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Evaluation of an intuitive, intelligent electrosurgical generator

Crystal D Ricketts, Mark D Glassett, Jeffrey W Clymer*, Kevin M Lewis and Paul R Borgmeier

All of Ethicon, Inc., 4545 Creek Rd, Cincinnati OH USA 45242, USA

Abstract

Introduction: While much has been reported about electrosurgery blades and their performance, there has been a dearth of literature on the component that plays just as important a role in the process of effective cutting and coagulation, namely the electrosurgical generator. This paper describes the new Megadyne Electrosurgical Generator, explains its novel algorithm for low-trauma cutting, Geometric Electron Modulation (GEM), and discusses the evaluation of its performance by health care professionals.

Methods: The generator was evaluated at three international sites. Scrub nurses with previous experience in electrosurgery set up the equipment, and surgeons (gynecological, colorectal and general) performed dissection, cutting and coagulation procedures in an animate porcine model. The nurses and surgeons then provided an assessment of the generator via a questionnaire.

Results: Over 90% of nurses agreed that the new generator was easy to set up and use. Two-thirds of nurses felt that the Megadyne generator was easier to set up and required less training than their current generator. Over 95% of surgeons agreed that the new generator provided effective hemostasis and dissection speed with an acceptable amount of thermal spread.

Conclusion: As demonstrated in both preclinical and clinical studies, the GEM mode provides effective tissue cutting with minimal thermal damage. Enhanced device performance is provided by the addition of a Soft Coag mode to complement the GEM cutting, and Auto Bipolar control for ease of application. These novel features of the Megadyne Electrosurgical Generator are supported with the evaluation by nurses and surgeons, who found the device easy to use and effective.

Introduction

Electrosurgery is a standard of practice, being used in 80% or more of all surgical procedures [1]. The first use of an electrosurgical generator during surgery took place on October 1, 1926 at Peter Bent Brigham Hospital in Boston [2], enabling the removal of a tumor that could not have been excised using traditional methods. While many advances in the safety and effectiveness of electrosurgical generators have been made since that time, the fundamental technology has remained the same.

Megadyne, now part of Ethicon, has been a pioneer in electrosurgery, with a 30-year legacy of innovating electrosurgical generators and electrodes (Figure 1). This article reviews the fundamentals of electrosurgery and clinical use of the Megadyne Mega Power Electrosurgical Generator. Technical improvements in generator design, and the evaluation of the setup and performance of the new Megadyne Electrosurgical Generator by nurses and surgeons are also presented.

Background

Traditional electrosurgical devices are used for cutting tissue and controlling bleeding in millions of procedures each year [3]. In simplest terms, electrosurgery is the cutting and coagulation of tissue using high-frequency electrical current. While the use of radio frequency (RF) energy produces thermal necrosis to the applied tissue, this is outweighed by the benefits of the cutting speed and the control of bleeding as compared to the use of a traditional scalpel [4].

Electrosurgical generators require the Cut and Coag modes to be set prior to the surgical procedure based on the surgeon's preference. These "constant power modes" are displayed in Watts (for example 30 Cut, 30 Coag), and deliver a set amount of energy to tissue independent of the tissue impedance. The minimum voltage to cut tissue is approximately 200 V [5]. Similarly, the necessary voltage to initiate and maintain plasma (i.e. ionized air) is near or just above 200 V [6], depending on the actual impedance, waveform, and generator settings. When using more than 200 V, the tissue effect increases and thus the tissue damage is greater. On the other hand, when using less than 200 V, the tissue effect decreases, and cutting or coagulation may be insufficient. In surgical practice, traditional electrosurgical generators using "constant power modes" may result in excessive thermal damage to tissues by delivering more than 200 V. For this reason, the use of these devices on the skin have been discouraged for many years. In contrast, the ideal goal for cutting is to use the minimum voltage possible, i.e., about 200 V, that will still form a plasma arc sufficient to cut tissue.

