Clinical Utility of Senhance® Augmented Intelligence

Inguinal Hernia

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Introduction

Hernia repair today is one of the most widely performed procedures worldwide. In 2021, the US hernia repair procedures included 59.4% through a traditional open approach, 27.1% via laparoscopy, and 13.5% with robotic assistance [1]. The emergence of digital laparoscopy and other technology advancements is expected to continue to evolve gold standard approaches for the treatment and repair of inguinal hernias. 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	Operating Room Experience	Patient Safety
Intraoperative Measurement	Telestration | Automated Camera Control	Haptics | Telestration | Automated Camera Control

Real-Time Data

Intraoperative Measurement

A patient-specific assessment for appropriate mesh for hernia repair is not a novel concept as individualization of mesh size can be an important factor in surgical outcomes [2]. However, quantifying parameters that define the treatment plan to reduce complications and recurrences is a modern way to approach hernia repair. Hernia recurrence ranges in the literature from 2% after MIS repair for both TEP and TAPP approaches [3] to 20% regardless of approach [4]. Among other factors, surgical risk factors for recurrence include mesh size and overlap, technique for mesh fixation, adequate dissection, and space creation [3]. All of which are rooted in the concept of measurement and quantification of the defect and mesh size.

Quantifying defect size intraoperatively is a critical step to ensure proper mesh size determination, ultimately ensuring adequate mesh coverage to reduce the risk of recurrence. As reported for ventral hernias, larger mesh size often is associated with a lower recurrence rate; therefore, underestimating the defect size could result in complications and eventual recurrence. Yet, placing a mesh that is too large can lead to more laxity, causing bulges or shifting. On the other hand, underestimating defect size and selecting a mesh too small for the hernia can also lead to increased recurrence [5]. It has been noted in a recent literature review that although there is little to no evidence, it seems that larger meshes can reduce recurrence rates [6]. Despite a lack of evidence, it's clear an accurate measurement is needed.

When selecting an appropriate mesh, there are several factors to consider specific to the mesh such as mesh shape (circular, oval, rectangular, etc.), material, ability to trim depending on the nature of the protective barrier, sizes available, etc. Similarly, the amount of overlap for a mesh can also vary as an example from 4-5cm around the mesh. Most recurrences are around edges of mesh due to inadequate fixation or shrinkage of mesh at the original operation [7]. Factors contributing to this determination include knowing the hernia defect size (for example, if the defect is more than 4cm a larger overlap may be preferred). Factors such as patient characteristics beyond the hernia margins and mesh material shrinkage rates are also being considered in this multi-faceted decision-making process.

Given the importance of ensuring appropriate hernia size and mesh size are known, there are limited methods to measuring defects today. Measuring methods vary drastically but generally include basic manual tools such as using a sterile ruler or umbilical tape to assist. Methods described in the SAGES Guidelines for measurement of Ventral Hernias, describe using spinal needles on opposite sides of the defect and using a measurement tool such as a sterile ruler to measure adjacent to the needle tip to ensure measuring at the proper angle. Also, a method noted from SAGES Guidelines is using an instrument tip when the portion of the instrument tip has a known length/width. For larger defects, this can be inaccurate and prone to errors especially when measuring from this type of angle [5]. Defects are often measured in two directions, which adds to the potential for inaccurate size determinations. A recent study noted five methods for measuring ventral hernias and noted a weak to moderate correlation only between the methods inferring that there is no consistent methodology or consensus on how to measure defects [8].

The Solution:

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

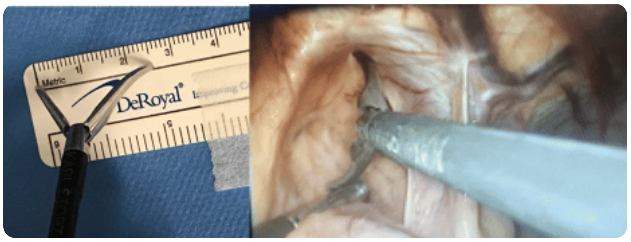
While there is minimal research on the definitive correlation between proper mesh fixation methods and hernia size, there is data to suggest a possible relationship [9]. Because of the historic lack of reliable and accurate intraoperative measurement tools, research to determine this correlation has been difficult to execute.

