การทดลองแบบกลุ่มเปรียบเทียบการปิดแผลผ่าตัดด้วย ออกทิลไซยาโนอคิลเลท กับ การเย็บด้วยไหมละลายแบบซับคิวทิคูล่าและการวิเคราะห์ความคุ้มค่าทางเศรษฐศาสตร์ด้านต้นทุนและประสิทธิภาพ

นายศุภกานต์ เตชะพงศธร

วิทยานิพนธ์นี้เป็นส่วนหนึ่งของการศึกษาตามหลักสูตรปริญญาวิทยาศาสตรมหาบัณฑิต
สาขาวิชาการพัฒนาสุขภาพ
คณะแพทยศาสตร์ จุฬาลงกรณ์มหาวิทยาลัย
ปีการศึกษา 2550

A RANDOMIZED CONTROLLED TRIAL COMPARING 2-OCTYLCYANOACRYLATE WITH ABSORBABLE SUBCUTICULAR SUTURE FOR SURGICAL INCISION WOUNDS CLOSURE AND COST-EFFECTIVENESS ANALYSIS.

Mr. Suphakarn Techapongsatorn

A Thesis Submitted in Partial Fulfillment of the Requirements

for the Degree of Master of Science Program in Health Development

Faculty of Medicine

Chulalongkorn University

Academic Year 2007

Thesis Title	A RANDOMIZED CONTROLLED TRIAL COMPARING 2-OCTYLCYANOACRYLATE WITH ABSORBABLE SUBCUTICULAR SUTRUE FOR SURGICAL INCISION WOUNDS CLOSURE AND COST-EFFECTIVENESS ANALYSIS
By	Mr. Suphakarn Techapongsatorn
Field of Study	Health Development
Thesis Principal Advisor	Associate Professor Somrat Charuluxananan
Thesis Co-advisor	Monwat Ngerncham

Accepted by the Faculty of Medicine, Chulalongkorn University in Partial Fulfillment of the Requirements for the Master's Degree

..... Dean of the Faculty of Medicine

(Associate Professor Adisorn Patradul, M.D.)

THESIS COMMITTEE

..... Chairperson

(Associate Professor Pongsak Yuktanandana, M.D., M.Sc.)

..... Thesis Principal Advisor

(Associate Professor Somrat Charuluxananan, M.D., M.Sc.)

..... Thesis Co-advisor

(Monwat Ngerncham, M.D., M.Sc.)

..... External Member

(Anan Manomaipiboon, M.D., M.Sc.)

..... Member

(Associate Professor Somrat Lertmaharit, M.Sc., M.Med.Stat)

ศุภกานต์ เตชะพงศธร : การทดลองแบบกลุ่มเปรียบเทียบการปิดแผลผ่าตัดด้วย ออกทิลไซยาโนอคิลเลท กับ การเย็บด้วยไหมละลายแบบซับคิวทิคูล่า และการวิเคราะห์ความคุ้มค่าทางเศรษฐศาสตร์ด้านต้นทุนและประสิทธิภาพ. (A RANDOMIZED CONTROLLED TRIAL COMPARING 2-OCTYLCYANOACRYLATE WITH ABSORBABLE SUBCUTICULAR SUTURE FOR SURGICAL INCISION WOUNDS CLOSURE AND COST-EFFECTIVENESS ANALYSIS) อ. ที่ปรึกษาวิทยานิพนธ์หลัก : รศ.นพ.สมรัตน์ จารุลักษณานนท์, อ.ที่ปรึกษาวิทยานิพนธ์ร่วม : นพ.มนวัตน์ เงินฉ่ำ 51 หน้า.

วัตถุประสงค์: เพื่อศึกษาเปรียบเทียบประสิทธิผลการปิดแผลผ่าตัดด้วยออกทิลไซยาโนอคิลเลท และการเย็บแผลด้วยไหมละลายแบบซับคิวทิคูล่า

รูปแบบการวิจัย: การศึกษาแบบกลุ่มเปรียบเทียบ และการวิเคราะห์ความคุ้มค่าทางเศรษฐศาสตร์

สถานที่ทำการวิจัย: ห้องผ่าตัดเล็กและห้องตรวจโรคผู้ป่วยนอก ภาควิชาศัลยศาสตร์ วิทยาลัยแพทยศาสตร์กรุงเทพมหานครและวชิรพยาบาล

ระเบียบวิธีวิจัย: ผู้ป่วยจำนวน 88 คน มารับการรักษาเพื่อผ่าตัดก้อนชนิดไม่ร้าย ในห้องผ่าตัดเล็ก ได้รับการสุ่มด้วยคอมพิวเตอร์เข้ากลุ่มศึกษา 2 กลุ่ม คือกลุ่มที่ปิดแผลด้วยวัสดุปิดแผลออกทิลไซยาโนอคิลเลท จำนวน 44 คนและกลุ่มที่เย็บปิดแผลด้วยไหมละลายแบบซับคิวทิคูล่า จำนวน 44 คน แล้วประเมินผลของการหายของแผลด้วย wound score ในวันที่ 7 หลังการปิดแผล โดยผู้เชี่ยวชาญทางด้านศัลยกรรม ซึ่งไม่มีส่วนเกี่ยวข้องในการแปลผลการวิจัยครั้งนี้ ร่วมกับการวิเคราะห์ความคุ้มค่าทางเศรษฐศาสตร์ด้านต้นทุนและประสิทธิภาพของการปิดแผลทั้งสองวิธี

ผลการศึกษา: การปิดแผลด้วยออกทิลไซยาโนอคิลเลท ให้ผลคะแนนในด้านการหายของแผลได้ดีกว่าการเย็บแผลด้วยไหมละลายแบบซับคิวทิคูล่า โดยให้ผลที่ดีกว่าในด้าน wound approximation (9.93 ± 0.34 VS 8.98 ± 2.35, $p = 0.002$, 95% CI 0.22-1.68), wound inflammation (9.86 ± 0.35 VS 8.33 ± 2.47, $p < 0.001$, 95% CI 0.76-2.29), wound epithelization (9.83 ± 0.44 VS 8.76 ± 2.48, $p = 0.018$, 95% CI 0.30-1.84) อย่างมีนัยสำคัญ และใช้เวลาในการปิดแผล ระยะเวลาการผ่าตัดน้อยกว่าการเย็บแผลด้วยไหมละลายแบบซับคิวทิคูล่า อย่างมีนัยสำคัญ (104.09 ± 14.40 VS 227.33 ± 39.16, $p < 0.001$, 95% CI 111.30-136.43) ผลการวิเคราะห์ความคุ้มค่าทางเศรษฐศาสตร์ด้านต้นทุนและประสิทธิภาพ ก็พบว่าการปิดแผลด้วยออกทิลไซยาโนอคิลเลท ได้ต้นทุนและประสิทธิภาพที่ดีกว่า

สรุป: การปิดแผลด้วยออกทิลไซยาโนอคิลเลท เป็นวิธีการที่สามารถทำได้อย่างมีประสิทธิผลในการปิดแผลผ่าตัด เมื่อเทียบกับเย็บแผลด้วยไหมละลายแบบซับคิวทิคูล่า

สาขาวิชา การพัฒนาสุขภาพ ลายมือชื่อนิสิต.....

ปีการศึกษา 2550 ลายมือชื่ออาจารย์ที่ปรึกษาวิทยานิพนธ์หลัก.....

ลายมือชื่ออาจารย์ที่ปรึกษาวิทยานิพนธ์ร่วม .....

4975007830 : MAJOR HEALTH DEVELOPMENT

KEY WORD: SURGICAL INCISION WOUND CLOSURE, 2-OCTYLCYANOACRYLATE TISSUE ADHESIVES, AND ABSORBABLE SUBCUTICULAR SUTURE

SUPHAKARN TECHAPONGSATORN: A RANDOMIZED CONTROLLED TRIAL COMPARING 2-OCTYLCYANOACRYLATE WITH ABSORBABLE SUBCUTICULAR SUTURE FOR SURGICAL INCISION WOUNDS CLOSURE AND COST-EFFECTIVENESS ANALYSIS. THESIS PRINCIPAL ADVISOR: ASSOC. PROF. SOMRAT CHALURUXANANON, THESIS COADVISOR: MONAWAT NGERNCHAM, 51 pp.

Objective: To compare the effectiveness of 2-octylcyanoacrylate and absorbable subcuticular suture for surgical incision wound closure.

Study designs: Randomized controlled trial and economic analysis.

Setting: Minor Operative room and outpatient surgical clinic, Department of Surgery, Bangkok Metropolitan Administration Medical College and Vajira hospital.

Research Methodology: 88 patients, who indicated for surgical removal of benign skin or subcutaneous lesion, were computed randomly assigned into two groups: 2-octylcyanoacrylate for wound closure (N = 44) and absorbable subcuticular suture for wound closure (N=44). The wound score was used for evaluation in 7^{th} day postoperative by independent professional observers. The cost-effectiveness analysis also performed alongside with trial.

Results: 2-octylcyanoacrylate had wound closure evaluation score, wound approximation (9.93 ± 0.34 VS 8.98 ± 2.35, $p = 0.002$, 95% CI 0.22-1.68), wound inflammation (9.86 ± 0.35 VS 8.33 ± 2.47, $p < 0.001$, 95% CI 0.76-2.29), wound epithelization (9.83 ± 0.44 VS 8.76 ± 2.48, $p = 0.018$, 95% CI 0.30-1.84), wound closure time (104.09 ± 14.40 VS 227.33 ± 39.16, $p < 0.001$, 95% CI 111.30-136.43) better than absorbable subcuticular suture with statistically significant. The 2-octylcyanoacrylate had better cost-effectiveness analysis than absorbable subcuticular suture.

Conclusion: 2-octylcyanoacrylate is effectiveness for surgical incision wound closure comparing with absorbable subcuticular suture.

Field of Study Health Development
Academic Year 2007

Student's Signature.....
Principal Advisor's Signature.....
Co-advisor's Signature.....

ACKNOWLEDGEMENTS

I would like to acknowledge the Bangkok Metropolitan Administration Medical College and Vajira Hospital who gave me a scholarship to participate in this program and all of my colleagues at The Department of Surgery for enabling me to learn thoroughly during my two years of education. As well, I would like to express my deep gratitude to my advisor, Associate Professor Somrat Charulaxananan, for his attention and helpful my thesis.

I am grateful to Associate Professor Somrat Lertmaharit for her help in comments and suggestion for statistical analysis, Dr. Anan Manomaipiboon and Dr. Monnawat Ngerncham for suggestion and correction of my thesis. I would like to thank Dr. Suksan Kanoksin and Ms. Jiwamol Kanoksilp for review and comment of my thesis.

I would like to thank my family, who supports all my efforts and forgives me for my absence in order to finish this thesis.

I would like to thank all administrative officers in CEU, Faculty of Medicine, Chulalongkorn University, who supported the important data used in this thesis.

Finally, I would like to acknowledge the patients who were the constant sources of my motivation and served as the inspiration for doing this project.

CONTENTS

LIST OF TABLES

LIST OF FUGURES

CHAPTER I

INTRODUCTION

Rationale and Background.

Wound defines as a bodily injury caused by physical means, with disruption of the normal continuity of structures [1]. A wound can be caused by almost any injurious agent and can involve almost any tissue or structure. The most useful classification of wounds from a practical point of view is that of Rank and Wakefield, who divided them into tidy and untidy wounds [2, 3]. Tidy wounds are inflicted by sharp instruments and contain no devitalized tissue; such wounds can be closed immediately with the expectation of quiet primary healing. Examples of these wounds are surgical incisions and cut from glass or knives. Skin wound will usually be single and clean cut. Untidy wounds result from crushing, tearing, avulsion, vascular injury or burns, and will contain devitalized tissue. Skin wounds will often be multiple and irregular. If such wounds are closed immediately, healing are unlikely to occur and may have complications. At best there may be wound dehiscence, infection and delayed healing. At worst, gas gangrene and death may result. The correct management of untidy wounds is wound excision or debridement all devitalized tissue to create a tidy wounds. Other wound classifications include open and closed wound, infected and non-infected wound, penetrating and non-penetrating wound. There are also wound classification from cause of wound; traumatic VS surgical incision wounds [3].

