

Peer Review File

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[Reviewer A]

Really its a good addition to literature pre existing studies, By applying the results practically the quality of life of patients with neurogenic bladder will be improved with adequate approaches.

Comment 1: Slight grammatical improvement before final publication recommended.

Reply 1: Thank you for your comment, we have polished the grammar throughout.

Changes in the text: Some grammatical correction throughout the paper.

[Reviewer B]

The Authors present a nice review on NIRS-based bladder volume monitoring. Just some minors:

Comment 1: Some figures and traces would be of great value.

Reply 1: Thank you for your suggestion. We have added 3D models to show the experimental set ups for the articles highlighted in our review. A mock-up of the bladder phantom proposed in our manuscript was also added.

Changes in the text: Added figures for the highlighted review articles and a figure to represent our proposed phantom.

Comment 2: Language should be slightly revised.

Reply 2: Thank you for your comment. We have revised some of the language used throughout the paper for clarity.

Changes in the text: Minor language changes throughout the paper.

[Reviewer C]

First, I would like to thank the authors for this article. I think that the question of an easy and disposable way to self-assess the bladder capacity could be really helpful for a lot of patients with voiding dysfunction.

Comment 1: I think that this article would greatly benefit from a more defined objective, possibly towards in-vitro, or in-vivo and in-vitro, validation methods for NIRS, as the title and the conclusion states it.

Reply 1: Thank you for this suggestion. We are striving towards a more standardized

in-vitro validation method.

Changes in the text: In-vitro validation was emphasized more throughout the text.

Please find my other remarks below:

INTRODUCTION

Comment 2: *Monitoring the bladder volume for patients who have to perform CISC is an insightful idea. I would argue that the need to perform CISC is required in patients with voiding dysfunction that may or may not be caused by neurogenic bladder. Thus, many non-neurologic patients would also benefit from such a device and the authors may consider to speak about all patients who have to perform CISC due to voiding dysfunction instead of neurogenic bladder only. (e.g., Girotti ME, MacCornick S, Perissé H, Batezini NS, Almeida FG. Determining the variables associated to clean intermittent self-catheterization adherence rate: one-year follow-up study. Int Braz J Urol. 2011;37(6):766-772. doi:10.1590/s1677-55382011000600013; <https://uroweb.org/guidelines/management-of-non-neurogenic-male-luts/chapter/disease-management>)*

Reply 2: It is true that many patients other than those with neurogenic bladder could potentially benefit. We freely acknowledge that any type of patient with voiding dysfunction could use these kinds of devices. However, restoring an indicator for bladder fullness could most directly benefit neurogenic bladder patients, thus we highlighted this patient group as the focus of our review.

Changes in the text: To provide more focus towards neurogenic bladder patients, the word “neurogenic” was included when mentioning bladder dysfunction throughout the review paper.

Comment 3: *“At worst, bladder overfilling can lead to leakage, distention, and severe complications”. I would delete the word “distention” as it is more a consequence than a complication, instead of infections, ureteric reflux or kidney failure.*

Reply 3: Thank you for the suggestion.

Changes in the text: The word “distention” was removed as suggested. Please see Page 3, line 60-61

Comment 4: *“Leading to more secluded lifestyles and a generally lower quality of life”. Do the authors have a reference about the lower quality of life? CISC usually do not decrease the quality of life of the patients as they often had previous symptoms due to their voiding dysfunction, but difficulties to perform CISC can lead to sub-optimal CISC schedules and abandon of the CISC (see above).*

Reply 4: While CSIC does not lead to a more secluded lifestyle and a general lower

quality of life, complications such as the inability to sense bladder fullness could lead to this outcome.

Changes in the text: An additional reference (Wheeler TL, De Groat W, Eisner K, Emmanuel A, French J, Grill W, et al. Translating promising strategies for bowel and bladder management in spinal cord injury. *Exp Neurol*. 2018 Aug;306:169–76) was added to support this statement. Please see Page 3, line 65

Comment 5: As I understand it, the review focuses on NIRS (results and validation methods), so the 1st part of the results (“a reliable method to estimate bladder volume is needed”) should be used as context in the introduction to avoid confusion.

Reply 5: Thank you for suggestion. As you had mentioned, our review is primarily focusing on the validation methods, but also providing a brief overview of all the studies that have utilized NIRS to create a device that can monitor the bladder volume.

Changes in the text: As suggested, we have moved the “a reliable method to estimate the bladder volume is needed” to the introduction section of our review. Please see Page 3-4, line 66-92.

Comment 6: The authors should state if the focus of this narrative review is on the results of NIRS in assessing bladder volume or on the approaches used in the literature to validate NIRS in assessing bladder volume.

