Thank you for the reviews on the paper.

We have tried to respond to all the authors questions and concerns. There have been few instances that the reviews have been taken positively, but due to the constraints of the study, no further changes could be done.

Reviewer 1:

● SNS is not yet a "novel" treatment for FI, it has been established since too many years.
Response: We have changed it to "a well-established"

● 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?
Response: A fecal diary was kept for all the patients. Preoperative and post operative assessments were done utilizing the Wexner Incontinence score and improvement of scores >50% were considered improvement. This has been further mentioned in the manuscript and appropriate reference for the score has been provided

In the INTRODUCTION:
● Some references are lacking in the text.
Response: We have tried to add few more references to the text

● Some abbreviations appear not explained the first time they appear.
Response: These have been corrected

● Is there any percentage published in the literature of explantations indicated by MRI needing? There is a literature highlighting that and it has been included in the manuscript with the appropriate reference
Response: We have added an addendum to the manuscript describing the percentage, its 23% of all removals based upon a study, which has been referenced as well

● Other changes are suggested in attached MS-Word document modified with Control Panel.
Response: Thank you very much. Have tried to address the suggestions

In the MATERIAL AND METHODS section, we can mention:

● Some references are lacking in the text.
Response: These have been added

● It could be very interesting to add some photographs or pictures about the procedure and the device.
Response: Our group had a previous review article on this topic which had included photographs. We were intending to report the findings in this study, so our group decided not to include pictures as introducing the technique was not our primary intention

• Is there any criteria to perform PNE or stage 1? It depends on surgeon discretion?
Response: It is surgeon discretion whether to perform PNE vs Stage 1, which has its own advantages and disadvantages. Some patients who had undergone PNE still required Stage 1 implantation where there were equivocal findings on PNE. This is further added in the manuscript.

● FUNDAMENTAL: Did the study had any ethical approval? Did the patients sign informed consent? How were the therapeutical results assessed? Defecation diary? Scales (Wexner)? QoL (FIQL, ...)?
Response: There is an IRB approval from Providence Hospital. Wexner incontinence score was used for the assessment of the therapeutic results, which has been described in the manuscript with appropriate reference provided

• Other minor changes are suggested in attached MS-Word document modified with Control Panel.

Response: Have tried to address these suggestions

RESULTS SECTION:

• I believe it could be interesting to describe better the patients, grade of FI (for example with a scale), symptons, etc.

Response: All patients who have bothersome severe fecal incontinence who have failed conservative measures including fibers, antidiarrheals, biofeedback are the ones who are offered sacral nerve stimulation. Wexner incontinence score was evaluated for the effectiveness of the treatment, and any symptom improvement >50% was considered as significant

• Are reported complications and their frequency comparable to the published with the previous devices?

Respnse: This has been addressed with a previous study compared to the current study which is elaborated in the discussion section. A study by Mellgren which had evaluated the findings in detail has been compared with our study, which showed similar findings.

• 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?

Fecal diary was kept and the Wexner incontinence score was evaluated for the effectiveness of the treatment, and any symptom improvement >50% was considered as significant

• Other minor changes are suggested in attached MS-Word document modified with Control Panel.

Response: We have tried to address these concerns

DISCUSSION SECTION:

• Some references are lacking.

Response: Have added few references

• Add more studies to the discussion and mention one of the available systematic reviews on SNS.

Response: Have tried to incorporate that in the new revised manuscript

• Other minor changes are suggested in attached MS-Word document modified with Control Panel.

Response: We have tried to address that

Newly I would like to congratulate authors for their work. Keep working in this way and trying to publish your research.

Reviewer 2:

-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

Response: Sacral nerve stimulation is a second line treatment in fecal incontinence and is offered to patient who have failed conservative measures including fibers, pelvic floor exercises and biofeedback. The patients who were offered this treatment were evaluated utilizing a defecation diary and Wexner incontinence score. Any improvement of scores >50% was considered effectiveness of the treatment, which is the same criteria utilized by previous studies as well, which have been referenced in this study

-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.