In human, regeneration of tissues is limited. Only epithelium and the liver can actually regrow; most tissues heal by repair, which results in scarring. Wound healing is the summation of number of processes that follow injury. These included coagulation, inflammation, matrix synthesis and deposition. These were followed by

angiogenesis, fibroplasia, epithelization, contraction, remodelling and scar maturation. If wound edges are apposed, healing proceeds rapidly to closure. This process was known as healing by first intention or primary healing. Wound closure is a technique to re-approximate the wound edge to assist and provide optimal wound healing [2].

Suturing is the most common method used for wound closure. Although wound closure with suture was safe and effective, it usually operator dependent, it is time-consuming, required painful injection of local anesthetic drugs, required specific instrument, carries the risk of a needle stick to the practitioner, and requires a return visit to suture removal.

Other methods for wound closure are skin staple, adhesive papertape, new tissue adhesives. There were many studies tried to demonstrate the efficacy, effectiveness and economic analysis between all of these methods but the definite conclusion is still not obtained. Selecting of the materials or device for wound closure depend on the type, site, length of wound and etc. Recently, the new tissue adhesives or 2-octylcyanoacrylate had been imported and approved by the Thailand Food & Drug Administration. This is a product to use for tissue adhesive in wound closure. Objective of this study is to investigate the effectiveness of the new tissue adhesive compared with the absorbable subcuticular suture for surgical incision wound closure.

CHAPTER II

LITERATURE REVIEW

Through “Pubmed” searching engine, the keywords “2-octylcyanoacrylate OR Dermabond OR octylcyanoacrylate” were searched. There were 170 articles found, of which 38 articles were about randomized controlled trial study. To review the specified articles, the keywords “subcuticular suture” together with “wound closure” OR “skin closure” were searched. There were 10 articles found, of which 5 articles were about randomized controlled trial study. The articles which seemed to be well matched or related to the research questions were selected and critical appraisal are following.

Wound can be classified as a tidy or untidy wound. The tidy wound may be caused from traumatic sharp cut injuries or surgical incision wound. These wounds require wound closure to optimize the wound healing and cosmetic outcome. The ideal method of wound closure should be easy to perform, safe, quick, inexpensive, painless or produce minimal discomfort, bacteriocidal, and result in optimal cosmetic appearance of the scar [4, 5].

Suturing is the most common and standard method used for wound closure from both traumatic and surgical incision wounds. Although suturing is safe and effective for wound closure, but it is operator dependent, required painful injection of a local anesthetic drug, it is time-consuming, requires specialized instrument, carries the risk of a needle stick to the practitioner, and requires a return visit to suture removal. Many complications would occur including wound dehiscence, wound infection, tissue allergy from suture materials that may cause small granulomata, leave stitch marks along the suture line and the late complication of the scar formation, despite meticulous suturing technique [4, 6]. Suturing The use of absorbable suture with subcuticular suture technique are an acceptable alternative to nonabsorbable suture

with simple suture technique because subcuticular suture was less likely to create wound separation and edge inversion [7]. The long-term cosmetic outcome seem to be at least as good and not required return for removal suture [8]. But the unexpected complication of absorbable suture or subcuticular suture had been reported, Holzhermer RG. founded the unexpected tissue reactions (inflammation, granuloma, extrusion, fistula, abscess) in the vicinity of Vicryl, and after removal of the suture material and the granulomatous tissue wounds healed without any further disturbance [9].

Many solutions to address these problems were developed including the new material or devices for compensated the suture materials e.g., adhesive papertape, skin staple.

Adhesive papertape or strips, commonly known as Steri-strips®, is the wound closure device that attaches the wound edge together and maintains the approximation until optimal wound healing. This material has been well established for wound closure in children. It was easy to use, fast, safe, painless without needle advantage. There is limitation of adhesive papertape in some situation of clinical practices. For example, the edge of serum oozing wound or wound exposed to moisture may not be successfully re-approximated with adhesive papertape as moisture decreased the adhesive strength. Sarifakioglu E. et al. suggested that the use of dressing sprays or benzoin before the adhesive papertape placement, bring up more adhesive power to the wound edge than adhesive papertape alone [10]. In clinical practice, adhesive papertape are used to reduce tension of the wound edge or add to other method of wound closure e.g., post-suturing.

Skin staple or clip is an alternative for wound closure device. In clinical practice, the use of skin staples is effective, safe, easy to perform without needle advantage. But there are minimal reports of this device. The studies of Lee D. suggested no difference between skin staple and sutures for dehiscence, infection, and satisfaction when assessed by patients or surgeons [11].

The tissue adhesive or tissue glue is currently popular for the wound closure especially in children. Common material of tissue adhesive is cyanoacrylate so-called fibrin glue. Cyanoacrylate was first manufactured in 1949. Cyanoacrylate tissue adhesives can be produced by a mix of cyanoacetate and formaldehyde in a heat vacuum along with a base to form a liquid monomer [12]. When the monomer contact with moisture of the skin's surface, it chemical structure will change into a polymer that binds the top epithelial layer. This polymer forms cyanoacrylate bridge, bind the two wound edges together and allow normal healing to occur underneath. The conversion from monomer to polymer occurs rapidly preventing seepage of the adhesive into the wound as long as the edges are well approximated. Heat is often generated during the change from monomer to polymer, and the heat may be felt on occasion by patients during application to the skin. Cyanoacrylates have also been shown to have antimicrobial properties [13, 14].

The first adhesive material was noted to have extremely inflammatory effects on tissues. N-butyl-2-cyanoacrylate, developed in the 1970s, was the first adhesive material to cause negligible tissue toxicity, good bonding strength, as well as acceptable wound cosmesis [15]. N-butyl-2-cyanoacrylate has been used in cartilage and bone grafting, coating corneal ulcers in ophthalmology, repairing damaged ossicles in otolaryngology, coating aphthous ulcers, embolization of gastrointestinal varices and embolization in neurovascular surgery. This adhesive material is not approved by the FDA but has been used in Canada and numerous other countries for more than 20 years due to some report of toxicity [16, 17].

2-octylcyanoacrylate, the latest in cyanoacrylate technology, has less toxicity and almost four times stronger in bonding than N-butyl-2-cyanoacrylate. Special plasticizers have been added to the formula to provide flexibility. This adhesive reaches maximum bonding strength within two and a half minutes and it has stable strength to heal tissue for seven days after repair.

The advantage of tissue adhesive include decreasing repairing time (operative time) with maximum bonding strength at 2.5 minutes and equivalent in strength to heal tissue for seven days of after repair, eliminate follow up visits for removal of sutures, can be applied using only a topical anesthetic, no needles, water-resistant covering and good cosmetic outcome at both short term and long term follow up visits [16, 18]. But there are limitations of skin adhesives. It can't use in some areas or types of wound such as jagged or satellite lacerations, bites, punctures or crush wounds, contaminated wounds, mucosal surfaces, axilla and perineum (high-moisture areas), hands, feet and joints (unless kept dry and immobilized).

Recently many studies regarding the efficacy of 2-octylcyanoacrylate were reported. The effectiveness of 2-octylcyanoacrylate for wound or skin closure had been performed in many type of wound such as breast surgery [19], clean head and neck wound [4,17], pediatric laceration wound [4], Pediatric surgical incision wound [14, 20-22], miniphlebectomy [23], and laparoscopic trocar wound [24]. There are four studies investigated the use of octylcyanoacrylate tissue adhesive comparing with suture, Toriumi et al compared 2-octylcyanoacrylate with 5/0 or 6/0 polyamide in benign skin lesion at face and neck [14], Greene et al compared 2-octylcyanoacrylate with 6/0 prolene in bilateral blepharoplasty [21], Shamiyeh et al. reported the comparison for wound closure in miniphlebectomy wound between 2-octylcyanoacylate and 5-0 monofilament suture [23], and Maartense et al compared 2-octylcyanoacrylate with 4/0 intracutaneous polioglecaprone in laparoscopic surgical wound [24]. All studies showed the effectiveness of 2-octylcyanoacrylate for wound closure compared with conventional wound closure technique.

There are three studies compared 2-octylcyanoacrylate with adhesive strips; Shamiyeh et al use 2-octylcyanoacrylate or suture with 5/0 monofilament suture or adhesive strips for skin closure in phlebectomy wound, but result showed closure with tissue adhesive takes the time of closure, more expensive than the adhesive tape or suture [23]. Mattick A et al use 2-octylcyanoacrylate or adhesive strips and show both

are similar in efficacy for pediatric laceration repair [4]. Maartense S et al. used 2-octylcyanoacrylate or adhesive papertape or poliglecaprone and show the efficacy all wound closure device, the closure with papertape was the fastest method and most cost-effectiveness [24].

The evaluation of the outcome measure; six studies reported wound dehiscence as an outcome. The times of wound examination for dehiscence varied between 1-90 days [14,23,25,26] and the 2-octylcyanoacrylate had good efficacy for wound healing in early phase compare with another wound closure device. The outcome of wound infection had proposed in 4 studies and showed 2-octylcyanoacrylate had efficacy for decrease wound infection rate more than another wound closure device [24,25,27,28]. The last and attractive outcome was cosmetic outcome, most study used this outcome as a primary outcome and evaluation at time between 2-12 months by cosmetic VAS score and concluded that 2-octylcyanoacrylate had good cosmetic outcome more than standard wound suturing [14,28-30].

About the view of cost-effectiveness, two studies show that 2-octylcyanoacrylate can significantly decrease health care costs [19,31], but the study of Maartense show adhesive papertape was the more cost-effective than the 2-octylcyanoacrylate [24].

CHAPTER III

RESEARCH METHODOLOGY

3.1 Research questions

3.1.1 Primary research question

Is the 2-octylcyanoacrylate tissue adhesives difference in surgical wound closure from the absorbable subcuticular suture?

3.1.2 Secondary research questions.

3.1.2.1 Is there any difference in time of surgical wound closure between 2-octylcyanoacrylate tissue adhesives and absorbable subcuticular suture?

3.1.2.2 In the health care provider's aspect, what is the cost-effectiveness for surgical incision wound closure between 2-octylcyanoacrylate tissue adhesives and absorbable subcuticular suture?

3.2 Objectives

3.2.1 Primary objective

To define the effectiveness of surgical wound closure with 2-octylcyanoacrylate tissue adhesives and absorbable subcuticular suture by using the wound closure evaluation score.

3.2.2 Secondary objectives

3.2.2.1 To compare the time of surgical wound closure between 2-octylcyanoacrylate tissue adhesives and absorbable subcuticular suture.

3.2.2.2 To define the decision analysis and cost effectiveness analysis of surgical wound closure between 2-octylcyanoacrylate tissue adhesive and absorbable subcuticular suture, in the health care provider's aspect.

3.3 Statistical hypothesis

3.3.1 Null hypothesis

The mean score of wound closure between a 2-octylcyanoacrylate tissue adhesive and absorbable subcuticular suture are inequivalence.

H_0: $\mu_O - \mu_S \geq 0$

3.3.2 Alternative hypothesis

The mean score of wound closure between a 2-octylcyanoacrylate tissue adhesive and absorbable subcuticular suture are equivalence.

