THE EFFECTIVENESS OF POLYDIOXANONE (PDO) THREAD FOR FACE LIFTING: A PILOT STUDY

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THESIS COMMITTEE

.....CHAIRPERSON
(Prof. Dr. Thamthiwat Nararatwanchai)

.....ADVISOR
(Lecturer Paisal Rummaneethorn)

.....EXTERNAL EXAMINER
(Assoc. Prof. Dr. Wongdyan Pandii)

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Kulyakrit Yurugs

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Author	Kulyakrit Yurugs
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ABSTRACT

The most effective way to treat sagging face is facelift operation but there are long downtime and a lot of risks then a lot of minimal invasive procedures were develop, thread lifting is the one of them. Nowadays polydioxanone thread was used to insert into skin in small and short piece for face lifting but this method lack of evidence base study to confirm the result. In order to determine the effectiveness and size effect of polydioxanone thread.15 Thai patients with facial laxity age between 35–55 years old were enrolled then treated with polydioxanone thread in cross technique (reticular pattern) 80 threads whole face. Patients were followed up for 4, 12 and 24 weeks after the treatment. Clinical outcomes were evaluated by compare a photo, which took by VISIA, between before, and after treatment by 3 independent doctors, skin elasticity was evaluated by Cutometer MPA580 and patient satisfaction was evaluated by questionnaire after treatment. The result found that at 4 weeks 6 patients were improvement and increase to 11 patients at 12 weeks and still the same result at 24 weeks. The skin elasticity decreases with time but returns to normal at 24 weeks. The most common side effect was mild swelling and bruising. Two patients had a few nodules on their face that completely resolve at 12 weeks, there was no serious complication. We can conclude that the polydioxanone thread lift may be one

of the alternative choices for minimally-invasive face lifting. It is easy to perform under topical anesthesia. It has minimal downtime and low risk of complication. This method is effective for improving jawline, marionette line and midface area but not for skin elasticity. This method is not appropriate for patient with too much sagging and need to combine with other modality to improve aesthetic outcome.

Keywords: Polydioxanone (PDO) thread/Face lifting/Thread lifting

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CHAPTER 1

INTRODUCTION

1.1 Background

In normal life, when we were old the body had deteriorated by time. Now, many people pay intention with their face which can see that many aesthetic clinic was opened to service for remain the younger looking. The characteristic of aging face has composite of skin discoloration, wrinkle, fold and the skin laxity which the important sign that shown an aging of skin.

There are many cause of skin laxity such as bone change that occur with age by thinning and small bone, some part of the fat component loss and loss of collagen and elastin at skin that decrease the skin elasticity. This problem has increase with age.

There are many methods to treat the sagging face. In the past, the most effective way to treat the laxity skin was face lift operation but this method has some limited such as patient with contraindication to surgery, allergy to anesthetic drug and long downtime. Afterward, in 1990 Sulamanidze was used a non-absorbable suture material with barbs along their length called APTOS thread to lifting the sagging face, this method was minimal invasive, easy and effective but the result depend on skill of doctor. This disadvantage of this method is a non-absorbable property of thread that cause of complication such as thread migration.

In 2005 another thread lift were developed by using a bio-absorbable cone instead of barbs but thread still use a non-absorbable (polypropylyne) that used worldwide in the name “Silhouette lift” but disadvantage of this thread likes a APTOS because of non-absorbable property.

Now, polydioxanone thread was used to lift up the laxity skin by insert short thread (about 4-6 cms) into deep dermis to subcuticular layer to inducing collagen

production. This method was very popular in Thailand and was done by many clinics and hospitals but this method lack of evidence base study to evaluate the effectiveness and determine side effect.

For the safety of this thread, there are many studies. In 1984 Chu and Williams were study about infection rate in monofilament and poly filament suture material, they conclude that the monofilament suture has lower rate of infection than polyfilament suture. In 1984 Henke study compare the property of absorbable material between PDO, polyglactin 910 (Vicryl, Ethicon GmbH, Norderstedt, Germany), catgut plain and polyester fibers, he found that polydioxanone thread has less tissue reaction and more tensile strength. Furthermore in 2007 Richard J. Huggins was histologic study in collagen change around the thread at SMAS layer in patient who done a second face lift operation, he found that the collagen and elastin increase around the thread especially in interstices area

This research uses Polydioxanone thread from MIRACU (Chungtee, Thailand.) which was permitted by Thai FDA to distributed. The threads will insert into the skin to determine lifting effect and evaluate the effectiveness before and after the procedure. The expectation of this study for find a new knowledge for face lifting, determine the side effect and for more research in the future.

1.2 Objective

To evaluates the effectiveness of polydioxanone thread for lifting the facial laxity and to determine the side effect of this procedure.

1.3 Research Question

Does polydioxanone thread have effectiveness for lift up the facial laxity?

1.4 Hypothesis

The polydioxanonethread has effectiveness for face lifting.

1.5 Conceptual Framework

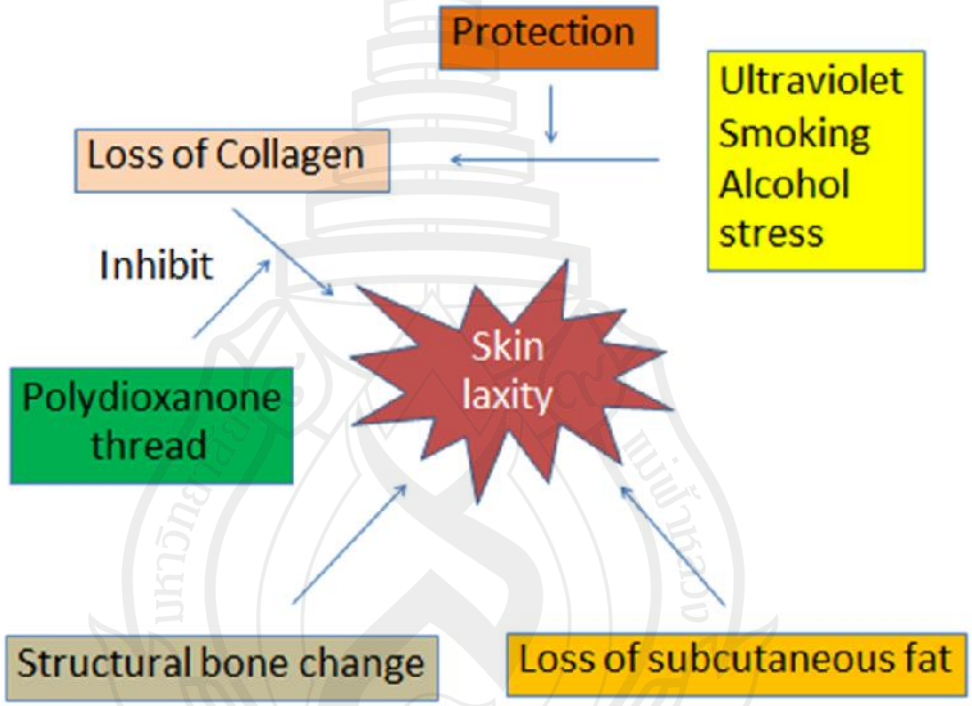


Figure 1.1 Conceptual Frame Work of this Thesis

From the figure 1.1: Cause of facial laxity have three factor, first is collagen depletion in the dermis, second is structural bone change and the third is loss of subcutaneous fat, which the last two factor occur only in extremely age. The causes of collagen depletion are ultraviolet, smoking, alcohol and stress that can prevented by sunscreen and controlled behavior. This research will inserts the polydioxanone thread for induce the collagen production to lift the laxity skin.

1.6 The Scope of Research

15 Thai patients with facial laxity age between 35–55 years old were enrolled then treated with polydioxanone thread in cross technique (reticular pattern) 80 threads whole face. Patients were followed up for 4, 12 and 24 weeks after the treatment. Clinical outcomes were evaluated by compare a photo, which took by VISIA, between before, and after treatment by 3 independent doctors, skin elasticity was evaluated by Cutometer MPA580 and patient satisfaction was evaluated by questionnaire after treatment.

CHAPTER 2

LITERATURE REVIEW

This research, researcher was studied some documents and relate research. The knowledge will present as follow.

1. Anatomy of the face
2. Skin aging and cause of aging skin
3. Wound healing
4. Face lifting procedure
5. Property of the Polydioxanone (PDO) thread

2.1 Anatomy of the Face

Before do something with face. We must try to understand the facial anatomy for avoid some serious complication from procedure. The anatomy of face was concluding as follow.

2.1.1 Skin

2.1.2 **The Subcutaneous Fat** (Rohrich & Pessa, 2007)

2.1.2.1 At the cheek area, subcutaneous was divided into a pocket which not link with the others (figure 2.1):

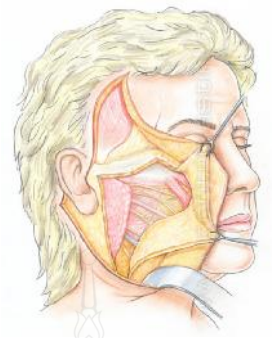
1. Medial cheek fat: is locates next to nasolabial fold.
2. Middle cheek fat: is locates above and front of the parotid gland, between medial part and temporal part.
3. Lateral temporal cheek fat: is locates on parotid gland and links with temporal fat and neck fat.

From Rohrich, R. J. & Pessa, J. E. (2007). The fat compartment of the face: Anatomy and clinical implications for cosmetic surgery. **Plastic and Reconstructive Surgery, 199**(7), 2219-2227.

Figure 2.1 Part of the Fat at the Face

2.1.3 SMAS (Superficial Musculo-aponeurotic System) Layer

SMAS layer (Mitz & Pyronie, 1976) divides the subcutaneous fat form fibrous band of parotid gland, masseter muscle and nerve branch of Facial nerve. It continue form fibrous band name “Galea” at scalp, temporo-parotid fascia of temporalis muscle and superficial cervical fascia of the neck. To success the face lifting procedure, this layer need to excises and sutures.



From Kamer, F. M. & Frankel, A. S. (1998). SMAS rhytidectomy versus deep plane rhytidectomy: An objective comparison. **Plast Reconstr Surg**, **102**(3), 878-881.

