การศึกษาเปรียบเทียบระหว่าง 2 ระบบของเครื่องเชื่อมปิดหลอดเลือดด้วยไฟฟ้าแบบ 2 ขั้ว ที่ใช้ในการหยุดการไหลของเลือด ในหลอดเลือดที่มีขนาดกลาง

นางสาวเดภิชา จินดาทิพย์

วิทยานิพนธ์นี้เป็นส่วนหนึ่งของการศึกษาตามหลักสูตรปริญญาวิทยาศาสตรมหาบัณฑิต
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COMPARISON BETWEEN TWO SYSTEMS OF ELECTROSURGICAL BIPOLAR VESSEL SEALING FOR THE HEMOSTASIS OF MEDIUM-SIZED ARTERIES

Miss Depicha Jindatip

A Thesis Submitted in Partial Fulfillment of the Requirements

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Thesis Title	COMPARISON BETWEEN TWO SYSTEMS OF ELECTROSURGICAL BIPOLAR VESSEL SEALING FOR THE HEMOSTASIS OF MEDIUM-SIZED ARTERIES
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Field of Study	Medical Science
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เดภิชา จินดาทิพย์ : การศึกษาเปรียบเทียบระหว่าง 2 ระบบของเครื่องเชื่อมปิดหลอดเลือดด้วยไฟฟ้าแบบ 2 ขั้ว ที่ใช้ในการหยุดการไหลของเลือด ในหลอดเลือดที่มีขนาดกลาง. (COMPARISON BETWEEN TWO SYSTEMS OF ELECTROSURGICAL BIPOLAR VESSEL SEALING FOR THE HEMOSTASIS OF MEDIUM-SIZED ARTERIES) อ.ที่ปรึกษา : รศ.นพ.ธันวา ตันสลิตย์, 64 หน้า.

วัตถุประสงค์ เพื่อเปรียบเทียบค่าเฉลี่ยของการทนทานต่อความดันน้ำเกลือ และวัดค่าความร้อนที่แผ่ออกไปทางด้านข้าง ระหว่างการใช้เครื่องเชื่อมปิดหลอดเลือดด้วยไฟฟ้าแบบ 2 ขั้วที่ผลิตขึ้นใหม่ (ฮีโมแซคแค็บ) กับเครื่องที่มีขายทางการค้า (เออร์เบไวโอ) ในหลอดเลือดที่มีขนาดกลาง

วิธีการศึกษา ทำการเชื่อมปิดหลอดเลือดแดงที่คอ (หลอดเลือดแดง คอมมอน แคโรทิด) ของสุกรจำนวนหกสิบเส้นโดยเครื่องฮีโมแซคแค็บและเออร์เบไวโอ ก่อนจะเชื่อมปิดหลอดเลือดทำการปล่อยน้ำเกลือและค้างความดันไว้ที่ 129.25 มิลลิเมตรปรอท จากนั้นหลอดเลือดถูกเชื่อมปิดด้วยอุปกรณ์ไบแคล้มป 150 ซึ่งต่อกับเครื่องฮีโมแซคแค็บหรือเครื่องเออร์เบไวโอ เมื่อการเชื่อมสิ้นสุดลงรอยเชื่อมที่ได้มีลักษณะโปร่งแสง และนำมาทดสอบการทนทานต่อความดันโดยการอัดน้ำเกลือไปสู่รอยเชื่อมที่ได้ ความดันถูกเพิ่มขึ้นจาก 129.25 มิลลิเมตรปรอท ไปจนถึง 361.9 มิลลิเมตรปรอท โดยเพิ่มความดันช่วงละ 77.55 มิลลิเมตรปรอท ในทุกๆช่วงการเพิ่มมีการค้างความดันรอไว้ประมาณ 10 วินาทีก่อนที่จะเพิ่มความดันต่อไป ผลของความดันที่ได้ถูกบันเมื่อเกิดการรั่วของน้ำเกลือออกจากรอยเชื่อมหรือเมื่อรอยเชื่อมสามารถทนทานต่อความดันได้ถึง 361.9 มิลลิเมตรปรอท หากการรั่วเกิดขึ้นระหว่างทำการเชื่อมหรือที่ 129.25 มิลลิเมตรปรอทภายในเวลา 10 วินาที รอยเชื่อมนั้นจะถูกพิจารณาว่าเป็นรอยเชื่อมที่ล้มเหลว นอกจากนี้ยังได้ทำการเชื่อมปิดหลอดเลือดเพิ่มอีกสี่สิบเส้นด้วยเครื่องเชื่อมทั้งสองระบบนี้ เพื่อนำไปตรวจทางจุลกายวิภาคศาสตร์เพื่อวัดการกระจายความร้อนที่แผ่ออกไปบนเนื้อเยื่อที่ถูกเชื่อมทางด้านข้างของรอยเชื่อมปิด

ผลการศึกษา ค่าเฉลี่ยของการทนทานต่อความดันน้ำเกลือของรอยเชื่อมปิดหลอดเลือดโดยเครื่องฮีโมแซคแค็บสูงกว่าของเครื่องเออร์เบไวโออย่างมีนัยสำคัญ (350.7 ± 33.7 และ 270.6 ± 85.8 มิลลิเมตรปรอท ตามลำดับ, p=0.00) ในขณะที่การกระจายความร้อนที่แผ่ออกไปบนเนื้อเยื่อที่ถูกเชื่อมทางด้านข้างมีค่าไม่แตกต่างกันระหว่าง 2 ระบบ (1.71 ± 0.36 และ 1.76 ± 0.40 มิลลิเมตร ตามลำดับ, p=0.63)

สรุปผล เครื่องฮีโมแซคแค็บมีประสิทธิภาพดี ไม่ด้อยไปกว่าเครื่องเออร์เบไวโอ ในการเชื่อมปิดหลอดเลือดที่มีขนาดกลางนอกร่างกายสัตว์ทดลอง

สาขาวิชา วิทยาศาสตร์การแพทย์ ลายมือชื่อนิสิต เดภิชา จินดาทิพย์

ปีการศึกษา 2549 ลายมือชื่ออาจารย์ที่ปรึกษา .....

487 47328 30: MAJOR MEDICAL SCIENCE
KEY WORDS: BURST-STRENGTH PRESSURE/ COLLATERAL THERMAL SPREAD

DEPICHA JINDATIP: COMPARISON BETWEEN TWO SYSTEMS OF ELECTROSURGICAL BIPOLAR VESSEL SEALING FOR THE HEMOSTASIS OF MEDIUM-SIZED ARTERIES. THESIS ADVISOR: ASSOC. PROF. TANVAA TANSATIT, M.D. 64 pp.

Objective: To compare the mean burst-strength pressure and measure the collateral thermal spread between the new EBVS (HemoSaccab) and the commercial EBVS (ERBE VIO) systems.

Materials and Methods: Sixty fresh common carotid arteries from swines were sealed with the HemoSaccab or the ERBE VIO systems. Before device applications, saline was perfused and held into the arterial lumen at the resting pressure of 129.25 mmHg. Then, the arterial segment was sealed with the BiClamp 150 instrument which attached to the HemoSaccab or the ERBE VIO generators. When the seal cycle finished, the seal was inspected visually for translucency. Then, saline was perfused toward the sealed end. Pressure was increased from 129.25 to 361.90 mmHg at a 77.55 mmHg increment. At each pressure increment, the pressure was maintained for 10 seconds before another increment of the pressure. Luminal pressure was recorded when saline leaks from the sealed end or pressure reached 361.90 mmHg. If leaking occurs during application of hemostasis or at 129.25 mmHg within 10 seconds, that seal is considered as sealing failure. An additional 40 arteries were sealed with two systems and sectioned for histological examination to measure the collateral thermal spread.

Results: Mean burst-strength pressure of the HemoSaccab was statistically significant higher than the ERBE VIO systems (350.7 ± 33.7 and 270.6 ± 85.8 mmHg, respectively, p=0.00). While the collateral thermal spread was not difference between the two systems (1.71 ± 0.36 and 1.76 ± 0.40 mm, respectively, p=0.63).

Conclusion: The HemoSaccab system is as effective as the ERBE VIO system to seal the medium-sized vessel.

Field of study Medical Science
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Student's signature Depicha Jindatip
Advisor's signature Tanvaa Tansatit

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CONTENTS

Page

CHAPTER **Page**

LIST OF TABLES

Table **Page**

LIST OF FIGURES

Figure **Page**

LIST OF ABBREVIATIONS

A	=	Ampere
BL	=	blood loss
CO_2	=	carbon dioxide
EBVS	=	Electrosurgical Bipolar Vessel Sealing
et al.	=	et alii
kHz	=	kilohertz
I	=	current
LP	=	titanium laparoscopic clip
MHz	=	megahertz
min	=	minute
ml	=	milliliter
mm	=	millimeter
mmHg	=	millimeter Mercury
OP time	=	operative time
P	=	Power
PC	=	plastic laparoscopic clip
s	=	second
S.D.	=	Standard Deviation
UCS	=	Ultrasonic Coagulating Shear
V	=	Volt, Voltage
W	=	Watt
Ø	=	diameter

CHAPTER I
INTRODUCTION

1. Background and Rationale

Electrosurgical bipolar vessel sealing (EBVS) system is commonly used in both open and laparoscopic surgeries such as gastrointestinal [1], hepatopancreatic, gynecologic [2], and urologic [3] surgical procedures to seal vessels for hemostasis. The EBVS has been developed safer and more effective than both traditional monopolar and bipolar cauteries. Traditional bipolar technique, that uses low current and high voltage, is unreliable sealing of vessels larger than 2 mm [4] resulting in sticking, charring, and significant thermal spread [5]. The EBVS produces high current and low voltage that is designed to permanently and reliably seal vessels up to 7 mm in diameter by denaturing collagen and elastin within the vessel wall and surrounding connective tissue [6]. The integrity of the seal is independent of a proximal thrombus and resists dislodgement because the seal is intrinsic to the wall structure [4]. Optimal seals are characterized by translucency and plastic resistance to deformation [7]. This device eliminates foreign body reaction due to suture, clips, and staples [8].

Although the suture ligations are the gold standard of hemostasis methods, they can be cumbersome and time-consuming [9, 10]. Hemostatic clips are quick and easy to apply [11], but they are still subject to dislodgement [7]. They interfere with each other if repeated applications are required in the same area and act as a nidus for adhesion formation [9]. Vascular staple loads are appropriate for largest vessels or for tissue bundles suspected of containing several sizable vessels, but clearly represent the high-cost option. In addition to electrosurgery, ultrasonic coagulating shear and laser system are also energy-based methods of hemostasis [12]. The ultrasonic coagulating shear uses ultrasonic energy to activate a cutting blade that simultaneously coagulates tissue, which can cause the risk of bleeding [3, 13]. Additionally, many issues reported that the ultrasonic coagulating shear can be used to coagulate vessels up to 3 mm in diameter [7, 9, 11]. In laser system, it has been associated with laparoscopic complications such as free laser beam deflection [14, 15]. Moreover, the EBVS can reduce operative time, blood loss, and instrument traffic

[1]. It creates the seal area which has the burst strength approximating that of suture and clips.

In addition to hemostasis of blood vessels, the EBVS can be applied on other structures. Some authors reported the good results in several procedures such as the lymphatic vessels [10], umbilical cord [16], uterine tube [16], spermatic cord [3], ureter [17], atrial appendage [18], lung parenchyma and bronchi with diameters up to 2 mm [5]. However, this device failed to seal common bile duct. This failure might be related to unique properties of protein matrix in the bile duct wall [19, 20]. Moreover, the EBVS was not recommended for sealing of the small bowel because of the low burst-strength pressure of the sealing in a porcine model [21]. In recent years, many manufacturers produce the commercial EBVS systems to use in nearly every operating room.

A research team consists of staffs from Faculty of Medicine and the Faculty of Engineering of Chulalongkorn University join with Heat Intertrade Company Limited to produce the HemoSaccab – the new electrothermal bipolar vessel sealing (EBVS) generator. Therefore, this study focused on the comparing of this new EBVS (HemoSaccab) generator with the commercial EBVS (ERBE VIO) generator. The purpose of this research was to present the effectiveness of the new EBVS (HemoSaccab) generator that is produced in Thailand.

2. Research Questions

2.1 Primary research question

Is the burst-strength pressure of the new EBVS system different from the commercial EBVS system?

2.2 Secondary research question

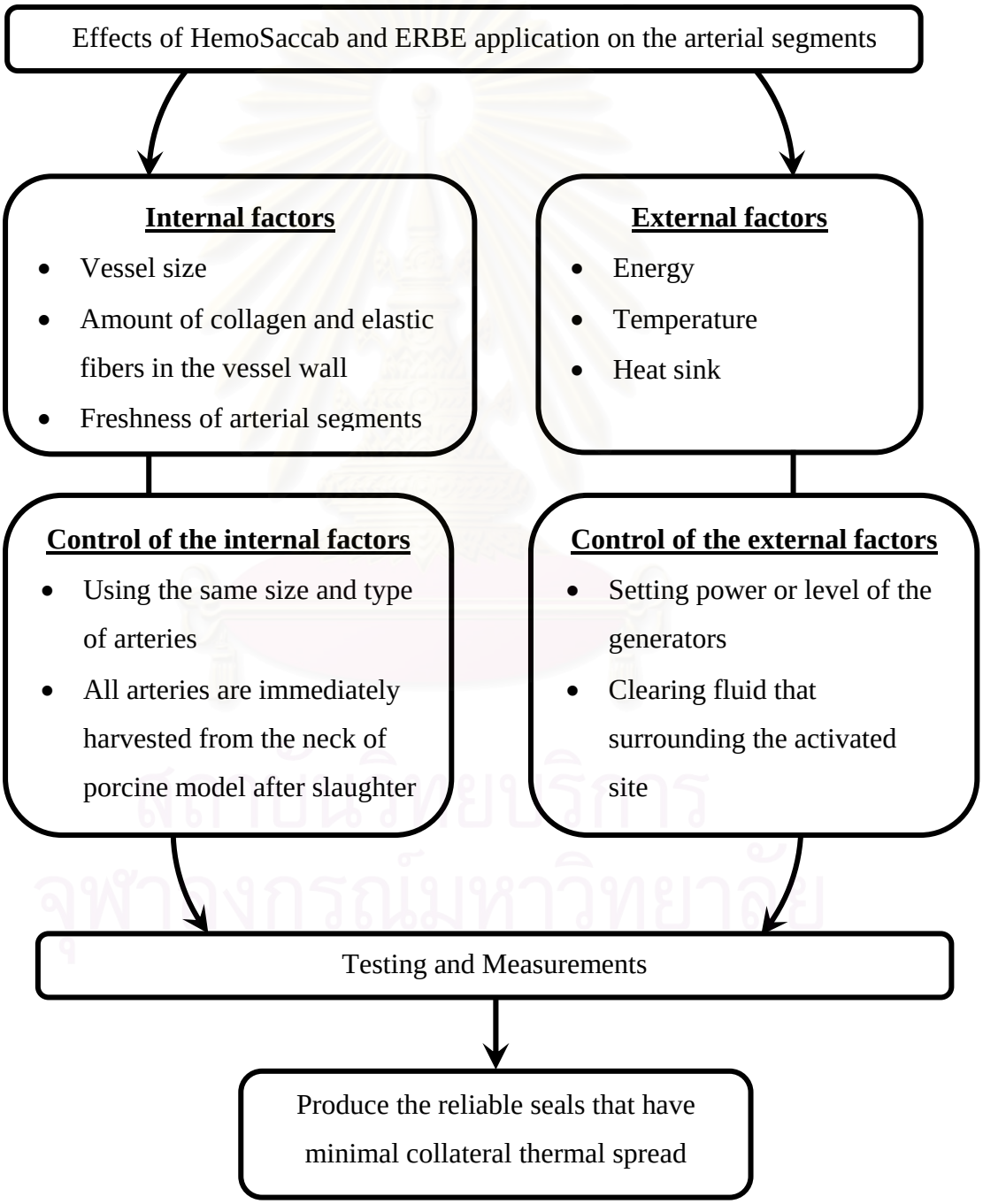
How wide is the collateral thermal spread of the systems?

