NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional Procedures Programme

Professional Expert questionnaire

Before completing this questionnaire, please read Conflicts of Interest for Specialist Advisers.

Please respond in the boxes provided.

Please complete and return to: azad.hussain@nice.org.uk and IPSA@nice.org.uk

Procedure Name:	**High tibial osteotomy using a magnetic rod device for precise alignment correction in early knee arthritis**

Name of Professional Expert: Phil Turner

Job title: Consultant Orthopaedic Knee Surgeon

Professional Regulatory Body: GMC X

Other (specify) ☐

Registration number: 2437521

Specialist Society: BOA and BASK

Nominated by (if applicable): BOA

1 About you and your speciality's involvement with the procedure

1.1 Do you have adequate knowledge of this procedure to provide advice?

X Yes.

☐ No – please answer no more questions and return the form

Comments:

I have extensive experience of osteotomy around the knee using plate fixation

1.2 Is this procedure relevant to your specialty?

X Yes.

☐ No - please answer no more questions. Please give any information you can about who is likely to be doing the procedure and return the form.

Comments:

1.3 Is this procedure performed by clinicians in specialities other than your own?

☐ Yes – please comment

X No

Comments:

1.4 If you are in a specialty that does this procedure, please indicate your experience with it:

X I have never done this procedure.

☐ I have done this procedure at least once.

☐ I do this procedure regularly.

Comments:

The specific procedure of using magnetic driven intramedullary nail distraction has been performed by very few surgeons in the UK but there is knowledge of it for those who regularly perform tibial osteotomy using other forms of fixation

1.5 If your specialty is involved in patient selection or referral to another specialty for this procedure, please indicate your experience with it.

X I have never taken part in the selection or referral of a patient for this procedure.

☐ I have taken part in patient selection or referred a patient for this procedure at least once.

☐ I take part in patient selection or refer patients for this procedure regularly.

Comments:

There have been no local surgeons who have taken on this technique and I have not seen the need to refer patients for it as alternative forms of fixation are well established

1.6 Please indicate your research experience relating to this procedure (please choose one or more if relevant):

X I have done bibliographic research on this procedure.

☐ I have done research on this procedure in laboratory settings (e.g. device-related research).

☐ I have done clinical research on this procedure involving patients or healthy volunteers.

☐ I have had no involvement in research on this procedure.

☐ Other (please comment)

Comments:

1.7 Please estimate the proportion of doctors in your specialty who are doing this procedure (choose one):

☐ More than 50% of specialists engaged in this area of work.

☐ 10% to 50% of specialists engaged in this area of work.

X Fewer than 10% of specialists engaged in this area of work.

☐ Cannot give an estimate.

Comments:

This is an informed estimation – I have a network of knee surgeons who perform osteotomies but I know of only 2 who have undertaken this specific technique

2 About the procedure

2.1 Does the title used above describe the procedure adequately?

X Yes

☐ No - If no, please suggest alternative titles.

Comments:

I think the term is adequate for those who are aware of the procedure but the title does not really capture the way that the rod works – it produces graduated correction

of alignment by using a magnetically driven motor to lengthen the rod and gradually change the alignment at the same time as encouraging new bone formation in the resulting regenerated wedge defect.

2.2 Which of the following best describes the procedure (choose one):

☐ Established practice and no longer new.

☐ A minor variation on an existing procedure, which is unlikely to alter the procedure's safety and efficacy.

X Definitely novel and of uncertain safety and efficacy.

☐ The first in a new class of procedure.

Comments:

The technique of gradual lengthening of bone using this technique is established but using the same scientific knowledge to produce angular correction of deformity in this situation is novel

2.3 What is/are the best comparator(s) (standard practice) for this procedure?

The closest standard practice is to perform one stage correction using an open wedge tibial osteotomy and plate fixation with or without bone graft to fill the resulting defect

2.4 Are there any major trials or registries of this procedure currently in progress? If so, please list.

Osteotomies around the knee can be entered into the UK Osteotomy Registry (UKOR)

2.5 Please list any abstracts or conference proceedings that you are aware of that have been *recently* presented / published on this procedure (this can include your own work). Please note that NICE will do a comprehensive literature search on this procedure and we are only asking you for any very recent or abstracts or conference proceedings which might not be found using standard literature searches. You do not need to supply a comprehensive reference list but it will help us if you list any that you think are particularly important.