Reply 6: Our review is focusing on the approaches used in literature to validate NIRS in assessing bladder volume as well as providing a brief overview of the studies that have utilized NIRS in assessing bladder volume and their results.

Changes in the text: Revised our title to clearly reflect the intention of the paper and changed various sections to make our purpose more identifiable.

Comment 7: The subject of the review would be clearer if it is clearly stated if validation means “in vivo”, “in vitro” or “in vitro and in vivo”. That would help readers to understand if they should expect a review of translational or clinical research.

Reply 7: Thank you for your suggestion. The focus of our study is in vitro validation. We will modify the text to make this clearer.

Changes in the text: We added the word in-vitro when mentioning validation in order to clearly convey the subject of our review throughout our paper. Furthermore, we made changes to the introduction to make it clear that we will be focusing on in vitro validation.

METHOD

Comment 1: The authors may delete the list of keywords as it is already reported in Table 1 and could add confusion.

Reply 1: TAU author guidelines states that about 3-5 keywords needs to be included within the manuscript. We do agree that this can cause some confusion due to the methodology of a narrative review also requiring keywords. Therefore, slight changes will be made to the main keywords to prevent any confusion.

Changes in the text: Removed ‘Near-Infrared Spectroscopy (NIRS)’ and ‘Non-Invasive Monitoring’ from the paper keyword list. We also added ‘Non-invasive’ to ‘Bladder Monitoring’, added ‘Bladder Phantom’, and ‘Neurogenic Bladder’. Please see Page 3, line 46.

Comment 2: The authors may state if they also included related articles in addition to the review.

Reply 1: Thank you for your suggestion.

Changes in the text: As suggested, within Table 1, we added whether we included related articles in addition to the review.

Comment 3: Regarding the keywords, did the authors try using the complete name (near infrared spectroscopy) in addition to the acronym? Did the authors considered using MeSH terms (Spectroscopy, Near-Infrared), and if not, why?

Reply 3: While MeSH terms are helpful in providing research results when using specific medical terminology, we found that the articles being produced were not relevant to near infrared spectroscopy for bladder monitoring. This could be due to the novelty of near-infrared being used for bladder monitoring. As for using the complete and acronym version of near infrared spectroscopy, we did use the full name along with the acronym to ensure that we were generating all the possible literature that was within our searching criteria.

Comment 4: Inclusion criteria are not stated in the Table 1.

Reply 4: Thank you for this comment, for transparency, we will revise our table to include this.

Changes in the text: Within Table 1, we have added the Inclusion criteria and described what we included in detail.

Comment 5: The language requirements are not stated in Table 1. In particular, did the authors included any Korean article or English literature only?

Reply 5: When writing the narrative review, only English literature was considered.

Changes in the text: We have included the language requirements as suggested within Table 1.

RESULTS (starting from “overview of bladder volume monitoring using light”)

Comment 1: *As in the previous parts, I think that this article would benefit from a clearer definition of its purpose. If the objective is to discuss the best phantom for testing NIRS, the authors may modify the table 2 to remove the ultrasound testings, as it may be confusing, and add details on how the studies on NIRS were performed. In particular, the methodology of the in vitro and in vivo parts could be detailed.*

Reply 1: Agreed, this review paper purpose is to specifically highlight NIRS-based devices. Therefore, ultrasound devices should be omitted.

Changes in the text: We removed any ultrasound paper from Table 2 and then added a column section to list each author's in-vitro validation method in detail. Please see Table file.

Comment 2: *The study from Fechner et al. (20) should be reported in table 2*

Reply 1: As Fechner et al. did not specifically report a NIRS device, we have decided to move this reference to the discussion section.

Changes in the text: We added the study from Fechner et.al to our discussion section, as the study provides insight into other methods that can be used in conjunction with NIRS. Please see Page 8-9, line 170-182.

Comment 3: *Regarding the study from Fechner et al. (20), I am not sure that mentioning the DSR method is really needed here, as it may add unwanted complexity instead of focusing on the population and on the technologies used to improve the accuracy of NIRS. If the authors wish to speak about the DSR, then I think that the DSR methods should be detailed for a better understanding.*

Reply 3: While reviewing this particular section, we agree that the information summarizing Fechner et. al works focused more on the DSR method rather than the population and the technologies used to improve the accuracy of NIRS. In addition, Fechner et. al study involving NIRS didn't include an in-vitro experiment. Therefore, we moved the reference Fechner et al. to the discussion section.

Changes in the text: Please see page 8-9, line 170-182.

Comment 4: *"5 males were only surveyed". Did the authors wanted to say "only 5 males"?*

Reply 4: During the revision process, this sentence was removed.

Changes in the text: While rewriting the section which included Fechner et. al, this sentence ended up being omitted.

