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Research Article

Safety and Performance of a Novel Tissue Sealer in Upper Gastrointestinal Procedures

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Abstract

Background: Hemostasis is essential for surgical success. Technological advancements have enhanced surgical practice with a wide range of energy devices available for sealing and/or cutting tissue and vessels, of which the advanced bipolar ENSEAL X1 Curved Jaw device (X1CJ) is one. This study examined usability and safety of X1CJ use in upper gastrointestinal (GI) procedures.

Methods: This prospective post-market study recruited subjects presenting for upper GI procedures. The patients were more than 18 years, primary procedure where at least one vessel was to be transected with X1CJ, provide informed consent were included. The study excluded the physical or psychological condition or concurrent enrollment in trial which could impact participation or endpoints. Primary performance endpoint was achievement of ≤ Grade 3 hemostasis for each vessel transected on a 4-point scale, with a grade of 4 indicating significant hemostatic intervention was required. Secondary performance endpoint was surgeon-rated scores for device usage. Safety endpoint was occurrence of adverse events (AEs) deemed device-related.

Results: 82 subjects (67.1% female) with a mean age of 53 years were studied. Procedures included cholecystectomy (34.1%), sleeve gastrectomy (18.3%), Roux-en-Y gastric bypass (15.9%), fundoplication (9.8%), jejunectomy (9.8%), ileectomy (8.5%), and hiatal hernia repair/surgery (2.4%). Hemostasis was achieved in 100% of the patients. Of the total of 121 vessels transected, the bulk were designated as Grade 1 (90.9%), followed by Grade 2 (4.1%), and Grade 3 (5.0%). Zero vessels transected were Grade 4. Surgeons described overall satisfaction in their experiences utilizing the X1CJ. Only one patient (1.2%) experienced an AE (decreased hemoglobin) which was deemed by the surgeon as possibly related to the study device and no serious device-related AEs occurred.

Conclusion: Results from this study demonstrate the acceptable safety and usability of the X1CJ in specific upper GI procedures.

Key Words: enseal x1 curved jaw tissue sealer; hemostasis; upper gastrointestinal surgery

1. Introduction

Efficient tissue and vessel sealing techniques in surgery are critical for the prevention of blood loss and ensuring optimal outcomes in open and minimally invasive surgeries (MIS). Hemostasis is essential for surgical success which decrease potential risks of post-operative complications associated with bleeding, reduce costs, and maintain surgical field visibility

particularly during MIS procedures.[1] For example, in colorectal surgery, blood loss has been identified as an independent risk factor for postoperative adverse events, cancer recurrence, and poorer overall survival.[2] Despite being a relatively routinely performed procedure, two common intraoperative complications of Nissen Fundoplication remain hemorrhage and injuries to abdominal organs - both of which may lead to significant blood loss and again highlighting the need for an efficient sealing device.[3,4]

Engineering advances have revolutionized surgical practice such that surgeon's now have a wide range of technologies available for cutting and/or sealing tissue and vessels. Historically, surgeons employed various methods for hemostasis, including both non-energy based (i.e., sutures, staples), and energy-based tools (comprised of traditional monopolar and bipolar electrosurgical devices, advanced bipolar sealing devices, and ultrasonic dissectors).[2,5] While it remains a surgeon's preference on which technology to employ for any particular patient, energy devices are currently used in the majority of procedures.[6]

Advanced vessel-sealing systems include ultrasonic devices (such as Harmonic Shearsl; Ethicon, USA), advanced bipolar electrosurgical technology (such as LigaSure; Medtronic, USA), and combination devices (such as Thunderbeat; Olympus, Japan). These have been widely adopted in a number of specialties, including colorectal surgery, gynecology and urology for an array of procedures including proctectomy, colectomy, hysterectomy, splenectomy, and thyroidectomy. [2]

