Surgeon Perspectives on Anastomotic Leaks and FluidAI's Stream™ Platform: Integrating Qualitative Insights for Technological Innovation

Olivia Rennie[1,2*], Manaswi Sharma[1], Nour Helwa[1]

[1]Department of Clinical Affairs, FluidAI Medical (Formerly NERv Technology Inc.), Kitchener, Canada
[2]Faculty of Medicine, University of Toronto, Toronto, Canada
Email: *orennie@fluidai.md

Abstract

Purpose: This article investigates the critical importance of integrating surgeons' direct input into the development of innovative technologies that address gaps in surgical care, including those aimed at reducing anastomotic leaks (AL), a major complication in gastrointestinal surgery. While traditional quantitative research methods are prevalent, they often overlook the invaluable insights of the surgeons who manage these complications firsthand. **Subjects and Methods:** This study employs a qualitative approach, utilizing semi-structured interviews with 40 surgeons from various specialties, including general, bariatric, colorectal, trauma, hepato-biliary, and thoracic surgery. The interviews were designed to probe the needs of surgeons, challenges currently faced, and gaps in clinical practice, research, and technology for detection and/or management of AL. The data were analyzed using thematic analysis, which revealed significant gaps in current technologies for early detection and prevention of leaks. **Results:** Surgeons expressed strong interest in FluidAI's Stream™ Platform, a non-invasive medical device designed to monitor postoperative drainage fluid in real-time, providing continuous data on AL risk. The ability of this platform to offer early prediction through pH and electrical conductivity analysis was particularly appealing to participants, who emphasized the importance of timely interventions in improving patient outcomes. The study's findings highlight not only the clinical challenges but also the emotional toll that AL takes on surgeons, underlining the need for innovations that are both data-driven and humanistic. **Conclusion:** By centering surgeons' perspectives, this research advocates for a human-centered approach to technological advancement, ensuring that new tools are both

clinically effective and aligned with the real-world needs of surgical practitioners.

Keywords

1. Introduction

When it comes to postoperative research and innovation, quantitative studies are a common strategy for probing the performance of new technology—whether that be in the lab during development, or out on the field in clinical practice. While there is no denying the value of these studies, it is also easy to lose sight of one of the most important stakeholders in surgical care—the surgeons themselves—in the process. In particular, when considering innovative means of addressing some of the deadliest and most costly complications, we must rethink, re-envision, and re-integrate holistic discussions into the research process. For those practicing gastrointestinal surgery, anastomotic leaks (AL) are one of the most feared postoperative complications, carrying high rates of morbidity and mortality, alongside significant economic costs to healthcare systems [1]-[3].

Despite the seriousness of AL, little has changed in recent years to improve patient outcomes. While surgical techniques continue to advance, creating an anastomosis still carries the risk of leakage. In order to optimize patient outcomes and minimize the impact of AL, it is imperative that new technologies are rigorously explored—but that this is not done in isolation. Rather, by bringing surgeons into humanistic and open conversations, their voices can be taken into account in profound ways during the research and development process, thus driving innovation at the source.

Highly influenced by Baigrie and Stupart's 2023 article, "Coping with anastomotic leaks as one gets older", we undertook an investigation combining our research on early leak prediction with a humanistic approach aimed at understanding the impact of leaks psychologically, emotionally, and the gaps that new technologies developed for leak prevention/prediction/diagnosis would need to fill [4]. What we present here is an example of how human-driven discussions surrounding surgical technologies pave the way not only for new data-driven insights to be derived, but also enables fears, concerns, and desires of surgeons to be brought into consideration during research and innovation.

The technology under exploration here is a medical device developed for early prediction of AL, FluidAI's Stream™ Platform, a cutting-edge medical device designed for the early prediction of AL through non-invasive and continuous monitoring of postoperative drainage fluid. The platform operates by analyzing two key biomarkers—pH and electrical conductivity—within the drainage fluid,

both of which can indicate early signs of anastomotic failure [5]-[7]. These biomarkers are continuously monitored through sensors connected to the drainage tubes, which are external to the patient. The data collected is then transmitted in real-time to an application accessible to clinicians, allowing for earlier leak risk prediction, assessment, and intervention (if applicable). In this study, the utility of this technology was explored with an eye towards the specific needs of surgeons, driven by considerations that were both psychological and scientific in nature.

