recently CE-marked OPTY-LINE system (NuVasive Specialized Orthopedics, San Diego, USA). The OPTY-LINE device is an extendable nail which is inserted into the proximal tibial intramedullary canal after the osteotomy is created in the conventional manner Figure 1A shows a schematic drawing of the full length OPTY-LINE device, including where it is fixed to the tibia. Following surgery the nail is slowly extended over a period of time until the distraction gap and thereby the bone correction angle is satisfactory, as measured by X-ray imaging. Figure 1B demonstrates schematically how the proximal mediolateral (ML) screw changes its angle in relation to the longitudinal axis of the nail as the distraction produces opening of the wedge via the anteroposterior (AP)screw. The null hypothesis is that there would be no difference in outcome for rate of bone healing and surgical accuracy in cases using the new OPTY-LINE design in comparison with cases using the established gold standard Tomofix plate. Timely healing of the osteotomy gap is of clinical importance since it will in the majority of cases allow the patient to resume activities such as sports even if the supporting device is removed.[6,10] Surgical accuracy is extremely important for successful outcome in high tibial osteotomy.[11] Inaccuracy leads to poorer outcomes with higher revision rates or conversion to arthroplasty. The main objective of this comparative study is therefore to assess and quantify the degree of bone regeneration on CT scan and thereby compare the bone healing process between the Tomofix plate and OPTY-LINE system. Furthermore, apart from introducing the surgical methodology for the new OPTY-LINE device, we explore the surgical accuracy achieved post-operatively and how patients perceive the device in terms of post-operative satisfaction rates and functionality of their corrected knee joint.

Patients & Methods

Study design and subjects

The study is a prospective, open label, two-armed, single-centre therapeutic study. The study is registered with ClinicalTrials.gov, identifier NCT02717845. Two cohorts of patients were enrolled into the study without randomisation. The participants either underwent HTO with the OPTY-LINE system or the Tomofix plate (DePuy Systhes, West Chester, USA). Patients were identified prospectively from surgical and clinic lists. Only males were enrolled into the study, to make the study more controlled and for two relevant reasons: to minimise fetal risk with increased ionising radiation; and to avoid confounding due to the known difference in bone density between males and females.[12]

A total of 12 patients were recruited into the study and it concerned 7 OPTY-LINE patients and 5 Tomofix patients. All patients were male and non-smokers, and they all met the eligibility criteria outlined in section 2.2. One of the OPTY-LINE subjects expired during follow-up, prior to the study follow-up visits, due to non-surgery nor medical device related reasons and therefore 6 OPTY-LINE patients remained for analysis. Table 1 shows an analysis of distribution of demographics – and baseline degree of osteoarthritis - and comparison between the two cohorts.

Eligibility criteria

Inclusion criteria were: treatment with medial open wedge proximal tibial osteotomy, either with Tomofix device or OPTY-LINE device for symptomatic medial compartmental osteoarthritis;

Provision of written informed consent; Males; Mental capacity. Exclusion criteria were: Under age (< 18 years); Patients lacking mental capacity; Females; Current use of nicotine products, including smoking; Patients who cannot understand English and therefore cannot be consented. Furthermore, the following pre-existing clinical exclusion criteria were applied for potentially eligible patients: Varus deformity greater than 10°; Flexion contracture greater than 15°; Knee flexion under 90°; Medial/lateral tibial subluxation over 1 cm; Medial bone loss of over 3 mm if demonstrated on radiographs; Inflammatory arthritis (including use of methotrexate); Arthritis in the lateral compartment; Patella baja; Weight over 115 kg; Severe patella femoral symptoms; Unaddressed ligamentous instability; Fixed flexion contracture; Known or suspected osteoporosis or osteopenia based on medical history and radiographic image; Requirement for other major surgical procedures at the time of the HTO surgery.

Surgical procedures & Rehabilitation

- Tomofix plate.

Opening wedge HTO was conducted according to the method outlined in Osteotomies around the Knee Indications-Planning-Surgical Techniques using Plate Fixators and Elson et al.[13,14]

- OPTY-LINE nail.