Figure 2.2 SMAS Layer

From the figure 2.2, The SMAS layer covers the muscle, nerve and important vessels. The procedure which done above this layer will be safe and less complication.

2.1.4 Muscle Layer

2.1.4.1 Muscle of the forehead, eye and eyebrow

2.1.4.2 Frontalismuscle

Frontalismuscle originates from frontal bone run across the forehead which lies on the galeaaponeurotica layer. Frontalisis the only one muscle that has the function for lift the eyebrows and cause of wrinkle at the forehead.

2.1.4.3 Orbicularis oculi muscle

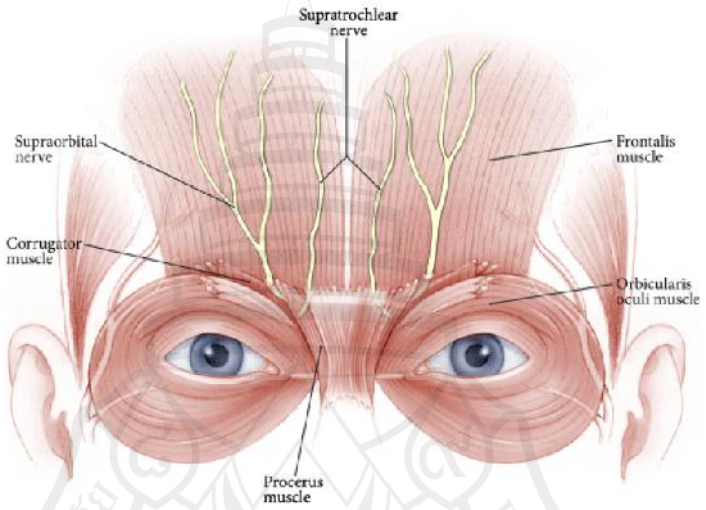
This muscle originates from frontal bone and have characterize in a circular thin layer around the eyes and some part of upper eyelids. Some part of them insert to temporal bone. The function of this muscle is help to close the eyes and pull down the eyelids.

2.1.4.4 Corrugator supercilii muscle

This muscle lies beneath to frontalis muscle. Function of this muscle is pull eye brow medially and responsible for wrinkle at the glabellar area.

2.1.4.5 Procerusmuscle

Procerus muscle lies on bridge of the nose, between both eyebrows. This muscle originates continue from Frontalis musclerun into lower part of the nasal bone and upper part of nasal cartilage. This muscle responsible for pulls eyebrows down and lift the nose up.



From Courtney, S., Mcguire, B. S., & Gladstone, H. B. (2009). Novel pretrichial browlift technique and review of methods and complications. **Dermatol Surg 35**(9), 1390-1405.

Figure 2.3 Group of Muscle at Upper Face Area

2.1.4.6 Muscle of facial expression

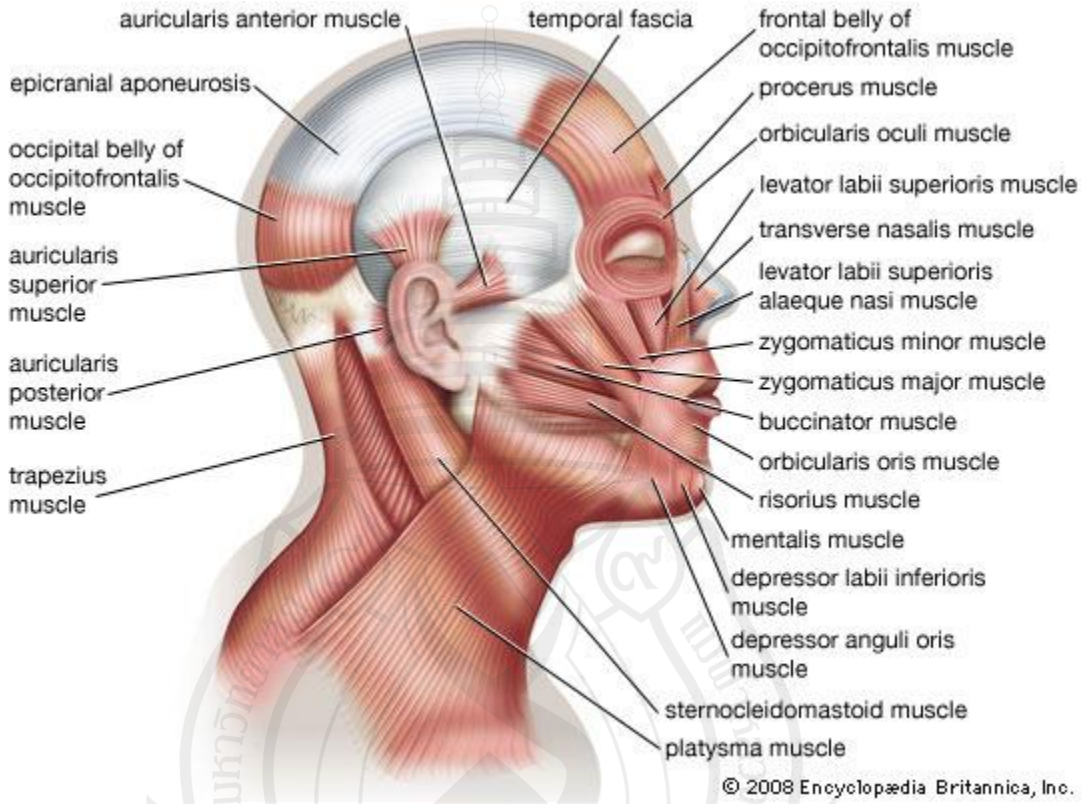
2.1.4.7 These groups of muscle are responsible for express the facial emotion. They have innervated by Facial nerve (CN VII).

2.1.4.8 Muscle of facial expression locates on the sheeks area as shown in figure 5, include:

1. Zygomaticus major muscle: Responsible for pull mouth angle upward and laterally.

2. Zygomaticus minor muscle: Responsible for pull mouth angle, help for smiling.

3. Risoriusmuscle: Responsible for pull mouth angle laterally.



From Encyclopedia Britannica. (2008). **Muscle system, human: Muscles of facial expression**. Retrieved June 26, 2012, from http://www.britannica.com/EBchecked/topic-art/1346374/119201/Muscle-of-facial-expression

Figure 2.4 Muscle of Facial Expression

2.1.4.9 Muscle of mastication

1. During mastication, four muscles of mastication (or musculimasticatorii) are responsible for adduction and lateral motion of the jaw. Other muscles, usually

associated with the hyoid such as the sternohyomastoid, are responsible for opening the jaw.

2. There are 4 muscle include :

1) The masseter

2) The temporalis (the sphenomandibularis is considered a part of the temporalis by some sources, and a distinct muscle by others)

3) The medial pterygoid

4) The lateral pterygoid

2.1.4.10 The muscles of mastication are all innervated by the trigeminal nerve (or CN V). More specifically, they are innervated by the mandibular branch, or V

2.1.5 Facial Nerve (CN VII)

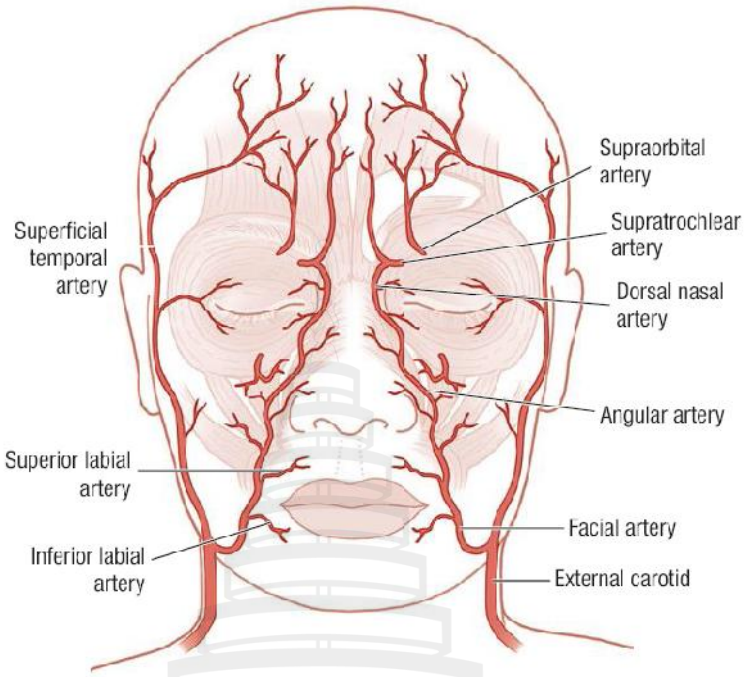
2.1.5.1 Cranial nerve7 has a function for controls the facial expression and taste form 2/3 anterior of tongue.

2.1.5.2 At the sheeks area, Facial nerve run through the parotid gland and divides into 5 branches as follow

1. Temporal(frontal) branch
2. Zygomatic branch
3. Buccal branch
4. Marginal mandibular branch
5. Cervical branch

2.1.6 Vessels

Blood supply of the face is a branch of the external carotid artery. The facial artery arises in the carotid triangle from the external carotid artery and, sheltered by the ramus of the mandible, passes beneath the digastric and stylohyoid muscles, over which it arches to enter a groove on the posterior surface of the submandibular gland then curves upward over the body of the mandible at the antero-inferior angle of the masseter, passes forward and upward across the cheek to the angle of the mouth, then ascends along the side of the nose, and ends at the medial commissure of the eye as shown in figure 2.5.



From Sumira, Z. A. (2008). Dermatologic surgery. In P. Brent (Ed.), **Introduction to anatomy and approach** (chapter 243, pp. 2289-2301). New york: McGraw-Hill.

