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PEER-REVIEW REPORT

Name of journal: *World Journal of Radiology*

Manuscript NO: 88315

Title: Outcomes and efficacy of MRI-compatible sacral nerve stimulator for management of fecal incontinence: a multi-institutional study

Provenance and peer review: Invited Manuscript; Externally peer reviewed

Peer-review model: Single blind

Reviewer's code: 02441035
Position: Associate Editor
Academic degree: MD

Professional title: Professor

Reviewer's Country/Territory: Italy

Author's Country/Territory: United States

Manuscript submission date: 2023-09-23

Reviewer chosen by: AI Technique

Reviewer accepted review: 2023-10-11 06:33

Reviewer performed review: 2023-10-26 02:36

Review time: 14 Days and 20 Hours

Scientific quality	[ ] Grade A: Excellent [ ] Grade B: Very good [Y] Grade C: Good [ ] Grade D: Fair [ ] Grade E: Do not publish
Language quality	[ ] Grade A: Priority publishing [Y] Grade B: Minor language polishing [ ] Grade C: A great deal of language polishing [ ] Grade D: Rejection
Conclusion	[ ] Accept (High priority) [ ] Accept (General priority) [ ] Minor revision [Y] Major revision [ ] Rejection
Re-review	[Y] Yes [ ] No

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Peer-reviewer statements	Peer-Review: [Y] Anonymous [ ] Onymous
	Conflicts-of-Interest: [ ] Yes [Y] No

SPECIFIC COMMENTS TO AUTHORS

The present study is rather important, as it is the first that concerns the clinical evaluation of the new MRI-compatible sacral nerve stimulation device. However there are some comment to make. The paper is presented in a rough and incomplete manner with regard to the effectiveness and complications of this system. -In particular the presentation of the treatment results was kept at minimum showing simply a pie chart with the 93,2% of patients improved, without any comparison with the results of studies with other types of sacral nerve stimulation devices. It is necessary to evaluate the effectiveness of this new system with St. Mark's incontinence score, Faecal Incontinence Severity Index score and Manchester Health Questionnaires, and counting the number of incontinence and fecal urgency episodes etc. These calculations should be done in basal conditions and at the end of follow-up and should be compared in a table with those of other studies with other InterStim devices, using the data obtained in each patient of each Institution participating to the study. These calculations should be done because the new MRI-compatible InterStim device could have been experimented on patients with less severe fecal incontinence with respect to the studies performed with the presently available InterStim devices, so that the real effectiveness may be lower. Effectiveness must be demonstrated, not just affirmed -Also the frequency and kind of complications and adverse events, as lead migration and fracture, bleeding, hematoma, infection, pain and the number of explantation described after MRI-compatible InterStim device should be compared in a table with those observed in other studies with the currently available InterStim systems, although the follow-up in the latter case was much longer. -The Authors should explain in detail why the studies of Elkelini MS (ref.

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20), Alsyoul M (ref 21) and Guzman-Negron JM (ref. 22), who assert a safe use of MRI with particular precautions in patients carrying an Interstim device for fecal or urinary incontinence, "should be very carefully interpreted" and that the "generalized conclusions based upon these studies off label would be very dangerous". Actually, Chermansky CJ et al (ref. 10) said that "Although we don't advocate the routine use of MRI following InterStim implantation, our experience suggests that MRI may be feasible under controlled conditions and without adverse events". Huang X et al (ref. 9) concluded that "MRI guidelines provided by the device manufacturer are the best resource for guidance for performing safe MRI scanning. Furthermore Sayed D et al. has provided a comprehensive practice guideline to determine when an MRI can be performed for each type of neuromodulation device implant. (Neuromodulation. 2020;23:893-911). From all these declarations it appears that MRI is not always harmful in presence of all systems for sacral stimulation as long as some precautions are applied and recent equipments are used. The Authors issue a hopeless sentence on all InterStim devices, but should take the above described observations into account in the discussion, because the reader must be correctly informed. -The English language should be improved. -Pag.6 line 3 of Procedure: please specify PNE. -Pag 8 line 8: what is 3.5?

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Reviewer's code: 04022623
Position: Peer Reviewer
Academic degree: PhD

Professional title: Adjunct Professor, Surgeon, Surgical Oncologist

Reviewer's Country/Territory: Spain

Author's Country/Territory: United States

Manuscript submission date: 2023-09-23

Reviewer chosen by: Yu-Lu Chen

Reviewer accepted review: 2023-11-01 21:20

Reviewer performed review: 2023-11-09 21:16

Review time: 7 Days and 23 Hours

Scientific quality	[ ] Grade A: Excellent [ ] Grade B: Very good [Y] Grade C: Good [ ] Grade D: Fair [ ] Grade E: Do not publish
Novelty of this manuscript	[ ] Grade A: Excellent [Y] Grade B: Good [ ] Grade C: Fair [ ] Grade D: No novelty
Creativity or innovation of this manuscript	[ ] Grade A: Excellent [Y] Grade B: Good [ ] Grade C: Fair [ ] Grade D: No creativity or innovation