3 Safety and efficacy of the procedure

3.1 What are the potential harms of the procedure?

Please list any adverse events and major risks (even if uncommon) and, if possible, estimate their incidence:

Adverse events reported in the literature (if possible please cite literature)

Anecdotal adverse events (known from experience)

Theoretical adverse events

Delayed union, loss of correction, need for removal of metalwork, failure of the magnetic driven motor, patient non-compliance, failure of fixation

3.2 Please list the key efficacy outcomes for this procedure?

Pain relief, appropriate knee scores pre and post op, duration of limited weight bearing, number of clinic visits during treatment, number of x-rays taken during treatment, number and type of re-operations required to complete treatment, number of cases where the metalwork has had to be removed, duration from completion of treatment to total knee replacement

3.3 Please list any uncertainties or concerns about the *efficacy* of this procedure?

Ultimately the technique should produce accurate correction of deformity to improve pain and function from medial compartment osteoarthritis of the knee but there are concerns over the complexity of the procedure, the cost and the extended cost of weekly clinic visits and X-rays to monitor progress to union

3.4 What clinician training is required to do this procedure safely?

Surgeons would already need to have experience of osteotomy using more traditional techniques and then attend a cadaveric course with image intensifier control to learn and practice the surgical technique

3.5 What clinical facilities are needed to do this procedure safely?

Standard theatre facilities with image intensifier and weekly OP facilities with X-rays available including the ability to take long leg AP erect alignment views of both lower limbs

3.6 Is there controversy, or important uncertainty, about any aspect of the way in which this procedure is currently being done or disseminated?

Uncertainty is over the proposed advantage of accuracy of the correction against the cost, clinical input and outcomes compared with more traditional techniques

4 Audit Criteria

Please suggest potential audit criteria for this procedure.

4.1 Beneficial outcome measures. This should include short and long term clinical outcomes, quality-of-life measures and patient related outcomes. Please suggest the most appropriate method of measurement for each and the timescales over which these should be measured:

EQ5D, Oxford knee score and KOOS scores are probably adequate and should be assessed at 3 months and 12 months post surgery. Technical measures of correction should be performed pre-surgery and at 3 and 12 months. Range of movement is also important as stiffness is a risk as well as producing fixed flexion deformity.

4.2 Adverse outcome measures. This should include early and late complications. Please state the post procedure timescales over which these should be measured.

Re-admission, re-operation, time for return to full weight bearing, time to return to work, surgical site infection, removal of metalwork, conversion to knee replacement

5 Uptake of the procedure in the NHS

5.1 If it is safe and efficacious, in your opinion, how quickly do you think use of this procedure will be adopted by the NHS (choose one)?

☐ Rapidly (within a year or two).

☐ Slowly (over decades)

X I do not think the NHS will adopt this procedure

Comments:

The complexity, cost and lack of any obvious advantages over more traditional osteotomy techniques makes it unlikely that the NHS would take this on.

5.2 If it is safe and efficacious, in your opinion, will this procedure be carried out in (choose one):

☐ Most or all district general hospitals.

X A minority of hospitals, but at least 10 in the UK.

☐ Fewer than 10 specialist centres in the UK.

☐ Cannot predict at present.

Comments:

This is an estimate based on the numbers of surgeons performing osteotomies in any significant numbers.

5.3 If it is safe and efficacious, in your opinion, the potential impact of this procedure on the NHS, in terms of numbers of patients eligible for treatment and use of resources:

☐ Major.

☐ Moderate.

X Minor.

Comments:

Each individual procedure is costly in terms of the implant, driver, clinic visits and X-rays. The number of procedures is therefore likely to be very small.

6 Other information

6.1 Is there any other information about this procedure that might assist NICE in assessing the possible need to investigate its use?

Comments:

Any of these procedures should be mandated to be recorded in the UK Osteotomy Registry and / or be part of a prospective trial. It should not be made available outside these restrictions

7 Data protection and conflicts of interest

7.1 Data Protection

The information you submit on this form will be retained and used by the NICE and its advisers for the purpose of developing its guidance and may be passed to other approved third parties. Your name and specialist society will be published in NICE publications and on the NICE website. The professional expert questionnaire will be published in accordance with our guidance development processes and a copy will be sent to the nominating Specialist Society. Please avoid identifying any individual in your comments.

