The Linear Cutting Stapler May Reduce Surgical Time and Blood Loss with Muscle Transection

A Pilot Study

Daniel C. Allison MD, MBA, Elke R. Ahlmann MD,
Anny H. Xiang PhD, Lawrence R. Menendez MD, FACS

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Abstract Because of skeletal muscle's density and vascularity, its transection with standard electrocautery can be tedious. In a pilot study we asked whether a linear cutting stapling device decreased surgical time, blood loss, transfusion rates, and complications in patients undergoing above-knee amputation when compared to traditional electrocautery. We retrospectively reviewed 11 patients with above-knee amputation cases using a linear cutting

stapling device over a 10-year period and compared those to 13 patients in whom we used electrocautery. The patients treated with the linear cutting stapling device had an average of 97 minutes of surgical time, 302 cc blood loss, and 1.55 units transfusion, compared to an average 119 minutes, 510 cc, and 2.15 units, respectively, with the electrocautery cases. Despite the trends, these parameters, as well as major complications, were similar in these two small groups. In skeletal muscle transection, we believe the linear cutting stapler is a reasonable and potentially cost-effective technical alternative to electrocautery, possibly resulting in less blood loss and shorter surgical time with similar rates of complications.

Level of Evidence: Level IV, therapeutic study. See Guidelines for Authors for a complete description of levels of evidence.

Each author certifies that he or she has no commercial associations (eg, consultancies, stock ownership, equity interest, patent/licensing arrangements, etc) that might pose a conflict of interest in connection with the submitted article.

Each author certifies that his or her institution has approved the human protocol for this investigation and that all investigations were conducted in conformity with ethical principles of research. This work was performed at University of Southern California, Baldwin Park, CA.

D. C. Allison
Division of Musculoskeletal Oncology, Southern California
Permanente Medical Group, 1011 Baldwin Park Boulevard,
Baldwin Park, CA 91706, USA

D. C. Allison (✉)
Department of Orthopedics, University of Southern California +
Los Angeles County Medical Center, USC University Hospital,
Los Angeles, CA, USA
e-mail: dallison12@hotmail.com

E. R. Ahlmann, L. R. Menendez
Department of Orthopedics, Keck School of Medicine,
University of Southern California + Los Angeles County
Medical Center, USC University Hospital, Los Angeles, CA,
USA

A. H. Xiang
Department of Biostatistics, University of Southern
California + Los Angeles County Medical Center, Los Angeles,
CA, USA

Introduction

Skeletal muscle is a dense and vascular soft tissue often encountered by the orthopaedic and general surgeon. Traditional techniques of muscle dissection include sharp dissection with a scalpel or scissors, blunt dissection with spreading instruments, and electrosurgical dissection. Advantages of sharp and blunt dissection include speed and accuracy at the expense of lack of hemostasis and tissue damage. Electrocautery may also be used, but causes contraction and retraction of the muscle and increases local tissue damage as shown histologically and delays wound healing—a finding that may be important in patients at risk for wound healing problems [10, 11].

The thigh contains more skeletal muscle mass per cross-sectional area than any other segment of the body [8]; therefore, above-knee amputation (AKA) represents an

ideal surgical procedure to analyze methods of skeletal muscle transection. AKA remains the salvage procedure for surgeons who handle severe or intractable cases of vascular disease, trauma, infection, and malignancy. Over 60,000 major lower limb amputations are performed each year in the United States [7]. Procedural efficiency remains an important variable in any surgery, and in the Civil War, well-trained surgeons could perform lower extremity amputations in less than 10 minutes, but experienced complications of blood loss, wound healing, and infection leading to a mortality rate of 28% to 52% [2]. Today, in academic centers and in the community, amputations are performed with similar goals of efficiency, but with a greater eye toward control of blood loss, soft tissue preservation, and uneventful wound healing. Increased surgical times are associated with charges of over \$60 per minute [6]. Further, contamination rates of open surgical trays increase to at least 15-minute intervals [3]. Blood loss is associated with financial costs as well as medical risks of transfusion reaction, increased intensive care unit and hospital stays, increased infection rates, and a 1.2 per 100,000 chance of hepatitis C viral transmission [4, 9, 13].

The linear cutting stapler (LCS), traditionally used for visceral transection and anastomoses, clamps soft tissue

and sharply cuts while ligating the margins with small, fine staples (Fig. 1A) and can transect large areas of muscle with speed and near complete hemostasis (Fig. 1B). This new technique may decrease blood loss and operative time when compared to standard techniques. Disadvantages of this technique include decreased accuracy of dissection, need for technical expertise, and inaccessibility in tight areas. A literature search revealed only two articles regarding the use of the LCS for muscle dissection. Both focusing on technique, they anecdotally state the method is feasible for muscle transection, reduces operative time, and does not increase complications [5, 12].