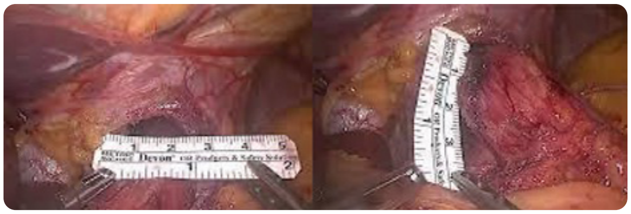
In a recent literature review to assess the optimum hernia repair technique in adolescent patients, it was noted that although there is no difference between two types of repairs (a high ligation of the sac and a repair using mesh), the size and nature of the presenting pathology can impact the treatment plan and techniques chosen [10]. Regardless, the concept of an individualized approach should include objective data for adult and adolescent patients and has the potential for applicability to pediatric patients.

It is widely accepted that current measurement techniques are not precise, so surgeons have learned to work around these inherent challenges to devise the appropriate patient-specific solution. Strong recommendations from the European Hernia Society 2019 guidelines note that surgeons tailor treatments based on expertise, resources, and patient- and hernia-related factors [11]. While the intent of technology is not to necessarily influence or dictate the preferred philosophy or technique, having objective measurement data on the defect itself can aid in informing the surgical process.

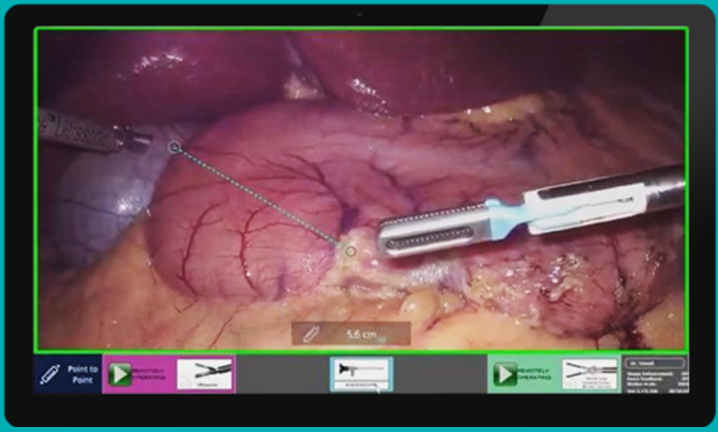
The Intelligent Surgical Unit (ISU) is the digital engine behind the Senhance Surgical System. The ISU contains AI and Machine Learning (ML) based software enabling surgeons to perform real-time digital 3D measurements while operating through two modes: point-to-point and along a contour. Point-to-point 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. 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. When estimating the size of a defect for mesh size, this modality can be useful as it accounts for the curvature of tissue, a nuance difficult to assess with traditional manual measurement methods. 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 [12]. 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

