

Advanced Cutting Effect System versus Cold Steel Scalpel: Comparative Wound Healing and Scar Formation in Targeted Surgical Applications

Brian J. Lee, MD, FACS*

Malcolm Marks, MD, FACS†

Dell P. Smith, MD, FACS‡

Cheryl A. Hodges-Savola, PhD§

Jennifer M. Mischke, MPH¶

Ryan D. Lewis, MD, MPH¶

Background: Use of electrosurgery for skin incisions has been controversial due to concerns of delayed healing, excessive scarring, and increased infection. Recent studies using modern electrosurgical generators that produce pure sinusoidal “CUT” waveforms have shown reductions in thermal damage along incisions made with these devices compared with their predecessors. This study compares scar formation in incisions made using a cold steel scalpel (CSS) or the ACE Blade and Mega Power Generator (ACE system, Megadyne Medical Products, Draper, Utah) from patient and blinded observer perspectives.

Methods: Subjects seeking plastic surgery were enrolled in the study. Incisions on one side of each subject’s body were made with a CSS while equivalent incisions on the contralateral side were made with the ACE system. Differences between incision methods were evaluated by assessment of scar formation by observers and assessment of patient satisfaction relating to scar formation at 120 days postsurgery.

Results: Observers rated incision vascularization, pigmentation, thickness, and relief. The mean observer score (\pm SD) of incisions made with the ACE system was 11.1 ± 4.4 while that of incisions made with the CSS was 10.8 ± 3.7 ($P < 0.0001$). Patients rated incision pain, itching, discoloration, stiffness, thickness, and irregularity. The mean patient score of incisions made with the ACE system was 9.4 ± 9.2 while that of incisions made with the CSS was 9.3 ± 8.5 ($P < 0.0001$).

Conclusions: Results showed noninferior wound healing/scar formation in skin incisions made with the ACE system compared with incisions made with a CSS. (*Plast Reconstr Surg Glob Open* 2014;2:e234; doi: 10.1097/GOX.0000000000000208; Published online 21 October 2014.)

Wound healing of the skin after surgical incision is a primary factor affecting patient morbidity and recovery time. Historically, the cold steel scalpel (CSS) has been the instrument of choice for surgical incisions because of ease of

use, accuracy, and predictable tissue damage. However, the use of CSS must be accompanied by electrocautery or coagulation to maintain hemostasis and a clear surgical field.

Although early electrosurgery devices were effective in reducing blood loss, they often left collat-

From the *Southwest Surgical Suites, LLC, Ft Wayne, Ind.; †Department of Plastic and Reconstructive Surgery, Wake Forest Baptist Health, Winston-Salem, N.C.; ‡Center for Plastic Surgery, Twin Falls, Idaho; §NAMSA, Minneapolis, Minn.; and ¶Megadyne Medical Products, Inc., Draper, Utah.

Received for publication May 17, 2014; accepted September 4, 2014.

The study is registered on ClinicalTrials.gov and the registration number/identifier is NCT01175889. The study was registered on August 3, 2010.

Copyright © 2014 The Authors. Published by Lippincott Williams & Wilkins on behalf of The American Society of Plastic Surgeons. *PRS Global Open* is a publication of the American Society of Plastic Surgeons. This is an open-access article distributed under the terms of the Creative Commons Attribution-NonCommercial-NoDerivatives 3.0 License, where it is permissible to download and share the work provided it is properly cited. The work cannot be changed in any way or used commercially.

DOI: 10.1097/GOX.0000000000000208

eral thermal tissue damage that was associated with prolonged healing and pronounced scarring. As a result, there has been long-standing reluctance to make full-thickness cutaneous incisions with these devices.¹⁻⁴ A common practice that persists today involves making the initial incision through epidermal layers with a CSS, then switching to an electrosurgical device to cauterize blood vessels and complete the incision. Although this approach results in optimal hemostasis and wound healing for the patient, it increases the likelihood that surgeons and their assistants will be injured as they pass a sharp CSS back and forth during surgery.⁵

