NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: **IP2109 Digital flexor tenotomy for diabetic foot**

Your information

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Nominated/ratified by (if applicable):	Click here to enter text.
Registration number (e.g. GMC, NMC, HCPC)	HCPC CH14466

How NICE will use this information:

The information that you provide on this form will be used to develop guidance on this procedure.

☐ Please tick this box if you would like to receive information about other NICE topics.

Your advice and views represent your individual opinion and not that of your employer, professional society or a consensus view. Your name, job title, organisation and your responses, along with your declared interests will also be published online on the NICE website as part of public consultation on the draft guidance, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate.

For more information about how we process your data please see our privacy notice.

☐ I give my consent for the information in this questionnaire to be used and may be published on the NICE website as outlined above. If consent is NOT given, please state reasons below:

Click here to enter text.

Please answer the following questions as fully as possible to provide further information about the procedure/technology and/or your experience.

1	Please describe your level of experience with the procedure/technology, for example: Are you familiar with the procedure/technology? Have you used it or are you currently using it? – Do you know how widely this procedure/technology is used in the NHS or what is the likely speed of uptake? – Is this procedure/technology performed/used by clinicians in specialities other than your own? – If your specialty is involved in patient selection or referral to another specialty for this procedure/technology, please indicate your experience with it.	I am familiar with assessing patients with apical pressure lesions or ulcers who may benefit from a flexor tenotomy (FT). I perform them frequently as part of my job both in theatre, outpatients and in the community setting. - FTs are used relatively frequently used in Multi-Disciplinary Foot Teams (MDFTs) across the UK, but the availability of the procedure relies on the skill of the team to be able to perform the procedure. The NHS has been slow to consistently utilise FT. In 2023 the International Working Group for the Diabetic Foot (IWGDF) amended their Offloading Guidelines to include FT due to a RCT that had been conducted which provided strong and moderate evidence in favour of FT. This has led to growing interest in the procedure being utilised in the outpatient setting under local anaesthetic (if anaesthesia is required). - Usually, within the MDFTs both podiatric and orthopaedic surgeons perform FTs. Vascular surgeons, diabetologists and podiatrists may also perform FTs. - Podiatrists usually see patients prior to them attending the MDFT and would refer to the MDFT for the procedure to be carried out if they aren't competent to do the procedure themselves.

2	– 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 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 published this research. I have had no involvement in research on this procedure. Other (please comment): I have audit data for approx. 50 patients who have undergone the procedure for curative and prophylactic purposes.
3	Does the title adequately reflect the procedure? Is the proposed indication appropriate? If not, please explain. How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design? Which of the following best describes the procedure (please choose one):	No, FT can also be utilised in patients without diabetes. No, because many patients, not just those with diabetes, may benefit from a FT. We see patients with a variety of co-morbidities that lead to apical pressure lesions or ulcerations that may benefit from a FT, e.g. peripheral neuropathy, peripheral arterial disease, inflammatory arthropathy, toe deformity. The IWGDF recommend FT for flexible 2-5 toe deformities. The procedure can also be used on the hallux and on semi-flexible toe deformities. It is a powerful procedure that can be used as an early and preventative strategy. The standard of care would be conservative care such as debridement, padding with felt or silicone protectors to offload the pressure area. If infection or osteomyelitis develops then treatment with antibiotics or surgery may be required, (partial or total toe/ray amputation). Established practice and no longer new. A minor variation on an existing procedure, which is unlikely to alter the procedure's safety and efficacy. Definitely novel and of uncertain safety and efficacy. The first in a new class of procedure.

