Clinical Utility of Senhance® Augmented Intelligence

Sleeve Gastrectomy

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Introduction

Sleeve gastrectomy procedures today are largely performed with laparoscopic techniques as 99% of procedures in the US in 2021 were done via this minimally invasive approach [1]. The benefits of a MIS approach are well researched with critical outcomes centered around optimized weight loss while balancing the risk of complications and Quality of Life improvements [2]. To accomplish the balance of weight loss with complications, an optimum sleeve size and shape must be achieved. The intent of this paper is to introduce innovative Augmented Intelligence (AI) solutions from Asensus Surgical, Inc. which are expected to shape a new era of surgery -- Performance-Guided Surgery™. The Senhance® Surgical System, with its novel AI capabilities, provides unprecedented access to real-time data, an improved operating room experience, and may enhance patient safety.

Real-Time Data

Intraoperative Measurement

Operating Room Experience

Telestration |
Automated Camera Control

Patient Safety

Haptics | Telestration
Automated Camera Control

Real-Time Data

Intraoperative Measurement

The definition and size of an ideal gastric sleeve is still largely debated in the bariatric community. However, it can be agreed upon that there are several factors to consider in creating the optimum configuration. Distance from pylorus (antral resection vs preservation), bougie size, and sleeve shape have all been noted as key contributors to patient outcomes [3,4].

There are several philosophies on what the ideal sleeve configuration should be with one consistent element being the assessment of the distance from the pylorus to start the resection. A variety of measurement tools are available today to accomplish this measurement task that fall within a wide range in terms of accuracy and precision. A common method is using a sterile ruler, or a known cut length of suture placed next to the anatomy to measure it [5]. Inaccuracies can occur with these methods given the mobility of tissue and ability to manipulate the sterile ruler or piece of suture for exact placement over the anatomy. A second, perhaps less common, approximation method is using an instrument tip such as a grasper to gauge the distance [5]. The opened jaws can be measured on the back table (approximately 3-4 cm wide) and once inserted back into the trocar, can be held next to the anatomy to estimate the distance from the pylorus. This method has obvious accuracy limitations. An alternative to estimating the distance from the pylorus is using the second branch of the right gastroepiploic artery as an anatomical landmark for the resection point. It has been shown that this distance is a relatively constant 4.5cm and can be used as a visual cue for the initial resection point [5]. There are likely multiple other surgeon preferences on how to assess this distance that are not found in the literature today. However, despite a lack of evidence on what the optimized distance should be, it's clear a more accurate measurement methodology is needed. While the intent of technology is not necessarily to influence or dictate the preferred philosophy of antrum resection or antrum preservation, having objective measurement data can aid in informing the surgical process.

The exact shape of a sleeve has been researched in terms of the impact to patient outcomes (weight loss and reflux primarily) with inconsistent results. Alhaj et al [6] categorized sleeves by shape into tubular, dumbbell, lower pouch, upper pouch groups. Although the results of associating shape to calibration device used are inconclusive, the study did show a trend towards reduced reflux and improved weight loss with the lower pouch shape. In another study, Toro et al [7] reported that sleeve shape is not correlated to weight loss; however, shapes with retained fundus may result in higher severity of reflux symptoms. Even with the ambiguity in the data across studies, to adequately quantify and study the optimal shape of the sleeve, accurate intraoperative measurement techniques would be beneficial to drive consistency and uniformity during resection.

