



## Reprocessed bipolar energy for laparoscopic colectomy: Is it worth it?



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### ABSTRACT

**Background:** Reprocessed (re-sterilized) bipolar energy devices represent one effort to reduce operative costs.

**Methods:** Between January 2014 to October 2015, 76 patients underwent laparoscopic colectomy using a reprocessed bipolar energy device and were case-matched to 76 patients from a prospectively-maintained database from November 2012 to December 2013 when an identical, new device was used. Outcomes included reprocessed device safety, efficiency and hospital costs.

**Results:** There was no difference in patient demographics, operative times or failed pedicle ligation requiring intervention between groups (all  $P > 0.05$ ). In 19.7% of reprocessed cases, the surgeon opened an additional new device after dissatisfaction with the reprocessed instrument. Operating room costs and total costs were less for the reprocessed device group (all  $P < 0.05$ ).

**Conclusion:** Reprocessed bipolar energy devices were associated with savings in operative expenses, however, larger studies are warranted due to the high surgeon dissatisfaction regarding safety concerns with the reprocessed equipment.

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## 1. Introduction

There is a growing awareness of the rising cost of health care in the United States that has shone a spotlight on avoiding wasteful practices. Despite these efforts, healthcare costs grew by 5.3% in 2014, totaling \$3 trillion dollars or over \$9000 per person.<sup>1</sup> With such increasing costs felt to be unsustainable, there is pressure to provide high-quality, but cost-effective care, using methods such as the Bundled Payments for Care Improvement (BPCI) initiative by the Centers for Medicare and Medicaid Services (CMS).<sup>2</sup> Colorectal surgery is not spared from these cost containment measures and there is a need to evaluate how we can safely deliver more cost-efficient care. As laparoscopic colorectal surgery, which has well known postoperative cost savings compared to open surgery, is more widely adopted, it is important to identify potential intra-operative sources for cost savings as well.<sup>3</sup>

One proposed method is to refurbish and re-sterilize (*i.e.*, “reprocess”) single use instruments. To date, these have had variable results. Reprocessed laparoscopic trocars showed inconsistent results for the force needed for port insertion and extraction. Unfortunately, they have shown more air leakage compared to new trocar devices.<sup>4</sup> Harmonic<sup>®</sup> Curved Shears (Ethicon Inc., Cincinnati, OH) have been evaluated in animal models with noted inferior hemostasis in the reprocessed models.<sup>5</sup> While these results are not as encouraging as many would have hoped, there remains a need for further study.

The LigaSure<sup>™</sup> Blunt Tip Laparoscopic Sealer/Divider 5 mm-37 cm (Covidien, Boulder, CO, USA) bipolar energy device is used in many laparoscopic colorectal procedures and also has a reprocessed version approved by the U.S. Food and Drug Administration (LigaSure<sup>™</sup>; Stryker Sustainability, Tempe, AZ, USA). The new version is a very useful device, but at \$505 per unit, adds significant cost to a procedure.<sup>6</sup> Stryker Sustainability Solutions reports the reprocessed version offers up to a 55% discount off the original device cost. Although the device has undergone testing to verify its performance, it is common for surgeons to be skeptical of the

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performance of a reprocessed device, especially for vessels up to the reported 7 mm device limit.

Our aim was to evaluate the safety and efficiency of the reprocessed device for dissection and pedicle ligation for laparoscopic colectomy compared to a new, identical model. Additionally, we sought to compare expenses and margins between the two groups to determine if there was an overall cost savings with the reprocessed device. We hypothesized that outcomes for both groups would be equivalent with a measured cost savings for the reprocessed energy group.

## 2. Materials and methods

From January 2014 to October 2015, 76 consecutive laparoscopic segmental resections were performed with a reprocessed bipolar energy (RE) device (LigaSure™ Blunt Tip Laparoscopic Sealer/Divider 5 mm–37 cm). Segmental resections included right and sigmoid colectomies only. Converted cases were excluded. These cases were matched (1:1) to laparoscopic colectomies performed prior to the study date with an identical model, new energy (NE) device (LigaSure™ Blunt Tip Laparoscopic Sealer/Divider 5 mm–37 cm). All patients who undergo laparoscopic colorectal resection are prospectively entered into a comprehensive database. This database was used for the match selection. NE and RE cases performed with fellows or residents were excluded to decrease variability. Patients were matched by age, diagnosis, Diagnosis Related Group (DRG) (329, 330, 331), prior abdominal surgery, operation performed, and BMI. Patients in the NE group were selected from the database from November 2012 to December 2013. All patient data was collected in an Institutional Review Board-approved dataset.