Figure 2.5 Vascular Supply of the Face

2.2 Skin Aging and Cause of Aging Skin

Aging skin is a condition that decreases the function of the organs including skin. The major cause of it is an environment such as ultraviolet radiation. The cause can divide to:

2.2.1 Intrinsic Aging

Cause of skin aging is DNA damages which done by free radicals. The mechanism is NF-KB was stimulated then cytokine IL-1, IL-6, vascular endothelial growth factor (VEGF) and tumor necrosis factor (TNF)-α, all of these will increase

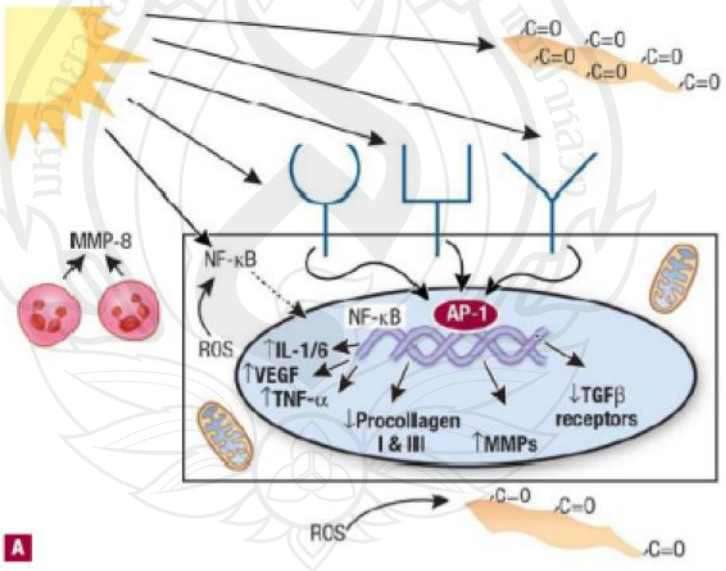
collagenase or matrix metalloproteinase (MMPs) transcription which stimulate collagen degeneration. Furthermore Procollagen I, III gene and Transforming growth factor (TGF)-β receptor were inhibited in order to decrease in collagen production.

2.2.2 Extrinsic Aging

The cause of extrinsic aging is Ultraviolet radiation which stimulates free radicals (ROS) production. Free radicals will stimulate IL-1 and TNF-αto stimulate AP-1 secretion then collagen I and collagen III production were inhibited. Moreover it will inhibits Transforming growth factor (TGF)-βin order to decrease in collagen production.

The sunlight will stimulate NF-KB secretion then collagen production will decrease and ultraviolet can direct damage to the collagen. The fragment of collagen will inhibit the collagen production in another way.

Smoking will stimulate the aging skin by decrease blood flow, inhibits production of anti-oxidant and then follow by DNA damages.



From Wulf, H. C., Sandby-Møller, J., Kobayasi, T. & Gniadecki, R. (2004). Skin aging and natural photoprotection. **Micron, 35**(3), 185-191.

Figure 2.6 Mechanism of Aging Skin by Sunlight

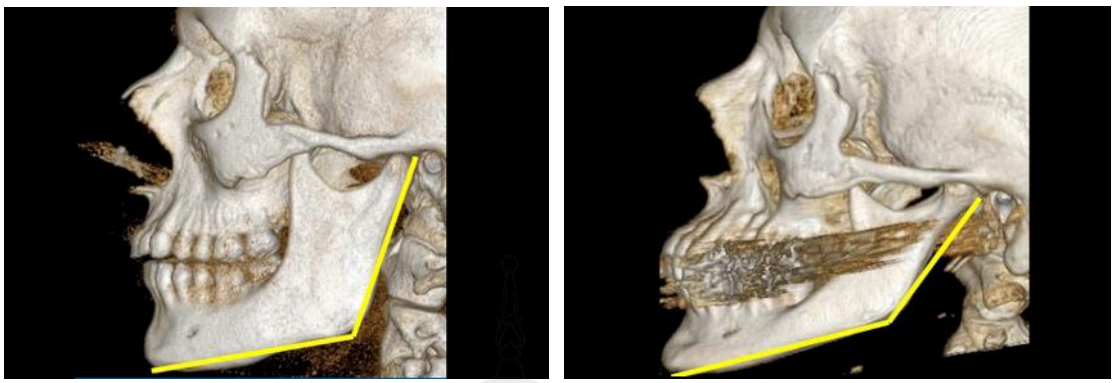
2.2.3 Pathophysiology of Aging Skin

2.2.3.1 Epidermis: Flattened dermal-epidermal junctioncause decrease in nutrient supplyand decrease in eradicate wasting product. That was seen in elderly age, when trauma it easily to scratch.

Thinning of epidermis is relate to the age that can see when the age about 30-80 years epidermis was thinning 10-50% (Ahmad et al., 2009). Furthermore keratinocyte and other cell change in size and shape such askeratinocyte. Keratinocyte will increase in size and not apoptosis by natural mechanism and finally change to cancer cell, Melanocyte and Langerhans cell are decrease in number and replication cause the healing ability of the skin decrease.

2.2.3.2 Dermis: 20% thinning and relate with age but in the area that not expose to the sunlight the process will start at age 80 (Wulf et al., 2004). Inflammatory response of keratinocyte was decrease so cytokine and inflammatory mediator secretion were decrease. Decrease in venule number and thinning of the venule layer but thickening in the wall of ateriole which relate to easily bruising in elderly age when trauma. Properties of Collagen, elastin and ground substance have changed cause in decrease of strength and elasticity of skin which collagen will decrease 1% per year (Ghadially, Brown, Sequeira-Martin, Feingold & Elias, 1995). Furthermore enzymecollagenase will degradecollagen (Elias & Ghadially, 2002; Plowden et al., 2004). Crosslink of elastin fiber was changed by calcium deposit which reduces the elasticity (MacLaughlin & Holick, 1985). For the ground substance, many enzyme are decreasing such asmucopolysaccharides, glycosaminoglycansand proteoglycans especially Hyaluronicacid. The change of skin by aging process was concluding in the table 2.1.

Moreover, in the muscle there is lipofusin accumulates cause the reducing of muscle tone and finally loss of muscle tone (Dayan, Abrahami, Buchner, Gorsky & Chimovitz, 1988). Subcutaneous fat was decrease (Donofrio, 2000), Maxilla, Mandible and frontal bone were thinning then the skin laxity is increasing in severity (Shaw et al., 2010).



From Shaw, R. B., Jr., Katzel, E. B., Koltz, P. F., Kahn, D. M., Girotto, J. A. & Langstein, H. N. (2010). Aging of the mandible and its aesthetic implications. **Plastic & Reconstructive Surgery, 125**(1), 332-342.

Figure 2.7 Structural Bone Change of the Mandible

Table 2.1 Pathophysiology of Aging Skin

Epidermis	Dermis	Appendages
Flattened dermal-epidermal junction Variable/decreased thickness Variable cell size and shape Occasional nuclear atypia Fewer melanocytes Fewer Langerhans cels	Atrophy (loss of dermal volume) Fewer fibroblasts Fewer mast cells Fewer blood vessels Shortened capillary loops Abnormal nerve endings	Depigmented hair Conversion of terminal to vellus hair Abnormal nail plates Loss of hair Fewer glands

2.3 Wound Healing

2.3.1 Wound Type

2.3.1.1 Full-thickness wound: Fully loss of epidermis, dermis and soft tissue. This type of wound heals by retraction of skin, granulation formation and reepithelization.

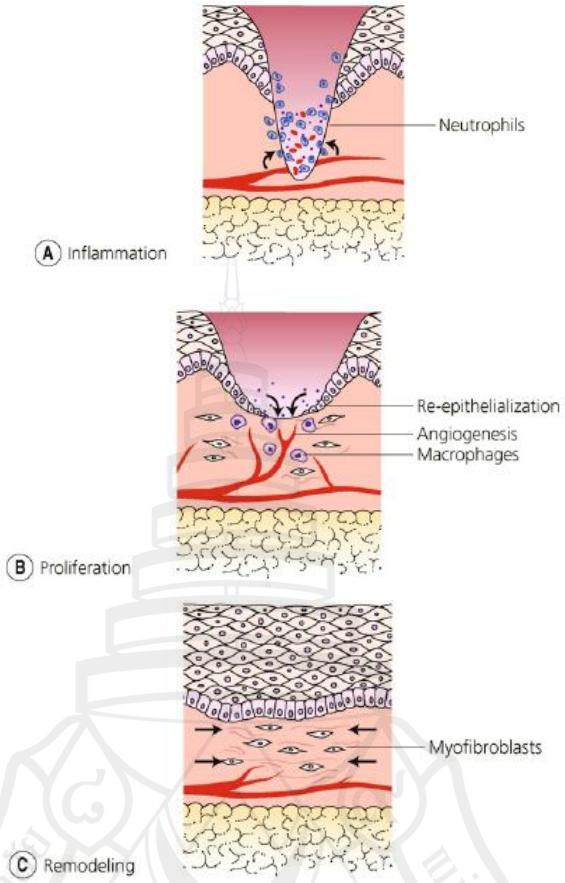
2.3.1.2 Partial-thickness wound: Total loss of epidermis but loss some part of dermis and soft tissue. This type of wound may cause by surgery or laser, heal by reepithelizationand some retraction.

2.3.2 Physiology of wound healing: can divided in 3 phase (Fonder et al., 2008)

2.3.2.1 Inflammatory phase: This phase has characterized by white blood cells aggregate into the wound which occur within 6 hours. Platelet and damaged cell secrete the factors that stimulate white blood cells and fibroblast. Dilation of vessels brings the white blood cells to destroy the germ and ruin cell easily. This phase take time about 72 hours after wound occur.

2.3.2.2 Proliferative phase: Macrophage secretesvascular endothelial growth factor (VEGF) to stimulate the healing process. Fibroblast is increasing to produce the collagen and increase blood vessel at the wound site. Keratinocyte migrates cover trauma area to seal the wound.

2.3.2.3 Remodeling phase: Increase in collagen storage and retraction of wound by fibroblast. Collagen was rearranged and myofibloblasts contract the wound to seal it. This phase take about 1 week after wound occur and at the 3 weeks wound will have strength about 20%



From Fonder, M. A., Lazarus, G. S., Cowan, D. A., Aronson-Cook, B., Kohli, A. R. & Mamelak, A. J. (2008). Treating the chronic wound: A practical approach to the care of nonhealing wounds and wound care dressings. **J Am Acad Dermatol**, **58**(2), 185-206.

