Vessel Sealing Reinvented: Initial Experiences with New Advanced Bipolar Vessel Sealing

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Background:
Vessel sealing in surgery has been shown to be a safe, reliable, and efficient hemostasis method with the benefit of leaving no foreign material in the body. A disadvantage of energy-based vessel sealing is the inherent heat that is generated during sealing, which may result in thermal injury to adjacent structures. Thermal injury to structures including bowel and nerve may result in post-operative complications. Also, vessel sealers generally do not replace surgical instruments such as fine dissectors as they typically have only one moveable jaw. This results in multiple instrument exchanges which is cumbersome, wasting time, and jeopardizing surgeon orientation.

Technology Description:
The Trinity device has incorporated the benefits of a highly functional surgical instrument with a fine tip and bilateral jaw motion. This was made possible due to development of the low power CoolSeal generator technology that optimizes sealing efficiency resulting in very fast seal times of less than 1.5 sec at only 35 Watts maximum power. Traditional systems deliver up to 350W by comparison. As thermal injury results from a combination of time at a given temperature, the optimized power and quick sealing times also function to minimize thermal injury.



Results:
100 primarily pediatric patients underwent a wide range of minimally invasive procedures using the 5 mm Trinity vessel sealing device. Thirty one hospitals used the device on a range of bowel, thoracic, and abdominal procedures (Figure 1). The average age of the patients was 10.1 yrs (range 2 wks-39 yrs) and average weight 46.0 kg (range 3.5 kg-185 kg) (Figure 2). The average number of seals per procedure was 47 indicating the device was used throughout the procedure in a multifunctional manner. There were no instances reported of intraoperative or post operative bleeding complications and no evidence of thermal injury. Following each procedure the surgeons rated the device performance using a 5-point Likert Scale across a range of performance factors. The overall average score was 4.56 indicating device performance was well above expectations (Figure 3).

Figure 1 - Number of Trinity cases across different procedure types (Bowel, Thoracic, and Abdominal)

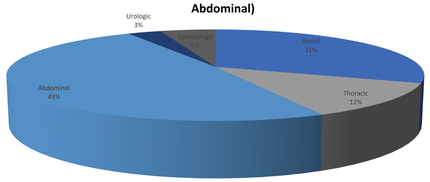


Figure 2 - No. of Procedures by Age Group

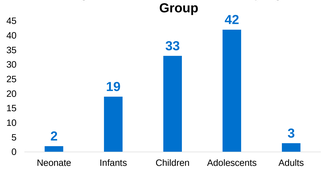
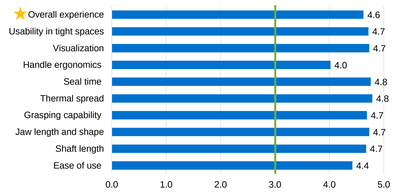


Figure 3 - Device Performance Mean Scores



Conclusions:
Initial experience with the Trinity device and CoolSeal™ technology demonstrated its utility and safety across a broad range of surgical procedures. There were no bleeding complications and no visible evidence of thermal injury indicating good device reliability and safety. The device performed well above expectations with respect to clinical effectiveness markers such as seal quality, visualization in tight spaces, seal time, and thermal spread. Ergonomic factors were also highly rated. The benefit of the dual-action capability was verified in that the device was used as the primary surgical instrument during the surgeries minimizing instrument exchanges. Further studies are recommended to quantify this impact.