There are many clinical benefits achieved through the use of energy devices such as reduced operative time, less operative blood loss, and fewer post-operative complications than non-energy-based technologies.[2,7,8] Despite this, risks associated with tissue and vessel sealing still exist including concerns of blood loss and thermal injury.[6] The ENSEAL X1 Curved Jaw device (X1CJ) is an advanced bipolar surgical instrument for open or laparoscopic surgical procedures used to seal and transect vessels and lymphatics, as well as to cut, grasp and dissect tissue during surgery with its curved, tapered tip which enables dissection and easier access to hard-to-reach areas (Figure 1). This device has a 360° continuous shaft rotation enabling the surgeon to adjust the orientation of the device without changing hand position. Additionally, the diversity of function is increased by separating the actions of cutting and sealing, allowing for specific actions tailored to the particular situation. While there are some published data regarding the use of X1CJ, there is sparse literature currently available in upper gastrointestinal surgery. [9,10] Thus, we present results from a post-market approval study of real-world use of the X1CJ in upper gastrointestinal (GI) procedures.

Figure 1: ENSEAL X1 Curved Jaw Tissue Sealer Device and Generator 11

2.Methods

The objective of this single-arm, prospective, post-market approval multi-center study was to demonstrate acceptable performance and safety of the X1CJ, and accompanying Generator11 (GEN11) when utilized per its instructions for use. The study was conducted in the USA and Great Britain (ClinicalTrials.gov Identifier: NCT04763421). The first patient consented in April 2021 and the last subject visit occurred in September 2023. Ethics approvals were obtained from local review boards prior to study onset and the study was conducted in compliance with Good Clinical Practice and the Declaration of Helsinki, as well as any other applicable local regulatory requirements.

Our study recruited subjects presenting for upper gastrointestinal (GI) procedures in which the X1CJ was slated to be used. Inclusion criteria

included: >18 years of age, primary open or laparoscopic procedure where at least one vessel was to be transected by the X1CJ, and a willingness to provide informed consent. Exclusion criteria were any condition which may potentially impair study participation, or enrollment in a concurrent trial which could impact study endpoints. All subjects provided informed consent. All procedures were performed using the individual institution's standard of care. Proposed recruitment included up to 120 subjects.

2.1 Device and Indication

The ENSEAL X1 Curved Jaw Tissue Sealer (Product Codes: NSLX125C, NSLX137C, or NSLX145C) are advanced bipolar electrosurgical devices used to seal and cut, exclusively powered by the GEN11 (Ethicon, Inc., Cincinnati, OH) that has been previously described.[11]

2.2 Endpoints

The primary performance endpoint was achievement of intraoperative ≤ Grade 3 hemostasis for each vessel transection based upon Siegel et. al. [12]:

Grade 1: no bleeding at transection site

Grade 2: minor bleeding at transection site, no intervention required

Grade 3: minor bleeding at transection site, mild intervention required (i.e., compression, monopolar device and/or touch-ups)

Grade 4: significant bleeding (e.g., pulsatile blood flow, venous pooling) requiring intervention such as extensive coagulation or ligation with use of additional hemostatic measures.

Secondary performance endpoints were based on surgeon-rated scores for various device usages: adhesiolysis, lymphatics or tissue bundles divided, tissue grasping, tissue cutting, or tissue dissection. A Likert-like 5-point scale was utilized: very dissatisfied, dissatisfied, neither satisfied or dissatisfied, satisfied, or very satisfied. The hemostasis grade for each vessel transected was assessed and data was collected on additional products required to achieve hemostasis. The safety endpoint was assessed by occurrence of adverse events (AEs) deemed device-related.

2.3 Data Collection

Baseline data captured included demographic information (age, gender, race, and ethnicity), relevant medical and surgical history, American Society of Anesthesiologists (ASA) Physical Status score,[13] and indication and primary procedure performed. Additional variables were compiled, including: body mass index (BMI), procedure conducted and its duration, vessel transected (and surgeon-approximated size), estimated intraoperative blood loss, concomitant procedure performed, whether any other energy device was utilized in the primary or concomitant procedure, requirement (and number) of X1CJ touchups for Grade 3, and length of stay (LOS). A generator questionnaire regarding each investigator's assessment of device functionality was completed after each case. Specifically, each surgeon was queried about their experience utilizing the GEN11 including its ease-of-use. Surgeon reported device-related AEs were captured over the course of the entire study period. A post-procedure follow-up visit occurred approximately 28 (±14) days to evaluate any further potential device-related AEs or primary procedure-related reoperations.