3. Objectives

3.1 To compare the burst-strength pressure between the systems on medium-sized arteries.

3.2 To examine the collateral thermal spread of both systems.

4. Conceptual Framework



5. Assumptions

1. The measurement has validity and reliability.
2. No impairments on the arterial segments.

6. Key Words

Burst-strength pressure, Collateral thermal spread

7. Operational Definitions

1. Hemostasis: Stopping blood flow. Electrical energy is frequently used during surgery for hemostasis.

2. Bipolar electrosurgery: The passage of high frequency alternating electric current through the tissue typically grasped between the tips of bipolar forceps.

8. Obstacles

The research is delayed because of waiting for the commercial EBVS system (ERBE VIO).

9. Expect Benefits and Applications

This research presents the reliability of the new EBVS system which compare to the commercial EBVS system. The highest purposes of this research are the development of science and technology in Thailand and this new EBVS system can be usage in surgical procedures.

CHAPTER II
REVIEW OF RELATED LITERATURES

1. General features of arteries and veins

The walls of arteries and veins are composed of three layers called tunics.

1.1 Tunica intima, the innermost layer of the vessel. It consists of three components: a single layer of squamous epithelial cells, the endothelium; the basal lamina of the endothelial cells; and the subendothelial layer, consisting of loose connective tissue.

1.2 Tunica media, the middle layer. This layer consists primarily of circumferentially arranged layers of smooth muscle cells. In arteries, it is relatively thick and extends from the internal elastic membrane to the external elastic membrane.

1.3 Tunica adventitia, the outermost connective tissue layer. It is composed primarily of longitudinally arranged collagenous tissue and a few elastic fibers. The tunica adventitia ranges from relatively thin in most of the arterial system to quite thick in the venules and veins (Fig.1).

Many studies reported the traditional bipolar cautery can not reliable sealed on vessels larger than 3 mm in diameter. The device occluded the lumen by shrinking the vessel wall and a proximal thrombus, absence of intrinsic fusion. Thus, it was reliable for hemostasis of small-size vessels. The EBVS was developed in stead of traditional bipolar cautery, it provided reliable hemostasis for vessels of any sizes up to 7 mm in diameter. However, many surgeons not often use the EBVS on large-sized vessels.

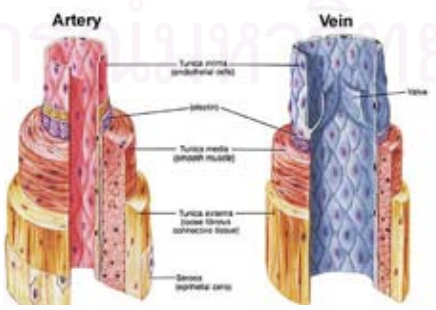


Figure 1. Three layers – adventitia, media, and intima layers – of the general vessel wall.

2. Hemostatic tools

2.1 Suture

Suture is the gold standard for hemostasis, it can be time-consuming and cumbersome during surgical procedure [9]. Multiple steps are required; these include application of hemostatic clamps, placement of ligatures for proximal and distal control, tying of the ligatures, dividing the vessel or tissue, and then cutting the sutures [11].

Mechanical alternatives to suture include clips and staples, which lessen the tedium of tying knots [8].

2.2 Hemostatic clips

These instruments are classified into 2 groups that are titanium clips and plastic clips. They are quick and easy to apply. Although clips create a dependable seal, the titanium clips carry the risk of dislodgment. They require precise dissection of vessels prior to application, can act as a nidus for adhesion formation [9], and interfere with each other if repeated applications are required in the same area [7]. Plastic clips have been designed with a toothed grasping surface and locking device to overcome the problem of clip dislodgment but still have the other disadvantages inherent to titanium clips [9].

2.3 Vascular staples

Vascular staples are appropriate for the largest vessels, or for tissue bundles suspected of containing several sizable vessels, but largely wasted for single-vessel application [7].

In 1993, Kerbl et al compared titanium clips and vascular stapling devices with suture ligation and concluded that these modalities provide bursting strength equivalent to that of suture ligation. However, titanium clips and stapling devices have added significantly to the cost of laparoscopic procedures [22].

Since the introduction of laparoscopic surgery [23], the development of energy-based methods has been introduced to control blood loss as an alternative to sutures, hemostatic clips, and vascular staples. The advantages of these instruments are the absent of foreign body reactions, and the reductions of instrument traffic [1] and operative time. These instruments are ultrasonic coagulating shear (UCS), laser, and electrosurgical vessel sealing (EVS).

2.4 Ultrasonic coagulating shear (UCS)

The ultrasonic coagulating shear converts electrical energy into mechanical vibrations by transferring high-frequency ultrasonic waves (55,000 cycle / second, Hz) to vibrating blade for tissue division and blood vessel coagulation simultaneously [19]. These can cause the risk of bleeding. The device provides reliable hemostasis for vessels up to 3 mm or less in diameter [7, 9, 11, 19, 22-23].

2.5 Laser

There are three commonly used lasers each having specific wavelengths: the neodynamic (Nd:YAG) laser (infrared), the potassium titanyl phosphate (KTP) laser (green light), and the argon laser (blue light). The ability of laser energy to heat tissue is dependent on power density, the laser wavelength, and the tissue pigmentation. A significant disadvantage of laser energy is highly absorbed by dark pigments. Thus, in a large or briskly bleeding vessel, the coagulated superficial layers tend to inhibit further penetration of energy. Two important hazards specifically associated with the use of lasers are past pointing and beam deflection. Past pointing injuries result from the laser beam passing through the target tissue and damaging deeper structures. In contrast, deflection of a free laser beam by collision of the probe against another instrument or hand tremors may cause damage to adjacent structures [14, 15].

2.6 Electrosurgical vessel sealing (EVS)

Traditional energy sources such as monopolar and bipolar cautery are associated with unpredictable, weak vessel sealing, and increased lateral thermal spread [24].

2.6.1 Monopolar cautery: the active electrode produces a sphere of intense coagulation around the tip of the instrument, conversion of electrical to thermal energy, and the return of current to ground (via return electrode and electrosurgical generator) using the patient as the intermediary conductor [25]. The return electrode should have a large surface area to protect against high current density that is the current per unit area. An intermittent high frequency current causes coagulation of vessels with little or no cutting. Hemostasis alone is accomplished when the waveform is pulsed on and off. If the return electrode is too small or not in good contact on the patient, burn injury can occur at that site. Other limitations of monopolar cautery are unable to reliably seal vessels larger than 2 mm and significant thermal spread.

2.6.2 Traditional bipolar cautery: the current will pass only from one electrode to other [26], uses low current and high voltage. It is reliable for vessels up to 2 mm in diameter. Two categories of this device are single probe and bipolar forceps.

2.6.2.1 Single probe: it is widely used to control upper gastrointestinal bleeding. The ceramic probe tip has three longitudinal gold electrodes of alternate polarity which are carried around to the end of the probe, allowing end or side application. The weld is made with the side of the probe completely across the vessel. Some authors reported that they also placed weight on top of the probe [27, 28].

2.6.2.2 Bipolar forceps: it uses current flow only between the two sides of the forceps [15] such that one part serves as the active electrode and its mate serves as the return electrode. Therefore, current passes only through the tissue held between the jaws of the forceps and not indiscriminately through the body of the patient [25].The device dehydrates the tissue of vessel walls, which is cause of the lumen is shrinked. Moreover, the sealed area also requires the proximal thrombus to enhance the strength of the coagulum.

Therefore, a new advanced bipolar vessel sealing has been developed as an alternative method of the traditional energy-based methods to eliminate the limitations of the traditional energy-based methods. The electrosurgical bipolar vessel sealing (EBVS) system is designed to produce high-current and low-voltage output. The high current melts the collagen and elastin within the tissue bundles and vessels, which quickly reform to create a plastic-like seal zone [19]. Tissues can be sealed without dissection or vessel isolation, which can cause unnecessary bleeding [3]. This device has been widely used in both open and laparoscopic procedures because the seal has an acceptable burst strength approximating that of suture and clips and can be used confidently on vessels up to 7 mm in diameter [4,7,9,22-24].

3. Electrosurgical bipolar vessel sealing ex vivo and in vivo

3.1 Burst strength pressure

During 1998 to 2003, there were several authors presented comparing the bursting pressure of vessels sealed with each devices.

Kennedy et al. [7] measured the bursting strength with occlusion by electrosurgical bipolar vessel sealing (LigaSure) in 331 arteries and veins of porcine models in 1998. The device had been shown to seal arteries and veins $\leq$ 5 mm in diameter with no complications (success burst, 761 ± 221 mmHg) and a 97% success rate in arteries up to 7 mm (success burst, 654 ± 227 mmHg) in diameter. Once the rather narrow-peak optimum sealing parameters were defined, they tested on 3- to 7-mm-diameter vessels for seal durability in survival studies and compared with UCS, traditional bipolar coagulation, surgical clips, and ligatures. They reported the UCS and traditional bipolar coagulator burst strengths exhibited considerable variability, often extending well below physiologic systolic pressures. The respective probabilities (± 90% confidence intervals) for burst strengths being less than 400 mmHg (~ systolic pressure × 3) were 0.95 (0.82-1.00) for the UCS, 0.28 (0.19-0.38) for the traditional bipolar coagulator, 0.02 (0.00-0.06) for the EBVS, 0.04 (0.00-0.13) for clips, and 0.00 (0.00-0.13) for ligatures. They concluded the seal of feedback-controlled sealing had an acute burst strength approximating that of ligatures and clips. The EBVS was easier to effect than intracorporeal suturing and knot tying, while UCS can be applied to occlude vessels up to 2 mm.

Latter in 2003, Landman et al. [22] compared the EBVS (LigaSure) with UCS, titanium clips, staples, suture, and two traditional bipolar devices in arteries and veins of 31 domestic pigs. They reported the EBVS successfully sealed all renal arteries and veins, only 2 of the 6 aortas were unsuccessful. Mean artery and vein diameter was 6.4 (range 3.5 to 9.2) and 11.2 (range 4.8 to 20.4), respectively. Mean bursting pressure in the successful arterial and venous trials were 529 and 207 mmHg, respectively. In all cases the EBVS seal failed before leak occurred from the titanium clips. One case of staple on the vena cava leaked before EBVS failure at pressure of 215 mmHg. There were no failures of suture ligation. The UCS sealed 5 of the 6 renal arteries and 3 of the 6 renal veins. Mean artery and vein diameter was 3.8 (range 2.8 to 4.8) and 9.9 mm (range 6.5 to 12.8), respectively. Mean bursting pressure in the successful arterial and venous trials were 921 and 342 mmHg, respectively. Two traditional bipolar devices sealed arteries and veins within range of 2.8-4.9 and 5.7-14.5 mm, respectively. Mean arterial bursting pressure in two traditional bipolar trials were 973 and 872 mmHg and mean venous bursting pressure were 409 and 245 mmHg. They concluded that the EBVS system was a viable option for laparoscopic management of arteries up to 6 mm and veins up to 12 mm in diameter. For vessels 3 mm or less, the UCS appeared to be effective and cause the least amount of acute peripheral tissue injury. Two traditional bipolar energy devices provided a seal that was not consistent and resulted in significant acute collateral tissue injury. Clips and staples still provide the most secure vessel occlusion with no discernible peripheral injury. However, staples were the most expensive occlusive modality.

Some studies had evaluated only vascular clips or staples with the energy-based modalities because these instruments were the mechanical alternatives to suture, which lessen the tedium of tying knot [8]. One of these studies reported in 1998, Spivak et al. [23] tested EBVS (LigaSure), UCS, and vascular clips (VC) on 96 arteries of small and medium sizes to compare the strength of hemostasis against elevated intraarterial pressure on a porcine model through a laparotomy. The EBVS successfully coagulated 9 of the 12 arteries. In 7 vessels, intraarterial pressure measurement revealed no breakdown of hemostasis at a level > 300 mmHg. In one vessel, the pressure reached 220 mmHg before breakdown occurred, and in another vessel, the pressure reached 110 mmHg. There were 3 failures, all occurring in the first half of the study. Excellent results were achieved using the VC on this group of

vessels. The UCS successfully coagulated 10 of 12 vessels. Eight applications in this group maintained a pressure of > 300 mmHg; one broke down at 220 mmHg and another at 130 mmHg. They concluded that all three devices were effective in maintaining hemostasis on small and medium-sized arteries. Likewise, Harold et al. [9] evaluated EBVS (LigaSure), UCS, titanium laparoscopic clips (LC), and plastic laparoscopic clips (PC) in 2003. In addition, the large-sized arteries of porcine model were also tested. Thus, each of the four devices was used to seal 16 specimens from each size group for burst testing. Both clips were statistically stronger than the thermal devices except at 4 or 5 mm, where the EBVS was as strong as the LC (601 vs. 593 mmHg). The EBVS's mean burst pressure was statistically higher than that of the UCS at medium (601 vs. 205 mmHg) and large-sized arteries (442 vs. 175 mmHg). The burst pressures of the UCS and EBVS at small-sized arteries were not statistically different.

