Reporting Guideline Checklist for IDEAL Stage 1: Idea

Section/Topic	Item No	Checklist Item	Reported on Page No
Title and Abstract			
Title and Abstract	1a	Identify the technique or device in the title, including IDEAL Stage 1 or 'first in human' 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, providing a clear explanation of the rationale for the new technique, including unmet clinical need	
	2b	Details of pre-clinical development of the technique, including assessment of risks of failure and analysis of efforts to avoid harm*	
Methods			
Design	3	Description of study design (e.g. case report or very small case series)	
Participants	4a	Transparent account of patient selection, with explicit detail about inclusion and exclusion criteria	

	4b	Informed consent process described, including explanation of risks and acknowledgement of level of experience with technique/device. If informed consent is not obtained due to unplanned technique or modification, describe the discussion with the patient after the innovation occurred	
	4c	Setting, location, and timeframe of when and where the novel technique was performed, including hospital characteristics and appropriate details regarding the operator/team (e.g. experience)	
Intervention	5a	Clear and detailed description of the new technique/device, including necessary pre- and post-procedure care	
	5b	Patient safety monitoring methods and safeguards	
Outcomes	6	Description of outcome measure(s) selected and how they were assessed, including patient reported outcome measures, if 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	
Results			
Baseline Data	7	Baseline demographic and clinical characteristics for each patient. Include 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)	
Intervention	8	Technical feasibility of technique, including visual aids (e.g. photographs, videos, etc) when available	
Outcomes	9	Appropriate clinical outcomes, including patient-reported outcome measures, when applicable	
Harms	10	Transparent account of all harms or unintended effects reported for each patient	

Discussion			
Stage End-Points	11	Author's overall appraisal of the new technique, including discussion of risks and harms reported and suggestions to avoid them in future cases based on initial experience	
Conclusions	12	Conclusions and relevance, including plans to progress to future IDEAL stages, or plans to discontinue further research	
Other information			
Protocol	13	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	14	Reference to ethical approvals obtained, and independent oversight, if applicable	
Funding	15	Sources of funding and support, role of funders, and other conflicts of interest	
Regulatory Approvals	16	Regulatory approvals being sought or obtained (e.g. CE Marking, FDA approval, etc) including the date of approval, if applicable	

* If the technique was an unplanned or spontaneous innovation or forced by circumstances, this should be explicitly stated, and the circumstances described briefly. All relevant checklist items should be completed.

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