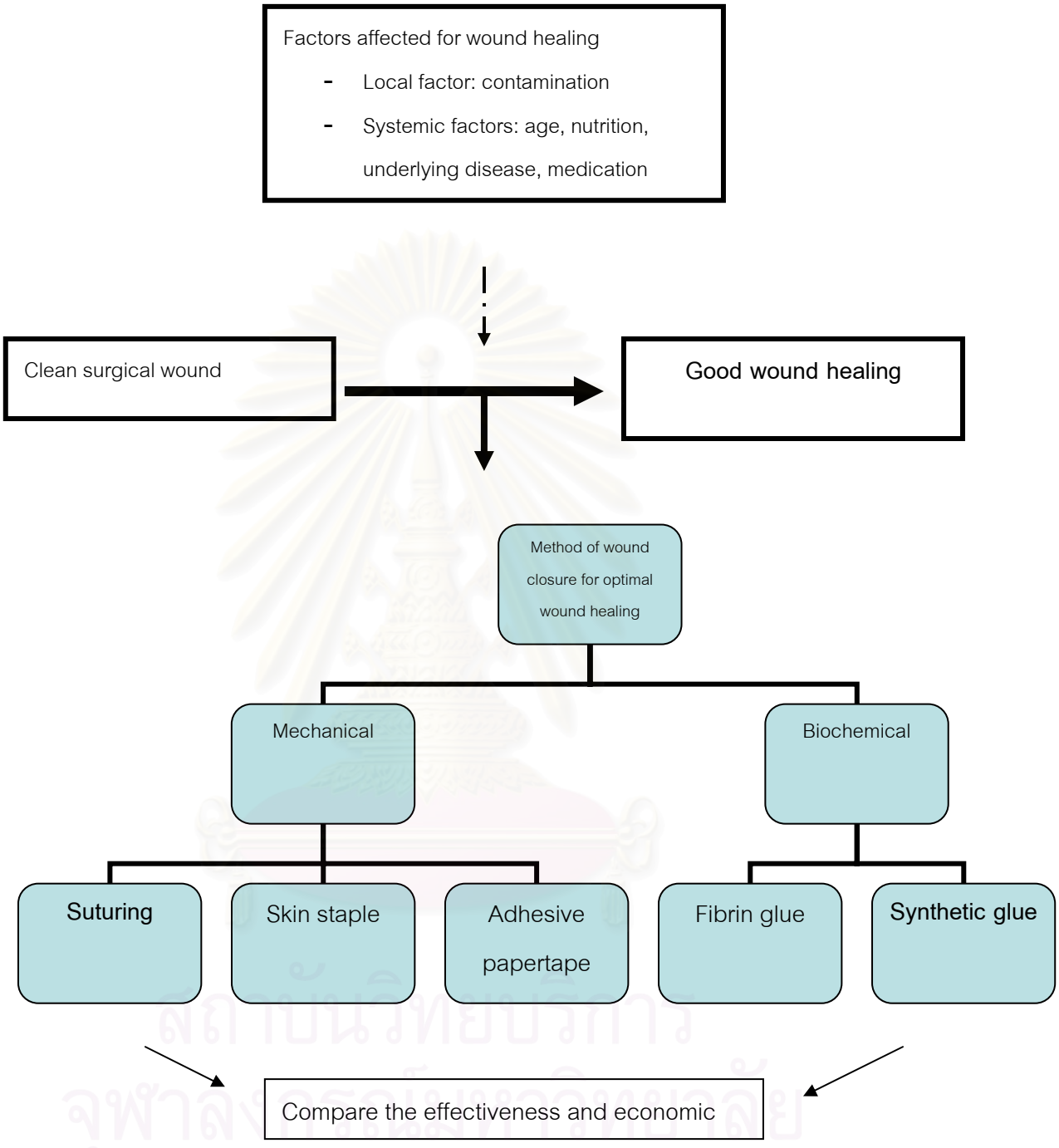
H_a: $\mu_O - \mu_S < 0$

μ_O = the mean score of wound closure in 2-octylcyanoacrylate tissue adhesive.

μ_a = the mean score of wound closure in absorbable subcuticular suture.

δ = The boundary of the range of equivalence, in this study accept the $|\delta|$ not more than 0.5.

3.4 Conceptual framework



3.5 Keywords.

Surgical incision closure, 2-octylcyanoacrylate, absorbable subcuticular suture, wound healing and surgical wound.

3.6 Operation definitions.

3.6.1 Wound

A wound is a type of physical trauma wherein the skin is torn, cut or punctured (an open wound), or where blunt force trauma causes a contusion (a closed wound). In pathology, it specifically refers to a sharp injury which damages the dermis of the skin.

3.6.2 Wound closure and wound healing

Wound healing, or wound repair, is the body's natural process of regenerating dermal and epidermal tissue. When an individual is wounded, a set of events takes place in a predictable fashion to repair the damage. These events overlap in time and must be artificially categorized into separate steps: the inflammatory, proliferative, and maturation phases.

3.6.3 Tissue adhesive

Substances used to cause adherence of tissue to tissue or tissue to non-tissue surfaces, as for prostheses. The tissue adhesive that common uses in clinical practice were fibrin glue or 2-octylcyanoacrylate. In this study, the tissue adhesive is 2-octylcyanoacrylate.

3.6.4 Wound closure complications

Wound closure complications were the complications that occur after the wound closure such as

- wound infection
- wound inflammation
- wound separation
- non-healing wound
- wound scar complication - keloid

3.7 Research design.

A prospective randomized controlled trial was design to answer the research question.

3.8 Research methodology

3.8.1 Populations and sample.

Target populations.

Patients underwent a surgical incision and require wound closure.

Sampled populations.

Patients underwent surgical incision closure in the Department of Surgery, Bangkok Metropolitan Administration Medical College and Vajira Hospital.

Study populations.

Patients who have all of the inclusion criteria and none of the exclusion criteria were recruited for the study.

3.8.2 Eligible criteria.

3.8.2.1 Inclusion criteria.

- Patients who have an indication for surgical incision wound closure in minor operation room with only one wound per patient.
- Length of wound less than 5 cm.
- Clean wound.
- Age 16-55 years.
- Agree to participate and sign the informed consent.

3.8.2.2 Exclusion criteria

- Traumatic wound.
- Site of wound at head, joint area and foot.

- Patients with history of heart disease, diabetes, renal failure, connective tissue disease, hypercoagulation state or cancer.

- Patients with history of allergy to suture materials or cyanocrylate.

3.8.3 Sample size calculation.

Sample size is calculated from the formula.

$$n = 2 \times s^2 \times [(Z_{\alpha/2} + Z_{\beta})]^2 / \delta^2$$

δ = the boundary of the range of equivalence,

s = SD of wound closure evaluation visual analog scale.

Given the $\propto$-error = 0.05 (two-tailed), $Z_{\alpha/2} = 1.96$.

Given the β-error = 0.1 (power 90%), $Z_{\beta} = 1.28$.

From the pilot study, the mean score of wound closure in 2-octylcyanoacrylate tissue adhesive group was 57.64 $\pm$ 0.50. The mean score of wound closure in absorbable subcuticular suture was 57.27 $\pm$ 0.47. So the sample size of this study were 40 patients per group or total 80 patients. It was estimated that 10% of the patients may be lost to follow-up. The estimated final sample size was 88 patients.

3.8.4 Randomization and allocation concealment.

3.8.4.1 Sampling process.

In the minor operation room, the patients who are a candidate for surgical incision wound closure, the surgeons will determined whether or not the patient fit the eligible criteria.

3.8.4.2 Randomization and allocation technique.

Patients who met the above eligible criteria were allocated to either treatment group or control group.

Treatment group: using the 2-octylcyanoacrylate tissue adhesives for wound closure.

Control group: using the absorbable subcuticular suture for wound closure.

A computer generating list of random number was chosen for this randomization. This process was performed by the research secretary; the result of allocation was contained in a sealed opaque envelope, which is sequentially numbered. After the patient was enrolled, the envelope will be open by the series.

3.8.4.3 Blinding methods.

The surgeon (researcher) and patients were not blinded about the type of wound closure. The type of wound closure was contained in a sealed opaque envelope and open in time of preparation for wound closure. The envelope was opened by the nurse and send the absorbable subcuticular suture or 2-octylcyanoacrylate tissue adhesives to the surgeon. The assessor of outcomes was blind about the type of wound closure. After the patients met the researcher for evaluating the wound, the wound dressing or film coat of tissue adhesive at the wound were removed, the patients were sent to assessors for evaluating wound closure evaluation score.

3.8.5 Research instrument

Research instrument in this study for evaluation of the primary outcome was the wound closure evaluation score.

The first stage of this study was a process of develop the “Wound closure evaluation visual analog scale”; this score was developed from literature review and opinion of surgeon. The wound closure evaluation visual analog scale was tested for validity and reliability from content expert.

Pilot study had been performed, wound care was evaluated at Department of Surgery, Bangkok Metropolitan Administration Medical College and Vajira Hospital for 10 patients and result for reliability analysis showed intraclass correlation coefficient of inter-observer equal as 0.90 and intraclass correlation coefficient of intra-observer equal as 0.95.

3.8.6 Intervention.

Interventions of this study start at time of wound closure. After the wound bed cleansing, wound bed preparation, and surgical hemostasis. Type of wound closure was selected.

Group A

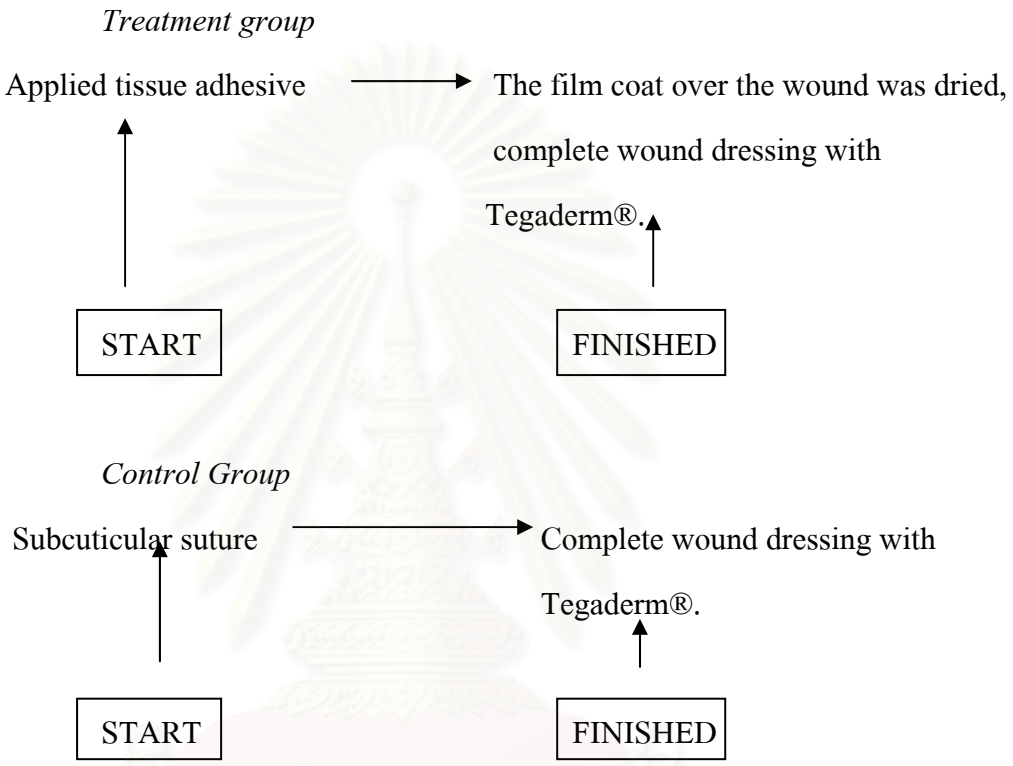
- The tissue adhesives using for wound closure in this study was octyl-2-cyanoacrylate or Dermabond® (product from Johnson and Johnson Company).
- The preparation of this tissue adhesive is the liquid fill in the small glass tube, when wound closure was started, the tissue adhesive was applied at the wound edge and extend around the wound edge about 1 cm, wait about 30 seconds then applied 2nd layer. It will form a film coats over the wound and become water-proof.
- The wound care recommendation was given to patients.
- The appointment date was 7th day post-wound closure.

Group B

- The wound closure was an absorbable subcuticular suture (polyglactin 910 number 4-0 or Vicryl® product from Johnson and Johnson Company).
- The wound care recommendation was send for patients.
- The appointment date was 7th day post-wound closure.