Moreover, Rumbaugh et al. [4] compared arterial bursting pressure after vessel closure using a vessel-sealing device (LigaSure), a ligate-and-divide stapling device (LDS), and 2-0 polydioxanone suture for ligation of the mesenteric vasculature (jejunal arteries) during small intestinal resection in 19 normal horses in 2003. Their studies showed the bursting pressure after 2-0 polydioxanone ligation (1,014.50 ± 279.05 mmHg) was significantly greater than mean bursting pressure after the EBVS (554.25 ± 228.79 mmHg), which was significantly greater than the mean bursting pressure after LDS (373.25 ± 183.69 mmHg). All vessels ligated with 2-0 polydioxanone failed at a site distant to the ligature, whereas vessels sealed with the EBVS failed at the seal. Nineteen of 20 vessels ligated with the LDS failed at the staple; 1 vessel failed at a site distant to the staple.

Carbonell et al. [24] compared the burst-strength pressure of vessels sealed with the PlasmaKinetics sealer (PK) and LigaSure sealing device (LS) in 2003. The PK and LS devices sealed 8 to 17 vessels each in three different size groups (2-3 mm, 4-5 mm, and 6-7 mm). They reported the mean bursting pressure of the PK and the LS seals were equal in the 2-3 mm vessels (397 ± 271 vs. 326 ± 154 mmHg, P=.49). The PK bursting pressures were significantly less than the LS in the 4-5 mm (389 ± 276 vs. 573 ± 126 mmHg) and the 6-7 mm groups (317 ± 83 vs. 585 ± 157 mmHg).

In 2006, Richter et al. [43] reported the mean burst-strength pressure of BiClamp-sealed arteries (842 ± 117 mmHg) did not differ from that of arteries sealed

with LigaSure (856 ± 102 mmHg), but were significantly higher than the burst-strength pressures of veins (155 ± 26 and 216 ± 71 mmHg, respectively).

Presthus et al. [8] used porcine vessels to evaluate the sealing ability of the Gyrus PKS SEAL vessel system in 2003. Initially 70 segments of carotid artery between 4-10 mm in diameter were used as an in vitro 'bench' model and a 95.5% success at the vessel seal withstanding 300 mmHg was achieved. Subsequently during an in vivo assessment on femoral, iliac, axillary, carotid and renal arteries (from 2.5 to 7 mm in diameter), 95.7% produced seals which withheld a burst pressure of 300 mmHg for 10 seconds. The endpoint burst pressure ranged from 565 to 1934 mmHg.

Recently, Shamiyeh et al. [29] tested the bursting strength of the EBVS (LigaSure) on 20 femoral veins of the pigs in 2006. This procedure was applied for the devascularization of the proximal stomach and distal esophagus to prevent recurrent variceal bleeding in portal hypertension. The mean burst pressure was 121 ± 37 mmHg. The same procedure was performed also with 20 human veins harvested during leg varicose vein surgery. The human saphenous veins presented bursting pressure of 178 ± 44 mmHg. Their results confirmed the safety of the sealed edge on porcine femoral veins as well as human leg veins. These values were higher than the expected portal pressure in patients with portal hypertension.

3.2 Histological finding

Various authors reported about the characteristic of the seal zone that was created by the EBVS.

In 1998, Kennedy et al. [7] described the optimal seals were characterized by translucency and plastic resistance to deformation. The internal elastic lamina was preserved, and occasional collagen bundles were seen to cross the former lumen. No luminal thrombus was ever interposed in the seal.

In 2001, Heniford et al. [6] reported the seal was made from partially denatured and reformed collagen and elastin within the tissue bundle and blood vessels.

In 2003, Landman et al. [22] observed that tissue changes extended into the adventitial and muscular layers of the vessels. They confirmed that the sealed area consisted of opposed vessel walls with non-fused internal elastic lamina. While, Presthus et al. [8] studied in macroscopically, minimal to moderate brown

discoloration was present over the site of union and extending over the edges of all specimens. Histologically, there was complete amorphous coagulation of adventitial collagen fibers with loss of media in the closure site.

Moreover, many authors reported the collateral thermal spread from the edges of the seal in 2003.

Landman et al. [22] studied in various sizes of arteries and veins of domestic pigs. The specimens were sealed with traditional bipolar devices, the thermal damage extended within range of 1-3.5 mm. Interestingly venous structures propagated thermal damage slightly farther than arterial structures, within range of 4-6 mm. The EBVS (LigaSure) caused less acute peripheral tissue damage that was only 2-3 mm. However, the harmonic scalpel resulted in the least acute peripheral damage of 0 to 1 mm.

Carbonell et al. [24] tested in 44 arteries that were harvested from domestic pigs. These arteries were sealed with the PlasmaKinetics sealer (PK) and LigaSure sealing device (LS). They found that thermal spread was not significantly different between the PK and LS in the 2-3 mm (1.5 vs. 1.2 mm, P = .27), the 4-5 mm (2.4 vs. 2.4 mm, P = .79), or the 6-7 mm vessel size groups (3.2 vs. 2.5 mm, P = .32).

Harold et al. [9] compared the UCS with the EBVS (LigaSure). They harvested 48 arteries of pigs for histology. Eight vessels in each of the three size groups (2-3, 4-5, 6-7 mm) were sealed with EBVS and UCS. Both the EBVS and UCS showed increasing thermal spread with increasing vessel size. However, there was no statistical difference in thermal injury between the devices at any vessel size (EBVS mean = 2.57 mm vs. UCS mean = 2.18 mm).

Presthus et al. [8] sealed 8 arteries from porcine model with the EBVS (PK). They reported that the thermal spread range from 0.4-2.3 mm from the edge of the closure site.

3.3 Electrosurgical bipolar vessel sealing in surgical unit

The EBVS is widely used in open and laparoscopic surgeries. Many issues reported the outcome of operative time and blood loss during the procedures, compared EBVS with conventional sutures, Ultrasonic coagulating shears, traditional electrosurgical cautery, clips, and staples. The results are showed in the table 1.

Table 1. Review of the operative time and blood loss in surgical procedures in the literatures

Study	EBVS		Conventional sutures		UCS		Traditional cautery	
	OP time (min)	BL (ml)	OP time (min)	BL (ml)	OP time (min)	BL (ml)	OP time (min)	BL (ml)
Colectomy								
- Targarona et al. [30]	110	100	-	-	120	100	180	200
Splenectomy								
- Romano et al. [31]	130*	70*	-	-	155*	180*	-	-
- Gelmini et al. [32]	120	65	-	-	-	-	-	-
Vaginal hysterectomy								
- Cronje & De Coning. [33]	32*	100*	40*	160*	-	-	-	-
- Levy and Emery. [34]	39.1	68.9	53.6	126.7	-	-	-	-
- Hefni et al. [35]	57±20	100*	66±25	100*	-	-	-	-
- Tamussino et al. [2]	199±33	-	213±45	-	-	-	-	-
Hemorrhoidectomy								
- Kwok et al. [36]	11*	0*	-	-	18*	2*	-	-
Thyroidectomy								
- Shen et al. [37]	2.9±0.1	-	3.6±0.1	-	-	-	-	-

Table 1. **(Cont.)** Review of the operative time and blood loss in surgical procedures in the literatures

Study	EBVS		Conventional sutures		UCS		Traditional cautery	
	OP time (min)	BL (ml)	OP time (min)	BL (ml)	OP time (min)	BL (ml)	OP time (min)	BL (ml)
Lobectomy of the parotid gland								
- Colella et al. [38]	136.4	-	155.8	-	-	-	-	-
Tonsillectomy								
- Lachanas et al. [39]	15±1.43	0	-	-	-	-	21±1.09	125
Radical prostatectomy								
- Daskalopoulos et al. [40]	125±1.3	569±29	144±2.6	685±24	-	-	-	-

* = Median, OP time = Operative time, BL = Blood loss

This Table 1 showed the procedures using the EBVS can reduce operative time and blood loss in surgical procedures.

From the previous studies, they showed the high effectiveness and benefits of the EBVS system. Therefore, our research group was interested on the EBVS system. The Faculty of Engineering of Chulalongkorn University and Heat Intertrade Company Limited had joined to produce the Electrothermal Bipolar Vessel Sealing (EBVS) generator. The Faculty of Medicine took charge of determining the efficacy of the generator. The aim of this research was to compare the effectiveness of this new EBVS (HemoSaccab) generator with the commercial EBVS (ERBE VIO) system on medium-sized arteries. The burst-strength pressure and the thermal spread were measured. These were quantitative assessments of efficacy.

CHAPTER III
RESEARCH METHODOLOGY

1. Target Population and Sample Population

Left and right common carotid arteries of swines were donated from a local butcher.

2. Inclusion Criteria

- Fresh abattoir swine common carotid arteries.
- Unlimited on sexes and ages of swines.

3. Exclusion Criteria

- The decomposed specimens.

4. Sample Size Determination

In previous study of Carbonell et al. in 2003, seventeen medium-sized arteries were sealed with 2 electrosurgical bipolar vessel sealing systems. The mean burst-strength pressure of the LigaSure device was 573 ± 126 mmHg and the PlasmaKinetics sealer was 389 ± 276 mmHg.

Continuous variables of two independent groups

$$n / group = 2(Z_{\alpha/2} + Z_{\beta})^2 \sigma^2 / (x_1 - x_2)^2$$

where; $Z_{\alpha/2} = Z_{0.05/2} = 1.96$ (two tail)

$Z_{\beta} = Z_{0.10} = 1.28$

σ^2 = Pooled variance

$= (n_1 - 1)S_1^2 + (n_2 - 1)S_2^2 / (n_1 + n_2 - 2)$

$= 40{,}026$

so; $n/group = 2(Z_{\alpha/2} + Z_{\beta})^2 \sigma^2 / (x_1 - x_2)^2$

$= 2(1.96 + 1.28)^2 (40{,}026) / (573 - 389)^2$

$= 24.82$

$\therefore$ The sample size was at least 25 arteries per group

5. Materials

Burst-strength pressure testing

- HemoSaccab generator
- ERBE VIO generator
- BiClamp device
- Oscilloscope
- Aneroid barometer
- Vernier calipers
- Stopwatch
- Hemostatic clamps x 2
- Operative scissors
- Operative knife
- Forceps x 2
- Nylon stepped connector
- 0.9 % normal saline 1,000 ml x 24
- Purse-string suture
- Latex examination gloves
- CO_2 tank

Histological technique

- Tissue processing apparatus
- Masson's trichrome stain
- Light microscope

6. Methods

6.1 Burst-Strength Pressure Testing

60 fresh common carotid arteries were immediately harvested from the neck of swine which donated from a local butcher. These arteries were cleaned from surrounding tissue and stored in a normal saline. Thirty vessels were sealed with the new EBVS (HemoSaccab, 330 kHz, Heat Intertrade Company Limited, Bangkok, Thailand) system and the other 30 vessels were sealed with the commercial EBVS (ERBE VIO, Elektromedizin GmbH, T, bingen, Geramany) system.

A nylon stepped connector was inserted into cut end of the arterial segment, secured with a purse-string suture. The other lumen of this connector was attached to a bottle of 0.9 % normal saline for infusion. Saline was pushed by CO_2 pressure that was controlled manually from the CO_2 tank. The intraluminal pressure was detected by the pressure monitoring system, calibrated regularly with an aneroid barometer inter-positioned between the bottle of normal saline and the CO_2 tank. The monitoring system measured pressure changes in psi (1 psi ~ 51.7 mmHg), allowed for a graduated increase in the intraluminal pressure from 0 to 775.5 mmHg (0-15 psi) approximately (Fig. 2).

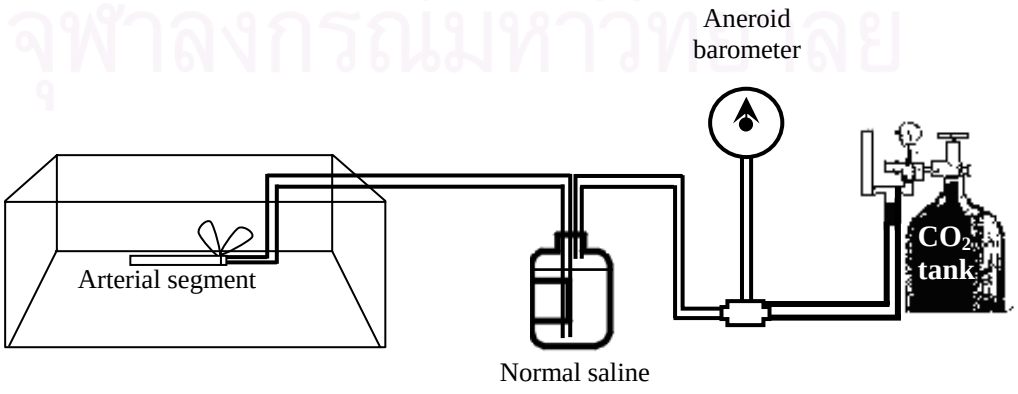
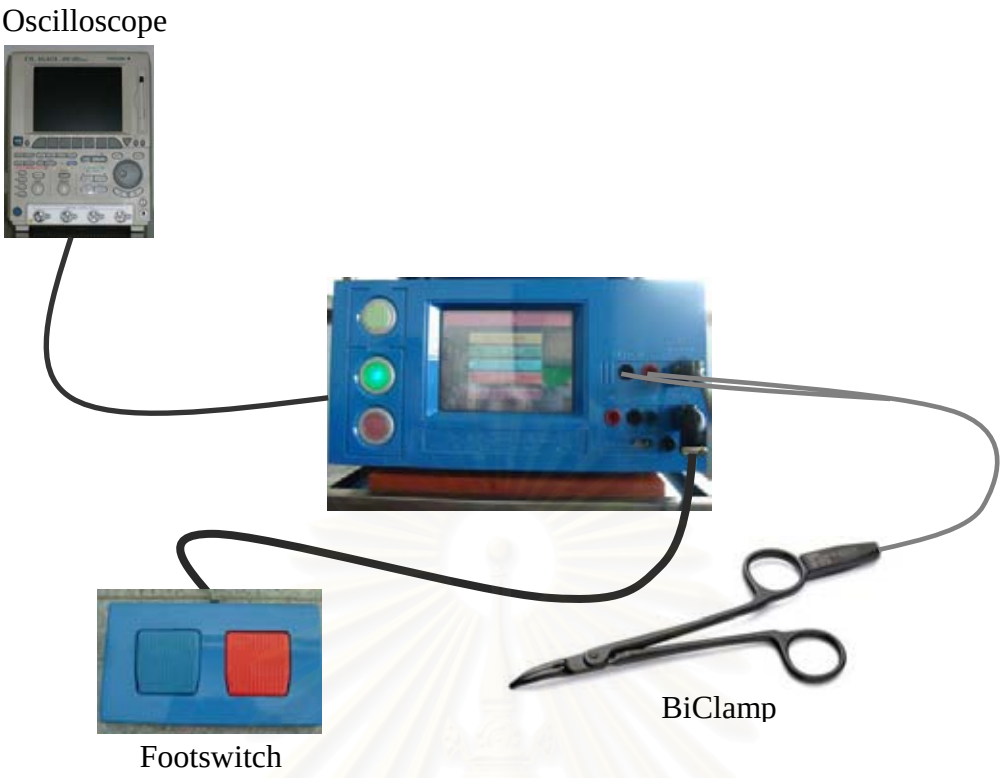


Figure 2. Pressure perfusion system.