The OPTY-LINE device surgical procedure was performed as follows: With the knee bent at 90-110 degrees with a bolster, medial para patellar approach to the tibial entry point was made. The entry point is at the anterior cortex of the tibia slightly medially in line with the tibial medullary canal. The position was verified with image intensification. Guide wire was inserted

and confirmed with orthogonal views to be inside the medullary canal. Reaming was preformed to 160 mm x 12.5 mm, and a trial nail was then inserted. The proximal end of the nail should sit flush with the tibial plateau. Following nail insertion, the AP screw is drilled. After removal of the trial nail the high tibial osteotomy was performed as per Elson et al.[13] Subsequently the OPTY-LINE nail was inserted and locked proximally and distally. After wound closure the magnet inside the nail was then identified and marked on the skin aided by the image intensifier. Post-operative correction is based on pre-operative planning and serial radiographs. Daily correction for each patient was typically 0.5 mm, divided into 2 sessions, starting five to seven days after the operation. Weekly follow up – up to six weeks - with long leg alignment radiograph views were performed to optimise the corrections.

- All patients

Post-operatively, patients returned to full mobility through the following steps: toe touch in first two weeks, partial weight bearing after 2 to 4 weeks, full weight bearing after 4 to 6 weeks (use of single crutch), and full weight bearing without aids from 6 weeks onwards. To minimize the risk of deep vein thrombosis developing, all patients were treated with a calf pump and administered clexane whilst in hospital, and prescribed rivaroxaban for two weeks once discharged home.

Correction planning and post-operative surgical accuracy assessments

The approach to planning the intended knee joint correction did not differ between the two medical devices. Pre-operative planning and post-operative assessments were conducted according to the method described by Elson et al.[13] For accuracy calculations, the weight-bearing

axis transecting the tibia (% Mikulicz point) was used. The absolute figures for surgical accuracy were calculated in relation to post-operatively achieved Milkulicz line minus the pre-operatively planned Mikulicz line. Therefore a value of zero can be considered a perfect correction.[15,16]

Study schedule

Apart from correction visits for OPTY-LINE patients, all study subjects were seen at baseline (within one month prior to surgery), and 3 & 6 months following their HTO procedure for collation of the patient and clinical outcome measures. At baseline, subject demographics were recorded. During each study visit, the following patient-reported outcome measures (PROMs) were collected: Visual analogue pain scale (standard 10 cm line), KOOS knee health questionnaire[20] and an osteotomy patient satisfaction questionnaire (see Annex 1). The latter questionnaire is based on three earlier published questionnaires, adopted for this study.[17,18,19]

CT imaging details

The primary outcome was the radiologist's assessment of healing, as determined from CT-imaging according to a 5-point Likert scale devised by Brosset et al.[20] This was performed by two radiologists, FF (rater 1) and JE (rater 2), each of whom have over 10 years' experience as a consultant radiologist. The Radiologist Impression Scoring system, and what each score equates to, is outlined in Table 2.

The CT apparatus used in this study was a Siemens Somatom Sensation (64 Slice) scanner. To minimise unnecessary exposure to ionising radiation, the image acquisition will start 3 cm above

the proximal osteotomy line and ending 3 cm below the inferior aspect of the gap. A standardised CT protocol with full detector coverage of 64 Slices, a slice thickness of 0.6 mm, peak kilovoltage of 120, product of tube current and exposure time of 140 mAs effective, and a pitch of 0.9 and a rotation time of 1 second, was used. Images were then reconstructed with very sharp kernel of B70s in 2 mm slices with a reconstruction increment of 2mm. In addition to the aforementioned Radiologist Impression Score, other parameters related to bone healing following HTO were recorded. The osteotomy margin is the angle between the superior osteotomy margin and the articular surface of the medial tibia plateau. In addition, the margin surface appearance was also recorded (smooth vs irregular). The osteotomy gap is the maximum gap within the osteotomy location, measured at the cortex on a coronal field of view. Callus characteristics were also defined for each subject; callus appearance can be divided into irritation callus and fixation callus respectively.[21] The presence of endosteal and periosteal bone healing was also recorded. In addition to a qualitative bone healing scoring, bone healing was also quantified by applying regions of interest (ROIs), measuring approximately 7mm^2 in size. This quantitative measurement was performed within the osteotomy gap on coronal reconstruction images on the picture archiving and communication system (PACS). The location of the ROI was as follows: for the defect area the ROI was positioned in the centre of the osteotomy gap between the superior and inferior margins a few millimetres beside the medial cortex of the proximal tibia and for inferior/superior areas it was placed circa 10 mm from the respective osteotomy margins. The purpose of measuring the ROI above and below the level of the osteotomy gap was to deliver references of normal bone marrow density of tibia of the same

individual. Bone density of the callus formation was assessed independently by the two abovementioned radiologists, with each using the same coronal mid-point slide.