Improvements in the design of electrosurgical devices have addressed some of the problems inherent in earlier versions. Modern generators that produce pure sinusoidal “CUT” waveforms and optimized power curves, coupled with specialized cutting tips or “blades,” have been shown to cleave and cauterize tissue rapidly and with less thermal damage. There is growing evidence that modern electrosurgical devices can reduce incision time, bleeding, and thermal tissue damage, leading to improved cutaneous wound healing and scar formation.^{5,6}

The ACE Blade and Mega Power Generator (ACE system, Megadyne Medical Products, Draper, Utah) is a next-generation electrosurgery system that is intended for use in a broad range of surgical procedures requiring the use of electrosurgery for cutting and cauterization. The specific geometry of the “blade” was designed to minimize blanching and thermal damage in skin incisions when used in conjunction with the generator’s Advanced Cutting Effect mode. The goal of this study was to demonstrate noninferiority of the ACE system to the CSS in cutaneous incision wound healing at 120 days postsurgery.

PATIENTS AND METHODS

Megadyne Medical Products, Inc., Draper, Utah, sponsored the study. None of the study participants had any administrative or business association with Megadyne Medical Products and derived no compensation from the study. The protocol was reviewed and approved by an institutional review board and subjects provided written informed consent before enrollment.

Three study sites in the United States recruited subjects who were (1) at least 18 years of age but no

older than 60 years of age; (2) planning to undergo abdominoplasty, bilateral breast reduction, bilateral breast lift, bilateral brachioplasty, bilateral lateral thigh and buttocks lifts, or any combination thereof; (3) able to discontinue anticoagulant therapy; (4) willing and able to comply with study follow-up procedures; and (5) willing to provide written informed consent. Subjects were excluded if they had (1) history of smoking in the 6 months before surgery; (2) history of type I or type II diabetes; (3) any active infection at enrollment; and (4) known coagulopathy.

The surgical procedures were performed under general anesthesia or sedation according to standard practices. The surgical procedure for each subject enrolled in the study included incisions with both a CSS and an ACE system. Photographs of an ACE Blade and a CSS are shown in Figure 1.

Because wound healing was not expected to differ between one side of the body and the other, all incisions made on one side of a patient’s body used one incision device (eg, CSS) while all incisions on the other side used the other device (eg, ACE system). Neither the subjects nor the blinded plastic surgeon observers who ultimately rated the incisions were told which incision device was used on a given side.

Demographic information and a brief medical and surgical history were obtained from each subject within 30 days of surgery. Study follow-up visits were at 10 days (or at suture removal), 30 days, and 120



Fig. 1. Devices used for incisions: cold steel scalpel (A) and ACE Blade electrode (B).

Disclosure: Drs. Lee, Hodges-Savola, and Mischke served as consultants for Megadyne Medical Products, Inc. Neither of the other authors has any financial disclosures. The Article Processing Charge was paid for by the authors.

days postsurgery. At each follow-up visit, patients and investigators evaluated the incisions on both sides of the body using scar assessment scales. At 120 days postsurgery, photographs were taken of each patient's incisions and were used by blinded, independent expert observers to assess wound healing and scar formation on both sides of the study subjects' bodies. Although scar maturation can take 1 year or longer, patient and observer evaluation of scars after the first 120 days following surgery was expected to reflect the trajectory of wound healing following surgical incisions with the 2 different devices.

The Patient Scar Assessment Scale (PSAS) was used by study subjects to rate the incisions at follow-up study visit(s) on days 10, 30, and 120. The PSAS evaluates scar pain, itching, discoloration, stiffness, thickness, and irregularity. Each element is scored on a 10-point scale with a higher score (eg, 9) indicating a poorer rating than a lower score (eg, 2). The scores from the 6 elements are summed for a total of 60 possible points.

The Observer Scar Assessment Scale (OSAS) was used by the physician investigators to rate the patients' scars at days 10, 30, and 120 postsurgery. The OSAS evaluates scar vascularization, pigmentation, thickness, relief, and pliability. As with the PSAS, each element is scored on a 10-point scale with a higher score indicating a poorer rating. The 5 elements are summed for a total of 50 possible points. A modified OSAS was used by blinded expert observers to rate the scars at 120 days postsurgery. Because photographs were used by the expert observers, the pliability element of the scale was omitted; thus, the modified OSAS consisted of an available total of 40 possible points.