Before the HemoSaccab and the ERBE VIO applications (Fig. 3A, B), the peripheral end of arterial segment was occluded with hemostatic clamps and perfused the normal saline at a resting pressure of 129.25 mmHg (~ normal systolic pressure). The outer diameter of the arteries was measured using sliding vernier calipers in millimeters. Then, the arterial segment was sealed with the HemoSaccab generator. This generator was set at 150 volt peak (from the pilot data, this volt peak was the appropriate level), connected to a digital oscilloscope that identified the amount of current delivery, actual voltage, and power output. The reusable open forceps – the BiClamp 150 instrument (smooth surface, Elektromedizin GmbH, T, bingen, Germany.) – attached to the HemoSaccab generator. The BiClamp instrument was placed across the arterial segment and was activated by the footswitch. The sealing process was terminated in 3 seconds after the current dropping. The seal was inspected visually for flatness, translucency, and discoloration (Fig. 4). Initially, this seal was maintained at resting pressure for 10 seconds. Then, saline pressure was increased for 77.55-mmHg increment from 129.25 to 361.90 mmHg (~ normal systolic pressure x 3). At each pressure increment, the pressure was maintained for 10 seconds before the next increment. Thus, the pressures at approximately 129.25, 206.8, and 284.35 mmHg (~ 2.5, 4, 5.5 psi, respectively) were then maintained for 10 seconds. When the pressure reached 361.90 mmHg (~ 7 psi), the infusion system was held at this pressure for 3 minutes (Fig. 5). The final pressure was recorded when saline leaked from the sealed end or pressure reached to 361.90 mmHg for 3 minutes. If leakage occurred during application of hemostasis or at resting pressure for 10 seconds, these were considered a hemostatic failure [23]. The same procedure was also performed with the ERBE VIO system at level 2 (143 volt peak) as recommended by the manufacturer. The sealing cycle was present in visual and audible signals. The AUTO stop function was adjusted to BiClamp and ended activation automatically when the best coagulation effect was achieved.



A.

B.

Figure 3. The HemoSaccab application (A) and the ERBE VIO application (B).

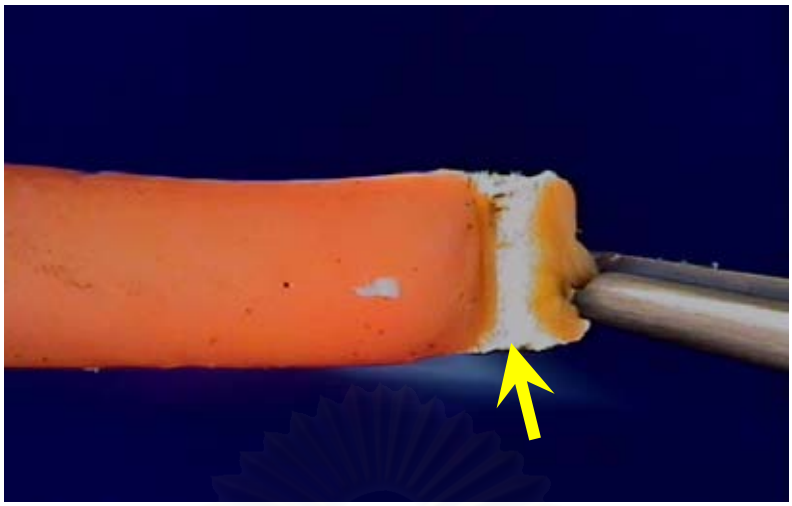


Figure 4. The seal zone (arrow) was inspected visually for flatness, translucency, and discoloration.

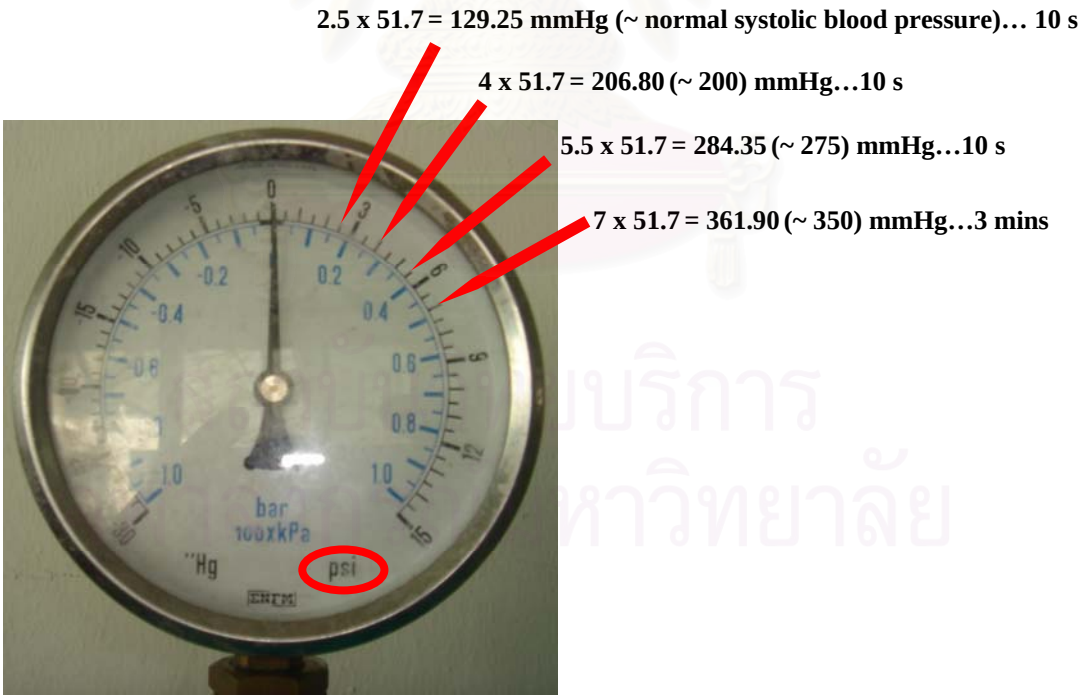


Figure 5. The pressures at 129.25, 206.80, and 284.35 mmHg (~ 2.5, 4, 5.5 psi, respectively) were maintained for 10 seconds. When the pressure reached to 361.90 mmHg (~7 psi), the saline was held at this pressure for 3 minutes.

6.2 Histological Analysis

An additional 40 arteries were harvested for histology. These arteries were sealed with the 2 systems and sectioned longitudinally. Each tissue sample was placed in a biopsy cassette and preserved in 10 % neutral-buffered formalin before processing and staining. The vessels were paraffin-embedded and sectioned in 3-5 microns thick. All sections were stained with Masson's trichrome for microscopic examination. The Masson's trichrome stain was used to identify collagen as blue and muscle as red. Thermal damage was easily visualized as a tinctorial change in the medial and adventitial collagen [41]. Thus, the collagen in the thermal injury area appeared red rather than blue.

The collateral thermal spread was then measured from edge of the sealed area to periphery along the blood vessel in millimeter (Fig. 6). The severity of the collateral thermal spread was graded on severe grade, moderate grade, and mild grade. The severe grade was defined in darkened red area next to the sealed edge. The moderate grade was light red mixed with blue area. The mild grade was the blue coagulated zone (Fig. 7). These 3 grades were measured and combined to the total distance of the thermal spread area, thus, one seal had four sides of total collateral thermal spread (Fig. 6). We selected the longest side for the representative of the total collateral thermal spread of the seal.

7. Data Analysis

Statistical analysis was undertaken with SPSS version 11.5. The Student's t-test was used to determine the difference between the systems. Comparison between groups of non-analogous data was performed using the Fisher's exact test. The difference was considered statistically significant at $p < 0.05$.

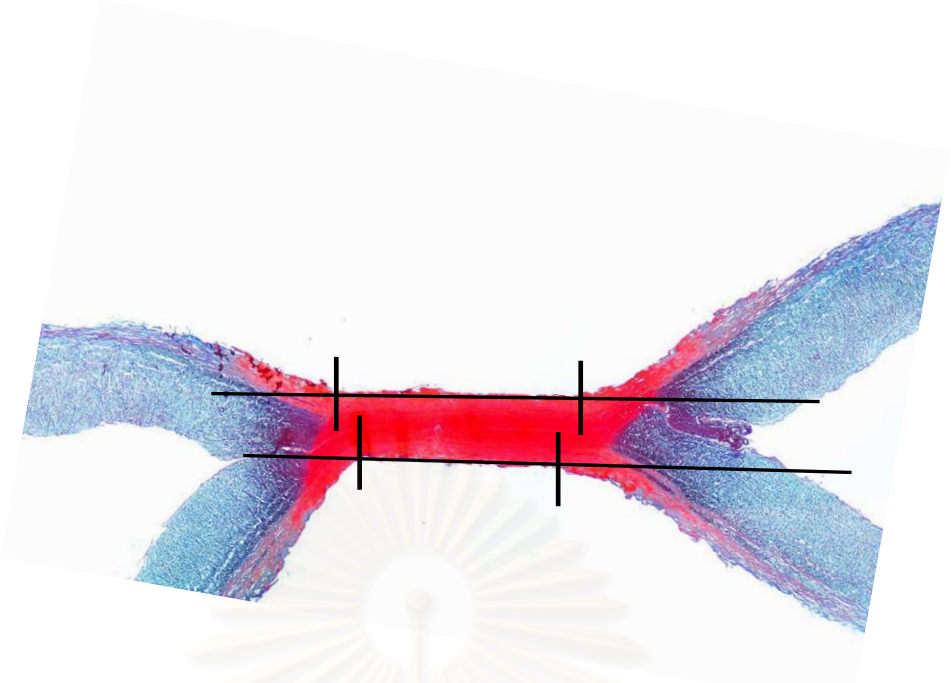


Figure 6. Histological image showed a longitudinal section of a swine common carotid artery. Four sides of the total collateral thermal spread were measured from edge of the sealed area to periphery.

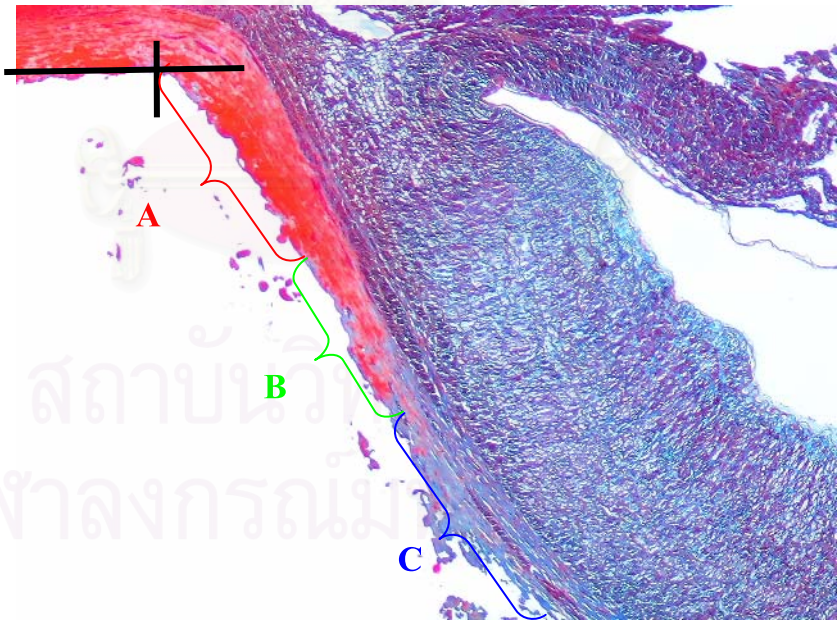


Figure 7. The three grades of the collateral thermal spread: the severe grade was defined in darkened red area from the sealed edge (A). The moderate grade was measured in light red area which combined with blue color (B). The mild grade was the blue coagulated zone (C).

CHAPTER IV
RESULTS

A total 100 common carotid arteries from the swines were studied for the burst-strength pressure and the collateral thermal spread. Fifty vessels were sealed with the HemoSaccab system and the other 50 vessels were sealed with the ERBE VIO system.

1. The Burst-Strength Pressure

Sixty segments of medium-sized arteries – common carotid arteries of swine – were sealed to evaluate the burst-strength pressure. The average diameter of 30 arteries that were sealed with the Hemosaccab system was 4.77 ± 0.58 mm (range: 3.90 to 5.80). The other 30 arteries that were sealed with the ERBE VIO system, the average diameter was 4.88 ± 0.50 mm (range: 3.90 to 5.90).

Vessel ligation with the HemoSaccab system produced excellent result, with no failure (0/30). Mean burst-strength pressure was 350.71 ± 33.72 mmHg. The intraluminal pressure of 26/30 seals reached to 361.90 mmHg (~ normal systolic pressure x 3) (Fig. 8), there were 21 seals that could sustain for 3 minutes (Fig. 9). Four of the 30 seals, the saline leaked at 336.05, 284.35, 284.35, and 206.80 mmHg, respectively (Table 2). The coagulum zone of all saline leakage cases was separated to open the lumen.