Figure 2.8 Wound Healing Process

2.4 Face Lifting Procedure

2.4.1 Face Lifts Operation (Rhytidectomy)

Many different procedures of rhytidectomy exist. The differences are mostly the type of incision, the invasiveness and the area of the face that is treated. Each surgeon practices multiple different types of facelift surgery. At a consultation the procedure with the best outcome is chosen for every patient. Expectations of the patient, the age, possible recovery time and areas to improve are some of the many factors taken in consideration before choosing a technique of rhytidectomy (Marcus, 2012).

In the traditional facelift, an incision is made in front of the ear extending up into the hairline. The incision curves around the bottom of the ear and then behind it, usually ending nears the hairline on the back of the neck. After the skin incision is made, the skin is separated from the deeper tissues with a scalpel or scissors (also called undermining) over the cheeks and neck. At this point, the deeper tissues (SMAS, the fascia suspension system of the face) can be tightened with sutures, with or without removing some of the excess deeper tissues. The skin is then redraped, and the amount of excess skin to be removed is determined by the surgeon's judgment and experience. The excess skin is then removed, and the skin incisions are closed with sutures and staples.

This method is highly effective but a lot of risks such as bleeding, hematoma, nerve injury and Infection etc. furthermore this method requires a long time to recover.

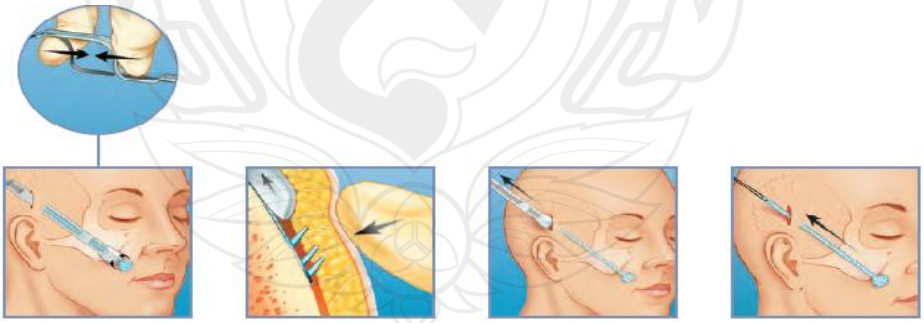
2.4.2 Endotine ST Fixation Device

Endotine ST is a bioabsorbable soft tissue fixation device (Coapt Systems Inc, Palo Alto, Calif) made ofpolylactic and polyglycolicacids which were approved by USFDA.

From Newman, J. (2006). The safety and efficacy of midface-lifting using an absorbable suspension device (Endotine ST). **Arch Facial PlastSurg, 8**(4), 245-251.

Figure 2.9 Endotine Device

This lifting method, physician need to incise the skin at temporal and sheek area to insert the devices. For brow lifting, physician will incises at forehead instead. This method needs some endoscope to locate the layer and area to fix device which device was fixed in the periosteam layer as show in figure 2.10.



From Griffin, R. (2012). **Endotine devices**. Retrieve June 23, 2012, from http://ks.microaire.com/endotine-multipoint-fixation-devices

Figure 2.10 Show How the Endotine Work

James Newman was research and collected the data from female patient whom done the Endotine face lifting from 2003 to 2004 about 10 cases, found thatthe Endotine was safe and effective.

2.4.3 Laser Device

Many lasers were used to stimulate the collagen production in dermis which cans divide by the mechanism as follow. (cosmetic dermatology: skin tightening with radiofrequency and other devices)

2.4.3.1 Ablative laser

The laser is used to generate the heat and damage to the epidermis and upper dermis then collagen was stimulated by inflammation and healing process. Most of this laser will good absorb by water such as fractional co2 laser and fractional Er:YAG.

2.4.3.2 Non-ablative laser

The laser is used to stimulate collagen production directly by heat. This group of laser 1,064 nm ND:YAG, Gental YAG.

2.4.4 Electrical Stimulation (PanG^{tm} lift)

This device combines the electronic muscle stimulation and low frequency ultrasound to stimulate the collagen production.

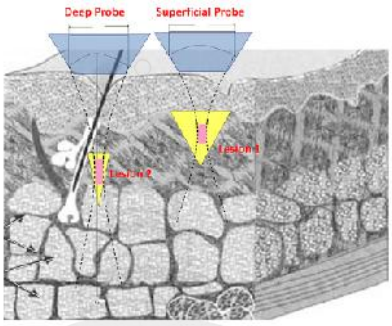
2.4.5 Non-ablative Radiofrequency

Radio frequency devices utilize the principle of volumetric heating, whereby resistance to the flow of an electrical current generates heat in the targeted tissue. Tissue impedance varies based on body site, which directly affects the amount of energy delivered. The resulting heat modifies collagen in the tissue, creating a contracted and denatured conformation that leads to subsequent tightening of the skin (Green, Dover & Kaminer, 2011).

2.4.6 Intensed Focus Ultrasound (IFUS)

The mechanism of this method is similar to Radiofrequency device but change the radiofrequency to ultrasound instead. The sound go directly to SMAS layer and

generate heat then the collagen will contraction immediately and follow by collagen production.



From Alam, M., White, L. E., Martin, N., Witherspoon, J., Yoo, S. & West, D. P. (2010). Ultrasound tightening of facial and neck skin: A rater-blinded prospective cohort study. **J Am Acad Dermatol, 62**(2), 262-269.

Figure 2.11 The Mechanism of Ultrasound Face Lifting

In 2010 Murad Alam was researched and collected the data for the patient which done an Intense Focus Ultrasound. He concludes that this method is safe and effective for brow lifting. Furthermore this machine was approved by US FDA for brow lifting.

2.4.7 Broad Band Infared

This technique uses an infared ray to stimulate the collagen production directly but the result is not clear and need to combine with other devices.

2.4.8 Thread lifting

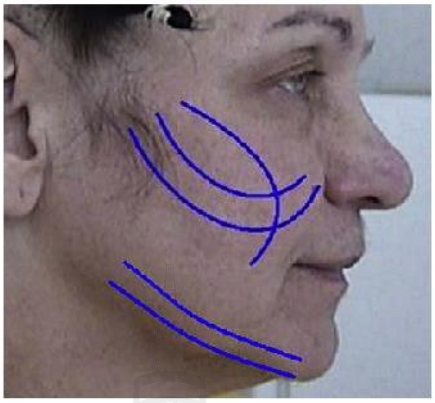
Due to a lot of risks and long downtime with face lift operation, thread lifting was developed to treat the skin laxity instead. Advantages of this method are short downtime, easy doing and minimal risks. The principal of thread lift is to hooks up the ptosis skin at SMAS layer to collect the laxity.

In 2002 Sulamanidze, M. A., Fournier, Paikdze & Sulamanidze, G. M were fisrt introduce of thread lifting method by using and non-absorbable material (Polyprolylene) in a name “APTOS” (anti-ptosis) thread. This thread has many barbs along their length to suspense the ptosis soft tissue. In the USA there are many trade names that approved in 2004 such as “Feather lift” and “Contour thread”.

From Sulamanidze, M. A., Fournier, P. F., Paikdze, T. G. & Sulamanidze, G. M. (2002). Removal of facial soft tissue ptosis with special threads. **DermatolSurg**, **28**(5), 367-371.

Figure 2.12 APTOS Thread and Needle Guide

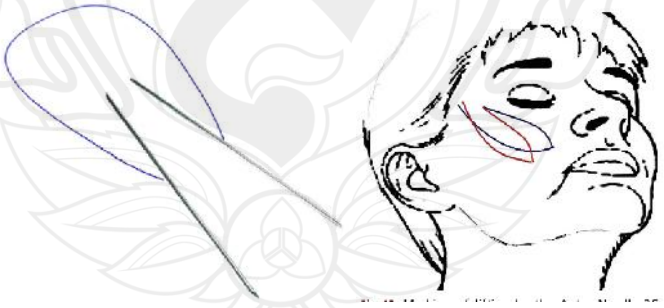
The APTOS thread lift procedure could be done by local anesthesia with 1% Lidocaine. Needle guide was inserted to lead the APTOS threads into the soft tissue layer or SMAS if possible. When thread was firmly suspense the soft tissue and was placed in the right plane, needle guide will be remove and the remain portion of the thread was cut off.



From Sulamanidze, M. A., Fournier, P. F., Paikdze, T. G. & Sulamanidze, G. M. (2002). Removal of facial soft tissue ptosis with special threads. **DermatolSurg**, **28**(5), 367-371.

Figure 2.13 Line of APTOS Thread Insertion

Afterward, APTOS thread was developed to 2 needles with one thread for curve insertion of the thread that more improvement of midface lifting.



From Sulamanidze, M. A., Fournier, P. F., Paikdze, T. G. & Sulamanidze, G. M. (2002). Removal of facial soft tissue ptosis with special threads. **DermatolSurg**, **28**(5), 367-371.

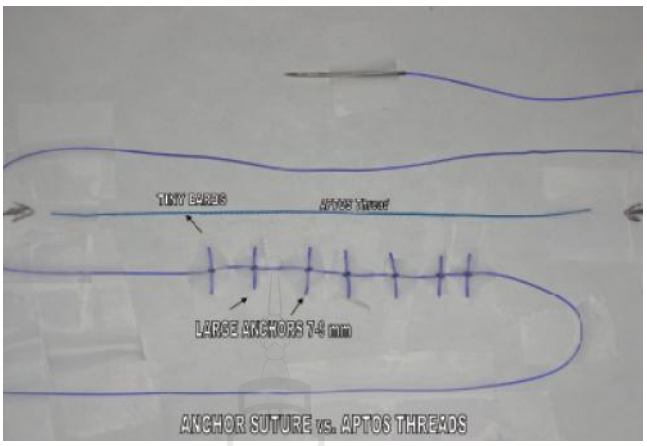
Figure 2.14 APTOS Thread with Two Needle Guid

In 2004 thread was developed into a strand shape (APTOS sping) to insert in the area that frequent movement such as marionette line.