☐ **AGREE** - I have read and understood this statement and accept that personal information sent to us will be retained and used for the purposes and in the manner specified above. For more information about how we process your personal data please see our privacy notice

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7.2 Declarations of interest by Specialist Advisers advising the NICE Interventional Procedures Advisory Committee

Nothing in your submission shall restrict any disclosure of information by NICE that is required by law (including in particular, but without limitation, the Freedom of Information Act 2000).

Please submit a conflicts of interest declaration form listing any potential conflicts of interest including any involvement you may have in disputes or complaints relating to this procedure.

Please use the "Conflicts of Interest for Specialist Advisers" policy as a guide when declaring any conflicts of interest. Specialist Advisers should seek advice if needed from the Associate Director – Interventional Procedures. Conflicts of Interest for Specialist Advisers

Declarations of interest form			
Philip G Turner – Specialist Adviser **I have no conflicts of interest**			
Type of interest	**Description of interest**	**Relevant dates**	
		Interest arose	**Interest ceased**

* Guidance notes for completion of the Declarations of interest form

Name and role	Insert your name and your position in relation to your role within NICE
Description of interest	Provide a description of the interest that is being declared. This should contain enough information to be meaningful to enable a reasonable person with no prior knowledge to be able to read this and understand the nature of the interest. Types of interest: **Direct interests** **Financial interests** - Where an individual gets direct financial benefits from the consequences of a decision they are involved in making. *For examples of financial interests please refer to the policy on declaring and managing interests.* **Non-financial professional and personal interests -** Where an individual obtains a non-financial professional or personal benefit, such as increasing or maintaining their professional reputation, from the consequences of a decision they are involved in making. *For examples of non-financial interests please refer to the policy on declaring and managing interests.* **Indirect interests -** Where there is, or could be perceived to be, an opportunity for a third party associated with the individual in question to benefit. A benefit may arise from both a gain or avoidance of a loss.
Relevant dates	Detail here when the interest arose and, if applicable, when it ceased.
Comments	This field should be populated by the guidance developer and outline the action taken in response to the declared interest. It should include the rationale for this action, and the name and role of the person who reviewed the declaration.

Thank you very much for your help.

Dr Tom Clutton-Brock, Interventional Procedures Advisory Committee Chair

Mirella Marlow Programme Director

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional Procedures Programme

Professional Expert questionnaire

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Please respond in the boxes provided.

Please complete and return to: azad.hussain@nice.org.uk and IPSA@nice.org.uk

Procedure Name:	**High tibial osteotomy using a magnetic rod device for precise alignment correction in early knee arthritis**
Name of Professional Expert:	David Elson
Job title:	Consultant Orthopaedic Surgeon
Professional Regulatory Body:	GMC ☑
	Other (specify)
Registration number:	4698340
Specialist Society:	1) Biological knee society (secretary & treasurer) 2) British Association for Surgery of the Knee (ex-executive committee member) 3) British Orthopaedic Association 4) Chairman of the United Kingdom Knee Osteotomy Register
Nominated by (if applicable):	I think I was nominated by NuVasive to offer an opinion

1 About you and your speciality's involvement with the procedure

1.1 Do you have adequate knowledge of this procedure to provide advice?

☐ **Yes.**

Comments:

Yes I have knowledge of the procedure being investigated

1.2 Is this procedure relevant to your specialty?

☐ Yes.

Comments:

Yes - Highly relevant. The nail is an innovative way to internally fix the bone segments in a high tibial osteotomy allowing for the post-operative correction to be adjusted and potentially improved

1.3 Is this procedure performed by clinicians in specialities other than your own?

☐ No

Comments:

This procedure is only for specialist knee surgeons. This procedure is not for the average orthopaedic generalist.

1.4 If you are in a specialty that does this procedure, please indicate your experience with it:

☐ I have done this procedure at least once.

☐ I do this procedure regularly.

Comments:

I have used the adjustable nail for 6-7 cases in the last 2 years. Previously there was no NICE guidance on this particular device. I therefore discussed local usage at the "New procedures committee" within my hospital, in order to be compliant with trust protocol.

1.5 If your specialty is involved in patient selection or referral to another specialty for this procedure, please indicate your experience with it.

☐ I have taken part in patient selection or referred a patient for this procedure at least once.

☐ I take part in patient selection or refer patients for this procedure regularly.