We therefore asked in a pilot study whether the LCS technique (1) reduced surgical time, (2) blood loss, (3) transfusion rates, and (4) overall complications compared to traditional electrocautery.

Materials and Methods

We retrospectively reviewed the medical records of all 30 patients who had an AKA by a single surgeon (LRM) between August 14, 1998 and August 6, 2007. The indications for AKA included malignancy, intractable infection, and failure of a previous limb-sparing procedure. We included patients in whom only AKA was performed and excluded those in which other time- or blood-consuming procedures were concurrently performed. Of the 30 patients with AKA we excluded six because other time- or blood-consuming procedures were concurrently performed. This left 24 patients, 13 performed with electrocautery and 11 with the LCS. The indication to use the LCS as opposed to electrocautery was based on the timing of the safe introduction of the device, with all electrocautery cases occurring consecutively before the LCS cases. We compared the two groups with regard to surgical time, blood loss, transfusions, and complications. No power analysis was performed initially (see Discussion for the post hoc power analysis). Age, gender, reason for amputation, and medical comorbidities were similar between the two groups (Table 1). Average followup was 45.3 months, a minimum of 14 months for the electrocautery group (average, 71.3 months; range, 14–112 months) and 4 months for the LCS group (average, 14.6 months; range, 4–33 months). No patients were lost to followup. The study was approved by our institution's Investigational Review Board.

The AKA procedure was performed without a tourniquet. A scalpel was used to incise the skin in a “fish mouth” fashion with equal anterior and posterior flaps at the appropriate level in regard to local soft tissue viability and the level of necessary osteotomy. Subcutaneous tissues and underlying fascia were dissected in line with the skin incision with electrocautery. Muscle was transected from

Fig. 1A–B (A) The LCS technique is pictured. (B) The muscle is shown after LCS transection.

Table 1. Patient characteristics and data

Age/Gender	Diagnosis	Comorbidities	Surgical time (minutes)	Estimated blood loss	Packed red blood cells (units)	Complications	Revision surgeries
Electrocautery							
83/M	Tibia osteomyelitis > squamous cell carcinoma	DM, HTN	100	75	2	PLP	None
87/F	Soft tissue sarcoma	PVD, HTN	105	112.5	0	None	Recurrence
64/F	Soft tissue sarcoma	DM, T4	75	350	2	Wound drainage	I&D and revision AKA
67/F	TKA infection	None	115	137.5	2	None	None
71/F	Soft tissue sarcoma	None	105	500	0	Femoral stump metastasis	Hip disarticulation
29/M	Knee endoprosthesis infection	None	224	3000	15	PLP, stump overgrowth	Bone revision
44/M	Tibia osteomyelitis	DM	153	400	2	None	None
24/M	Knee endoprosthesis infection	None	82	500	2	PLP	None
26/F	Knee endoprosthesis failure	HTN	80	100	0	None	None
64/M	Soft tissue sarcoma	None	72	100	0	None	None
75/M	PVNS + TKA infection	None	207	310	0	Severe PLP	PVNS excision
48/M	Soft tissue sarcoma	None	82	350	0	Severe PLP/neuroma	Neuroma excision
51/M	Distal femur osteomyelitis	HTN	144	700	3	None	None
LCS							
72/F	Soft tissue sarcoma	HTN, CAD, PPD+	88	250	1	PLP	None
32/M	Soft tissue sarcoma	?	120	550	1	PLP	None
82/F	Lymphoma + distal femur osteomyelitis	CAD, HTN, HCE, T4	96	150	0	Infection	I&D and revision AKA
62/M	Osteosarcoma	HTN, HCE, gastritis	77	150	2	None	None
51/F	Soft tissue sarcoma	HTN, asthma, migraines	95	250	2	Deep infection, PLP	I&D and revision AKA
48/F	Squamous cell carcinoma	Obesity	94	450	5	Wound necrosis	Hip disarticulation
47/M	Tibia osteomyelitis	None	90	100	0	None	None
67/F	TKA infection	ESRD, HTN, CAD, DM, obesity	92	500	2	Mild PLP	None
36/M	Soft tissue sarcoma	None	126	400	0	Severe PLP, neuroma	Neuroma excision
70/F	Soft tissue sarcoma	Bleeding D/O, breast ca, HCE	77	125	0	Mild PLP	None
48/F	Knee endoprosthesis infection	Morbid obesity	110	400	4	Wound dehiscence	I&D and wound vacuum

