Reference number: 2206
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Clinical Commissioning Policy:

Direct Skeletal Fixation for transfemoral limb loss (adults) [2206]

Summary

Direct Skeletal Fixation is recommended to be available as a routine commissioning treatment option for transfemoral limb loss within the criteria set out in this document.

The policy is restricted for use in adults to avoid disruption of the growth plate in younger patients.

Committee discussion

Clinical Panel considered the evidence base and the decision was made to progress the policy as for routine commissioning. Please see the Clinical Panel report for full details of Clinical Panel's discussion.

The Clinical Priorities Advisory Group committee papers can be accessed here: Clinical commissioning policy: Direct skeletal fixation for transfemoral limb loss (adults)

What we have decided

NHS England has carefully reviewed the evidence to treat Direct Skeletal Fixation in patients with transfemoral limb loss. We have concluded that there is enough evidence to make the treatment available at this time.

The evidence review which informs this commissioning position can be accessed here: Clinical commissioning policy: Direct skeletal fixation for transfemoral limb loss (adults)

Links and updates to other policies

This document updates a not routinely commissioned policy statement that was published in February 2019, for Osseointegration for Transfemoral Amputation in Adults. This can be accessed: 1628-cc-policy-statement-osseointegration-for-transfemoral-amputation-adults.pdf (england.nhs.uk).(NHS England, 2019).

This current policy is linked to the Service Specification D01/S/d for Complex Disability Equipment – Prosthetic Specialised Services for People of all Ages with Limb Loss.

Plain language summary

About transfemoral limb loss

Transfemoral limb loss refers to limb deficiency through the knee or above, either from birth or due to amputation. The majority of lower limb amputations are a consequence of peripheral arterial disease; other causes include trauma, diabetes and tumour. Lower extremity amputation has profound implications for a patient's functional capability, mobility, and quality of life.

About conventional socket prostheses

Following surgery, the current treatments for amputees are custom sockets attached to a prosthetic limb. The type of prosthesis that is recommended will depend on patient-specific factors and the type of amputation. For any prosthesis, prolonged physiotherapy and rehabilitation is required and therefore this is not a suitable option for every patient. Friction between the residual limb and socket can cause pain and skin breakdown, and for the patients who experience these complications the current alternative is the use of mobility aids such as crutches or a wheelchair. This can lead to, or make worse, pre-existing conditions including obesity, diabetes, vascular disease, osteoporosis, and mental health conditions.

About direct skeletal fixation

Direct skeletal fixation (DSF) is a form of surgery, also known as osseointegration, which replaces the need for an amputee to wear a socket upon which normally a prosthesis would be attached. It involves placing an implant (a rod usually made of titanium) through the skin into the bone which may be carried out in two separate operations or as a single operation. In the first stage, the implant is inserted into the central part of the remaining bone. The second stage of the procedure is undertaken either during the same operation or approximately 3 – 6 months later, after the wound has completely closed and has healed and the implant has set into the bone. The second stage involves connecting the implant to a small metal extension which goes through the skin, allowing the prosthetic limb to be attached to the implant within the bone. A period of rehabilitation follows during which a training prosthesis is used.

Patient selection should be carried out by a multidisciplinary team (MDT), including a surgeon experienced in amputation and bone and soft tissue reconstruction as well as rehabilitation specialists, with expertise in prosthetics and implant design.

Epidemiology and needs assessment

A study of all transfemoral amputation procedures in England 2003-2008 found that there were 13,500 procedures undertaken in this time period (12,800 above the knee and 700 through the knee) which equates to 2,300 transfemoral amputations per year (Moxey et al, 2010). A subsequent study covering a 10-year period 2003-2013 reported 22,600 lower limb amputations above the knee amputations, equating again to 2,300 transfemoral amputations per year (Ahmad et al, 2016). In England, the aetiology of lower limb amputations is as follows: vascular disease 90%, trauma 5%, neoplasm 1%, other causes 4% (Stewart and Trimming, 2008). This figure of 2,300 is likely to have improved in recent years because of improved diabetic and peripheral vascular disease management, and access to interventional radiology. Therefore, of approximately 2,000 transfemoral amputations per year, 120 are secondary to trauma or neoplasm and amputations of other aetiologies are excluded from this policy.

A literature search and analysis of patients referred to UK prosthetic services estimates that 60% of those with transfemoral amputation are too infirm for referral to limb fitting so 40% would be referred for prosthetics (Stewart and Trimming, 2008). Therefore, of 120 possible patients with transfemoral amputations due to trauma or neoplasm, 48 would be referred to prosthetic services.

