NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: **IP692/2 Direct skeletal fixation of limb or digit prostheses using intraosseous transcutaneous implants**

Your information

Name:	Alex Woollard
Job title:	Consultant Plastic Surgeon
Organisation:	Royal Free London Foundation Trust
Email address:	
Professional organisation or society membership/affiliation:	British Association of Plastic, Reconstructive and Aesthetic Surgery, British Association of Aesthetic Surgery, European Association of Plastic Surgery
Nominated/ratified by (if applicable):	Click here to enter text.
Registration number (e.g. GMC, NMC, HCPC)	6051471

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consultation on the draft guidance, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate.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.

Yes ☐ 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 expert in the field of direct skeletal fixation. I have been performing this surgery since 2018 and have completed an International Fellowship in DSF under Prof Al Muderis. I am published in the field. I have been using this technology both in the axial skeleton and in the craniofacial skeleton. Specifically, in relation to the axial skeleton, I have performed over 60 cases using press fit devices (OPL and OTN). The vast majority of those cases have been related to my private practice in the UK where I work within an MDT setting. We also have an international MDT for complex cases and are closely linked to other DSF groups in both Europe (Holland and Germany) and Australia. This technology is not routinely available in the NHS in England in the axial skeleton, although it is in the craniofacial setting. There is a limited availability in Scotland (5 cases per year), and in some exceptional circumstances related to patients who have previously been involved in clinical trials (Roehampton and RNOH). If it were to become routinely available I suspect the uptake would be very large since in the majority of amputations the advantages in terms of a return to normal ADLs is clearly great. some instances, where a socket is not feasible, it is the only way to restore a patient to prosthetic use. However, this makes defining criteria for DSF very difficult indeed. I suspect that to offer this on the NHS would be difficult and prove extremely costly.

		The surgery itself is technically very complex, not from the Orthopaedic side, but from a soft tissue perspective. All the of the aspects that lead to a successful outcome surgically are related to the management of the soft tissue, and almost all the complications arise from the soft tissues and the stoma. It is possible to achieve a stable long-lasting solution but only with significant experience. Managing the problems associated with the stoma and residuum is a significant challenge and requires multiple returns to theatre in the first few years as the tissues become ptotic. For this reason adoption in the NHS is likely to result in poor outcomes and complications. From my experience in this field I would recommend that any service be based around an MDT led by individuals who can manage the soft tissue component. In the UK this surgery is only routinely performed by plastic surgeons at the Royal Free Hospital (Myself, Mr Norbert Kang and Mr Yazan Al-Ajam). I am aware of some military cases performed through the Royal Orthopaedic Hospital in Birmingham and Mr Gupta running a limited service in Glasgow. Prof Al Muderis has visited the UK to perform a single case with the St George's team on a Roehampton clinical trial patient from the OPRA study and I have implanted an ITAP study patient with an OPL implant at The Royal National Orthopaedic Hospital. As a group myself, Mr Kang and Mr Al-Ajam have close links with other DSF groups in Europe and have been involved with revising some of their complex cases.
2	− Please indicate your research experience relating to this procedure (please choose one or more if relevant):	I am routinely involved in this surgery and as a group we publish and present our data at a National and International level. Other (please comment)
3	Does the title adequately reflect the procedure? 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):	The title **"IP692/2 Direct skeletal fixation of limb or digit prostheses using intraosseous transcutaneous implants"** adequately describes the procedure. Established practice and no longer new. The number of cases worldwide has now grown to such a level that I feel that this is now established practice. However, the technique of managing the soft tissues is still evolving and certainly represents an ongoing concern to reduce complication rates. The skills required to achieve a stable, dry stoma are very far outside the skill mix of most orthopaedic surgeons and success in DSF will hinge on a general acceptance that this is primarily a soft-tissue operation. The input from the rehabilitation community with targeted physiotherapy and prosthetics is also crucial to the long-term success.

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?	Whilst it does have the potential to replace current standards of care, in my opinion it would be best served as an adjunct. In the majority of cases, current socket-based treatment is adequate and, particularly in the very active below knee amputee, may potentially supersede DSF.
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?	Most of the changes in technique, and improvements in outcome, relate to a gradual evolution in the management of the soft tissues. Alongside that, the rehab protocols are now tailored to specific problem areas that are specific to each patient. In the last ten years the number of cases worldwide has increased dramatically, and this has improved the availability and delivery of replacement parts and the supply chains. It has also enabled the evidence base for DSF to grow with most of the thousands of patients on DSF clearly doing very well.

Current management

6	Please describe the current standard of care that is used in the NHS.	The current standard of care is a socket fitted prosthesis. There is considerable variability in the frequency of new socket provision. In the case of lower limb prosthetics it is often difficult to achieve a really good fit and many patients suffer from soft problems associated with that. They will typically have a new socket made annually. Upper limb amputees fair much worse and the usefulness of NHS upper limb prosthetics to improve their quality of life versus their discomfort and weight means that >50% stop using them within two years of being issued.
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?	DSF is the only alternative to socket fitted prosthetics

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?	The benefits of DSF are that the patient is then loading through the axial skeleton. This bypasses the skin-socket interface and can reduce a number of the typical problems seen in traditional sockets (abrasions, poor fit, sweating, loss of stability, poor outcomes in duration of use/ease of donning and doffing/pain from the socket/reduced ADLs). The additional benefits come through osseoperception, improved long-term bone density (especially in women), increased activity/independence, reduced pain associated with socket use including pressure on neuromas, reduced phantom pain associated with increased osseoperception.
9	Are there any groups of patients who would particularly benefit from using this procedure/technology?	DSF is particularly beneficial in those who have failed traditional sockets. This is particularly true in bilateral amputees and those with short stumps. Additionally those with a concomitant brachial plexus or brain injury can often do better with the simpler quick-release connectors that can be applied one-handed.
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?	Certainly the patients who have done well tend to be difficult to get back for long term follow up. That said, the initial follow up is intensive and almost all patients have to return to theatre at least once in the first year. The stability of the stoma is critical, and this relies on intensive follow up in the first 12 months. Long term, the patients still need a similar level of follow up with rehabilitation and prosthetics to maintain the external parts and service the prosthetic elements. The outcomes show that, especially in those who have failed traditional sockets, DSF definitely provides significant benefits for patients and potentially reduces the burden on health and social care through increased independence and less care requirements. It has the potential to return patients to work.
11	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	Ideally this should be performed by an MDT (minimum: plastic surgeon, anaesthetist, physio, prosthetist, clinical psychologist, microbiologist, radiology, rehabilitation physician, OT) in a location that can provide on-site rehabilitation in a residential setting. Availability of HDU level of care is beneficial. There needs to be provision of primary and long-term care with availability of servicing for implant and connectors with the knowledge base to manage these issues. The majority of clinical issues are soft-tissue related so require ongoing support from plastic surgery to manage them. The surgical techniques needed to maintain the stoma are very heavily technical and specific to each

		patient and this necessitates a high knowledge base and specific understanding of how to identify and manage the problems. Finally, this is not something that should be considered in a trauma setting. The centre should ideally be a tertiary/quaternary centre
12	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	This is complex surgery. Significant training is required to have sufficient skills to manage the soft tissues at the primary surgery but also to manage the soft tissue complications in the first (and subsequent) years of follow up.

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	The common concerns with DSF are around infection. However, this needs to be qualified into deep bone infection leading to the loss of the implant (which is low, approx. 1.4% in the OPL large series) and soft tissue infections (which are common, all patients will have at least one in the first year). In patients who lose their implant due to infection, it is possible to make arrangements for re-implantation and all patients known to have undergone this procedure have returned to stable use of their bone-anchors. There is also a possibility of localised infection around the stoma particularly when the stoma remains 'wet' due to poor soft tissue handling. This is approximately 25% in our series (60+) but, in most cases, this can be managed through debridement and a short course of antibiotics provided the stoma can be stabilised. In these cases they return to a steady-state and do not require long term antibiosis. Approximately 4% suffer periprosthetic fractures and these can usually be managed with standard orthopaedic techniques and the patient returns to normal DSF use. The incidence of implant failure is very low and usually related to a major fall. The most recent generations of press-fit implants are even more robust (approximately 2-3/1000 implants fail) We have received anecdotal evidence of patients who have committed suicide after deep infection leading to loss of implant (and with that quality of life) who were refused reimplantation.

14	Please list the key efficacy outcomes for this procedure/technology?	1) Timed up and go (TUG) scores 2) 6-minute walk test (distance in metres) 3) K-levels 4) EQ5D questionnaires 5) Raw figures for complications such as periprosthetic fractures, infections, revision procedures
15	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	There needs to be a centrally held register of cases (ISPO were earmarked to perform this role but we don't know what has happened with this plan) Upper and lower limb patients should be considered separately
16	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	The efficacy and long-term stability of screw-fit devices in the lower limb is not clear. The majority of the technology has moved towards press-fit devices, and this has resolved some of those concerns
17	If it is safe and efficacious, in your opinion, will this procedure be carried out in (please choose one):	Given the small numbers that would be considered for treatment by the NHS, the surgery should be restricted to a small number of centres who can offer the requirements of the full MDT and rehabilitation provision. This should NOT be done in a trauma setting and would be best suited to a tertiary/quaternary centre. Plastic surgery should be at the core of any service given the importance of the soft tissues in the success of the procedure. If expansion were then considered it should be done under a controlled system led by experienced surgeons.

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	1) Enthesopathy, a Cause for Persistent Peristomal Pain after Treatment with an Osseointegrated Bone-Anchor: A Retrospective Case Series by Norbert Venantius Kang, FRCS (Plast), Alexander Woollard, FRCS (Plast), Sanjay Gupta, FRCS (Orth), Dominika Michno, MD, Eliza Davison, MRCS, Beth Langley, BSc 2) Periprosthetic osseointegration fractures are infrequent and management is familiar by J. S. Hoellwarth, K. Tetsworth, J. Kendrew, N. V. Kang, O. van Waes, Q. Al-Maawi, C. Roberts, M. Al Muderis 3) Use of an osseointegrated intraosseous transcutaneous amputation prosthesis (ITAP) for amputated fingers by Mr Norbert V Kang, Mr Yazan Al-Ajam, Mr Alexander Woollard, Mrs Nikki Burr 4) PhD Thesis for Dr Robin Atallah – On the safety of bone-anchored prostheses in lower extremity amputation, Radbound University, Holland by Dr Robin Atallah

	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.	
19	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	No
20	Please list any other data (published and/or unpublished) that you would like to share.	

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)?	Less than 100
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	Beneficial outcome measures: 1) Timed up and go (TUG) scores 2) 6-minute walk test (distance in metres) 3) K-levels 4) EQ5D questionnaires Adverse outcome measures: Raw figures for complications such as periprosthetic fractures, infections, revision procedures

	procedure timescales over which these should be measured:	

Further comments

23	If you have any further comments (e.g. issues with usability or implementation, the need for further research), please describe.	DSF has the potential to radically improve the quality of amputee rehabilitation. However, it is vulnerable to failure when performed by those who have not appreciated its nuances. It lies across an orthoplastics border, but the success or failure of the surgery depends fundamentally on the treatment of the soft tissues (where the surgery is complex). The soft-tissue surgery is far more complex than the bony component (which is relatively straightforward). We have seen this already in the UK with the failure of previous trials of both OPRA and ITAP implants. It will be very unkind to have a list of criteria for treatment within the NHS which will restrict the implementation of DSF to only a small group of individuals (e.g. short bilateral transfemoral amputees), even if this may be the only option for independent ambulation in this particular group.

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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
Choose an item.	I am a director of a company that acts as an agent for OGAAP supplying OPL implants within the UK.	**2018**	
Choose an item.			
Choose an item.			

X 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:	Alex Woollard
Dated:	**4th December 2023**

NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: **IP692/2 Direct skeletal fixation of limb or digit prostheses using intraosseous transcutaneous implants**

Your information

Name:	Colette Shaw
Job title:	Prosthetist
Organisation:	STEPS Prosthetics
Email address:	
Professional organisation or society membership/affiliation:	BAPO
Nominated/ratified by (if applicable):	BAPO Professional Affairs Committee
Registration number (e.g. GMC, NMC, HCPC)	HCPC PO00737

How NICE will use this information:

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

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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?	I have received certification training from Integrum in the prosthetic fitting of their OPRA Implant System. I have also worked as part of the multi-disciplinary team with the surgical team at London International Patient Services, based in the London Clinic, to assess patients for this procedure. I continue to be involved in the prosthetic treatment of 1 patient who has undergone this procedure.
	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?	I understand that this procedure is not currently approved by NHS England and is only performed privately in England or through the MOD.
	– Is this procedure/technology performed/used by clinicians in specialities other than your own?	Yes, surgical teams including orthopaedic and plastics will perform this procedure and work in collaboration with prosthetists and physiotherapists to provide the rehabilitation pre- and post-surgery.