For the ERBE VIO system, this produced 4 failures in 30 applications, thus the rate of success was 86.67 % (26/30). Mean burst-strength pressure was 270.59 ± 85.82 mmHg. The values of the burst-strength pressure in this success rate revealed high variation, with a range of 180.95 to 361.90mmHg. Ten of the 30 seals reached to 361.90 mmHg (Fig. 8), there were only 3 seals that sustain for 3 minutes (Fig. 9). Two of the 30 seals, the pressure reached to 336.05 mmHg before saline leakage occurred. At 284.35 mmHg, there were 6/30 sealed leakage. Six of the 30 seals, the saline leaked at 206.80 mmHg. And 2/30 seals were leaked at 180.95 mmHg (Table 2). In 2 of the saline leakage cases, the coagulum broke at the sides of the sealed wall.

Table 2. Burst-strength pressure for medium-sized arteries

System	Diameter (mm)	Mean burst-strength pressure (mmHg)	Results	Success rate
HemoSaccab (30 arteries)	4.77±0.58 (3.90-5.80)	350.71±33.72*	1 = 206.80 mmHg 2 = 284.35 mmHg 1 = 336.05 mmHg 26, > 360 mmHg	100 %**
ERBE VIO (30 arteries)	4.88±0.50 (3.90-5.90)	270.59 ± 85.82*	4 failures 2 = 180.95 mmHg 6 = 206.80 mmHg 6 = 284.35 mmHg 2 = 336.05 mmHg 10, > 360 mmHg	86.67 %**

*p = 0.00, **p = 0. 11

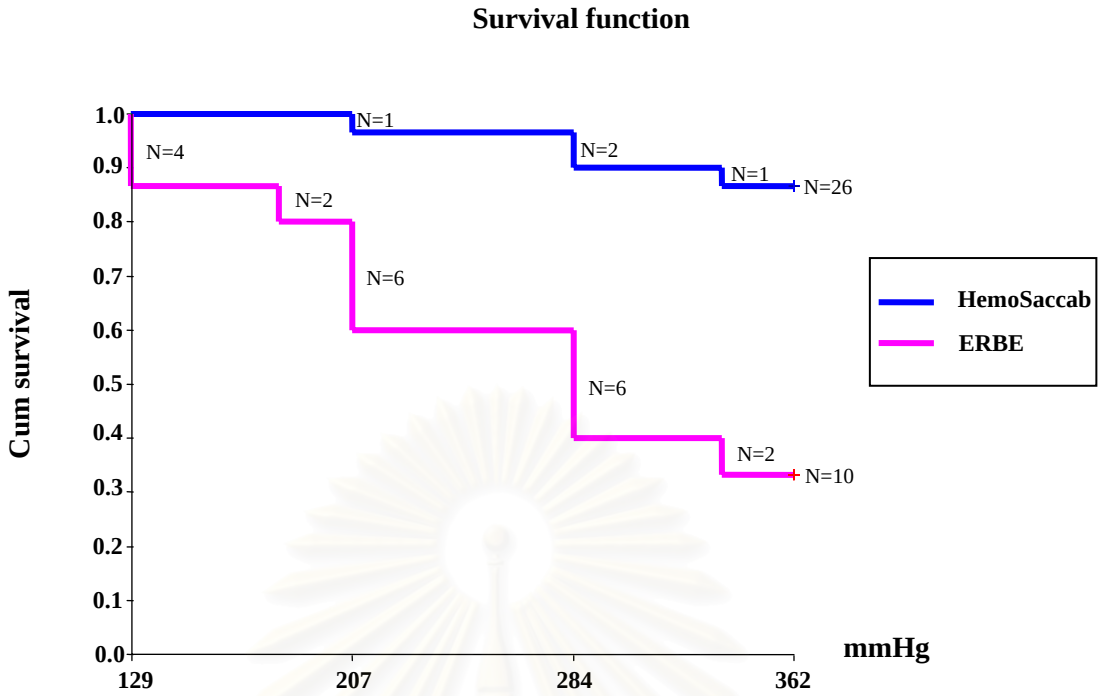


Figure 8. The survival function graph showed percentage of the survival seals when increased the pressure from 129.25 mmHg to 361.90 mmHg.

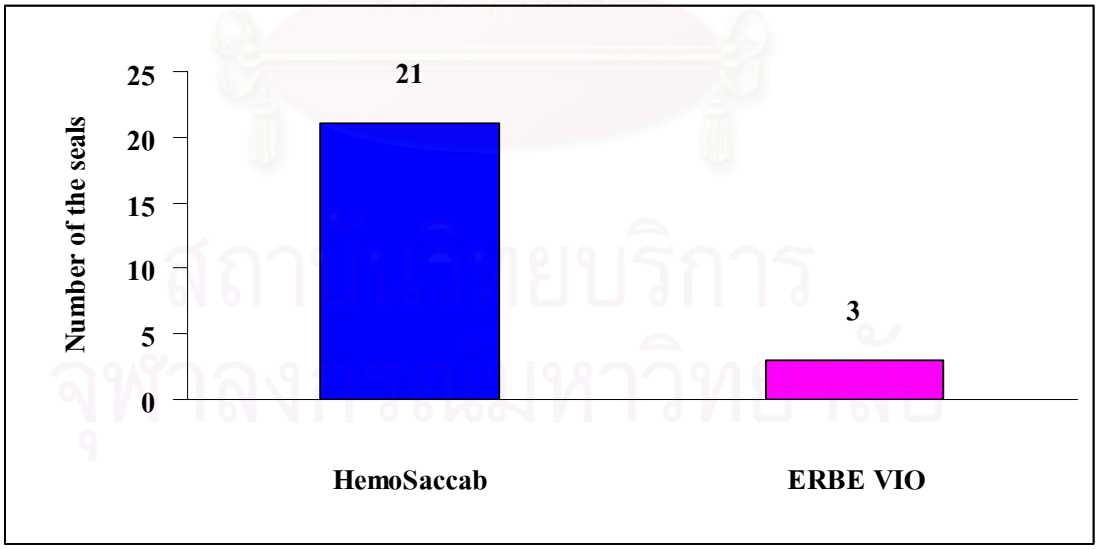


Figure 9. Number of the seals that reached 361.90 mmHg and sustained for 3 minutes after bipolar fusion by the HemoSaccab and the ERBE VIO systems.

2. The Collateral Thermal Spread

In longitudinal sections of swine common carotid arteries, Masson's trichrome was introduced to stain 40 sections. The average diameter of twenty arteries that were sealed with Hemosaccab system was 4.43 ± 0.47 mm (range: 3.70 to 5.40). The other 30 arteries that were sealed with the ERBE VIO system, the average diameter was 4.68 ± 0.50 mm (range: 4.00 to 5.80). The changes of the color including cells and tissues from the normal vessel wall were evaluated to identify the thermal damage area.

The homogeneous sealed zone consisted of the adventitia and media layers of the artery wall. These were presented in difference darkened red color; the adventitia layer was the darkened red-orange color, while the media layer was the darkened red-pink color (Fig. 10). All 20 seals of the HemoSaccab system performed the homogeneous sealed zone. On the other hand, the ERBE VIO system presented five heterogeneous sealed zones (Fig. 11).

The collateral thermal spread: the severe, moderate, and mild grades of each section were measured and combined to the total distance of the thermal spread area. The severe grade usually closed to the edge of the sealed zone. The moderate grade was in the middle of the collateral thermal spread area. The mild grade often located at the end (Fig. 12). For the HemoSaccab application, the mean length of the severe, moderate, and mild grades was 0.72 ± 0.27, 0.41 ± 0.24, and 0.58 ± 0.20 mm, respectively. Likewise the ERBE system, the mean length of the severe, moderate, and mild grades was 0.71 ± 0.30, 0.45 ± 0.30, and 0.61 ± 0.20 mm, respectively (Fig. 13). Consequently, the mean total thermal spread was 1.71 ± 0.36 mm (range: 1.25 to 2.71 mm) for the HemoSaccab system and 1.76 ± 0.40 mm (range: 1.03 to 2.38 mm) for the ERBE VIO system. There was no difference between the systems (Table 3).

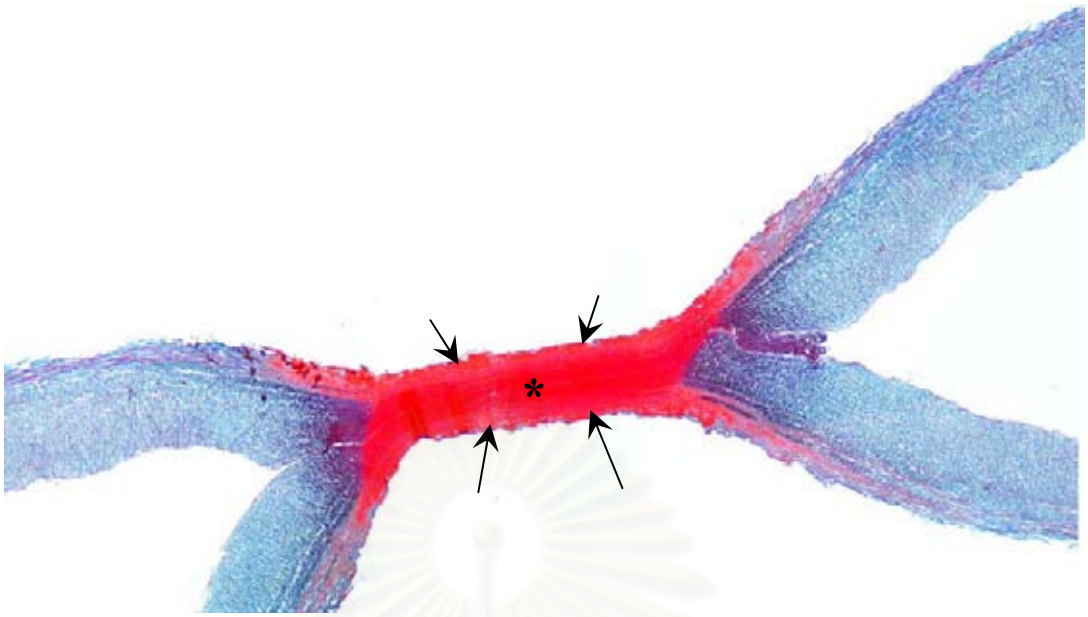


Figure 10. Masson's trichrome stain of the homogeneous sealed zone: the adventitia layer was the darkened red-orange color (arrow), the media layer was the darkened red-pink color (*). Magnification: x 40.

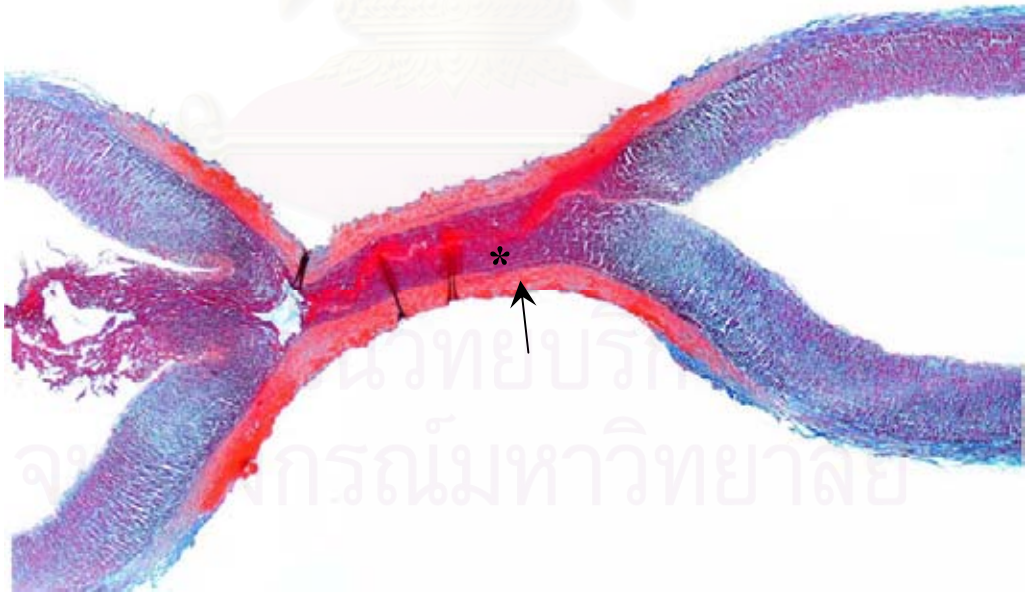


Figure 11. Masson's trichrome stain of the heterogeneous sealed zone: the adventitia layer was the darkened red-orange color (arrow)**,** while the media layer performed the purple color (*).Magnification: x 40.

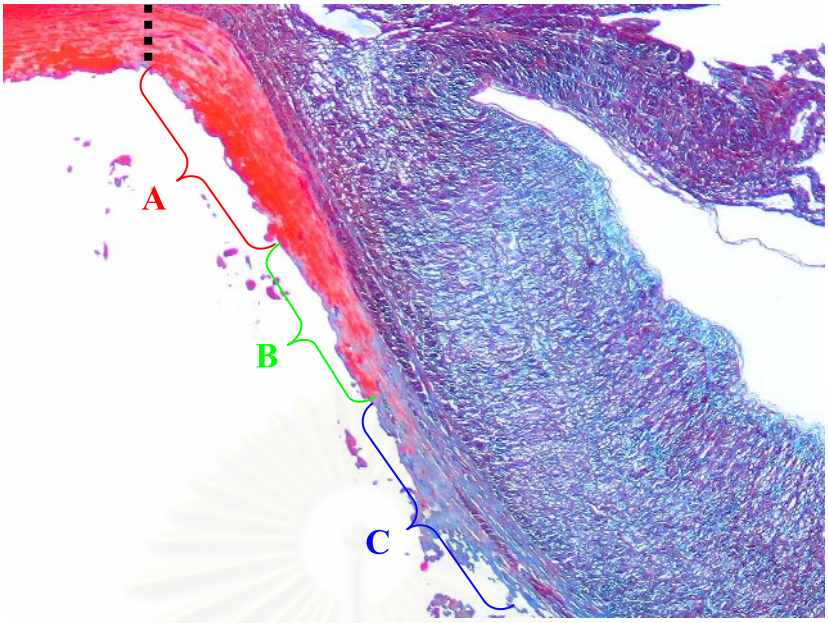


Figure 12. The area of the severe grade (A), moderate grade (B), and mild grade (C) from the edge of the sealed zone. Magnification: x 40.