The above analysis of UK prosthetic services notes that 4500 patients with limb loss at any level were referred to limb fitting services in 1997-1998, and also notes that about 1% of those referred to the UK prosthetic services have a congenital limb deficiency (Stewart and

Trimming, 2008). Therefore 45 patients with congenital limb deficiency at any level would have been referred. Transfemoral limb loss made up 8.8% of all referrals that year, so roughly 8.8% of 45 patients with congenital limb deficiency are relevant to this policy, which is 4 patients.

Therefore, up to 52 patients per year may meet the initial policy criteria of transfemoral amputation or limb loss due to trauma, malignancy or congenital limb loss who are referred to limb fitting teams. However, the majority of these patients will tolerate conventional sockets, and it is only those who cannot who are relevant to this policy. There will also be a backlog of up to 100 patients from previous cohorts who meet these criteria as estimated by clinical consensus.

Implementation

NHS England will routinely commission direct skeletal fixation for transfemoral limb loss with the patient pathway (see figure 1) for adult patients meeting the criteria outlined below. The intervention involves a two-stage process. Both stages can be done during one procedure or in two separate procedures, depending on components used and patient factors.

Available prosthetics and surgical procedure

Implant manufacturers and inventors currently in use are listed below:

1. Osseointegrated Prostheses for the Rehabilitation of Amputees (OPRA), Integrum, Branemark
2. Integral Leg Prosthesis (ILP, previously Endo-Exo Prosthesis), ESKA Orthopaedic, Grundei
3. Osseointegrated Prosthetic Limb (OPL), Osseointegration International/Permedica, Al-Muderis

There is no clinical evidence of superiority of one implant over another, and the prosthetic hardware is the same across all three. Decision regarding which implant to use will be made by regional MDT as below, depending on patient factors, availability, surgical experience.

The intervention involves a two-stage process. Both stages can be done during one procedure or in two separate procedures, depending on components used and patient factors. The evidence review includes papers who have used the two procedures, and papers where a single procedure was used. There is no evidence suggesting superiority of a single procedure or two procedures, however it is noted that if two procedures are performed this will involve an interim period where the patient will be restricted to a wheelchair by necessity. The decision will be made by regional MDT who will consider factors including patient factors, surgical experience and availability of critical care given the procedural and peri-operative risks.

Inclusion criteria

Patients may be referred for regional MDT consideration from a local limb fitting centre if the MDT at their local centre feels that they fulfil **ALL** of the following criteria:

- Adult patients who have transfemoral limb loss (unilateral or bilateral) as a result of:
    - Trauma **OR**

    - Congenital deficiency **OR**
    - Malignancy
- Patient is unable to mobilise using a conventional socket (confirmed by clinical assessment) despite having actively participated in the limb fitting process at their local limb fitting centre for at least 12 months. This includes participation in the pre limb fitting process and engagement with the prosthetic team for rehabilitation, pain management, as well as participation in management plans regarding any issues with the sockets that have been trialled.
- Are primarily wheelchair users as defined by use of a wheelchair for over 50% of waking hours

The regional MDT will make the final decision on patient selection based on patient history, assessment and imaging if the patient fulfils **ALL** of the following criteria, in addition to the criteria above:

- Has full skeletal maturity
- Is able to participate in an extensive post operative physiotherapy and rehabilitation programme of up to 12 weeks duration
- Is suitable for surgery based on medical history and physical anatomy
- Has mental capacity to consent to the procedure, and is fully aware of risks including implant failure, and is able to psychologically tolerate this risk.

The regional MDT must include, at a minimum, a consultant orthopaedic surgeon, an anaesthetist, a consultant rehabilitation physician, a specialist physiotherapist, a clinical psychologist, a specialist occupational therapist, a representative from the local limb fitting service and a specialist prosthetist who endorse the intervention in this patient.

Exclusion criteria

An individual meeting **ANY** of the following criteria:

- Active deep tissue infection in target limb
- Diabetic
- Weight over manufacturer limit for the device[1]
- Chronic regional pain syndrome (CRPS) (previous or current), due to risk of recurrence of CRPS post operatively, and potential for surgery to worsen symptoms of CRPS
- Inability or refusal to participate in post implant rehabilitation
- Severe osteoporosis as defined by a Bone Mineral Density T score of < -3.5 standard deviations (Gregson et al, 2022)
- Current smoker [due to associated vasculopathy and risk of implant failure] A “non-smoker” in this instance is defined as someone who has never smoked or who has

[1] If weight increases after the procedure to the extent that the weight exceeds the manufacturers recommended limit, patients should be advised not to use the prosthetic.

successfully quit smoking for at least 4 to 8 weeks prior to the procedure (WHO, 2020) (National Centre for Smoking Cessation and Training, 2020) (NICE, 2021).