	– If your specialty is involved in patient selection or referral to another specialty for this procedure/technology, please indicate your experience with it.	I have experience working as part of the multi-disciplinary team with the surgical team at London International Patient Services, based in the London Clinic, to assess patients for this procedure
2	– Please indicate your research experience relating to this procedure (please choose one or more if relevant):	I have not been involved in research on this procedure. Other (please comment)
3	Does the title adequately reflect the procedure? 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):	Yes It has a completely different approach to traditional prosthetic sockets with a direct mechanical link between the prosthesis and the body via the bone anchored implant as opposed to traditional sockets which connect the body to the prosthesis via an indirect mechanical link by transferring forces to the skeleton through the soft tissues of the residual limb. The first procedure was performed in 1990 so it is not a new procedure. Established practice and no longer new.
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?	I believe that is would be used as an addition to existing standard care where a patient cannot tolerate a traditional socket or where there are significant benefits to be gained in using OI over a traditional socket.
5	Have there been any substantial modifications to the procedure technique or, if applicable, to devices involved in the procedure?	There are several surgical teams now providing this procedure worldwide however I only have direct experience of Integrum's OPRA system and to my knowledge, there have been no substantial modifications to the procedure technique or to the Axor unit which connects the abutment to the prosthesis.

	Has the evidence base on the efficacy and safety of this procedure changed substantially since publication of the guidance?	

Current management

6	Please describe the current standard of care that is used in the NHS.	Traditional prosthetic sockets.
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.

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 of socket related problems such as skin irritations, pressure issues, volume fluctuation and sweating. - Improved sitting comfort. - Enhanced proprioception and osseoperception - Increased range of motion of proximal joint, e.g. hip joint for transfemoral amputees - Improved control of prosthesis through a more direct connection - Direct loading of the bone may improve bone density longer term.
9	Are there any groups of patients who would particularly benefit from using this procedure/technology?	In my opinion trans-femoral and trans-humeral amputees would benefit particularly well from this procedure.
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?	Yes, it could allow more patients to benefit from prosthetic rehabilitation who cannot tolerate a traditional socket which will benefit the healthcare system by them being able to mobilise and therefore remain fitted and more independent. It is however a more invasive procedure and could lead to more hospital visits if there are any issues with infection.
11	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	None prosthetically.
12	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	Training for prosthetists and physiotherapists in the rehabilitation process following the procedure and ongoing care and maintenance for the prosthetic adapter which connects to the abutment.

Safety and efficacy of the procedure/technology

13	What are the potential harms of the procedure/technology?	Risk of infection

	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	Risk of fracture proximal to the implant side and need orthopaedic surgery to treat fracture and/or stump revision.
14	Please list the key efficacy outcomes for this procedure/technology?	Improvement in patient-reported outcome measures Improved activity level and quality of life
15	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	Infection rate and suitable patient selection
16	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	Not that I am aware.
17	If it is safe and efficacious, in your opinion, will this procedure be carried out in (please choose one):	Fewer than 10 specialist centres in the UK. Cannot predict at present.

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).	Scientific data & resources - Integrum

	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.	
19	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	Since December 2020, the OPRA™ Implant System holds a PMA for the treatment of transfemoral (above-knee) amputations. As the OPRA™ Implant System is equally functional in transhumeral (above-elbow) amputations, Integrum aims to broaden the regulatory approval in the US. The OPRA™ Implant System clinical study on the below-knee amputation level recently received FDA approval, and recruitment to the study will start as soon as the protocol is approved by the Investigational Research Board (IRB). Once the study is finalized, Integrum will be able to use the data in any future regulatory process.
20	Please list any other data (published and/or unpublished) that you would like to share.	

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)?	It is difficult to estimate this however I would suggest up to 10% of transfemoral amputees (est. 200) and 50% of transhumeral amputees (est. 50) annually.
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	Beneficial outcome measures – taken at baseline (prior to procedure) then at 3, 6, 9 and 12 months' post- procedure. Lower limb amputee outcome measures: - Plus M - TAPES-R

	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:	- L-test - 2-minute walk test - 6-minute walk test - 4-square step - T-test Upper limb amputee outcome measures: - TAPES - Quick DASH - Box and Block test - ACMC Adverse outcome measures: - Infection rates - Fracture rates - Trips and falls

Further comments

23	If you have any further comments (e.g. issues with usability or implementation, the need for further research), please describe.	

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Choose an item.			
Choose an item.			
Choose an item.			

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Print name:	**Colette Shaw**
Dated:	**14/12/23**

NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: **IP692/2 Direct skeletal fixation of limb or digit prostheses using intraosseous transcutaneous implants**

Your information

Name:	David Alan Leonard
Job title:	Consultant Plastic, Reconstructive & Hand Surgeon
Organisation:	Leeds Teaching Hospitals NHS Trust
Email address:	david.leonard6@nhs.net
Professional organisation or society membership/affiliation:	British Society for Surgery of the Hand, British Association of Plastic, Reconstructive & Aesthetic Surgeons,
Nominated/ratified by (if applicable):	BSSH
Registration number (e.g. GMC, NMC, HCPC)	6148091

How NICE will use this information:

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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?	I am familiar with osseointegration technology and procedures from study of published literature, and completion of a visiting fellowship in the surgical care of amputees at a number of leading hospitals in the United States, including the Walter Reed Military Medical Center in Bethesda, Maryland. I have not personally undertaken prosthetic osseointegration in my practice, and it's use in the United Kingdom to date has been limited. In addition to an MOD funded clinical trial recruiting military amputees, which reported positive results with consistent quality of life and cost-effectiveness benefits, some small cohorts of patients have been treated, mostly in the private sector. Case have been performed in London, Birmingham and Glasgow, and perhaps other centres. In the absence of NHS commissioning and positive NICE guidance I expect uptake to remain limited, however provided the necessary financial and regulatory support I expect uptake would be enthusiastic in a small number of specialist centres with experience of providing regional or supra-regional services for appropriately selected patients. Osseointegration of prosthetics is typically provided on a multidisciplinary basis by orthopaedic surgeons and plastic & reconstructive surgeons, working within a multidisciplinary team including

	– If your specialty is involved in patient selection or referral to another specialty for this procedure/technology, please indicate your experience with it.	rehabilitation medicine physicians, prosthetists, physio and occupational therapists, and clinical psychologists. I have visiting fellowship experience of the MDT approach to patient selection for osseointegration of prosthetic limbs, and a joint ortho-plastic to surgery for these cases.
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.
3	Does the title adequately reflect the procedure? How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design?	Yes, the title adequately reflects the procedure. The standard of care for major amputees (both upper and lower limb) is prosthetic rehabilitation using compressive or suction based socket and suspension systems. This technology is long established, and offers the majority of amputees satisfactory outcomes. However such systems fundamentally rely on non-anatomical load transfer, and are associated with poor fit, pain and skin problems in a proportion of patients. In transfemoral amputees in particular conventional prostheses are associated with limited range of movement in the hip, poor biomechanical efficiency and excess energy expenditure, all of which contribute to limited mobility. Osseointegration is an innovative approach that offers direct skeletal fixation of a fixture to which the prosthetic limb is then attached, via a percutaneous connector. This avoids socket-associated complications such as poor fit and skin breakdown, and can offer reduced energy expenditure, improved range of movement and overall mobility. While this technology is innovative, it can no longer truly be described as “novel”, as the first human implantation was performed in Sweden in 1990, preceding which pre-clinical studies in animal models had been under way since the 1960s. Published clinical series now report outcomes for some of the currently available devices with follow up over 15 years.

	Which of the following best describes the procedure (please 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.~~ ~~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?	Current evidence indicates that the majority of amputees are adequately served by conventional socket-fit prostheses, which are a cost-effective option with a low risk of major complications. For those patients who cannot tolerate, are not suitable for, or have significant skin or other complications as a result of conventional prostheses I think osseointegration offers significant potential as an alternative, available in addition to existing options, for appropriately selected patients.
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?	Details of the surgical technique vary between centres, and the various implant systems currently available on the market, but all follow the same basic principles. Preoperative planning must include assessment of adequacy of bone stock, and consideration of the integrity, quality and shape of the soft tissues in the residuum. Surgery may be single stage, in which case the soft tissues are prepared and the device brought through the skin at the time of implantation in the bone; or two stage, in which case the device is implanted, but left buried for a period between 6 weeks and 6 months, prior to soft tissue reshaping, preparation of the stoma, and exteriorisation of the abutment followed by graduated increase in weight bearing. There are currently 5 major devices available on the market; Osseoanchored Prosthesis for the Rehabilitation of Amputee (OPRA), Compress Transcutaneous Implant (CTI), Integral Leg Prosthesis (ILP), Osseointegrated Prosthetic Limb (OPL), and Percutaneous Osseointegrated Prosthesis (POP). While the literature includes reports on each, there is, as yet, no clear evidence from high quality studies to direct the choice of one system over another. Since the publication of guidance on direct skeletal fixation of limb or digit prostheses using intraosseous transcutaneous implants IPG270 in 2008 there have been several key developments in the evidence base, in addition to an overall increase in the number of publications reporting

		experience with and outcomes of these procedures – which while individually lacking impact, taken together these indicate maturation in the field and improvement, and greater consistency, in outcomes, and an improved safety record, with increased clinical familiarity and introduction of standardised rehabilitation protocols. I would highlight the following in particular: 1. Improving outcomes for amputees: The health-related quality of life and cost utility analysis of osseointegration prosthetics in transfemoral amputees. C Handford et al., Injury (2022) 53;4114-4122 Two centre, retrospective analysis of prospectively collected patient reported health outcome data including health utility and cost analysis. Total of 80 patients included all UK military personal who underwent femoral osseointegration, and a cohort of femoral osseointegration patients from Australia. Maximum follow up 10.5 years. Pooled EQ5D HUV scores improved from 0.64 to 0.73 at 5 years, 0.74 at 6 years and continued improving to 10.5 year extent of study. Subgroup analysis of those starting with EQ5D HUV <0.60 reached a cost/QALY of <£30,000 at 5 years and statistically significant improvement in EQ5D HUV. While this study is subject to the limitations of the its retrospective design, it is nonetheless robust and provides strong quality of life and cost-efficacy arguments in support of prosthetic osseointegration particularly in patients unable to mobilise with conventional prostheses (correlating with the study cohort with starting EQ5D HUV <0.60). 2. The safety of one-stage versus two-stage approach to osseointegrated prosthesis for limb amputation; a systematic review. E Banducci et al, Bone Joint Open (2023);4-7:539-550 PRISMA compliant systematic review. Inclusion of adults with upper or lower limb amputation who underwent one or two stage osseointegration procedure and had follow up with reporting of complications. While there are significant limitations to this study (to the extent that the headline finding that one-stage procedures are preferable to two-stage due to lower incidence of complications, particularly superficial infection, osteomyelitis and implant failure should be treated with extreme caution) the literature reviewed nonetheless highlights a gradual increase in uptake of this technology, and albeit not explicitly analysed, speaks to a learning curve effect and maturation of the technology and techniques (more recent studies, specifically including the

		single-stage papers reviewed, demonstrate lower complication rates – with the key confounder that they benefit from the cumulative experience of earlier efforts). 3. Thumb amputations treated with osseointegrated percutaneous prostheses with up to 25 years follow up. Y Li et al JAAOS Glob Res Rev (2019);3:3097 Single centre retrospective study of 13 patients who received osseointegrated prosthetic thumb between 1990 and 2014. Small study, but extended follow up duration. Again highlights learning curve / technical advances over duration of study, encouragingly achieving 100% cumulative success rate with standardised design and rehabilitation subsequent to 2005. Consistent with reports on major limb osseointegration, complications included superficial infections, deep bone infection and implant failures though noteably these were all early in the experience. Functional outcome measures were broadly equivalent to microsurgical toe transfer. This study again lacks statistical impact and has several clear limitations, but should be acknowledged for its duration of followup, and demonstration of technical improvement to a very high level of success post 2005. I think it demonstrates that osseointegrated prosthetic replacement of the thumb may have a place alongside other well established procedures such as webspace deepening, and microsurgical toe transfer in patients who may be unsuitable for such procedures, or be unwilling to accept the donor site cost of the later.

Current management

6	Please describe the current standard of care that is used in the NHS.	The current standard of care in the NHS for major limb amputees is prosthetic rehabilitation using conventional socket-fit prostheses utilising compression or suction-based suspension systems. The current standard of care for thumb amputation includes surgical deepening of the 1st webspace, elongation of the thumb residuum with bone graft, or microsurgical transfer of a toe. Osseointegration of prostheses is not routinely available for any of these indications.