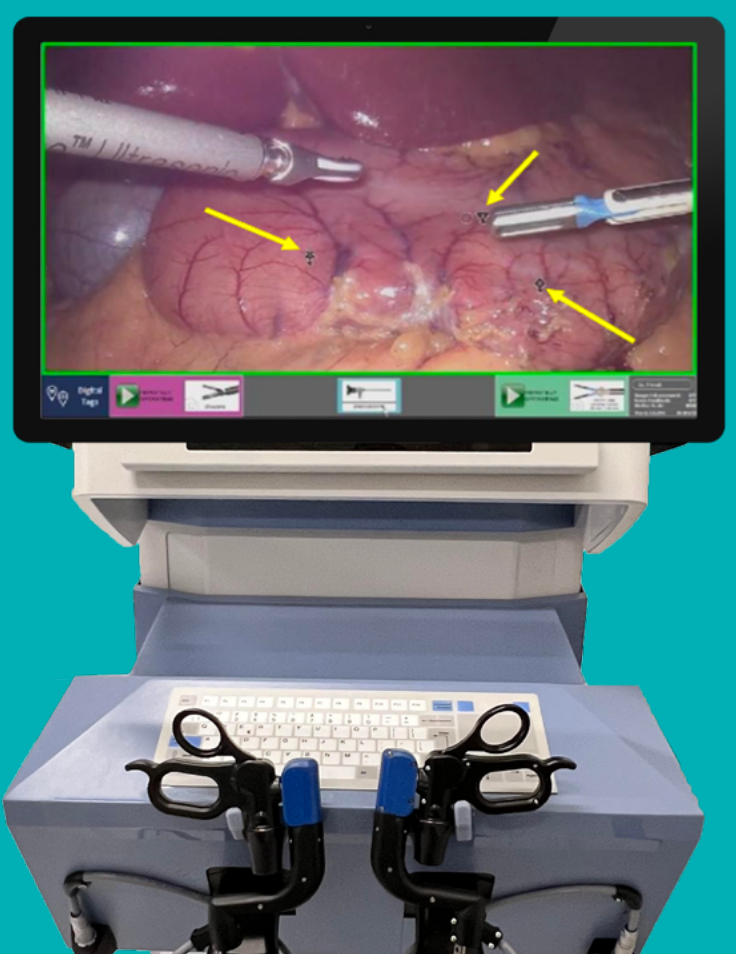


Operating Room Experience

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 [13]. 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 [14].

Digital tags shown on the anatomy noting key anatomical features



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

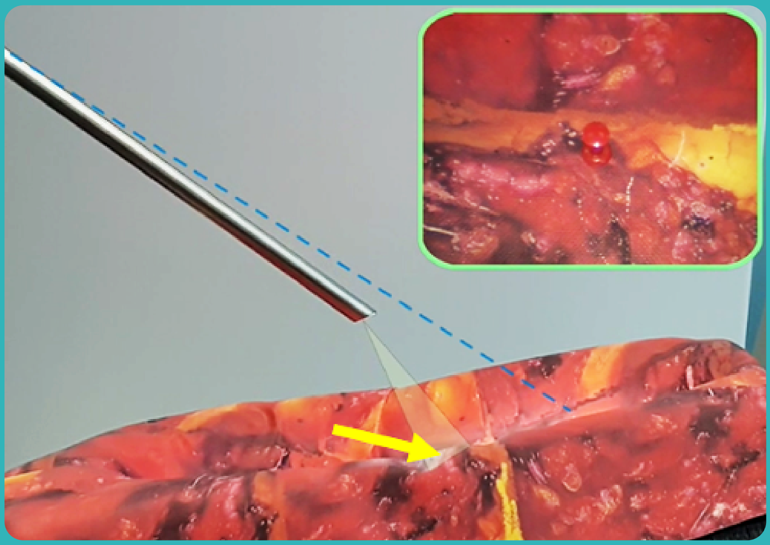
Augmented Intelligence can play a part in managing patient safety during a procedure by driving consistency and reducing distractions from a basic physical or mental task. Three elements of AI that can enhance patient safety are haptics, automated camera control, and telestration.

One of the concerns with robotic systems without haptic feedback is the reliance on the surgeon to estimate forces exerted on organs, based only on visual cues of tissue deformation [15]. Cundy et al [16] demonstrated that suture damage occurred in 2.6% of sutures and is more likely to occur during the learning curve of robotic-assisted surgery as the surgeon gains experience with the perceptual skills required in the absence of having haptic feedback [16]. It can be presumed that the incidence of broken sutures or loose sutures due to a lack of haptic feedback that can traditionally be found in robotic systems without tactile feedback could be reduced with haptics more closely mirroring the feel of traditional instruments. 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 like traditional laparoscopic techniques [12].

Another nuance of traditional laparoscopic techniques is camera control, which is largely assumed to be a standard operating principle for laparoscopy 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 [12]. 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 during flap closure. Smart Zoom modality enables zooming directly to a point in the center of the screen and automatically adjusts motion for any effects of an angled endoscopic lens such as a 30-degree endoscope [12]. 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.

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).



Operating room communication 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 [13]. The impact of poor OR communication could be one of patient safety, particularly in a teaching facility. One of the key factors in reducing risk of complications is knowing the anatomy and having the ability to correctly identify and preserve line of sight for anatomical landmarks [17]. During training and throughout the learning curve, a thorough knowledge of anatomy goes a long way in avoiding most of the complications seen in hernia repair [17].

Conclusion

Although the optimal hernia repair methods, materials, and techniques are not widely agreed on, it remains critical to have accurate, objective real-time data. 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 inguinal hernias.

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