Reporting Guideline Checklist for IDEAL Stage 2b: Exploration

Section/Topic	Item No	Checklist Item	Reported on Page No
Title and Abstract			
Title and Abstract	1a	Identify the novel technique/device being investigated and the type of study conducted (e.g. multi-centre, prospective cohort or feasibility RCT), including the IDEAL stage in the title or abstract	
	1b	Provide a structured summary of background, methods, results, and conclusions	
Introduction			
Background and objectives	2a	Review of existing scientific literature, including reference to IDEAL Stage 1 and 2a reports in previous publications, if applicable	
	2b	Specific objectives stated, including reaching consensus on aspects necessary to conduct an RCT, or consensus that an RCT is not appropriate or feasible	
Methods			
Design	3	Description of multi-centre study design, with prospective collection of standard data across centres	

Participants	4a	Detailed account of patient inclusion and exclusion criteria	
	4b	Informed consent process described, including explanation of risks and acknowledgement of level of experience with technique/device	
	4c	Setting, location, and timeframe of recruitment and follow-up, including when and where the data were collected, as well as hospital characteristics and appropriate details regarding the operator/team (e.g. prior experience with novel technique)	
Intervention	5a	Clear and detailed description of technique, or reference to it, including an assessment measure for quality of adherence to the technique for operators/teams	
	5b	Description or reference to learning curve assessment of operators/team using pre-defined objective quality metrics	
	5c	Patient safety monitoring methods and safeguards	
Outcomes	6	Description of pre-specified primary and secondary outcome measures selected and how they will be assessed, including patient reported outcome measures, when appropriate, utilising those measures that are standardised and validated, when available and applicable. When these are not available, provide rationale for the outcome measure(s) used	
Statistical methods	7	Statistical methods used to describe baseline characteristics and evaluate primary and secondary outcomes, when appropriate, including methods for additional analysis (e.g. learning curve analysis, pre-specified subgroup analysis)	

Stakeholder Values	8	Describe or reference attempts to evaluate patient and surgeon preferences and values relevant to future RCT trial design and conduct, including any qualitative work done to ascertain views about randomization	
Results			
Baseline data	9	Patient baseline demographic and clinical characteristics, including how many patients were assessed for treatment and a description of which patients were included, excluded, or refused, and why (to be displayed in a flow diagram format, when appropriate)	
Learning Curves	10	Report of learning curve assessment results for operators/team based on pre-defined objective quality metrics, including statistical analysis, if feasible	
Outcomes	11	Describe results of each pre-specified outcome measure, including patient reported outcome measures, where appropriate	
Harms	12	Transparent account of all harms or unintended effects reported	
Stakeholder Values	13	Report findings of attempts to evaluate patient and surgeon preferences and values relevant to future RCT trial design and conduct, including any qualitative work done to ascertain views about randomization	
Discussion			
Limitations	14	Study limitations, addressing sources of potential bias	

Stage End-Points	15a	Pre-planned review of results and discussion of appropriateness of progressing to RCT or pilot/feasibility study	
	15b	Has agreement been reached about standard technique, including accepted variants, and quality standards based on operator/team experience during this stage?	
	15c	Has agreement been reached for appropriate target patient population and indications, including identification of subgroups for which the applicability of the technique is considered uncertain?	
	15d	Has agreement been reached regarding appropriate outcome measure(s) for a trial, including an estimated power calculation of the primary outcome for a future trial?	
	15e	Has agreement been reached regarding the appropriate comparator treatment for a trial?	
	15f	Are operators and patients willing to accept randomisation between the proposed treatments (establishing equipoise)?	
	15g	Ensure potential harms from learning curves are addressed by training and mentoring prior to Stage 3, where appropriate	
Conclusion	16	Conclusions and relevance, including plans to evaluate the technique/device in a high-quality RCT against the current standard of care. If not planning to further evaluate in IDEAL Stage 3 study, please explain	
Other information			

Protocol	17	Please quote reference or DOI if a protocol was written in advance and made available. If a protocol was not made available, consider including as a supplement if the journal allows	
Ethics	18	Reference to ethical approvals obtained, and independent oversight, if applicable	
Funding	19	Sources of funding and support, role of funders, and other conflicts of interest	
Regulatory Approvals	20	Regulatory approvals being sought or obtained (e.g. CE Marking, FDA approval, etc) including the date of approval, if applicable	

Bilbro NA, Hirst A, Paez A, et al. The IDEAL Reporting Guidelines: A Delphi Consensus Statement Stage specific recommendations for reporting the evaluation of surgical innovation [published online ahead of print, 2020 Jul 7]. Ann Surg. 2020;10.1097/SLA.0000000000004180. doi:10.1097/SLA.0000000000004180