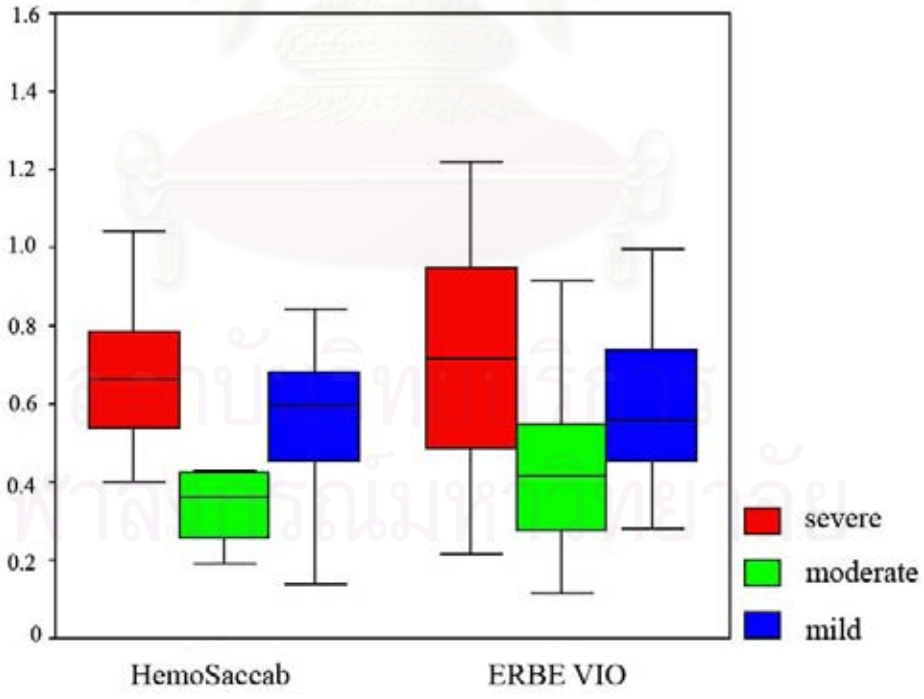


Figure 13. The severe, moderate, and mild grades of the collateral thermal spread of the HemoSaccab system compared to those of the ERBE VIO system.

Table 3. Mean total collateral thermal spread (extend of coagulative necrosis in mm from seal edge) for medium-sized arteries

System	Number of vessels	Diameter (mm)	Mean total collateral thermal spread (mm)
HemoSaccab	20	4.43 ± 0.47 (3.70-5.40)	1.71 ± 0.36 (1.25-2.71)*
ERBE VIO	20	4.68 ± 0.50 (4.00-5.80)	1.76 ± 0.40 (1.03-2.38)*

*p = 0.63

3. Other Parameters

Sealing time and power output of the HemoSaccab were recorded by the digital oscilloscope (Fig. 14), while those of the ERBE VIO were showed on the screen of the generator. The sealing time was 6.50 ± 1.87 seconds (range: 3.80 to 11.00 seconds) for the HemoSaccab system and 8.06 ± 1.41 seconds (range: 4.00 to 11.00 seconds) for the ERBE VIO system. The maximal power output was found to be higher after the ERBE VIO system (124.70 ± 14.45 watts, range: 96.00 to 148.00 watts) than the HemoSaccab system (69.32 ± 12.16 watts, range: 43.50 to 94.70 watts), while the average power output of the HemoSaccab and the ERBE VIO systems was 32.15 ± 5.31 (range: 20.18 to 42.37) and 29.34 ± 3.75 (range: 23.00 to 43.00) watts, respectively. These parameters were significant differences between the systems. In addition, the current and the actual voltage of the HemoSaccab system were also measured by an oscilloscope (Fig. 14); these were 3.10 ± 0.97 amps (range: 1.50 to 3.3 amps) and 203.75 ± 36.04 volts (range: 131.25 to 265.58 volts), respectively. The current and the maximal voltage of the ERBE VIO system were not reported because these values could not be detected by the oscilloscope (Table 4). However, the patent of this system reported the pattern of sealing cycle that showed in Fig. 15.

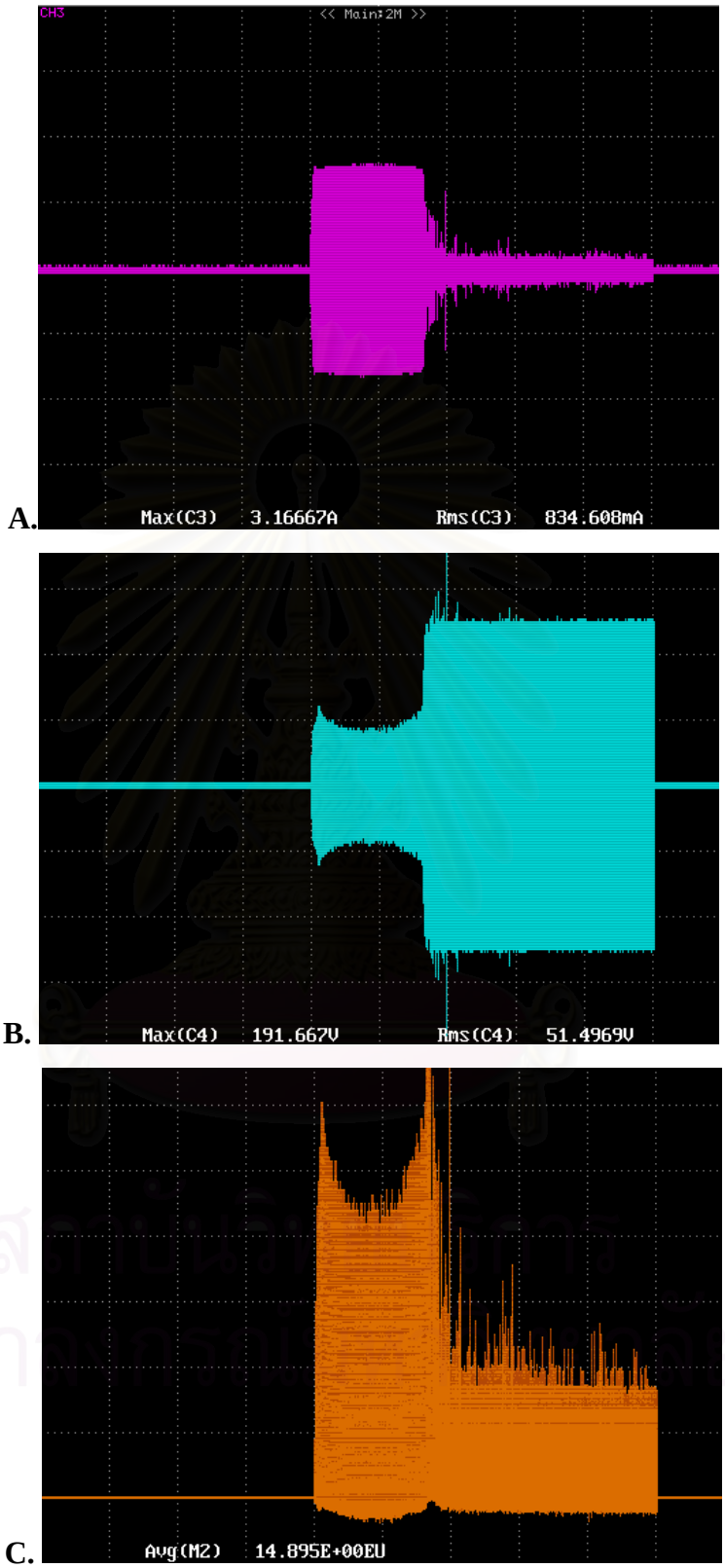


Figure 14. The parameters of the HemoSaccab system were detected by the oscilloscope – the current delivery (A), the voltage (B), and the power output (C).

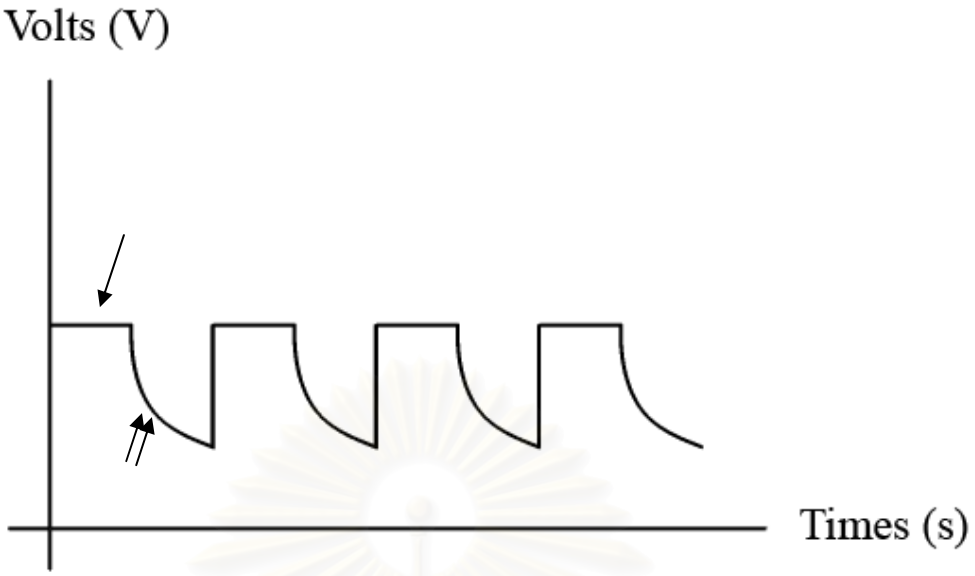


Figure 15. The pattern of sealing cycle of the ERBE VIO generator**.** The ERBR VIO generator have a feedback-controlled system that apply a precise amount of energy (arrow) to vessel walls while they are being held in tight apposition under pressure, including through a cool-down phase (double arrow), to produce a unique translucent seal of partially denatured protein.

Table 4. Mean sealing time, maximal & average power output, voltage, and current delivery of all 100 medium-sized arteries after application of the HemoSaccab and the ERBE VIO systems

	HemoSaccab	ERBE VIO
Number of vessels	50	50
Mean sealing time (secsonds)	6.50 ± 1.87*	8.06 ± 1.41*
Mean maximal power output (Watts)	69.32 ± 12.16**	124.70 ± 14.45**
Mean average power output (Watts)	32.15 ± 5.31***	29.34 ± 3.75***
Mean maximal voltage (Volts)	203.75 ± 36.04	-
Mean current delivery (Amps)	3.10 ± 0.97	-

*p = 0.00, **p = 0.00, ***p = 0.00

CHAPTER V
DISCUSSION AND CONCLUSION

The commercial EBVS generators are continuously developed. These generators often use closed-loop control loops to adjust the voltage and the current to keep the output power constant [42]. This control is advantage to use in various tissues, thus, it can facilitate the surgeons in many surgical procedures. However, the commercial EBVS generators are a high-cost equipment, it is not available in several surgical units. Therefore, our study attempt to create the new EBVS generator that is produced in Thailand.

From the previous studies, most of them often selected various sizes of arteries; small-, medium, and large-sized vessels. Kennedy et al. [7] assessed seal acute burst strength on various artery and vein diameters, within range of 1.0 to 11.3 mm in diameter. While Landman and coworkers [22] tested on 3.5 to 9.2 mm in diameter for arteries and 4.8 to 20.4 mm in diameter for veins. Presthus et al. [8] sealed arteries on 4.0 to 10.0 mm in diameter. In Carbonell's [24] and Harold's [9] studies, they classified the arteries in three size groups that are small-, medium-, and large- sized arteries (2-3, 4-5, and 6-7 mm, respectively). As a consequence, they could seal the arteries that have diameters up to 7 mm. Nevertheless, surgeons recommended that they often found the medium-sized vessels during the clinical procedures. Therefore in this study, we selected the common carotid arteries of swine, sized within range 3 to 6 mm in diameter for the representative of medium-sized arteries. Likewise, Spivak and coworkers used the small- and medium-sized arteries, within range of 0.25 to 0.5 and 2 to 3.5 mm in diameter, respectively. However, sized 2 to 3.5 mm should be rather small-sized arteries than medium-sized arteries (Table 5).

In burst-strength pressure evaluation, many studies recorded these outcomes at the highest pressure that the saline leakage occurred to present the durability of the sealed area. In the first part of Kennedy's study [7], the readout captured maximum pressure when the occlusion burst, or the pressure reached its maximum of 900 mmHg, while Tanvaa et al. [44] defined the endpoint at 776 mmHg. Carbonell et al. [24], Harold et al. [9], and Landman et al. [22] considered the final pressure at the time of the seal rupture. Likewise Presthus et al. [8] and Ritcher et al. [43], they

pushed the normal saline to the sealed end until the seal bursted, they reported the end point burst pressures of their studies ranging from 565 to 1934 and 360 to 1240 mmHg, respectively. However, these values are more than sufficient for clinical needs [43]. In 1998, Spivak and coworkers recorded the burst-strength pressure at which disruption of the coagulum occurred or noted when the pressure reached 300 mmHg. Likewise our study, we defined the maximal pressure at about 360 mmHg because it approximated 3 times of the normal systolic blood pressure. Arterial seals that could withstand this pressure might be considered as adequate strength of the seals (Table 6). Additionally, we thought that the sustaining time at the lower pressure could influence to the strength of the seals (Fig. 5). Consequently, the luminal pressures at 129.25, 206.80, and 284.35 mmHg were then maintained for 10 seconds. Presthus et al. [8] reported ten seconds approximated the amount of time that would be taken to assess seal integrity before cutting during a clinical procedure. When the pressure reached to 361.90 mmHg, we held the saline at this pressure for 3 minutes because this time related to the platelet plug and blood clot in the medium- to large-sized vessels. Hence, all seals that passed 3-minute interval of 361.90-mmHg pressure should not rebleed because of the supporting of platelet plug and clot formation.

Four failures of the ERBE VIO system occurred from the automatic stop of the system before artery was completely sealed. In contrast, the HemoSaccab system could successfully produced 100 percents of success rate due to we set the sustaining time for 3 seconds after the current drop to ensure the tissue desiccation. Thus, this system then produced the reliable seals which could resist to the high blood pressure.