Statistical analysis

Study data was entered in Microsoft Excel and analyses were conducted using SPSS v20. The a-priori power calculation was performed using GPower 3.1 freeware. The required sample size to obtain 80% power and 5% significance was 10 subjects total with 5 subjects per treatment group. This was based on a hypothetical difference in radiologist mean healing score at month 6 between the two devices measuring 2, standard deviation of 1, with a one-sided Mann-Whitney U-test applied (exact test outcome). For comparison of quantitative assessment of bone formation between Tomofix and OPTY-line cohorts, Mann-Whitney U-test was also applied. Concordance between the two radiologists' scores was assessed with Kendall's coefficient of concordance. Any statistical difference between the baseline demographics of the two cohorts for demographics was assessed with two-sided Mann-Whitney test for ordinal and continuous data, and Fisher's exact test for binary data. KOOS patient reported outcome data and magnitude of error of accuracy was assessed by application of a two-sided Mann-Whitney U test. In line with the power calculation, for bone density analysis, one-sided Mann-Whitney U-test was applied. Loss to follow-up was not taken into account as subjects were to remain under clinical supervision by the Orthopaedic department during the study period.

Results

Table 2 displays the data for the Likert scale radiologist's impression score and also for the quantitative analysis using pixel density on images in PACS. The average bone healing status for OPTY-LINE at 6 months is 'union virtually complete' whereas for Tomofix it is 'progressive healing'. These results are mirrored to a large extend with digital quantification analysis at 6 months. The characteristics of the regeneration in the lesion align with the radiologist impression score. At six months, 4 out of 6 OPTY-LINE cases show the presence of fixation callus, whereas this type of more developed callus is only seen in 1 out of 5 Tomofix cases. In all other cases irritation callus is the predominant feature. Figure 2 shows representative CT imaging for one Tomofix and one OPTY-LINE patient at 3 and 6 months post-operative respectively. CT imaging also revealed 4 out of 6 type I and 1 out of 6 type II hinge fractures in the OPTY-LINE cohort, whereas in the Tomofix cohort 3 out of 5 patients had a type I and 2 out of 5 had a type II hinge fracture.

The surgical accuracy achieved for each patient, and comparison analysis between the two cohorts, is summarised in Table 3. The OPTY-LINE device achieved a median improvement of more than 10 points - equating to achieving a minimal perceptible clinical improvement (MPCI) [22] - for each of the KOOS sub-scales, which are pain, symptoms (, activities of daily living (ADL), sport & recreation (S&R) and quality of life (QoL). KOOS score improvements were also observed in the Tomofix cohort, but to a lesser degree, with only S&R and QoL reaching MPCI levels (full data set available in Annex 2). When compared, of note is the difference in terms of the KOOS score at baseline for OPTY-LINE versus Tomofix (p-value,

two-sided Mann-Whitney U-test): pain 68 vs 44 (0.052); symptoms 58 vs 41 (0.009); ADL 71 vs 47 (0.052); S&R 22 vs 6 (0.13); and 32 vs 20 (0.33). An initial descriptive patient-reported satisfaction appraisal of each respective treatment shows little to no difference in how they perceive the outcome of the surgery (see Annex 1 for full graph summarising outcomes at 3 and 6 months post-surgery). At six months, both OPTY-LINE and Tomofix score a median of 'satisfied' for general and pain related patient satisfaction, whereas for daily activities and sports & recreation they both score 'neutral'. The data to some extent mirrors the KOOS data.