2. Methods

2.1. Research Design

This study employed a qualitative research design, centered on semi-structured interviews with 40 surgeons from various specialties across the United States, including general, bariatric, colorectal, trauma, hepato-biliary, and thoracic surgery. Surgeons were selected based on specific criteria: board certification, 5 - 30 years of surgical practice, performing at least seven surgical procedures per month, and having a role in departmental decision-making regarding new technologies. Recruitment ensured diversity by limiting the number of participants from a single state or hospital, and ensuring a balance between academic and private/community practices (Figure 1).
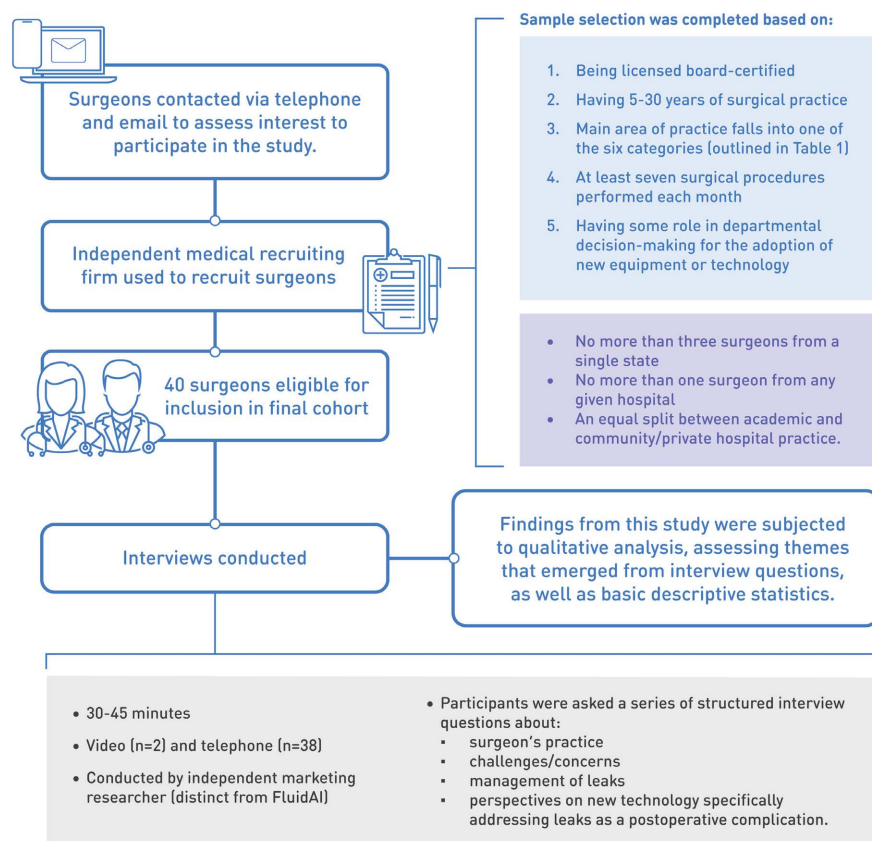
Figure 1. Summary of study methods.

2.2. Data Collection

Interviews were conducted via telephone (n = 38) or video (n = 2) through an independent medical recruiting firm, lasting 30 - 45 minutes, and covered topics such as current practices, gaps in postoperative care, challenges in managing leaks, and initial reactions to Stream™ Platform. Interviews were audio-recorded, transcribed, and subjected to qualitative analysis, assessing themes that emerged from interview questions, as well as basic descriptive statistics.

3. Results

3.1. Participant Demographics

The study engaged 40 surgeons from six different specialties, including general, bariatric, colorectal, trauma, hepato-biliary/pancreatic, and thoracic surgery. The participants were diverse in terms of their years of practice (ranging from 5 to 30 years) and geographical distribution, ensuring a broad spectrum of perspectives. Surgeons reported performing an average of 35 surgeries a month (averaged across specialties), with a mix of scheduled and emergency procedures (**Figure 2**, **Table 1**). Unsurprisingly, trauma surgeons had the highest proportion of emergent/urgent surgeries (42%), while hepato-biliary/pancreatic surgeons reported the fewest (4%).


Figure 2. Geographical distribution of participants. Numbers 1 - 4 represent sample size from each respective state.