Relationships between power, current, impedance (a more general term for resistance), and voltage are fundamental concepts in understanding how an electrosurgical generator works. The key terms and various formulas which demonstrate their interdependency are shown in Figure 2.

***Correspondence to:** Jeffrey W Clymer, Ethicon, Inc., 4545 Creek Rd, Cincinnati OH USA, Tel: 513337-3318; E-mail: jclymer@its.jnj.com

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1985: Megadyne founder, Dr. G. Marsden Blanch, develops E-Z Clean® PTFE Coated Electrodes, the first PTFE coated non-stick electrosurgical tips.

1991: Release of E-Z Clean® coated Laparoscopic Electrodes provided improved dissection and coagulation for a variety of surgical applications, as manufacturers looked to provide added safety and efficiency features.

1999: Introduction of the Indicator Shaft™. The patented, inner yellow, insulation shaft alerts clinicians to nicks or holes in the outer insulation, indicating it is time to discard and replace the electrode.

2001: Launch of the Mega Soft™ Patient Return Electrode. This pad provided an alternative to the traditional "sticky pad" and offered a new level of safety and comfort.

2005: Mega Power™ Electrosurgical Generator was released to improve overall functionality in a surgical setting and to increase the proficiency of the surgical staff. Proprietary Advanced Cutting Effect (ACE) Mode is launched, which modulates the power to create a low voltage plasma.

2015: Megadyne launched the Zip Pen™, a smoke evacuation pencil that removes electrosurgical smoke from the OR. The unique design allows surgeons to experience comfortable and precise electrosurgery while minimizing the hazards of inhaling surgical smoke.

2020: The Megadyne Electrosurgical Generator is released to provide simplicity and intelligence within the operating room. Proprietary Geometric Electron Modulation (GEM) Mode is launched, which expands upon the ACE Mode power modulation technology established in the Mega Power Electrosurgical Generator.

Figure 1. History of megadyne innovation

Voltage:	V	(force to move electron charge)
Current:	i	(flow of electron charge)
Resistance:	R	(resistance to current flow)
Ohm's Law:	$V = i \times R$	
	$i = V / R$	
	$R = V / i$	
Power:	$P = i \times V$	
	$P = V^2/R$	
	$P = i^2 \times R$	

Figure 2. Key relationships in electricity

Geometric Electron Modulation technology

Geometric Electron Modulation (GEM) technology incorporated in the Megadyne Electrosurgical Generator is fundamentally different from standard electrosurgical devices. GEM technology focuses the energy to the tapered edges of a specially designed blade and modulates the power level to create a low voltage plasma. The generator maintains a constant minimum voltage required for cutting at the surgical site, whereas standard electrosurgical devices maintain a constant power, allowing the voltage to increase to excessive levels. By optimizing voltage for the blade geometry and modulating power based on tissue impedance, GEM achieves an optimal cutting effect, resulting in significantly less thermal damage vs. traditional electrosurgery [7]. To obtain a "GEM effect," there are two components required: a tapered blade and a generator mode that modulates power.

First, the blade utilized must have tapered blade edges (Figure 3), so that the energy rides along a vapor film, or plasma, which is created by electrical arcs traveling from the blade to the tissue [8]. The tapered blade edges are geometrically designed to lyse the cells with the least amount of energy required. In contrast, wider blades disperse the current very broadly and reduce the total energy delivered to the target tissue, resulting in less effective cutting. Therefore, a wider blade requires increased power to achieve a similar electrosurgical cutting effect.

Second, GEM Technology generators use a proprietary feedback algorithm to adjust the generator power to maintain constant minimum voltage at the surgical site as impedance dynamically changes (Figure 4). Different tissue types inherently possess different impedance levels, requiring the level of power to be adjusted. With GEM, the generator intelligently maintains 200 V by sensing tissue impedance and adjusting power to hold the voltage constant, without requiring power adjustment throughout the procedure. The constant voltage allows the user to cut through different tissue types with minimal thermal damage.