In addition to following wound healing/scar formation as a function of time postsurgery, subjects were evaluated for adverse events (AEs). AEs were documented and rated according to their severity (mild, moderate, severe) and relationship to the device (ACE system, CSS) used to make the incision (related, possibly related, unrelated, unknown).

Statistical Methods

The study sample size was determined based on a 1-sided paired *t* test for noninferiority of the ACE system to the CSS. Assuming a common standard deviation of 8 points (20% of the 40-point modified OSAS), a sample size of 43 subjects was needed to give 80% power to detect a difference $\mu_{ACE} - \mu_{CSS}$ of greater than $\delta = 5$ points at 1-sided significance level $\alpha = 0.05$.

Demographics, medical history, and procedural data were assessed by tabulations of the mean and standard deviation for continuous measures. The

measures included (but were not limited to) age, gender, ethnicity, race, body mass index, procedure type, and procedure time.

Primary effectiveness analysis evaluated the difference in modified OSAS scores between the ACE system side and the CSS side for each subject at 120 days postsurgery. Secondary effectiveness analysis evaluated the difference in PSAS scores between the ACE system side and the CSS side for each subject at 120 days postsurgery. Safety analysis was based on Fisher's exact test for the proportion of body sides with serious and device-related AEs.

Surgical Methods

Standard procedures were used throughout the surgeries; the only difference from one side to the other was the device used to make the cutaneous incisions. Abdominoplasties involved a horizontal incision placed just within or above the pubic area. The length of the incision depended on the amount of skin to be removed. Standard breast reductions were performed; the surgeon for each case performed the bilateral procedure according to individual preference, using the same incision pattern on both sides.

RESULTS

Eighty-one subjects were enrolled in the study. Six subjects were withdrawn by the investigators when the surgery was postponed (1 subject) or when the surgeries were performed using only CSS (5 subjects). Procedures using both the ACE system and CSS were completed on 75 subjects; of these, 1 subject withdrew from the study and 9 were lost to follow-up. Sixty-five subjects completed all study visits, and 64 subjects completed the self-assessment at 120 days postsurgery (Fig. 2).

All subjects were females and ranged in age from 22.3 to 60.0 years (median age was 41.0 years; Table 1). The majority of the subjects sought abdominoplasty (53.2%) or bilateral breast reduction (40.5%). The remaining subjects underwent bilateral breast lifts or brachioplasties.

Primary Effectiveness Analysis

Photographs of study incisions taken 120 ± 14 days postsurgery were scored by 2 independent board-certified plastic surgeons serving as blinded observers. Usable photographs were available for 57 subjects. The tabulated scoring is shown in Table 2. Mean scores for each element ranged from 1.3 to 2.4 for incisions made with the ACE Blade and from 1.4 to 2.3 for incisions made with the CSS. The difference in modified OSAS score between treatment sides ($OSAS_{ACE} - OSAS_{CSS}$) was calculated for each subject, where each side served as one of a pair of