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?	Viewed broadly, the competing options for major amputation are conventional prosthetic attachment; for thumb amputation, cosmetic prostheses, mechanical prostheses (such as marketed by Naked Prosthetics), surgical webspace deepening, bone grafting or toe transfer; and in very highly selected patients with upper limb amputation, allotransplantation (provided via the UK Hand Transplant Program in Leeds). However, I think it is inappropriate to consider these are competing technologies, but rather options with for which there are rather widely varying indications and contraindications. The vast majority of amputees have their needs adequately met by conventional and currently available prosthetic options. For those who do not, the disability, morbidity and quality of life impacts can be profound, and carry very significant associated healthcare costs and opportunity loss. Selecting patients from this later cohort for more complex options such as hand / upper extremity transplantation (beyond the scope of this review) or osseointegration offers potential for significant quality of life / health state benefit.

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?	For patients with transfemoral amputation who fail to mobilise adequately with conventional prostheses: improved mobility and biomechanical efficiency, reduced pain, reduced skin and socket fit related complications. Overall this can be expected to deliver a significant quality of life improvement. For other major limb amputees: reduced skin and socket fit related complications, improved biomechanical efficiency and anatomical force transfer potentially making wear and use of microprocessor lower limb and myoelectric transhumeral prostheses more comfortable and efficient (data on this as yet less robust, and cost-efficacy yet to be studied for these groups). For patients with thumb amputation not suitable for current surgical options such as 1st web space deepening or toe transfer but requiring a functional prosthetic: functional prosthetic with potential for sensory feedback through osseoperception.
9	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Most obvious benefit appears to be to transfemoral amputees who fail to mobilise adequately with conventional prostheses.
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?	Yes. Improved outcomes, and fewer hospital visits for amputees who fail to adequately rehabilitate with conventional prostheses. Recent data indicates osseointegration offers cost-effective alternative for these patients. Potential broader societal benefit from allowing these patients to return to independent mobility and employment.
11	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	No changes to existing facilities. This procedure can be delivered by competent ortho-plastic surgical teams working in currently available NHS facilities.
12	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	Assuming that surgeons planning to undertake these procedures will already have familiarised themselves with the relevant literature and technical descriptions and are suitably qualified in relevant specialties (orthopaedics, plastic & reconstructive surgery) I do not think specific further

		training is required. However technical specialist support from representatives of the device manufacturers to ensure familiarity and safe use of device and instrumentation, and use according to standardised protocols would be appropriate. Peer education from experienced practitioners, where available, may offer additional benefit in sharing best practice and “technical tips”.

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	Potential harms include: Superficial infection: some studies indicate approx. 30%. Vast majority low grade, amenable to treatment with oral antibiotics alone. Deep infection: varies with series – Al Muderis JBJS 2016 (10.2106/JBJS.15.00808) 0% deep bone infection with 2 stage OPL implant for transfemoral amputees. Tilander et al CORR 2017 (10.1007/s11999-017-5507-2) reports 10 year cumulative risk of deep bone infection requiring implant removal for OPRA at 9% (important to note learning curve effect over this extended follow up and expectation that patients receiving this implant with today’s standardised technique and rehabilitation will experience considerably lower rate at 10 years). Periprosthetic fracture: One study reports 4.2% in transfemoral OI (compared to historical fracture rates in lower limb amputees of 2-3%), with risk factors including female sex and elevated BMI. Failure of osseointegration: Reported in association with infection in some earlier reports but not a significant feature of more recent literature (single case in Al Muderis JBJS 2016 (10.2106/JBJS.15.00808) which I believe indicates maturation of technology, surgical technique and rehabilitation protocols. Implant Failure: All devices now include fail safe mechanisms (akin to skiboot bindings) to protect against injury and fracture of the fixation or periprosthetic bone in the event of trauma and uncontrolled loading. Implant failure requiring surgical intervention is rare (2 cases in Al Muderis JBJS 2016 (10.2106/JBJS.15.00808). Implant failure at the failsafe is not universally reported. Stoma Hypergranulation and/or soft tissue redundancy: Up to 20%. Majority requiring conservative treatment. Surgical techniques to maximise stability of percutaneous interface and

		minimise these risks have recently been clearly summarised (Souza et al PRS (2020) 146(6):1394-1403. All of the above are reported in the literature, indeed, the safety profile and incidence of complications is a component of essentially all the primary studies on osseointegration in the literature. I am not aware of any additional anecdotal adverse events not reported, nor any theoretical adverse events.
14	Please list the key efficacy outcomes for this procedure/technology?	Key outcomes include improved prosthetic fit, reduced pain, improved range of joint motion, improved biomechanical efficiency in mobilising, all of which translate to improved mobility.
15	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	While follow up over 10 years in some series indicates that this technology is no longer truly novel, as discussed above the overall number of reported cases remains relatively low. Reports therefore tend to capture a learning curve effect with better efficacy and safety profiles in those cases performed more recently. The net effect of this is that efficacy, and complications rates are as yet reported with quite a low level of certainty – but I think the trend within the dataset over time is important, and is encouraging. Per the Handford 2022 paper, quality of life improvement and cost effectiveness is best in those patients with the most significant disability at start point (ie transfemoral amputees failing to reliably mobilise on conventional prosthetics despite appropriate support). The efficacy for and cost-efficacy for this group is clear. For less stringently selected groups of amputees (for example, a transfemoral amputee mobilising in a conventional prosthesis, but at considerable excess energy expenditure and with frequent skin problems, pain and fit issues) I think the literature supports utility and efficacy; such patients may well derive (considerable) benefit from this technology were it available to them, potentially with considerable reduction in lifetime healthcare use and therefore cost. However further experience and data will be required to evidence this position.

		Considerable uncertainty remains regarding utility for upper limb (transhumeral) amputees. This group of patients face very considerable disability, particularly if bilateral. Conventional prosthetic options such as cable-driven split hooks can offer very significant functional capacity, but particularly for bilateral amputees, fitting such devices often requires assistance. Myoelectric prostheses fitted at transhumeral level are currently heavy, and again fitting these can pose a signficiant challenge. Osseointegration offers anatomical load bearing and potentially more convenient attachment, and anecdotally offer these patients very considerable benefits. With regard to safety I think the chief outstanding uncertainty is what level of complications will be observed with wider adoption of this technology beyond the very small number of centres currently providing it. While there has not been a formal analysis of the technology maturation or learning curve with this technology, the literature quite consistently indicates lower complication rates and better outcomes in recent studies versus those at the outset of the clinical osseointegration experience. My expectation therefore would be that current literature likely reflects a realistic baseline for a service provided through a relatively small number of regional or supraregional centers.
16	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	No major controversy, broader experience would be expected to clarify the uncertainty which remains regarding outcomes, longevity and safety. The choice of implant system has not yet been reliably addressed in the literature and as yet I do not think the literature supports use of any particular system over another. This will be an important area of investigation in due course but will require expanded uptake to adequately power the necessary studies.
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.~~

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.	Nil more recent that latest publications
19	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	TFAOS – Transfemoral Amputee Osseointegration Study and TAOS – Transhumeral Amputee Osseointegration Study (both ongoing, led by investigators at Henry M Jackson Foundation for the Advancement of Military Medicine, Bethesda, MD, USA).
20	Please list any other data (published and/or unpublished) that you would like to share.	Nil

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)?	I don't have a clear estimate for this, but have requested it from my colleagues in rehabilitation medicine who will be able to estimate this on the basis of regional data and will forward once data to hand.
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	Beneficial outcome measures: Successful osseointegration Successful stoma healing Successful mobilisation

	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:	Pain score improvement Reduced prosthetic services utilisation (medium to long term) Implant survivorship (medium to long term) Patient Reported Outcome Measures Validated Quality of Life Measures Adverse outcome measures: Superficial infection Deep infection (osteomyelitis) Implant failure / explant Periprosthetic fracture (early vs late) Stoma over granulation

Further comments

23	If you have any further comments (e.g. issues with usability or implementation, the need for further research), please describe.	My personal view, based on published literature, anecdotal evidence, and experience in surgical care of amputees is that this technology offers considerable potential benefit for patients with proximal amputations. In selected patients, particularly those transfemoral amputees unable to mobilise reliably with a conventional prosthesis this can be expected to translate into cost-effective improvements in quality of life. Greater experience will clarify remaining questions regarding outcomes and complications, and drive refinements in technology, surgical technique and rehabilitation protocols. Access to this technology for selected patients through regional or supraregional centers with robust MDT processes, paired to a national registry would offer a pragmatic combination of addressing the unmet needs of this patient group, with a mechanism to drive further learning, process and outcomes optimisation, and potentially support related research and technical innovation.

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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
Choose an item.			
Choose an item.	No conflicts of interest to disclose		
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:	**David Alan Leonard**
Dated:	**15th December 2023**

NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: **IP692/2 Direct skeletal fixation of limb or digit prostheses using intraosseous transcutaneous implants**

Your information

Name:	Dr Moheb Gaid
Job title:	Consultant in Rehabilitation Medicine
Organisation:	NCHC NHS Trust
Email address:	
Professional organisation or society membership/affiliation:	GMC, BSPRM
Nominated/ratified by (if applicable):	BSPRM
Registration number (e.g. GMC, NMC, HCPC)	5205708

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	I manage patient with limb loss and reviewed few patients with direct skeletal fixation (DSF). I also received training on the management of amputees with Direct Skeletal Fixation The procedure is currently not used in the NHS. However, some veterans had DSF under the current military implant pathway and has sense been discharged to the NHS. I have also reviewed patients who had this done as part of the Birmingham and Stanmore trial and currently managed under the NHS DSF requires to be implanted by an experienced orthopaedic surgeon who has familiarity and experience with the procedure. Then long-term management is carried out by a rehabilitation team including, consultant in rehabilitation medicine, physiotherapist and prosthetist with familiarity with DSF

	procedure/technology, please indicate your experience with it.	I deal with handful of patients with DSF as part of my role as consultant in rehabilitation medicine
2	− Please indicate your research experience relating to this procedure (please choose one or more if relevant):	I have had no involvement in research on this procedure
3	Does the title adequately reflect the procedure?	Yes, however, I feel this is too general, as most of the published research are carried out for lower limb amputation at a transfemoral level. To focus the guidelines, and subsequent implications, I recommend specifying the title to lower limb loss at a transfemoral level (**Direct skeletal fixation of lower limb prostheses using inter-osseous transcutaneous implants for patient with transfemoral amputation)**
	How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design?	This approach would be novel compared to the current practice of making a customised prosthetic socket to contain the residual stump. This approach relies on surgical implantation of an intramedullary device inside the residual femur, then attach it to an external abutment that connects to the prosthetic limb.
	Which of the following best describes the procedure (please 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.~~ **Definitely novel and of uncertain safety and efficacy.** The procedure has been used in the UK in research context, and currently funded by the MoD for veterans and servicemen and women who meet the criteria. There has been world-wide research and adoption of this procedure for the selected few amputees who meet the criteria of having DSF and could not use a conventional prosthetic socket for various reasons. ~~The first in a new class of procedure.~~
4	Does this procedure/technology have the potential to replace current standard care or	No

	would it be used as an addition to existing standard care?	Majority of amputees would require the conventional prosthesis with a socket to transfer the weight and ground reaction from the prosthetic limb to their skeletal system on walking. Minority of patients – where the stump is too short, or they had extensive severe skin breakdown and cannot tolerate a conventional socket. They could be considered for DSF if no contraindication to that procedure
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?	There are various implants depends on what system will be adopted, and the procedure can be done as single stage or two stage implantation. The proposed guidelines should rely on the current literature in deciding which procedure and implant to use – this is still a growing area of research with no decisive superiority of one implant over the rest. Currently there are no NICE guidelines on DSF There is enough evidence base to build up guidelines for DSF

Current management

6	Please describe the current standard of care that is used in the NHS.	Currently, under NHSE commissioning guidelines, we do not accept patients who had DSF privately, however, we manage those discharged from the MoD and those who had it done in research
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, this procedure is unique and does not have equivalent in the NHS

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?	Ability to use a prosthetic limb if they failed to use conventional socket DSF offer improved proprioceptive feedback and arguably better mobility for the selected patient
9	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Fit healthy patients who had limb loss of non-vascular aetiology but cannot use a conventional prosthesis due to short stump, severe skin and soft tissue loss of the residual stump
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?	No It is likely to keep it the same – previous visits due to socket alterations and skin effect from using conventional sockets will be reduced, but other DSF related issues (stoma infection, leakages, operative complications, replacement of abutment) are likely to offset any reduction in hospital visits
11	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	Not much change, as we already have all the devices we require to align the prosthetic components. DSF specific tools are required but they are part of what a prosthetic limb centre should expect to have. The main cost would be in the acute and implantation phase
12	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	Yes. However, training already in place in most prosthetic centres to deal with patients with DSF as we already reviewing some of those patients across England.