Traditional cut modes utilize constant power, so the power remains the same regardless of blade depth in the tissue. For instance, if a surgeon makes an incision to a depth of 10 mm, and then changes to a depth of 5 mm, the interface resistance is increased by a factor of approximately two and therefore the voltage must increase to maintain the set power. Voltage beyond 200 V creates added thermal damage. However, with GEM Technology, the depth of cut does not affect thermal damage. In the same scenario, if a surgeon decreases the depth of incision by a factor of two, the generator modulates the power to maintain a constant voltage of approximately 200 V, thereby minimizing the thermal damage. This ability to sense tissue impedance

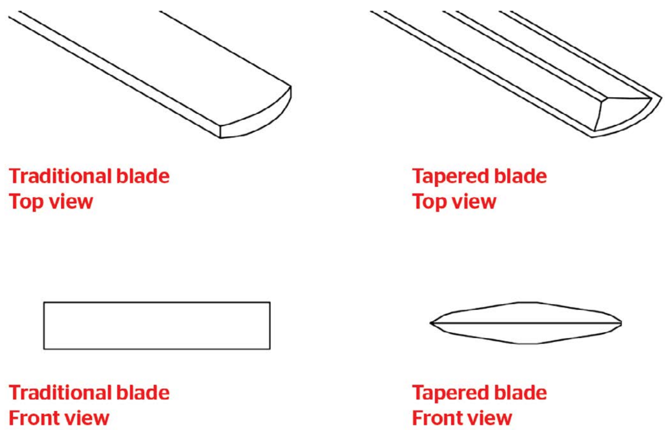

Figure 3. Traditional and tapered blade design

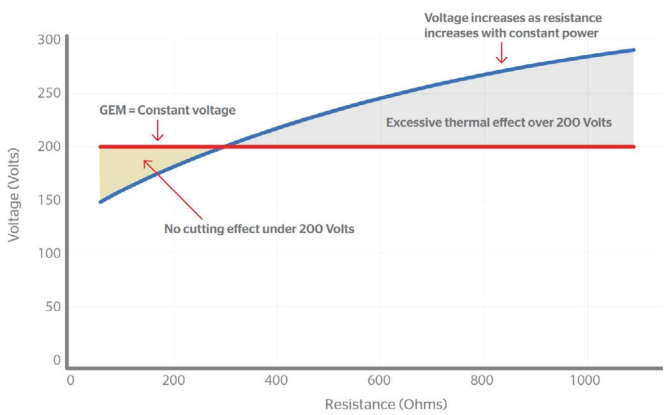

Figure 4. Comparison of constant power (traditional) and constant voltage (GEM) modes

Figure 5. The Megadyne Electrosurgical Generator

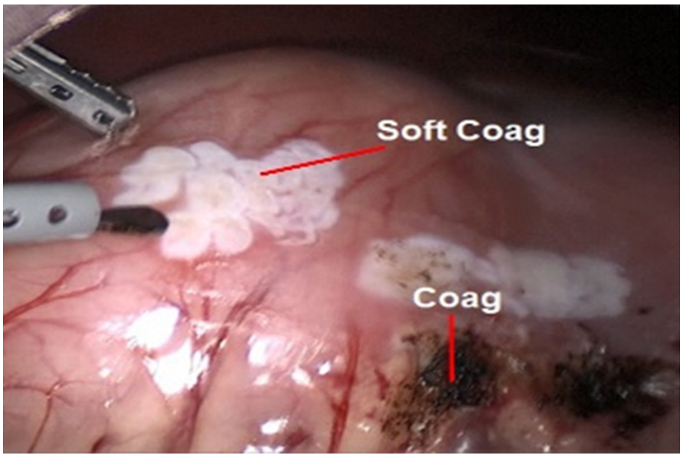

Figure 6. Tissue effect of Soft Coag mode vs (standard) Coag mode in porcine stomach

and adapt its power output allows the Megadyne Electrosurgical Generator to optimize energy delivery to minimize tissue damage through proprietary software and algorithms.