From Sulamanidze, M. A., Fournier, P. F., Paikdze, T. G. & Sulamanidze, G. M. (2002). Removal of facial soft tissue ptosis with special threads. **DermatolSurg**, **28**(5), 367-371.

Figure 2.15 APTOS Spring

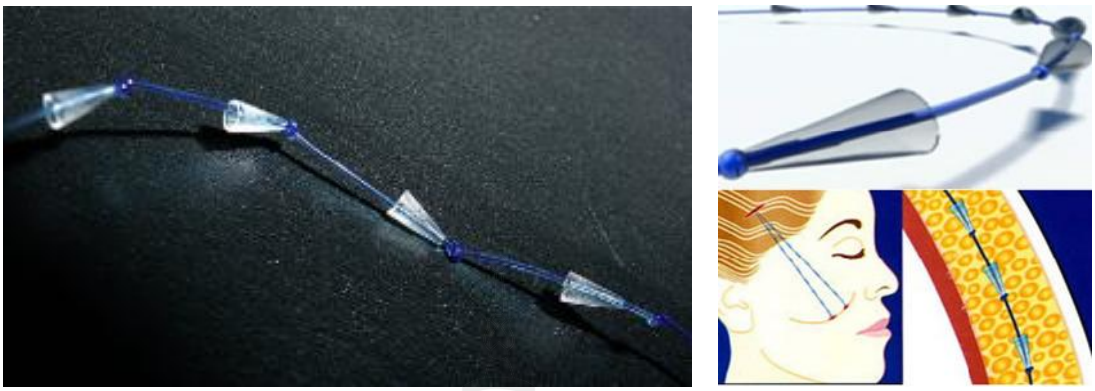
In 2006, Eremia & Mark were use an absorbable material (Maxon and PDO) size 2-0 instead of polypropylene but this procedure use an anchor knotted that made by 0 thicknesses from same material to hook up the soft tissue. This procedure was use a needle guide similar as the APTOS and need to fixed the thread in the temporal fascia which the result was effective.



From Eremia, S. & Mark, A.W. (2006). Novel face-lift suspension suture and inserting instrument: Use of large anchors knotted into a suture with attached needle and inserting device allowing for single entry point placement of suspension suture. Preliminary report of 20 cases with 6- to 12-month follow-up. **DermatolSurg**, **32**(3), 335-345.

Figure 2.16 Compare Between Absorbable Anchors Knotted Thread with APTOS Thread

In the same year, US FDA was approved the thread name “Silhouette lift”. This thread uses bio-absorbable cones, which made of polyglycolic acid; instead of barbs that were used in APTOS but the thread still uses a non-absorbable material then side effect are the same as APTOS.



From Collins, M. (2010b). **Silhouette lift**. Retrieve June 23, 2012, from http://www.facelift-pedia.com/facelift-blog/silhouette-lift/silhoulette-lift-3/

Figure 2.17 Silhouette Thread

Another thread was use is a gold thread. This thread is very popular in Europian country but not sure in origin.This thread made of 99.99% pure gold, 25-50 cms long. This thread was inserted into the skin in reticular pattern. The mechanism is unknown but it believed that this method increase the collagen production by inflammatory process, finally the skin was lifting by increase collagen. Disadvantage of this method are allergic reaction to the gold that induce the skin fibrosis, Chronic pain by inflammatory process and due to gold is a heavy metal that mean patient can not done a radiologic examination after gold thread insertion.

From Collins, M. (2010a). **Gold thread lift**. Retrieve June 23, 2012, from http://www.facelift-pedia.com/facelift-blog/gold thread-lift

Figure 2.18 Gold Thread and Lines of Insertion

Now, polydioxanone thread is used to insert into the skin to stimulate collagen production by inflammation and healing process. From the study of Huggins, Freeman, Kerr & Mendelson (2007), he done a skin biopsy at in patient whom done a second face lift operation, found that there are many collagen and elastin fiber produce around the thread especially at interstice area as shown in figure 2.19. From this study we can assume that the thread can induce the collagen and elastin production. Advantage of this method that this thread is an absorbable suture that means no foreign substance when the threads completely dissolve.

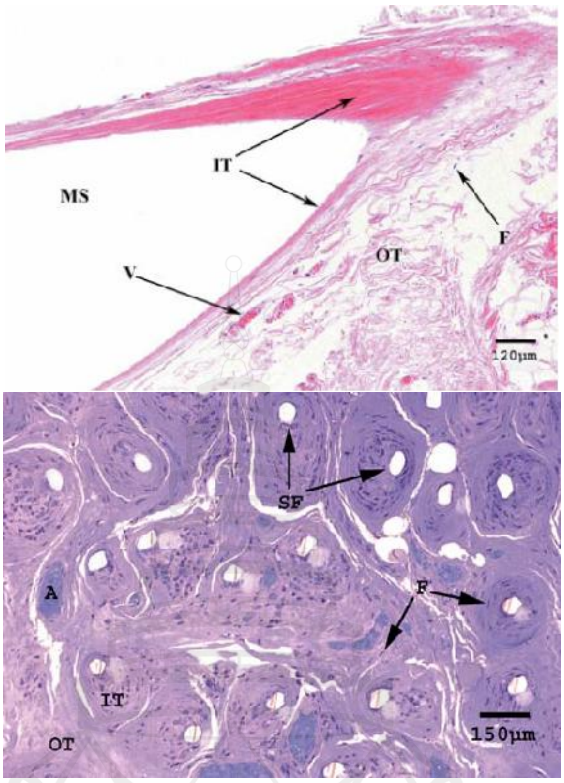
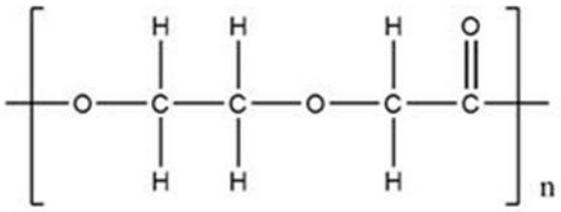


Figure 2.19 Histologic finding of Monofilament suture from temporal region (6 years in-situ, H&E stain, oblique section. This staining reveals collagen as lightpink with fibroblasts and other connective tissue cells as purple. Theinner tunica (IT) of collagen is thin and dense, seen encapsulating thesuture (MS). Fibroblasts (F) and vessels (V) are distributed throughoutthe outer tunica (OT) of loose.)

2.5 Property of the Polydioxanone (PDO) Thread

Polydioxanone thread is a monofilament absorbable suture material which made of p-dioxanone by ring-opening polymerization with catalyst by heat.



Polydioxanone

Figure 2.20 Chemical Structure of Polydioxanone

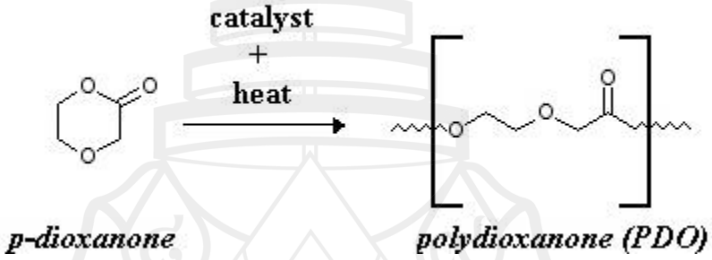


Figure 2.21 Ring-opening Polymerization Reaction

Polydioxanone is used for biomedical applications, particularly in the preparation of surgical sutures. Other biomedical applications include orthopedics, plastic surgery, drug delivery, cardiovascular applications, and tissue engineering.

It is degraded by hydrolysis, and the end products are mainly excreted in urine, the remainder being eliminated by digestive or exhaled as CO2. The biomaterial is completely reabsorbed in 6 months. Although polydioxanone is hydrolyzed much more slowly than the other synthetic absorbable sutures foreign body reactions to this material are judged to be minimal (Moy, Lee & Zalka, 1991). Polydioxanoneretains 74 percent of its original strength at two weeks, 58 percent at four weeks and 41 percent at six weeks.

For the safety of this suture, there are many research and conclude that this thread are low rate of infection (Chu & Williams, 1984), less tissue reaction when compare with others thread (Melton & Hanke, 1996; Parara, Manios, de Bree, Tosca & Tsiftsis, 2011), less tissue fibrosis (Laufer, Merino, Trietsch & DeCherney, 1984), less scar

(Chantarasak & Milner, 1989) and excellent aesthetic outcome (Edwards & Elson, 1995). The property of each thread compare with polydioxanone was shown in table 2.2

Table 2.2 Property of Each Suture Material

	Suture material			
	Type	**Memory**	**Tissue reactivity**	**Tensile strength Half-life**
Non absorbable				
Cotton	Twisted	Low	Very high	-
Nylon (Ethilon, Dermalon)	Monofilament	High	Low	-
Nylon	Braided	Low	Low	-
Polybutester (Novafil)	Monofilament	High	Low	-
Polyester, uncoated (Mersilene)	Braided	Low	Low	-
Polyester, coated (Ethibond)	Braided	Low	Low	-
Polypropylene (Prolene, Surgilene)	Monofilament	Very high	Very low	-
Silk	Braided/twist	Very Low	High	-
Stainless steel	Monofilament/ braided/twist	Very high	Very Low	-
Absorbable				
Catgut, fast absorbing, mild Chromic	Twisted	Very high	High	2 days
Catgut	Twisted	Very high	High	4 days
Catgut, Chromic	Twisted	Very high	High	1 wk
Polygalactin 910 (Vicryl)	Braided	Very low	Low	2 wk
Polyglycolic acid (Dexon)	Braided	Very low	Low	2 wk

Table 2.2 (continued)

Suture material				
	Type	**Memory**	**Tissue reactivity**	**Tensile strength Half-life**
Absorbable				
Poliglecapone 25 (Monocryl)	Monofilament	Low	Very low	1 wk
Polyglyconate (Maxon)	Monofilament	Low	Very low	1 mo
Polydioxanone (PDS)	Monofilament	High	Very low	1 mo

From Melton, J. L. & Hanke, W. C. (1996). Wound closure materials. In G. P. Lask, R. L. Moy (Eds.), **Principles and techniques of cutaneous surgery** (p. 77). New York: McGraw-Hill.