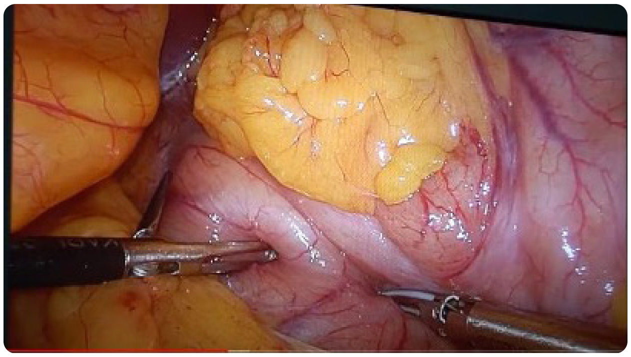
To avoid a dumbbell deformity that may need to be resolved with a conversion to bypass, it can be conceived that measurement functionality could be useful to predict which patient could progress to a dumbbell deformity. Such measurements may include gastroesophageal junction, incisura, and antrum although further research is needed to determine the correlation between these landmarks, bougie size, stomach volume, etc. and outcomes. However, to execute research in this space tools that enable accurate intraoperative measurement are needed.

The Solution:

Real-Time Digital Point-to-Point and Contour Measurement

The Intelligent Surgical Unit (ISU) is the digital engine behind the Senhance® Surgical System. The ISU contains AI and Machine Learning (ML) based software enabling surgeons to perform real-time digital 3D measurements while operating through two modes: point-to-point and along a contour. Point-to-point mode measures a 3D straight line distance between the projections of the two instruments on the tissue. The projections are shown on the screen with a cursor on the tissue surface to easily visualize the measurement. Straight line distance measuring between two points can be useful in situations where there may be tension or pressure or where there is tissue movement that may impact a measurement. This may also be a convenient tool for new users starting with digital features to correlate the digital readings back to what they may be used to seeing with manual techniques for a greater comfort level when working through any learning curve. The clinical utility of measuring the distance between the pylorus to gauge resection starting point is clear. Contour mode is similar to point-to-point except the measurement takes into account the contour of the anatomy instead of measuring along a straight line. Point-to-point is analogous to using a rigid ruler where contour functionality can be compared to using a measuring tape. It could be conceived that utilizing a contour measurement could provide additional data and correlation between sleeve size and bougie size. Both modalities enable distance measurement in centimeters (cm) and display a live number that continuously updates when the two instrument tips are in motion, allowing for a seamless experience [8]. With these digital measurement tools available on the Senhance® Surgical System, there is now a consistent mechanism to access real-time objective data.

Manual methods of intraoperative measurement



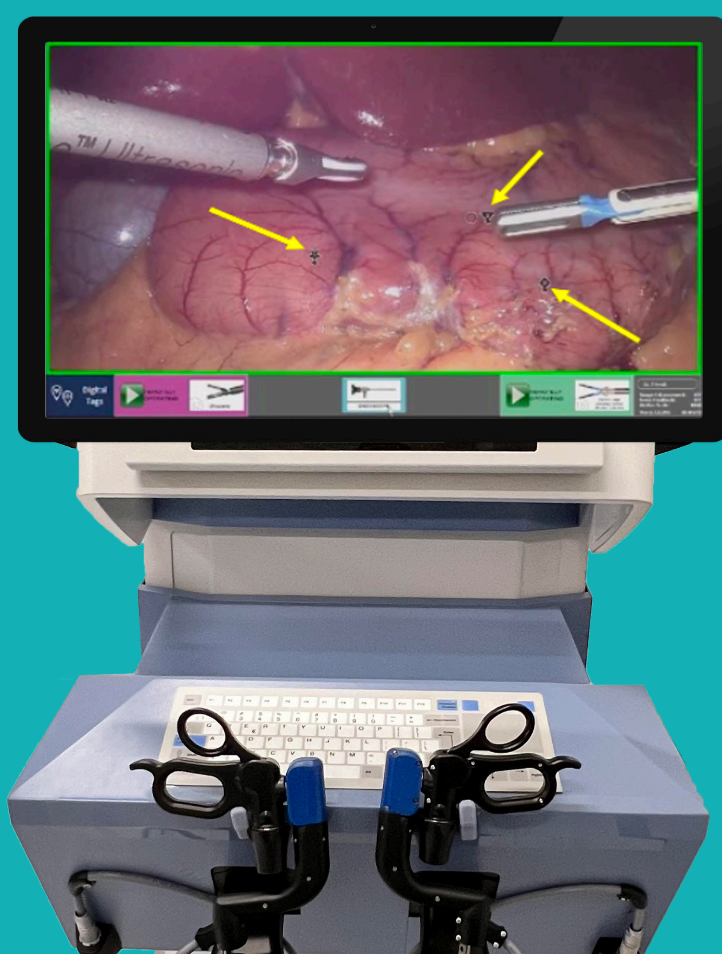
Point-to-point digital measurement tool is enabled on the Senhance® Surgical System