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:	Surgical complications during and after DSF Stoma site and bone, implant infection, leakage Risk of bone fractures increased during falls

	Adverse events reported in the literature (if possible, please cite literature) Anecdotal adverse events (known from experience) Theoretical adverse events	
14	Please list the key efficacy outcomes for this procedure/technology?	Ability to mobilise, walk and gain independency after failing to use a conventional prosthesis
15	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	Patients have to be selected carefully against certain criteria excluding high risk patients who are likely to develop complications (mainly infection and periprosthetic fractures) -Osteopenia and osteoporosis -Severe peripheral arterial disease -Uncontrolled diabetes -Risk of falls (e.g. chronic neurological disorders) -Smoking -High BMI (DSF weight limit is currently 100kg) -Patients who are not fit to use a conventional prosthesis due to general frailty and weakness rather than short stump or skin / soft tissue related issues
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.** *Small number of patients, I estimate less than 5% of current transfemoral amputees. I expect the procedure should be restricted to a surgical team who is able to perform the procedure regularly with enough volume to maintain their skills and competencies.* ~~Fewer than 10 specialist centres in the UK.~~ ~~Cannot predict at present.~~

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.	Summary of previous literature can be found in this article: JBJS Rev. 2020 Mar; 8(3): e0043. Published online 2020 Mar 11. doi: 10.2106/JBJS.RVW.19.00043 PMCID: PMC7161721 PMID: 32224634 Osseointegration for Amputees
19	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	Yes
20	Please list any other data (published and/or unpublished) that you would like to share.	

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)?	Less than 5% of new active amputees with transfemoral amputation I estimate this to be less than 50 patients annually across England
22	Please suggest potential audit criteria for this procedure/technology. If known, please describe:	Beneficial outcome measures: Improved walking and independency for patients who cannot use conventional prosthesis Improved proprioceptive feedback and possibly reduce falls risk in this group

	− 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:	Adverse outcome measures: Infection (2%) Leakage and discharge (common) Periprosthetic fractures

Further comments

23	If you have any further comments (e.g. issues with usability or implementation, the need for further research), please describe.	

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Declarations of interests

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Type of interest *	Description of interest	Relevant dates	
		Interest arose	Interest ceased
Choose an item.	I have no conflict of interest in this regard.		
Choose an item.			
Choose an item.			

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

Print name:	**Dr Moheb Gaid**
Dated:	**24/22/2023**

NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: **IP692/2 Direct skeletal fixation of limb or digit prostheses using intraosseous transcutaneous implants**

Your information

Name:	Gemma Trotter
Job title:	Patient
Organisation:	RLUG User Group
Email address:	
Professional organisation or society membership/affiliation:	Roehampton user group
Nominated/ratified by (if applicable):	Click here to enter text.
Registration number (e.g. GMC, NMC, HCPC)	Click here to enter text.

How NICE will use this information:

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

X☐ 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.

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X☐ 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?	I was one of the original 18 research cases of this procedure in 2003 at Queen Mary's hospital Roehampton. I have had 3 bone anchors and am very familiar with the procedure and technology having spent 20 years of ups and downs of the procedure. I have experienced the best of the NHS when this was first trialled at Roehampton under the care of Professor Kingsley Robinson & Mr Ward. This was when our research trials were performed fantastically well. After Prof Robinson retired, and Mr Ward stopped all operations relating to this procedure. I have witnessed the whole original team leave and the patients have suffered through a lack of provision over the years. I feel my input should be listened to as I have seen the demise and worry for the future arrangements for new patients going for this procedure.
	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?	I am currently on my 3rd bone anchor. This latest one was put in 2019 in Holland. I have had nearly 20 trips abroad to sort out the issues and complexities of my Osseo problems as we have had no support in the UK. Yes I know of most of the UK patients who were part of the trial, still using it and having failed. The uptake shouldn't be sanctioned until we have a trained team to delivery the whole package of Osseo. I know for a fact we don't have this available in the NHS.

	− If your specialty is involved in patient selection or referral to another specialty for this procedure/technology, please indicate your experience with it.	
2	− Please indicate your research experience relating to this procedure (please choose one or more if relevant):	I have had no involvement in research on this procedure. But I have been part of the patient cohort who were the original research cases in the UK. I am the living proof of this procedure in the UK Other (please comment)
3	Does the title adequately reflect the procedure? 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):	Yes Its very innovative and when successful its almost unmeasurable in terms of success. But when problems come from lack of supervision and trained staff in the NHS massive issues can occur with big harm to patients in a medical and phycological way. Definitely novel and of uncertain safety and efficacy.
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?	No, this procedure is in such infancy stages with UK trained doctors/surgeons/rehab consultants. It can only be delivered with huge changed first before more patients suffer with lack of support when issues arise.

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?	Yes in the first trial stages there was the screw fit implant (OPRA). In the past decade the push fit implant has taken more precedence worldwide with good and bad results. The hardware is completely different and the skill of the surgery is also different. Managing both systems is a challenge especially when the team your left with have had no training in the system. There have been many changes to the hardware used and also the surgical techniques performed.

Current management

6	Please describe the current standard of care that is used in the NHS.	Abysmal. This is the reason I have asked and asked to be part of the team to develop the best possible NHS team if this procedure is going to be performed on the NHS. I know where the problems started and what needs to be done for the safety of the patients who are either still using the system, or needing revision, or brand new patients having it done.
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.

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?	If this procedure is started well with good patients selection. A trained and experienced surgeon is involved, a good rehab consultant, a good rehab team made up of a experienced prosthetist and physiotherapist then yes a patient can have huge improvement to their life as an amputee. The system of osseo isn't the issue, it's the support and lack of after care which causes the failures and complications to be worsened.
9	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Younger, more active patients. Generally any amputee who looks after their well being and health generally. I would say anyone between the age of 20-75 could benefit from this procedure.
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?	Yes but only if its done well in the first place. The team in the UK is no where near skilled enough to take this on. Yes I believe this procedure done correctly would give greater outcomes and fewer visits for making conventional limbs. Saving huge amounts of time and money for the NHS.
11	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	There needs to be a trained team to deliver this procedure. We don't have one. Roehampton aren't the experienced team they were. We have almost no experience in the hospital and this needs urgent action to prevent more catastrophises happening. We as a cohort of patients have heavily relied on overseas treatment, and since this has been stopped only this year, there are many patients including myself who have experienced huge issues and no one willing to help. There are so many changes I would like to see before this was a NICE approved procedure.
12	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	Yes lots for the entire team. I am happy to embellish more on all the elements I feel need addressing.

Safety and efficacy of the procedure/technology

13	What are the potential harms of the procedure/technology?	When complications occur like infection, when left undetected or unmonitored it can eat bone and destroy tissue and take more leg away. It can also cause other medical issues with pain

	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	and infection in the body. Phycological issues can occur when no one will help you when you have issues. You only get the full story from patients who are on the receiving end of the procedure and associated complications. I am one of them, and happy to be a advocate for change to the delivery of this procedure In the future for the benefit of everyone involved. I have so much experience to share with the complcations I have been faced with that this knowledge should be shared and learned from.
14	Please list the key efficacy outcomes for this procedure/technology?	It should be safe. It should be delivered in a proper protocol way with follow up. None of which is achievable until you have the correct people, facilities, experience to do it safely and successfully.
15	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	I have huge concerns with the team chosen to be delivering this procedure and technology. They have no experience in the field of a very specialised procedure. Much more training is needed. Without experience in the team delivering this procedure, your just conducting more experiments on patients which isn't necessary when developing the team should be done first so its safer and more successful for patients.
16	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	Yes, implant manufacturers are very influencing on the choice of componentry used. Also the risks.
17	If it is safe and efficacious, in your opinion, will this procedure be carried out in (please choose one):	Fewer than 10 specialist centres in the UK. & Cannot predict at present. Just one centre of excellence should be started first and then expansion.

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.	
19	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	
20	Please list any other data (published and/or unpublished) that you would like to share.	

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)?	Unknown
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	Beneficial outcome measures: Being able to use a prosthetic daily and lead a normal life Be pain free and be able to walk great distances. Be able to carry out daily tasks and work. Adverse outcome measures: When infections happen and aren't picked up or acted on. When problems arise and aren't dealt with. When the implant breaks or fails what process In place for complications. Loss of more of the human body due to infection or defects. Over a lifetime this will need monitoring if problems

	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:	arise, but the normal practice is check up 6 month, 1 yr, 2 yr, 5 yr, 10 yr. And at any point in between when pain or issues arise.

Further comments

23	If you have any further comments (e.g. issues with usability or implementation, the need for further research), please describe.	Lots of research needs to be done to resolve the problems associated with bone anchored prosthesis. Skin/metal interface. Infection control. Bone defects.

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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
Choose an item.			
Choose an item.			
Choose an item.			

X☐ 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:	**Gemma Trotter**
Dated:	**4/12/2023**

NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: **IP692/2 Direct skeletal fixation of limb or digit prostheses using intraosseous transcutaneous implants**

Your information

Name:	Lynne Powell
Job title:	Senior Prosthetist
Organisation:	NHS GGC
Email address:	
Professional organisation or society membership/affiliation:	BAPO
Nominated/ratified by (if applicable):	Click here to enter text.
Registration number (e.g. GMC, NMC, HCPC)	PO04024

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?	I have limited experience with the Australian method of direct skeletal fixation. We have been using this procedure with trans femoral amputees only. I have fitted a prosthesis to one patient with this procedure. There are other patients in our service with this procedure. I am familiar with the components used for the external prosthesis. I have observed the surgical procedure being performed.
	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?	Currently this procedure is available in NHS Scotland, accessed by one health board only (NHSGGC). To date we have carried out this procedure with 4 patients. We have locally agreed criteria to establish suitability. Uptake is restricted by the operating surgeon, the acceptance criteria and cost of parts. Currently the procedure is performed by a Consultant Orthopaedic surgeon working in oncology. The patient has intensive physiotherapy after this procedure.

	– If your specialty is involved in patient selection or referral to another specialty for this procedure/technology, please indicate your experience with it.	Any of the prosthetists in our team can refer a patient for discussion. Any referred patient will be discussed in an MDT meeting. This meeting is attended by the surgeon, physiotherapists, prosthetists, a psychologist and specialist prosthetics coordinator.
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. (However there are plans to pull some of our experience and data together) Other (please comment)
3	Does the title adequately reflect the procedure? 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):	Yes, I believe the title adequately reflects the procedure. While the concept of direct skeletal fixation has been around for many years now, it is far from our standard approach to treating trans femoral amputees. It has not been adopted as routine procedure in NHS Scotland. The Australian method we have adopted is a well-established method being used across the world. 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 has the potential to replace standard care (fitting of sockets) to some of our trans femoral amputation population, but would not be appropriate for all.
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?	I'm not aware of any. I'm not aware of any change.

Current management

6	Please describe the current standard of care that is used in the NHS.	Current standard of care is to provide fit trans femoral amputees with a prosthesis using a socket and traditional suspension methods. This involves a short period of physiotherapy immediately after their amputation and limb fitting. They routinely return to the service for adjustments to socket fit or parts. Patients undergoing direct skeletal fixation attend an intensive block of physiotherapy (approximately 50 sessions over 6 months). We follow the Australian Osseointegration Protocol. Subsequently, they attend the service less as there is no longer a socket to work on. We review our patients annually, and also review as per the requirement for the maintenance of the MPK.

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?	Other versions of direct skeletal fixation are available, for example Branemark.

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?	Direct skeletal fixation gives the patient significant freedom of hip movement, improved proprioception and improved comfort. This results in reduction in gait deviations and energy expenditure.
9	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Many groups of patients could benefit from this procedure. Particularly active patients will get significant benefit from this procedure.
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?	My experience to date shows there is an intensive period of input following surgery, but then results in fewer attendances in the long term.
11	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	There needs to be adequate surgical support and nursing. Psychological preparation and support is also needed. Capacity required for daily physiotherapy attendances. Familiarity with parts are required for prosthetists.
12	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	Surgical training is essential. Management of over granulation

Safety and efficacy of the procedure/technology

13	What are the potential harms of the procedure/technology?	Risk of infection. Ongoing management of stoma. Risk of bone fracture

	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	Risk of need for higher amputation. However, we have not experienced any adverse incidents.
14	Please list the key efficacy outcomes for this procedure/technology?	
15	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	
16	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	
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.

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.	
19	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	Not aware
20	Please list any other data (published and/or unpublished) that you would like to share.	

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)?	
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.	We have completed EQ-5D-5L, ABC, Plus-M, RNLI, TUAG, L-test, AMP pro, timed walk tests. Beneficial outcome measures: Adverse outcome measures:

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

Further comments

23	If you have any further comments (e.g. issues with usability or implementation, the need for further research), please describe.	

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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
Choose an item.			
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:	**Lynne Powell**
Dated:	**22/11/23**

View results

Respondent

51 Anonymous

181:51
Time to complete

1. Project Number and Name - (Can be found on email) *

IP692/2 Direct skeletal fixation of limb or digit prostheses using intraosseous transcutaneous implants

Your information

2. Name: *

Mark Thoburn

3. Job title: *

Clinical Lead Prosthetist

4. Organisation: *

Blatchford / MOD/NHS

5. Email address: *

6. Professional organisation or society membership/affiliation: *

ISPO BAPO

7. Nominated/ratified by (if applicable):

8. Registration number (e.g. GMC, NMC, HCPC) *

PO02190

How NICE will use this information:

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

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: https://www.nice.org.uk/privacy-notice

9. I give my consent for the information in this questionnaire to be used and may be published on the NICE website as outlined above. *

- (●) I agree
- ( ) I disagree

The procedure/technology

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

10. Please describe your level of experience with the procedure/technology, for example:

    Are you familiar with the procedure/technology?