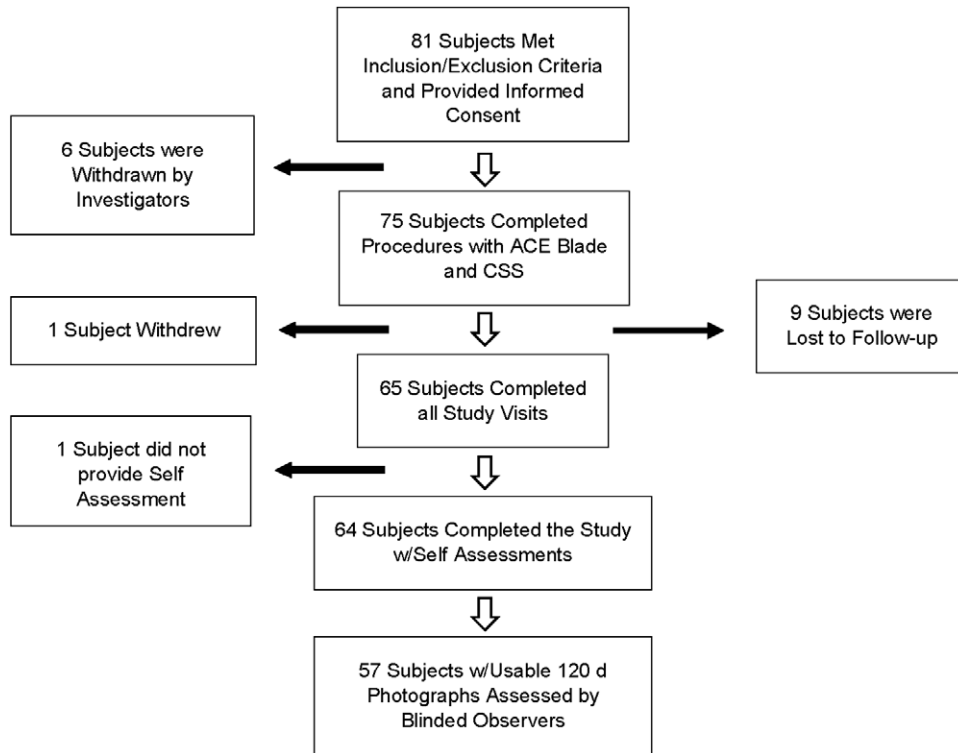


Fig. 2. Study subject accountability.

Table 1. Study Subject Demographics

Measure (or Parameter)	No. Subjects
Mean age (y) ± SD	41.7 ± 8.9 (79)
Median age [min, max]	41.0 [22.3, 60.0]
Gender	
Male	0% (0/81)
Female	100% (81/81)
Ethnicity	
Hispanic or Latino	4.9% (4/81)
Not Hispanic or Latino	95.1% (77/81)
Race	
American Indian/Alaska Native	0% (0/79)
Asian	1.3% (1/79)
Black or African American	12.7% (10/79)
Native Hawaiian or Other Pacific Islander	0% (0/79)
White	86.1% (68/79)
Other	0% (0/79)
Mean BMI ± SD	28.7 ± 7.2 (81)
Median BMI [min, max]	27.4 [17.7, 54.0]

Numbers are mean ± SD (N) and median [min, max] for continuous measures and percent (count/N) for discrete measures. Demographic information is presented for all subjects who were enrolled in the study. Two subjects did not provide their age and 2 subjects did not provide their race. BMI, body mass index.

matched observations. The mean difference and a 1-sided upper 95% confidence bound were computed for the overall scores. Noninferiority of the ACE system to the CSS in wound healing/scar formation as measured by the OSAS was established by the upper confidence bound for the mean difference in OSAS scores being ≤ 5 points (Table 3).

Table 2. Modified OSAS Scores (Photographic Evaluation)

Measure	Day 120
ACE Blade side	
Vascularization	2.4 ± 1.2 (57)
Pigmentation	2.0 [1.0, 6.0]
Thickness	1.8 ± 1.0 (57)
Relief	2.0 [1.0, 5.0]
Overall score (max 40 points)	2.0 ± 0.8 (57)
Cold steel scalpel side	
Vascularization	2.0 [1.0, 4.0]
Pigmentation	1.3 ± 0.5 (57)
Thickness	1.0 [1.0, 3.0]
Relief	1.0 [1.0, 3.0]
Overall score (max 40 points)	11.1 ± 4.4 (57)
	10.0 [3.0, 23.0]
Cold steel scalpel side	
Vascularization	2.3 ± 0.9 (57)
Pigmentation	2.0 [1.0, 6.0]
Thickness	2.0 ± 0.8 (57)
Relief	2.0 [1.0, 5.0]
Overall score (max 40 points)	1.9 ± 0.8 (57)
	2.0 [1.0, 5.0]
	1.4 ± 0.6 (57)
	1.0 [1.0, 3.0]
	10.8 ± 3.7 (57)
	10.0 [3.0, 24.0]

Numbers are mean ± SD (N); median [min, max] for continuous measures. Score for each photograph is the average of the scores obtained by 2 observers.

