Author’s response to reviews

Title: Lead Fixation in Deep Brain Stimulation: Comparison of Three Lead Anchoring Devices in China

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Reviewer reports:

Dipankar Nandi, D.Phil. (Reviewer 1): Excellently written. Detailed. Thorough. However, some concerns / comments:

1. Study design: not sure how relevant is immediate intra-op DBS lead shift?; if one wishes to test the efficacy of a fixation device it would perhaps be advisable to look for shift in position over time - six months / one year

Response: Thank you for pointing this out. We agree with you that long-term position is quite important. However, the purpose of this paper is studying the performance of lead anchoring device during the DBS surgery. DBS lead shift is usually caused by air in the skull or the loss of CSF. Lead anchoring device which is designed for the fixation of the lead on the skull has been used widely. Conventionally, it is believed that once the lead is locked by the lead anchor, the lead would not move in the remaining operations. However, we found that shifts would happen by using the images from the C-arm X-ray. Immediate X-ray could also provide sufficient and timely location information. Then the surgeons had to adjust the positions instantly which were critical to the programming postoperatively.
2. Only measures shift in depth, arguably the dimension of the least clinical significance (the DBS lead has four contacts)

Response: The shift in depth is the most prevalent problem in DBS surgery. Many factors can play a role in the clinical efficacy. Sometimes the contact location is perfect, but the clinical response is limited.

3. Not clear what is "traditional fixation device"

Response: Sorry for the unclear here. A traditional fixation device consists of a base ring and a cap. Compared to the fixation device we used, it doesn’t have an additional locker to fix the position of the lead. This part has been added to the revised manuscript in line 92-94 (or page 4) by figure 1.

4. The worst performing device recorded a shift of 1.52 mm +/- 1.02 mm (deeper) - would that influence the clinical outcome if one simply chose the contact second from deepest

Response: Yes, that’s feasible. There are always four contacts for programming, and the closest contact to the target works better. That is the aim of this study, how precisely the fixation device can provide for targeting. We didn't correlate the outcomes with the clinical efficiency, but it presents evidences that the intraoperative imaging is necessary for the lead position.

Reviewer 2 (Reviewer 2): PEER REVIEWER ASSESSMENTS:

PEER REVIEWER COMMENTS:

GENERAL COMMENTS: The study is interesting and well written. It provides useful information about the most used lead anchoring devices for DBS

Response: Thank you for your encouraging words.

REQUESTED REVISIONS:

My major concern is that authors put together the lead fixation from Medtronic and PINS as "traditional". Are they exactly the same? - in the discussion authors discussed this but I think this should be emphasized in the Introduction. maybe if they separate the six traditional (Medtronic)
and the 20 traditional from PINS would be interesting, once they are comparing the different designs. If they were really put together, authors should say that the new lead fixation devices are potentially better than the "traditional" and that these latter are similar regarding their manufacturer.

Response: Thank you very much for your insightful suggestions. We have made changes in the text accordingly. The description of the traditional fixation device was edited to the revised manuscript in line 92-94 (or page 4) by figure 1. Briefly, the traditional one consists of a base ring installed on the burr hole and a cap to press the lead on the groove of the base ring without the lead clamp, which is not patented as the Stimloc of Medtronic and Touchloc of SceneRay. So, we put the traditional ones together and also edited the conclusion in line 39-41 (page 2) and line 266-268 (page 10), in which we believe that the newly designed lead fixation devices have presented its advantages to the traditional one.

ADDITIONAL REQUESTS/SUGGESTIONS:

considering a better description and picture of each lead anchoring device (improve figure 1 quality with real pictures and a better description). I also believe that they need to clarify who measured the shift between the two positions. If it were the treating surgeon, this may be considered as a bias and should be add to the study limitation. add p values in the Results presented in the abstract. I also believe that authors should be clear to say that the new design lead anchoring devices requires less adjustment then the first generation. Figure 4 is also in the discussion. figures are generally add in Methods or Results

Response: Thank you again for your helpful suggestions. We revised this manuscript, which has been highlighted in the “Abstract”, “Limitation” and “Figure captions” part with the contents appropriately. 1. Figure 1 consisted of real products with relevant description; 2. The surgeon measured the shifts (line 256-257, page 9); 3. p values were added in the abstract (line 32-38, page 2); 4. The conclusion was updated in line 39-41 (page 2) and line 266-268 (page 10); 5. Figure 4 was presented in the Results.