Clinical Utility Of A New Articulating Tissue Sealer In Laparoscopic Colorectal Surgery

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Abstract

Background: The fixed location of ports, complex anatomy, and deep/tight spaces limit exposure and continue to be a challenge with current energy devices in laparoscopic surgery. We describe the initial experience with an articulating advanced bipolar energy device.

Methods: We performed a prospective, single-arm, multicenter, observational study of laparoscopic colon resections with the ENSEAL G2 Articulating Tissue Sealer. This study was undertaken and financed in its entirety by the manufacturer of the ENSEAL G2 Articulating Tissue Sealer, Ethicon (Cincinnati, OH). Assessments included frequency of articulation and perpendicular transections, surgeons’ experience (via questionnaire) and perceived workload of device use (via NASA Task Load Index).

Results: Twenty-nine consecutive procedures, ranked high, medium, and low in complexity (52%, 38%, and 10%, respectively) were included. Average procedure time was 164.9 ± 53.3 min and device implementation time was 40.7 ± 29.6 min. Estimated blood loss was 109±111 cc. Of 4,153 device activations, 59% were articulated. Of 167 isolated vessel transections, 48% used articulation and 83 % were perpendicular. Compared to use of non-articulating devices, ability to get 1) around corners/behind structures, 2) into deep/tight spaces, and 3) straight across vessels were rated as “better” in 93%, 79%, and 72% of the cases, respectively. The device was considered to reduce the need to pass the vessel sealing device to assistants and to reduce instrument exchanges 69% and 55% of the time, respectively. Raw NASA-TLX score was 34.8±16.5.

Conclusion: High frequency use of the tissue sealer in articulated mode, minimal blood loss, and usefulness ratings were reported. Usefulness ratings, particularly enabling better angles of transection in tight spaces, and getting around corners to mobilize flexures, underscore the value of articulating energy devices in laparoscopic surgery. The perceived workload of using articulating features was low.

KEYWORDS: ENSEAL, colon resection, laparoscopic, articulating, bipolar energy, vessel seal, dissection
Disclosure

This study was undertaken and financed in its entirety by the manufacturer of the ENSEAL® G2 Articulating Tissue Sealer, Ethicon (Cincinnati, OH). This study is registered at the National Institutes of Health website (www.clinicaltrials.gov, identifier: NCT02044770) and was approved by Institutional Review Boards at all three centers prior to study initiation. Informed consent was obtained from every participant in accordance with Good Clinical Practice (GCP) guidelines and the Declaration of Helsinki.

Some authors of this manuscript are consultants for Ethicon and three (M. Gutierrez, Edward Chekan, and Michael Schwiers) are clinical research professionals employed by Ethicon.

Introduction

The difficulty with tissue exposure encountered in some colorectal procedures remains a challenging aspect of laparoscopic surgical treatment. During a colon resection, the surgeon must be able to access complex anatomy in deep and tight spaces in order to optimize angles of approach to the target tissue. This includes mobilization of fixed tissues such as the descending and ascending colon, and mobilization around corners including splenic and hepatic flexures. Many devices are available for vascular control during laparoscopic colorectal procedures but electrothermal bipolar vessel sealers and ultrasonic coagulating shears are among the most popular (1). Considering that reliable vessel seals are important for adequate hemostasis in surgery, surgeons must understand effects of a particular sealing device on the target tissue. Advanced bipolar vessel sealers apply electrical power to the tissue with high frequency and low voltage, which results in elastin and collagen thermal denaturation that can seal blood vessels up to 7mm in diameter (2). Sealing of vessels in a manner that minimizes tension has been identified as an important technical principal of bipolar devices (3 & 4). A recent preclinical study suggested that vessels larger than 5mm in diameter should be approached perpendicularly for the strongest possible seal (5).

To optimize the use of a new medical device, it is important to understand both the functionality of the device as well as the intrinsic properties of tissue to which the device is applied (6). Meaningful improvements in blood vessel sealing should occur as a result of a perpendicular approach from the device with respect to target tissue (5). Robotic systems can optimize approach angles due to their ability to increase the degrees of freedom of the end effector, providing articulation/rotation capabilities for access to structures such as the rectum and...
mesorectum (7). Robotic laparoscopic approaches can also provide colorectal surgeons with increased ability to reach superiorly within the abdomen and work around corners such as those encountered at the splenic and hepatic flexures (8). However, the use of a robotic system for laparoscopic surgery necessitates increased operative time as well as expense (9). Hence, an articulating laparoscopic energy device was designed envisioning that some benefits of the robotic laparoscopic approach could be achieved with a much simpler methodology.

