NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: **1797 - Focal articular prosthetic resurfacing for treating articular cartilage defects in the knee**

Your information

Name:	CM Gupte
Job title:	Consultant Orthopaedic Surgeon
Organisation:	Imperial College/BASK
Email address:	[redacted]
Professional organisation or society membership/affiliation:	BASK
Nominated/ratified by (if applicable):	Click here to enter text.
Registration number (e.g. GMC, NMC, HCPC)	GMC 4342319

How NICE will use this information: the advice and views given in this questionnaire will form part of the information used by NICE and its advisory committees to develop guidance or a medtech innovation briefing on this procedure/technology. Information may be disclosed to third parties in accordance with the Freedom of Information Act 2000 and the Data Protection Act 2018, complying with data sharing guidance issued by the Information Commissioner's Office. 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interests will also be published online on the NICE website as part of the process of public consultation on the draft guidance, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate.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:

I give my consent to my name being published but not my email.

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

Please note that questions 10 and 11 are applicable to the Medical Technologies Evaluation Programme (MTEP). We are requesting you to complete these sections as future guidance may also be produced under their work programme.

1	Please describe your level of experience with the procedure/technology, for example: Are you familiar with the procedure/technology?	Yes
	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 have used it in various forms Yes I use the technology and refer patients 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 done bibliographic research on this procedure. YES I have done research on this procedure in laboratory settings (e.g. device-related research). YES I have done clinical research on this procedure involving patients or healthy volunteers.NO I have published this research.NO I have had no involvement in research on this procedure. Other (please comment)
3	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):	Innovative although it has been present in various forms for 20 years. Established practice and no longer new. Established but with newer versions of procedure under review A minor variation on an existing procedure, which is unlikely to alter the procedure's safety and efficacy. YES Definitely novel and of uncertain safety and efficacy. NO The first in a new class of procedure. NO
4	Does this procedure/technology have the potential to replace current standard care or	YES

	would it be used as an addition to existing standard care?	

Current management

5	Please describe the current standard of care that is used in the NHS.	Microfracture is the current standard of care.It is cheap and easily accessible and performed. However it has inferior results, although it is unclear whether the inferiority is marginal oir more significant.
6	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?	

Potential patient benefits and impact on the health system

7	What do you consider to be the potential benefits to patients from using this procedure/technology?	Patients below 50yrs of age with focal chondral defects
8	Are there any groups of patients who would particularly benefit from using this procedure/technology?	As above
9	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 Yes if successful result.
10 - MTEP	Considering the care pathway as a whole, including initial capital and possible future costs avoided, is the procedure/technology likely to cost more or less than current standard care, or about the same? (in terms of staff, equipment, care setting etc)	Higher cost.
11 - MTEP	What do you consider to be the resource impact from adopting this procedure/technology (is it likely to cost more or less than standard care, or about same-in terms of staff, equipment, and care setting)?	Higher cost
12	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	Clinics operating theatres, skilled surgeons

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

Safety and efficacy of the procedure/technology

14	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	Failure could lead to deterioration of symptoms and need for further expensive surgery such as joint replacement.
15	Please list the key efficacy outcomes for this procedure/technology?	Pain, mobility, ADLs, reduced need for further interventions.
16	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	Failure could lead to deterioration of symptoms and need for further expensive surgery such as joint replacement.
17	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	
18	If it is safe and efficacious, in your opinion, will this procedure be carried out in (please choose one):	A minority of hospitals, but at least 10 in the UK. Cannot predict at present.

Abstracts and ongoing studies

19	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.	
20	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	

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)?	3500
22	Are there any issues with the usability or practical aspects of the procedure/technology?	Skillset of surgcial team
23	Are you aware of any issues which would prevent (or have prevented) this procedure/technology being adopted in your organisation or across the wider NHS?	Cost, and training requirement

24	Is there any research that you feel would be needed to address uncertainties in the evidence base?	Yes
25	Please suggest potential audit criteria for this procedure/technology. If known, please describe: − Beneficial outcome measures. These should include short- and long-term clinical outcomes, quality-of-life measures and patient-related outcomes. Please suggest the most appropriate method of measurement for each and the timescales over which these should be measured. − Adverse outcome measures. These should include early and late complications. Please state the post procedure timescales over which these should be measured:	Beneficial outcome measures: SF36, EQ 35, IKDC score, Tegner activity score, Oxford knee score. Adverse outcome measures: Above scores Need for reoperation Infection DVT/PE

Further comments

26	Please add any further comments on your particular experiences or knowledge of the procedure/technology,	We have performed a systematic review which is under consideration for publication.

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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.			
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:	**CM Gupte**
Dated:	**02/12/2021**

NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: **1797 - Focal articular prosthetic resurfacing for treating articular cartilage defects in the knee**

Your information

Name:	Click here to enter text. Paul Joseph Jermin
Job title:	Click here to enter text. Consultant Orthopaedic Surgeon & Honorary Senior Lecturer Keele University
Organisation:	Click here to enter text. Robert Jones & Agnes Jones Orthopaedic Hospital
Email address:	Click here to enter text. [redacted]
Professional organisation or society membership/affiliation:	Click here to enter text. GMC, BOA, ESKKA, ICRS
Nominated/ratified by (if applicable):	Click here to enter text.
Registration number (e.g. GMC, NMC, HCPC)	Click here to enter text. GMC 6101720

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

Please note that questions 10 and 11 are applicable to the Medical Technologies Evaluation Programme (MTEP). We are requesting you to complete these sections as future guidance may also be produced under their work programme.