I have been providing prosthetic treatment and rehabilitation to serving and veteran amputees who have received osseo integration surgery since 2014. During that time I have treated 21 patients, many of whom have received bilateral implants. All of my experience relates to the implant being in the femur.I have also assisted my colleagues in the NHS who have required guidance and training when receiving veteran patients in to their service post discharge.

11. 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.

    To the best of my knowledge the procedure has had limited availability within the NHS, with most of the surgery being performed as part of various trials. Most of the surgeries I have been involved with took place in NHS facilities but were funded by the MOD or LIBOR funding. It has been widely available for private patients in the uk for several years, but I have not been personally involved in this. All of my patients are reviewed at an Interdisciplinary Team clinic , consisting of a minimum of Rehab consultant, amputee specialist Physio and prosthetist, before being considered for referral to the Ortho / plastics team for surgical consideration. Indications for being put forwards for surgical consideration would be: Non smoker, history of issues with socket fit / comfort, potential for significant limb use post surgery, absence of significant flexion contractures on amputated limb, understanding of psychological impact of having implant protruding through skin, and infection risks.

12. 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).
    - [x] 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

13. Does the title adequately reflect the procedure?

- [x] Yes
- [ ] Other

14. Is the proposed indication appropriate? If not, please explain

yes

15. How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design?

This surgery has existed for amputees since 1990, so it is not really new, but it has become much more available internationally over the last 10 years. Clearly replacing any style of non invasive prosthetic socket with an osseo integrated implant is a significant change in treatment, however the intended outcome, to enable the amputee to achieve the best possible functional outcome, should be the same with both treatment modalities. The basics of the procedure have remained similar throughout the 10 years I have been involved although various changes have been made to some of the external adapters required to connect the implant to the prosthetic limb.

16. Which of the following best describes the procedure:

- [x] 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.

17. Does this procedure/technology have the potential to replace current standard care or would it be used as an addition to existing standard care?

I would not expect this procedure to replace the current, socket based, standard care, but it should be available as an addition to available treatment options for appropriate patients

Current management

18. Please describe the current standard of care that is used in the NHS.

Amputees are provided with a clinically appropriate prostheic socket utilising an appropriate and cost effective method of suspension. This socket will be adjusted or replaced as required to enable the user to achieve the best possible outcomes.

19. 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?

there are several versions of the osseo integration procedure, generally described as press fit or screw fit, but all would be covered by the description provided in the briefing

Potential patient benefits and impact on the health system

20. What do you consider to be the potential benefits to patients from using this procedure/technology?

improved mobility, reduced energy consumption, reduced sweating, less appointments in the prosthetic dept, improved quality of life, reduction in discomfort

21. Are there any groups of patients who would particularly benefit from using this procedure/technology?

amputees with the ability to achieve regular limb use who experience significant socket fitting issues, possible due to the condition of the soft tissues of the residual limb. Multiple amputees or those with upper limb issues that make donning traditional prosthetic sockets difficult and time consuming

22. 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?

I would expect an amputee with osseo integration to achieve improved outcomes, spend less time at prosthetic appointments, ambulate more, and spend less time in a wheelchair, with the associated improvements in health

23. What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?

The surgical procedure is already possible at several hospitals in the UK, prosthetic treatment post surgery is similar to standard treatment, with limbs being set up according to manufacturers instructions, so no significant changes would be required. Rehabilitation post surgery should be provided to ensure optimal outcomes.

24. Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?

Treating prosthetists would need training on the products that connect the surgical implant to the prosthesis, this is similar to any new prosthetic product on the market.

Safety and efficacy of the procedure/technology

25. 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

    The implant is transcutaneous and the subsequent stoma presents an infection risk. Several of the patients I have treated have required oral antibiotics for recurring infections but I am not aware of any implant rejections in our patient cohort.

26. Please list the key efficacy outcomes for this procedure/technology?

    improved mobility (increase in distance achieved in 6 minute walk test)
    reduced wheelchair use
    perceived reduced energy expenditure
    improved patient satisfaction

27. Please list any uncertainties or concerns about the efficacy and safety of this procedure/technology?

    Despite this type of surgery having been possible since 1990, the uptake has been slow and it is only in the last 10 years or so that the main bulk of patients have received these implants. Therefore there is a lack of really long term evidence

28. Is there controversy, or important uncertainty, about any aspect of the procedure/technology?

    not in my opinion, those clinicians that are unsure about it have generally not been involved with it, so there uncertainty stems from a lack of exposure to the surgery and its benefits

29. If it is safe and efficacious, in your opinion, will this procedure be carried out in:

- ( ) 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.

Abstracts and ongoing studies

30. 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.

    A review of physical improvements and quality of life for veterans following Osseointegration surgery, and rehabilitation at DMRC StanfordHall. Mark Thoburn ISPO conference Manchester 06/10/23

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

32. Please list any other data (published and/or unpublished) that you would like to share.

Other considerations

33. 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)?

unknown

34. 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.

RNLI
PEQ

35. Please suggest potential audit criteria for this procedure/technology. If known, please describe:

Adverse outcome measures.

These should include early and late complications. Please state the post procedure timescales over which these should be measured:

Further comments

36. If you have any further comments (e.g. issues with usability or implementation, the need for further research), please describe *

none

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.

37. Type of interest: *

- [ ] Direct: financial
- [ ] Non-financial: professional
- [ ] Non-financial: personal
- [ ] Indirect
- [x] No interests to declare

38. Description of interests, including relevant dates of when the interest arose and ceased. *

none

39. 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. *

    - (●) I agree
    - ( ) I disagree

Signature

40. Name: *

    Mark Thoburn

41. Date: *

    29/11/2023

NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: **IP692/2 Direct skeletal fixation of limb or digit prostheses using intraosseous transcutaneous implants**

Your information

Name:	Matthewh Huges
Job title:	Prosthetist/Orthotist
Organisation:	Dorset Orthopaedic
Email address:	
Professional organisation or society membership/affiliation:	HCPC
Nominated/ratified by (if applicable):	Click here to enter text.
Registration number (e.g. GMC, NMC, HCPC)	PO00837

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?	I have been consistently working with patients who have undergone Osseointegration (OI) surgery for the past 10 years. Since 2018 we have been working alongside Norbert Kang and Alex Woollard, both plastic surgeons at the Royal Free Hospital in London where we have developed a pathway for patients to undertake this treatment privately.
	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?	As above, we currently look after 70+ amputees who have undergone this procedure I am aware that NHS England have a cohort of legacy funded OI patients and that in recent years some surgery has been undertaken for military personal in Birmingham. Prosthetically I am unaware of the experience of treating OI patients outside of my organisation.

	– If your specialty is involved in patient selection or referral to another specialty for this procedure/technology, please indicate your experience with it.	In our practice we are regularly discussing the option and potential benefit of OI with patients who may benefit from the procedure. It is certainly not suitable for all patients, however for those who have chronic long-term issues with conventional sockets wit can where appropriate be the difference between walking and not walking We have a clear and easy referral pathway for patients to have surgical assessments. Myself and a colleague (Moose Baxter) join an MDT assessment clinic with the team at the Royal Free every month The monthly MDT clinics typically have at least 3 new patients.
2	– Please indicate your research experience relating to this procedure (please choose one or more if relevant):	I have had no involvement in research on this procedure. Other (please comment)
3	Does the title adequately reflect the procedure? 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):	Yes OI has been in our field for 30 years but has seen a huge increase in its use and uptake in the last 10 years. For us this technique whilst still not mainstream Is not novel and is part of our normal daily clinical activity. Established practice and no longer new.
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?	I see OI as an additional process to conventional prosthetic socket fittings. This will definitely not replace the use of sockets
5	Have there been any substantial modifications to the procedure technique or,	There have been multiple iterations of the implant itself used and the external connectors and fail safe mechanisms over the years.

	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?	I very much see it that the clinicians involved in this treatment need to have extensive understanding of the componentry and rehabilitation involved to bring successful outcomes. At present whilst there are multiple manufacturers of the implants and connectors these are not interchangeable with hybrid limb builds.

Current management

6	Please describe the current standard of care that is used in the NHS.	Currently prosthetic users engage with local DSC's to provide conventional socket prostheses
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

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?	Benefits revolve around comfort and ability. This procedure should primarily support those patients who struggle to use convential socket prostheses. OI removes socket fit issues, increases ROM at the body joint proximal to the level of amputation, allows a greater freedom of movement, allows greater sitting comfort the removal of socket interface issues has ultimately lead patients being able to do mor for longer.
9	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Bilateral Trans Femoral amputees and Trans Humeral amputees
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?	In our experience at Dorset it should lead to far fewer appointments typically needed at a DSC annually by an amputee. For established OI patients we are seeing them in the clincs infrequently compared to when they wore conventional socket prostheses. This should lead to prosthetists having more time to spend with traditional socket patients and ultimately reduce lead/waiting times for appointments and new limbs
11	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	Nothing from a prosthetic perspective, I cannot comment surgically.
12	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	Yes there is specific training needed with respect to the specific componentry being used and there is a whole rehabilitation protocol tht is important to be followed which will involve the training of the physio team.

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	There is likely an increased risk of injury from patients being more active, and therefore more at risk of injury due to being more regularly in situations that could lead to falls etc. Following lower limb OI individuals tend to be much more stable and well balanced on their prostheses and have a reduced risk of falling. Some of the OI components are designed to fail to preserve the integrity of the implant, but these parts can then be replaced.
14	Please list the key efficacy outcomes for this procedure/technology?	Increased mobility and comfort
15	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	Where this procedure is being undertaken by an appropriately skilled clinical team with a full MDT approach outcomes are very good
16	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	Not that I am aware of, the key is knowledge and training, I cannot comment on the surgical apect.
17	If it is safe and efficacious, in your opinion, will this procedure be carried out in (please choose one):	Fewer than 10 specialist centres in the UK.

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.	
19	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	
20	Please list any other data (published and/or unpublished) that you would like to share.	

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)?	Unknown, as mentioned we currently look after 70+ indivial patients who have undergone this procedure which I would suggest resembles a large chunk of the current UK OI population
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.	Beneficial outcome measures: We currently use the below outcomes measures for all our OI patients SF-36 2/6 MWT 10m WT TUG ABC-UK LCI-5

	– Adverse outcome measures. These should include early and late complications. Please state the post procedure timescales over which these should be measured:	Adverse outcome measures: Infection rates Failures currently recorded by our medical team at the Royal Free

Further comments

23	If you have any further comments (e.g. issues with usability or implementation, the need for further research), please describe.	This procedure can have a hugely positive impact for the right amputee, careful slelection is viatl to ensure the right patients undergo this option.

NICE National Institute for Health and Care Excellence

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
Choose an item.			
Choose an item.			
Choose an item.			

X 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:	**MATTHEW HUGHES**
Dated:	**13/12/23**

View results

Respondent

18 Anonymous

09:27
Time to complete

1. Project Number and Name - (Can be found on email) *

IP692/2 Direct skeletal fixation of limb or digit prostheses using intraosseous transcutaneous implants

Your information

2. Name: *

Moose Baxter

3. Job title: *

Head of Clinical Services / Consultant Prosthetist

4. Organisation: *

Dorset Orthopaedic Company Ltd

5. Email address: *

6. Professional organisation or society membership/affiliation: *

International Society of Prosthetics and Orthotics (ISPO)

7. Nominated/ratified by (if applicable):

BAPO

8. Registration number (e.g. GMC, NMC, HCPC) *

HCPC: PO03611

How NICE will use this information:

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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: https://www.nice.org.uk/privacy-notice

9. I give my consent for the information in this questionnaire to be used and may be published on the NICE website as outlined above. *

- (●) I agree
- ( ) I disagree

The procedure/technology

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

10. Please describe your level of experience with the procedure/technology, for example:

    Are you familiar with the procedure/technology?

Since 2015 I have been working in the rehabilitation of an increasing number of amputees following osseointegration surgery.
Between myself and my clinical colleagues (across 6 UK sites) we maintain the prosthetic and physiotherapy rehabilitation of more than 60 individuals. I support our clinical team with training in osseointegration prosthetic technology (fitting, exchanging and maintenance) and with ongoing support with the individual patients that are being treated.
We treat individuals who have undergone the surgery in Sydney, London, and in Germany.
I have completed training in the UK, Germany, Australia and the Netherlands on the external componentry (interchangeable by the prosthetist)
I am regularly called upon by prosthetists working in the NHS (typically for VPP funded patients with multiple OI implants) to support them in replacing or adjusting the external osseointegration parts.