The surgical device evaluated in this study is the first laparoscopic articulating advanced bipolar instrument designed to improve surgical access to tight spaces and allow the surgeon to work around corners through a 5mm port. With up to 110 degrees of articulation, the device can accommodate additional angles to coagulate and mechanically transect tissue during laparoscopic and open procedures. The articulating design is intended to improve operating efficiency by enabling a perpendicular approach for optimized vessel sealing and by limiting the need for additional incisions. In addition, the exchange of instruments between ports and passing of the energy device to an assistant are reduced, thus contributing to improved ergonomics for the surgeon. The aim of the current study was to assess how surgeons use the ENSEAL® G2 Articulating Tissue Sealer in colorectal procedures, without influencing them with regard to behavioral changes for accommodation of the device.

**Materials and Methods**

This was a prospective, single arm, observational study of the use of the ENSEAL® G2 Articulating Tissue Sealer (hereafter referred to as ENSEAL® Articulating) (Ethicon Endo-Surgery, Inc. Cincinnati, OH) conducted by four colorectal laparoscopic surgeons at three surgical practices in the United States. All surgeons were in-serviced and trained in the use of the device. The study population included adults (age ≥18 years) undergoing planned laparoscopic colon resection (any extent) involving mobilization of the splenic and/or the hepatic flexure. No alterations to the centers’ established surgical procedure or aftercare practices were introduced by this study, which was sponsored by the manufacturer of ENSEAL® Articulating and registered in www.clinicaltrials.gov (NCT02044770). All centers followed a single protocol approved by Institutional Review Boards and obtained appropriate informed consent from all participants. All surgeons completed questionnaires to characterize their laparoscopic approach and volume of laparoscopic colectomies/lower anterior resections before study initiation.
Advanced Bipolar Energy Device

The ENSEAL® Articulating (Figure 1) is a surgical tool used for coagulation and transection of vessels of ≤7mm in diameter and vascular bundles, as well as tissue dissection. The instrument consists of a grip housing assembly, a 35-cm rotating and articulating shaft, a moveable jaw, and an I-BLADE® in the jaws. The instrument’s shaft can be articulated (up to 110 degrees) using an articulation wheel. The jaws of the device have atraumatic teeth for grasping and holding tissue when clamped. Bipolar energy is delivered to the clamped tissue when the energy activation button is pressed. The tissue in the jaws is compressed, coagulated, and transected by closing the handle and advancing the I-BLADE® across the length of the jaws. Temperature is controlled at the tissue interface. A polymer compound within the jaw uses Positive Temperature Coefficient (PTC) technology to modulate energy flow and maintain constant temperature (approximately 100°C), minimizing tissue sticking, charring, and smoke.

Ethnographic Data

Ethnography-based research methodologies were used in this study to assess the facts on the ground regarding how the articulating energy device performs for different users and in their own environments for colorectal procedures. Ethnography-based research includes various types of quantitative and qualitative data and provides unique insights into user experience beyond anecdotal data. Digital video recordings of the surgical procedure were performed and evaluated by a third party consultancy group (Design Science Consulting Inc., Philadelphia, PA), not associated with the study sites, specializing in the conduct of field research involving ethnographic data. Video recordings involved the use of three cameras: one providing laparoscopic internal views of device use and tissue structures, another providing audio and external views of the procedure, and a third camera that captured a computer screen displaying streaming data from the generator G11. Videography imaging and audio, synchronized with the streaming data from the GEN11 generator (to verify device activations), were evaluated for identification and characterization of study parameters related to device activations. The surgeons were blinded to the results of the video reviews throughout the study.

NASA-TLX
The NASA Task Load Index (NASA-TLX) was developed by NASA's Ames Research Center\textsuperscript{10 & 11} and has been applied in human factors research\textsuperscript{12-14}. The NASA-TLX is a subjective, multidimensional assessment tool used in this study to rate the perceived workload of the use of ENSEAL\textsuperscript{®} Articulating during a single surgical procedure (the task). The tool consists of six subscales/dimensions that are rated for the task within a 100-points range with 5-point intervals. These ratings are then combined into the task load index\textsuperscript{15}.