Comments:
As indicated above I have used this device 6-7 times before and so was involved in patient selection for these and other potentially eligible cases. I think the real value of the adjustable nail device is in securing greater surgical accuracy due to the ability to perform post-operative correction. To my mind the most suitable cases are those where it may be difficult to guarantee surgical accuracy for technical reasons.

The best examples where it is difficult to guarantee surgical accuracy are

1) Double osteotomies where the correction is spread over both the femur and tibia (the tibia can then be adjusted in the post operative period to achieve the intended correction)
2) High joint line convergence angle identified on pre-operative long leg x-rays where it can be difficult to judge exactly how much opening will occur in the medial compartment after osteotomy. The nail is therefore well suited to making a slowly adjusted correction, the knee axis can be parked very close to the intended correction once the medial opening becomes apparent in the post operative period.

1.6 Please indicate your research experience relating to this procedure (please choose one or more if relevant):

☐ I have done bibliographic research on this procedure.

☐ I have done clinical research on this procedure involving patients or healthy volunteers.

Comments:

I have read about the procedure as much as possible before using it in my patients. I was planning to contribute data from my patients to a local study of this device. This work is on-going and is not yet published.

1.7 Please estimate the proportion of doctors in your specialty who are doing this procedure (choose one):

☐ Fewer than 10% of specialists engaged in this area of work.

Comments:

This procedure is firstly only for those surgeons who perform osteotomy around the knee. This is a growing number of knee surgeons in Britain. As leaders in the speciality of knee osteotomy we offer education of interested surgeons at the courses that run in the UK *(2 per annum from Basingstoke knee osteotomy master class, London Osteotomy master class, Northern Osteotomy master class)* and the data framework to evaluate results provided by the national registry (UKKOR). I would estimate that there are perhaps 250 UK knee surgeons regularly performing knee

osteotomy within their practice because osteotomy has great utility in catering for those patients who find themselves in the treatment gap (symptoms resistant to conservative measures, but often considered too young to undergo arthroplasty).

Of this group who perform osteotomy the adjustable nail is a more advanced device, which I would envisage only being used by 20-30% of these surgeons if the correct patients were identified.

2 About the procedure

2.1 Does the title used above describe the procedure adequately?

☐ Yes

Comments:

Tibial osteotomy has indications that reach further than “early knee arthritis”, so this title may need revising to more accurately represent the indications. For example osteotomy may be used in moderate to advanced arthritis or may be used to offload a restorative cartilage or meniscal procedures. To simplify perhaps choose: *high tibial osteotomy using a magnetic rod device for precise alignment correction*

2.2 Which of the following best describes the procedure (choose one):

☐ The first in a new class of procedure.

Comments:

Tibial osteotomy is well established in current practice but the adjustable magnetic nail as a fixation device is definitely novel with no comparable device to fulfil this purpose

2.3 What is/are the best comparator(s) (standard practice) for this procedure?

Tibial osteotomy with angular stable plate fixation. The gold standard is the Tomofix plate (Synthes in Solothurn, Switzerland) which, in a sample taken from the national osteotomy registry (UKKOR – Sept 2019) was used in 83% of 2144 cases.