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 am a knee specialist working in an orthopaedic centre of excellence. My main area of interest is cartilage regeneration and is an an area our unit is well known for internationally. Focal resurfacing technology is a very useful tool to have for a cartilage specialist. I have been very pleased by the clinical results the patients I have used it in have achieved. I have been using focal resurfacings for the last 5 years. I am familiar with the Episurf devise having been taught on its technique several years ago. I also published a review paper a few years ago on the topic of focal resurfacings. I have recently created a national complex cartilage meeting with fellow cartilage specialists from all around the UK. From this meeting, I get the impression that these devices are not being used very often within the UK. The technology can be used within the ankle and shoulder but I think their usage is quite rare in these areas. I am directly involved in patient selection for this procedure and receive referrals from other surgeons / units for its consideration.

	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 published the following article on focal resurfacings: focal resurfacing implants in the knee and partial knee replacements. Jermin PJ, Yates J, McNicholas M. Trauma & Orthopaedics, 29; 1, 38-47. Feb 2015 Actively involved in recruiting for EPIC trial – an RCT comparing focal resurfacings with microfracture
3	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):	This procedure is relatively innovative but one that has been around for a while. There are several brands of focal resurfacings available and all work off differing concepts. I feel their data should be looked at separately rather than collectively. The 3 that I am aware of are the hemicap: this has been around for several years, is an off the shelf metal implant. It's results on the Australian joint registry have historically not been great. It would appear there is great variability in surgeons' indications for using this. There is also the Episurf procedure – this is a PSI & bespoke metal implant with good 7 year data. Lastly, there is the Biopoly which is an off the shelf plastic implant, I have not seen any published data on its performance. The hemicap I would say is established practise (although infrequently performed). The Episurf & Biopoly are variations upon this. I would expect (this is my opinion rather than evidence base) that both of these implants should improve the clinical results significantly as compared to the more established hemicap.

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?	The newer implants have the potential to supersede the hemicap (which I would not describe as current standard of care). If units are not currently using a focal resurfacing device, they have the potential to add to their surgical portfolio.

Current management

5	Please describe the current standard of care that is used in the NHS.	This is a very nebulous question. Generally, standard of care would fall into either cartilage regeneration or joint replacement.
6	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?	None directly competing procedure that I am aware of

Potential patient benefits and impact on the health system

7	What do you consider to be the potential benefits to patients from using this procedure/technology?	Improvements in pain and quality of life. Avoiding the need to perform a joint replacement which often have a poor outcome for these patients
8	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Patients who have have failed cartilage regeneration or patients who have a focal cartilage defect but would be unfavourable for biological therapy.
9	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?	There is no established pathway for these patients. These are a group of patients that may undergo joint replacement surgery, the results of which are very variable in this population group. Dissatisfied joint replacement patients often undergo multiple investigations and are revised frequently in clinic. This procedure has the potential to result in a greater improvement in patients' quality of life compared with alternatives.
10 - MTEP	Considering the care pathway as a whole, including initial capital and possible future costs avoided, is the procedure/technology likely to cost more or less than current standard care, or about the same? (in terms of staff, equipment, care setting etc)	This is difficult to answer as there are so many procedures than can be done for this pt group and there is no current standard of care as such. At a rough estimate, I would guess that it may result in less cost
11 - MTEP	What do you consider to be the resource impact from adopting this procedure/technology (is it likely to cost more or less than standard care, or about same-in terms of staff, equipment, and care setting)?	These devices are very niche and are not done in any great quantity in the UK. I would hope they would result in an overall reduction in cost of treating these patients but the impact on the NHS as a whole is likely to be tiny.

12	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	In units that are established in the field of comprehensive treatment cartilage treatment, not much at all. In a unit looking to adopt this practice, it would depend upon which devise they chose to introduce.
13	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	Yes but it is specific to the implant. For an established surgeon, it is not a difficult procedure to learn

Safety and efficacy of the procedure/technology

14	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 harm lies in the potential failure of these devices – if the knee wears out and they need to be revised (to a joint replacement). I would imagine that converting one of these into a knee replacement would not lead to any overt morbidity / compromise in results but it is, currently, an unknown.
15	Please list the key efficacy outcomes for this procedure/technology?	Not sure what is meant by efficiency outcomes
16	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	Longevity, effect on subsequent joint replacements
17	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	Long term survivorship is still unknown with newer devices

18	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

19	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.	Nothing I am aware of that is not widely available
20	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	EPIC knee study looking at the Episurf device

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)?	At a rough estimate based up my practise, probably about 25-40 pts a year

22	Are there any issues with the usability or practical aspects of the procedure/technology?	Not that I am aware of
23	Are you aware of any issues which would prevent (or have prevented) this procedure/technology being adopted in your organisation or across the wider NHS?	Awareness and having suitable pts referred
24	Is there any research that you feel would be needed to address uncertainties in the evidence base?	We could do with putting these devices on the NJR
25	Please suggest potential audit criteria for this procedure/technology. If known, please describe: − Beneficial outcome measures. These should include short- and long-term clinical outcomes, quality-of-life measures and patient-related outcomes. Please suggest the most appropriate method of measurement for each and the timescales over which these should be measured. − Adverse outcome measures. These should include early and late complications. Please state the post procedure timescales over which these should be measured:	Beneficial outcome measures: Oxford knee score, EQ-5D, WOMAC & survivorship. Ideally, these would be measured pre op & (at least) 1 year pots op Adverse outcome measures: Re-operation over lifespan of device

Further comments

26	Please add any further comments on your particular experiences or knowledge of the procedure/technology,	

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Type of interest *	Description of interest	Relevant dates	
		Interest arose	Interest ceased
Choose an item.	None to declare		
Choose an item.			
Choose an item.			

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Print name:	**Click here to enter text.Paul Joseph Jermin**
Dated:	**Click here to enter text.08.12.21**