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Scientific significance of the conclusion in this manuscript	[ ] Grade A: Excellent [ ] Grade B: Good [Y] Grade C: Fair [ ] Grade D: No scientific significance
Language quality	[ ] Grade A: Priority publishing [Y] Grade B: Minor language polishing [ ] Grade C: A great deal of language polishing [ ] Grade D: Rejection
Conclusion	[ ] Accept (High priority) [ ] Accept (General priority) [ ] Minor revision [Y] Major revision [ ] Rejection
Re-review	[ ] Yes [Y] No
Peer-reviewer statements	Peer-Review: [Y] Anonymous [ ] Onymous
	Conflicts-of-Interest: [ ] Yes [Y] No

SPECIFIC COMMENTS TO AUTHORS

Firstly, I would like to congratulate you by trying to add more information on this issue. I consider that your study needs to be improved in some of its parts. I proceed to perform some commentaries for each manuscript section: I proceed to perform some commentaries for each manuscript section: In the ABSTRACT: • SNS is not yet a "novel" treatment for FI, it has been stablished since too many years. • This is an issue for all the manuscript and its design. Authors mention "68 patients reported significant improvement of symptoms". How was this improvement analysed? Authors employed any Clinical scale or defecation diary? Did they consider Quality of Life (QoL)? If authors employ "significant" is there any statistical analyses? In the INTRODUCTION: • Some references are lacking in the text. • Some abbreviations appear not explained the first time they appear. • Is there any percentage published in the literature of explantations indicated by MRI needing? • Other changes are suggested in attached MS-Word document modified with Control Panel. In the MATERIAL AND METHODS section, we can mention: • Some references are lacking in the text. • It could be very interesting to add some photographs or pictures about the procedure and the device. • Is

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there any criteria to perform PNE or stage 1? It depends on surgeon discretion? • FUNDAMENTAL: Did the study had any ethical approval? Did the patients signed informed consent? How was the therapeutical results assessed? Defecation diary? Scales (Wexner)? QoL (FIQL, …)? • Other minor changes are suggested in attached MS-Word document modified with Control Panel. RESULTS SECTION: • I believe it could be interesting to describe better the patients, grade of FI (for example with a scale), symptons, etc. • Are reported complications and their frequency comparable to the published with the previous devices? • The same I have mentioned before… What is this improvement in FI described? How is it reported or measured? Is patient opinion? Is there any objective or subjective evaluation? Defecatory diary? Scale? Is QoL considered in the results? • Other minor changes are suggested in attached MS-Word document modified with Control Panel. DISCUSSION SECTION: • Some references are lacking. • Add more studies to the discussion and mention one of the available systematic reviews on SNS. • Other minor changes are suggested in attached MS-Word document modified with Control Panel. Newly I would like to congratulate authors for their work. Keep working in this way and trying to publish your research.

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RE-REVIEW REPORT OF REVISED MANUSCRIPT

Name of journal: *World Journal of Radiology*

Manuscript NO: 88315

Title: Outcomes and efficacy of MRI-compatible sacral nerve stimulator for management of fecal incontinence: a multi-institutional study

Provenance and peer review: Invited Manuscript; Externally peer reviewed

Peer-review model: Single blind

Reviewer's code: 02441035
Position: Associate Editor
Academic degree: MD

Professional title: Professor

Reviewer's Country/Territory: Italy

Author's Country/Territory: United States

Manuscript submission date: 2023-09-23

Reviewer chosen by: Ji-Hong Liu

Reviewer accepted review: 2023-11-27 08:58

Reviewer performed review: 2023-11-29 16:12

Review time: 2 Days and 7 Hours

Scientific quality	[ ] Grade A: Excellent [ ] Grade B: Very good [ ] Grade C: Good [Y] Grade D: Fair [ ] Grade E: Do not publish
Language quality	[ ] Grade A: Priority publishing [ ] Grade B: Minor language polishing [Y] Grade C: A great deal of language polishing [ ] Grade D: Rejection
Conclusion	[ ] Accept (High priority) [ ] Accept (General priority) [ ] Minor revision [Y] Major revision [ ] Rejection
Peer-reviewer	Peer-Review: [Y] Anonymous [ ] Onymous

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statements	Conflicts-of-Interest: [ ] Yes [Y] No

SPECIFIC COMMENTS TO AUTHORS

Unfortunately the answers to the requests expressed in the review are not satisfactory. In fact the request of a more detailed evaluation of the fecal incontinence severity with adequate texts before and after the stimulation period for a correct comparison with the results of other InterStims, was not fulfilled. In the Procedure section the Authors added the following sentence: Wexner incontinence scores were evaluated in the pretreatment and the post treatment phase, but the results of this evaluation were not found in the text, tables or figures. The request concerning the comparison of complications ad adverse events with those of other studies was not granted, with the excuse that the follow-up of the other studies was longer, without considering that the difference in follow-up length would have been taken into account in the evaluation. The authors didn't even indicate that 3.5 at the end of the Results section is a standard deviation by adding (SD) after 3.5 in the text. The English language has not been improved sufficiently. For these reasons I consider not definitely demonstrated the conclusion that the MRI compatible InterStim has the same level of effectiveness and complications as the InterStims on the market.