Time of wound closure

The time of wound closure was recorded when start the wound closure and finish when complete wound dressing. This time was recorded by circulating nurse in second.



3.8.7 Outcome measurement.

3.8.7.1 Independent variables.

Independent variable in this study was the type of wound closure and the other collected variables were sex, age and type of operation.

3.8.7.2 Outcome variables.

Outcome variables in this study were the wound closure evaluation score, time of wound closure.

3.8.8 Economic analysis.

The technique of decision analysis was used. This technique is a well documented method for integrating data from a wide variety of sources to explore population policy options and to help inform difficult decisions about individuals. The method consists of defining a clinical problem, identifying the components of the decision, arranging the components of the decision as a "tree" which describes the possible pathways to particular outcomes, and quantifying the probabilities of passing down each branch of the tree. This enables the expected consequences of different decisions to be calculated. It is also possible to use a decision tree to make quantitative estimates of the cost that would be expected to arise from different decisions by assigning a value to each of the different screening tests and interventions. This allows the cost of each decision to be estimated and the "best" decision to be identified.

In this study, cost-effectiveness analysis of surgical incision wound closure with two types of wound closure techniques; 2-octylcyanoacrylate tissue adhesive and absorbable subcuticular suture were compared.

A decision tree was constructed for described the different clinical outcome after wound closure. At each node or branching of the tree, probabilities or proportions were given and calculated by using Bayes theorem.

The internal validity of the model was approved by a group of expert clinicians. The ultimate model had been utilized to calculate the expected outcomes of different screening strategies.

A cost-effectiveness analysis was accomplished, based on direct medical costs to estimate the total cost per patient for wound closure.

Sensitivity analyses were performed by varying the cost of suture material and tissue adhesives to identify which assumptions or values had the most influence on the outcomes of different strategies. These influential variables were then combined in one way sensitivity analysis fashion to determine the critical values at

which the advantage of one policy over another would be lost. The calculations were performed using TreeAge (DATA) professional decision analysis software.

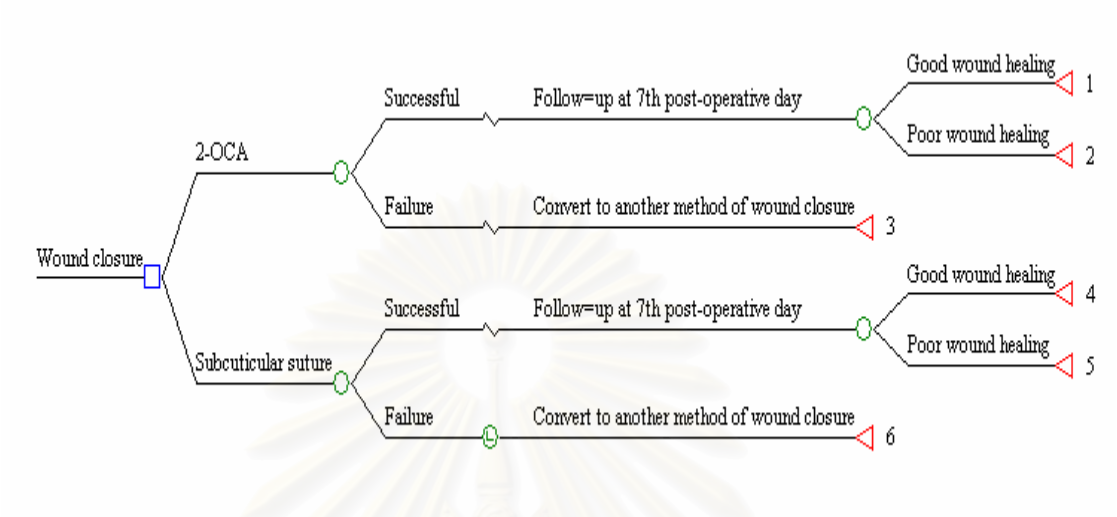


Figure 1: The decision tree for cost effectiveness analysis.

Table 1: List of direct medical cost in this study

	Cost (Baht) / unit
Procedure charge	2,500
Suture material – polyglactin 910 No.4-0	163
2-octylcyanoacrylate	440
Tegaderm	10
Steri-strip	22.50
Medication	
Dicloxacillin	3.25
Paracetamol	0.50

This study used the provider view for analysis the effectiveness of material for wound closure. This cost was in Thai Baht that charged from Bangkok Metropolitan Administration Medical college and Vajira hospital, this include 10% hospital charge. So in group A or using the 2-octylcyanoacrylate for wound closure, the total direct

medical cost was 3,051 Baht (procedure charge + 2-OCA + tegaderm + medication) and group B the cost was 2,796.50 Baht (procedure charge + suture material + steri-strip + tegaderm + medication).

3.9 Data collection.

The data collection forms or case record forms (Appendix C) comprised of four separate forms.

- Demographic data: filled by assistant nurse.
- Time of wound closure: filled by assistant nurse.
- Wound closure evaluation visual analog scale: filled by the assessors of the main outcome.
- Cost used for wound closure: filled by assistant nurse.

All of the data being measured were summarized in Table 2.

Table 2: Summary of measurements.

Variables	Scale	Description of data
1. Baseline characteristics		
Age	Continuous	Mean, SD
Site of wound	Nominal	Frequency
Length of wound (cm)	Continuous	Mean, SD
Type of operation	Nominal	Frequency
2. Primary variables		
Wound closure evaluation VAS	Continuous	Mean, SD
3. Secondary variables		
Cost use for wound closure	Continuous	Mean, SD
Time of wound closure	Continuous	Mean, SD
4. Safety variables		
Adverse events	Nominal	Frequency

3.10 Data analysis.

3.10.1 Analysis strategy.

This randomized controlled trial was designed to evaluate the effectiveness of tissue adhesive in wound closure evaluation visual analog scale compared with absorbable subcuticular suture in patients who required surgical incisional wound closure. The statistical analysis focused on the detection of significant differences between the tissue adhesive and absorbable subcuticular suture in wound closure evaluation visual analog scale at the endpoint or 7^{th} day post-wound closure.

In general, the data were analyzed on an intention-to-treat (ITT) basis. An intention-to-treat analysis was an analysis of data by the groups to which subjects are assigned by random allocation, even if the subject does not take the assigned therapy, does not receive the correct therapy, or does not follow the protocol.

Independent continuous variables with a normal distribution were analyzed using unpaired t-test. For continuous variables without a normal distribution, the Mann-Whitney U test was used.

Independent categorical variables were analyzed using Chi-square test or Fisher's exact test.

3.10.2 Indices calculation.

Baseline characteristics include age, sex, site of wound, type of operation, and length of wound.

The continuous variables include age, length of wound; this data were presented using mean and standard deviation.

The categorical variables include sex, site of wound; type of operation this data were presented in number and percentage of patients in each category.

Statistical analysis was not applied to compare baseline characteristics between the study groups. Owing to the power of randomization, it was expected that

the baseline characteristics of both groups were comparable. However, if there were clinical difference between groups in some baseline variables that potential by affected the primary outcome, these variables will be adjusted by using multiple logistic regression. Such variables include length of wound.

Primary outcome or the total wound closure evaluation visual analog scale; this data was presented in mean score and SD. The unpaired t-test was used for analysis between both groups. In case that data was not normal distribution, the Mann-Whitney U test was used.

Secondary outcome include cost use in wound closure, time of wound closure; both data were presented in mean and SD. The unpaired t-test was used for analysis between both groups. In case that data was not normal distribution, the Mann-Whitney U test was used.

Safety was evaluated using frequency of adverse events, and presented with descriptive statistics.

Test of hypothesis was conducted at the two-sided, 0.05 level of significant and confidence interval of 95%.

Table 3: Summary of Statistical analysis

Variables	Scale	Statistics
1. Primary outcome variables		
Wound closure evaluation VAS	Interval	Unpaired t-test or Mann-Whitney U test
2. Secondary variables		
Cost use for wound closure	Continuous	Economic analysis
Time of wound closure	Continuous	Unpaired t-test or Mann-Whitney U test
3. Safety variables		
Adverse events	Nominal	Fisher's exact test

3.11 Ethical considerations.

The protocol and details of the study were submitted to the Ethical Committee of the Bangkok Metropolitan Administration Medical College and Vajira hospital and Faculty of Medicine, Chulalongkorn University for approval.

The material that used in this study was a product of Johnson & Johnson company, but the researcher was not received any funds or other benefit from the company.

The objectives of this study were explained to the patients in details. Informed consent was a prerequisite to enter the study and the patients had the right to exit the study at any time without affecting the quality of care. In case of any complication or adverse events, the researcher will take full responsibility until full recovery.

3.12 Identification of limitations.

There were some limitations about the cost of tissue adhesives and absorbable subcuticular suture that used in this study. The funds for research in Bangkok Metropolitans Administration Medical College and Vajira hospital are only 60,000 Baht per research. I plan to find the sources for support my research.

3.13 Generalizing from the findings.

If the result of this study show the benefit of tissue adhesive in wound closure evaluation visual analog scale, time of wound closure, cosmetic result or wound scar complications, and cost analysis. This material may be a one choice for wound closure especially in pediatrics or in trauma case.

CHAPTER IV

RESULTS

4.1 Baseline characteristics data

During March to July 2008, all 112 patients who underwent excisional biopsy at minor operating room, Department of Surgery, Bangkok Metropolitan Administration Medical College and Vajira Hospital and wound care had be performed. There were 88 patients who met the eligible criteria of this study.

From the randomization process, there were 44 cases in Group A; using a 2-octylcyanoacylate for wound closure and 44 cases in group B; using a polyglactin 910 number 4-0 subcuticular suture for wound closure. The baseline characteristics of the study populations were shown in Table 4.

The mean age of the patient was 36.38 $\pm$ 8.99 years. The range of patient's age was 18-55 years. There were 39 male patients (44.3%) and 49 female patients (55.7%). The patients' diagnosis were epidermal cyst for 32 cases (36.4%), benign lipomatous lesion for 30 cases (34.1%), foreign body granuloma for 9 cases (10.2%), and benign naevi for 17 cases (19.3%). The lesion located in the chest wall area was found for 20 cases (22.7%), in abdominal wall area for 40 cases (45.5%) and in extremities area for 28 cases (31.8%). All of them received excision of lesion for treatment of their disease. The average wound length was 2.75 cm with standard deviation of 0.58 (range from 1.6 – 4.0 cm).

Table 4: Baseline characteristics of the study populations.

	Number (%) or Mean ± SD		
	Total (n=88)	**2-OCA (n= 44)**	**Subcuticular suture (n=44)**
Age (year)	36.38 ± 8.99	34.23 ± 8.56	38.52 ± 8.89
Gender			
Male	39 (44.3)	22 (50%)	17 (38.6%)
Female	49 (55.7)	22 (50%)	27 (61.4%)
Diagnosis			
Epidermal cyst (ICD-10 = L720)	32 (36.4%)	14 (31.8%)	18 (40.9%)
Benign lipomatous lesion (ICD-10 = D179)	30 (34.1%)	16 (36.4%)	14 (31.8%)
Benign naevi (ICD-10 = D239)	17 (19.3%)	5 (11.4%)	4 (9.1%)
FB granuloma (ICD-10 = L980)	9 (10.2%)	9 (20.5%)	8 (18.2%)
Site of lesion			
Chest wall	20 (22.7%)	10 (22.7%)	10 (22.7%)
Abdominal wall	40 (45.5%)	19 (43.2%)	21 (47.7%)
Extremities	28 (31.8%)	15 (34.1%)	13 (29.5%)
Average wound length (cm.)	2.75 ± 0.58	2.84 ± 0.62	2.68 ± 0.54

There were two cases in group A and two cases in group B that lost follow-up period. All of them had been called for follow-up with satisfactory wound results without serious complications. In group B; one patient had left to another hospital, and

another one missed appointment. But all patients in group A believed that there was no problem of their wound healing. So, they were lost follow-up. (Figure 2).