\textbf{Study Parameters}

Total procedure time was defined as the time from first incision to time of last stitch. Device implementation time was recorded with the external camera and defined as the sum of all time episodes in which the study device remained in a trocar/port. Two types of device implementation time were computed (a) Articulation time, defined as the portion of time in which the device is articulated and (b) Non-articulation time, defined as the portion of the time in which the device is not articulated. The total number of activations and the number of articulated and non-articulated activations were recorded by the third-party data review agency from video/audio recordings. Articulated and non-articulated activations done to seal and transect isolated vessels were further categorized as perpendicular or angulated. Perpendicular activations were defined as transections in which the jaw of the device was positioned at an approximate angle of approach between 80-100 degrees to the vessel. Angulated transections were defined as transections with an approximate angle of approach of <80 degrees and >100 degrees. The proportion of activations for tissue dissection (not on larger vessels that are first isolated for transection) was also computed.

Non-energy use of the device was defined as the portion of device implementation time in which the device is not used for dissection, sealing, or transection using energy. The following variables related to the use of the device not involving energy activations were assessed (separated by articulated and non-articulated use): use to atraumatically draw tissue back to expose target tissue, to grasp, and for cold dissection. The number of intraoperative primary failures of hemostasis (i.e., bleeding after division of a vessel/vascular bundle that resulted in the need to use another device to control bleeding) was reported.

\textbf{Statistical Analysis}

This was a user-center observational study not intended to test any formal hypotheses; therefore, the sample size was not statistically powered. The target study sample (N=30) was not expected to be representative of the entire population but was considered adequate to make observations of real life practices.
and describe early experiences with the articulating energy device in laparoscopic colon resection surgery.

Descriptive statistics are provided for all endpoints as appropriate for continuous or categorical variables. Analysis of the NASA-TLX was consistent with the recommendations for that tool.

**Results**

Table 1 summarizes the preoperative characteristics and procedure variables of the laparoscopic colon resections (N=29) consecutively recruited in this study from February 2014 to May 2014. The average BMI was 28.9 ± 6.2, procedure time was 164.9 ± 53.3 min, device implementation time was 40.7 ± 29.6 min, and estimated blood loss was 109 ±111 cc. There were two conversions to open, due to unexpected intraoperative findings following successful colon mobilization. On average, 143 device activations per procedure were observed in this study. Surgeons rated the complexity of each procedure (in the context of all procedures of a given type in their experience), 52%, 38%, and 10% of the procedures were rated high, medium, and low complexity, respectively. In Figure 2, it can be observed that the average number of articulated activations increased with procedure complexity; however, the difference did not reach statistical significance (p > .05). The categorization of all device activations in this study are summarized in Figure 3, in terms of use of articulation, type of activations (i.e. isolated vessel transection, tissue dissection, or energy application without advancing the I-blade) and, angle of approach to isolated vessels. Figure 4 illustrates the similarities in terms of the percentage of perpendicular vs. non-perpendicular vessel transections among articulated and non-articulated activations.

The average of the aggregate device activation times is summarized in Figure 5; of 4,153 total activations, 59% (n = 2,452) were articulated. Figure 6 summarizes the results of the Surgeon’s Experience survey. Ability to get (1) around corners/behind structures, (2) into deep/tight spaces and (3) straight across vessels was rated “better” in 93%, 79%, and 72% of the cases, respectively. The device was considered to reduce (1) the need to pass the vessel sealing device to assistants and (2) instrument exchange, in 69% and 55% of the cases, respectively. The articulating feature was described as particularly useful in getting around corners to take down the flexures (in 22 of 29 mentions) and in adhesiolysis.
There were 144 “Seal Only” activations (without advancing the I-Blade), 58% (n=83) of which were done prior to transecting an isolated vessel. The rest of the “Seal Only” activations (42%) were second-pass seals done after transections of isolated vessel to double seal (technique preference). Thirty-three percent (n=22) of the “Seal Only” activations were articulated and 64% (n=39) not articulated.

Figure 7 summarizes the mean and STD for the NASA-TLX composite and individual domain scores. The raw composite NASA-TLX score was 34.8 ± 16.5 (10-73). These average composite and individual index scores are within the “Low” perceived workload grade of the scale (0-50). Table 2 provides a summary for the average number of non-activated (no energy application) tasks performed with the ENSEAL® Articulating.