4	Does this procedure/technology have the potential to replace current standard care or would it be used as an addition to existing standard care?	It would be used in addition to the current standard of care when the conservative measures fail. FT has the potential to be used more frequently and earlier in the patient journey to address non-healing wounds to prevent chronic ulceration, infection and amputation. It has the potential to hugely reduce the minor and major amputations rates which are rising nationally.
5	Have there been any substantial modifications to the procedure technique or, if applicable, to devices involved in the procedure? Has the evidence base on the efficacy and safety of this procedure changed substantially since publication of the guidance?	No, a tenotomy can be performed with a robust/sharp needle (19g) or a scalpel blade. This RCT led to FT being included in the IWGDF Offloading guideline in 2023. Prior to this a systematic review was available. Andersen, J. A., Rasmussen, A., Engberg, S., Bencke, J., Frimodt-Møller, M., Kirketerp-Møller, K., & Rossing, P. (2022). **Flexor Tendon Tenotomy Treatment of the Diabetic Foot: A Multicenter Randomized Controlled Trial.** *Diabetes Care*, *45*(11), 2492–2500.

Current management

6	Please describe the current standard of care that is used in the NHS.	The standard of care would be conservative care such as debridement, padding with felt or silicone protectors to offload the pressure area. Offloading footwear can also be utilised. If infection or osteomyelitis develops then treatment with antibiotics or surgery may be required, (partial or total toe/ray amputation). Some units are offering FT but this varies within each trust as it relies on a member of the team having the skill to carry out the procedure.
7	Are you aware of any other competing or alternative procedure/technology available to the NHS which have a similar function/mode of action to this? If so, how do these differ from the procedure/technology described in the briefing?	No, only formal surgical correction/management of the toe deformity which would be carried out in the theatre setting. Toes can be surgically straightened by digital fusion or arthroplasty of the distal or proximal interphalangeal joints. Partial toe amputations can also be performed to reduce apical pressure, heal ulceration and treat osteomyelitis. Formal surgical correction would require theatre space and would carry a greater level of cost, risk and a lengthier recovery period for the patient.

Potential patient benefits and impact on the health system

8	What do you consider to be the potential benefits to patients from using this procedure/technology?	Reduction in minor and major amputation rates. Rapid healing of chronic wounds. Improved quality of life. Lower mortality rates. Cost saving intervention with reduced attendance at podiatry and MDFT clinics. Antibiotic stewardship as less chronic wounds to treat.
9	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Those with diabetes or peripheral neuropathy as they are predisposed to developing clawed toes. Also, those with peripheral arterial disease and other 'high risk' foot pathologies leading to apical toe ulcerations or pressure areas.
10	Does this procedure/technology have the potential to change the current pathway or clinical outcomes to benefit the healthcare system? Could it lead, for example, to improved outcomes, fewer hospital visits or less invasive treatment?	It is a powerful procedure that can heal ulcers rapidly. This has the advantages mentioned in section 8. The quicker a wound heals the less costly it is to the healthcare system. Yes, if wounds heal fewer hospital/clinic attendances are required. Elective and emergency surgery can then potentially be avoided. The procedure could be carried out by community foot protection teams much earlier in the pathway to prevent more severe presentations.
11	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	Appropriate needles, blades, gloves, skin prep and local anaesthetic. Training courses to ensure the competence of non-surgical specialities carrying out the procedure.
12	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	Not when done by podiatric or orthopaedic surgeons. Other specialities would require training and competencies. The Royal College of Podiatry are currently looking at providing a training course to ensure competence and indemnity cover for podiatrists carrying out FTs.

Safety and efficacy of the procedure/technology

13	What are the potential harms of the procedure/technology? Please list any adverse events and potential 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	FT may fail to heal all apical wounds. Infection and osteomyelitis may require surgery. The most significant risk is transfer lesions/ulcers if an isolated toe has had a FT as the pressure can transfer to adjacent toes. There is a theoretical risk of interrupting the blood supply to the toe which may lead to ischaemia of the toe. Swelling, infection, bleeding, nerve damage, scarring, recurrent toe deformity, osteomyelitis, transfer of lesion/ulcer(s) to adjacent toes, floating toe and toe instability. As above. Infection tracking up the tendon proximally into the foot (I have never seen this occur).
14	Please list the key efficacy outcomes for this procedure/technology?	Healing rate, recurrence rate, transfer lesions, pressure reduction, ulcer free days.
15	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	Little uncertainty as it is a low-risk procedure with a high clinical impact.
16	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	No.
17	If it is safe and efficacious, in your opinion, will this procedure be carried out in (please choose one):	Most or all district general hospitals. A minority of hospitals, but at least 10 in the UK. Fewer than 10 specialist centres in the UK. Cannot predict at present. Many other NHS sites could be utilised e.g. acute, community, outpatients etc.