Discussion

This is the first report on the use and performance of the OPTY-LINE nail in HTO, and first evidence that the achieved bone regeneration in the osteotomy gap at 6 months post-surgery is significantly better with OPTY-LINE compared to Tomofix. Although the application of the OPTY-LINE device in patients with osteoarthritis is novel, the applied technology is well-established. It has its roots in the PRECICE intramedullary limb lengthening system; a magnetic rod and a motorized external remote controller (ERC) with rotational magnetic field are used to gradually extend the limb.[23] The PRECICE system has been shown to be highly accurate in terms of achieving a desired lengthening.[24,25]

The gradual elongation with OPTY-LINE also allows fine tuning of the MiKulicz correction axis point, whereas with Tomofix the surgeon is dependent purely on pre-operative imaging and calculations to try and achieve an as accurate as possible correction. This is evident from the accuracy results for OPTY-LINE and Tomofix respectively. Where 3 out of 5 Tomofix cases

have an absolute accuracy of < 10, in the case of OPTY-LINE all cases are within 10. Even with the small sample size applied in this pilot study, the difference is nearly statistically significant. The range of corrections seen in the Tomofix cohort is not uncommon for HTOs conducted with said device.[16] At 3 months post-surgery both cohorts contain undercorrected and overcorrected cases, whereas at 6 months there are signs – in 5 out of 6 cases - that the corrections for OPTY-LINE are not sustained and that there may have been a degree of compression of the osteotomy gap. More cases need to be carried out to ascertain if this is an accidental observation or whether this is a characteristic of the OPTY-LINE device which needs to be taken into account when planning surgery. Loss of correction has previously been shown to be a rarity in HTOs carried out using Tomofix, with only up to 2% of cases showing such signs.[26,27]

Regardless of the medical device system applied, for open wedged HTO it is imperative that the open wedge is healed and repopulated by new bone, to restore strength and allow full recovery following HTO. Regeneration will take place naturally, although some surgeons apply aids to promote bone healing, such as allografts or synthetic bone substitutes. Research into filling of the wedge has shown that there is no significant advantage to using the filler – both in terms of stability and bone healing time of the wedge.[20,28] Therefore, in this present study, for the Tomofix cohort filler was not applied; with OPTY-LINE, since initially only the cut is made and a wedge is created in the weeks post-surgery, filler is not indicated. As mentioned in the introduction, osteotomy patients often wish to return to being physically active, including participation in sports. However, surgeons often find it very difficult to decide when their patient can indeed return to unrestricted sports. This is

253 partially because it is often very difficult to quantify the bone healing process precisely on
254 radiographs. Experiments on osteotomy cases and in other mammals have shown that CT
255 imaging is the best option for appraising healing since radiography overestimates the degree
256 of healing.[29,30] This study's primary outcomes, the radiologist impression scores and
257 quantitative bone healing quotient scores using CT imaging, were highly comparable at 3
258 and 6 months for each medical device, though lower concordance was found at 6 months,
259 where the standard deviation was much larger for bone healing quotients. This can be
260 explained by the fact that the radiologist impression score is based on an evaluation of the
261 whole lesion, whereas for the digital quantification only one sub-region was captured. Due
262 to the nature of healing, there may be 'hotspots' of healing with callus foci distorting the
263 actual average degree of newly bone formed. Although each patient's natural bone density
264 was taken into account, this artefact could not be avoided because the selected region was
265 in a consistent position within the gap to avoid selection bias. On the other hand, human
266 interpretation of bone regeneration may introduce bias due to the subjective (human
267 assessment) nature of the assessment. There are some signs of this at 3 months with slightly
268 poor concordance, but inter-rater concordance was extremely high for the 6 months
269 samples. Each of the bone regeneration appraisal techniques used, radiologist impression
270 score and bone healing quotient, therefore has a flaw. The combined application of the two
271 approaches is warranted because they corroborate each other. With the assessment
272 techniques in mind, the osteotomy gap in patients fitted with the OPTY-LINE device healed
273 significantly better than those fitted with Tomofix. Whilst OPTY-LINE achieves virtual
274 complete regeneration at 6 months, in the case of Tomofix the healing time stretches

