National Institute for Health and Care Excellence

IP692/2 Direct skeletal fixation of limb prostheses using an intraosseous transcutaneous implant

IPAC date: 12th September 2024

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1.	Consultee 4 NHS England	1.1 Draft recommendations	This section may be misleading as it is not for use in the NHS at the current time as set out in the policy published in 2019. https://www.england.nhs.uk/publication/clinical-commissioning-policy-direct-skeletal-fixation-for-transfemoral-limb-loss/	Thank you for your comments. IPAC considered consultee's comments about the NHS England Clinical commissioning policy: direct skeletal fixation for transfemoral limb loss (adults) and evidence review published in 2023. Draft recommendation in 1.1 states that *'direct skeletal fixation of limb prostheses using an intraosseous transcutaneous implant can be used in the NHS while more evidence is generated. It can only be used with special arrangements for clinical governance, consent, and audit or research'.* Special arrangements mean that there are uncertainties about whether a procedure is safe or effective. These will need to be carefully explained to a patient before they make a decision. A special arrangements recommendation places emphasis on the need for informed consent. This includes both the patient (or

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				carer) and senior medical staff, such as the clinical governance lead in their trust. Clinicians using these procedures should collect data, either by audit or research. If there's no method of data collection already available, an audit tool along with the guidance will be published. It doesn't mean the procedure should be commissioned. The guidance does not state that the procedure should be done in the NHS and it does not also assess cost effectiveness. NHS clinical commissioning policy states that although there is sufficient evidence to commission this treatment but due to the relative prioritisation process for funding procedures in 2023/24, 'NHSE has concluded that, balanced against other relative priorities that were also considered during this process, direct skeletal fixation for transfemoral limb loss will not be funded at this time within the resources available'. NHS commissioning decision and NICE guidance are separate and should not be interpreted as the procedure should be commissioned although they may influence decision makers.
2.	Consultee 4 NHS England	1.2 Draft recommendations	This section may be misleading as it is not for use in the NHS at the current time as set out in the policy published in 2019.	Thank you for your comment.

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			https://www.england.nhs.uk/publication/clinical-commissioning-policy-direct-skeletal-fixation-for-transfemoral-limb-loss/ No provider selection has been completed with regard to the delivery of this procedure/service and any associated ongoing rehabilitation requirements. This would be a low volume surgery, due to its limited indication and would be restricted to a small number of commissioned providers. This procedure should not be provided at the discretion of individual clinical governance leads.	See response above regarding 1.1 draft recommendation. The draft guidance does specify that the procedure should be done only in specialist centres. IPAC considered your comment but decided not to amend section 1.2 which currently states as follows: • *Clinicians wanting to do direct skeletal fixation of limb prostheses using an intraosseous transcutaneous implant should:* • *Inform the clinical governance leads in their healthcare organisation.* • *Ensure that people (and their families and carers as appropriate) understand the procedure's safety and efficacy, and any uncertainties about these.* • *Take account of NICE's advice on shared decision making, including NICE's information for §he public.* • *Audit and review clinical outcomes of everyone having the procedure. The main* efficacy and safety outcomes identified in this guidance can *be entered into NICE's interventional procedure outcomes audit tool (for use at local discretion).*

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				Discuss the outcomes of the procedure during their annual appraisal to reflect, learn and improve.
3.	Consultee 4 NHS England	1.3 Draft recommendations	This section may be misleading as it is not for use in the NHS at the current time as set out in the policy published in 2019. https://www.england.nhs.uk/publication/clinical-commissioning-policy-direct-skeletal-fixation-for-transfemoral-limb-loss/	Thank you for your comments. See response above regarding 1.1 recommendation. IPAC considered your comment but decided not to amend section 1.3 which currently states as follows: *Healthcare organisations should:* • *Ensure systems are in place that support clinicians to collect and report data on outcomes and safety for everyone having this procedure.* • *Regularly review data on outcomes and safety for this procedure.*
4.	Consultee 4 NHS England	1.4 Draft recommendations	This section may be misleading as it is not for use in the NHS at the current time as set out in the policy published in 2019. https://www.england.nhs.uk/publication/clinical-commissioning-policy-direct-skeletal-fixation-for-transfemoral-limb-loss/ No patients should be selected for treatment as it is not available at the currently time. This procedure should not be considered as a routine alternative to the current socket provision. This procedure should not be considered as a routine alternative to the current socket	Thank you for your comments. See response above regarding 1.1 recommendation. IPAC considered your comment but decided not to amend section 1.4 which currently states that *Patient selection should be done by a multidisciplinary team with specific training and experience in the procedure and should include:*