4.2 The Wound Closure Evaluation Score

For the tools used in evaluating the result of wound closure, the "Wound Closure Evaluation Score" was developed. This content and structural validity was performed under the consensus of 10 general surgeons, 1 cardiothoracic surgeon, 4 plastic surgeons, 1 pediatric surgeon, 1 orthopedic surgeon, 1 oto-larlyngologist and 2 obstetric-gynecologists. The tool was tested for reliability by using evaluation of the 10 cases with a polyglactin 910 number 4-0 subcuticular suture for wound closure. The reliability analysis result showed intraclass correlation coefficiency of inter-observer equal to 0.90 and intraclass correlation coefficient of intra-observer equal to 0.95.

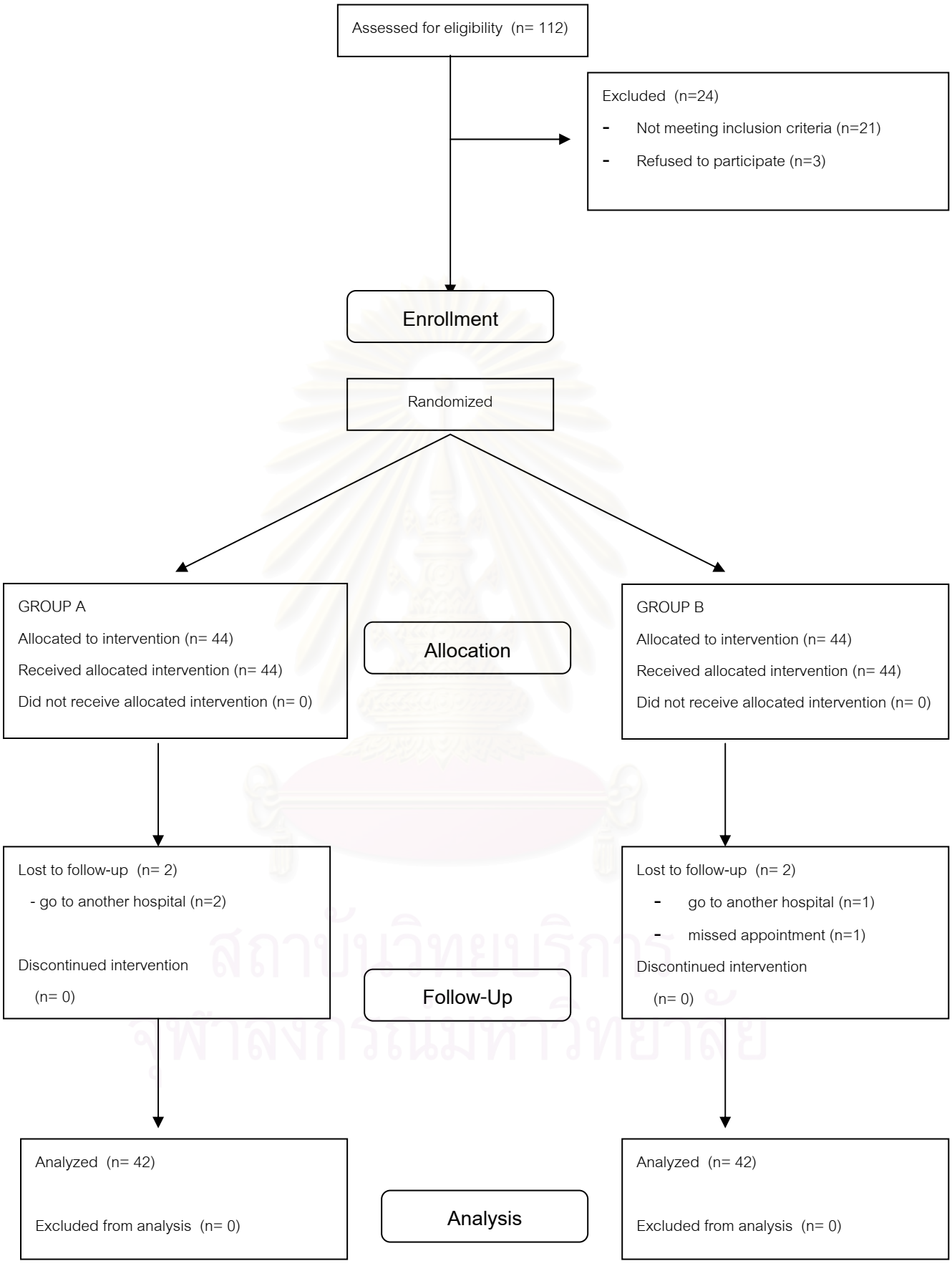


Figure 2: CONSORT flowchart.

4.3 Primary outcome analysis.

The primary outcome of this study was wound closure evaluation score. The data was checked and found to be non-normally distributed. It seemed skewness to the left as shown in Figure 3.

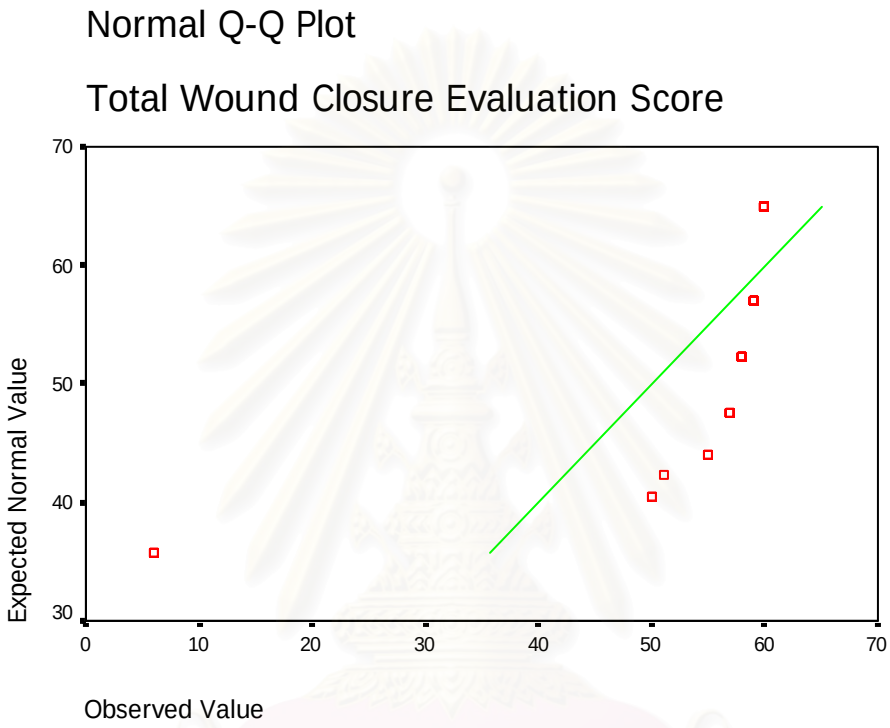


Figure 3: Normal Q-Q plot of total wound closure evaluation score.

This graph showed that most of wound closure evaluation score were in range of 50-60 points. This may be caused from the study that included only clean wounds, small incision (not more than 4 cm). Then the result of wound closure was good. All of patients had no wound infection and wound collection. Therefore, it was found that the average total wound closure evaluation score in group A was 59.19 $\pm$ 1.09 and group B was 53.76 $\pm$ 2.11. The average total wound closure evaluation score in both groups were statistically significant difference using Mann-Withney U test ($p < 0.001$), 95% CI 1.21 to 9.64.

As there were no cases with poor outcome in parameter of wound infection and collection, so both groups were compared only in view of wound approximation, border of wound, wound inflammation, and wound epithelization. (Table 5)

Table 5: The comparison between both group about wound approximation, border of wound, wound inflammation, and wound epithelization.

	Group A		Group B		*p-value**
	Mean ± SD	**Median**	**Mean ± SD**	**Median**	
Wound approximation	9.93 ± 0.34	10.00	8.98 ± 2.35	10.00	0.002
Border of wound	9.64 ± 0.79	10.00	8.86 ± 2.51	10.00	0.989
Wound inflammation	9.86 ± 0.35	10.00	8.33 ± 2.47	9.00	< 0.001
Wound epithelization	9.83 ± 0.44	10.00	8.76 ± 2.48	10.00	0.018

* using Mann-Whitney U test

The average score of wound approximation in group A was 9.93 ± 0.34 and group B was 8.98 ± 2.35. There were statistically significant difference between both groups *(p* = 0.002), 95% CI 0.22 to 1.68.

The average score of wound border in group A was 9.64 ± 0.79 and group B was 8.86 ± 2.51. There was no statistically significant difference between both groups *(p* = 0.989), 95% CI 0.02 to 1.60.

The average score of wound inflammation in group A was 9.86 ± 0.35 and group B 8.33 ± 2.47. There was statistically significant difference between both groups ($p < 0.001$), 95% CI 0.76 to 2.29.

The average score of wound epithelization in group A was 9.83 ± 0.44 and group B was 8.76 ± 2.48. There was statistically significant difference between both groups ($p = 0.018$), 95% CI 0.30 to 1.84.

4.4 Secondary outcome analysis

The time of wound closure was the secondary outcome of this study. The average operative time in group A was 294.55 ± 55.10 seconds, and group B was 300.23 ± 55.96 seconds. The average wound closure time in group A was 104.09 ± 14.40 seconds, and group B was 227.95 ± 39.39. There were no statistically significant differences in both groups about operative time ($p = 0.71$), but there were statistically significant differences in both groups about wound closure time using unpaired t-test ($p < 0.001$), 95% CI 111.30 to 136.43. The data is shown in Table 6.

Table 6: The comparison between both groups about operative time and wound closure time.

	Group A	**Group B**	***p*-value***
	Mean ± SD	**Mean ± SD**	
Operative time (second)	294.55 ± 55.10	300.23 ± 55.96	0.71
Wound closure time (second)	104.09 ± 14.40	227.33 ± 39.16	<0.001

* using unpaired t-test

4.5 Cost-effectiveness analysis

For this result, the unsuccessful closure was not occurred in both groups, so the chance node of unsuccessful closure was deleted. The final decision tree was shown in Figure 4.

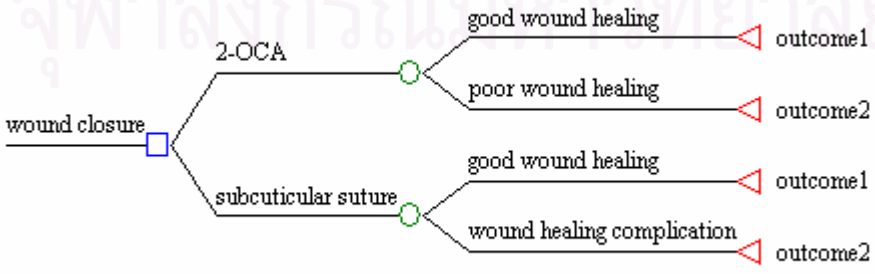


Figure 4: Decision tree for cost-effectiveness analysis.

The additional cost in poor wound healing were

- In case of require further medication, added cost of antibiotic and topical antibiotic was 149 Baht.
- In case of require re-operation, added cost of re-operation were 3,000 Baht including procedure charge 2,500 + suture material 250 + dressing material 50 + medication 200 Baht.

The summary of cost in this study were shown in Table 7.

Table 7 : Summary of cost (Baht) used in decision tree.

	Baht	
	2- OCA	**Subcuticular suture**
Excisional lesion with wound closure	3,051	2,796.50
Present of wound complication with require further medication	3,200	2,945.50
Present of wound complication with require re-operation	6,051	5,796.50

The total cost used for good wound healing when using 2-octylcyanoacrylate for wound closure was 3,051 Baht and when using subcuticular suture was 2,796.50 Baht. But the complication in subcuticular suture was more than 2-octylcyanoacrylate in view of wound inflammation, wound approximation and wound epithelization, in poor wound approximation it may require re-operation, and in case of present of wound inflammation and poor wound epithelization may require further medication. The cost used in case of require further medication in group A was 3,200 Baht, the cost used in case of require re-operation in group B was 5,796.50 Baht and the cost used in case of require further medication in group B was 2,945.50 Baht.