11. 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 aware that it is not a surgical procedure that is widely or routinely available on the NHS, so the number of patients getting their post-surgical rehab in the NHS is low. There are a great many individuals who would benefit from the procedure if it were available. Any surgery being offered should only be performed when there is a comprehensive post-surgical and long term rehab plan (physio and prosthetist) in place.

- Currently prosthetists are the only specialty responsible for the setup, repair and exchange of the external osseointegration parts. This is the correct process as the maintenance and alignment of the components is critical to successful and safe use, and aligned with typical prosthesis setup. Although aligned with the traditional prosthetist role there are very few with experience or confidence in treating OI patients amongst prosthetists working in the NHS.

- In private practice we are regularly discussing the option and potential benefit of OI with individuals who may benefit from the procedure. It is certainly not suitable for all patients, but our clinical teams consider it as a possible beneficial option for all amputee patients they are treating. We have a clear and easy referral pathway for patients to have surgical assessments. I join an MDT assessment clinic with the team at the Royal Free every month (which the majority of the referrals come from me or my clinical team) as well as on 3 or 4 occasions per year hosting the surgical team at one of our clinics to assess patients interested in finding out whether it's an option for them. The monthly MDT clinics typically have at least 3 new patients, and the quarterly "taster clinics" have up to 8 patients each.

12. 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.
- [x] I have had no involvement in research on this procedure.
- [ ] Other

13. Does the title adequately reflect the procedure?

- (•) Yes
- ( ) Other

14. Is the proposed indication appropriate? If not, please explain

15. How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design?

It is a fundamental variation from socket fitting prostheses, but for our patient group and clinicians it is not particularly novel or new as it is so well established as a treatment route.

16. Which of the following best describes the procedure:

- (●) 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.

17. Does this procedure/technology have the potential to replace current standard care or would it be used as an addition to existing standard care?

Currently and initially it is most commonly to be pursued as a route instead of the existing standard care (sockets) for those that standard care is not effective at allowing them to be full time prosthetic users, or for those who are seeking a higher level of comfort/activity than sockets allow. Although it has the potential to grow massively in its popularity if access is increased socket fitting prostheses are still likely to be to optimal route for the majority of amputees, likely primarily due to comorbidities and suitability for surgery.

18. Have there been any substantial modifications to the procedure technique or, if applicable, to devices involved in the procedure?

I will comment on my relevant area of expertise (prosthetic fitting following OI surgery) rather that the surgical techniques:
There have been various generation of, and changes in, the different options for external OI componentry sitting between the implant and the traditional prosthetic components. Each manufacturer has their own components and hybrid build (of the OI parts) must be avoided. All of the variations are generally pursuing various aspects of safety release mechanisms and ease of donning/doffing for patients.
It is very important that treating prosthetists remain up-to-date with their knowledge of the different component options and suppliers.

19. Has the evidence base on the efficacy and safety of this procedure changed substantially since publication of the guidance?

20. Do you think the guidance needs updating?

Current management

21. Please describe the current standard of care that is used in the NHS.

Patients are given a traditional socket that they wear over their residual limb, which attaches a prosthesis to them. If they are for any reason unable to tolerate a traditional socket design they cannot wear a prosthesis and are therefore wheelchair bound. The principles of socket design is attempting to stablise the underlying bony anatomy of the residual limb through the medium of (typically unstable) soft tissues. This soft tissue is typically sensate and often prone to breakdown as well as fluctuate in volume. OI surgery removes many of the barriers to comfortable, successful, consistent and safe walking by enabling the prosthesis to load the bone directly.

22. 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

Potential patient benefits and impact on the health system

23. What do you consider to be the potential benefits to patients from using this procedure/technology?

There are a great number of benefits to individuals that can have a significant impact upon them and their quality of life on a daily basis. These include:
- It allows patients who would not be able to mobilise with traditional sockets the opportunity to walk.
- The prosthesis is attached directly to the skeleton loading the body in the manner in which it is designed. This maintains bone density and structural alignment of the joints.
- The patients have more control over the prosthesis allowing for fine movement and increased balance and confidence. Patients can achieve movements such as crossing their legs which is difficult in a traditional socket.
- The lack of socket allows patients to sit comfortably without a socket digging into the back of their leg, toileting can be done without the removal of their prosthesis or having to perch on a toilet seat.
- Patients have more sensory feedback through the osseointegration allowing them to accurately determine where their foot is and what surface it is placed on, improving their ability to mobilise over varied terrain.
- Our body shape is constantly changing, whether hormonal or due to fat percentage. Traditional sockets do not adapt to our changing anatomy whereas osseointegration does not rely on soft tissue for comfortable and effective prosthetic use.
This is not an exhaustive list.

24. Are there any groups of patients who would particularly benefit from using this procedure/technology?

Those who cannot tolerate a traditional socket, or those for whom the discomfort linked to traditional sockets limits their ability to mobilise as much as they did prior to their amputation. This will particularly include (but is not limited to): Bilateral amputees. Individuals with particulars short residual limbs. Individuals with heterotopic ossification. Transhumeral amputees.

25. 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?

Yes, patients typically need far fewer appointments, and come in only for mechanical repairs whilst having a more active lifestyle than they would with sockets. There are many health benefits associated with a less sedentary lifestyle. Those who would be immobile without the surgery typically become physically active and be able to stand and walk, reduced the likelihood of future health issues related to inactivity.

Yes it could, and in many cases likely it would.

26. What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?

From a rehabilitation perspective there would be little to no change to current facilities. There is a large knowledge, experience and confidence gap to be filled within NHS prosthetist facilities.

27. Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?

Yes, training and experience with the external prosthetic componentry from all relevant manufacturers of components would be required – and this is likely to be "out of the comfort zone" for a lot of prosthetists even following training.

Safety and efficacy of the procedure/technology

28. 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

I will not comment on any risks of surgery, and leave this to others with relevant expertise.
There is likely an increased risk of injury from patients being more active, and therefore more at risk of injury due to being more regularly in situations that could lead to falls etc. Following lower limb OI individuals tend to be much more stable and well balanced on their prostheses and have a reduced risk of falling.
Some of the OI components are designed to fail to preserve the integrity of the implant, but these parts can then be replaced. This can be more complicated when the dual cone breaks rather than when the bushing breaks, for example.

29. Please list the key efficacy outcomes for this procedure/technology?

The key outcome is that the patient can walk further/longer than previous. There are many outcome measures that can be performed; functional and in terms of self-defined quality of life.

30. Please list any uncertainties or concerns about the efficacy and safety of this procedure/technology?

So long as a full MDT approach is taken, and issues addressed as and when they occur, in my experience there tends to be a general trend towards improvements in overall quality of life and mobility.

31. Is there controversy, or important uncertainty, about any aspect of the procedure/technology?

As I've said, there is commonly a lack of confidence amongst prosthetists, even once trained, to complete some aspects of exchanging external OI connectors (such as removing a dual cone).

32. If it is safe and efficacious, in your opinion, will this procedure be carried out in:

- ( ) 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.

Abstracts and ongoing studies

33. 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.

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

35. Please list any other data (published and/or unpublished) that you would like to share.

Other considerations

36. 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)?

37. 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.

    SF-36
    2/6 MWT
    10m WT
    TUG
    ABC-UK
    LCI-5

38. Please suggest potential audit criteria for this procedure/technology. If known, please describe:

    Adverse outcome measures.

    These should include early and late complications. Please state the post procedure timescales over which these should be measured:

Further comments

39. If you have any further comments (e.g. issues with usability or implementation, the need for further research), please describe *

    n/a

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.

40. Type of interest: *

- [ ] Direct: financial
- [ ] Non-financial: professional
- [ ] Non-financial: personal
- [ ] Indirect
- [x] No interests to declare

41. Description of interests, including relevant dates of when the interest arose and ceased. *

n/a

42. 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. *

- (●) I agree
- ( ) I disagree

Signature

43. Name: *

Moose Baxter

44. Date: *

15/10/1984

View results

Respondent

17 Anonymous

28:50
Time to complete

1. Project Number and Name - (Can be found on email) *

IP692/2 Direct skeletal fixation of limb or digit prostheses using intraosseous transcutaneous implants

Your information

2. Name: *

Mr Norbert V Kang-Budialam

3. Job title: *

Consultant Plastic Surgeon

4. Organisation: *

Royal Free Hospital NHS Trust

5. Email address: *

6. Professional organisation or society membership/affiliation: *

British Association of Plastic, Reconstructive and Aesthetic Surgery and British Society for Surgery of the Hand

7. Nominated/ratified by (if applicable):

8. Registration number (e.g. GMC, NMC, HCPC) *

GMC: 3336999

How NICE will use this information:

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9. I give my consent for the information in this questionnaire to be used and may be published on the NICE website as outlined above. *

- (●) I agree
- ( ) I disagree

The procedure/technology

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

10. Please describe your level of experience with the procedure/technology, for example:

    Are you familiar with the procedure/technology?

I have expert knowledge of the procedure and technology. I have been working in this field since 2005 and have multiple publications in the literature related to bone-anchor surgery and related fields.

I have performed direct skeletal fixation after major limb amputation in 69 cases since 2007 and have performed another 36 cases for reconstruction in the craniofacial skeleton or hand. I have used a variety of different implant systems including:
OPRA (Swedish implant) – 3 major limb cases (one transhumeral and two transfemoral)

ITAP (UK implant) – 4 major limb cases (1 transhumeral and 3 transfemoral) and 17 patients with craniofacial (14 implants) and hand (19 implants) problems

OPL (Australian implant) 60 major limb cases (mostly transfemoral but also 6 transhumeral and 5 transtibial)

OTN (Dutch implant) – 2 major limb cases (both transfemoral)

Southern (South African implant) 14 craniofacial cases (42 implants) and 2 hand cases (2 implants)

11. 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.

Since 2018, I have been using the OPL and/or Southern implant systems at least once a month in my private practice in the UK. The OPL implants are used for major limb amputations. The Southern implants are used for either hand or craniofacial reconstruction.

The procedure is not used routinely in the NHS for major limb reconstruction after amputation but is widely used for prosthetic reconstruction in the craniofacial skeleton. Most likely, the speed of uptake would be very large if direct skeletal fixation of a prosthesis using a bone-anchor after major limb amputation were to be fully funded by the NHS. However, I believe that using NHS funding for direct skeletal fixation in this way would be a monumental and costly mistake since the likelihood for many poor outcomes will be very high given the way that the treatment would be delivered – at present. The surgery is technically very difficult – especially the soft-tissue management. The soft-tissue management after bone anchor surgery is especially poorly done and poorly understood by most orthopaedic surgeons who try to take up the procedure for the first time – even with training. Those orthopaedic surgeons who do perform the procedure routinely (in other countries) acknowledge that they struggle with this aspect of the surgery and (over time), they describe how they have had to learn to become "plastic" surgeons (in all but name) in order to be able to perform the surgery successfully. In contrast, the bony parts of the procedure are easily understood (even by plastic surgeons) and mostly formulaic. Therefore, there is an argument for saying that the procedure should be (mostly) performed by plastic surgeons with minimal input from orthopaedic surgeons rather than a procedure that should be led by orthopaedic surgeons. Moreover, most of the complications related to this surgery are soft-tissue related and therefore poorly understood by most orthopaedic surgeons. As a result, what tends to happen is that (when things go wrong) patients get very confused as to who is in charge of their care having to move from pillar to post instead of being under the care of one surgical team who can manage all of their problems. Much better to have their care delivered by one surgical team with the appropriate experience from the beginning.

As a routine procedure in the UK, this surgery is only being performed by Plastic surgeons (myself, Mr Alex Woollard, Mr Yazan Al-Ajam) at the Royal Free Hospital. On a very intermittent basis, it has also been performed by Mr Sanjay Gupta (orthopaedics in Glasgow). Recently, there were a handful of cases (6 patients) performed by the orthopaedic surgeons in Birmingham in 2021. Before this, there was a larger series of 21 cases performed in Birmingham but the surgeon who performed the surgery has now left the UK. There has been one case performed at St George's Hospital in Tooting in 2022.

I am sufficiently experienced in this surgery that we are now treating referrals from continental Europe and having to deal with complicated cases requiring direct skeletal fixation with bone-anchors referred from abroad. We also (intermittently) receive referrals from orthopaedic

colleagues and rehabilitation physicians in the UK who have run into difficulties with bone-anchored implants put in by others in the UK.