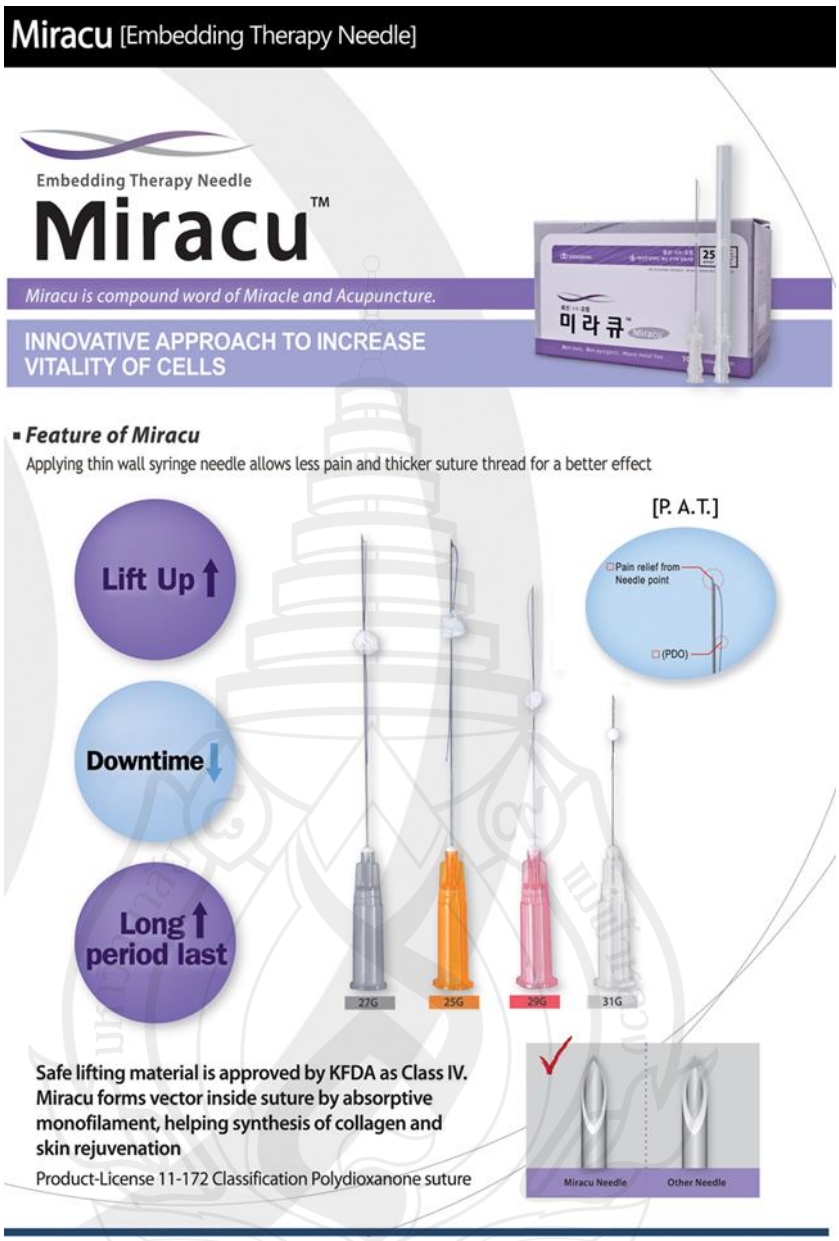


Figure 2.22 Polydioxanone Thread with Needle (Miracu, Dongbang, Korea)

CHAPTER 3

RESEARCH METHODOLOGY

3.1 Study Design

Open-label Clinical Trial

3.2 Study Population

Thai patients age 35-55 years old, both genders with facial laxity.

3.3 Sample

Thai patient ages 35–55 years old, both genders with facial laxity, who want to treat their facial laxity at Mae FahLuang University Hospital, Bangkok.

3.4 Sample Size Determination

The sample size was calculated from the formula of one sample, using the ratio of measurement from the previous study (Eremia & Mark, 2006).

From the formula $n_0 = \frac{z^2_{\alpha/2} PQ}{d^2}$

Assign α= 0.05, $Z_{0.025}$= 1.96, P = 0.90

d = 20% P = 0.18

n_0= 11

P value (0.9) come from the result of thread lifting by Eremia and Mark in 2006 that 90% of the patients were improvement

A drop-out rate of 20% is expected

So fifthteen patients (n_0 = 15) will be recruited.

3.5 Selection Criteria

3.5.1 Inclusion Criteria

3.5.1.1 Thai patient age 35-55 years old

3.5.1.2 Healthy patient with facial skin laxity and want to collect their facial laxity

3.5.1.3 All patients can be followed up at 1 weeks, 4 weeks, 12 weeks and 24 weeks after the treatment

3.5.1.4 All patients are required to sign an informed consent form of benefits, risks and possible complications of the treatment and the publication of photographs.

3.5.2 Exclusion Criteria

3.5.2.1 Patient with local infection or local skin disease that might alter the wound healing.

3.5.2.2 Patient with history of keloid.

3.5.2.3 Patient with Bleeding tendency or take a medicine alter the blood clot.

3.5.2.4 Patient with history of smoking.

3.5.2.5 Allergy of topical anesthesia.

3.5.2.6 Patient whom done the lifting procedure within 6 months such as RF devices, intensed focus ultrasound, thread lifting, botulinum toxin injection and filler injection.

3.5.2.7 Pregnancy and lactation.

3.5.2.8 Medical illnesses that could influence the wound healing, such as poorly controlled diabetic mellitus, coagulopathy, photosensitivity, electrical implantation and immunosuppressant.

3.5.2.9 Use of isotretinoin, hormones, prednisolone, antiplatelet and anticoagulant within six months and NSAIDS within one week before the study.

3.6 Study Location

Mae Fah Luang University Hospital, Bangkok

3.7 Intervention

All patients were treated with polydioxanone threads (Miracu, Dongbang, Korea) 80 threads whole face. The threads are inserting into deep dermis to subcuticular layer in a cross-technique (reticular pattern), the number and size of thread use vary in each area as show in table 3.1.

Table 3.1 Number and Size of the Threads Use in Each Area

Area	Needle size (G)	Thread size (USP)	Thread diameter (mm)	Thread length (mm)	Number of thread use
Forehead	27	6/0	0.400	40	20
Midface	25	5/0	0.530	60	40
Submandible	25	5/0	0.530	60	10
	27	6/0	0.400	40	10

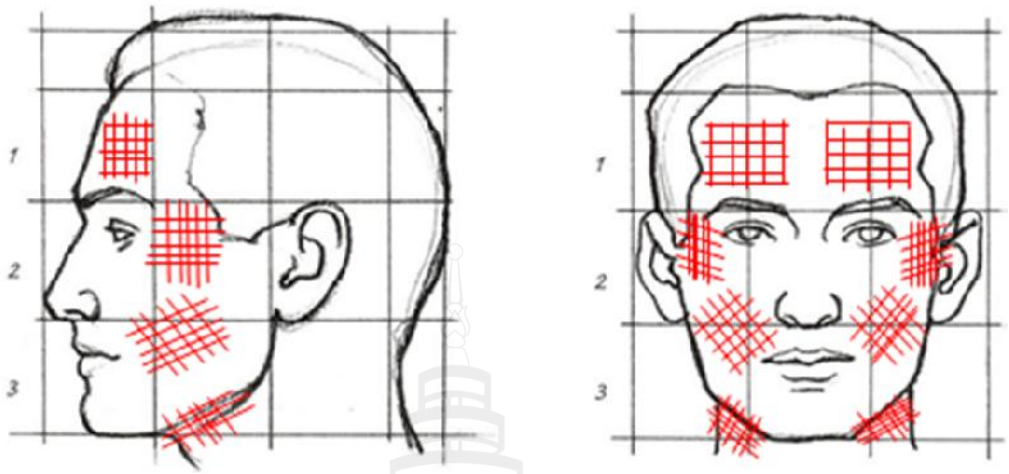


Figure 3.1 Line of Thread Insertion

All threads are sterilized and ready to use as show in figure 25.Threads use in this research was approve by Thai FDA and distributed by CHUNG TEE (Thai) import export CO., LTD.

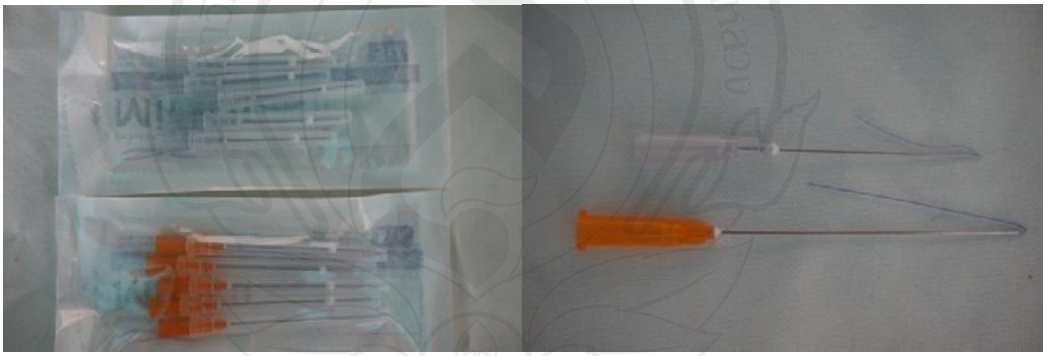


Figure 3.2 Polydioxanone Threads Used in This Research

3.8 Study Procedures

3.8.1 Patients are selected to enroll in the study according to the inclusion and exclusion criteria.

3.8.2 The researcher intensively explains the purpose of the research, process during the study, benefits and possible complications of the treatment.