Table 1. Breakdown of specialties, years in practice, and surgeries per month of final participant cohort.

Specialty	Average Years in Practice	Average Surgeries per Month
General Surgery (n = 7)	23	39
Bariatric Surgery (n = 7)	17	41
Colorectal Surgery (n = 7)	23	43
Trauma Surgery (n = 7)	25	29
Hepato-Biliary/Pancreatic Surgery (n = 7)	18	33
Thoracic Surgery (n = 5)	11	28

3.2. Surgeons' Concerns and Challenges

A significant finding from the interviews was the overwhelming concern among surgeons regarding anastomotic leaks. Of the 40 surgeons interviewed, 32 (80%) mentioned AL as a major complication that "keeps them awake at night", often without prompting. This concern was more prevalent than other postoperative complications such as bleeding, sepsis, and wound infections. The majority of participants (95%) stressed the critical importance of early prediction of AL, emphasizing that timely intervention could significantly improve patient outcomes. Only a small minority (5%) believed that the timing of leak detection had minimal impact on the patient's prognosis (Figure 3). These insights underscore the deep-seated anxiety among surgeons regarding AL and highlight the need for effective tools to detect leaks early.
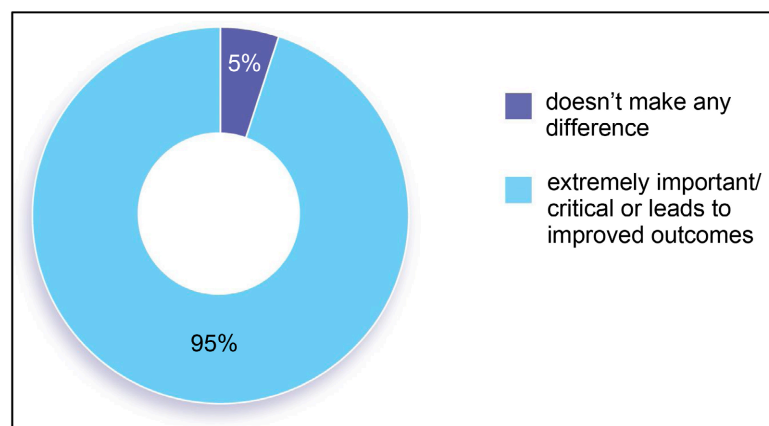
Figure 3. Importance of early prediction of anastomotic leaks.

3.3. Current Gaps in Technology

Despite advancements in surgical techniques, many surgeons expressed frustration with the current lack of effective tools for early detection of AL. The interviews revealed that surgeons are eager for technologies that can provide continuous, real-time data, enabling them to manage patients more proactively. However, 70% of the participants admitted they were unaware of any recent technological advancements specifically designed to address AL. While some surgeons had adopted options such as fluorescent imaging technologies to assess vascular perfusion during surgery, satisfaction with these tools was moderate. Many surgeons felt that while these technologies were helpful, they did not significantly alter treatment course, or improve clinical outcomes. This gap in available technology highlights a critical area in need of innovation.

3.4. Reactions to Stream™ Platform

When presented with the concept of FluidAI's Stream™ Platform, the response from surgeons was predominantly positive, with 82.5% expressing interest or curiosity. The platform's non-invasive nature and its potential to continuously monitor postoperative drainage fluid were particularly appealing to the partici-

pants. Surgeons appreciated the prospect of using the device as an early predictor of anastomotic leak risk, which could allow for more timely interventions and potentially better patient outcomes. In addition to this positive reception, some surgeons voiced considerations regarding the need for more detailed information on any novel device's predictive value, sensitivity, and specificity, before they could fully endorse its widespread use in clinical practice.