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			provision. Any patient selection would need to be in line with the published policy and any referral and assessment would need to be undertaken in line with the published service specification. There is a not for routine commissioning policy in place and therefore there is no associated service specification, as the procedure is not available in the NHS.	• *an orthopaedic surgeon experienced in amputation and device implantation* • *a plastic surgeon with experience in the necessary bone and soft tissue reconstruction* • *an anaesthetist and* • *rehabilitation specialists including:* ○ *experts in prosthetics* ○ *occupational therapists and clinical psychologists.*
5.	Consultee 4 NHS England	1.5 Draft recommendations	Agree with this statement. However - there are no identified specialised centres currently identified or commissioned to provide the assessment, surgery or rehabilitation of patients for this procedure. There is not a commissioned service for this procedure and it therefore is not available in the NHS.	Thank you for your comments. Consultee agrees with 1.5 which currently states as follows: '*The procedure should only be done in specialised centres by a multidisciplinary team with specific training and experience in the procedural techniques, and management and rehabilitation after the procedure'.* IPAC also considered consultee's comments about the NHS England Clinical commissioning policy: direct skeletal fixation for transfemoral limb loss (adults) and evidence review published in 2023.
6.	Consultee 3 Public	Section 1	From reading through the many experts and professionals, the general feeling I am getting is that this procedure is welcomed to be a procedure on the NHS. I don't believe it's got enough support to be a routine procedure. I also	Thank you for your comments. The draft guidance does specify that the procedure should be done only in specialist centres. It has not been recommended for

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			don't feel we have the expertise and experience to be able to carry this out in a routine or even one off capacity. There are some extremely skilled individuals who have a wealth of experience and knowledge on how to overcome issues with DSF, which the NHS won't allow to help on already complex issues on patients who already live with DSF. The patients with implants already have no access to experienced specialists unless they pay privately. This is where I don't believe rolling this into the NHS will be a good consideration. The NHS would need to collaborate with other professionals to teach the correct skills needed to be able to deliver this procedure and so far to date, no collaboration has been allowed or used. So the NHS team is ill-equipped and will not be able to deal with the issues which commonly come with this procedure. If the surgical and rehab team could be taught by skilled surgeons, and understand the unique challenges which will be faced and need to be overcome, then this would only be the beginning. Training and gaining experience is the first consideration to this project, and nothing can go forward until this massive element is covered. This would mean collaboration with UK and European surgeons who have the experience and skills. Without this approach, I believe if the NHS rolled this out as a routine procedure, there could be huge consequences for the patient to have to live with. Patients are desperate so will agree to	routine use in the NHS with standard arrangements. Section 1.5 states that '*the procedure should only be done in specialised centres by a multidisciplinary team with specific training and experience in the procedural techniques, and management and rehabilitation after the procedure'.*

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			anything but this in the long term carries huge risk.	
7.	Consultee 6 British Orthopaedic Association	Section 1	Whilst there is a place for direct skeletal fixation of limb prostheses using an intraosseous transcutaneous implant in a very select group of patients, the British Orthopaedic Association (BOA) is concerned that the guidance does not give sufficient weight to the long-term management and support of patients and the consequences for the NHS. The groundswell of enthusiasm to use this novel technique is understandable and this is reflected in the responses NICE has received to date, largely from the independent sector where to date most recipients of direct skeletal fixation limb prostheses have been treated; often funded by clinical negligence or personal injury claims which rarely provide for the long-term consequences that we now see. These consequences (reported by patients in the survey reports to NICE and by BOA members consulted in preparing this response) include: 1. the incidence of major infection is very high (approaching 50-100%) and this ultimately necessitates implant removal 2. implants can suffer fatigue and broken components necessitating intervention 3. periprosthetic fracture is a risk, either acutely or later on. Proponents of the technique are now advocating its use in young individuals, whereas	Thank you for your comments. IPAC considered consultee's views in their deliberations. The NHS England Clinical commissioning policy: direct skeletal fixation for transfemoral limb loss (adults) and evidence review published in 2023 has been considered by the committee as part of their discussions at IPAC 1. https://www.england.nhs.uk/wp-content/uploads/2023/11/2206-direct-skeletal-fixation-ehia.pdf https://www.england.nhs.uk/publication/clinical-commissioning-policy-direct-skeletal-fixation-for-transfemoral-limb-loss/ IPAC considered your comments and added a committee comment about monitoring long term outcomes in young people in 3.9. IP guidance evaluates the safety and efficacy of an intervention. It does not assess cost-effectiveness or comparative effectiveness.