In cases that saline leakage, most of these were generally separated the opposite wall of the coagulum to open the lumen. In some cases that sealed with the ERBE VIO system, saline leaked at the sides of the sealed wall. These defects might be the results of an over heating or charring on the sealed area. These observation and recording of the disrupted seals are brought to adjust the suitable parameters to continuously improve the HemoSaccab generator.

In 2003, Landman et al. [22] reported that the area of the complete sealed zones was consisted of the adventitia and the media layers of the vessel wall. On the contrary, Presthus et al. [8] reported that there was complete amorphous coagulation of adventitial collagen fibers with loss of media in the closure site (Table 7). The observation of our study found that the entire adventitia layer melted in this seal, whereas the amount of the media layer varied. It may depend on severity of the

vaporization. If the vessel was humid, tissue vapor was produced as air bubbles, inner two third of the media was cut off or collapsed from the sealed area (Fig. 16). In vessel with less humidity, the vaporization was less or not occurred, the sealed area would contain the entire media layer (Fig. 17).

In five cases of the ERBE VIO application, the sealed area of these was incomplete which were presented in illustratable histology. The melted zone of these seals was heterogeneous, and not continued along the zone, this area of the media was stained blue color between the red adventitia (Fig 11). Even if, these heterogeneous seals were not the seal failures because they could resist to the pressure at about normal systolic blood pressure and sustained for 10 seconds after application, these were predicted that they could not withstand higher pressure.

From the previous studies, the method of the measuring of the thermal spread is still unclear. As a consequence, our study determined this injury from the edge of the sealed zone toward the normal tissue as the collateral thermal spread. This classified into 3 zones – the severe, moderate, and mild grades – according to the histological appearance of the Masson's trichrome staining (Fig. 7 and 12). After measured all 3 zones, we then gathered them and the longest one from the four sides was selected as the representative value. This method might be more valid for the measurement of the total collateral thermal spread and can be used for assess thermal damage of the sealed arteries.

For the result of the collateral thermal spread, Tanvaa et al. [44] presented the statistical difference of the thermal spread that used the hand made BVS with the HemoSaccab generator and the BiClamp with the ERBE VIO generator in 2006. Therefore, our study then controlled the instrument factor by using the BiClamp with both HemoSaccab and ERBE VIO generators. The result of the collateral thermal spread was not significant differ between two generators. From these 2 studies, the outcomes indicated that the efficiency of the HemoSaccab generator was equivalent to that of the ERBE VIO generator. Conversely, the distance of the collateral thermal spread may be from the variation of the instrument. It can be confirmed from the study of Cambell and coworkers [12], they demonstrated that the collateral thermal spread was significant differ between 2 sealing instruments (LS 1000 vs. LS1100 devices) with the same generator (Ligasure).

The sealing cycle of the HemoSaccab system was terminated 3 seconds after the current dropping from tissue desiccation. This 3-second time was determined from

the pilot study to ensure completely coagulation of the arterial wall. If the total sealing cycle was immediately finished when the current dropped, the sealed area had not durability from the result of the insufficient desiccation. In contrast, the total sealing time was too long, the increasing of electrode sticking, tissue charring, and thermal damaging were occurred.

The limitation of this study was the EBVS systems were compared ex vivo. The tissue reaction, pulsatile arterial-pressure fluctuation, and the clotting mechanism might have an influence on the EBVS in the living animals. However, we designed to test the efficacy of the HemoSaccab system in animal models in the future.

In conclusion, this study showed the mean burst-strength pressure of the HemoSaccab system was significant higher than the ERBE VIO system. Whereas, the collateral thermal spread was not significant difference between two systems. Therefore, this study indicates that the HemoSaccab system is as effective as the ERBE VIO system to seal the medium-sized vessel ex vivo.

Table 5. The artery and vein sizes

Year	Author	Vessel sizes (mm)	
		Arteries	**Veins**
1998	Kennedy et al.	1.0-11.3	1.0-11.3
1998	Spivak et al.	0.25-0.5 (Small) 2-3.5 (Medium)	-
2003	Landman et al.	3.5-9.2	4.8-20.4
2003	Presthus et al.	4.0-10.0	-
2003 2003	Carbonell et al. Harold et al.	2-3 (Small) 4-5 (Medium) 6-7 (Large)	-
2006	Our study	3.7-5.9 (Medium)	-

Table 6. The final burst-strength pressure

Year	Author	Final burst-strength pressure
1998	Kennedy et al.	Seal rupture, or the pressure reached its maximum of 900 mmHg
1998	Spivak et al.	Seal rupture, or noted when the pressure reached ~ 300 mmHg
2003	Landman et al.	Seal rupture
2003	Presthus et al.	Seal rupture
2003	Carbonell et al.	Seal rupture
2003	Harold et al.	Seal rupture
2006	Ritcher et al.	Seal rupture
2006	Tanvaa et al.	Seal rupture, or the pressure reached its maximum of 776 mmHg
2006	Our study	Seal rupture, or noted when the pressure reached ~ 360 mmHg

Table 7. The components of the complete sealed zone

Year	Author	The component of the complete seal zone
2003	Landman et al.	- Tissue changes extended into the adventitial and muscular layers of the vessels
2003	Presthus et al.	- Adventitial collagen fibers with loss of media in the closure site
2006	Our study	- All of adventitia layer - Some seals had all media layer to be the component of the seals - Some had only 1/3 of media layer that would be the part of the seals, the other 2/3 was collapsed or cut off from the sealed area

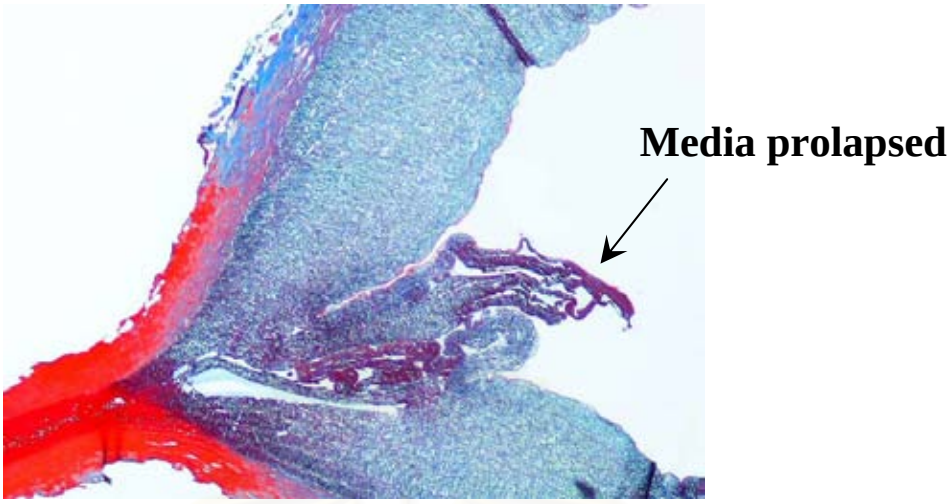


Figure 16. Histological image showed the complete sealed zone that contained most of the adventitia layer and the 1/3 of the media layer. Arrow indicated 2/3 of media prolapsed.

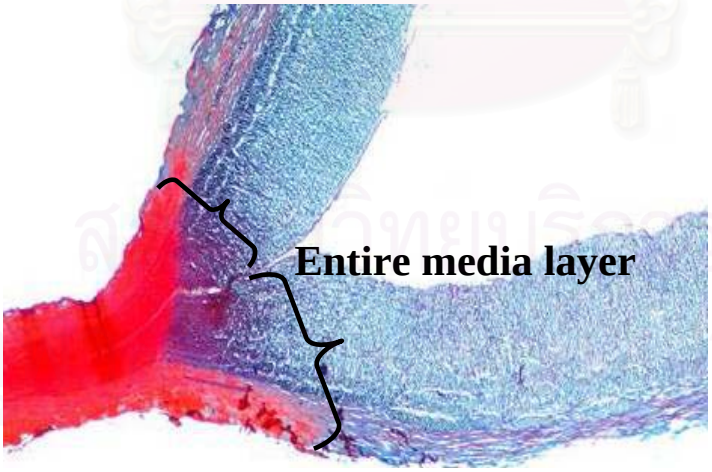


Figure 17. Histological image showed the complete sealed zone that contained the entire of the adventitia and the media layer.

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APPENDICES

APPENDIX A

Principle of the Electrosurgery

Electrosurgery has been described as high-frequency electrical current passed through tissue to create a desired clinical effect. As the current is delivered, it passes through and heats the tissues. This differs from electrocautery, in which electrical current heats an instrument and a clinical effect is realized when the heated tool is applied to the tissues.

Electrosurgery generators operate in the 200 kHz to 3.3 megahertz (MHz) range (Fig. 1). This is well above the range where neuromuscular stimulation or electrocution could occur.

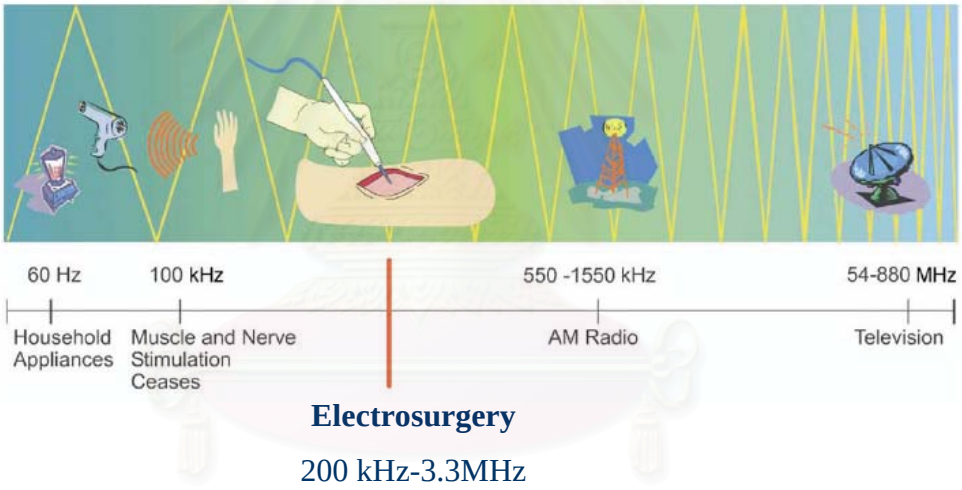

Figure 1. Applications of different current frequencies.

The current output of electrosurgical generators can be modulated to deliver different waveforms to the tissue, depending on the so-called mode. As the output waveforms change, so does the corresponding tissue effect. In general, electrosurgical generators provide energy delivery in two types of modes: continuous and interrupted. The continuous mode of current output is most often referred to as the “cut” mode and delivers electrosurgical energy as a continuous sinusoidal waveform. The interrupted mode of current delivery is referred to as the “coag” or coagulation mode. Modern electrosurgical generators can offer a wide variety of electrical waveforms. In addition

to the pure “cut” mode, there are often blended modes that modify the degree of current interruption (so-called duty cycle), to achieve varying degrees of cutting with hemostasis (Fig. 2).

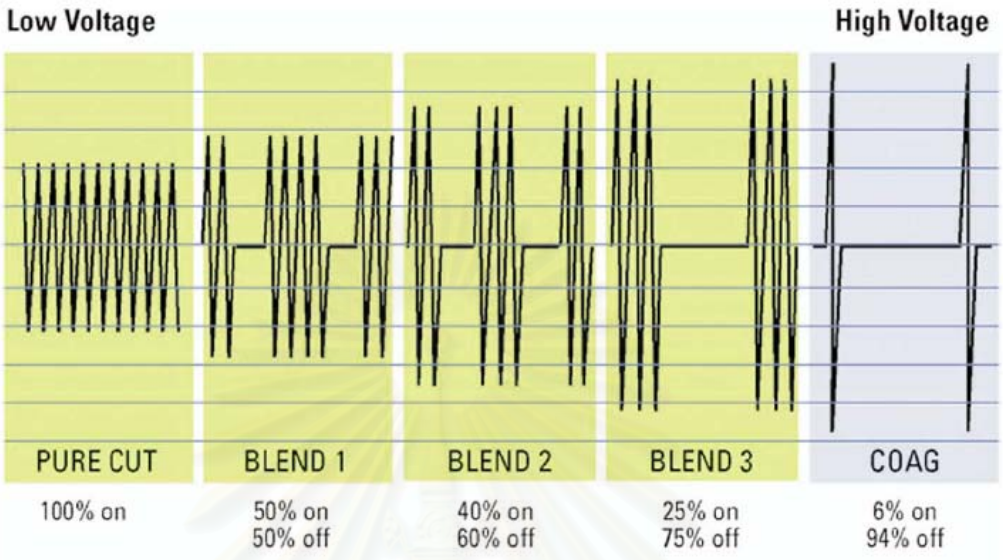

Figure 2. Relationship of instrument settings to voltage and current interruption.

It is possible to cut in the interrupted “blend” and “coag” mode by using a combination of surgical technique and appropriate adjustment of the generator power output. However, the higher voltages of "blend" and "coag" create progressively wider zones of thermal damage at the margins of the incision. The benefit of using the continuous current of the “cut” mode is that the desired surgical effect can be achieved with less voltage (Fig. 3).

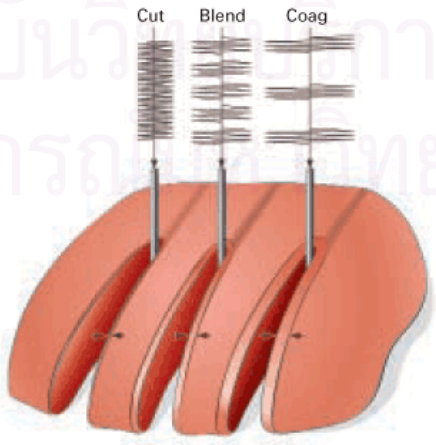

Figure 3. Relative voltage and thermal spread at different generator settings.

Tissue effects that can be achieved with electrosurgery can be roughly divided into three basic groups: cutting, fulguration, and desiccation. Electrosurgical cutting divides tissue with electric sparks that direct intense heat to the tissue over a very limited surface area, producing maximum current density and delivering the greatest amount of heat over a very short time. This causes tissue temperature to rapidly exceed 100°C, vaporizing the intracellular contents of the tissue. The surgeon can most easily achieve this effect by using the continuous or “cut” mode of the generator while holding the electrode slightly away from the target tissue to create a spark (Fig. 4).