2.4 Are there any major trials or registries of this procedure currently in progress? If so, please list.

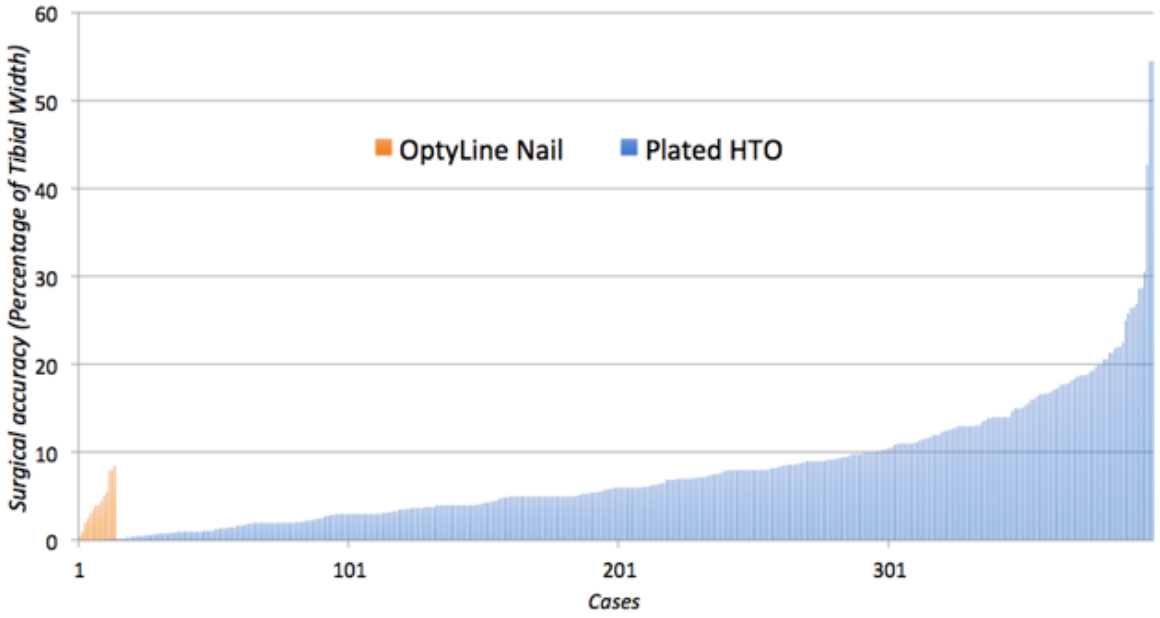
The United Kingdom Knee Osteotomy Registry (UKKOR: www.ukkor.co.uk) is the national registry for knee osteotomies. I chaired a steering committee to establish the registry October 2014. The registry is dedicated to recording patient outcomes and now has data on over 2000 cases which, is the largest data set for osteotomy procedures in the world. The majority of these procedures are utilising plate fixation

to hold the osteotomies in position set at the time of surgery. The adjustable nail utilises post operative correction to modify the position of the osteotomy and alter the leg shape in the post operative period

2.5 Please list any abstracts or conference proceedings that you are aware of that have been *recently* presented / published on this procedure (this can include your own work). Please note that NICE will do a comprehensive literature search on this procedure and we are only asking you for any very recent or abstracts or conference proceedings which might not be found using standard literature searches. You do not need to supply a comprehensive reference list but it will help us if you list any that you think are particularly important.

1) The surgical accuracy of knee osteotomy. The knee 24 (2017) 167-169. Is an editorial (Written by myself). This explains the concept, definition, and distribution of surgical accuracy for knee osteotomy. Low values represent better surgical accuracy.

2) Accuracy in high tibial osteotomy and post-operative correction with magnetic nail technology. Shaw C, Dawson MJ. Podium Presentation at Kreibich Registrar meeting, Northern Deanery June 2019. *The graph below extracted from Colin Shaw's presentation demonstrates improved surgical accuracy (lower values) in the OptyLIne Nail group*



3) Improving accuracy in high tibial osteotomy: Use of magnetic nail distraction technology. DOI: https://doi.org/10.1016/j.knee.2017.08.040

4) OPTY-LINE remote-controlled adjustable intramedullary device implantation in open-wedge high tibial osteotomy: A prospective proof-of-concept pilot and comparison with Tomofix fixed-plate device method.
J Orthop Surg (Hong Kong). 2019 Sep-Dec;27(3):2309499019864721. doi: 10.1177/2309499019864721.

3 Safety and efficacy of the procedure

3.1 What are the potential harms of the procedure?

Please list any adverse events and major risks (even if uncommon) and, if possible, estimate their incidence:

Adverse events reported in the literature (if possible please cite literature)

Screw back out. Reported in Colin Shaw's presentation at registrar meeting.

Anecdotal adverse events (known from experience)