The primary safety outcomes were estimated blood loss and additional interventions required for vascular pedicle ligation. Additional interventions were defined as any application of additional monopolar or bipolar energy after the initial ligation, the application of clips or a stapling device. Efficiency was assessed by comparing operative time between groups. Secondary endpoints included post-operative outcomes including length of stay and reoperations.

Cost information, including operative and inpatient hospital postoperative costs, for all patients was provided by the hospital's chief financial officer. More specifically, direct expenses (*i.e.*, operative), charges and total costs for the overall hospitalization were evaluated for all patients in both groups. Total profit margin was defined as payment received minus total expenses (direct and indirect).

If surgeons were dissatisfied with the device and/or there was any concern about the safety of the device, a new bipolar energy device was opened. Surgeon reasons for dissatisfaction included incomplete seal, ergonomics of closing the jaws or difficulty opening the jaw after a seal cycle. These patients were included in the RE group and the additional cost of a new device was included in our analysis.

Pedicle bleeding was defined as any intervention required after the final seal cycle was complete. This included the application of mono-polar energy to the seal line proximally or distally, the need for clips or the application of an endovascular gastro-intestinal stapler. If additional disposable equipment was required to control bleeding, the cost was accounted for in the final tabulation. The only variable and difference in direct expense between the groups was the use of the reprocessed energy device.

### 2.1. Operative technique

All segmental resections were performed with an identical

technique using a medial-to-lateral approach with intracorporeal vascular dissection, ligation and colonic mobilization. For the laparoscopic right colectomy procedure, all anastomoses were performed extracorporeally following vascular ligation through a periumbilical incision. All additional disposable instrument costs were controlled. For laparoscopic sigmoid colectomies, the anastomosis was performed intracorporeally and the costs were also controlled for all disposable instruments.

### 2.2. Statistical analysis

Categorical variables were compared using Fisher's exact test or Chi-square Test. Quantitative variables were compared using Wilcoxon rank-sum test and presented as median and interquartile range or mean ( $\pm$ ) standard deviation unless otherwise specified. A *p*-value less than 0.05 was considered significant.

## 3. Results

From January 2014 to October 2015, 76 laparoscopic segmental resections without a trainee were performed with the reprocessed bipolar energy (RE) device. The cost of the reprocessed device was \$225. These were then matched to 76 laparoscopic segmental resections with new bipolar energy (NE) from the database. The new bipolar energy LigaSure™ cost was \$505. The patients were similar, with no significant differences in any of the matching criteria (Table 1).

Operative time, estimated blood loss and length of stay were similar between the two groups (Table 2). Three patients (3.9%) in the RE group required an additional intervention for pedicle bleeding after ligation. In each case monopolar energy was successfully applied at the transection line. In each of these cases the estimated blood loss from the bleeding pedicle was less than 10 ml. Four patients (5.2%) in the NE group had bleeding from the pedicle that required additional intervention. In three of these patients, the bleeding was controlled with monopolar energy and was also less than 10 ml in each case. In one case, clips were required to control pedicle bleeding and the estimated blood loss was 50 ml during this portion of the procedure. One patient in each group required re-operation. The patient in the RE energy group was taken back for suspected anastomotic leak and had a negative laparoscopy. The one patient in the NE group was taken back for anastomotic leak requiring a Hartmann's procedure.

In 15 cases (19.7%) the surgeon was dissatisfied with the reprocessed equipment and requested a new model. The reasons for surgeon dissatisfaction were difficulty with the jaw opening

**Table 1**  
Matched patients in the reprocessed bipolar energy (RE) group and the new bipolar energy (NE) group.

Variable	RE (n = 76)	NE (n = 76)	P value
Age (y), median (IQR)	66 (28–92)	66 (34–88)	0.71
Gender, female (%)	35 (46)	38 (50)	0.26
BMI	33	31	0.63
Prior Abdominal Surgery (%)	31 (40.8)	30 (39.5)	0.84
<b>Diagnosis (%)</b>			
Polyp	8 (10.5)	8 (10.5)	NA
Cancer	44 (57.9)	44 (57.9)	NA
Diverticulitis	18 (23.7)	18 (23.7)	NA
Crohn's	6 (7.9)	6 (7.9)	NA
<b>Colectomy Type (%)</b>			
Right	30 (39.5)	30 (39.5)	NA
Left	46 (60.5)	46 (60.5)	NA

BMI: body mass index; IQR: interquartile range.

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