beyond six months post-surgery. Previous research has shown that even at one year post-surgery, consolidation of the wedge created with a Tomofix fixed plate is complete in just under 90% of cases.[30] Of note is where OPTY-LINE regeneration is observed in the lesion; callus formation is seen in both the lateral and medial compartments (see Figure 2A and 2B). On the other hand, In line with what has previously been reported, the Tomofix osteotomy gap is repopulated from the lateral side (Figure 2C and 2D), beginning at the hinge point where the distance between existing bone is the least.[30,32] There is a body of evidence supporting the notion that smaller osteotomy gaps heal faster than large gaps.[33,34] Due to the gradual enlargement of the osteotomy gap, OPTY-LINE lesions can take advantage of this phenomenon. Furthermore, internal fixation with a degree of flexibility encourages bone healing and maturation, resulting in more callus formation.[35] This may possibly explain why healing in the OPTY-LINE cases was more advanced than in Tomofix cases. Schröter and colleagues previously showed that unstable hinge fractures and smoking may delay bone healing.[35] All the subjects in this study were non-smokers, and therefore this does not pose an issue in terms of potential confounding. As expected using CT in preference to radiography the diagnosis of at least a type 1 fracture was almost universal and three type II fractures were also observed. Since distribution was not skewed towards one cohort in particular, their overall confounding effect (if any) on the relative healing outcomes between the two cohorts is unlikely to be significant but should be borne in mind nonetheless.

Despite this being a prospective, clinically and demographically matched comparison of OPTY-LINE and Tomofix, medical device allocation was not random. Furthermore, there was

297 no controlling for KOOS score at baseline, particularly pain before surgery, and in the
298 resulting analysis it transpired that there was a significant difference in said scores between
299 the two cohorts at baseline. This covariate may introduce a degree of bias in terms of
300 patient-related outcome measures post-operatively and possibly even closure of the
301 osteotomy gap if there are biomechanical reasons underpinning the poor KOOS scores. In
302 contrast, OPTY-LINE patients were marginally older on average. Potential bias and the small
303 sample size limit the conclusions that can be drawn on the relative effects each device can
304 have on patients' pain, quality of life and ability to engage in activities of daily living and
305 sports. A future definitive trial will need to address these potential shortcomings, through
306 the introduction of randomisation and stratification for KOOS score. Nonetheless, it appears
307 that OPTY-LINE patients are at a minimum as 'satisfied' as Tomofix patients with the
308 procedure at 6 months post-operation. The trend seen at 3 months for patient satisfaction,
309 with a possibly a poorer performance for OPTY-LINE, may reflect the nature of the new
310 device. OPTY-LINE patients need to undergo the daily elongation procedure for up to six
311 weeks after surgery, whereas Tomofix patients have effectively completed their correction
312 once off the operating table. Since a lot of patients do not return to playing sports after
313 more than six months following HTO [6,7,10], the potential impact of OPTY-LINE on return to
314 physical activity was not assessed in detail in this proof of concept study due to the limited
315 follow-up period. Nonetheless, both OPTY-LINE and Tomofix patients achieved a MPCI at six
316 months in terms of KOOS sports sub-score. The 'neutral' score in terms of patient
317 satisfaction for both devices indicates that it is possibly too early to gauge opinion on this
318 specific topic at six months post-surgery.

Conclusions

The OPTY-LINE medical device is a new modality for high tibial open-wedge osteotomy in which post-operative distraction of the osteotomy cut creates a wedge that can be fine-tuned in terms of gap and thereby correction angle. The initial performance results in this proof of concept study indicate that the device facilitates early bone regeneration and shows promise in terms of surgical accuracy and patient satisfaction that can be achieved. More definitive trials are indicated to evaluate the (long-term) performance of OPTY-LINE.

Ethical approval

Approval was obtained from the UK's National Research Ethics Service, North-West Lancaster Committee, reference 16/NW/0017.

Informed consent

Written informed consent was obtained from all participants in accordance with the Declaration of Helsinki (Good Clinical Practice), as part of the study protocol.

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445 **Table 1, demographics and baseline characteristics of study subjects**

Parameter	OPTY-LINE (n = 6)	Tomofix (n = 5)	p-value
Age, mean in yrs (mean SD)[#]	51 (8)	49 (11)	0.79
Weight, mean in kg (mean SD)[#]	88 (18)	97 (18)	0.43
Height, mean in cm (mean SD) [#]	178 (5)	179 (7)	0.54
BMI, mean in kg/m^2 (mean SD) [#]	28 (6)	30 (5)	0.54
Leg affected, n (left/right)[@]	4 / 2	5 / 0	0.46
Length of stay, mean in days (range)[#]	1 (1)	1 (1-2)	0.66