LCS = linear cutting stapler; PVNS = pigmented villonodular synovitis; DM = diabetes mellitus; HTN = hypertension; PVD = peripheral vascular disease; T4 = hypothyroidism; CAD = coronary artery disease; HCE = hypercholesterolemia; ESRD = end-stage renal disease; PLP = phantom limb pain; I&D = incision and drainage; AKA = above-knee amputation.

anterior to posterior as it was encountered. In the electrocautery group, muscle was transected using electrocautery in the coagulation mode. In the LCS group, muscle was transected primarily using the EZ-45 gastrointestinal anastomosis stapler (Ethicon Endo-surgery, Cincinnati, OH) as shown (Fig. 1A). The superficial femoral artery and vein were ligated with suture ligatures, stick ties, and hemoclips. The bone was osteotomized with an oscillating saw. The sciatic nerve was ligated with a suture as proximally as possible and then transected sharply at this level. Adductor myodesis was routinely performed. Bone wax was placed over the distal femoral canal with overlying layered closure of the fascia, subcutaneous tissue, and skin. A drain was not routinely placed. The wound was dressed and wrapped with a compressive dressing.

Postoperatively, physical therapy was initiated on postoperative Day 1 for mobilization and prone rests to prevent hip flexion contracture.

Patients were followed in clinic on weeks 1, 2, 6, and 12 and then every 3 months for the first 2 years.

From the medical records, we recorded the surgical time, blood loss, transfusions, and complications (Table 1). Surgical time was determined by subtracting the time “surgery end” from “surgery start” (skin-to-skin time) as recorded by the anesthesiologist in the anesthesia record. Blood loss was determined as an average of the surgeon’s and anesthesiologist’s estimate of blood loss; the surgeon’s estimate of blood loss was taken from the dictated operative note, and the anesthesiologist’s estimate of blood loss was taken from the transcribed anesthesia record. We reviewed the anesthesia record and hospital chart for blood transfusions given during the surgery and associated inpatient stay. Complications were determined by a review of the medical record for intraoperative, acute postoperative, and delayed complications. Major complications were defined as adverse events requiring surgical intervention.

The outcome variables were entered into an Excel (Microsoft Corp, Redmond, WA) spreadsheet, in which means and standard deviations were calculated. The average surgical time, blood loss, transfusions, and complications of each group were then analyzed with the two-group t-test to determine differences. Rates of major complications between groups were compared by t-test and chi square test. Statistical software SAS (SAS Institute Inc, Cary, NC) and MedCalc (MedCalc Software, Broekstraat, Belgium) were used for data analysis.

Results

The mean surgical time for the LCS and electrocautery group was similar ($p = 0.18$) (97 minutes versus

Table 2. Results summary

Outcome measure	Electrocautery group	LCS group	Difference with LCS (%)	p Value
Mean estimated blood loss (cc)	510	302	−208.1 (−40.8%)	0.39
Mean surgical time (minutes)	119	97	−22 (−18.5%)	0.18
Mean transfusions (units)	2.1	1.6	−0.6 (−28.0%)	0.65
Complications	6/13	5/11	— (−0.7%)	0.98

LCS = linear cutting stapler.

119 minutes, respectively). The mean estimated blood loss for the electrocautery group was also similar ($p = 0.39$) (510 cc versus 302 cc, respectively) (Table 2) as were the average units of blood transfused for the electrocautery group (2.2 units) was similar to the LCS group (1.55 units) ($p = 0.65$).

The number of major complications was similar ($p = 0.98$) between the two groups: six of 13 in the electrocautery group and five of 11 in the LCS group (Table 2). The nature of these complications was similar between the two groups. In the electrocautery group, one patient developed wound drainage and was treated with incision and drainage and revision AKA, and two patients developed stump problems that required revision surgery (hip disarticulation and revision AKA). Five patients in this electrocautery group developed phantom limb pain, two of whom were treated with revision surgery. One patient in this electrocautery group developed local recurrence of sarcoma, which was treated with revision AKA and inguinal lymph node dissection. In the LCS group, two patients developed wound necrosis and dehiscence, both of whom were treated with revision surgeries (hip disarticulation and revision AKA). Also in this LCS group, two patients developed deep infection, both resolving after incision and drainage with revision AKA. Five patients in the LCS group developed phantom limb pain, one of whom required neuroma excision. All instances of phantom limb pain in each group resolved or were well controlled with medication or surgery (Table 1).

Discussion

We investigated a new technique for muscle transection that may improve the problems of prolonged operative time and increased blood loss associated with traditional methods. In comparing the new LCS with the standard electrocautery, we asked if the LCS has an effect on surgical time, blood loss, transfusions, and complications.