2.4 Statistics

The number and percentage of vessels where hemostasis was achieved (≤ Grade 3) were summarized and a 95% confidence interval estimated for each procedure. Counts and percentages were provided for type, size, and number of vessels transected, grading scale distribution for all vessels transected, number of times X1CJ touch-ups were required, and the need for additional measures to obtain hemostasis on vessels (i.e., other advanced energy devices or hemostatic measures). Further, a summary of AEs and Serious Adverse Events (SAEs) was performed by procedure and sub-procedure group.

3.Results

A total of 82 subjects (55 females, 27 males) with a mean age of 53 years (20-84 range) and a mean body mass index of 33.0 ± 11.2 kg/m^2 were included in this study. The majority of the subjects had ASA physical status of II and III scores (46.3% and 42.7%, respectively) and had never smoked (73.2%). Baseline data are presented in Table 1. Subjects presented for cholecystectomy (34.1%) sleeve gastrectomy (18.3%), Roux-en-Y gastric bypass (15.9%), fundoplication (9.8%), jejunectomy (9.8%), ileectomy (8.5%), hiatal hernia repair/surgery (2.4%), and other (1.2%), Table 2. The majority of cases were performed laparoscopically (85.4%) with one conversion to open (1.4%).

Vessel skeletonization occurred in 39 patients (47.6%). Standard of care prophylactic use of sutures or clips prior to vessel transection was reported in 11.0% of the cases. There was fibrotic tissue (3.7%), inflamed tissue/vessels (4.9%) and adhesions (39.0%) observed but no atherosclerotic tissue or calcified tissues/vessels reported. The overall mean procedure duration was 2.12 hours (0.5 – 10.1 range).

Measure	**Values**
Total # of subjects	82
Age at consent (years)	
Mean ± SD [Median]	52.56 ± 17.2 [52.0]
Range	20.0; 84.0
Sex, n (%)	
Female	55 (67.1%)
Male	27 (32.9%)
Ethnicity, n (%)	
Hispanic or Latino	1 (1.2%)
Not Hispanic or Latino	76 (92.7%)

Not reported	5 (6.1%)
Race, n (%)	
Black or African American	6 (7.4%)
White	72 (88.9%)
Not reported	3 (3.7%)
Body Mass Index (kg/m^2)	
Mean ± SD [Median]	33.00 ± 11.21 [28.90]
Range	17.8; 59.0
ASA, n (%)	
I	8 (9.8%)
II	38 (46.3%)
III	35 (42.7%)
IV	1 (1.2%)
V	0
Smoking Status, n (%)	
Current Smoker	7 (8.5%)
Former Smoker	15 (18.3%)
Never Smoked	60 (73.2%)

Table 1: Baseline Characteristics of Subjects

Total # subjects	82
Surgical Approach	
Laparoscopic	70/82 (85.4%)
Open	12/82 (14.6%)
Conversion to Open	1/69 (1.4%)
Fundoplication	8 (9.8%)
Hiatal hernia repair	2 (2.4%)
Cholecystectomy	28 (34.1%)
Sleeve gastrectomy	15 (18.3%)
Roux-en-Y gastric bypass	13 (15.9%)
Jejunectomy	8 (9.8%)
Ileectomy	7 (8.5%)
Other	1 (1.2%)

Table 2: Specifics Related to the Procedure Performed

Of the 121 total vessels transected, surgeons indicated the majority of vessels were 3-5 mm (77.7%); 19.8% being designated <3 mm; and 2.5% >5-7 mm. On the hemostasis grading scale, the bulk were designated as Grade 1 (90.9%), followed by Grade 2 (4.1%), Grade 3 (5.0%) and none as Grade 4 (Table 3). Of the 6 vessels transected as Grade 3, mild compression was used on 5 with touch-ups utilizing the X1CJ device being done on them all. Successful hemostasis, defined as Grade 3 or lower, was achieved on 100% of vessels. Mean estimated intraoperative blood loss was 60 mL (range 0.0; 500.0) with zero subjects requiring blood transfusion. The X1CJ was not utilized in any of the concomitant procedures which occurred in 15.9% of the patients. Length of stay was 3.74 days (range 0.0; 47.0) with one subject being released outside of the 30-day follow-up period.