In group A, there were 31 cases (73.81%) had good wound healing, 11 cases (26.19%) had poor wound healing with required further medication and none required re-operation. In group B, there were 16 cases (38.09%) had good wound healing, 23 cases (54.77%) had poor wound healing with required further medication and 3 cases (7.14%) required re-operation. (Table 8)

Table 8 : Result of wound closure outcome.

	Number (%)	
	2- OCA	**Subcuticular suture**
Good healing without complication	31 (73.81 %)	16 (38.09 %)
Poor wound healing and require further medication	11 (26.19 %)	23 (54.77 %)
Poor wound healing and require further re-operation	0 (0%)	3 (7.14 %)

The cost-effectiveness analysis by using the rollback from decision analysis show in figure 4, 5.

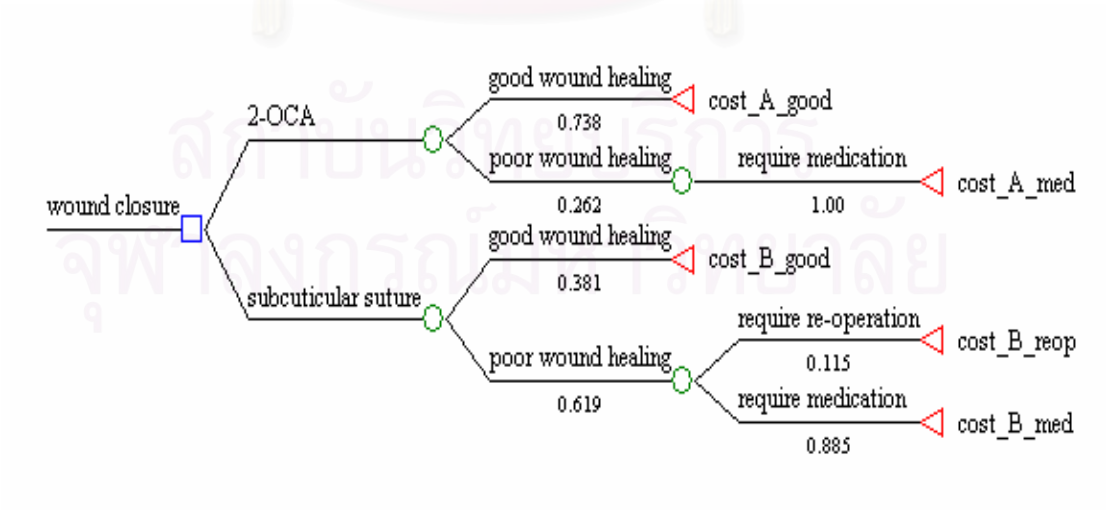


Figure 5: Final decision tree with result of probability from the study.

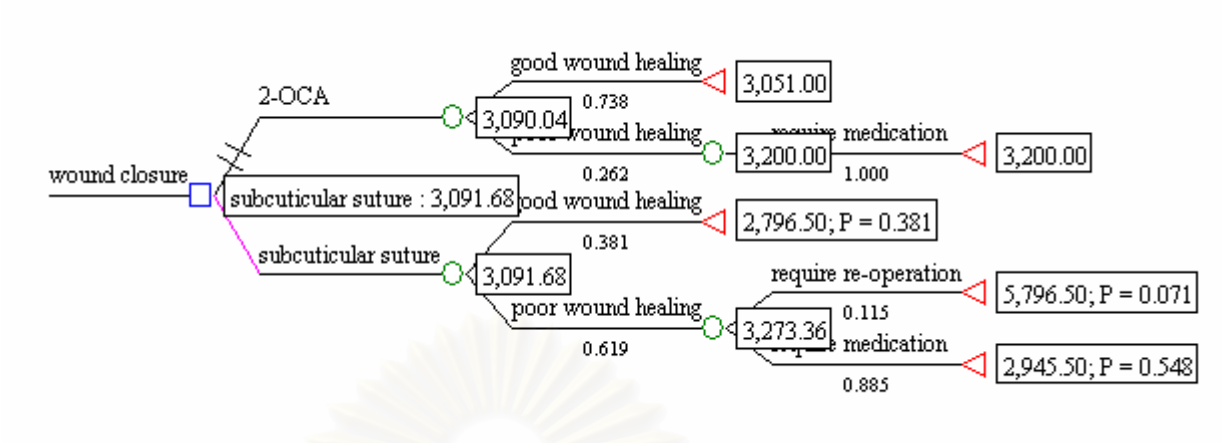


Figure 6: The summary of cost-effectiveness analysis.

The root cost in group A was 3,090.04 Baht and group B was 3,091.68 Baht. There were different only 1 Baht and the cost-effectiveness analysis show the using of 2-octylcyanoacrylate had cost-effectiveness more than polyglactin 910 subcuticular suture for wound closure.

CHAPTER V

DISCUSSION AND CONCLUSION

Discussion

Surgeon is the medical doctor who cares the surgical patient. Most of them require surgical management. The principle of surgery may create wound on patient called surgical wound. In some cases, the wound may be caused from trauma called traumatic wound. With variety of the nature of the wound, type of the wound, site of the wound or the length of the wound, surgeons who care for the patient should have basic and advanced knowledge about the wound care and management.

Wound closure is a process of wound care and management which may be the main part treatment in both surgical and traumatic wounds. Several wound or skin closure techniques has been developed for aggravating the complete wound healing without or minimized complication, such as skin suture, adhesive tape, skin staple and tissue adhesives.

Suturing is the most common and standard method used for wound closure both in traumatic and surgical wounds. There are several types of suture materials in this purpose, absorbable or non-absorbable, and several suture techniques such as simple suture, vertical mattress, horizontal mattress, subcuticular technique. Although suturing is safe and effective for wound closure, but it requires painful injection of a local anesthetic drug, it is time-consuming and operator dependent, needs specialized instrument and carries the risk of a needle stick to the practitioner, requires a return visit to suture removal. Suture may cause small granuloma, stitch marks along the suture line, and risk wound scar [4, 6]. Many complications are present despited meticulous suturing technique such as wound dehiscence, wound infection, tissue allergy from suture materials and the late complication of the scar formation. The subcuticular suture techniques with absorbable suture are the acceptable alternative

simple suture technique with nonabsorbable suture because the short term outcome in subcuticular suture, was less likely to have wound separation and edge inversion [7]. The long-term cosmetic outcome seems to be at least as good and not required return for removal suture [8]. But the unexpected complication of subcuticular suture with absorbable suture had been reported, Holzhermer RG. founded the unexpected tissue reactions (inflammation, granuloma, extrusion, fistula, and abscess) in the vicinity of Vicryl, and after removal of the suture material and the granulomatous tissue wounds healed without any further disturbance [9].

The tissue adhesive or tissue glue is currently popular for wound closure. 2-octylcyanoacrylate is common available adhesive tissue material in Thailand. The advantage of adhesive tissue material is shortening repairing time (operative time) reduction with maximum bonding strength at 2.5 minutes and it strength is also equivalent to healed tissue at seven days post repairing. The adhesive tissue material also eliminates follow up visit for removal of sutures. It can be applied by using only a topical anesthetic, no needles, water-resistant covering and good cosmetic outcome at both short term and long term follow up visits [16,18]. However, it can't be used in some areas or types of wound such as jagged or satellite lacerations, bites, punctures or crush wounds, contaminated wounds, mucosal surfaces, axilla and perineum (high-moisture areas), hands, feet and joints (unless kept dry and immobilized).

In this randomized controlled trial, comparing between the tissue adhesive or 2-octylcyanoacrylate (Dermabond®, Johnson&Johnson company) with absorbable subcuticular suture or polyglactin 910 (Vicryl®, Johnson&Johnson company) in the view of effectiveness for incision wound closure, wound closure time and the cost-effectiveness analysis.

Overall analysis showed the 2-octylcyanoacrylate had better wound approximation score, wound inflammation score and wound epithelization score than the absorbable subcuticular suture. But in the view of border of wound score, there was

no statistically significant difference between both groups. There was no wound infection and wound collection in this study.

For the wound approximation or the evaluation of wound dehiscence, the study showed that 2-octylcyanoacrylate generated better healing wound. Same as the study of Toriumi DM [14], Shamiyeh A [23], Cheng W [25], Sinha S [26] showed the 2-octylcyanoacrylate had good efficacy for wound healing in early phase comparing with another wound closure device. So the 2-octylcyanoacrylate can be effectiveness for maintaining the strength over the wound during period of wound closure.

There was no wound infection, wound collection in this study. This might be from the study that selected only clean wound with small wound size. These wounds also located in areas that had low risk of infection and were also shallow. The patients had no risk of bleeding, so they didn't have the risk of wound collection.

For border of wound, the study found that 2-octylcyanoacrylate provided better result, though not significant. The arrangement of wound border might be done more meticulously than 2-octylcyanoacylate using. If the wound is deep, using adhesive tissue material to close wound may need re-approximating the wound edge with absorbable suture at dermis layer for better alignment of wound border.

For wound inflammation, the study founded that 2-octylcyanoacylate was good in reducing erythema of wound edge and inflammation which were not caused by infection but was believed to result by allergic reaction from foreign body of suture material. Only one study mentions about wound inflammation was the study of Holzhermer RG. founded the unexpected tissue reactions in the vicinity of Vicryl®, after removal of the suture material, this granulomatous tissue wounds healed without any further disturbance [9]. So, avoiding suturing with polyglactin 910 in order to reduce remaining of foreign body in the wound would help prevent complications. However, during the follow-up period, the patient may need further treatment with higher medical spending. So, the use of adhesive tissue material may be the suitable option of this purpose.

For wound epithelization, the study founded that using 2-octylcyanoacylate to close wound would create thin film covering the wound. After 7-10 days, the wound is healed and the thin film will be peeled off. The already completed wound epithelization will lead to wound healing. The study also founded that using 2-octylcyanoacylate provided better wound epithelization score than suturing. There was no mentions about this topic from previous study.

For wound closure time, the study found that using 2-octylcyanoacylate would shorter wound closure time than suturing. This can reduce total operating time and also prevent accidental injury to medical practitioners.

Coulthard et al. reported the systematic review and metaanalysis between various tissue adhesive and sutures, eight randomization trials were included (630 patients). No statistically significant differences were found between various tissue adhesives and sutures) for dehiscence, infection, satisfaction with cosmetic appearance when assessed by patients' or surgeons' general satisfaction. However a statistically significant difference was found for surgeons' assessment of cosmetic appearance with mean difference 13 (95%CI 5 to 21), the higher mean rating for the tissue adhesive group [32].

In the era of sufficient economy, the view of economic analysis is the important part to decide whether to use the new technology for treatment. Adhesive tissue material is new in Thailand. Though it provides good effectiveness in wound closure, but we should compare its cost with the result.

About the view of cost-effectiveness, two studies showed that using 2-octylcyanoacrylate can significantly decrease health care costs [19, 31]. But the study of Maartense showed that adhesive papertape was more cost-effective than the 2-octylcyanoacrylate [24]. In this study, the provider view for cost-effectiveness analysis was used. The 2-octylcyanoacrylate had cost-effectiveness more than the polyglactin 910 subcuticular sutures only 1 Baht. So 2-octylcyanoacrylate was cost-effectiveness better than polyglactin 910 subcuticular sutures in clean and small incision wound

closure.

The evaluation of the wound closure outcome, there were used three indicators for evaluation of wound closure outcome in early and long term period. First indicator was wound approximation or separation or dehiscence, this indicator is very important for wound evaluation in early period or suture removal date [14, 23, 25, 26], second indicator was wound infection [24-28], and the last and attractive outcome indicators was cosmetic outcome which usually evaluation in long term period after wound closure [28-30]. The evaluation of scar formation in long term complication for wound closure is the most apparent and concrete criteria of wound evaluation. This can be well assessed as satisfactory level of both surgeon and patient.

