Author’s response to reviews

Title: Experience of AMS 700 LGX penile prosthesis for preserving penile length in Korea

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Hayley Henderson
Editor-in-Chief
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Manuscript revision BURO-D-17-00273R1 " Experience of AMS 700 LGX penile prosthesis for preserving penile length in Korea "

Dear Editor-in-Chief,

I deeply appreciated for the comments on our manuscript. We have revised our previous paper based on the comments made by the referee. We hereby submit a copy of the revised paper electronically. We are also sending a revision letter describing our responses to comments of the reviewers in a point-by-point fashion. We would highly appreciate if you could review this paper again for publication in BMC Urology Journal.
Reviewer reports:

Ranjith Ramasamy (Reviewer 1): This a retrospective study whose purpose was to report the results of all Implantable Penile Prosthesis (IPP) surgeries with the AMS 700 LGX performed by a single surgeon over a 1.5 year period (N=342). Outcomes were assessed by having participants fill out the International Index of Erectile Function (IIEF) at 3, 6, and 12 months postoperatively, and by recording penile length preoperatively, at 6, and at 12 months postoperatively. Additionally, all complications were recorded. They found that IIEF scores were significantly improved, length was significantly increased, and recorded a single wound infection and 10 mechanical failures.

The results of this study are consistent with prior studies demonstrating that though some patients have perceived decrease in erection size, when objectively measure, there is no decrease following IPP. Particularly for the AMS 700 LGX, prior research by negro et. al. has already demonstrated improved IIEF, no loss of penile length, and low complication rates. This study has a significantly larger sample size, but lacks novelty. Furthermore, the study points out that no validated survey has been developed for evaluating patients after IPP but makes conclusions regarding patient's satisfaction with the procedure nonetheless.

1. The paper includes all patients who underwent AMS 700 LGX IPP from 10/14 - 4/16, did any patients receive other implants? It would be interesting to know the ratio of patients who together with their urologists chose this device?

Yes, some patients receive AMS 700 CX and CXR. Following your comment, we revised our manuscripts. “Patients were received AMS 700 LGX, AMS 700 CX (American Medical Service, Minneapolis, MN, USA), or AMS 700 CXR (American Medical Service, Minneapolis, MN, USA) at the time of surgery. Approximately, Half of patients were received AMS 700 LGX and 30 % of patients were received AMS 700 CX and 20% of patients were received AMS 700 CXR” was inserted to Methods.
2. The paper says "No funding was obtained for this study," but do you have any conflicts of interest to disclose, for example, sponsored dinners or trips from AMS?

We do not have any conflict of interest to disclose like sponsored dinner or travels from company.

3. In the first paragraph you write, "Therefore, if patients are frustrated postoperatively with their penile length, daily inflation of the penile prosthesis is recommended to these patients for producing corporal expansion, followed by surgical replacement with a longer cylinder [2]", however the citation does not related to this.

Following your comment, we revised our manuscripts.

4. It appears to me that there would likely be a bias for the surgeon of record to measure a larger penile length post-operatively, were any steps taken to decrease this bias?

Your comment, which surgeon measure a larger penile length post-operatively is totally reasonable. In order to decrease the bias of measuring penile length, we instruct to one specific nurse how to measure penile length and only this staff measured and recorded penile length. This method would be helpful to reduce bias.

5. Were the results of the IIEF scores, and the Penile length scores on a normal distribution? It would be good to see that date. Otherwise a student's t test is difficult to interpret. If the results were not on a normal distribution an ANOVA could be performed.

We review our raw data of the IIEF scores and the penile length scores and the data show normal distribution. So, we think that Student’s t test is appropriate statistical method.

6. Did you measure patient's subjective belief about the change in penile length? It would be interesting to know if they continued to believe their penile length was decreasing.

Unfortunately, we did not measure patient’s subjective belief about the change in penile length.
7. Your infection rate was less than .33%. That is very impressive! Do you use a no touch technique?

Yes, we use a no touch technique. Furthermore, since long surgical time might have many chance to infect, we make a lot of effort to reduce surgical time.

We highly appreciate your invaluable comments.

Jason R. Kovac (Reviewer 2): The authors present the results of a single series of patients who have had a IPP inserted by a single surgeon in Korea. IIEF scores as well as penile flaccid lengths were apparently recorded and followed over time.

I have a few questions.

1. How come the erect length was not also measured with time? Is this data available? The flaccid penile length could be theorized to increase with time due to the length-girth expansion of the AMS device. This happens with erections and consistent device use. Thus the larger the erect penis, the more flaccid length one can obtain. Can the two be tied together with the data that has been obtained? The authors touch on this in page 6, ~line 24.

Your comment, which the larger the erect penis, the more flaccid length one can obtain is totally reasonable. Chen et al commented that the length of the stretched penis provides a reliable estimation of its maximal elongation during erection. So, we did not represent the erect length. Following your comment, we revised our manuscripts. “The penile length could be increased with time owing to the length expansion of the IPP. The larger the erect penis, the more flaccid penile length one can acquire” was added to the background. “The mean and penile length with the IPP fully inflated was 11.8 ± 1.2 at baseline, 12.6 ± 1.0 at 3 months, 12.6 ± 1.1 at 6 months, and 12.7 ± 1.2 at 12 months. There was a statistically significant difference in penile length with the IPP fully inflated from baseline to 3, 6 and 12 months (P < 0.001). No statistically difference in penile length with the IPP fully inflated was shown between 6 and 12 months. (P = 0.14)” was added to the results.
2. The conclusion could be a little more focused. The authors state that the IPP could be used to "preserve the penile length" but that's not really an indication for the IPP to be placed. Perhaps a re-write of this sentence and the conclusions would help tease out the final point of the study a little better.

Following your comment, we revised our manuscripts. “preserve the penile length’ was change to “prevent penile shortening”.

3. The AMS LGX has been around for a while, it has not "recently” been developed (page 6, line 34)

Following your comment, we revised our manuscripts. “recently” was removed from background.

4. Was the patient weight recorded? that could have resulted in some differences in the "pubo-penile skin junction to the penile meatus". If this data is not available then perhaps this should be listed as a limitation?

Unfortunately, we did not record patient weight. So, “Finally, we did not record patient weight that could have resulted in some difference in the stretched flaccid penile length.” was inserted to discussion.

5. Detailed explanation of how the IPP surgery was done is not necessary for this type of a research paper

Following your comment, we revised our manuscripts. “The details of the IPP implantation ~ high submuscular space” was removed from Methods.

6. 10 patients experienced mechanical malfunction... at what time period did this happen. is this data available?

Mechanical malfunction was happen from 2 month to 11 month after operation.

7. Table 2, what is the P value comparing? how is this comparison made?
Statistically Comparing preoperative IIEF and all of the follow up period (postoperative3, 6, 12 month) is P-value in the table 3.

8. Figure 1-3 just seem to restate the findings in table 2. is there a point to these figures?
We inserted figure 1-3 to make it easy for the reader to understand improving IIEF score after operation.

9. There is mention of the flaccid penile length in the abstract and in the conclusions; however, nothing is shown in the tables or the figures of this data.
Following your comment, we revised our manuscripts.
We highly appreciate your invaluable comments.