Secondary Effectiveness Analysis

Participating subjects completed the PSAS at days 10, 30, and 120 postsurgery; results are shown in Table 4. The mean overall scores for incisions made

Table 3. Difference in Overall OSAS Scores at 120 Days

	ACE System	CSS Blade	Difference (ACE – CSS)	95% CI for Difference	P
OSAS Score Day 120	11.1±4.4 (57) 10.0 [3.0, 23.0]	10.8±3.7 (57) 10.0 [3.0, 24.0]	0.3±4.6 (57) 0.0 [-7.0, 12.0]	(-0.9, 1.5)	<0.0001

Numbers are mean ± SD (N), median (min, max). P-value is from a paired *t* test for the noninferiority hypotheses $H_0: \mu_{ACE} \geq \mu_{CSS} + 5$. CI, confidence interval.

Table 4. PSAS Scores During the First 120 Days Postsurgery

Measure	Day 10	Day 30	Day 120
ACE Blade side			
Is the scar painful?	1.8±2.3 (68) 1.0 [0.0, 9.0]	1.6±2.1 (67) 1.0 [0.0, 8.0]	0.7±1.4 (64) 0.0 [0.0, 8.0]
Is the scar itching?	2.2±2.5 (68) 1.0 [0.0, 10.0]	1.6±2.0 (67) 1.0 [0.0, 8.0]	0.8±1.6 (64) 0.0 [0.0, 9.0]
Is the color of the scar different?	2.4±2.8 (63) 2.0 [0.0, 10.0]	2.9±2.8 (65) 2.0 [0.0, 9.0]	2.8±2.8 (64) 2.0 [0.0, 10.0]
Is the scar more stiff?	2.1±2.7 (64) 1.0 [0.0, 10.0]	2.2±2.7 (68) 1.0 [0.0, 9.0]	1.7±2.1 (64) 1.0 [0.0, 8.0]
Is the thickness of the scar different?	2.2±2.8 (64) 1.0 [0.0, 10.0]	2.5±2.6 (68) 2.0 [0.0, 9.0]	1.9±2.3 (64) 2.0 [0.0, 9.0]
Is the scar irregular?	1.8±2.8 (64) 0.0 [0.0, 10.0]	2.1±2.7 (68) 1.0 [0.0, 10.0]	1.5±2.3 (64) 1.0 [0.0, 10.0]
Overall score (max 60 points)	12.0±13.1 (68) 6.5 [0.0, 56.0]	12.6±12.2 (68) 9.5 [0.0, 49.0]	9.4±9.2 (64) 7.0 [0.0, 36.0]
Cold steel scalpel side			
Is the scar painful?	1.8±2.1 (68) 1.0 [0.0, 8.0]	1.6±2.3 (68) 1.0 [0.0, 10.0]	0.6±1.0 (64) 0.0 [0.0, 4.0]
Is the scar itching?	2.1±2.3 (68) 1.0 [0.0, 10.0]	1.7±1.8 (68) 1.0 [0.0, 8.0]	0.8±1.4 (64) 0.0 [0.0, 8.0]
Is the color of the scar different?	2.3±2.8 (63) 1.0 [0.0, 10.0]	2.9±2.9 (68) 3.0 [0.0, 10.0]	2.7±2.6 (64) 2.0 [0.0, 10.0]
Is the scar more stiff?	1.7±2.4 (64) 1.0 [0.0, 10.0]	2.3±2.5 (68) 2.0 [0.0, 9.0]	1.7±2.1 (64) 1.0 [0.0, 8.0]
Is the thickness of the scar different?	2.0±2.4 (63) 1.0 [0.0, 10.0]	2.9±2.6 (68) 3.0 [0.0, 9.0]	2.0±2.3 (64) 1.5 [0.0, 9.0]
Is the scar irregular?	1.7±2.5 (64) 0.0 [0.0, 10.0]	2.4±2.7 (68) 2.0 [0.0, 9.0]	1.6±2.3 (64) 1.0 [0.0, 10.0]
Overall score (max 60 points)	11.0±11.3 (68) 7.0 [0.0, 45.0]	13.7±11.7 (68) 12.0 [0.0, 48.0]	9.3±8.5 (64) 7.0 [0.0, 32.0]

Numbers are mean ± SD (N); median [min, max] for continuous measures.

with the ACE Blade were 12.0, 12.6, and 9.4 at days 10, 30, and 120, respectively. Scores were similar for incisions made with the CSS: mean overall scores were 11.0, 13.7, and 9.3 at days 10, 30, and 120, respectively. Patient impressions and satisfaction as measured by the 60-point PSAS were evaluated in a manner similar to that used for analysis of the modified OSAS score. With a *P*-value less than 0.0001, noninferiority of the ACE system to the CSS was established with respect to the overall PSAS scores at 120 days (Table 5).