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			the implant life expectancy is unlikely to any greater than 20 years (taking NJR data for uncemented hip aseptic loosening as a baseline comparator). As a consequence, many of these patients may come to rely on wheelchair use in later life, an outcome that would have been much less likely if initially offered a conventional prosthesis. Again, advocates of direct skeletal fixation limb prostheses do not raise these long-term considerations in seeking to expand the offering to younger recipients. The NICE overview identifies there are no comparative studies with conventional rehabilitation or prosthetics, so the only evidence available is typically single centre developer institutions with inherent bias. This is at odds with the move by NICE to taking an integrated approach by doing comparative analyses of the costs and benefits for all appropriate treatment options. The novelty and short-term benefits of direct skeletal fixation limb prostheses in carefully selected patients are of course attractive, however with a growing more active older population, the long-term management and consequences of the technique must be given greater weight by NICE. In this light, the BOA would urge NICE to again reflect on the following NHS England evidence review and proposed policy: 1. https://www.england.nhs.uk/wp-	

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			content/uploads/2023/11/2206-ccp-direct-skeletal-fixation-for-transfemoral-limb-loss-adults-updated.pdf 2. https://www.england.nhs.uk/wp-content/uploads/2023/11/2206-direct-skeletal-fixation-ehia.pdf 3. https://www.england.nhs.uk/publication/clinical-commissioning-policy-direct-skeletal-fixation-for-transfemoral-limb-loss/	
8.	Consultee 1 NHS clinician Orthopaedic limb reconstruction surgeon (member BOA trauma committee)	Section 1	I am an orthopaedic limb reconstruction surgeon. I work in the NHS and not in the private sector. I am the lead orthopaedic surgeon for the amputee service through Queen Mary's Hospital, Roehampton. I have taken over the care of all historic DSF patients who had surgery as part of a trial on the NHS - this cohort of patients is now under my care after direction from NHSE. I am providing my personal views, but also represent the British Orthopaedic Association (I have not been able to get an access code in time). I sit on the BOA trauma committee, and am the lead for our national trauma guidelines. My comments are as follows: Osseo has a role and could be a very important intervention in a very small group of selected individuals. Many of the responses to this consultation are from those who perform this surgery in the private sector. It is vital that the NHS position is considered. I have no doubt	Thank you for your comments. IPAC considered consultee's views in their deliberations and amended section 3.8 about significant risk of serious complications including infections and removals.

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			about the transformative nature of the surgery, which others who have responded here have highlighted very clearly. However,... Any policy should consider the potential for future serious problems, which are commonly under reported and not emphasised enough due to the inherent bias in many of the responses to date. In my own clinical experience, now looking after one of the older cohorts of patients I have made the following observations: the incidence of major infection is very high (approaching 50-100%) and this ultimately necessitates implant removal Implants can suffer fatigue and broken components necessitating intervention Periprosthetic fracture is a risk, either acutely or later on. All the 3 scenarios above could fall to the NHS to solve, even if there is no NHS policy for new implants, and NICE needs to recognise this. The majority of DSF is performed in the private sector, and in the main is funded through litigation (either clinical negligence or personal injury claims). Unless those claims include provisions for future issues such as those mentioned above, it may well end up falling to the NHS to solve them.	
9.	Consultee 1 NHS clinician	Section 1	NHSE has already conducted an evidence review and defined a proposed policy, so I would hope NICE will consider this:	Thank you for your comments.