Safety

No adverse events or complications associated with the use of the ENSEAL® Articulating (e.g., inadvertent tissue trauma, blood transfusions, readmissions, and mortality) were reported. Only three (0.07%) activations required the use of a second device to control bleeding. Two cases were converted to open (due to unexpected intraoperative findings); however, the conversion took place after successful mobilization of the colon with the ENSEAL® Articulating.

Discussion

The ethnographic analysis of this series of colorectal cases provided a quantitative analysis of the operative cases captured on video and illustrated the capability of the device in providing the surgeon with a perpendicular vessel approach angle. Movement of the articulation wheel on the device allows the distal jaw to swing approximately 55° of the shaft in either direction. The articulated mode was used frequently (59% of the 4,153 device activations) and a large number of isolated vessel transections were possible with a perpendicular approach (84%). Such advantageous vessel sealing angles were possible even in patients with varying anatomy and body habitus without changing the typical port placement.

Vessel sealing outcomes were good with minimal blood loss recorded. The optimization of trocar placement for one quadrant typically means suboptimal placement for the other quadrants; i.e. the trocar placement that is ideal for rectal mobilization is suboptimal for freeing up the colonic flexure. This articulating device was able to overcome many of the limitations of straight shaft laparoscopy.
by allowing for an additional plane of movement. As such, maneuvering around the flexures was easier (79% of the cases) and articulation was used more commonly in highly complex cases compared to low complexity cases. All three left hemi colectomies included in this study were rated as high in complexity and their articulation time was two times higher than the non-articulation time in the same procedures and at least three times higher than the rest of the procedures (except for transverse colectomy). Thus, articulation of the energy device was most helpful in the toughest cases in this study. It’s possible that articulating energy devices will help with exposure in other challenging patient populations, i.e. morbidly obese patients or those with a significant history of previous abdominal surgeries.

In-context surveys and validated measurements of perceived burden of use were used to yield insights into the pros and cons of the articulating energy device. The NASA-TLX scores further supported articulation and showed evidence of fewer handoffs, increased ability for the surgeon to overcome fixed pivot points and overall surgeon comfort and ease. Although there was frequent use of the device for non-energy tasks such as blunt dissection, grasping, or drawing tissue back; when the instrument shaft elbow is articulated, such jobs seemed to become slightly more tedious. This may be due to the fact that when the instrument is fully articulated, movement of surgeons’ hands up, down, left, or right does not directly transfer to the same movement direction inside the patient. Surgeons in this study appreciated the increase in the range of motion of the device but commented on a slight increase in the complexity of usage. In seven cases, the ergonomics or ease of use of the device was reported as worse than those encountered with non-articulating tissues sealers. These minor ergonomic struggles may improve with more frequent use and experience.

Several limitations were present in this study. First, it was designed to be purely observational and was limited by lack of comparative groups. However, the intent was not to be inferential, but rather to gather initial clinical experience with the device in an attempt to formulate hypotheses for future clinical trials. In addition, the overall small sample size and relatively low numbers of each specific procedure could limit precision in understanding the instrument’s performance. However, the nature of the ethnographic data across all uses of the device, provided thousands of observations for characterization of use and performance. Lastly, the imbalance of complexity across procedure types also limits the ability to fully characterize the utility of the device. This is difficult to control in a prospective manner, since procedure complexity only becomes fully known during and after completion of the surgery.
The strength of the study, however, was that it utilized ethnography-based techniques (also called contextual inquiry) for observing and documenting real-world use of the device. Such techniques have been used to determine the facts on the ground (i.e. the situation in reality as opposed to theoretical) regarding how a product performs for different users and in certain environments for a given procedure. It provides unique insights into user experience beyond anecdotal data, and includes various types of quantitative and qualitative data.

Conclusions

The high frequency use of ENSEAL® Articulating in articulated mode; minimal blood loss; and the usefulness ratings reported in this study, particularly with regard to enabling better angles of transection in tight spaces, underscore the value of articulating advanced energy devices in laparoscopic surgery. The elements of the NASA-TLX tool suggest that the perceived workload of using the articulating feature is low. Variations in technique indicate that in some instances surgeons can use the device to seal tissue without transecting simultaneously. Additional studies comparing articulating to similar non-articulating instruments may help further elucidate any technical advantages of this newer technology and make stronger conclusions with regard to operating time, improved outcomes, and cost containments.