The new Megadyne Electrosurgical Generator (Figure 5) was designed with the proprietary GEM Mode (previously ACE mode in the Megadyne Mega Power Electrosurgical Generator) and expands the power modulation technology with two additional settings: GEM High and GEM Low. GEM High Mode is designed to provide surgical speed and efficiency, similar to the previous ACE mode of the Megadyne Mega Power Electrosurgical Generator. GEM Low Mode provides approximately half the power of GEM High Mode and is designed to provide more surgical control and tactile feedback. This allows the surgeon to cut with slower speeds, such as may be desired around more delicate structures. In addition, the resulting half power of GEM Low mode results in equivalent or less thermal damage and surgical smoke as compared to the GEM High Mode.

The Megadyne Electrosurgical Generator is a microprocessor-controlled, isolated output high frequency generator that can be customized by the user for each procedure through the use of the various power modes and instrument settings. There are 3 different cut modes, 4 coag modes and 2 bipolar modes with an optional Auto Bipolar feature. A complete comparison of the modes available in the Megadyne Electrosurgical Generator is given in Table 1. For most of the power modes, the generator's microprocessor controls the output of the generator with a constant power output based on the impedance of the tissue. An exception to this constant power output is the GEM cut modes. The bipolar modes are regulated to provide constant power over low impedances and then switch to a more constant voltage mode as the impedance increases. This algorithm results in quick sealing initially, but then as the tissue dries and tissue impedance increases, the generator rapidly decreases the power to avoid excessive tissue damage.

The Megadyne Electrosurgical Generator was designed to be easy to set up and use by the clinical staff. The displays are highly visible and easy to read with a simple user interface and dedicated push button design. This design dedicates a button to each individual function and power mode helping to make the pre-op setup simple, increasing efficiency and reducing the risk of errors in set up. New features include a Soft Coag mode, which is designed to provide coagulation and desiccation at a slow rate with deep thermal penetration. Soft Coag is a contact coagulation mode that uses a continuous waveform like Cut mode, but at much lower voltages. With the electrode in direct contact with tissue, there is little to no arcing at these voltages. For bipolar mode, an Auto Bipolar feature can be selected to remove the need for a footswitch; the electrode is activated automatically when tissue is sensed within the tines of the forceps and deactivated when the tines are separated. The user can select a long (1 second), short (0.5 second), or no delay prior to onset of energy delivery.

Methods

To evaluate the usability of the Megadyne Electrosurgical Generator (Ethicon, Inc., Cincinnati, OH, USA), scrub nurses and surgeons performed simulated surgical procedures in an animal model. Afterwards, nurses were asked about the ease of setup and usability, and surgeons were asked to provide feedback on the settings and modes used, and the ability to cut and coagulate tissue. Nurses were from the United States, whereas surgeons were from the United States, Germany and Japan. In Germany, surgeons were also asked to evaluate Auto Bipolar delay, and the Auto Bipolar start/stop function. In Japan, surgeons were specifically asked about coagulation modes. All participants reviewed the instructions for use prior to beginning. Participating surgeons and nurses signed a consent form and were assured that their participation in the study was voluntary and their survey responses were not individually identifiable. The participants received an honorarium for participation but were blinded to the identity of the study sponsor.

Nurses

Nurses were asked to connect the monopolar pencil and bipolar forceps and foot pedal. They were then asked to adjust the monopolar Pure Cut setting to 30 W, Coag 1 to 30 W, and Bipolar to 20 W. All other settings were left unchanged. Nurses were also asked to adjust the settings as needed when a surgeon performed different tasks. These activities mimicked tasks performed during a normal surgical procedure (e.g., setting up the generator, entering preferences, adjusting power, etc.).