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	Orthopaedic limb reconstruction surgeon (member BOA trauma committee)		https://www.england.nhs.uk/wp-content/uploads/2023/11/2206-ccp-direct-skeletal-fixation-for-transfemoral-limb-loss-adults-updated.pdf https://www.england.nhs.uk/wp-content/uploads/2023/11/2206-direct-skeletal-fixation-ehia.pdf https://www.england.nhs.uk/publication/clinical-commissioning-policy-direct-skeletal-fixation-for-transfemoral-limb-loss/	The NHS England Clinical commissioning policy: direct skeletal fixation for transfemoral limb loss (adults) and evidence review published in 2023 has been considered by the committee as part of their discussions at IPAC 1. https://www.england.nhs.uk/wp-content/uploads/2023/11/2206-direct-skeletal-fixation-ehia.pdf https://www.england.nhs.uk/publication/clinical-commissioning-policy-direct-skeletal-fixation-for-transfemoral-limb-loss/
10	Consultee 1 NHS clinician Orthopaedic limb reconstruction surgeon (member BOA trauma committee)	Section 1	I am not a nay sayer. But I am a realist and pragmatist. There is huge enthusiasm out there for this surgery, but it is either by people who work primarily in the independent sector, or those who are yet to perform the surgery and do not have a full understanding of the long term consequences. BUT, people who do not manage the complications and consequences of these complications are only exposed to one side of the coin... My biggest concern is not the groundswell of enthusiasm to put these implants in, but more the inevitable eventual volume of work managing them in an ongoing fashion. This is by far and away the biggest drain on my bandwidth in terms of number of patients versus	Thank you for your comments. IPAC considered views about complications, long term consequences and burden of managing these patients and amended section 3.8.

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			hours spent. They need dedicated specific clinics, they come from all over, they are more demanding than anyone else, and when it goes wrong they want it sorted there and then, often with totally unrealistic expectations. I worry that a lot of the unwanted burden these patients generate will fall to the NHS, even if the initial surgery is performed in the private sector and NICE should consider this point.	
11	Consultee 4 NHS England	2.2 current treatment	The conventional prosthesis usually has a socket, which is custom made from a plaster cast of the stump [suggest inserting the additional following text] every effort is made to ensure individuals have a good fitting and comfortable socket. The following statement would benefit from additional context - such as the frequency/severity of occurrence. "This can cause pain, ulceration and improper distribution of body weight that can affect balance and lead to falls. This may mean the user has limited use of the prosthesis or may have to abandon it for a period because of poor fit"	Thank you for your comments. IPAC considered your comment and amended 2.2 as follows: *The customised prosthesis is fitted to replace the function of the missing limb and provide cosmesis for major amputations. The type of prosthesis depends on what part of the limb is missing. Conventionally, the prosthesis is attached to the residual stump by belts and cuffs, suction, or by a suspension system. The conventional prosthesis usually has a socket, which is custom made from a plaster cast of the stump. Every effort is made to ensure individuals have a good fitting and comfortable socket. One of the main problems with this type of prosthesis is rubbing between the stump and the socket. This can cause pain, ulceration and improper distribution of body weight that can affect balance and lead to falls. This may mean the user has limited use of the prosthesis or may have to abandon it for a period because of poor fit.*

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12	Consultee 5 Company	2.3 The procedure	Please define "OIP" in the document. Most publications refer to an "OI" implant rather than an "OIP" implant. Referring to an OIP implant is confusing.	Thank you for your comment. The team amended OIP to OI throughout the documents for consistency with publications on this procedure.
13	Consultee 5 Company	2.4 The procedure	Additional problems include: 1) Wear and tear of the connector components and the constant cost of replacement parts. 2) Having rehabilitation (mainly prosthetic) staff who are able to understand the mechanics of the connector systems and how to repair or replace these. 3) Having a constant and reliable source of connector components. Without these, the OI implant is completely useless. 4) Currently, there is only very limited access to the specialist surgical and rehabilitation support needed to look after patients undergoing this treatment. Access to treatment by a knowledgeable and experienced clinician on the NHS is a major problem.	Thank you for your comments. Section 3.9 of the guidance states that significant post operative care is needed.
14	Consultee 4 NHS England	2.5 The procedure	"It is usually done in 2 operations" The word 'usual' may need context, as it is not a 'usual' procedure in England. It should state that usual practice internationally is 2-stage.....	Thank you for your comments. IPAC considered your comment and amended section 2.5 as follows: *Direct skeletal fixation of limb prostheses using an OI implant is done under general or regional anaesthesia (depending on the level of amputation). The procedure can be done in 2 stages. A 2-stage operation is separated by a period of time.*
15	Consultee 5	2.5 The procedure	This section is completely misleading. Globablly, the majority (composed of thousands	Thank you for your comments.