The author has been assisted by team of experts in various fields. They had agreed to set up “wound closure evaluation score” in order to use for assessment of initial healing evaluation or during the suture removal period of 1-2 weeks after suturing. The issues that need to be evaluated include wound approximation (separation or dehiscence), wound infection, wound collection, irregularity of wound border, wound inflammation, and wound epithelization. So, wound closure evaluation score was developed and use this tool as the evaluated the main outcome of this study. From the pilot study, participants in the meeting have comprehended the evaluation score and can well gather information by using the score. The result for reliability analysis shows intraclass correlation coefficient of inter-observer equal to 0.90 and intraclass correlation coefficient of intra-observer equal to 0.95. This reflects possibility of using the score in healing wound evaluation. The author expected this tool can be used for evaluated and predicted the outcome of wound healing. From the result of this study, the author founded the problems of this tools for predict the wound healing outcome. The total wound closure evaluation score consisted of sum of six indicators (wound approximation, wound infection, wound collection, border of wound, wound inflammation and wound epithelization), in case of clean and small incision wound, there were minimal risk of wound infection or collection, and total

wound score also high. There were only three indicators (wound approximation, wound infection, and wound collection) when present of poor outcome it required re-operation. But the indicators of border of wound, wound inflammation and wound epithelization, it required only further medication for treatment in case of poor outcome. So, the total wound closure evaluation score can't used to predicted the total outcome of wound healing. The further study about indicators, various type of wound, length of wound will be investigated.

Conclusion

The 2-octylcyanoacrylate is one of effectiveness for incision wound closure comparing with absorbable subcuticular suture in terms of wound approximation, wound inflammation, wound epithelization, and wound closure time. The cost-effectiveness analysis showed 2-octylcyanoacrylate better too.

REFERENCES

[1] Taylor EJ. Dorland's illustrated medical dictionary. 27th edition ed. Philadelphia: W.B.Saunders Co.,; 1988.

[2] Coleman DJ. Wound, Tissue repair and scar. In: R.C.G. Russel, NS Williams, C.J.K. Bulstrode, editor. Bailey & Love's Short Practice of Surgery. 24th ed: Arnold; 2004. p. 84-94.

[3] Barbul A. Wound healing. In: Brunicardi FC, editor. Schwartz's Principles of Surgery. 8th ed. New York: The McGraw-Hill Companies, Inc.; 2005. p. 223-48.

[4] Mattick A, Clegg G, Beattie T, Ahmad T. A randomised, controlled trial comparing a tissue adhesive (2-octylcyanoacrylate) with adhesive strips (Steristrips) for paediatric laceration repair. Emerg Med J. 2002 Sep;19(5):405-7.

[5] Singer AJ, Giordano P, Fitch JL, Gulla J, Ryker D, Chale S. Evaluation of a new high-viscosity octylcyanoacrylate tissue adhesive for laceration repair: a randomized, clinical trial. Acad Emerg Med. 2003 Oct;10(10):1134-7.

[6] Singer AJ, Nable M, Cameau P, Singer DD, McClain SA. Evaluation of a new liquid occlusive dressing for excisional wounds. Wound Repair Regen. 2003 May-Jun;11(3):181-7.

[7] Harold KL, Goldstein SL, Nelms CD, Matthews BD, Sing RF, Kercher KW, et al. Optimal closure method of five-millimeter trocar sites. Am J Surg. 2004 Jan;187(1):24-7.

[8] Karounis H, Gouin S, Eisman H, Chalut D, Pelletier H, Williams B. A randomized, controlled trial comparing long-term cosmetic outcomes of traumatic pediatric lacerations repaired with absorbable plain gut versus nonabsorbable nylon sutures. Acad Emerg Med. 2004 Jul;11(7):730-5.

[9] Holzheimer RG. Adverse events of sutures: possible interactions of biomaterials? Eur J Med Res. 2005 Dec 7;10(12):521-6.

[10] Sarifakioglu E, Sarifakioglu N. Dressing spray enhances the adhesive strength of surgical dressing tapes. Indian J Dermatol Venereol Leprol. 2006 Sep-Oct;72(5):353-6.

[11] Lee KW, Sherwin T, Won DJ. An alternate technique to close neurosurgical incisions using octylcyanoacrylate tissue adhesive. Pediatr Neurosurg. 1999 Aug;31(2):110-4.

[12] Quinn J, Wells G, Sutcliffe T, Jarmuske M, Maw J, Stiell I, et al. Tissue adhesive versus suture wound repair at 1 year: randomized clinical trial correlating early, 3-month, and 1-year cosmetic outcome. Ann Emerg Med. 1998 Dec;32(6):645-9.

[13] Quinn J, Maw J, Ramotar K, Wenckebach G, Wells G. Octylcyanoacrylate tissue adhesive versus suture wound repair in a contaminated wound model. Surgery. 1997 Jul;122(1):69-72.

[14] Toriumi DM, O'Grady K, Desai D, Bagal A. Use of octyl-2-cyanoacrylate for skin closure in facial plastic surgery. Plast Reconstr Surg. 1998 Nov;102(6):2209-19.

[15] Bruns TB, Worthington JM. Using tissue adhesive for wound repair: a practical guide to dermabond. Am Fam Physician. 2000 Mar 1;61(5):1383-8.

[16] Bruns TB, Robinson BS, Smith RJ, Kile DL, Davis TP, Sullivan KM, et al. A new tissue adhesive for laceration repair in children. J Pediatr. 1998 Jun;132(6):1067-70.

[17] Maw JL, Quinn JV, Wells GA, Ducic Y, Odell PF, Lamothe A, et al. A prospective comparison of octylcyanoacrylate tissue adhesive and suture for the closure of head and neck incisions. J Otolaryngol. 1997 Feb;26(1):26-30.

[18] Arunachalam P, King PA, Orford J. A prospective comparison of tissue glue versus sutures for circumcision. Pediatr Surg Int. 2003 Apr;19(1-2):18-9.

[19] Gennari R, Rotmensz N, Ballardini B, Scevola S, Perego E, Zanini V, et al. A prospective, randomized, controlled clinical trial of tissue adhesive (2-octylcyanoacrylate) versus standard wound closure in breast surgery. Surgery. 2004 Sep;136(3):593-9.

[20] Bernard L, Doyle J, Friedlander SF, Eichenfield LF, Gibbs NF, Cunningham BB. A prospective comparison of octyl cyanoacrylate tissue adhesive (dermabond) and suture for the closure of excisional wounds in children and adolescents. Arch Dermatol. 2001 Sep;137(9):1177-80.

[21] Greene D, Koch RJ, Goode RL. Efficacy of octyl-2-cyanoacrylate tissue glue in blepharoplasty. A prospective controlled study of wound-healing characteristics. Arch Facial Plast Surg. 1999 Oct-Dec;1(4):292-6.

[22] Ong CC, Jacobsen AS, Joseph VT. Comparing wound closure using tissue glue versus subcuticular suture for pediatric surgical incisions: a prospective, randomised trial. Pediatr Surg Int. 2002 Sep;18(5-6):553-5.

[23] Shamiyeh A, Schrenk P, Stelzer T, Wayand WU. Prospective randomized blind controlled trial comparing sutures, tape, and octylcyanoacrylate tissue adhesive for skin closure after phlebectomy. Dermatol Surg. 2001 Oct;27(10):877-80.

[24] Maartense S, Bemelman WA, Dunker MS, de Lint C, Pierik EG, Busch OR, et al. Randomized study of the effectiveness of closing laparoscopic trocar wounds with octylcyanoacrylate, adhesive papertape or poliglecaprone. Br J Surg. 2002 Nov;89(11):1370-5.

[25] Cheng W, Saing H. A prospective randomized study of wound approximation with tissue glue in circumcision in children. J Paediatr Child Health. 1997 Dec;33(6):515-6.

[26] Sinha S, Naik M, Wright V, Timmons J, Campbell AC. A single blind, prospective, randomized trial comparing n-butyl 2-cyanoacrylate tissue adhesive (Indermil) and sutures for skin closure in hand surgery. J Hand Surg [Br]. 2001 Jun;26(3):264-5.

[27] Keng TM, Bucknall TE. A clinical trial of tissue adhesive (histoacryl) in skin closure of groin wounds. Med J Malaysia. 1989 Jun;44(2):122-8.

[28] Ozturan O, Miman MC, Aktas D, Oncel S. Butylcyanoacrylate tissue adhesive for columellar incision closure. J Laryngol Otol. 2001 Jul;115(7):535-40.

[29] Hollander JE, Singer AJ. Application of tissue adhesives: rapid attainment of proficiency. Stony Brook Octylcyanoacrylate Study Group. Acad Emerg Med. 1998 Oct;5(10):1012-7.

[30] Quinn J, Lowe L, Mertz M. The effect of a new tissue-adhesive wound dressing on the healing of traumatic abrasions. Dermatology. 2000;201(4):343-6.

[31] Osmond MH, Quinn JV, Sutcliffe T, Jarmuske M, Klassen TP. A randomized, clinical trial comparing butylcyanoacrylate with octylcyanoacrylate in the management of selected pediatric facial lacerations. Acad Emerg Med. 1999 Mar;6(3):171-7.

[32] Coulthard P, Worthington H, Esposito M, van der Elst M, van Waes OJF. Tissue adhesives for closure of surgical incisions. Cochrane Database of Systematic Reviews 2002, Issue 3. Art. No.: CD004287. DOI: 10.1002/14651858.CD004287.pub2

APPENDICES

APPENDICES A

คำแนะนำสำหรับผู้เข้าร่วมโครงการวิจัย

ชื่อโครงการวิจัย การศึกษาเปรียบเทียบการปิดแผลผ่าตัดด้วยออกทิลไซยาโนอคิลเลทกับการเย็บแผลด้วยไหมละลายแบบซับคิวทิคูล่า และวิเคราะห์ความคุ้มค่าทางเศรษฐศาสตร์ของต้นทุนและประสิทธิภาพ

ผู้วิจัย นายแพทย์สุภกานต์ เตชะพงศธร

อาจารย์ที่ปรึกษา ศ.นพ.สมรัตน์ จารุลักษณานันท์

สถานที่วิจัย ภาควิชาศัลยศาสตร์
วิทยาลัยแพทยศาสตร์กรุงเทพมหานครและวชิรพยาบาล

ผู้สนับสนุนการวิจัย มูลนิธิวิจัยทางการแพทย์วชิรพยาบาล

ท่านได้รับเชิญให้เข้าร่วมโครงการวิจัยโดยมีวัตถุประสงค์ดังนี้

1. ทำไมต้องศึกษาเรื่องนี้

การปิดบาดแผลผ่าตัดมีวิธีการหลายวิธี วิธีการที่ใช้เป็นมาตรฐานในปัจจุบันคือการเย็บแผล แต่การเย็บแผลมักทำให้เกิดภาวะอันไม่พึงประสงค์ เช่น รอยจากการเย็บ ปฏิกิริยาของร่างกายต่อไหมเย็บ การศึกษานี้เป็นการศึกษาประสิทธิภาพของกาวทางการแพทย์ และการเย็บแผลแบบไหมละลาย เพื่อใช้ในการปิดบาดแผลผ่าตัดเพื่อทดแทนการเย็บแบบเดิม

2. วัตถุประสงค์

เพื่อศึกษาเปรียบเทียบการใช้กาวทางการแพทย์ชนิดออกทิลไซยาโนอคิลเลทและการเย็บแผลแบบไหมละลาย ในการปิดแผลผ่าตัด รวมถึงศึกษาความคุ้มค่าทางเศรษฐศาสตร์ด้านต้นทุนและประสิทธิภาพ