Surgeons

In the United States and Germany, surgeons were asked to use monopolar to test cut and coagulation modes and the GEM mode with ACE Blade 700, and to use bipolar to test coagulation modes with the Ethicon Endopath Bipolar Forceps. Surgical procedures performed in a porcine model included a colonic mobilization, omentectomy, skin flap, small bowel resection or total hysterectomy with or without oophorectomy depending on the surgeon's specialty. In Japan, surgeons were asked to specifically use monopolar to test Soft Coagulation using the surgeon preferred handpieces on pulmonary, hepatic, gastric, mesenteric and lymphatic tissue.

After the procedures, the surgeons evaluated the generator via predefined questionnaires on attributes of speed, tissue effect, char,

Table 1. Modes available in the Megadyne Electrosurgical Generator

Mode	Waveform	Max Vpp	Power Range	Tissue Effect
Monopolar Cut Modes				
Pure Cut	400 kHz	1500 V	300 W	Standard cutting effect
Blend Cut	400 kHz 50% duty	2500 V	200 W	Combination of cutting with coagulation effect
GEM* High	400 kHz	860 V	150 W	Efficient cutting with minimal thermal damage
GEM Low	400 kHz	600 V	75 W	More controlled cutting with tactile feedback
Monopolar Coagulation Modes				
Coag 1	2.5 µs pulse @32 kHz	5000 V	120 W	Dissection with coagulation
Coag 2	2.5 µs pulse @30 kHz	4900 V	120 W	Dissection with milder coagulation
Spray	2.5 µs pulse @22 kHz	5800 V	120 W	Fulguration, broad area of hemostasis, superficial
Soft Coag	400 kHz	470 V	120 W	Slower desiccation with deeper penetration
Bipolar Modes				
Micro	400 kHz	450 V	80 W	Precise
Macro	400 kHz	590 V	80 W	Rapid

*Geometric Electron Modulation

sticking and hemostasis in comparison to the generator they currently use. The Soft Coag mode was evaluated only in Japan, whereas the functionality of the Auto Bipolar feature was only tested in Germany on harvested tissue. Each study participant signed a consent form prior to the interview.

Animal procedures were approved by the local Institutional Animal Care and Use Committees and conducted in accordance with the Guide for the Care and Use of Laboratory Animals and applicable animal welfare regulations in AAALAC-accredited facilities.

Results

A total of 34 surgeons (18 US, 8 German and 8 Japanese), and 18 US nurses completed the questionnaires. Surgeons represented the areas of gynecological, colorectal, and general surgery. All surgeons and nurses had previous experience with electrosurgery, with most familiarity with the Medtronic FT10, Force Triad, ConMed 5000 or Erbe VIO3 generators. None of the surgeons or nurses reported previous experience with the Megadyne Mega Power Electrosurgical Generator.

Results of the questionnaires are given in Table 2 for the surgeons and Table 3 for the nurse. Over 95% of surgeons agreed that the generator operated appropriately with regards to hemostasis, speed and tissue effects. Likewise, over 90% of nurses agreed that the generator was easy to set up and use. Two-thirds of nurses felt that Megadyne Electrosurgical Generator was easier to set up and required less training than their current generator.

Separately, 22 German surgeons used Auto Bipolar in their surgeries. Of the 22 surgeons, 2 preferred the long 1 second delay, 8 preferred the 0.5 second delay and 12 did not want a delay. Surgeons preferred to turn the generator off manually rather than wait for the auto stop to occur.

A total of 8 Japanese surgeons, representing colorectal, gastric, general, hepatic and thoracic specialties, evaluated the generator. All surgeons had previous experience with electrosurgery with most familiarity with the Medtronic FT10 and Erbe VIO3. On average, surgeons preferred the speed of the Megadyne Electrosurgical Generator Soft Coag mode to their current generator and felt there was no difference between their current generator on tissue effect, eschar build-up, sticking and hemostasis.