- Peripheral vascular disease [as cause for amputation]
- Concerns from MDT regarding patient and/or carer's ability to psychologically tolerate implants protruding through skin
- Amputation distal to transfemoral amputation level
- Previous radiotherapy to the target femur, including groin and knee
- Current immunosuppression (the level of immunosuppression which would preclude treatment with this intervention is determined by the MDT who will be providing the treatment. Immunosuppression describes both primary or secondary, which can be due to treatments including but not limited to; systemic steroids, chemotherapy and anti-cancer medication, anti-tumour necrosis factor therapy, methotrexate, interleukin-6 inhibitors)

Certain exclusion criteria pertain to anatomical unsuitability for this procedure including: osteoporosis, amputation distal to through knee disarticulation, weight over manufacturer limit and previous radiotherapy to anatomical areas involving femur.

Certain exclusion criteria are due to significantly elevated risk of infection including: active deep tissue infections, diabetic patients, current smokers and peripheral vascular disease

Certain exclusion criteria involve groups of patients in whom there is no evidence for the effectiveness of DSF, because in all papers used in the evidence summary these groups come under the exclusion criteria. These include: current immunosuppression, patients with peripheral vascular disease as cause of amputation, previous radiation exposure to femur, diabetics, severe osteoporosis.

Stopping criteria

The MDT assessing a patient for suitability for this intervention can pause or stop their assessment if patients meet any of the criteria outlined below:

- Condition changing to extent of no longer meeting inclusion criteria
- Non-engagement with limb fitting services or rehabilitation services
- During the assessment process, patient weight increases such that it exceeds manufacturer limit for the device

Furthermore, if a patient develops sepsis pre-operatively the intervention should not be undertaken until this has resolved.

Monitoring and rehabilitation

Patients should be managed at a suitable specialist centre under the care of a regional MDT including at least a consultant orthopaedic surgeon, a consultant rehabilitation physician, a specialist physiotherapist, a specialist occupational therapist and a specialist prosthetist.

Rehabilitation is a key part of management of these patients and involves inpatient early partial weightbearing with physiotherapy post procedure until discharge. Patients are anticipated to require residential supervised rehabilitation at a suitable centre to begin 2 weeks post-surgery, for at least 6-weeks with a 1-week break. This initial phase of rehabilitation is required to be residential and supervised due to requirement for loading

under strict control. Two further 3-week periods of residential supervised rehabilitation, separated by 3-week periods at home are usually required before discharge back to community after 12 weeks total rehabilitation. The centre organising the rehabilitation period must enable liaison with the local limb fitting team to enable future follow up.

Following discharge from the surgical centre where inpatient rehabilitation was completed, patients will be managed by their local limb fitting centre for ongoing care. At this point stoma surveillance will become the responsibility of the patient and the local limb fitting team.

They should however have a surgical follow up and assessment at least annually by the MDT at the centre where they were operated which is likely to include clinical examination, physiotherapy assessment, radiographic assessment and assessment of activity level. Annual assessment will be switched to patient initiated follow up at a time point where the MDT at the surgical centre where the patient was operated feel this is appropriate.