Response: We have tried to create a table and tried to highlight the complication and adverse events in previous studies and our study. Again, caution should be given as our study only provides data on 1 year follow up, as compared to other studies with longer follow up, thus with a possibility of more adverse events for previous studies

-The Authors should explain in detail why the studies of Elkelini MS (ref. 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.
Response: The previously available Interstim systems were not FDA approved for use with MRI and at least 23% of the implant removals were because patient required MRI. This is the main premise of developing this current technology and the scope of our study as well.
The studies previously done for feasibility of MRI with the SNS were done with small sample size, and this might be the reason why the previous authors had come to the conclusion that the results "should *be very carefully interpreted*" and that the "*generalized conclusions based upon these studies off label would be very dangerous*". These statements are not the opinion of ours, rather these were the inferences drawn by the previous authors.

The evidence provided by Huang X et al. is based upon the currently available InterStim lead which is considered to be MRI safe (conditionally safe in the recommended settings) and which is the basis of the study that has been discussed in the paper. I apologize that this was not referenced appropriately, however, I have referenced it in the revised manuscript.

Furthermore. the study by Chermansky (2011), had similar issues with low sample size. Their study also mentioned that og f the 15 MRIs performed, the lumbar spine was imaged in eight studies, the pelvis was imaged in one study, and the remaining examinations involved imaging the brain or cervical spine. The previous SNS system were already deemed conditionally safe to use with MRI of head and C spine, and the previous system was not recommended for use below the head.

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.
Response: Our attempt is to provide a better understanding of the current technology that is available, which would only add to the benefit of previously available InterStim by being it safe while performing MRI.

The English language should be improved.
Response: Attempt has been made to improve the language. Further suggestions are appreciated

-Pag.6 line 3 of Procedure: please specify PNE.
Response: This has been specified with a complete description before the abbreviated form

-Pag 8 line 8: what is 3.5?
Response: This is the Standard deviation from mean

Response to re-review

Thank you very much for your valuable input into our work. We really appreciate your effort into reviewing the work. To the best of our ability, we have tried to fulfil and respond to the reviews presented.

Reviewer comments

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.

Response: We do have some limitations of how the data was recorded among multiple surgeons; some only recorded improvement in symptoms. I have included a datasheet of one of the surgeons involved in the study to highlight how the data was recorded. Hopefully this helps clarify the situation and the limitation authors were encountering.

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.

Response: All the surgeons involved in the study were part of the breed of surgeons who had trained in the institution from where Wexner grading/score was invented and as such the surgeons involved religiously follow this score as part of their evaluation. Again, with the limitations as to how the data was captured into the database was the main reason of not being able to completely fulfil the requisite**.**

The request concerning the comparison of complications and 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.

Response: As the baseline data for the studies were different, no direct comparison can be made, however we have tried to highlight the different adverse effects and complications encountered in the other studies in the table that we have added with the revised manuscript. We do concede that the study period of our study was short so our conclusions were based upon our short interval of follow up, however we will continue to monitor the situation and will try to gather more information in the coming days to have more robust and a longer period data.

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.
Response: I sincerely apologize and have included this in the revised text this time around.

The English language has not been improved sufficiently.
Response: We have tried our best to improve the situation and had also asked multiple authors to independently screen the manuscripts for more clarity and better use of professional English language. However further suggestions are welcome. We are committed to improve and we would certainly embrace all the suggestions we can get so that we can improve our situation

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.
Response: We do see that the study, although short-term and less powered, has at least given us an information about the benefits of the newer technology. The effectiveness and safety profile at least in the short term have been good. We do believe that the technology is here to stay, however, we do have to be cautious in the future and further refinements might be necessary based upon the long-term data so that the technology

we will be able to build will benefit more and more patients in the future with this condition. And most importantly, this being the first study of its kind evaluating the MRI compatible device with no other studies available in this subject, we do believe this study being multi-institutional, does add to the literature, with a building block to future long term follow up and further studies as well.