Table 2. Summary of Results from the surgeon questionnaire on the Megadyne Electrosurgical Generator (MES)

Statement	*% Agree (n=34)*
MES provided the expected tissue effects	94%
MES provided the appropriate dissection speed	100%
MES provided the appropriate hemostasis	97%
MES provide an appropriate amount of thermal spread/damage	97%

Table 3. Summary of results from the nurses questionnaire on the Megadyne Electrosurgical Generator (MES)

Statement	*% Agree (n=18)*
MES is easy to use	100%
MES is easy to set up	94%
MES displays are easy to read	89%
MES requires minimal training (is intuitive)	83%
MES requires less time to set up and turn over between procedures compared to their current generator	67%
MES requires less nurse training to set up and operate than their current generator	67%

Discussion

While there are many articles evaluating cutting and sealing devices, be it electrosurgical, ultrasonic or laser, there are few studies that discuss the specifics of generators and their algorithms. A recent paper introduced a generator with a novel bipolar mode [9], however no description of the algorithm was included in the discussion. In this paper we have explained how the Megadyne generator electrosurgical cutting and coagulation functions and how it results in minimal thermal damage. The performance of the previous version of the generator is summarized for the following preclinical and clinical studies.

In a preclinical evaluation of an earlier version of the Mega Power generator [10], the monopolar mode provided lower rates of bleeding, while the bipolar mode produced lower temperatures and less tissue damage. Evaluation in a porcine model determined that the GEM mode (termed Feedback Mode in the article) produced significantly less smoke than the ordinary Cut mode, especially in conjunction with the sharp-edged, PTFE-coated ACE blade [4]. The GEM mode was recommended especially for skin cutting and fascia dissection. These features and benefits are still present in the new Megadyne Electrosurgical Generator.

A common criticism of the use of electrosurgery in cutaneous incisions is that there is unacceptable thermal damage with delayed wound healing or increased risk of infection [11-13]. A comparison of the Mega Power generator with ACE blade to both cold steel scalpel and standard electrosurgery was performed in a porcine model of skin incisions, and the healing of wounds were monitored over a period of 6 weeks [7]. Via histopathologic analysis, the Mega Power dermal scar width was comparable to cold steel scalpel, but significantly less than for electrosurgery. In addition, wound strength and cosmesis were similar between Mega Power and scalpel, with both significantly superior to electrosurgery.

The GEM technology was previously identified as Advanced Cutting Effect (ACE). This identical system was compared to cold steel scalpel for wound healing and scar formation in a variety of plastic surgery procedures [14]. Observer ratings of ACE blade incision vascularization, pigmentation, thickness and relief were non-inferior to those for scalpel, and patient scores of incision pain, itching, discoloration, stiffness, thickness and irregularity were likewise non-inferior for ACE blade versus cold steel scalpel. Use of the ACE blade with the Mega Power generator has also produced positive results in the treatment of cutaneous neurofibromatosis [15]. In a single session, hundreds of neurofibromas were able to be excised, with low complication rates and high levels of clinical outcomes and patient satisfaction.

The GEM mode of the Mega Power generator with the ACE blade has been compared to the PULSAR II generator at settings of 7 and 9 in patients undergoing abdominoplasty [3]. Thermal injury in the flap remnant was equivalent between GEM and the PULSAR II at setting of 7, but significantly less for GEM compared to a PULSAR II setting of 9.

This paper describes a new version of the Megadyne Electrosurgical Generator, which now includes a choice of GEM mode settings, a Soft Coag mode and an Auto Bipolar switching feature. In preclinical testing, nurses and surgeons agreed that the Megadyne generator was easy to set up and operate and provided the expected electrosurgical performance. Building upon an extensive history of clinical performance, the Megadyne Electrosurgical Generator combines the intelligent features of GEM technology with a simple-to-use interface. This innovative technology should provide an overall enhancement in electrosurgical procedures.

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