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	Company		of patients) who have already had their OI surgery performed have had it done in one-stage using a press-fit implant. By comparison, a large minority have had a screw-fit implant placed in two-stages but the relative numbers between one-stage and two-stage put those who have had a two-stage procedure in the definite minority. Even patients undergoing treatment with a press-fit implant often have this done in one-stage. So, by rights, this document should refer to a one-stage procedure as being the standard of care. Not a 2-stage procedure. The implication that the second stage must be done 2 - 6 months later also suggests that the writers have misunderstood how the process of osseointegration works. As long as there is primary stability during the first 3 - 6 months after insertion, then osseointegration will proceed regardelss of when the implant is loaded. So, there is no need for a second operation to re-expose the distal end of the implant etc..etc... The document should not refer to an "OIP" implant. This is confusing. Please refer to an "osseointegrated" or "OI" implant. No one who works in the field refers to osseointegrated implants as "OIP" implants other than the National Institutes for Health.	IPAC considered your comment and amended 2.5 as follows: *Direct skeletal fixation of limb prostheses using an OI implant is done under general or regional anaesthesia (depending on the level of amputation). The procedure can be done in 1 or 2 stages. A 2-stage operation is separated by a period of time* The team amended OIP to OI throughout the documents for consistency with publications on this procedure.
16	Consultee 5 Company	2.6 The procedure	This is not true. One-stage procedures outnumber two-stage procedures by a significant number. Globally, there have been	Thank you for your comment.

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			many thousands of one-stage procedures and only hundreds of two-stage procedures performed.	IPAC considered your comment and deleted section 2.6.
17	Consultee 4 NHS England	2.7 The procedure	It would be helpful for this section to be expanded with further evidence as to optimal rehabilitation requirements. Rehabilitation is an essential part of the procedure. Without appropriate rehabilitation, individuals will not be able to effective use and benefit from the implant.	Thank you for your comments. IPAC considered your comment and amended 2.7 as follows: *A period of extensive physiotherapy and rehabilitation follows after the procedures, and the load on the prosthesis is gradually increased until full weight-bearing is allowed a few weeks later.*
18	Consultee 4 NHS England	2.7 The procedure	Further expansion of the extensive nature of the physiotherapy and rehabilitation required would be beneficial to add.	Thank you for your comment. IPAC considered your comment and amended 2.7 as follows: *A period of extensive physiotherapy and rehabilitation follows after the procedures, and the load on the prosthesis is gradually increased until full weight-bearing is allowed a few weeks later.*
19	Consultee 5 Company	2.7 The procedure	This paragraph is misleading. Is this referring to physiotherapy performed after a one-stage procedure or after the first stage of a two-stage procedure? The physiotherapy needed after both scenarios is certainly extensive but is very different depending on which NICE decides to recommend. If it is referring to the loading regimen after a one-stage procedure and after the 2nd stage of a two-stage procedure then these are certainly similar. However, the guidance should indicate what it is referring to accordingly. Moreover, that physiotherapy and	Thank you for your comments. IPAC considered your comment and amended 2.7 as follows: *A period of extensive physiotherapy and rehabilitation follows after the procedures, and the load on the prosthesis is gradually increased until full weight-bearing is allowed a few weeks later.*