446 *# Mann-Whitney U-test, two-sided; @ Fisher's exact test*

447 **Table 2, Radiologists' impression scores and quantitative assessment of bone healing**

Time point	Type of rating	OPTY-LINE (median; min to max)	Tomofix (median; min to max)	p-value[#]
3 months post-operatively	***A***			
	Average of 2 raters	1.75 (1 to 2)	0.5 (0 to 2)	0.041^
	Inter-rater concordance*	0.83	0.80	
	B			
	Average of 2 raters	0.40 [0.19]	0.32 [0.077]	0.27
	Inter-rater concordance*	0.89	1	
6 months post-operatively	***A***			
	Average of 2 raters	4 (3 to 4)	2 (1 to 4)	0.041^
	Inter-rater concordance*	1	1	
	B			
	Average of 2 raters	1.78 [1.58]	1.30 [1.74]	0.089
	Inter-rater concordance*	0.89	0.64	
Scoring values	**A**: Radiologist's impression score 0 = no healing (0-20%); 1 = some healing (21-40%); 2 = progressive healing (41-60%); 3 = advanced healing (61-80%); 4 = union virtually complete (81-100%) **B**: Digital quantification of bone healing Bone density quotient = ROI defect area / ((ROI superior area + ROI inferior			

	area)/2)

** Measured with Kendall's coefficient of concordance (W); # - One-sided Mann-Whitney U-test; ^p-value < 0.05 considered statistically significant; ROI = region of interest.*

Table 3, Analysis of achieved versus intended Mikulicz at 3 & 6 months follow-up.

Device	Patient no.	Planned Mikulicz value		Achieved Mikulicz value, 3 months [SD]	Surgical accuracy targeting error*	Surgical accuracy (absolute value, [SD])		Achieved Mikulicz value, 6 months [SD]	Surgical accuracy targeting error*	Surgical accuracy (absolute value, [SD
OPTY-LINE	1	55		50	-5	5		48	-7	7
	2	55		58.9	3.9	3.9		53	-2	2
	3	55		53.4	-1.6	1.6		51	-4	4
	4	55		54.9	-0.1	0.1		51.8	-3.2	3.2
	5	55		55.6	0.6	0.6		53.3	-1.7	1.7
	6	55		60.3	5.3	5.3		61.6	6.6	6.6
	Mean					2.8 [2.3]				4.1 [2.3
Tomofix	7	50		67.4	17.4	17.4		73	23	23
	8	55		66	11	11		71.2	16.2	16.2
	9	55		64	9	9		63.8	8.8	8.8
	10	55		49.2	-5.8	5.8		48.8	-6.2	6.2
	11	55		53.7	-1.3	1.3		49.4	-5.6	5.6
	Mean					8.9 [6.0]				12 [7.5
p-value# (OPTY-LINE vs Tomofix)						0.052				0.052