12. 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.
- [x] No need to do any bibliographic research since I carry out this type of surgery routinely a

13. Does the title adequately reflect the procedure?

- (•) Yes
- ( ) Other

14. Is the proposed indication appropriate? If not, please explain

Yes

15. How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design?

In my opinion, use of a bone-anchor for direct skeletal fixation of a prosthesis for reconstruction of an amputated limb, amputated digit or after loss of part of the craniofacial skeleton is now established practice. However, the surgery is technically demanding and should only be done by specialists with the necessary technical skills who are actively involved in research and adequately supported in terms of the necessary funding, ancillary specialists (i.e.. physios, OTs, prosthetists, psychologists, microbiologists, engineers, scientists, radiologists, neurophysiologists, and others) and by rehabilitation teams skilled in the art of looking after these patients. There is (nowadays) nothing particularly novel about the surgery itself.

16. Which of the following best describes the procedure:

- (●) 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.

17. 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 should definitely be a procedure that is used in addition to existing standards of care and should never replace the use of standard socket-fitted prosthetics which will continue to be used for the majority of amputees.

18. Have there been any substantial modifications to the procedure technique or, if applicable, to devices involved in the procedure?

The main (recent) modifications to the procedure relate to a better understanding of:

1) Soft-tissue management
2) Rehabilitation protocols
3) Improved supply chains for parts and consumables attached to the bone-anchors

The evidence base for the efficacy of the procedure for prosthetic reconstruction after major limb amputation has been vastly improved since 2011 by the fact that there are now thousands of patients worldwide who have been treated with a bone-anchor. Most of these patients are doing very well. The use of this procedure in the craniofacial skeleton has been established long ago and this is a mature and well understood technology in this area.

19. Has the evidence base on the efficacy and safety of this procedure changed substantially since publication of the guidance?

Yes. There are many thousands more patients who have undergone treatment with a bone-anchor and so knowledge and understanding of the potential risks and complications is now better understood.

20. Do you think the guidance needs updating?

Yes, but that does not mean that this treatment should be made freely available on the NHS.

Current management

21. Please describe the current standard of care that is used in the NHS.

1) A patient suffers from a major upper or lower limb amputation (e.g. after trauma, cancer, peripheral vascular disease)

2) They attend a limb fitting centre for rehabilitation and fitting of a socket-fitted prosthesis

3) If they are a lower limb amputee, they have to endure repeated surgery to the residual limb and replacement of the socket (typically once every year) until the day they die. In 80% of cases, the patients put up with the discomfort and insecurity of the socket-secured prosthesis since they are not given any other alternative. For those with a very short residual limb which cannot be fitted with a socket, they have to endure mobilising with elbow crutches or a wheelchair.

4) If they are an upper limb amputee, they have to put up with the poorly fitted socket-and-strap secured prosthesis that chafes and has poor function. After this, >50% of cases will abandon the prosthesis within two years of having it issued since it confers no added benefit in terms of function or cosmesis.

22. 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?

The only competing technology to Direct Skeletal Fixation for securing a prosthesis to the residual limb after major limb amputation is the current (standard) method for securing a prosthesis to the residual limb using a socket or straps. Sockets and straps have been in use for many thousands of years and this technology (and its limitations) are now well understood. DSF is superior to a standard socket-fitted prosthesis in many ways since it allows a prosthesis to be secured directly to the axial skeleton. Biomechanically, this allows the patient to mobilise in a way which is much closer to normal compared to a socket-fitted prosthesis.

Potential patient benefits and impact on the health system

23. What do you consider to be the potential benefits to patients from using this procedure/technology?

1) Improved comfort (fewer problems with neuroma pain, skin ulcers)
2) Decreased energy required to walk with a prosthesis secured to a bone-anchor
3) Improved independence when walking (for lower limb amputees)
4) Improved distances for walking (for lower limb amputees)
5) Less need for revision surgery for the residual limb in the years after implantation
6) No need for socket revisions (especially for lower limb amputees)
7) Allows patients with very short residual limbs to secure a prosthesis to their skeleton
8) Allows upper limb amputees to get rid of their sockets and straps and to improve their use of a prosthesis for more than just cosmesis

24. Are there any groups of patients who would particularly benefit from using this procedure/technology?

1) Young patients
2) Patients with a short residual limb
3) Patients with a missing eye, ear or nose
4) Upper limb (transhumeral and transradial) amputees

25. 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?

The procedure has the capacity to radically alter the current pathway for treatment after amputation. However, treatment should only be delivered by surgical teams who have the right technical skills and attitudes to look after amputees and who are willing to treat the rehabilitation services as pre-eminent in making decisions about who to treat and when.

Treatment with direct skeletal fixation could definitely lead to improved outcomes and fewer hospital visits, but only if the treatment is performed by specialists who are properly trained. However, all surgical treatments related to this procedure will always be very invasive and the necessary expertise to be able to deliver this treatment routinely is difficult to learn.

26. What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?

You would need to have a centre dedicated to the treatment of amputees using this particular procedure (and any related procedures necessary to maintain the health of the bone-anchor). Most likely, you would need one centre in London, another in the midlands and another in the North of England.

This centre would need to be fully funded by the NHS in terms of not just the surgery, but the cost of the implants, consumables and any revision procedures that would be necessary after implantation. Current data suggests that anywhere between 50% to 25% of patients will need at least one additional procedure for the residual limb after implantation. This is to deal with soft-tissue redundancy, stoma revisions, neuroma surgery etc…etc…

The centre would need an operating theatre which was available solely for this type of surgery with appropriate anaesthetic, radiology, microbiology, psychology, physiotherapy, OT, neurophysiology, prosthetic, engineering, and rehabilitation physician support. This is probably easiest to achieve in an existing NHS facility with these elements simply ring-fenced to deliver care to patients undergoing this particular treatment.

27. Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?

Yes. Training is the most critical part of delivering the procedure and is the hardest part to achieve. Especially acquiring the right attitudes towards delivery of this treatment. It is not like putting in a hip replacement and the prejudices learnt from doing such procedures routinely may be actively harmful in terms of delivering treatment to patients undergoing bone-anchor surgery.

Safety and efficacy of the procedure/technology

28. 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

We are aware of at least 2 patients who have committed suicide as a result of problems following failure of their bone-anchored implants. So psychology support is a critical component of any program of treatment.

That said, the implants themselves are very, very, very safe, and earlier concerns about the possibility of overwhelming infection (especially related to OPRA two-stage screw-in implants) have been vastly over-stated following the introduction of the easier to use press-fit implants like OPL and OTN. Even the risk of mechanical failure of the current generation of press-fit implants is very, very low (2 -3 implants per thousand) and generally related to a major fall.

The most frequent risks relate to persistent problems with localised (i.e. not systemic) infection around the stoma, and persistent peristomal pain which may interfere with the ability of the patient to use their bone-anchor for its intended purpose. These occur with a frequency which varies from 100% (for localised soft-tissue infection) to 25% for localised osteomyelitis. Peristomal pain occurs at some point in the patient journey in 100% of patients and the treatment of this discomfort differs according to aetiology.

The much-feared risks of a periprosthetic fracture after a fall are real (about 4% overall) but are easily treated with further surgery (e.g. a dynamic hip screw). Mostly, they can be mitigated by good rehabilitation support so that patients do not undertake activities that result in falls in the first place.

29. Please list the key efficacy outcomes for this procedure/technology?

The key measures for success include:
1) Timed up and go (TUG) scores
2) 6-minute walk test (distance in metres)
3) K-levels
4) EQ5D questionnaires
5) Raw figures for complications such as periprosthetic fractures, infections, revision procedures

30. Please list any uncertainties or concerns about the efficacy and safety of this procedure/technology?

1) There is a need to separate out data for upper and lower limb patients
2) Teams must be more honest about the exact revision rates in their series
3) Patients often “hop around” from one surgeon to another. So, data on outcomes may be missed.

31. Is there controversy, or important uncertainty, about any aspect of the procedure/technology?

None

32. If it is safe and efficacious, in your opinion, will this procedure be carried out in:

- ( ) 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.

Abstracts and ongoing studies

33. 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.

    1) Enthesopathy, a Cause for Persistent Peristomal Pain after Treatment with an Osseointegrated Bone-Anchor: A Retrospective Case Series by Norbert Venantius Kang, FRCS (Plast), Alexander Woollard, FRCS (Plast), Sanjay Gupta, FRCS (Orth), Dominika Michno, MD, Eliza Davison, MRCS, Beth Langley, BSc
    2) Periprosthetic osseointegration fractures are infrequent and management is familiar by J. S. Hoellwarth, K. Tetsworth, J. Kendrew, N. V. Kang, O. van Waes, Q. Al-Maawi, C. Roberts, M. Al Muderis
    3) Use of an osseointegrated intraosseous transcutaneous amputation prosthesis (ITAP) for amputated fingers by Mr Norbert V Kang, Mr Yazan Al-Ajam, Mr Alexander Woollard, Mrs Nikki Burr
    4) PhD Thesis for Dr Robin Atallah – On the safety of bone-anchored prostheses in lower extremity amputation, Radbound University, Holland by Dr Robin Atallah

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

    No, but all of the most responsible surgeons involved in this field (including ourselves) collect data on outcomes routinely.

35. Please list any other data (published and/or unpublished) that you would like to share.

Other considerations

36. 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)?

Probably 100 per year in the UK.. This is based on the following back of an envelope calculation.

Number of major upper limb amputations per year in the UK = 300

Number of major lower limb amputations per year in the UK = 8000

Of the upper limb amputees, most will be traumatic, and the rest will be secondary to cancer. The maximum benefit from direct skeletal fixation for upper limb amputees will come to those who have suffered a transhumeral amputation. At lower levels (e.g. transradial) recovery of useful function with no prosthesis will (likely) be superior to that with the current level of prosthetic technology available to most patients from the NHS. However, there are always exceptions to this generalisation. Patients with a high risk of recurrence of their original disease (especially cancer) will not benefit from this surgery. They must also be young enough and motivated enough to endure the surgery. So, no more than 10 – 20 cases per year.

Of the lower limb amputees, most of these patients will suffer from an amputation due to peripheral vascular disease and/or diabetes. The data show that 50% of patients with peripheral vascular disease or diabetes who suffer from a transfemoral amputation will die from a vascular related event within 12 months of the amputation. Therefore, although direct skeletal fixation can work in this group of patients, their co-existing diseases (especially cardiac and renal) will make them wholly unsuitable for this treatment – especially the rigorous rehabilitation needed. The patients most likely to benefit from direct skeletal fixation in the lower limb are young, otherwise fit individuals with a high transfemoral amputation. Young, fit individuals with a below knee amputation who are struggling to cope with a socket-fitted prosthesis should also be considered for surgery, especially when the amputation is planned electively. This will allow immediate implantation with a bone-anchor to be considered in the same operative procedure. So, no more than 80 to 90 patients who would fall into this category per year - to begin with.

37. 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.

Beneficial outcome measures:
1) Timed up and go (TUG) scores
2) 6 minute walk test (distance in metres)
3) K-levels
4) EQ5D questionnaires

Adverse outcome measures:
Raw figures for complications such as periprosthetic fractures, infections, revision procedures

38. Please suggest potential audit criteria for this procedure/technology. If known, please describe:

Adverse outcome measures.

These should include early and late complications. Please state the post procedure timescales over which these should be measured:

1) Number of patients suffering infective complications (both early and late) affecting the bony and the soft-tissues
2) Number of patients suffering from peristomal complications (especially enthesopathy pain, peristomal pain and tenderness, persistent peristomal discharge and peristomal granulation)
3) Patients suffering from implant loss, mechanical failure of the implant
4) Number of patients suffering from periprosthetic fractures
5) Number of patients suffering from implant loss
6) Number of patients needing soft-tissue revision after implantation
7) Number of patients undergoing re-implanation after removal of an implant
8) Number of patients suffering from adverse outcomes due to connector problems
9) Number of patients needing surgery for nerve-related problems

Further comments

39. If you have any further comments (e.g. issues with usability or implementation, the need for further research), please describe *

The procedure (direct skeletal fixation for limbs) is generally straight-forward, and the outcomes are predictable but only in the hands of teams who are appropriately trained. This is very problematic because the knowledge and skills needed to make this procedure work are held by only a few individuals in the UK. Although training more individuals to do the surgery will certainly improve access, inculcating the necessary attitudes needed to make the surgery work are also necessary. All too often, what I have observed over the last 20 years in this field of work is how egos and the need to try and garner fame have interfered with the process of producing safe and consistent outcomes.

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.

40. Type of interest: *

- [x] Direct: financial
- [ ] Non-financial: professional
- [ ] Non-financial: personal
- [ ] Indirect
- [ ] No interests to declare

41. Description of interests, including relevant dates of when the interest arose and ceased. *

I act as an agent for Osseointernational Australia PTL to supply OPL implants and consumables in the UK

42. 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. *

    - (●) I agree
    - ( ) I disagree

Signature

43. Name: *

    Mr Norbert V Kang-Budialam

44. Date: *

    17/11/2023

View results

Respondent

39 Anonymous

34:09
Time to complete

1. Project Number and Name - (Can be found on email) *

IP692/2

Your information

2. Name: *

paul fenton

3. Job title: *

consultant orthopaedic surgeon

4. Organisation: *

queen eizabeth hospital, birmingham

5. Email address: *

6. Professional organisation or society membership/affiliation: *

FRCS, BOFAS, OTS, AO

7. Nominated/ratified by (if applicable):

8. Registration number (e.g. GMC, NMC, HCPC) *

6024501

9. I confirm that:

· I am a registered practising professional in the UK/NHS and in good professional standing

· I have specialist knowledge in the technology or disease area

· I will declare all conflicts of interest in relation to the technology under consideration

· I will abide by NICE's governance policies and comply with NICE's processes and methods

· I will abide by the timelines for this topic, as communicated by the coordinator/administrator.