Operating Room Experience

Telestration | Automated Camera Control

Communication within the operating room among the surgical team, including the surgeon, has long been noted as an important factor in ensuring a successful and optimized OR experience. However, in a recent survey it was noted that 93% of respondents indicated that OR noise interfered with team communication, hearing, and focus [9]. It has also been described that as many as 30% of team exchanges are considered communication failures. Of these, approximately a third resulted in effects which jeopardized patient safety [10].

Point-to-point digital measurement tool is enabled on the Senhance® Surgical System



Telestration functionality of the Senhance® Surgical System includes the use of digital tags. Digital tagging allows surgeons to note key anatomical structures to supplement verbal communications and avoid ambiguity that can lead to prolonged OR time or inadvertent injury. In a teaching setting, instructing residents on where to retract, noting key anatomical structures, or describing where to grab and manipulate tissue using digital tagging could be a useful tool to concisely communicate with residents and OR staff. For example, using digital tags to identify critical structures could assist in avoiding inadvertent incisions during dissection. Another use case is instructing a resident or assistant where to retract by noting anatomical locations with a digital tag. Further research is required to better quantify the impact of this feature, but initial surgeon feedback has reinforced that it could have a positive impact on the general OR workflow as well as offer a seamless way to avoid a serious complication.

A second AI capability of the Senhance® Surgical System that enhances the operating room experience is automated camera control. These automated camera control capabilities, such as Follow Me and Smart Zoom, not only may enhance patient safety as previously noted, but also can aid in reducing the cognitive load on the surgeon. Intuitively, any pause in surgery or distraction to the surgeon's thought process to adjust equipment could be detrimental to the workflow and cause inadvertent strain on the mental load of the surgeon. The ability to seamlessly tag and work around anatomical anomalies as they're uncovered during surgery is also a key dimension of enhanced workflow and patient safety.

The Solution:

Telestration and Automated Camera Control

Patient Safety

Haptics | Telestration
Automated Camera Control

Augmented Intelligence can play a part in managing patient safety during a procedure by driving consistency and reducing distractions from a basic physical or mental task. Three elements of AI that can enhance patient safety are haptics, automated camera control, and telestration.

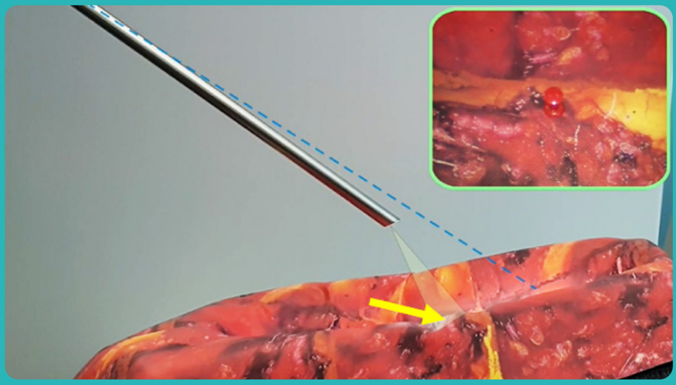
One of the concerns with robotic systems without haptic feedback is the reliance on the surgeon to estimate forces exerted on the incision point and anatomical structure inside the abdominal cavity, based only on visual cues of tissue deformation [11]. By contrast, the Senhance® Surgical System has incorporated haptic feedback technology as part of the teleoperation to allow surgeons to have the real-time tactile response during the surgery similar to traditional laparoscopic techniques [8].