3.8.3 The patients sign an informed consent form for participation in the study.

3.8.4 The information of the patient is recorded.

3.8.5 Before treatment and each follow up, the researcher takes a photograph of each patient using VISIA® Complexion Analysis System, of which the following is required:

12 megapixel resolution

Automatic focus

Automated white balance correction

Facial positions: Left 37°, Center 0°, Right 37°

Multi-spectral Imaging (standard daylight fluorescent lighting, cross Polarized flash, and ultraviolet lighting)

Then skin elasticity was evaluated by Cutometer MPA580 at the same session.

Power supply 100-240 V AC, 0.3 A, 50-60 Hz

Dimensions 26 x 25.5 x 7 cm

Weight 3.2 kg

Computer PC with Windows® 98 or higher; Windows® Vista 32 bit version

Interface USB (for Windows® NT please ask for serial port)

3.8.6 Before the treatment procedure, the treatment areas are cleansed with a mild soap. Anesthetic cream (2.5% lidocaine/prilocain, EMLA, APP Pharmaceuticals) is applied to the treatment area with occlusion for one hour. After that, the anesthetic cream is removed and the face is cleaned with 70% alcohol.

3.8.7 The researcher does the intervention.

3.8.8 After the treatment, the researcher applies cold compression to relieve the patient's burning sensation.

3.8.9 Pain score during thread lifting is recorded by the patient as soon as possible after complete the procedure.

3.8.10 Side effects are evaluated after the procedure and each follow up at 1 week, 4 weeks, 12 weeks and 24 weeks.

3.8.11 Patients are appointed to take photographs and evaluate the skin elasticity at, 4 weeks, 12 weeks and 24 weeks.

3.8.12 Three independent dermatologists evaluate the improvement of patients' facial laxity by compare before and after treatment.

3.8.13 The patients are asked to evaluate their results and their satisfaction by questionnaire.

3.8.14 The data is collected and analyzed by statistical methods.

3.8.15 Discussion and conclusion of the study is written.

3.9 Outcome Measurement & Data Collection

3.9.1 Primary Outcome Measurement

Three Independent dermatologists compare the patients' photographs taken by VISIA® to evaluate the improvement of facial laxity between before treatment and 4 weeks, 12 weeks and 24 weeks, using the grading scale from -1 to 1 (-1 = worse, 0 = no change, 1 = improved)

3.9.2 Secondary Outcome Measurement

3.9.2.1 Skin elasticity was evaluated by comparing the scores obtained from Cutometer MPA580

3.9.2.2 Patient assessments

Patients are asked to evaluate their satisfaction with the treatments using grading scale from -1 to 1 (-1 = worse, 0 = no change, 1 = improved)

3.9.2.3 Measurement of side effects

The patients are asked to record the following adverse effects after the treatment and each follow up date:

1. Pain score, ranging from no pain (0) to the most pain (10)

2. Swelling: Severity ranging from none (0), least (1), little (2), medium (3), very (4) and Most(5)

3. Bruising: Severity ranging from none (0), least (1), little (2), medium (3), very (4) and Most(5)

4. Migration: Severity ranging from none (0), least (1), little (2), medium (3), very (4) and Most(5)

5. Pimple/lump: Severity ranging from none (0), least (1), little (2), medium (3), very (4) and Most(5)

6. Thread palpating: Severity ranging from none (0), least (1), little (2), medium (3), very (4) and Most (5).

The researcher evaluated the side effects after treatment and each follow up:

1. Edema: Severity ranging from none (0), mild (1), Moderate (2) and severe (3).

2. Bruising: Severity ranging from none (0), mild (1), Moderate (2) and severe (3).

3. Migration: Severity ranging from none (0), mild (1), Moderate (2) and severe (3).

4. Papule/Nodule: Severity ranging from none (0), mild (1), Moderate (2) and severe (3).

5. Infection: Severity ranging from none (0), mild (1), Moderate (2) and severe (3).

3.10 Data Analysis

3.10.1 Effectiveness as Evaluated by Dermatologists

Calculate the mean of facial laxity improvement scores from the three dermatologists each week and conclude the result:

If mean score more than zero and two or more doctor give +1 score; this subject will label as better.

If mean score equal to zero or more than zero but only one doctor give +1 score; this subject will label as same (no change).

If mean score less than zero we conclude that this subject is worse.

The data are calculated into percentile.

3.10.2 Skin Elasticity by Cutometer MPA580

3.10.2.1 Calculate the mean of facial skin elasticity scores before treatment and each follow up week.

3.10.2.2 Compare the mean skin elasticity score before treatment with each follow up week. The paired t-test statistics is used to evaluate the difference, at the level of significance $\alpha<0.05$.

3.10.3 Patient Assessments

Patient satisfaction are calculated into percentile

3.10.4 Measurement of Side Effect Effects

The side effects both evaluated by researcher and patients are calculated into percentile.

CHAPTER 4

RESULTS

This experimental research has a goal for evaluated the effectiveness, satisfaction and side effect of polydioxanone thread (PDO) for face lifting, which compare result between before and after thread lifting at 4 weeks, 12 weeks and 24 weeks.

Data analysis can divide in to 3 parts:

1. General characteristics of the samples.
2. Data analysis
3. The satisfaction and side effects

4.1 General Characteristics of the Sample

Demographic information

15 Thai subjects, no gender specific, age between 35-55 years old with facial laxity and want to be collected the laxity which can be treated and follow up at Mae Fah Luang Hostipal Bangkok. One subject was drop out of the project before the end of the study for some reasons. Only 14 patients was completed the research project.

Table 4.1 General Characteristics of the Sample

Factor

	n	**percentage**
Gender		
Male	4	28.57
Female	10	71.43

Table 4.1 (continued)

Factor

	n	Percentage
Age (Years)		
35 - 40 year	6	42.85
41 - 45 year	5	35.72
46 - 50 year	3	21.43
51 - 55 Year	0	0
Mean±SD	41.14±5.48	
Median(Min-Max)	41.5(34-50)	
Pain score		
Mean±SD	5.00±2.04	
Median(Min-Max)	5(0-7)	

Form table 4.1 show general characteristic of the sample. 14 patients were evaluated at the end of the project. Most of the patients were female, 10 cases, (71.43%) and 4 cases were male (28.57%). The mean age of the patients was 41.14±5.48 year. (Min 35 year, Max 50 year). Pain score during the procedure was 5.00±2.04score (Min 0, Max 7).

Table 4.2 Three Independents Doctors Evaluation Data and Result Conclusion at 4 Weeks

Patient	Doctor evaluation			
	Doctor 1	Doctor 2	Doctor 3	Conclusion
1	+1	+1	+1	Better
2	0	+1	0	Same
3	+1	+1	+1	Better
4	0	0	0	Same
5	+1	+1	+1	Better

Table 4.2 (continued)

Patient	Doctor evaluation			
	Doctor 1	**Doctor 2**	**Doctor 3**	**Conclusion**
6	0	+1	+1	Better
7	0	0	0	Same
8	+1	0	+1	Better
9	+1	0	-1	Same
10	0	+1	0	Same
11	+1	0	-1	Same
12	+1	+1	0	Better
13	+1	+1	0	Better
14	+1	+1	+1	Better

Note. +1 = better, 0 = same, -1 = worse,

Conclusion: Same = 6, Better = 8 (compare between before thread lifting with 4 weeks after procedure)

The conclusion uses the mean score of three independent doctors. If mean score more than zero and two or more doctor give +1 score; this subject will label as better. If mean score equal to zero or more than zero but only one doctor give +1 score; this subject will label as same (not change) and if mean score less than zero we conclude that this subject is worse.

Table 4.3 Three in Dependents Doctor Evaluation Data and Result Conclusion at 12 Weeks

Patient	Doctor evaluation			
	Doctor 1	**Doctor 2**	**Doctor 3**	**Conclusion**
1	0	+1	+1	Better
2	+1	+1	+1	Better
3	+1	+1	+1	Better
4	0	0	+1	Same
5	0	+1	+1	Better
6	0	+1	0	Same
7	+1	+1	-1	Better
8	+1	0	+1	Better
9	+1	0	-1	Same
10	+1	+1	+1	Better
11	+1	0	0	Better
12	+1	+1	0	Better
13	+1	+1	0	Better
14	+1	+1	+1	Better

Note. +1 = better, 0 = same, -1 = worse

Conclusion: Same = 6, Better = 8 (compare between before thread lifting with 12 weeks after procedure)

The conclusion uses the mean score of three independent doctors. If mean score more than zero and two or more doctor give +1 score; this subject will label as better. If mean score equal to zero or more than zero but only one doctor give +1 score; this subject will label as same (not change) and if mean score less than zero we conclude that this subject is worse.

Table 4.4 Three in Dependents Doctor Evaluation Data and Result Conclusion at 24 Weeks

Patient	Doctor evaluation			
	Doctor 1	**Doctor 2**	**Doctor 3**	**Conclusion**
1	+1	+1	+1	Better
2	+1	0	+1	Better
3	+1	+1	+1	Better
4	+1	0	0	Same
5	+1	+1	0	Better
6	+1	0	0	Same
7	0	+1	+1	Better
8	+1	0	+1	Better
9	0	0	0	Same
10	+1	0	+1	Better
11	0	+1	+1	Better
12	+1	+1	0	Better
13	+1	+1	+1	Better
14	+1	+1	+1	Better

Note. +1 = better, 0 = same, -1 = worse

Conclusion: Same = 6, Better = 8 (compare between before thread lifting with 24 weeks after procedure)

The conclusion uses the mean score of three independent doctors. If mean score more than zero and two or more doctor give +1 score; this subject will label as better. If mean score equal to zero or more than zero but only one doctor give +1 score; this subject will label as same (not change) and if mean score less than zero we conclude that this subject is worse.