** 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.

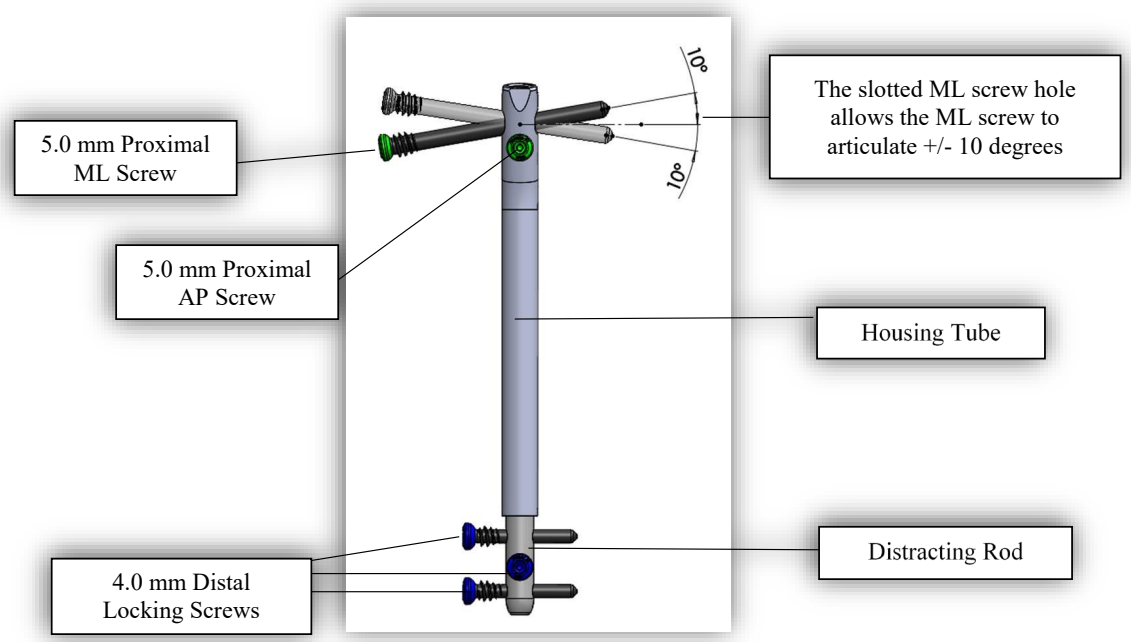
462

463 **Figure 1, OPTY-LINE device for high tibial osteotomy**

464 A - Schematic drawing of the complete device, depicting the locations of the four screws for fixation and
465 the housing tube containing magnet, gears and threaded pin which is distracted in stages post-
466 operatively. ML = medial-lateral; AP = anterio-posterior. Image courtesy of Nuvasive Specialized
467 Orthopedics.

468 B - Schematic drawings of the status of the high tibia and knee joint immediately post-surgery (left) and 6
469 weeks later (right) following distraction of the rod within the OPTY-LINE device. Image courtesy of
470 Nuvasive Specialized Orthopedics.