Another nuance of traditional laparoscopy techniques is camera control, which is largely assumed to be a standard operating principle for laparoscopic techniques. Throughout the procedure, the camera is often repositioned and adjusted to ensure the target anatomy is in the field of view. This process is accomplished by either the surgeon, requiring a pause in the operation and removing hands from instruments to adjust, or by the assistant, still resulting in a pause in the operation and requiring effective communication between the surgeon and assistant.

The Senhance® Surgical System offers multiple camera control modalities managed entirely by the surgeon without a pause in the operation. Follow Me modality enables movement controlled by the ISU such that the camera dynamically tracks motion of an instrument visible in the camera image instead of having to manually control and adjust it by the surgeon or assistant [8]. AI camera control with this modality assists in tight spaces such that the continuous camera control is enabled without having to ask an assistant or requiring the surgeon to take their hands off an instrument as in standard laparoscopic techniques. This modality is particularly useful when following instruments over a large distance as when moving along the greater curvature of the stomach when dividing short gastric vessels. Smart Zoom modality enables zooming directly to a point in the center of the screen without having to adjust the physical camera position (Image 2) [8]. This feature allows the surgeon to maintain anatomical landmarks of interest in the field of view during dissection. These multiple camera modes allow for greater flexibility and efficiency while accommodating surgeon preferences to preserve focus on the operative site, which may positively impact safety of the procedure.

Another philosophy on where to begin the resection is that the actual measurement value from the pylorus may not be as critical as using patient-specific landmarks to judge what the ideal sleeve size should be [5]. Patient specific approaches may not rely as heavily on quantified measurement tools; however, it could be more critical to know exact landmarks for making this assessment. Anatomy is inconsistent between patients and the shape of the stomach can vary between U-shaped, backwards L shaped, etc. and because of this, the optimum distance from the pylorus for the resection point can vary to maximize weight loss and minimize potential complications. Common anatomical landmarks include the transition point between the antrum and body of the stomach which can be seen on the greater curvature or the

Smart Zoom modality automatically adjusting the camera to maintain the anatomy in the center of the screen (yellow arrow) instead of zooming along a straight trajectory (blue dotted line)



second branch of the right gastroepiploic artery. Once an anatomical point is located, it needs to be marked for future reference. This can be accomplished through a variety of methods including using the tip of a felt pen or marking the tissue with the Senhance® Ultrasonic System or other instrument energy devices.

Another major contributor to the final shape of the stomach are staple lines. Non optimal staple lines could be a contributor to unintended sleeve shapes such as dumbbell deformity associated with twisting of the staple line which could require revision surgery. While rare at an occurrence rate of 0.7% - 4%, postoperative stenosis caused by twisting can occur [12, 13]. One strategy to avoid this complication is to ensure an ideal staple line path is marked, making sure cuts are symmetric on the anterior and posterior walls to avoid potential twisting.

Digital Tagging is a unique feature of the Senhance® Surgical System that can potentially allow surgeons to place digital tags on key anatomical landmarks or areas of interest during the procedure. This is a quick and digital alternative to using inconsistent manual methods that exist today. In addition, it can be conceived that digital tags could be useful for mapping out the trajectory of the staple line to avoid inadvertent or unintended sleeve shapes. This could be incredibly valuable as an instructional tool to demonstrate where critical anatomical landmarks are, particularly in a teaching facility.

Conclusion

Although an ideal sleeve configuration for optimized weight loss while minimizing complications is not agreed upon in the bariatric surgeon community, having a means of accessing objective real-time data to define an optimum configuration is critical to establishing a new gold standard surgical approach. Augmented intelligence tools such as real-time measurement, telestration, haptic feedback, and automated camera control are now available to support the performance-guided intraoperative experience and accelerate the learning curve by providing meaningful objective data and enhanced surgeon control. Through the utilization of these tools, there is a potential opportunity to achieve consistent patient outcomes, controlled procedure cost, and an efficient OR experience for the treatment of patients with obesity.

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