Figure 4. Use of continuous current “pure cut” mode.

Fulguration is most often used in the context of sparking to tissue using the interrupted or “coag” mode of the generator. Because the interrupted mode delivers energy for about6%of the activation time, less heat is generated and the sparks create a coagulum rather than vaporize the tissue. The higher voltage of the “coag” waveform coagulates and chars the tissue over a larger area than the lower-voltage “cut” mode does (Fig. 5).

Figure 5. Use of interrupted current “coag” mode resulting infulguration.

Electrosurgical desiccation occurs when the active electrode is in direct contact with the tissue. Contact with the tissue reduces the current concentration, leading to less heat production. This result in the tissue drying out and a coagulum being formed (Fig. 6).

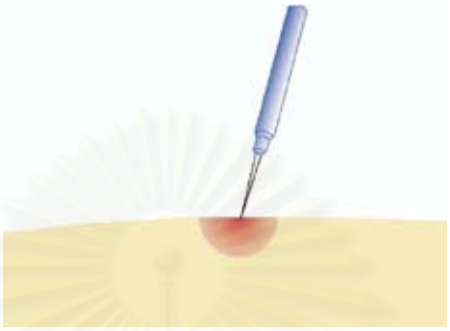

Figure 6. Electrode tissue contact results in desiccation.

Type of Electrosurgical instruments

Electrosurgical technology offers essentially two types of devices for energy delivery: monopolar and bipolar. In monopolar electrosurgery, the generator produces the current, which travels through an active electrode and into target tissue. The current then passes through the patient's body to a patient return electrode where it is collected and carried safely back to the generator (Fig. 7).

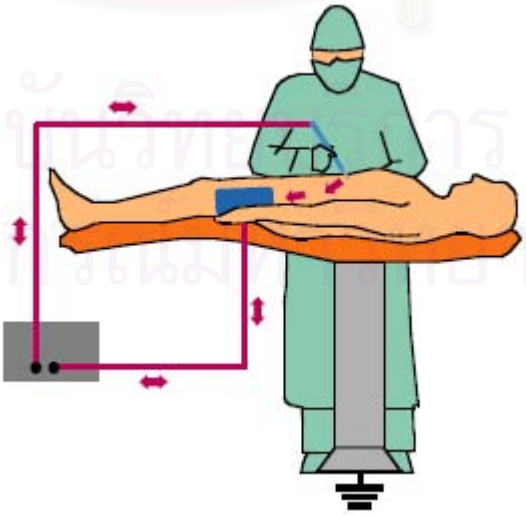

Figure 7. Monopolar Circuit

Bipolar instruments resemble surgical forceps, with both the active electrode and the return electrode functions being performed at the surgical site. The electrosurgical energy does not travel through the patient but is confined to the tissue between the forceps. Because of this configuration, bipolar delivery of energy clearly offers very little chance for unintended dispersal of current (Fig. 8).

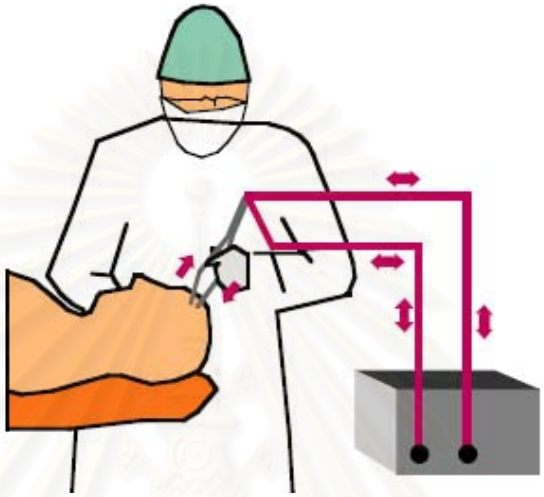

Figure 8. Bipolar Circuit

Adaptive Technologies

1. Vessel Sealing Technology

Vessel sealing technology is an electrosurgical technology that combines pressure
and energy to create a seal. It has been developed that is designed to reliably seal vessels and tissue bundles for surgical ligation both in laparoscopic and open surgery applications. It applies a unique form of bipolar electrosurgery in combination with optimal pressure delivery by the instruments in order to fuse the vessel walls and create a permanent seal. The output is feedback-controlled so that a reliable seal is achieved in minimal time, independent of the type or amount of tissue in the jaws. The result is reliable seals on vessels up to and including 7 mm in diameter or tissue bundles with a single activation. The thermal spread is significantly reduced compared to traditional bipolar systems and is comparable to ultrasonic coagulation. The seal site is often translucent (Fig. 9), allowing evaluation of hemostasis prior to cutting. Seal strengths are comparable to mechanical ligation techniques such as sutures and clips and are significantly stronger than other energy-based techniques such as standard bipolar or ultrasonic coagulation. The seals have been proven to withstand more than three times normal systolic blood pressure.

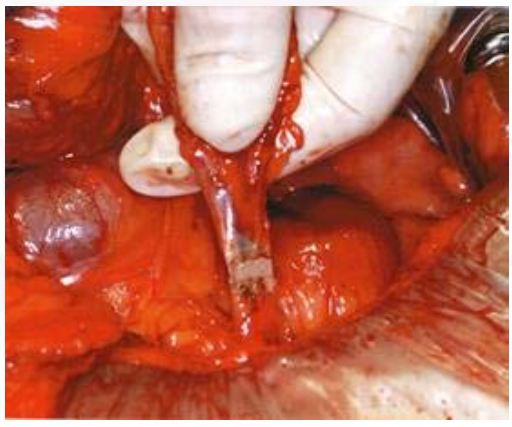

Figure 9. The seals area that produces by electrosurgical bipolar vessel sealing system.

2. Argon-Enhanced Electrosurgery

Electrosurgical delivery of energy using monopolar instruments can be enhanced by incorporating a stream of argon gas to improve the surgical effectiveness in maintaining hemostasis over larger surfaces. The argon beam, as it is sometimes called, owes its development largely to liver transplantation, where coagulation of large, oozing hepatic, retroperitoneal, and diaphragmatic surfaces is required. Traditional Bovie electrosurgical pencils do not function in a liquid (blood) environment because the current is dispersed. The argon beam unit overcomes this problem by adding a column of argon gas passing over the electrode, in line with its tip. The argon gas becomes fully ionized by the electrosurgical energy and also acts to displace (blow away) the blood. Because argon is a noble gas, it allows the current to arc from the electrode to the underlying tissue, following the path of the column of gas, creating a diffuse superficial coagulation ideal for obtaining hemostasis over large surface areas. The argon beam units use a standard generator and grounding pad, but typically use a higher current in coagulation mode to desiccate the target tissues (Fig. 10).

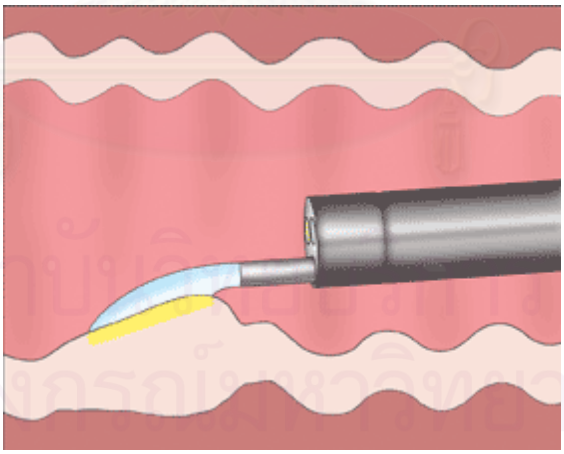

Figure 10. Argon plasma coagulation

3. Radiofrequency Ablation system

Alternating current through the tissue creates friction on a molecular level. Increased intracellular temperature generates localized interstitial heating. At temperatures above 60°C, cellular proteins rapidly denature and coagulate, resulting in a lesion (Fig.11).

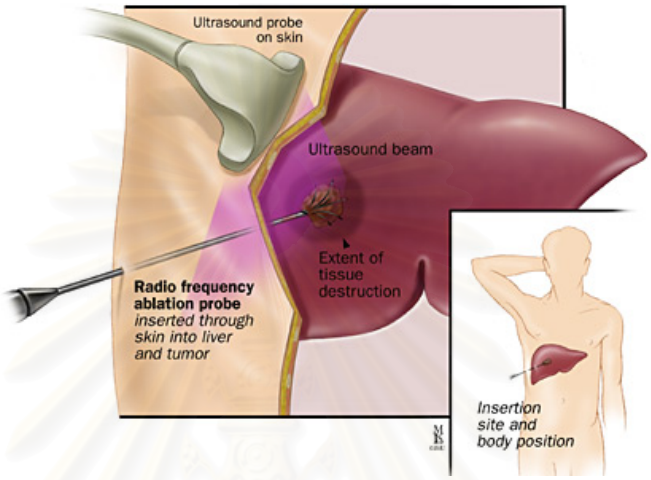

Figure 11. Percutaneous radio frequency ablation.

APPENDIX B

The Electrosurgical Bipolar Vessel Sealing generators and instrument in this study

1. HemoSaccab generator (Version II)

HemoS a c c a b

S = Vessel sealing

a = Argon plasma coagulation (monopolar)

c = Cutting (monopolar)

c = Coagulation (monopolar)

a = Ablation

b = Bipolar coagulation

HemoSaccab, the prototype of radiofrequency (330 kHz) electrosurgical generator is produced for the experimental purpose. This HemoSaccab unit is designed for flexible utilizations. This can be set to operate in various modes of operation including the monopolar cutting and coagulation mode, bipolar coagulation mode, tumor ablation mode, argon-enhanced electrosurgery, and vessel sealing mode. Voltage-control system, high current and short circuit protection are the main features of HemoSaccab. Mode and power are selected and determined at the front screen.

2. ERBE VIO 300 D

The ERBE VIO 300D is a general purpose ESU providing monopolar and bipolar modes, with a BiClamp upgrade. The BiClamp instruments are connected to the ESU via the MF (multi-functional) receptacle. This allows instrument detection and the ESU automatically configures the appropriate default power setting for the instrument. Output sockets are interchangeable by a qualified technician, allowing the surgeon to choose several MF monopolar and bipolar sockets. BiClamp instruments are intended for coagulation and cannot produce an incision. The ESU will automatically switch the power off to the BiClamp instrument when a good seal is deemed to have been achieved. An audible tone signals ESU activation and a ‘beep’ signals completion.

- Maximum CUT output 300 Watt (at 500 ohms)
- Maximum COAG output up to 200 Watt
- Frequency 350 kHz

3. BiClamp 150

The vessels are grasped with the jaws of the BiClamp and coagulated (thermofusion, vessel sealing). The BiClamp software of the electrosurgical system VIO ensures an optimal coagulation result which seals vessels and tissue bundles up to and including 7mm in diameter. The patented AUTO STOP function automatically stops the coagulation process once optimal hemostasis has been achieved, thereby reducing the risk of lateral thermal injuries. The tissue is then severed mechanically inside the visible coagulation zone. This coagulation or thermofusion is so effective that an additional ligature, a suture or an additional conventional coagulation is usually not required. eals vessels and tissue bundles up to and including 7mm in diameter.

- length: 150mm
- Jaw angle: 23 degrees
- Seal width: 0,5/3,4 mm x 18 mm
- Average thermal spread: 2mm
- Re-usable 50 times (autoclavable at 2 bar 134° C - 138° C).

APPENDIX C

In this study, we evaluated the collateral thermal spreading by Masson's trichrome stain.

1. <u>Solutions:</u>

Bouin's solution

Picric acid saturated aqueous solution…….75.0 ml

37-40% Formaldehyde…….25.0 ml

Glacial acetic acid……...5.0 ml

Weigert's iron hematoxylin

Solution A

Hematoxylin…….. 1.0 gm

95% Alcohol…….…….100 ml

Solution B

29% Ferric chloride solution…….....4.0 ml

Distilled water…….. 95.0 ml

Concentrated hydrochloric acid……..1.0 ml

Working solution

Equal parts of Solution A and Solution B

Biebrich Scarlet-acid fuchsin solution

1% aqueous Biebrich scarlet…… 90.0 ml

1% aqueous Acid fuchsin…….10.0 ml

Glacial acetic acid……...1.0 ml

Phosphomolybdic-phosphotungstic acid solution

Phosphomolybdic acid…….....5.0 gm

Phosphotungstic acid…….....5.0 gm

Distilled water…… 200.0 ml

Aniline blue solution

Aniline blue……... 2.5 gm

Glacial acetic acid……...2.0 ml

Distilled water…….100.0 ml

Acetic water solution

Glacial acetic acid……...1.0 ml

Distilled water…….100.0 ml

2. <u>Staining procedures:</u>

1) Deparafinize and hydrate to distilled water.
2) Mordant in Bouin's fixative for 1 hour at 56° C, or overnight at room temperature.
3) Cool and wash in running water until yellow color disappears.
4) Rinse in to distilled water.
5) Weigert's iron hematoxylin solution or 10 minutes. Wash in running water 10 minutes.
6) Rinse in to distilled water.
7) Biebrich scarlet-acid fuchsin solution for 15 minutes.
8) Rinse in to distilled water.
9) Phosphomolybdic-phosphotungstic acid solution for 10 minutes.
10) Rinse in to distilled water.
11) Aniline blue solution for 8 minutes.
12) Rinse in to distilled water.
13) Acetic water 1% only 1 dip.
14) Rinse in to distilled water.
15) Dehydrate and mount in permount.

3. Results:

Nuclei……...Black
Muscle fibers, cytoplasm, keratin, intercellular fibers….Red
Collagen, mucus……...Blue

APPENDIX D

This thesis was a part of electrosurgical generator development which was financially supported by National Electronics and Computer Technology Center **(NECTEC)**, National Science and Technology Development Agency **(NSTDA)**.

NECTEC
a member of NSTDA

BIOGRAPHY

Miss Depicha Jindatip was born on February 14, 1983 in Samutprakarn, Thailand. She received her Bachelor degree of Science (Physical Therapy) with the second class honours in 2004 from the Department of Physical Therapy, Faculty of Allied Health Science**,** Chulalongkorn University, Bangkok, Thailand. She has enrolled in graduate program for Master degree of Medical Science at Chulalongkorn University since 2004.