Personal data submitted to NICE can be used for the purposes of carrying out its CHTE outputs. Personal data will be held on NICE's databases and I may be contacted in the future by NICE after the completion of this topic. *

- (●) I agree
- ( ) I do not agree

10. I confirm that:

· I am a registered practising professional in the UK/NHS and in good professional standing

· I have specialist knowledge in the technology or disease area

· I will declare all conflicts of interest in relation to the technology under consideration

· I will abide by NICE's governance policies and comply with NICE's processes and methods

· I will abide by the timelines for this topic, as communicated by the coordinator/administrator.

Personal data submitted to NICE can be used for the purposes of carrying out its CHTE outputs. Personal data will be held on NICE's databases and I may be contacted in the future by NICE after the completion of this topic. *

- (●) I agree
- ( ) I do not agree

How NICE will use this information:

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

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: https://www.nice.org.uk/privacy-notice

11. I give my consent for the information in this questionnaire to be used and may be published on the NICE website as outlined above. *

- (●) I agree
- ( ) I disagree

The procedure/technology

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

12. Please describe your level of experience with the procedure/technology, for example:

    Are you familiar with the procedure/technology?

i have been involved with the birmingham osseointegration, treating injured veterans, since 2016. i have been part of the team delivering surgery for these patients and am now the lead clinician supervising follow up of a cohort of 28 osseointegration patients.

13. 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.

this procedure is not currently used in the NHS, our team receives regular enquiries about NHS patients who wish to be considered for this procedure.

the procedure is performed by orthopaedic and plastic surgeons working in teams

i have direct experience of invovlement in the MDT process of patient selection

14. 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.
- [x] our team continues to collect data on our patient cohort and has published several paper

15. Does the title adequately reflect the procedure?

- (●) Yes
- ( ) Other

16. Is the proposed indication appropriate? If not, please explain

yes

17. How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design?

in a UK context this is a novel approach to the management of a small subset of amputees who cannot achieve good function with conventional prosthetics.
the procedure is relatively well established in other parts of the world.

18. Which of the following best describes the procedure:

- ( ) 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.

19. Does this procedure/technology have the potential to replace current standard care or would it be used as an addition to existing standard care?

this procedure does not replace conventional amputation techniques and prosthetic fitting. it is likely to be indicated in a small group of amputees as outlined above.

20. Have there been any substantial modifications to the procedure technique or, if applicable, to devices involved in the procedure?

the technique and implant technology have evolved over time but are now established techniques.

21. Has the evidence base on the efficacy and safety of this procedure changed substantially since publication of the guidance?

there is an increasing body of evidence demonstrating the safety, efficacy and cost-effectiveness of this technique, specifically our group recently published evidence suggesting that OI was cost effective in patients who could not mobilise with conventional above knee prosthetics where the OI implant lasted for longer than 5 years.

22. Do you think the guidance needs updating?

yes

Current management

23. Please describe the current standard of care that is used in the NHS.

there is no current standard of care for OI in the NHS

24. 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

Potential patient benefits and impact on the health system

25. What do you consider to be the potential benefits to patients from using this procedure/technology?

our group of patients are spend considerably more time mobilising and in many cases have been able to return to work and recreational activities following this procedure

26. Are there any groups of patients who would particularly benefit from using this procedure/technology?

above knee amputees who are largely wheelchair bound due to inability to mobilise with conventional prosthetics

27. 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?

    this procedure will improve outcomes in the group outlined above with a significant improvement in quality of life.
    it will not reduce the need for follow up or ongoing prosthetics. it is a more invasive procedure.

28. What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?

    develop a small number of specialist centres in the country that can deliver a surgical pathway for these patients and work closely with rehabilitation teams with the relevant experience. the surgical and rehab teams would form MDT's to select suitable patients.

29. Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?

    this is a technically difficult and unforgiving procedure. in my opinion in should be delivered in specialist centres by orthoplastic surgical teams (ie orthopaedic and plastic surgeons working together).
    the teams should have experience in managing peri-implant fractures and prosthetic joint infection as these are the most serious potential complications.

Safety and efficacy of the procedure/technology

30. 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

    the commonest complications requiring further treatment are:
    1. soft tissue revision- often minor procedures to optimise function
    2. peri-implant fracture- managed successfully with standard fracture treatment techniques
    3. infection involving the bone/implant- significant infection is rare but in the worst case would need revision surgery with a similar strategy to the management of prosthetic joint infection

31. Please list the key efficacy outcomes for this procedure/technology?

    time in prosthesis, ease of donning prosthetic limb, walking distance and cadence, ability to work.

32. Please list any uncertainties or concerns about the efficacy and safety of this procedure/technology?

    the long term outcomes are unproven, the incidence of significant deep infection is likely to increase with time and ongoing surveillance and reporting is required.

33. Is there controversy, or important uncertainty, about any aspect of the procedure/technology?

    the procedure and technology are well established, the long term outcomes are unknown.

34. If it is safe and efficacious, in your opinion, will this procedure be carried out in:

- ( ) 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.

Abstracts and ongoing studies

35. 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.

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

    the MOD research team based at imperial continue to gather data on our cohort of patients

37. Please list any other data (published and/or unpublished) that you would like to share.

Other considerations

38. 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)?

i would estimate 10-20 procedures in a handful of centres in the UK.

39. 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.

EQ5D
timed up and go
6 minute walk

40. Please suggest potential audit criteria for this procedure/technology. If known, please describe:

Adverse outcome measures.

These should include early and late complications. Please state the post procedure timescales over which these should be measured:

fracture
deep infection (as defined by agreed criteria)
revision surgery (suggest monitored via a mandatory nationwide registry)

Further comments

41. If you have any further comments (e.g. issues with usability or implementation, the need for further research), please describe *

this is a hugely promising procedure but in my opinion should only be offered to carefully selected patients

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.

42. Type of interest: *

- [ ] Direct: financial
- [ ] Non-financial: professional
- [ ] Non-financial: personal
- [ ] Indirect
- [x] No interests to declare

43. Description of interests, including relevant dates of when the interest arose and ceased. *

nil

44. 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. *

    - (●) I agree
    - ( ) I disagree

Signature

45. Name: *

    paul fenton

46. Date: *

    21/03/2024

View results

Respondent

19 Anonymous

24:36
Time to complete

1. Project Number and Name - (Can be found on email) *

IP692/2

Your information

2. Name: *

Paul Hindle

3. Job title: *

Consultant Orthopaedic Surgeon

4. Organisation: *

Providence Health Care

5. Email address: *

6. Professional organisation or society membership/affiliation: *

Royal College of Surgeons. College of Physicans and Surgeons if British Columbia

7. Nominated/ratified by (if applicable):

8. Registration number (e.g. GMC, NMC, HCPC) *

CPSBC 55672 (previous GMC number 6101360)

How NICE will use this information:

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

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: https://www.nice.org.uk/privacy-notice

9. I give my consent for the information in this questionnaire to be used and may be published on the NICE website as outlined above. *

- (●) I agree
- ( ) I disagree

The procedure/technology

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

10. Please describe your level of experience with the procedure/technology, for example:

    Are you familiar with the procedure/technology?

    Yes. I looked after approximately 25 patients with 35 stems and have personally used them in ten patients. I have also revised complications and managed patients up to ten years post implantation.

11. 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.

It is used rarely, currently not funded by NHS. I believe St. Geroge's have approval for doing some revision cases for patients who have had implants inserted as part of earlier trials bit have failed, usually due to infection. NHS Scotland has also inserted a few stems. There should not be wide spread uptake as this is a specialized procedure that needs as experienced MDT to manage them.

It is not used by other specialties although there are some plastic surgeons implanting them in the private sector in London.

Selection was by an MDT of orthopaedics, plastics and rehab.

12. 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.
- [x] I have done research on this procedure in laboratory settings (e.g. device-related research).
- [x] I have done clinical research on this procedure involving patients or healthy volunteers.
- [x] I have published this research.
- [ ] I have had no involvement in research on this procedure.
- [ ] Other

13. Does the title adequately reflect the procedure?

- [x] Yes
- [ ] Other

14. Is the proposed indication appropriate? If not, please explain

Yes

15. How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design?

Very innovative compared to the standard of care which is continued prosthetic use and increased wheelchair use. This procedure gets patients walking again which has personal, financial and socioeconomic benefits.

16. Which of the following best describes the procedure:

- [x] 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.

17. 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 replace socket fitting for prosthetics in those who are unable to get a socket to work effectively. It would not be for use in all amputees, just those who have completed a course of rehab, have managed to get walking but for one of a number of reasons cannot tolerate a socket interface.

18. Have there been any substantial modifications to the procedure technique or, if applicable, to devices involved in the procedure?

No, this has been used in hundreds of patients globally, particularly in Northern Europe, Australia and the USA.

19. Has the evidence base on the efficacy and safety of this procedure changed substantially since publication of the guidance?

No

20. Do you think the guidance needs updating?

No

Current management

21. Please describe the current standard of care that is used in the NHS.

Repeated attempts at socket fitting and using a wheelchair

22. 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

Potential patient benefits and impact on the health system

23. What do you consider to be the potential benefits to patients from using this procedure/technology?

Eliminating the need for repeated prosthetic visits to try and get sockets to fit.
Returning patients to walking, this has huge benefits to the patient as demonstrated by my publication in the literature. It also cost effective with respect to QALYs even when you don't include the benefits of returning people to work.

24. Are there any groups of patients who would particularly benefit from using this procedure/technology?

Trasnfemoral amputees with the physical reserve to undergo rehabilitation

25. 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 leads to significant increases in EQ5D scores for patients who cannot get standard sockets to fit. This means the 3-4 visits to a prosthetist are removed. There are the potential for complications which can require hospital visits but the majority of patients do well with no complications.

26. What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?

Surgical and hospital facilities already exist, a unit has already been established with expertise between the ROH Birmingham and UHB NHS FT.
The main issue is in-patient rehabilitation modelled on the DMRC Stanford Hall.

27. Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?

Surgeons are already trained at ROH Birmingham and St. George's in London. Rehabilitation training can liaise with DMRC Stanford Hall.

Safety and efficacy of the procedure/technology

28. 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

    Infection, approximately a 5% risk with a 2% risk of implant removal at 10 years.
    Periprosthetic fractures requiring fixation
    Dual cone breakage, requires replacement
    Long term loosening, not seen in any non-infected patients in our cohort

29. Please list the key efficacy outcomes for this procedure/technology?

    Time walking / prosthetic use. EQ-5D. Infection rates, requirement for revision surgery

30. Please list any uncertainties or concerns about the efficacy and safety of this procedure/technology?

    Risk of being utilized by those unfamiliar leading to increased complication rates

31. Is there controversy, or important uncertainty, about any aspect of the procedure/technology?

    how to create soft tissue stoma around implant.

32. If it is safe and efficacious, in your opinion, will this procedure be carried out in:

- ( ) 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.

Abstracts and ongoing studies

33. 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.

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

35. Please list any other data (published and/or unpublished) that you would like to share.

    Health related quality of life and cost analysis for direct skeletal fixation following transfemoral amputation. Injury, 2022

Other considerations

36. 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)?

I don't know, a relatively small number of those patients with transfemoral amputations. Would not recommend in the elderly, diabetics or vasculopaths who account for the majority of cases. Should be for more physically able patient that have had trauma or tumours.

37. 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.

Eq5D, survival scores, six minute walking test, timed up and go

38. Please suggest potential audit criteria for this procedure/technology. If known, please describe:

Adverse outcome measures.

These should include early and late complications. Please state the post procedure timescales over which these should be measured:

Infection rate, major and minor (surgery vs. antibiotics)
Revision surgery.

Further comments

39. If you have any further comments (e.g. issues with usability or implementation, the need for further research), please describe *

This should be limited to 2 or 3 centres at most.
All patients should be followed with a national registry with regular data collection to ensure appropriate usage and outcomes

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.

40. Type of interest: *

- [ ] Direct: financial
- [ ] Non-financial: professional
- [ ] Non-financial: personal
- [ ] Indirect
- [x] No interests to declare

41. Description of interests, including relevant dates of when the interest arose and ceased. *

None, have now emigrated to Canada so will not be personally involved in any future NHS service

42. 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. *

    - (●) I agree
    - ( ) I disagree

Signature

43. Name: *

    Paul Hindle

44. Date: *

    24/11/2023