Patient pathway

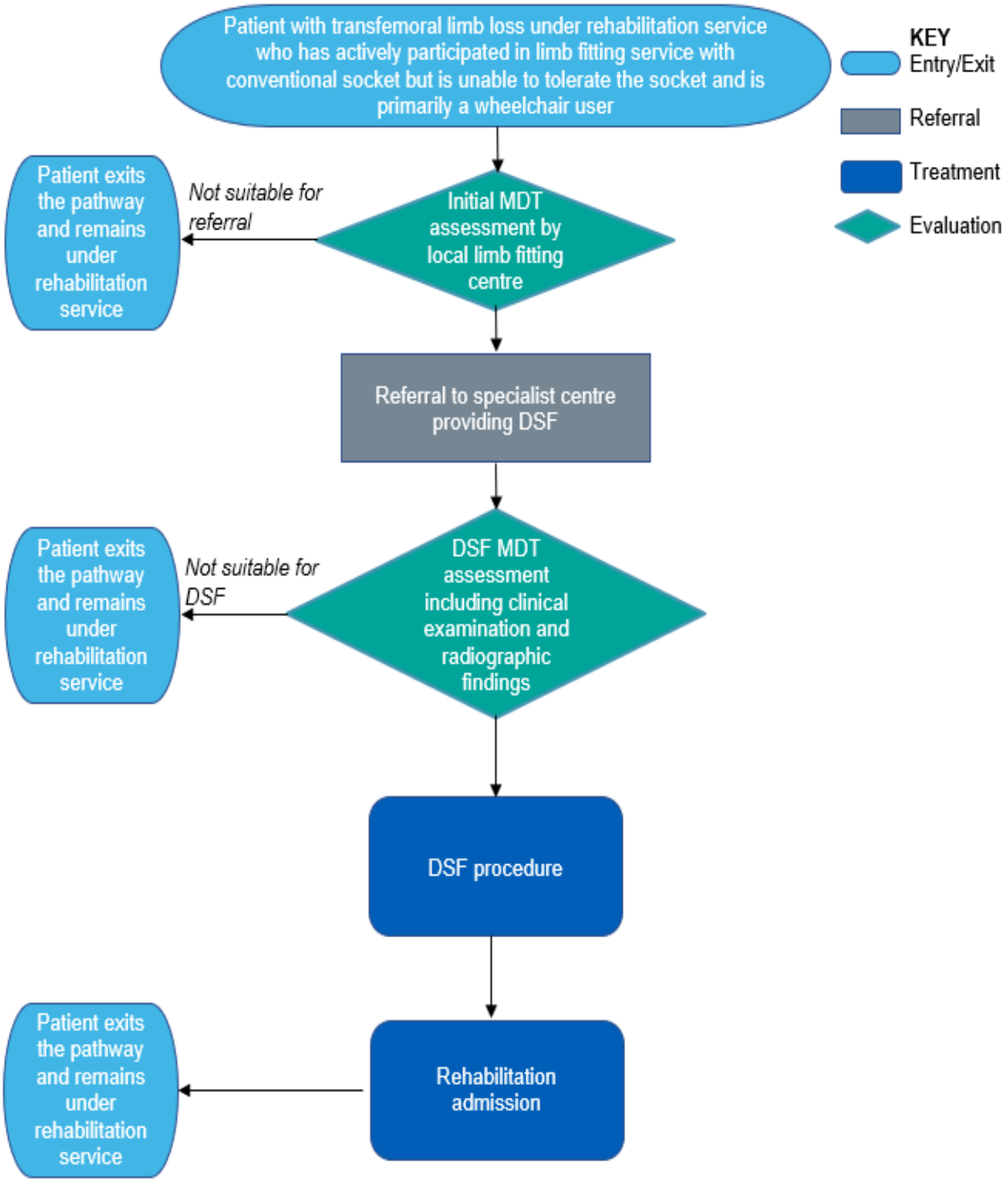

Figure 1 – patient pathway for DSF intervention

Governance arrangements

All commissioned providers treating adult patients with this intervention will be required to assure itself that the internal governance arrangements have been completed before the intervention is prescribed. NHS England will require assurance of this process or documented evidence that these processes are in place.

Provider organisations must register all patients using prior approval software and ensure monitoring arrangements are in place to demonstrate compliance against the criteria as outlined, including the audit requirements specified below.

Mechanism for funding

The funding and commissioning will be managed through the agreed arrangements for specialised commissioning.

This procedure will be funded through an agreed local tariff.

Audit requirements

All information on patients being assessed as appropriate for Direct Skeletal Fixation will be required to be entered on the prior approval system. This will ensure that only patients assessed as eligible and meeting the criteria will proceed to surgery.

Outcomes will be measured at patient annual review and patients will be comprehensively monitored for ongoing improvement in mobility and general well-being as quantified by validated scoring systems. At a minimum, data on the following parameters will be collected:

- 6 minute walk test or 2 minute walk test if patient is unable to complete 6MWT
- Timed up and go test
- EQ-5D score, a widely used generic (disease non-specific) quality of life (QoL) instrument

Data on any adverse effects will also be collected, at a minimum:

- Infection rates and severity
- Implant failure

Policy review date

This document will be reviewed when information is received which indicates that the policy requires revision. If a review is needed due to a new evidence base then a new Preliminary Policy Proposal needs to be submitted by contacting england.CET@nhs.net.

Our policies provide access on the basis that the prices of therapies will be at or below the prices and commercial terms submitted for consideration at the time evaluated. NHS England reserves the right to review policies where the supplier of an intervention is no longer willing to supply the treatment to the NHS at or below this price and to review policies where the supplier is unable or unwilling to match price reductions in alternative therapies.

Equality statement

Promoting equality and addressing health inequalities are at the heart of NHS England's values. Throughout the development of the policies and processes cited in this document, we have:

- Given due regard to the need to eliminate discrimination, harassment and victimisation, to advance equality of opportunity, and to foster good relations between people who share a relevant protected characteristic (as cited under the Equality Act 2010) and those who do not share it; and
- Given regard to the need to reduce inequalities between patients in access to, and outcomes from healthcare services and to ensure services are provided in an integrated way where this might reduce health inequalities.

Definitions

Full skeletal maturity	Skeletal maturity can be evaluated from the size and shape of bones and the degree of mineralisation or ossification. When the bone is fully mature, there is no longer potential for longitudinal growth.
Acquired amputation	Amputation as a result of trauma or surgery
Congenital absence (congenital deficiency)	Patients born without a limb due to a genetic condition
6 minute walk test	Distance in metres a patient can mobilise; a validated measure of functional capacity in amputees
TUG test	Timed up and go test; the time taken in seconds for a patient to mobilise without assistance from sitting to standing, walk 3 metres, walk back, and sit down.

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