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			rehabilitation is very specialist and should only be done by properly trained staff. Otherwise, things can (and do) go wrong.	
20	Consultee 1 NHS clinician Orthopaedic limb reconstruction surgeon (member BOA trauma committee)	3.2 The evidence	The evidence is still lacking or of low quality - people are quoting their own case series. As an academic, this is not high quality data and it is obvious that these publications have significant limitations, bias or flaws.	Thank you for your comment. The rationale in the draft guidance states that 'The evidence for this procedure is limited in quality and mainly from observational studies.'
21	Consultee 1 NHS clinician Orthopaedic limb reconstruction surgeon (member BOA trauma committee)	3.2 The evidence	There is nothing in the NICE consultation about complications or long term issues requiring future surgery (implant removal, deep infection, periprosthetic fracture). https://www.nice.org.uk/guidance/GID-IPG10351/documents/321	Thank you for your comment. Section 1 of the guidance states that there is evidence of serious complications which leads to additional interventions. This is also mentioned under the section *'why the committee made these recommendations'*. Safety outcomes are reported in detail in the 'Overview of evidence'.
22	Consultee 1 NHS clinician Orthopaedic limb reconstruction surgeon (member BOA trauma committee)	3.2 The evidence	The NICE overview identifies there are NO comparative studies versus conventional rehab or prosthetics, so the only evidence available is typically single centre developer institutions with inherent bias: https://www.nice.org.uk/guidance/GID-IPG10351/documents/overview	Thank you for your comment. This has been mentioned in the 'Overview of evidence'.
23	Consultee 2 NHS Clinician	3.2 The evidence	Results in the below paper for UK Military Veterans who received DSF with public funding in Birmingham (DMS/NHS collaboration) shows sustained EQ5D improvements out beyond 5	Thank you for your comments and informing about the ongoing data collection for UK Military Veterans who received DSF.

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			years and cost effectiveness. This can be found in the subgroup analysis and I do not believe is included in your literature search. Handford C, McMenemy L, Kendrew J, Mistlin A, Akhtar MA, Parry M, Hindle P. Improving outcomes for amputees: The health-related quality of life and cost utility analysis of osseointegration prosthetics in transfemoral amputees. Injury. 2022 Dec;53(12):4114-4122. doi: 10.1016/j.injury.2022.10.007. Epub 2022 Oct 17. PMID: 36333155. There is ongoing prospective data collection for this cohort of UK Veterans impartially through Imperial College London focusing on complications, PROMs, Gait and Functional Outcomes. This will continue to publish at key time points.	This paper (Handford 2022) was not identified in the original or update searches. The team included this paper in the overview under 'other relevant studies' section.
24	Consultee 5 Company	3.2 The evidence	There are additional key measures of efficacy which should be considered when compared to a standard socket-fitted prosthesis: 1) Length of time (per day) that a prosthesis is worn 2) Time taken to don and doff a prosthesis 3) Number of visits per year to a rehab centre for adjustment of the prosthetic solution	Thank you for your comments. Only key efficacy outcomes reported in published papers are summarised in the evidence summary.
25	Consultee 4 NHS England	3.4 The evidence	It is not clear as to whether the broader prosthetic patient community were involved in the development of the IPG beyond patients who have had the procedure?	Thank you for your comments. NICE asks people who have had the procedure to comment as we are not

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				considering evidence on comparative procedures. IP looks at efficacy and safety of the procedure. Seventeen commentaries from people who have had this procedure were discussed by the committee. Submissions provided by 1 patient organisation representing people who have had this procedure were discussed by the committee.
26	Consultee 1 NHS clinician Orthopaedic limb reconstruction surgeon (member BOA trauma committee)	3.4 The evidence	The patients who have responded describe the significant number of interventions that they have had to go through (one patient describes 20 procedures and ongoing), therefore highlighting the potential burden of work this cohort of individuals require: https://www.nice.org.uk/guidance/GID-IPG10351/documents/specialist-advice-questionnaires	Thank you for your comment. IPAC considered your comment and amended section 3.8 to reflect the points raised.
27	Consultee 4 NHS England	3.7 Committee comments	This statement should reflect that provision of a microprocessor prosthetic would need to be in line with the criteria as set out in published NHS England policy.	Thank you for your comments. IPAC considered your comment but decided not to amend 3.7 which currently states that *'this procedure may be paired with a microprocessor prosthetic'.*
28	Consultee 4 NHS England	3.11 Committee comments	Patient selection for the procedure would need to be in line with published NHS England policy. If commissioned, the referral pathway for this procedure would be through the patients NHS prosthetic centre.	Thank you for your comments. IPAC considered comments about NHSE policy but decided not to amend 3.11 which currently states that *'The patient experts explained how the procedure could be life-changing for some people but there is always a risk of complication. One patient expert said that infection can be extremely serious and lead to*