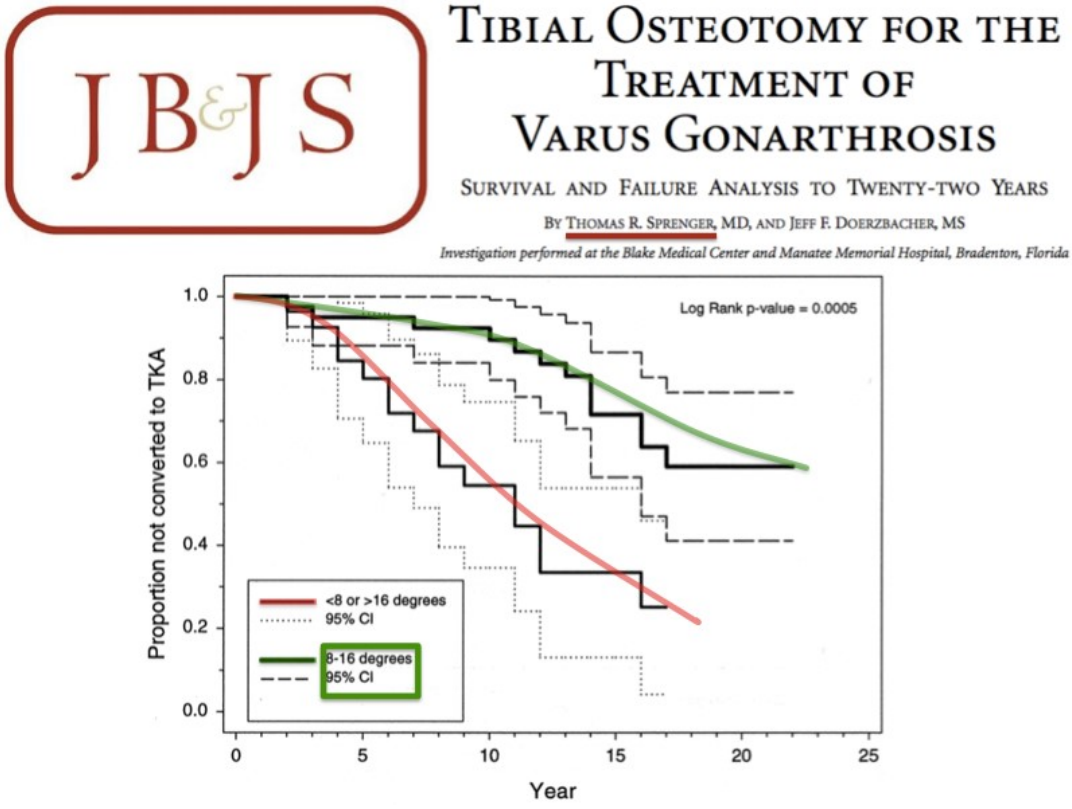
One of my patients became nervous and reluctant to use the magnetic prescription because this then caused bony pain for 1-2 hours after each small lengthening. This was an understandable discomfort but this took some time to coax her into completing her prescription to achieve her osteotomy target. Once at target correction she did very well (Oxford knee score 47) and had no further problems

Theoretical adverse events

Motor failure either failing to drive increased length when stimulated by the magnet or failing to stop lengthening after withdrawal of the magnet. On reflection these events would be close to impossible given that it is the magnetic field, which drives the motor and so there would be no power to continue drive after the magnet was taken away from the nail vicinity.

3.2 Please list the key efficacy outcomes for this procedure?

Increased surgical accuracy has been demonstrated by use of this device. There is evidence that increased surgical accuracy (achieving alignment in the target zone) increases the longevity (improved survivorship) of the osteotomy procedure (see survival curves in paper by Sprenger):



3.3 Please list any uncertainties or concerns about the *efficacy* of this procedure?

I have no concerns that this procedure is effective. In my cases (n=7) I have been able to increase my surgical accuracy and these patients have had improved PROMS in comparison to a larger group of plated HTO cases.

3.4 What clinician training is required to do this procedure safely?

For surgeons already competent at performing a tibial osteotomy this part of the procedure will require no further training. All orthopaedic surgeons become familiar with the techniques required to perform tibial nailing during treatment of traumatic tibial fractures during their training where long bone nailing is an index procedure counting towards the award of certificate of completion of training. It therefore requires the surgeon to apply both sets of already learned skills to complete this procedure. If there is uncertainty for the new clinician then a visitation could be arranged to see the adjustable nailing procedure performed by a surgeon familiar with this technique.

3.5 What clinical facilities are needed to do this procedure safely?

Instruments included with the device are suitable for the completion of the osteotomy cut and the full operation.

Each hospital performing this procedure would need to have facilities to perform long leg alignment views. It is necessary to perform between 3 and 4 long leg views (at fortnightly intervals) in the post-operative period to monitor the achieved correction and make post-operative adjustments to the magnetic prescription.

3.6 Is there controversy, or important uncertainty, about any aspect of the way in which this procedure is currently being done or disseminated?

No, the procedure has only been targeted at sub specialist knee surgeons with experience of tibial osteotomy. This appears to be an appropriate launch strategy for this device coming onto the market.