Abstracts and ongoing studies

18	Please list any abstracts or conference proceedings that you are aware of that have been recently presented / published on this procedure/technology (this can include your own work). Please note that NICE will do a comprehensive literature search; we are only asking you for any very recent 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.	N/A.
19	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	NIHR bid has been resubmitted to evaluate which toes should have a FT and to look at pressure measurements pre and post FT.
20	Please list any other data (published and/or unpublished) that you would like to share.	The MDFT in Salford are publishing their data showing that a podiatrist safely performed FT which was more cost effective than FT being carried out by an orthopaedic surgeon. My audit data of 37 patients with active ulcers found: Hallux ulcers= 4 cases, healed in a mean time of 23 days (SD 9.49) Lesser toe ulcers= 33 cases, healed in a mean time of 30.3 days (SD 53.85) The mean duration of ulcer presence prior to FT was 4.8 months (SD 4.79)

Other considerations

21	Approximately how many people each year would be eligible for an intervention with this procedure/technology, (give either as an estimated number, or a proportion of the target population)?	All ‘at risk’ foot patients with apical lesions such as corns, callus and ulcers could benefit from assessment for FT. Numbers would be difficult to predict but there would be many patients in community podiatry clinics and acute MDFT clinics across the country that would benefit from this procedure.

22	Please suggest potential audit criteria for this procedure/technology. If known, please describe: – Beneficial outcome measures. These 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. – Adverse outcome measures. These should include early and late complications. Please state the post procedure timescales over which these should be measured:	Beneficial outcome measures: Healing success Time to healing Ulcer free days Remission at 12 and 24 months Adverse outcome measures: Failure to heal Ulcer recurrence Transfer lesions/second site ulceration related to tenotomy Infection/Osteomyelitis Instability or floating toe Surgery required e.g. toe amputation

Further comments

23	If you have any further comments (e.g. issues with usability or implementation, the need for further research), please describe.	FT are frequently performed safely in community clinics by podiatric surgeons. They can be done safely in the clinic or outpatient setting. Podiatrists in foot protection teams work in an ideal environment and stage in a patient's pathway to carry out FT when conservative care fails. This would prevent patients reaching the MDFT with more significant infection or ulceration as treatment would be timelier. There would be training and competency requirements for these skills to be developed and implemented into the clinical remit for podiatrists, but the Royal College of Podiatry are currently supporting the development of a training course to ensure members can provide such care in a safe and supported way.

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Declarations of interests

Please state any potential conflicts of interest relevant to the procedure/technology (or competitor technologies) on which you are providing advice, or any involvements in disputes or complaints, in the previous **12 months** or likely to exist in the future. Please use the NICE policy on declaring and managing interests as a guide when declaring any interests. Further advice can be obtained from the NICE team.

Type of interest *	Description of interest	Relevant dates	
		Interest arose	Interest ceased
Non-financial professional	I am on the research team that has submitted a NIHR bid to research flexor tenotomy.	**2023**	**Ongoing**
Choose an item.			
Choose an item.			

☐ I confirm that the information provided above is complete and correct. I acknowledge that any changes in these declarations during the course of my work with NICE, must be notified to NICE as soon as practicable and no later than 28 days after the interest arises. I am aware that if I do not make full, accurate and timely declarations then my advice may be excluded from being considered by the NICE committee.

Please note, all declarations of interest will be made publicly available on the NICE website.

Print name:	**Helen Milnes**
Dated:	**15/12/2025**