Comment 5: *"Pascal Fechner et al. had stated that an in vivo study needs to be*

performed to test their A.I model realistically. In addition, they had stated that with their initial study 5 males were only surveyed. Therefore, a more heterogenous and a larger population needs to be surveyed, as well as an in vivo study with a large group needs to be conducted with a device using their proposed model.”. This paragraph looks like the authors directly cited Fechner et al. Could the authors reformulate to show that they express their own opinion?

Reply 5: Thank you for this comment.

Changes in the text: This sentence has been revised. Please see Page 8-9, line 170-182.

Comment 6: *“How can optical bladder monitoring be validated?” : As this part focuses on the bladder phantom, the sub title may precise that the subject is in vitro testing.*

Reply 6: Thank you for your suggestion.

Changes in the text: In order to discern whether the validation would be either in-vitro or in-vivo, the subtitle was changed to “How can optical bladder monitoring be validated in an in-vitro setting?”. Please see page 7, line 135.

Comment 7: *I understand that the authors want to describe a model useful for testing US and NIRS. Nonetheless, as the phantom is filled by the investigator, isn't the gold standard the volume filled into the phantom? Thus, authors may stress the pertinence of the proposed model for NIRS testing and downplay the US testing part, as it would be more a bonus as a way to compare to experimental techniques?*

Reply 7: The phantom described allows for water to be injected into a balloon, as a substitute for a bladder. While it could be assumed that the amount of water injected is accurate, we think it is still important for the phantom to be compatible with the real-world Gold-standard. This could be useful for comparison between technologies, such as Bland Altman analysis. By allowing the phantom to be compatible with both ultrasound and NIRS, the accuracy as well as margin of error of both technologies can be compared.

Changes in the text: Added this justification to the discussion on why the phantom should also be compatible with ultrasound. Please see Page 8, line 162-167.

Comment 8: *A figure of the proposed phantom could be helpful to help the reader to understand what the authors proposed.*

Reply 8: Thank you for your suggestion.

Changes in the text: We added our proposed bladder phantom in a 3D format within the figure file. Please see page 8 line 159-162 for a brief description.

Comment 9: *“Using values reported in literature, abdomen tissue can be simulated*

using the phantom”. It could be helpful to precise if the authors are speaking of the ballistic gelatin phantom.

Reply 9: The optical characteristics of ballistics gelatin could be manipulated to mimic abdomen tissue.

Changes in the text: Clarified that the ballistics gelatin could optically mimic abdomen tissue.

Abstract

Comment 1: *The same general remarks about the need for a more specific objective apply to the abstract. Please see also the remarks about neurogenic bladder and voiding dysfunction.*

Reply 1: Thank you for this insight, we believe that it would also be very helpful to define the objective more clearly.

Changes in the text: Throughout the paper, in-vitro was added before the word validation to present a more defined objective.

Comment 2: *The “Background and Objectives” part should be condensed. The mention of a specific goal (review of NIRS or review of validation approaches for NIRS) at the end of this part would improve greatly the understanding of the article.*

Reply 2: Thank you for your suggestion.

Changes in the text: We condensed our “Background and Objectives” section and stated our specific goal of the review. Please see page 2, line 24-34.

Comment 3: *The authors may specify that the proposed bladder phantom is an in vitro approach.*

Reply 3: Thank you for your suggestion.

Changes in the text: We have added the term ‘in vitro’ when mentioning our bladder phantom throughout the paper.

[Reviewer D]

I congratulate with your work. The paper is well written and easy to be read. The structure is adequate to a narrative review.

Comment 1: *The methods section is too synthetic: language selection? how many abstract were found and how many abstract were selected/discarded after being read?*

pathology selection?

Reply 1: Thank you for this suggestion. For more clarification and transparency, In the methods section of the paper, we included the language selection, and in Table 1, we included both the language selection, the number of abstracts found, and the number of articles that was discarded and selected.

Changes in the text: Table 1 was updated to include language selection, number of abstracts found, and number of articles included or excluded.

Comment 2: *The topic is interesting, but the description of the papers is really essential. We lack information on the population on which the devices have been tested (if they have been testes) and we completely lack information on the results.*

Reply 2: Thank you for your comment. Due to the novelty of the application, the two articles highlighted in our report were still in the proof-of-concept stage, and only a single healthy subject was measured in each. At this time, there has not been any documented clinical tests using NIRS-based bladder volume monitoring devices on patients. This information was already included in the text; however, we have added language to emphasize the novelty of this application.

Changes in the text: Language was added to stress novelty of this application. There is no clinical trial yet for the monitoring of bladder volume with this type of technology .

Comment 3: *The paper lacks a discussion.*

Reply 1: The section title “discussion” will be added to the review paper for more visibility.

Changes in the text: Discussion header added.