Acknowledgments

We gratefully acknowledge the work of Design Science Consulting Inc. (Philadelphia, PA) in data characterization/classification from reviews of the surgical audio/video recordings and the support of statistician Michael Schwiers in the statistical analyses and summaries.

References


Figure 1. ENSEAL® G2 Articulating Tissue Sealer (ENSEAL® ART)
Figure 2. Number of articulated and non-articulated activations of the ENSEAL® Articulating device by procedure complexity. The number of articulated activations increased with procedure complexity.
**Figure 3.** Categorization of all device activations.
* Energy application without advancing the I-Blade (simultaneous transection).
Perpendicular transection = 80-100 degree angles relative to the transected vessel
Figure 4. Percentage of perpendicular vs non-perpendicular vessel transections in articulated and non-articulated device activations. No clear isolated vessel transections were identified by third party video review in the transverse colectomy procedure (n=1), only 152 activations for tissue dissections, 123 (81%) articulated and 29 (19%) non-articulated.
**Figure 5.** Articulated and non-articulated, average gregate time of all activations per procedure. * n=1
Figure 6. Surgeon’s Experience Survey. These questions were answered immediately after each procedure based on the surgeon’s experience using the ENSEAL\textsuperscript{®}. Articulating in the context of each surgeon’s past experience using non-articulating tissue sealers.
**Figure 7.** NASA-TLX perceived workload of using the ENSEAL® Articulating device in each colectomy (mean ± STD) overall and individual dimensions scores.
Table 1. Demographics- baseline characteristics- and procedure variables

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Overall (N = 29)</th>
<th>Right colectomy (n = 17)</th>
<th>Lower anterior resection (n = 8)</th>
<th>Left colectomy (n = 3)</th>
<th>Transverse colectomy (n = 1)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (yr)</td>
<td>60.8 ± 11.9</td>
<td>62.9 ± 14.1</td>
<td>57.4 ± 7.9</td>
<td>56 ± 6.6</td>
<td>67</td>
</tr>
<tr>
<td>(33-83)</td>
<td>(33-83)</td>
<td>(49-70)</td>
<td></td>
<td>(49-62)</td>
<td></td>
</tr>
<tr>
<td>BMI (Kg/m²)</td>
<td>28.9 ± 6.2</td>
<td>29.1 ± 6.9</td>
<td>30.3 ± 4.6</td>
<td>22.3 ± 1.2</td>
<td>34</td>
</tr>
<tr>
<td>(17-42)</td>
<td>(17-42)</td>
<td>(25-39)</td>
<td></td>
<td>(21-23)</td>
<td></td>
</tr>
<tr>
<td>Operative time (min)</td>
<td>164.9 ± 53.3</td>
<td>136.8 ± 30.7</td>
<td>206.4 ± 47.7</td>
<td>229.7 ± 56.2</td>
<td>116.0</td>
</tr>
<tr>
<td>(89-288)</td>
<td>(89-195)</td>
<td>(151-288)</td>
<td></td>
<td>(169-280)</td>
<td></td>
</tr>
<tr>
<td>Device implementation time (min)</td>
<td>40.7 ± 29.6</td>
<td>33.4 ± 21.0</td>
<td>35.1 ± 12.6</td>
<td>101.3 ± 44.6</td>
<td>29.0</td>
</tr>
<tr>
<td>(11-136)</td>
<td>(11-103)</td>
<td>(17-59)</td>
<td></td>
<td>(51-136)</td>
<td></td>
</tr>
<tr>
<td>Estimated blood loss (cc)</td>
<td>109.5 ± 111.1</td>
<td>88.2 ± 59.9</td>
<td>165.6 ± 189.4</td>
<td>83.3 ± 28.9</td>
<td>100.0</td>
</tr>
<tr>
<td>(5-600)</td>
<td>(5-225)</td>
<td>(25-600)</td>
<td></td>
<td>(50-100)</td>
<td></td>
</tr>
<tr>
<td>Gender F/M</td>
<td>16/13</td>
<td>11/6</td>
<td>4/4</td>
<td>1/2</td>
<td>0/1</td>
</tr>
<tr>
<td>(%</td>
<td>(55%/45%)</td>
<td>(65%/35%)</td>
<td>(50%/50%)</td>
<td>(33%/67%)</td>
<td>(0%/100%)</td>
</tr>
<tr>
<td>White (Caucasian)</td>
<td>29 (100%)</td>
<td>17 (100%)</td>
<td>8 (100%)</td>
<td>3 (100%)</td>
<td>1 (100%)</td>
</tr>
<tr>
<td>Benign disease/condition</td>
<td>15 (52%)</td>
<td>9 (53%)</td>
<td>4 (50%)</td>
<td>1 (23%)</td>
<td>1 (100%)</td>
</tr>
<tr>
<td>Device implementation (%) of Operative time</td>
<td>24.4 %</td>
<td>23.9%</td>
<td>18.4%</td>
<td>42.9%</td>
<td>25%</td>
</tr>
<tr>
<td>Ports used</td>
<td>4 (3-6)</td>
<td>4 (4-4)</td>
<td>4 (3-5)</td>
<td>5 (4-6)</td>
<td>4</td>
</tr>
<tr>
<td>Device exchanges between ports</td>
<td>2 (0-20)</td>
<td>2 (0-7)</td>
<td>3.5 (2-10)</td>
<td>16 (6-20)</td>
<td>1</td>
</tr>
<tr>
<td>-------------------------------</td>
<td>----------</td>
<td>--------</td>
<td>-----------</td>
<td>---------</td>
<td>---</td>
</tr>
<tr>
<td>Times device passed to assistant</td>
<td>3 (0-17)</td>
<td>2 (0-8)</td>
<td>3 (1-13)</td>
<td>6 (3-17)</td>
<td>5</td>
</tr>
<tr>
<td>Times surgeon changed positions*</td>
<td>1 (0-8)</td>
<td>0 (0-4)</td>
<td>2 (0-15)</td>
<td>5 (4-8)</td>
<td>0</td>
</tr>
<tr>
<td>Changes in table tilt</td>
<td>1 (0-10)</td>
<td>1 (0-5)</td>
<td>2.5 (0-6)</td>
<td>7 (2-10)</td>
<td>1</td>
</tr>
</tbody>
</table>