3.5. Surgeons' Preferences for Leak Prediction

The study also revealed variability in surgeons' preferences regarding the types of leaks they wished to detect. Approximately 34% of the surgeons expressed a desire to be informed about both clinical and sub-clinical leaks, reasoning that even sub-clinical leaks could deteriorate and warrant conservative care, such as NPO (nothing by mouth) management. On the other hand, 26% of the surgeons preferred to be notified only of clinical leaks, citing concerns that awareness of sub-clinical leaks could lead to unnecessary tests and interventions. The remaining 40% of participants were unsure about their preferences, largely due to the novelty of early leak prediction as a concept (**Figure 4**). This uncertainty highlights the need for further education and discussion within the surgical community about the benefits and potential drawbacks of early leak prediction.
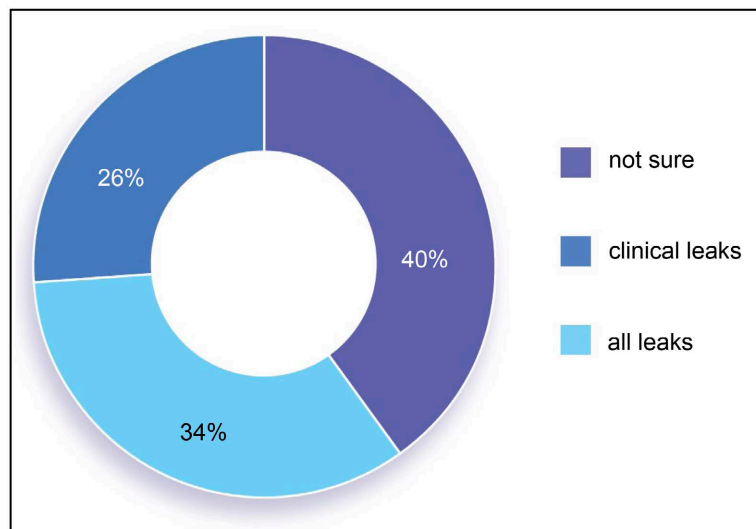

Figure 4. Leaks surgeons want to know about.

4. Discussion

This study provides a detailed exploration of surgeons' perspectives on anastomotic leaks (AL) and highlights the critical gaps in current technologies for their early prediction. The findings align with existing literature, which underscores the significant morbidity and mortality associated with AL in gastrointestinal surgery [1] [2]. The surgeons interviewed in this study, who collectively represent a broad spectrum of surgical specialties, uniformly expressed deep concern over the impact of AL, often citing it as a complication that profoundly affects their

professional confidence and mental well-being.

Anastomotic leaks are among the most feared postoperative complications due to their high associated morbidity, mortality, and the potential for long-term patient suffering. Previous studies have shown that AL can lead to prolonged hospital stays, increased healthcare costs, and significantly worse outcomes for patients [2]. The surgeons in this study echoed these concerns, with 80% of participants highlighting AL as the complication that "keeps them awake at night". This finding is consistent with the literature, where the psychological burden on surgeons who must manage AL is well-documented. For instance, a paper by Donohue *et al.* (2022) noted that surgeons often experience significant stress when dealing with AL, which can impact their decision-making and overall job satisfaction [8].

Despite advances in surgical techniques and postoperative care, there remains a glaring lack of effective tools for the early detection of AL. This study's findings reveal that most surgeons are dissatisfied with current technologies, which do not significantly alter patient outcomes. This dissatisfaction is supported by recent research, which indicates that although new surgical tools and techniques have been developed, they have not substantially reduced the incidence or severity of AL [3]. The surgeons' call for technologies that provide continuous, real-time data is noteworthy. Continuous monitoring could potentially allow for earlier intervention, which is crucial given that delays in diagnosing AL can lead to severe complications, including sepsis and multi-organ failure [1] [2]. Moreover, a study by Yang *et al.* (2018) highlights pH as a valuable predictor of AL, demonstrating that abnormal pH levels in drainage fluid can serve as an early warning sign for potential complications [5]. This finding supports the use of parameters such as pH monitoring in Stream™ Platform as a viable method for early leak prediction. Additionally, research has also established the significance of electrical conductivity in predicting leaks, further validating the dual-biomarker approach employed by Stream™ Platform [6] [7].

The positive reception of FluidAI's Stream™ Platform by the majority of surgeons interviewed suggests there is a significant demand for innovative solutions that address the shortcomings of existing technologies. The platform's ability to non-invasively monitor drainage fluid and provide real-time data was seen as a substantial advancement, particularly in the context of AL prediction. This enthusiasm mirrors findings from other studies that emphasize the need for better postoperative monitoring tools to improve patient outcomes [4]. Future research and development should aim to address questions surgeons voiced surrounding considerations such as performance metrics (false positive and negative rates, sensitivity, specificity), cost, and necessity of drain use. These questions are consistent with broader concerns in the adoption of new medical technologies, where cost-effectiveness and ease of integration into existing clinical workflows are critical factors influencing uptake.