3. จะปฏิบัติต่อท่านอย่างไร

ท่านจะได้รับการสอบถามเกี่ยวกับอายุ เพศ โรคที่เป็นอยู่ และจะบันทึกไว้ในแบบสอบถาม ต่อมาท่านจะได้รับการผ่าตัดตามโรคที่ท่านเป็นอยู่ตามมาตรฐานวิชาชีพ ภายหลังการผ่าตัดเสร็จวิธีการปิดแผลซึ่งบรรจุเรียงตามลำดับในซองปิดผนึกจะถูกเปิดออกดูโดยพยาบาล และส่งวัสดุดังกล่าวให้กับแพทย์ผู้ผ่าตัดเพื่อทำการปิดแผลต่อไป

4. ประโยชน์

ท่านจะได้รับการปิดแผลผ่าตัดด้วยวัสดุคือกาวทางการแพทย์ชนิด ออกทิลไซยาโนอคิลเลทหรือการเย็บแผลแบบไหมละลายอย่างใดอย่างหนึ่ง โดยวัสดุดังกล่าวท่านไม่ต้องเสียค่าใช้จ่าย

เพิ่มเติมแต่อย่างใด และท่านจะได้รับการดูแลตามมาตรฐานวิชาชีพ โดยนัดมาพบเพื่อประเมินบาดแผลในอีก 1สัปดาห์

5. ท่านจำเป็นต้องเข้าร่วมโครงการนี้หรือไม่

ไม่จำเป็น ขึ้นอยู่กับตัวท่านเอง และแม้ว่าท่านไม่สะดวกที่จะเข้าร่วมโครงการวิจัย ก็จะไม่มีผลกระทบต่อการรักษาอาการเจ็บป่วยของท่านแต่อย่างใด

การรักษาความลับของท่าน

ผู้วิจัยจะเก็บข้อมูลเฉพาะเกี่ยวกับตัวท่านไว้เป็นความลับ และจะเปิดเผยต่อหน่วยงานหรือสาธารณชนเฉพาะเป็นภาพรวมสรุปผลการวิจัยด้วยเหตุผลทางวิชาการ โดยไม่มีการระบุชื่อของท่าน

6. เจ้าหน้าที่หรือแพทย์ผู้ที่ท่านสามารถติดต่อได้

นายแพทย์ศุภกานต์ เตชะพงศธร ภาควิชาศัลยศาสตร์ วิทยาลัยแพทยศาสตร์กรุงเทพมหานครและวชิรพยาบาล โทรศัพท์ 0-2244-3282, 08-6811-4122

APPENDICES B

หนังสือให้ความยินยอมเข้าร่วมในโครงการวิจัย

ทำที่……..……..……

วันที่……..……

ข้าพเจ้า……. อายุ……..ปี

อยู่บ้านเลขที่…….ถนน…….....หมู่ที่…….

แ ข ว ง /ต ำ บ ล ……เ ข ต /อ ำ เ ภ อ ……

จังหวัด…….

ขอทำหนังสือนี้ให้ไว้ต่อหัวหน้าโครงการวิจัยเพื่อเป็นหลักฐานแสดงว่า

ข้อ 1 ข้าพเจ้าได้รับทราบโครงการวิจัยของ นพ.ศุภกานต์ เตชะพงศธร เรื่อง การศึกษาเปรียบเทียบการปิดแผลผ่าตัดด้วยออกทิลไซยาโนอคิลเลทกับการเย็บแผลด้วยไหมละลายแบบซับคิวทิคูล่า และวิเคราะห์ความคุ้มค่าทางเศรษฐศาสตร์ของต้นทุนและประสิทธิภาพ

ข้อ 2 ข้าพเจ้ายินยอมเข้าร่วมโครงการวิจัยนี้ด้วยความสมัครใจ โดยมิได้มีการบังคับ ขู่เข็ญหลอกลวงแต่ประการใด และพร้อมจะให้ความร่วมมือในการวิจัย

ข้อ 3 ข้าพเจ้าได้รับการอธิบายจากผู้วิจัยเกี่ยวกับวัตถุประสงค์ของการวิจัย วิธีการวิจัย ประสิทธิภาพความปลอดภัย อาการหรืออันตรายที่อาจเกิดขึ้น รวมทั้งประโยชน์ที่จะได้รับจากการวิจัยโดยละเอียดแล้วจากเอกสารการวิจัยที่แนบท้ายหนังสือให้ความยินยอมนี้

ข้อ 4 ข้าพเจ้าได้รับการรับรองจากผู้วิจัยว่า จะเก็บข้อมูลส่วนตัวของข้าพเจ้าเป็นความลับ จะเปิดเผยเฉพาะผลสรุปการวิจัยเท่านั้น

ข้อ 5 ข้าพเจ้าได้รับทราบจากผู้วิจัยแล้วว่าหากมีอันตรายใดๆ ในระหว่างการวิจัยหรือภายหลังการวิจัยอันพิสูจน์ได้จากผู้เชี่ยวชาญของสถาบันที่ควบคุมวิชาชีพนั้นๆ ได้ว่าเกิดขึ้นจากการวิจัยดังกล่าว ข้าพเจ้าจะได้รับการดูแลและค่าใช้จ่ายในการรักษาพยาบาลจากผู้วิจัยและ/หรือผู้สนับสนุนการวิจัย และจะได้รับค่าชดเชยรายได้ที่สูญเสียไปในระหว่างการรักษาพยาบาลดังกล่าวตามมาตรฐานค่าแรงขั้นต่ำตามกฎหมาย ตลอดจนมีสิทธิได้รับค่าทดแทนความพิการที่อาจเกิดขึ้นจากการวิจัยตามมาตรฐานค่าแรงขั้นต่ำตามกฎหมายและในกรณีที่ข้าพเจ้าได้รับอันตรายจากการวิจัยถึงแก่ความตาย ทายาทของข้าพเจ้ามีสิทธิได้รับค่าชดเชยและค่าทดแทนดังกล่าวจากผู้วิจัยและ/หรือผู้สนับสนุนการวิจัยแทนตัวข้าพเจ้า

ข้อ 6 ข้าพเจ้าได้รับทราบแล้วว่า ข้าพเจ้ามีสิทธิจะบอกเลิกการร่วมโครงการวิจัยนี้เมื่อใดก็ได้ และการบอกเลิกการร่วมโครงการวิจัยจะไม่มีผลกระทบต่อการได้รับบรรดาค่าใช้จ่าย ค่าชดเชย และค่าทดแทนตามข้อ 5 ทุกประการ

ข้อ 7 หัวหน้าผู้วิจัยได้อธิบายเกี่ยวกับรายละเอียดต่างๆของโครงการ ตลอดจนประโยชน์ของการวิจัย รวมทั้งความเสี่ยงและอันตรายต่างๆ ที่อาจจะเกิดขึ้นในการเข้าโครงการนี้ให้ข้าพเจ้าได้ทราบ และตกลงรับผิดชอบตามคำรับรองในข้อ 5 ทุกประการ

ข้าพเจ้าได้อ่านและเข้าใจข้อความตามหนังสือนี้โดยตลอดแล้ว เห็นว่าถูกต้องตามเจตนาของข้าพเจ้า จึงได้ลงลายมือชื่อไว้เป็นสำคัญ พร้อมกับหัวหน้าผู้วิจัยและต่อหน้าพยาน

ลงชื่อ……ผู้ยินยอม
(……...)

ลงชื่อ……หัวหน้าผู้วิจัย
(……...)

ลงชื่อ……พยาน
(……...)

ลงชื่อ……พยาน
(……...)

หมายเหตุ 1) กรณีผู้ยินยอมตนให้ทำวิจัย ไม่สามารถอ่านหนังสือได้ ให้ผู้วิจัยอ่านข้อความในหนังสือให้ความยินยอมนี้ ให้แก่ผู้ยินยอมให้ทำวิจัยฟังจนเข้าใจดีแล้ว และให้ผู้ยินยอมตนให้ทำวิจัยลงนาม หรือพิมพ์ลายนิ้วหัวแม่มือรับทราบในการให้ความยินยอมดังกล่าวด้วย

2) ในกรณีผู้ให้ความยินยอมมีอายุไม่ครบ 20 ปีบริบูรณ์ จะต้องมีผู้ปกครองตามกฎหมายเป็นผู้ให้ความยินยอมด้วย

APPENDICES C

Case record form

		Coding
ID	……	❑❑❑
Age (yr)	……	❑❑
Sex	❑ 1. Male ❑ 2. Female	❑
Diagnosis **ICD**	…… ……	 ❑❑❑❑
Operation	……	
ICD	……	❑❑❑❑❑
Date (ddmmyy)	……	❑❑❑❑❑❑
Length of wound (cm)	……	❑.❑❑
Site of wound	❑ 1. Face ❑ 2. Neck ❑ 3. Chest wall ❑ 4. Abdominal wall ❑ 5. Back ❑ 6. Extremities	❑❑
Underlying disease	❑ 1. No ❑ 2. Yes, detail……..	❑
Medication	❑ 1. No ❑ 2. Yes, detail……..	❑

Time (second)		
● Time of start procedure (A)	……	
● Time of start wound closure (B)	……	
● Time of finished procedure (C)	……	
● Total time of operation (B-A)	……	❑❑
● Total time of wound closure (C-B)	……	❑❑

Cost record

Direct medical cost			Coding
❑ Procedure charge		2,500 Baht	❑❑❑❑
❑ Suture material			
○ vicryl 4-0	Number ……	Cost/unit 163 Baht	❑❑❑❑
❑ Octylcyanoacrylate	Number ……	Cost/unit 400 Baht	❑❑❑❑
❑ Dressing material			
○ Tegaderm	Number ……	Cost/unit 10 Baht	❑❑❑❑
○ Steri-strip	Number ……	Cost/unit 22.50 Baht	❑❑❑❑
❑ Wound dressing fee	Number ……	Cost/unit ……	❑❑❑❑
❑ Medication			
○ Dicloxacillin	Number ……	Cost/unit 3.25 Baht	❑❑❑❑
○ Paracetamol	Number ……	Cost/unit 0.50 Baht	❑❑❑❑
○ other			

Wound Closure Evaluation Visual Analog Scale

No. of study population……..	Evaluation date .....

1. **Wound approximation**	
Good wound approximation along the wound	10
Wound dehiscence	0

2. Wound infection	
No presence of wound infection	10
Presence of severe wound infection	0

3. Wound collection	
No wound collection	10
Presence of serum oozing	0

4. **Wound border**	
Good wound regularity	10
Worst outcome of wound regularity	0

5. **Wound inflammation or tissue reaction**	
No presence of wound inflammation	10
Presence of severe wound inflammation	0

6. **Wound epithelization**	
Good wound epithelization	10
No wound epithelization	0

Remark: **Score of question 1 or 2 = 0 ⇨ Score in question 3-6 = 0**

VITAE

NAME		Suphakarn Techapongsatorn
PRESENT TITLE AND AFFILIATION		Medical doctor, level 8 General Surgery II, Department of Surgery, Bangkok Metropolitan Administration Medical College and Vajira hospital.
BIRTH DATE AND PLACE		October 18, 1972 Thailand
CITIZENSHIP		Thai
EDUCATION:	**1990-1996**	M.D. Khon Kaen University
	1996-1999	Resident in General Surgery, Department of Surgery, Faculty of Medicine, Khon Kaen University.
	1997	Diplomate, Clinical Sciences, Khon Kaen University.
	1999	Diplomate, Thai Board of Surgery, Medical Council of Thailand
	2001	Diplomate, Thai Board of Family Medicine, Medical Council of Thailand
	2006	Certificate in Advanced Laparoscopic Surgery, World Association of Laparoscopic Surgeons, New Delhi, India
	2006	Certificate of student and instructor of Advanced Trauma Life Support® (ATLS®)
	2007	Certificate in Advanced Trauma Operative Management (ATOM™), University of Connecticut, USA
	2008	Certificate of Tutor in Basic Surgical Skills, Royal College Surgeons of Edinburgh.