The limitations of this study begin with the sample size. The high *p* values associated with the large mean differences suggest the study is underpowered. Therefore, a post hoc power analysis was performed to determine the sample size needed to determine statistical differences and equivalences between the mean values of outcomes of these two groups. Set to an alpha level of 0.05 and a beta level of 0.20, the sample size needed to confidently assume our differences in surgical time and blood loss were not the result of chance is 45 and 114 patients per group, respectively. Because of fervent attempts at limb salvage, AKA has become a procedure of last resort; therefore, fortunately, the cases at a single institution are limited. Finding a more common procedure with extensive muscle dissection or reproducing a multicenter study would increase the statistical power. The outcomes measured have inherent limitations. Recorded surgical times may be skewed by intraoperative delays that have nothing to do with the procedure itself (ie, waiting for personnel, searching for equipment). Surgeons' and anesthesiologists' estimates of blood loss may be subjective and biased. The retrospective nature of the study resulted in some poorly detailed or incomplete data in regard to outcomes, such as level of function, pain, exact time to wound healing, and minor complications that did not require intervention. A diligent surgical team that performs efficiently and documents meticulously decreases the error associated with these measures.

Procedure duration will always remain a key outcome in surgical practice, and we should also consider clinically important matters. Costs per minute use of operating time are excessive, and contamination on surgical tables increases to at least 15-minute intervals [3, 6]. If our differences were not obtained by chance, the 22-minute (18.5%) difference is clinically important in this regard. Accordingly, an article describing LCS use in radial neck dissection, noted "reduced operative time" anecdotally in "approximately 150 cases," though they gave no data or statistical analysis [5].

Blood loss also remains a key surgical outcome measure. The Advanced Trauma and Life Support guidelines categorize hemorrhagic shock according to amount of blood loss (Classes I–IV) [1]. In a 70-kg patient, 750 cc represents the difference among the four classes of shock. One can then assume an increment of 750 cc of blood loss is clinically important. Furthermore, in the case of a procedure with close to this amount of blood loss (510 cc for the electrocautery group), any reduction that takes this blood loss safely out of this 750-cc range can also be considered clinically important; for example, a 250-cc (50%) reduction in this case. Again, assuming that our 208 cc difference in blood loss did not occur from chance alone, our difference falls closely to this clinically important figure. No previous study regarding the use of the LCS

in muscle transection makes mention of resultant changes in blood loss.

In addition to hematoma and wound problems, the main morbidity associated with increased blood loss is the need for transfusion. Because risks and costs associated with transfusion increase with each unit transfused, one can assume that 1 unit is a clinically important increment. The 0.6-unit difference in means found in our study comes close to this figure, but our high *p*-value indicates a high probability of this difference being related to chance alone. As with blood loss, no previous LCS study described transfusion as an outcome.

Our complications were defined as any adverse event requiring a surgical intervention, and as such, each unit of complication (a surgical intervention) can be deemed important [4, 9, 13]. The differences in complications did not come close to 1 unit in our study and were therefore of no clinical importance. The aforementioned study regarding the use of the LCS in radical neck dissection described "no complications related to the stapler" in its 150 cases [5], and the other LCS article that briefly describes five cases of free tissue transfer to the face, notes 100% flap survival and "nonproblematic" staples at 10-month followup [12]. In concurrence with these two previous studies, the current study demonstrates no increased rate of complications.

The gains achieved with using the LCS must be weighed against the costs. Using the LCS as the primary means for muscle transection in AKA costs an estimated \$1000 to \$2000 in stapler and cartridge reloads. This cost must, in turn, be measured against the potential savings in decreased operating room time and blood loss. One study states that operating room time costs \$63.39 per minute [6], which means that 22 minutes of decreased surgical time would save \$1394.58 per case, if their analysis is accurate. The complications associated with increased blood loss and transfusion rates such as increased intensive care unit stays, hospital stays, infections, and complications have additional economic value [4, 9, 13]. We must also consider that increased use of the LCS in extra-abdominal general and orthopaedic surgeries will result in decreased cost of the device through economies of scale.

Our study demonstrates the LCS for muscle transection in AKA is a feasible technique. The difference in mean surgical time was 22 minutes, in mean blood loss was 208 cc, and in transfusion rates was 0.6 unit in favor of the LCS. We believe these differences clinically important, although the difference in surgical time only trended toward statistical significance. A better powered study might show these differences to be statistically significant. The LCS in cases involving extensive muscle transection is potentially cost-effective, and may result in decreased surgical time and blood loss without increased complications.

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