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				the further loss of bone. Both experts agreed that patient selection was a vital factor in deciding who has the procedure but that age should not predetermine whether someone is able to adhere to rehabilitation or recovery'.
29	Consultee 5 Company	3.11 Committee comments	This is only true if the current dogma about how to perform a below knee amputation remains unchallenged.	Thank you for your comments. 3.13 currently states that *'The committee were informed that it is more difficult to secure an implant in a tibia than a femur, because of the shape of the bone'.*
30	Consultee 1 NHS clinician Orthopaedic limb reconstruction surgeon (member BOA trauma committee)	General	There are people pushing for DSF in very young individuals, whereby the implant life expectancy cannot be more than 20-25 years (taking NJR data for uncemented hip aseptic loosening as a baseline comparator) and as such many of these patients who may have been OK prosthetic users, might end up as wheelchair users in later life. Many proponents of DSF do not consider the very long term future issues. Again this may fall to the NHS to solve even if the original surgery was conducted in the independent sector.	Thank you for your comments. IPAC considered your comment and added a committee comment about monitoring long term outcomes in young people in 3.9.
31	Consultee 4 NHS England	unmet need (Overview page 4)	This section would benefit from an indication of the frequency/severity of the reported problem. This section does not set out the population size of unmet need.	Thank you for your comments. The 'unmet need section' in the overview on page 4 has been amended.
32	Consultee 7 St George's university hospital	General	1. DOH funded research trial at done at Queen Mary's hospital, Roehampton in late 1990s. 2. 19 Trans-femoral OI patients all done at Kingston hospital, London by 1 surgeon	Thank you for your comments. We only consider efficacy evidence that has been published in peer-reviewed literature.

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	NHS Foundation trust		(Swedish OPRA system) and 1 private osseo which was adopted (total 20) 3. Most osseo users have active lifestyles and need a “highly responsive amputee MDT” which can only be provided in large centres with adequate resources and clinicians and also good links with orthopaedic services. 4. Follow up between 112- 320 months. 5. More than 100 additional procedures were done over this period of time and most of them involved change of abutment or abutment screws. 6. Most of these procedures were done in patients who engaged in high impact activities causing mechanical implant failures. 7. Most osseo users had an active lifestyle, were employed and enjoyed a better quality of life . 8. Although clear guidance on activities was provided, not all patients were complaint with this guidance and this is difficult to control or monitor. Some have engaged in high impact activities which contributed to repeated abutment failures. 9. Implant removals due to deep infection led to some bone loss which made re-implantation surgery more complicated. a. 8 remain non-infected to date b. 10 deep infections to date 4 implants removed and non-limb wearers/ socket users	

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			1 implant removed and had re-implant with OPL 2 removed and waiting for press- fit implant (OPL) 1 implant due for removal 2 mild and stable deep implant infection – needing close monitoring 10. Some patients eventually became non-prosthetic users (4/19) 11. Superficial infections are not infrequent can be fully treated with a course of oral antibiotics 12. Recurrent “superficial” infections often indicated a deeper problem and further investigations. 13. 1 patient had fracture neck of femur twice 14. No major stoma problems except 1 patient who had multiple surgeries and 2 re-implants.	
33	Consultee 7 St George's university hospital NHS Foundation trust	General	Summary 1. Patient selection should include very strict inclusive and exclusion criteria. 2. Amputee rehab MDT should be involved in patient selection along with surgical team. 3. Regular planned follow up clinics with MDT are mandatory to reduce risk of implant failure and therefore a significant amount of extra resources will be needed for specialist centres managing these patients. This includes training and dedicated sessions for RM consultant, nursing, prosthetists and physios. A formal scoping of this additional resources should be done to make sure adequate long-term support is provided for this group. 4. Patients should be counselled that they may	Thank you for your comments. IPAC considered your comments and amended 3.8 to include potential problems. Currently 1.4 covers patient selection by an MDT.

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			potentially become non-osseo users in future if the implants have to be removed and further re-implantation surgery cannot be performed safely.	
34	Consultee 1 NHS clinician Orthopaedic limb reconstruction surgeon (member BOA trauma committee)	General	The responders so far to NICE have conflicts of interest (some, but not all declared). One group does NOT have an orthopaedic surgeon working routinely with them and the plastic surgeons perform this surgery which is a huge concern. I have anecdotal personal experience of them pushing this procedure aggressively.	Thank you for your comment. The committee are aware of conflicts of interest that have been declared by the professional experts in their submitted questionnaires.

"Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees."