

## Peer Review File

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### Reviewer A

**Comment 1:** Geraci et al. conduct a study to validate the safety and feasibility of the Thoraguard Surgical Drainage System for patients undergoing robotic pulmonary resection. Compared to an analogue system, a higher number of air leaks were detected and resulted in decreased chest tube duration and hospital length of stay.

The suggestions were listed below:

1. The comparison was 200 patients retrospectively reviewed with more complications than the patients having digital drainage system. Is there any factors related to the higher complication rate? Is it possible that these factors also influenced the major findings of digital chest drainage (shorter chest tube duration and shorter hospital stay)? Please explained it and may mentioned it in the discussion or limitation section.

**Reply:** Thank you for this comment. We do not have a clear understanding why the complication rate is higher in the retrospective cohort. The study was conducted with the same surgeon, employing the same approaches, in the same hospital setting. We used 200 patients (as opposed to 50 or 100) which we thought would equal out these variables, but complications remained higher in the comparison group. Yes, certainly this is a limitation that we must include in the limitation section. By using medians, the effect of outlier values are reduced, such as those with a complication the lead to a much longer chest tube duration or length of stay.

**Changes in the text:** “The comparison arm of this study is limited, primarily, by its retrospective design, inviting potential selection bias. While the demographics were well matched, the analogue group had a longer operative time and a greater frequency of complications, both of which may have influenced chest tube duration and hospital length of stay.”

**Comment 2:** 2. Recently, a network meta-analysis, comparing chest drainage system, external suction chest drainage system and water seal chest drainage system, reported digital chest drainage system is associated with 0.68 days shorter chest tube duration and 1.4 days shorter hospital stay than the suction chest drainage system. The study may support the major outcome of this study. (Promising Effects of Digital Chest Tube Drainage System for Pulmonary Resection: A Systematic Review and Network Meta-Analysis)

**Reply:** Thank you for sharing this paper. We will include it in our review.

**Changes in the text:** Added reference #9 to comment section, “A meta-analysis assessing 3,399 patients reported a significantly reduced chest tube duration of 0.68 days and reduced length of stay of 1.4 days with the use of a digital drainage system.”

**Comment 3:** 3. Digital chest drainage system costs more than water seal chest drainage system. The findings in this study, shorter chest tube duration and hospital stay, could disclosed financial benefit or not.

**Reply:** Yes, we agree with this comment. Given that this was an initial safely and feasibility study, above all else, we did not include cost variables. Also, the company did not have cost for these units established at the time. It is our aim, as part of a future research project, to assess the financial value of using these devices. We have found them to be particularly safe to use at home/ after discharge, which has significantly reduced hospitalization and therefore, costs. Yes, the units are more costly up front vs the analogue systems, but the savings in hospitalization generates a net value.

**Changes in the text:** Added “financial value,” to the concluding statement about further research, which now reads, “Further research is ongoing to determine the optimal threshold of air leak for chest tube removal, prognostic indicators of air leak duration, system use the in outpatient setting, financial value, and assessment of patient-centered reporting on system usability.”

**Comment 4:** 4. Did the staffs complete the post-use qualitative survey anonymously.

**Reply:** Yes, the surveys were anonymous.

**Changes in the text:** “Anonymously” was added to the methods section, which now reads: “At the completion of the safety and feasibility trial, an post-use qualitative survey was administered anonymously to health care providers involved in the operative and perioperative care of patients with the Thoraguard system.”

**Comment 5:** 5. In the survey questions, the surgeon and the nurse reported differently. The surgeon reported a higher stisfication about Thoraguard’s ability to measure air leak and patients’ ability to ambulate with Thoraguard’s, but the nurse disclosed not much difference. (Half to 1/3 reported the same). Is there any explainable reason?

**Reply:** Some of the differences in reporting could have to do with the limited number of participants in each group, particularly, the surgeon group of only 5. We also found

the response by the nurses as “same” to ambulation on suction with the traditional system to be surprising, given that the patient is affixed to the wall in this scenario. Perhaps they were thinking “in room” ambulation, but this still remains unclear.

While no users were asked follow-up questions, we may postulate that Surgeons assess air leak through quantification with a digital system, whereas nurses at our institution assess air leak as “Yes/No.” Similarly, because patients at our institution are commonly ambulated at water seal, differentiation of mobile suction may be less noticeable.

**Changes in the text:** No changes made.

## **Reviewer B**

**Comment 6:** I am honored to have an opportunity to review this article describing the safety and effectiveness of new digital drainage system after pulmonary resection. The reviewer congratulates the authors on their hard work. The manuscript is well written, but some concerns should be addressed.

1. Operative time was significantly shorter in the Thoraguard group than in the Analogue group (122 min. vs 149 min.,  $p=0.003$ ). Is this due to the difference in the timing of surgery, that is, the proficiency of the surgeon? If so, I think it would greatly affect the drainage duration and postoperative hospitalization

**Reply:** The difference in operative time remains unexplained. We attempted to use a large number of retrospective patients (200, instead of 50 or 100) in order to minimize the differences in each comparison group. These were the 200 patients prior to the initiation of the digital drain study. The study was completed by the same surgeon, using the same techniques/ approaches, the same perioperative team, and the same hospital setting. It is unclear why there is a difference in operative time. This limitation is reported in the comments section.

**Changes in the text:** “While the demographics were well matched, the analogue group had a longer operative time and a greater frequency of complications, both of which may have influenced chest tube duration and hospital length of stay.”

**Comment 7:** 2. In this study, the authors found the Thoraguard system identified a greater number of air leaks in the PACU than the analogue system, 72% versus 23% respectively ( $p<0.001$ ). I’m not sure why this superior detection leads to an early removal of chest drainage tube in the Thoraguard group. Is this due to the Thoraguard system's ability to regulate intrathoracic pressure? Or, due to be able to reduce chest

tube-associated interventions such as clamp trials?

**Reply:** We appreciate this comment, which was also mentioned by another reviewer. We should not imply that a higher detection rate leads to early removal. Language to this effect in the abstract and manuscript have been changed and/or deleted. These are two separate observations, which are a result of the Thoraguard's accuracy in detection. So, it's the accuracy in defining the air-leak that leads to early removal as the surgeon is assured that the air leak has resolved or continues. Equally, "superior detection" can be replaced with "superior assessment", as digital air leak assessment is not exclusively for the benefit of identifying air leak resolution, but also for the documentation of presence of air leak and trending of progress.

Yes, the accuracy of the system reduces the need for clamp trials, and thus reduces chest tube duration. We did not collect data related to clamp trials in this study. However, this is our anecdotal experience.

The system does not regulate intrathoracic pressure or apply any therapy that reduces chest tube duration.

**Changes in the text:** Changes implying detection leading to reduced chest tube duration have been amended throughout the manuscript. We have avoided causality language as this is not supported by the data; only associations.

## **Reviewer C**

**Comment 8:** The authors reported some advantages of the Thoraguard surgical drainage system. It provides safe and effective drainage for the patients with pulmonary resection.

**Reply:** Thank you, yes, reporting safe and effective use of this new system was the primary intention of the study.

**Changes in the text:** No changes made.

## **Reviewer D**

**Comment 9:** The authors submitted their manuscript untitled: "Use of a Novel Digital Drainage System after Pulmonary Resection".

They conducted a three-part study, firstly assessing the feasibility/safety of this novel digital drainage system on 50 patients treated with RATS Lobectomy, secondly comparing the results with a retrospective cohort of 200 patients also treated with RATS Lobectomy but with an analogue drainage system, and thirdly with a clinician feedback survey.

The manuscript was of interest, well designed, and I found no report of previous assessment of this device in the literature.

My comments are below:

1. The manuscript is well written. English is ok.

**Reply:** Thank you. We appreciate your comments and recommendations to improve the manuscript.

**Changes in the text:** No changes made.

**Comment 10:** 2. Regarding result in Table 2 and Table 3. Usually the p value is given for a group of variable and not for each variable. As an example, an overall p value for pathology in table 2 should be given instead of a separated p value for malignancy, benign and infectious disease. This remark also concern the type of operation in table 3.

**Reply:** Thank you. Yes, we agree with the group P-value and have recalculated the variables in SPSS and reported the single P-value in the tables for both Operation and Disease.

**Changes in the text:** P-values changed in Tables 1 and 2.

**Comment 11:** 3. The study is well conducted despite not being a prospective randomized trial, which is usually the best methodology to perform such study (Pompili. Ann Thorac Surg. 2014 Aug;98(2):490-6; discussion 496-7). Thus, even if the two cohorts are similar (excepted regarding surgery duration), the retrospective design may potentially leads to a measurement bias, as air leaks may have been underreported in the medical report. Undoubtedly the digital drainage system are more precise than analogue drainage system, but the difference may be heightened by this bias. Please comment on that.

**Reply:** Yes, we agree with this limitation to the paper. The primary goal of the paper is to report our safety and feasibility arm of the paper. A retrospective review gives

the report greater context despite not being perfectly matched. We did not believe the data necessary for a propensity matched study was warranted. We have acknowledged this limitation in the comment section.

Air leaks in the analogue group are likely more common than reported because of the subjective nature and the “moment in time” assessment methodology. McGuire et al (2015, Digital versus analogue pleural drainage phase 1: prospective evaluation of interobserver reliability in the assessment of pulmonary air leaks) highlighted the potential for interobserver variability. The digital system’s use of tracking and displaying air leak data over time will likely detect more active air leaks.

**Changes in the text:** “The comparison arm of this study is limited primarily by its retrospective design, which is subject to selection bias. While the demographics were well matched overall, the analogue group had a longer operative time and a greater frequency of complications, both of which may have influenced chest tube duration and hospital length of stay. Essentially, these groups were not propensity matched, limiting the strength of our conclusions.”

**Comment 12:** 4. I suppose that prior to the use of the Thoraguard device, the study team also used other digital drainage system. This is reinforced by the comparison with other digital drainage displayed in table 4. Surgeons and Nurses both reported a better assessment of air leaks on this device compared to other digital drainage devices. A comment between this digital drainage system (thoraguard) and other digital drainage devices (pro & cons) should be of interest for the reader in order to understand why the authors attributed a better air leaks detection with this device.

**Reply:** Yes, while we do have experience with other digital drainage systems, we believed this direct comparison would distract from the central messages of the paper. Our goals were to present safety and feasibility with some comparison to the analogue systems. A shoot-out between the digital systems is difficult, as it would require a significant enrollment to generate a difference. While anecdotally, we believe this unit is superior in accuracy and functionality, this is little more than our opinion and therefore, we don’t believe should be a force of this paper. We report the survey results to situation the unit in the context of other options, simply to note that users were overall satisfied with its function.

For the reviewer, however, these are the structural differences between the units, which we believe results in a superior clinical experience. These, to date, however, are only our opinions.

<u>Feature</u>	<u>Thoraguard</u>	<u>Thopaz+</u>
Minimum Air Leak Measurement	1 ml/min	Rounding function: 0 – 5 ml/min = 0

		5 – 15 ml/min = 10
Gravity Mode / Water Seal	0 cmH <sub>2</sub> O	-8 cmH <sub>2</sub> O
Pleural Assessment Mode	Always	Only when Air Leak = 0
Canister Size	1200 mL	300, 800, 2000 mL
System Operation	Touchscreen	Push button
Handle Positioning	Retractable	Fixed

**Changes in the text:** No changes made.

**Comment 13:** 5. Lastly, authors highlighted in the comment section that digital drainage devices have been retained in the literature to be associated with better precision, shorter drainage duration and shorter postoperative hospital stay. With this in mind, I regret the comparison with an analogue system, which we know is now outdated, and not with any other existing digital drainage system.

**Reply:** This was the initial use of this system in human patients as this is a new technology, despite similar systems already in the market. The primary import is to report feasibility and safety. With this established, there is potential for a comparison with another digital systems, however, the number of enrollment needed for this study would be significant. Our goal with the retrospective arm was to add to the existing literature supporting the use of digital systems and show that it was reproducible with the next Thoraguard unit. Surely, more nuanced comparisons will be generated in the future given the ability of these units to collect data. These will be exciting reports, but beyond the scope of our initial report.

**Changes in the text:** No changes made.

## Reviewer E

**Comment 14:** The authors retrospectively evaluated the safety and feasibility of the Thoraguard system to compared to an analogue drainage system in patients underwent robotic pulmonary resection. They found that a higher number of air leaks were detected and resulted in decreased chest tube duration and hospital length of stay in patents using the Thoraguard system. User survey data reported superior air leak detection, display of clinical data, and ease of use of the Thoraguard system.

While there have already been papers on postoperative drain management using digital systems, this study contains valuable results using a new device. The authors have accomplished a commendable study.

I have the following concern.

#### Comment

In the PACU, air leaks were detected at a higher rate in the Thoraguard group.

However, drain removal was faster in the Thoraguard group.

Do these results mean that air leaks in the PACU do not need to be considered a problem in the clinical course? Is it because quantification of air leak is more important than qualitative in this system?

What is the scientific opinion on the clinical importance of leaks in the PACU?

**Reply:** Thank you for this comment. The detection of air-leak in the PACU holds value in a number of ways. Primarily, it is a reflection of the accuracy of the Thoraguard system. This means that there are air-leaks that the analogue, qualitative, systems are not capturing. While many surgeons are not ready to remove the tube in the PACU, the same concept applies on POD#1. Meaning, there is likely a group of patients that have a leak that is not detected on an analogue system. Anecdotally, this manifests as post-pull pneumothorax, of which all surgeons have experienced. Secondly, there will likely be prognostic information that we can research regarding the volume/ min flow of air that will predict when the air-leak may resolve. We have included some of this data in the manuscript, that is: "patients with a peak air leak less than 100 ml/min (32 patients, 64%), had a decreased median chest tube duration of 1 day (IQR 0-1) versus 2.8 days (1-3 IQR) (P=0.004)." Further research is needed to define these values and predictive algorithms. Capturing accurate leaks, such as with the Thoraguard, will make this possible. Lastly, we also believe that there will be instances in which removal of the chest tube in the PACU is the appropriate management, if no leak is measured. This requires accurate detection. While this is not our current practice, we will continue to research the use, or lack of use, of chest tubes post robotic lung resection.

**Changes in the text:** No changes made.

#### Reviewer F

**Comment 15:** I have read with interest your manuscript especially because you were presenting a new digital chest drainage which is always a good new.

I have liked the drainage system based on the results of the survey, because the system seems to be easy to use and highly informative. I agree with the authors the use of the system is feasible and it has shown a good safe profile. However I do not see the real advantages of it. That is the reason to suggest a major review.

Comments for improvement:

- All patients had been operated on by the same surgeon but in different periods of time. Therefore, I think it would be desirable to elaborate and present the experience



of the surgeon for both subsets of patients.

**Reply:** Thank you for this comment. We have attempted to limit our opinions regarding our perceived benefits of the Thoraguard system and have presented our data for the thoracic community to interpret, to consider possible benefits, and consider application to their own practices. The primary advantage of the system is its accuracy. Accuracy allows faster removal of the chest tube, because the team is assured that the leak is gone. Anecdotally, it has reduced the need for clamp trials and has reduced the incidence of post pull pneumothorax. The system is entirely portable, which means it can maintain suction and allow ambulation, which is a significant improvement from being attached to wall suction. The system is easily interpreted by all members of the team, such that communication is streamlined—no longer did one member of the team see a leak, and the other did not. Essentially, interobserver variability is gone. Also, the unit can be used effectively as an outpatient. All of these observations, however, are beyond the scope of an initial safety and feasibility trial and should be addressed in separate focused research, which is ongoing at our institution.

**Changes in the text:** No changes made.

**Comment 16:** - It is interesting to note that patients in the Thoraguard system have a larger number of air leak detected however this detection is of no clinical meaning because they have the chest tube removed faster and a shorter length of stay. On the other hand, no patient in either group needed chest tube re-insection because of post-removal significant pneumothorax. What is the real advantage? Would you please comment on that

**Reply:** Thank you for this comment. The detection of air-leak in the PACU holds value in a number of ways. Primarily, it is a reflection of the accuracy of the Thoraguard system. This means that there are air-leaks that the analogue, qualitative, systems are not capturing. While many surgeons are not ready to remove the tube in the PACU, the same concept applies on POD#1. Meaning, there is likely a group of patients that have a leak that is not detected on an analogue system. Anecdotally, this manifests as post-pull pneumothorax, of which all surgeons have experienced. Secondly, there will likely be prognostic information that we can research regarding the volume/ min flow of air that will predict when the air-leak may resolve. We have included some of this data in the manuscript, that is: "patients with a peak air leak less than 100 ml/min (32 patients, 64%), had a decreased median chest tube duration of 1 day (IQR 0-1) versus 2.8 days (1-3 IQR) ( $P=0.004$ )." Further research is needed to define these values and predictive algorithms. Capturing accurate leaks, such as with the Thoraguard, will make this possible. Lastly, we also believe that there will be instances in which removal of the chest tube in the PACU is the appropriate management, if no leak is measured. This requires accurate detection. While this is

not our current practice, we will continue to research the use, or lack of use, of chest tubes post robotic lung resection.

**Changes in the text:** No changes made.

**Comment 17:** - On the other hand you comment on the suction advantages provided by the new system but you are only using suction the first night after surgery. Then you removed the chest tube in the vast majority of the patients having almost no time to evaluate this capacity. Can you elaborate based on the short number of patients (if any) the clinical observed advantages (if any)

**Reply:** Thank you. Our patients are instructed to ambulate the night of surgery, making the portability of the unit an important consideration. Equally, not all surgeons are comfortable discharging their patients on POD#1. While this has been our practice, the national average is a 4-5 day hospitalization, where the importance of ambulation will be heightened. As we note in the manuscript, “Theoretically, the benefit of a digital chest drain would be greatest in patients with a longer postoperative hospitalization for chest tube drainage.”

**Changes in the text:** No changes made.

**Comment 18:** - You properly report the length of stay, however you are mixing concepts because there a certain group of patients that having the chest tube removed stay in the hospital for other reasons (which is totally normal). I would suggest splitting the analysis of the length of stay in two: general LOS and LOS related to chest tube duration for better understanding of the influence of the chest drainage system on it.

**Reply:** We appreciate that there is a difference here, but we did not collect the difference between LOS related to chest tube duration and overall LOS. However, this can be inferred from the reported chest tube days, which are shorter in the digital system, which is statistically significant. This reveals the potential influence of the chest drainage system on LOS, although given its retrospective nature, it is only an association. The overall LOS mirrors an intention to treat analysis, where the outcomes are measured in a real work, particle application.

**Changes in the text:** “There was a decrease in chest tube duration of 1 day (IQR 0-2) versus 2 days (IQR 2-3) (P=0.042).”

**Comment 19:** - Does both populations received any perioperative chest physiotherapy? Were them enrolled in any fast track program?

**Reply:** We do employ a number of aspects of “enhanced recovery” in our standard of care, such as preoperative analgesia, minimally invasive robotic surgery, early ambulation, etc. All patients, in both groups, were treated with the same protocols. We do not include chest physiotherapy in our care, but patients do use an incentive spirometer.

**Changes in the text:** No changes made.

## **Reviewer G**

Title:

Use of a Novel Digital Drainage System after Pulmonary Resection

Study Design:

Trial of a new digital pleural drainage system with prospective and retrospective components

Prospective observational cohort study (n=50):

50 lung resection cases where device was used

Retrospective cohort-study (n=250):

50 patients from observational study were compared to 200 controls who underwent analog device drainage after lung resection

User survey (n=23)

Study period = 22 months

Objective:

1. Assess safety and feasibility of using new digital drainage system
2. Compare outcomes to analog drainage device
3. Evaluate usability and performance qualitatively

Outcomes:

1. Dynamics of chest tube drainage
2. Chest tube duration
3. Perioperative complications
4. Usability/ performance

## Comments to the Authors:

The authors should be congratulated for generating objective data on a newer digital device designed to monitor and drain the pleural space. The manuscript reads well. However, it would still benefit from further grammatical and syntax review. The following comments are organized according to the section of the manuscript to which they apply.

### Abstract

**Comment 20:** This is not a cross-sectional study design. The multiple phases do not make this cross-sectional.

**Reply:** Thank you for this correction. We have simplified the language in the abstract and manuscript to more accurately define the study design. We have defined this primarily, as an observational study.

**Changes in the text:** Changes to describe the study design as not cross-section, but observational, has been made throughout the manuscript. As the abstract reads, “A three-part study was conducted: a prospective observational safety and feasibility trial, a retrospective comparison of patients managed with an analogue drainage system, and a clinician user-feedback survey.”

**Comment 21:** Some conclusions are not supported by the data. To determine if the digital device is more sensitive to detect air leaks, the same cohort of patients would have to be evaluated with both digital and analog drainage devices. This would require a very complex experimental setup. It is already known that digital devices detect much smaller air leaks and this is highlighted by the fact that removal of chest drains is considered safe even when there is a measurable air leak.

**Reply:** We agree that the digital devices are more sensitive and therefore identify air-leaks more often than an analogue system. We also agree regarding the complex design and practical clinical limitations of having patients connected to multiple drains. In our opinion, the observed difference between the systems in air-leak detection was significant enough to report, regardless of study design.

The detection of air-leak in the PACU holds value in a number of ways. Primarily, it is a reflection of the accuracy of the Thoraguard system. This means that there are air-leaks that the analogue, qualitative, systems are not capturing. While many surgeons are not ready to remove the tube in the PACU, the same concept applies on POD#1. Meaning, there is likely a group of patients that have a leak that is not detected on an analogue system. Anecdotally, this manifests as post-pull pneumothorax, of which all surgeons have experienced. Secondly, there will likely be prognostic information that

we can research regarding the volume/ min flow of air that will predict when the air-leak may resolve. We have included some of this data in the manuscript, that is: "patients with a peak air leak less than 100 ml/min (32 patients, 64%), had a decreased median chest tube duration of 1 day (IQR 0-1) versus 2.8 days (1-3 IQR) (P=0.004)." Further research is needed to define these values and predictive algorithms. Capturing accurate leaks, such as with the Thoragaurd, will make this possible. Lastly, we also believe that there will be instances in which removal of the chest tube in the PACU is the appropriate management, if no leak is measured. This requires accurate detection. While this is not our current practice, we will continue to research the use, or lack of use, of chest tubes post robotic lung resection.

**Changes in the text:** No changes made.

**Comment 22:** Chest tube duration is a major determinant of LOS. The authors should be careful not to imply causality when referring to the association between the use of digital devices and reduced LOS.

**Reply:** We agree that while chest tube duration is a major determinant of LOS, we cannot imply causality between the digital devices, only report an association. That said, we found a statistically significant difference in chest tube duration between the groups.

**Changes in the text:** We have changed the language in the text to refrain from implying causality for all conclusions and have replaced these instances with "associations" given the retrospective nature of the study design. We have equally decreased the claim of accuracy and have focused on reported data.

For example, "Compared to 200 prior patients who were managed with an analogue drainage system, the Thoraguard system identified air leaks after surgery and was associated with a reduced chest tube duration and hospital length of stay."

We have removed the following sentence from the comment section: "This superior detection rate led to a difference in chest tube duration and hospital length of stay."

Introduction

No specific comment.

Methods

**Comment 23:** The author should specify that phase I was an observational trial.

**Reply:** We agree and have made the appropriate changes throughout the abstract and manuscript.

**Changes in the text:** All instances regarding the initial prospective arm of the study have been defined as “observational.”

**Comment 24:** How does this device report transpleural airflow? What is the frequency of airflow measurement? If the airflow is graphed on the device display, how is the graph generated? When the outcome of airflow prior to chest tube removal was recorded, which number was used (numerical display or graph)? How is the numerical display of airflow generated (is it an average of multiple measurements)? This technical information may help the readership better understand how this technology works.

**Reply:** The device reports air-flow through the device in mL/min and the frequency of measurement is near continuous. In separate menus, the device graphs this data over time by various increments of time (e.g 6 hours, 12 hours) as well has for fluid output. The airflow prior to chest tube removal was recorded based on the numerical display (which would be the same current value graphically). As described in the methods, “to determine air leak rate, the control module uses a tachometer on the pump to count revolutions of the motor in conjunction with pressure measurements and pump speed.”

**Changes in the text:** No changes made.

**Comment 25:** What were the criteria used to determine if an air leak was clinically resolved when using the digital drainage device? For instance, with other devices, the airflow must be less than a certain threshold value for several consecutive hours (e.g.: < 30 mL/min for 8 hours). There is a reference to this in the Comment section, but this information belongs in the Methods. Also, there is no time interval specified. How long was the patient observed to have an air leak < 20 mL/min before the chest tube was removed? The authors should provide a measure of central tendency for this time interval for the 50 patients in the prospective observational cohort. This will be of interest to readers contemplating the use of this device.

**Reply:** There is a section in the paper titled “Chest Tube Management,” that includes the information requested. Specifically, “In the Thoraguard group, when an air leak flow rate was below 20 ml/min for at least 6 hours, we considered chest tube removal per the discretion of the operating surgeon.” The section has other details of our protocol, including suction/ waterseal, provocative tests, and fluid volumes.

**Changes in the text:** No changes made.

**Comment 26:** How was the air leak assessed in the recovery room for patients who had analog drainage (cough, Valsalva, suction, no suction, etc.)? Was the methodology standardized for all patients?

**Reply:** In the PACU, patients with an analogue chest drain were assessed for air leak on water seal, while instructed to cough. This was standardized in all patients.

**Changes in the text:** The following has been added to the Chest Tube Management section, “In the PACU, patients with an analogue chest drain were assessed for air leak on water seal, while instructed to cough.”

**Comment 27:** The “dynamics of chest tube drainage” outcome needs to be defined. What exactly is being measured?

**Reply:** We agree that this is overly vague. We have changed the text to be more accurate.

**Changes in the text:** “Safety and feasibility were assessed based on clinical outcomes, air and fluid chest tube drainage, chest tube duration, and associated perioperative complications.”

**Comment 28:** What is the relevance of comparing all perioperative complications? Why not focus on chest tube related and/or pleural complications which are more relevant to using a new pleural drainage system.

**Reply:** We included all complications in an effort to be inclusive of all possible safety concerns. It’s plausible that any event, such as bleeding for example, could be attributed to the chest tube system, so in a setting of first use, all events were recorded and reported.

**Changes in the text:** No changes made.

**Comment 29:** How did the authors determine the size of the retrospective comparison cohort? Why is it four times larger? Did the authors consider propensity score matching to create their 4:1 comparison cohort? Why is 4:1 necessary?

**Reply:** Our goal with the comparison group was to generate enough data to create as equal groups as possible. We considered a propensity matched study, which would

have greatly strengthened our conclusions, but the amount of retrospective data collection necessary to match the 50 patients was prohibitive. A review of all the data for 200 patients itself was a significant undertaking. 4:1 does not have any magic statistical significance, but we thought it was generous enough to create an appropriate comparison group.

**Changes in the text:** No changes made.

## Results

**Comment 30:** Why are there no statistical comparisons of the results of the survey?

**Reply:** We did not generate statistics for this data because of the low number of participants. The point of including the survey is to give readers a general reflection of the usability and ease of function with the new system. It is not rigorous, but we did not believe that to be necessary in a user survey, which is already subject to selection bias and low power.

**Changes in the text:** No changes made.

**Comment 31:** Table 2: What are the units for air leak volume?

Maximal air leak volume is expressed in mL/min which is a unit used to measure airflow (or volume of air drained per unit of time). There needs to be a clearer distinction between airflow (i.e., volume per unit of time) and air volume.

**Reply:** Yes, thank you for this comment. We agree that we are measuring flow, but reporting volume in the manuscript. We have corrected this throughout to be a measure of flow. Clinically, we refer to this as “volume,” but you are correct, this is flow.

**Changes in the text:** All instances of “volume,” has been changed to “flow” in the manuscript.

**Comment 32:** Rows 7,8, and 9 are difficult to interpret.

**Reply:** I apologize, but I do not understand which phrases this comment is referencing. In the manuscript, rows 7, 8, and 9 are authors.



**Changes in the text:** No changes made.

**Comment 33:** There are no reported chest tube management outcomes such as complications arising from premature chest tube removal. It is briefly stated in the text, but it should also be included in the table. Also, this is unnecessarily repeated in lines 79 and 81.

**Reply:** We have included a row in the Table 2 to include the requested data for complications arising from premature chest tube removal, specifically, reinsertion of a chest tube.

**Changes in the text:** “Chest tube complications” added to Table 2.

**Comment 34:** Explain the relevance of operative time to the objectives of the study. Why was the operative time longer in the analog cohort? Was this related to case complexity?

**Reply:** Thank you for this comment. We do not have a clear understanding why the complication rate is higher in the retrospective cohort. The study was conducted with the same surgeon, employing the same approaches, in the same hospital setting. We used 200 patients (as opposed to 50 or 100) which we thought would equal out these variables, but complications remained higher in the comparison group. Yes, certainly this is a limitation that we must include in the limitation section. By using medians, the effect of outlier values are reduced, such as those with a complication the lead to a much longer chest tube duration or length of stay. The retrospective group were not noted to be of a variable complexity.

**Changes in the text:** “The comparison arm of this study is limited, primarily, by its retrospective design, inviting potential selection bias. While the demographics were well matched, the analogue group had a longer operative time and a greater frequency of complications, both of which may have influenced chest tube duration and hospital length of stay.”

**Comment 35:** If air leak detection is reportable with this study design (and this is not clear based on my previous comments), then an effort should be made to compare the cohorts regarding risk factors for prolonged air leak. For instance, the proportion of R upper lobe procedures in each group could be added.

**Reply:** We appreciate this comment, but disagree that reporting risk factors for air leak is necessary for reporting the frequency of detection. While certainly, we believe

matching patients in a comparison study as equally as possible is important; we did this to the best of our ability by demographics and operative course. As mentioned prior, we did not have the resources to collect data for a propensity matched study, which is noted in the comment section as a limitation of the study.

**Changes in the text:** “The comparison arm of this study is limited primarily by its retrospective design, which is subject to selection bias. While the demographics were well matched overall, the analogue group had a longer operative time and a greater frequency of complications, both of which may have influenced chest tube duration and hospital length of stay. Essentially, these groups were not propensity matched, limiting the strength of our conclusions.”

**Comment 36:** Line 84: mL/min is a unit of airflow measurement not volume. This semantic error must be corrected throughout the manuscript

**Reply:** We agree. As previously mentioned, we have reviewed the manuscript to make these corrections throughout.

**Changes in the text:** Flow has been substituted for volume throughout.

**Comment 37:** As I understand from conversations with the company making this device, there is wireless communication functionality to display patient data remotely. Was this functionality used during the trial? Could the personnel who have used this be surveyed for their feedback on this enhancement over other digital drainage devices?

**Reply:** Yes, there are plans for wireless communication functionality in future generations of the Thoraguard system. In this study, however, this was not used. This feature will be particularly valuable for using these devices as home/ outpatient setting.

**Changes in the text:** No changes made.

**Comment 38:** Was digital drainage data exported from the devices and saved for analysis of the efficiency of chest tube management? For instance, what was the average delay between the time at which the air leak resolution criteria were met, and the chest tube was removed? This is briefly alluded to in the Comment section.

**Reply:** Yes, data regarding the time between when criteria for removal have been met and actual chest tube removal are collected. We did not measure these prospectively during this initial trial. However, we are working to develop a system where the unit will alert the user when criteria is met, such that efficient and earliest tube removal

can be considered. We do plan on researching these topics in future studies.

**Changes in the text:** No changes made.

**Comment 39:** It would be interesting to see a statistical comparison of the answers to the survey to determine if there is a significant difference between “better” and “the same”. A visual analog scale would have been a better choice to quantify the answers.

**Reply:** We did not generate statistics for this data because of the low number of participants. The point of including the survey is to give readers a general reflection of the usability and ease of function with the new system. It is not rigorous, but we did not believe that to be necessary in a user survey, which is already subject to selection bias and low power.

**Changes in the text:** No changes made.

**Comment 40:** Comment. See my comments in the abstract section regarding the detection of air leaks. Again, the authors imply cause-and-effect relationships between the sensitivity of the device to detect air leaks and duration of chest tube drainage and LOS. This conclusion is not supported by the data presented.

**Reply:** We have changed the language of the abstract and conclusion to avoid stating a cause-and-effect relationship as we agree, these are only associations. We also deleted the inferences that a greater detection rate “resulted” in the observed outcomes as this is also not supported by the data.

**Changes in the text: Example from abstract, also replicated in the conclusion:**  
“Compared to an analogue system, the Thoraguard system detected a higher number of air leaks and was associated with decreased chest tube duration and hospital length of stay. User survey data reported superior air leak detection, display of clinical data, and ease of use of the Thoraguard system.”

**Comment 41:** Limitations should also include those related to retrospective study designs. It is doubtful that the retrospective comparison provided an “accurate comparison” as stated.

**Reply:** Yes, we agree. This has been added to the limitations.

**Changes in the text:** “The comparison arm of this study is limited primarily by its retrospective design, which is subject to selection bias. While the demographics were well matched overall, the analogue group had a longer operative time and a greater

frequency of complications, both of which may have influenced chest tube duration and hospital length of stay. Essentially, these groups were not propensity matched, limiting the strength of our conclusions.”