Total	121
Vessel Size:	
3 to 5 mm	94 (77.7%)
<3 mm	24 (19.8%)
>5 to 7 mm	3 (2.5%)
Hemostasis Grading Scale:	
Grade 1	110 (90.9%)
Grade 2	5 (4.1%)

Grade 3	6 (5.0%)
Grade 4	0

Table 3: Vessel Transection Summary

A total of nine surgeons participated in the study and described overall satisfaction with experiences utilizing the X1CJ. The device was used for adhesions 30 (36.6%), lymphatics 6 (7.3%), tissue grasping 30 (36.6%), tissue cutting 35 (42.7%), and tissue dissection 49 (59.8%). Surgeons graded their experience based on a Likert-like scale and reported 100% satisfied/completely satisfied with the use of the device for removal or division of adhesions. Similarly, 83.4% of responses showed surgeons were satisfied/very satisfied when dividing lymphatic bundles. In terms of tissue cutting, 85.7% of surgeons were satisfied/very satisfied, while 98.0% were satisfied/very satisfied with dissection. The majority of surgeons reported strong agreement that the GEN11 operated as intended (92.7%). Surgeons strongly agreed that the touchscreen allowed for easy set-up and operation (91.5%). An additional survey was completed by surgeons as soon after they had completed their second procedure. These surgeons reported experiencing less hand fatigue compared to any previous advanced bipolar device used (66.7%), reduced need for instrument changes during surgery (77.8%), and overall felt that in critical cases, the X1CJ performed better than previous device used (66.6%) (Table 4).

One patient (1.2%) experienced an AE which was deemed as possibly related to the study device. This AE, which was deemed mild, was a decreased hemoglobin level and remained unresolved to the end of the study period.

Measure	**Value**
Full Analysis Set	82
X1CJ Results	
Number of adhesions removed or divided by X1CJ	30/82 (36.6%)
Percent satisfied with the adhesion removal or division by X1CJ	30/30 (100.0%)
Number of lymphatics bundles divided by X1CJ	6/76 (7.3%)
Percent satisfied with lymphatics bundles division by X1CJ	5 (83.4%)
Number of tissue bundles divided by X1CJ	23/82 (28%)
Percent satisfied with tissue bundles division by X1CJ	22/23 (95.7%)
Number of times X1CJ used for tissue grasping	30/82 (36.6%)
Percent satisfied were you with the tissue grasping by X1CJ	24/30 (80.0%)
Number of times X1CJ used for tissue cutting	35/82 (42.7%)
Percent satisfied were you with the tissue cutting by X1CJ	30/35 (85.7%)
Number of times X1CJ used for tissue dissection	49/82 (59.8%)
Percent satisfied were you with the tissue dissecting by X1CJ	48/49 (97.9%)
Number of times any other energy device (monopolar, traditional bipolar, advanced bipolar, ultrasonic) was used during the primary procedure	45/82 (54.9%)
Type of any energy device used:	
Monopolar	27 (60.0%)
Advanced Bipolar	4 (8.9%)
Ultrasonic	14 (31.1%)
GEN11 Results	
Software Version Used	
2016-1.1	59 (72.0%)
Other	23 (28.%)
Number of times generator-related alarms occurred	2/82 (2.4%)
Number of times generator performed as intended	80/82 (97.6%)