OSAS Scores

Physician investigators also evaluated their patients' wound healing during follow-up visits. Because they were not blinded to the incision methods used, results from their assessments were not used for the study's endpoints to avoid potential bias in the analysis. Scores by nonblinded physician observ-

ers at 10, 30, and 120 days postsurgery are shown in Table 6. The mean overall scores for incisions made with the ACE Blade were 9.5, 10.6, and 10.1 at days 10, 30, and 120, respectively. Scores were similar for incisions made with the CSS: mean overall scores were 9.8, 11.7, and 10.1 at days 10, 30, and 120, respectively.

Safety Analysis

AE analysis was based on Fisher's exact test for the proportion of surgical sites (ie, sides of patients) with serious and device-related AEs after undergoing each procedure. Table 7 summarizes the AEs that were identified during the course of the study. No wound infection or hypertrophic scarring occurred in any incisions, and no differences in AEs were detected when incisions made with ACE Blades were compared with those made with CSS.

Table 5. Difference in Overall PSAS Scores at 120 Days

	ACE System	CSS Blade	Difference (ACE – CSS)	95% CI for Difference	P
PSAS Score Day 120	9.4±9.2 (64) 7.0 [0.0, 36.0]	9.3±8.5 (64) 7.0 [0.0, 32.0]	0.0±6.1 (64) 0.0 [-22.0, 30.0]	(-1.5, 1.6)	<0.0001

Numbers are mean ± SD (N), median (min, max). P-value is from a paired t test for the noninferiority hypotheses $H_0: \mu_{ACE} \geq \mu_{CSS} + 7.5$ vs $H_A: \mu_{ACE} < \mu_{CSS} + 7.5$.
CI, confidence interval.

Table 6. OSAS Scores (Nonblinded Physicians)

Measure	Day 10	Day 30	Day 120
ACE Blade side			
Vascularization	1.7±1.0 (67) 2.0 [0.0, 7.0]	1.9±0.8 (66) 2.0 [0.0, 4.0]	1.9±1.3 (64) 2.0 [0.0, 6.0]
Pigmentation	1.7±1.0 (67) 2.0 [0.0, 7.0]	2.1±0.8 (66) 2.0 [0.0, 5.0]	2.2±1.4 (64) 2.0 [0.0, 6.0]
Thickness	2.0±0.8 (67) 2.0 [0.0, 4.0]	2.3±1.0 (67) 2.0 [1.0, 6.0]	2.1±1.2 (64) 2.0 [0.0, 6.0]
Relief	2.1±0.9 (67) 2.0 [0.0, 4.0]	2.2±0.9 (67) 2.0 [0.0, 5.0]	2.0±1.2 (64) 2.0 [0.0, 6.0]
Pliability	2.1±0.8 (67) 2.0 [0.0, 4.0]	2.2±1.0 (67) 2.0 [0.0, 5.0]	1.9±1.0 (64) 2.0 [0.0, 5.0]
Overall score (max 50 points)	9.5±3.6 (67) 10.0 [0.0, 18.0]	10.6±3.9 (67) 10.0 [1.0, 23.0]	10.1±5.5 (64) 10.0 [0.0, 27.0]
Cold steel scalpel side			
Vascularization	1.7±0.9 (67) 2.0 [0.0, 5.0]	2.1±0.9 (67) 2.0 [0.0, 5.0]	1.9±1.2 (64) 2.0 [0.0, 6.0]
Pigmentation	1.6±0.7 (67) 2.0 [0.0, 3.0]	2.2±0.8 (67) 2.0 [0.0, 5.0]	2.2±1.3 (64) 2.0 [0.0, 6.0]
Thickness	2.0±0.8 (67) 2.0 [0.0, 4.0]	2.4±1.0 (67) 2.0 [0.0, 5.0]	2.1±1.1 (64) 2.0 [0.0, 5.0]
Relief	2.3±0.9 (67) 2.0 [0.0, 4.0]	2.6±1.1 (67) 3.0 [0.0, 6.0]	2.0±1.1 (64) 2.0 [0.0, 5.0]
Pliability	2.2±0.7 (67) 2.0 [0.0, 4.0]	2.4±1.0 (66) 2.0 [0.0, 5.0]	1.9±1.0 (64) 2.0 [0.0, 5.0]
Overall score (max 50 points)	9.8±3.4 (67) 10.0 [0.0, 18.0]	11.7±4.2 (67) 11.0 [0.0, 24.0]	10.1±4.9 (64) 10.0 [0.0, 25.0]