* With respect to the patient
Table 2. Non-activated use of the device

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Overall (N = 29)</th>
<th>Right colectomy (n = 17)</th>
<th>Lower anterior resection (n = 8)</th>
<th>Left colectomy (n = 3)</th>
<th>Transverse colectomy (n = 1)</th>
</tr>
</thead>
<tbody>
<tr>
<td>N of tasks/actions</td>
<td>1978</td>
<td>1146</td>
<td>584</td>
<td>167</td>
<td>81</td>
</tr>
<tr>
<td>Drawing tissue back/in</td>
<td>25.4 ± 15.5</td>
<td>25.1 ± 15.4</td>
<td>29.5 ± 17.7</td>
<td>13.0 ± 5.3</td>
<td>35</td>
</tr>
<tr>
<td>Grasping</td>
<td>11.6 ± 9.9</td>
<td>11.4 ± 10.8</td>
<td>8.4 ± 5.6</td>
<td>16.6 ± 13.6</td>
<td>25</td>
</tr>
<tr>
<td>Cold dissection</td>
<td>31.6 ± 17.4</td>
<td>31.6 ± 14.3</td>
<td>35.1 ± 25.9</td>
<td>26.0 ± 9.6</td>
<td>21</td>
</tr>
<tr>
<td>N of movements</td>
<td>1843</td>
<td>1156</td>
<td>528</td>
<td>133</td>
<td>26</td>
</tr>
<tr>
<td>Drawing tissue back/in</td>
<td>28.3 ± 22.0</td>
<td>28.8 ± 26.3</td>
<td>35.3 ± 6.8</td>
<td>16.3 ± 19.3</td>
<td>9</td>
</tr>
<tr>
<td>Grasping</td>
<td>9.2 ± 7.5</td>
<td>9.5 ± 8.6</td>
<td>9.9 ± 6.9</td>
<td>7.3 ± 4.1</td>
<td>6</td>
</tr>
<tr>
<td>Cold dissection</td>
<td>31.9 ± 20.2</td>
<td>34.0 ± 22.3</td>
<td>30.3 ± 19.4</td>
<td>31.0 ± 1.4</td>
<td>11</td>
</tr>
</tbody>
</table>

Mean ± SD (range) per subject