471 **A**



472

B

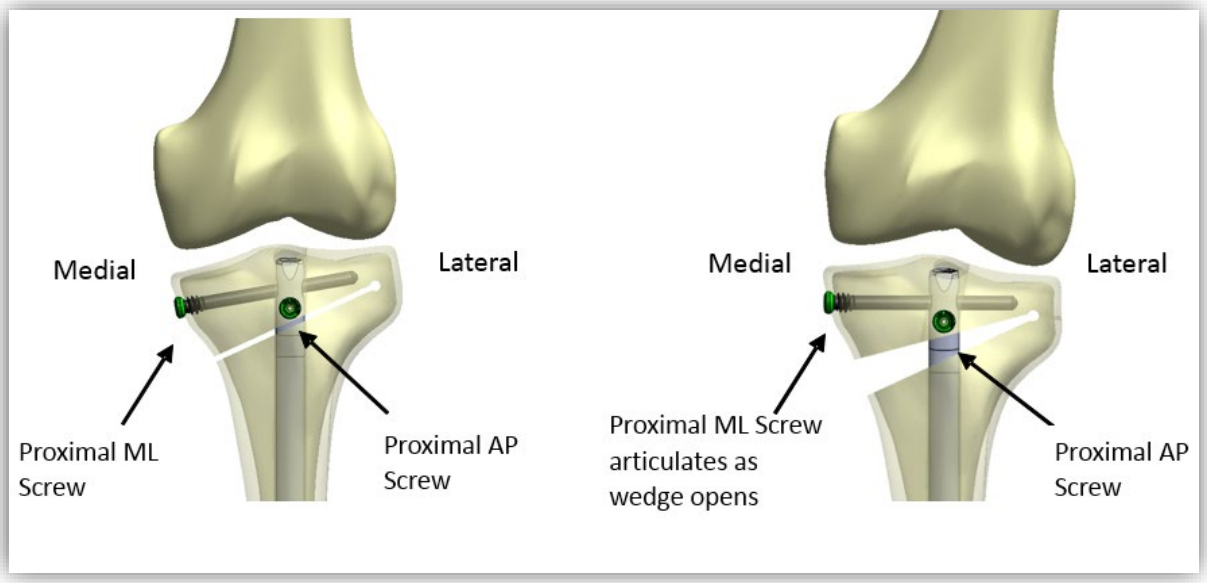
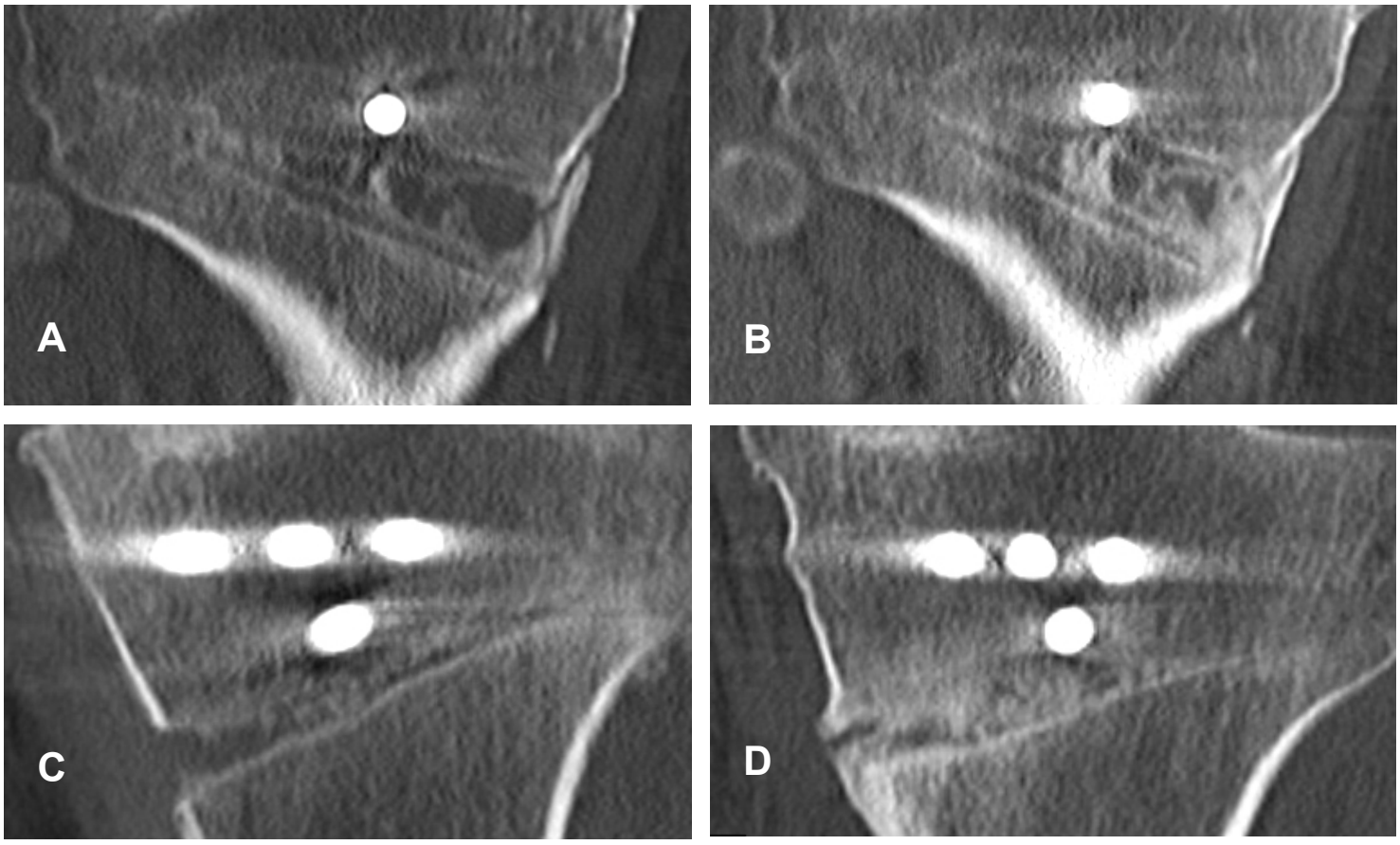

Medial
Lateral
Proximal ML Screw
Proximal AP Screw
Medial
Lateral
Proximal ML Screw articulates as wedge opens
Proximal AP Screw

Figure 2, Representative coronal imaging of osteotomy lesions at 3 & 6 months post-surgery

With both the Tomofix and OPTY-LINE device there an increase in callus formation is observed when the two post-surgical timepoints of 3 and 6 months are compared (A vs B and C vs D) respectively. At 3 and 6 months the healing for Tomofix cases compared to OPTY-LINE is less pronounced at particularly the medial edge of the osteotomy gap (A vs C and B vs D respectively). A, OPTY-LINE at 3 months; B, OPTY-LINE at 6 months; C, Tomofix at 3 months; D, Tomofix at 6 months.



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