Numbers are mean ± SD (N); median [min, max] for continuous measures.

Table 7. All Adverse Events

Event Type	ACE System	Cold Steel Scalpel	P
Wound dehiscence	1.3% (1/75)	1.3% (1/75)	1.0000
Wound infection—cellulitis	0% (0/75)	0% (0/75)	NA
Wound infection—suppurative	0% (0/75)	0% (0/75)	NA
Hypertrophic scar	0% (0/75)	0% (0/75)	NA
Other event	1.3% (1/75)	1.3% (1/75)	1.0000

Numbers are percent (count/N) for number of subjects experiencing an event. P-value is from Fisher’s exact test. There were no serious adverse events or unanticipated adverse device effects.
NA, not applicable.

DISCUSSION

In the United States, there are approximately 36 million surgical procedures performed each year. Although surgeons use electrosurgery to cut and coagulate tissue in more than 80% of these procedures, a CSS is often used to make the initial skin incision because of concerns that electrosurgical electrodes may cause thermal damage, resulting in delayed wound healing or poor cosmetic outcomes.

Many of the electrosurgical devices used today are monopolar. In monopolar mode, current passes from the generator to the active electrode at the incision site, through the patient’s body, to the patient return electrode and back to the generator to complete the circuit. For cutting and coagulation to occur, current must flow uninterrupted through the entire circuit. A break in the circuit or changes in tissue impedance will disrupt or alter current flow, increasing the likelihood of an inconsistent inci-

sion. These electrosurgical devices require manual adjustments of the settings based on the anatomy of the surgical site and the nature of the surgical procedure.^{3,6}

The ACE system delivers computer-controlled constant voltage with an optimized power curve and consistent cutting effect to the surgical site regardless of the tissue impedance. Accordingly, there is no need for manual adjustment of the power settings within a particular operational mode because the system does it automatically. In addition, the ACE system's electrosurgical tip has been geometrically optimized to work with the constant voltage delivered by the system's generator in ACE mode or in COAG mode, resulting in a single electrosurgery device that can be effectively used for skin and deep tissue incisions and blood vessel coagulation.

Study results show that the ACE system produces full-thickness cutaneous incisions that form scars which are equivalent to those of paired contralateral incisions made with CSS in terms of appearance and texture. Noninferiority of the ACE system, compared with CSS, was established by expert observers and patients alike. Although the primary and secondary effectiveness outcomes were the results of assessments made at 120 days postsurgery, PSAS and OSAS results obtained at earlier study time points (day 10 and day 30 postsurgery) were consistent with those obtained at 120 days (Tables 4 and 6).

Data from the PSAS showed similar pain and itching scores for both the ACE system and CSS; as expected, mean scores for these elements declined between day 10 and day 120 (Table 4). Scar color, stiffness, thickness, and irregularity as scored by patients were similar at both days 10 and 120, regardless of whether the incisions were made with the ACE system or the CSS. Assessments by observers were also consistent between days 10 and 120, regardless of the incision device (Table 6).