Percent times the touchscreen allowed for easy set-up and operation	79/82 (96.4%)
Surgeon Experience Survey*	
N	9
Type of advanced bipolar device previously used:	
None	1/9 (11.1%)
ENSEAL G2 Curved and Straight Tissue Sealer	2/9 (22.2%)
Ligasure Maryland	4/9 (44.4%)
Thunderbeat	1/9 (11.1%)
Other	3/9 (33.3%)
I found that overall the X1CJ performed better than my previous device on critical tasks	6/9 (66.6%)
I experienced less fatigue with X1CJ compared to previous device	6/9 (66.7%)
I found the cut and seal buttons were easily distinguishable on the X1CJ	7/9 (77.7%)
I found the cut and seal buttons were easily distinguishable on the X1CJ	7/9 (77.7%)
I found the X1CJ reduced number of instrument changes compared to previous device	7/9 (77.8%)
I found the X1CJ was easier to use compared to my previous device	5/9 (55.5%)

*This survey was completed as soon as they had completed their second procedure

Table 4: X1CJ and GEN11 Usability Survey Results

4.Discussion

The adoption of advanced bipolar energy demonstrably reduces operative times, improves patient outcomes, and has shown an improvement in cost effectiveness in certain procedures. [14-16] Given the rapid introduction of novel surgical technologies, post-market analysis programs are crucial for ensuring patient safety. Hemorrhage is a well-documented complication, which we evaluated by a hemostasis grade achieved using this new advanced bipolar energy technology. This clinically relevant hemostasis model was similarly used in several post-market surveillance studies as well as an effectiveness and usability study. [11,12,17]

Specifically, post market surveillance on similar ENSEAL X1 products have shown satisfactory hemostasis in different types of colectomies, gynecological, and thoracic procedures.[17] However, upper GI procedures are lacking in similar surveillance. This study reports on the use of the X1CJ in several of the most commonly performed upper GI procedures. Similar outcomes to a prior real-world post-market surveillance study for a similar device, the ENSEAL X1 Large Jaw Tissue Sealer. When used on the enteral system, 100% hemostasis was achieved on all vessels transected (and all procedures performed) as Grade 3 and below hemostasis.[17] Similarly, our study showed that 100% of vessels transected with the X1CJ achieved hemostasis at Grade 3 and below. The majority were Grade 1 with no intraoperative bleeding occurring.

One long-standing benefit of advanced bipolar devices is their ability to seal vessels that are greater than 2 mm and including 7 mm. [18,19]. In the current study, 77% of vessels sealed were 3-5 mm with 2.5% were 5-7mm, which is consistent with predicate device usage. In our study, one patient was reported to have a low hemoglobin level post procedure. This event was deemed to be possibly device-related. No other adverse events were reported deemed related to device usage throughout study.

Research in advanced bipolar devices has resulted in the rapid evolution of new product designs. For example, curved jaw devices with tapered tips were engineered for tissue dissection and manipulation, adaptable energy modulation for temperature control to reduce lateral thermal spread, and separated functions to cut and seal. The initial effectiveness and usability study performed on *in-vivo* porcine models, showed that 100% of surgeons deemed the X1CJ as acceptable for hemostasis, dissection, transection and tissue manipulation.[11] In clinical application, of the 60% of surgeons in this cohort who utilized X1CJ for dissection, 97% were satisfied/very satisfied with usage for this purpose. Adhesiolysis was performed by 37% of surgeons and of those, 100% were satisfied/very satisfied. Tissue cutting was heavily utilized as well with 85% being satisfied/very satisfied. Generally, surgeons described overall satisfaction with their utilization of X1CJ with 66.6% reporting that on critical tasks, they were confident the X1CJ performed in a superior manner to their previous device. Surgeons reported that GEN11 functioned as intended. Specifically, surgeons described its ease-of-use and simple set-up as benefits.

One limitation of this study was the sample size which was a small observational cohort.

5.Conclusion

Our study aimed to provide real-world insights into the safety and usability of the X1CJ device. The X1CJ continued to demonstrate effectiveness and safety in the upper gastrointestinal procedures presented in this study. Additionally, surgeons reported the device functioned satisfactorily as designed based on its real-world application.

Ethical Approvals

Institutional Review Board or Ethics Committee approvals were obtained prior to study onset in the US (#IRB00083466), UK (#20/LO/1135), and Italy (#3608).

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