4 Audit Criteria

Please suggest potential audit criteria for this procedure.

4.1 Beneficial outcome measures. This should include short and long term clinical outcomes, quality-of-life measures and patient related outcomes. Please suggest the most appropriate method of measurement for each and the timescales over which these should be measured:

As chairman of UKKOR, I am inevitably going to suggest that outcomes from the adjustable nail procedure are recorded by utilising the structure already devised in the registry to record patient outcomes. The PROMS recorded in UKKOR include.

Pre-operative:

- EQ-5D,
- Oxford Knee Score,
- Oxford Knee Score Activity Participation Questionnaire,
- Knee Osteoarthritis and Injury Outcome Score (KOOS),
- VAS pain (0-100),
- Self-Assessment Co-Morbidity Questionnaire

Post operative scores at 1,2,5, 10, 15, 20, 25, 30 years:

- EQ-5D,
- Oxford Knee Score,
- Oxford Knee Score Activity Participation Questionnaire,
- Knee Osteoarthritis and Injury Outcome Score (KOOS),
- VAS pain (0-100)

In addition the registry includes forms for the operative procedure (The adjustable nail is included as one of the possible devices), device removal and revision osteotomy or revision to arthroplasty as end points, which could be called upon to generate future survival data.

4.2 Adverse outcome measures. This should include early and late complications. Please state the post procedure timescales over which these should be measured.

The registry sends the patient an email at 6 weeks and 1 year to enquire about any patient reported complications in addition there is an ad-hoc form for surgeons to report any adverse reactions

5 Uptake of the procedure in the NHS

5.1 If it is safe and efficacious, in your opinion, how quickly do you think use of this procedure will be adopted by the NHS (choose one)?

☑ Slowly (over decades)

Comments:

Highly specialised procedure so uptake is unlikely to be rapid despite the potential advantages of increased surgical accuracy.

5.2 If it is safe and efficacious, in your opinion, will this procedure be carried out in (choose one):

☑ A minority of hospitals, but at least 10 in the UK.

Comments:

5.3 If it is safe and efficacious, in your opinion, the potential impact of this procedure on the NHS, in terms of numbers of patients eligible for treatment and use of resources:

☑ Moderate.

Comments:

Hard to judge as we anticipate an increased use of knee osteotomy to cater for patients in the treatment gap in years to come. We anticipate that there may be 10,000 patients per annum under treated in the treatment gap at present when the UK figures are compared to osteotomy usage in neighbouring European countries

6 Other information

6.1 Is there any other information about this procedure that might assist NICE in assessing the possible need to investigate its use?

Comments:

7 Data protection and conflicts of interest

7.1 Data Protection

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Declarations of interest form			
Type of interest	**Description of interest**	**Relevant dates**	
		Interest arose	**Interest ceased**
Financial, professional interest	*As chairman of UKKOR I have previously taken responsibility for funding the registry, this has mainly been through industry stakeholder*	2017	2018

	sponsorship. Several different industrial sponsors have supported the registry. *In 2017 the Registry received a one off grant of £10k in value from NuVasive*		

* Guidance notes for completion of the Declarations of interest form

Name and role	Insert your name and your position in relation to your role within NICE
Description of interest	Provide a description of the interest that is being declared. This should contain enough information to be meaningful to enable a reasonable person with no prior knowledge to be able to read this and understand the nature of the interest. Types of interest: **Direct interests** **Financial interests** - Where an individual gets direct financial benefits from the consequences of a decision they are involved in making*. For examples of financial interests please refer to the policy on declaring and managing interests.* **Non-financial professional and personal interests -** Where an individual obtains a non-financial professional or personal benefit, such as increasing or maintaining their professional reputation, from the consequences of a decision they are involved in making. *For examples of non-financial interests please refer to the policy on declaring and managing interests.* **Indirect interests -** Where there is, or could be perceived to be, an opportunity for a third party associated with the individual in question to benefit. A benefit may arise from both a gain or avoidance of a loss.
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Comments	This field should be populated by the guidance developer and outline the action taken in response to the declared interest. It

	should include the rationale for this action, and the name and role of the person who reviewed the declaration.

Thank you very much for your help.

Dr Tom Clutton-Brock, Interventional Procedures Advisory Committee Chair

Mirella Marlow Programme Director