The variability in surgeon's preferences regarding the detection of clinical versus sub-clinical leaks highlights the complexity of this issue. While some surgeons see

value in detecting all leaks, others are concerned about the potential for over-treatment and unnecessary interventions. This debate reflects a broader discussion in the medical community about the risks and benefits of early leak prediction. For example, early detection of sub-clinical conditions in other fields of medicine has sometimes led to over-treatment, which can cause harm to patients and increase healthcare costs [9]. Therefore, any new technology for AL detection must carefully balance the benefits of early prediction with the potential risks of unnecessary interventions.

5. Conclusion and Future Directions

This study underscores the urgent need for innovation in the detection and management of anastomotic leaks. The positive response to FluidAI's Stream™ Platform showcases the potential for this technology to fill a critical gap in current postoperative care. As such technologies are explored, further research should continue to validate their accuracy, cost-effectiveness, and overall impact on patient outcomes. Future studies should also examine the long-term effects of using such technologies on both patient recovery and surgeon well-being. By addressing these issues, we can move closer to developing tools that not only improve clinical outcomes, but also support surgeons in their challenging work.

Authors' Contributions

All authors were involved in the analysis of data, writing, and review of this study.

Conflicts of Interest

O.R., M.S. and N.H. are full-time employees of FluidAI Medical. A third party was used for contacting surgeons and conducting interviews. All authors declare no other conflicts of interest.

References

[1] Gessler, B., Eriksson, O. and Angenete, E. (2017) Diagnosis, Treatment, and Consequences of Anastomotic Leakage in Colorectal Surgery. *International Journal of Colorectal Disease*, **32**, 549-556. https://doi.org/10.1007/s00384-016-2744-x

[2] Turrentine, F.E., Denlinger, C.E., Simpson, V.B., Garwood, R.A., Guerlain, S., Agrawal, A., *et al*. (2015) Morbidity, Mortality, Cost, and Survival Estimates of Gastrointestinal Anastomotic Leaks. *Journal of the American College of Surgeons*, **220**, 195-206. https://doi.org/10.1016/j.jamcollsurg.2014.11.002

[3] Flor-Lorente, B., Noguera-Aguilar, J.F., Delgado-Rivilla, S., García-González, J.M., Rodriguez-Martín, M., Salinas-Ortega, L., *et al*. (2023) The Economic Impact of Anastomotic Leak after Colorectal Cancer Surgery. *Health Economics Review*, **13**, Article No. 12. https://doi.org/10.1186/s13561-023-00425-y

[4] Baigrie, R.J. and Stupart, D. (2023) Coping with Anastomotic Leaks: Harder as One Gets Older? *British Journal of Surgery*, **110**, 395-396. https://doi.org/10.1093/bjs/znac455

[5] Yang, R., Wang, Y., Li, X. and Zhang, X. (2018) The Role of pH Monitoring in Early

Detection of Anastomotic Leaks after Colorectal Surgery. *World Journal of Gastro-enterology*, **24**, 3434-3442.

[6] Ben-David, M., Carmeli, I., Orgad, R., Nathansohn-Levi, B., Yered, T., Shor, E., *et al.* (2022) Implantation of an Impedance Sensor for Early Detection of Gastrointestinal Anastomotic Leaks. *Journal of Surgical Research*, **278**, 49-56. https://doi.org/10.1016/j.jss.2022.04.041

[7] Jones, T.S., Patel, P., Lee, M. and Santos, M. (2019) Electrical Conductivity as a Predictor of Anastomotic Leaks in Colorectal Surgery: A Prospective Study. *Journal of Surgical Research*, **243**, 108-114.

[8] Donohue, K., Rossi, A. and Patel, N.M. (2022) The Agony of Acute Anastomotic Leak. Managing the Emotional Impact. *Seminars in Colon and Rectal Surgery*, **33**, Article ID: 100883. https://doi.org/10.1016/j.scrs.2022.100883

[9] Carter, S.M., Rogers, W., Heath, I., Degeling, C., Doust, J. and Barratt, A. (2015) The Challenge of Overdiagnosis Begins with Its Definition. *BMJ*, **350**, h869. https://doi.org/10.1136/bmj.h869