During the past 20–25 years, many studies have evaluated cutaneous incision parameters following the use of different methods of incision. Because each study has been unique in its design and outcome measures, it is difficult to directly compare results from one study to the next. The majority of the reports have focused on differences in incision time, blood loss, postsurgical pain, and wound complications as a function of different incision methods.^{5–7} The few reports that describe the cosmetic appearances of surgical wounds made with electrosurgical devices versus those made with CSS either did not involve full-thickness cutaneous incisions with both devices,⁸ included assessment of scar appearance by the operating surgeon and not by a blinded observer(s)

or patients,⁹ or evaluated a relatively small number of subjects.¹⁰

The present study differs from most of the earlier studies in several important ways. First, it focuses on scar cosmesis, and its outcome measures are based on scar assessments by blinded, expert observers and the patients themselves. Because of the nature and extent of the study's surgical procedures, the patients' perceptions of their scars are important indicators of the ACE system's effect on wound healing and scar formation. Next, this study incorporates validated scar assessment surveys to document observer and patient impressions of scar sensation (ie, pain/itching), texture, and appearance.^{11,12} The PSAS and OSAS return numeric results rather than nominal results, which leads to greater consistency of scores. The assessment scales have been shown to be appropriate subjective tools for the evaluation of burn scars¹¹ and surgical linear scars.¹² Finally, more than twice the number of paired results were evaluated in the ACE system study (64 evaluated by patients and 57 evaluated by observers) compared with those evaluated by others (10; 19 paired results).

CONCLUSIONS

These findings support the use of the ACE electrosurgical system throughout the entire incision process for surgeries involving extensive skin incisions. The ACE system effectively cuts, coagulates, and dissects, without causing dissipated thermal injury and its consequential adverse effects on wound healing.

Ryan D. Lewis, MD

Megadyne Medical Products, Inc.,
11506 S State Street
Draper, UT 84020
E-mail: rlewis@megadyne.com

REFERENCES

1. Rappaport WD, Hunter GC, Allen R, et al. Effect of electrocautery on wound healing in midline laparotomy incisions. *Am J Surg.* 1990;160:618–620.
2. Kumagai SG, Rosales RF, Hunter GC, et al. Effects of electrocautery on midline laparotomy wound infection. *Am J Surg.* 1991;162:620–622; discussion 622–623.
3. Papay FA, Stein J, Luciano M, et al. The microdissection cautery needle versus the cold scalpel in bicoronal incisions. *J Craniofac Surg.* 1998;9:344–347.
4. Soballe PW, Nimbkar NV, Hayward I, et al. Electric cautery lowers the contamination threshold for infection of laparotomies. *Am J Surg.* 1998;175:263–266.
5. Ly J, Mittal A, Windsor J. Systematic review and meta-analysis of cutting diathermy versus scalpel for skin incision. *Br J Surg.* 2012;99:613–620.
6. Aird LN, Brown CJ. Systematic review and meta-analysis of electrocautery versus scalpel for surgical skin incisions. *Am J Surg.* 2012;204:216–221.

7. Chrysos E, Athanasakis E, Antonakakis S, et al. A prospective study comparing diathermy and scalpel incisions in tension-free inguinal hernioplasty. *Am Surg*. 2005;71:326–329.
8. Dixon AR, Watkin DF. Electrosurgical skin incision versus conventional scalpel: a prospective trial. *J R Coll Surg Edinb*. 1990;35:299–301.
9. Kumar V, Tewari M, Shukla HS. A comparative study of scalpel and surgical diathermy incision in elective operations of head and neck cancer. *Indian J Cancer* 2011;48:216–219.
10. Chau JK, Dzigielewski P, Mlynarek A, et al. Steel scalpel versus electrocautery blade: comparison of cosmetic and patient satisfaction outcomes of different incision methods. *J Otolaryngol Head Neck Surg*. 2009;38:427–433.
11. Draaijers LJ, Tempelman FR, Botman YA, et al. The patient and observer scar assessment scale: a reliable and feasible tool for scar evaluation. *Plast Reconstr Surg*. 2004;113:1960–1965; discussion 1966–1967.
12. van de Kar AL, Corion LU, Smeulders MJ, et al. Reliable and feasible evaluation of linear scars by the Patient and Observer Scar Assessment Scale. *Plast Reconstr Surg*. 2005;116:514–522.