Table 4.5 Skin Elasticity Score at Each Follow Up Week

Patient	Skim elasticity score			
	Before treatment	**Weeks 4**	**Weeks 12**	**Weeks 24**
1	0.8989	0.9020	0.8990	0.9143
2	0.8391	0.8118	0.8828	0.7701
3	0.7732	0.7697	0.7923	0.8652
4	0.9461	0.9418	0.9427	0.7910
5	0.8841	0.8225	0.8026	0.9337
6	0.9250	0.7562	0.8903	0.9179
7	0.8497	0.8214	0.7605	0.9545
8	0.7060	0.7621	0.6322	0.7967
9	0.9081	0.7414	0.7055	0.7850
10	0.8282	0.7647	0.7012	0.9643
11	0.9637	0.9404	0.7220	0.9345
12	0.9249	0.8728	0.6556	0.8702
13	0.9554	0.7188	0.6667	0.8343
14	0.8120	0.9173	0.8571	0.8523
Mean ± SD	0.87 ± 0.07	0.82 ± 0.08	0.78 ± 0.10	0.87 ± 0.07
Min	0.7060	0.7562	0.6322	0.7701
Max	0.9637	0.9418	0.9427	0.9643

From the table 4.5: The mean skin elasticity score of patients are 0.87 then decreasing to 0.82 at weeks 4, the score still decreasing to 0.78 at 12 weeks. The mean score is increasing to 0.87 at weeks 24.

4.2 Data Analysis

Table 4.6 Result of Lifting, Evaluated by Three Independent Dermatologists

	worse		same		better	
	n	**%**	**n**	**%**	**n**	**%**
week4	-		6	42.86	8	57.14
week 12	-		3	21.43	11	78.57
week24	-		3	21.43	11	78.57

Form the table the result of face lifting evaluated by 3 independent doctors shows that at 4 weeks after treatment the sample was label as better8 case (57.14%), look same 6 case (42.86%) and no sample was label as worsening. At 12 weeks after treatment the samples were label as better 11 cases (78.57%), the same 3 case (21.43%) and none of it was label as worsening. The results at 24 weeks are the same as 12 weeks after the procedure.

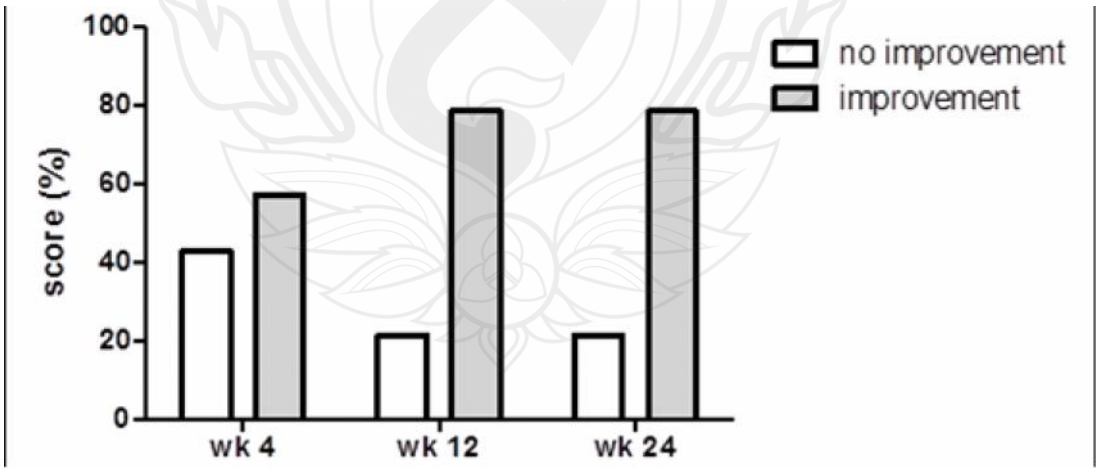


Figure 4.1 The Improvement of Lifting Effect of Patients Between 4 Weeks, 12 Weeks and 24 Weeks

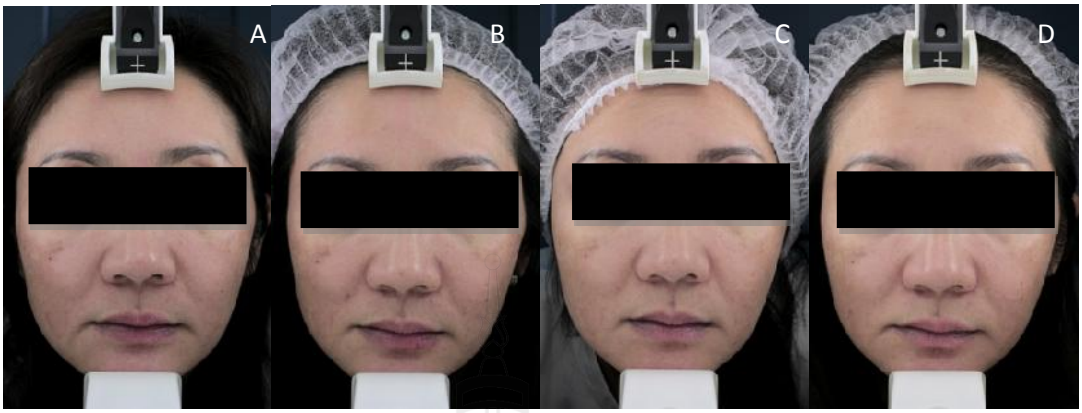


Figure 4.2 Patient Photographs (Front View) Between Before Treatment (A), 4 Weeks (B), 12 Weeks (C), and 24 Weeks (D) After the Procedure

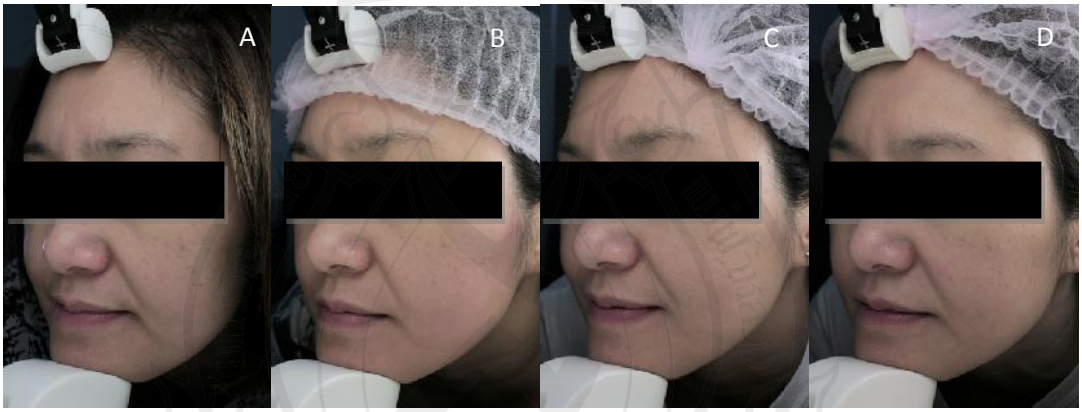
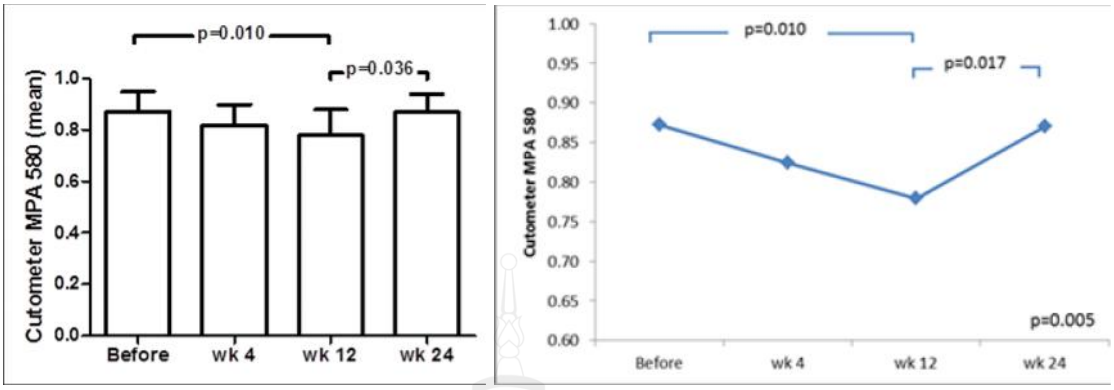


Figure 4.3 Patient Photographs (Left Lateral View) Between Before Treatment (A), 4 Weeks (B), 12 Weeks (C), and 24 Weeks (D) After the Procedure

Table 4.7 Compare the Skin Elasticity Score Between Before Treatment, 4 Weeks, 12 Weeks and 24 Weeks

	n	Mean±SD	Paired Differences	t	df	p-value
Before treatment	14	0.87±0.08	0.05±0.09	1.979	13	0.069
Week4		0.82±0.08				
Before treatment	14	0.87±0.08	0.09±0.12	2.998	13	0.010
Week12		0.78±0.10				
Before treatment	14	0.87±0.08	0.00±0.10	-0.070	13	0.945
Week24		0.87±0.07				
Week4	14	0.82±0.08	0.05±0.10	1.741	13	0.105
Week12		0.78±0.10				
Week4	14	0.82±0.08	-0.05±0.10	-1.795	13	0.098
Week24		0.87±0.07				
Week12	14	0.79±0.10	-0.08±0.12	-2.356	13	0.036
Week24		0.87±0.07				
Paired t-test						

Form the table found that the skin elasticity was decrease at 4 weeks after treatment when compare to before treatment but not significant in statistic (Paired t-test). While at the 12 weeks skin elasticity was significant decrease ($p<0.05$) when compare with before thread. At 24 weeks the result is nearly before thread lifting. When compare each week, there are significant in statistic between weeks 12 and weeks 24.



One-way repeated measured ANOVA

Figure 4.4 Compare the Skin Elasticity Between Before Treatment, 4 Weeks, 12 Weeks and 24 Weeks

4.3 Satisfaction and Side Effect

Participant was asked to reply the questionare to evaluate the satisfaction of polydioxanone thread face lifting method which meaning is refer to

Worsening = face more laxity, Same = face not change, Improvement = laxity look better

The details were shown below

Table 4.8 Patient Satisfaction for Polydioxanone Thread for Face Lifting

	worsening		**same**		**improvement**	
	n	**%**	**n**	**%**	**n**	**%**
Week4	-		-		14	100.00
Week12	-		-		14	100.00
Week24	-		-		14	100.00

From the table in 4 weeks all patients satisfy the result of thread lifting method (100%) and the same result in 12 and 24 weeks.

This research was recorded the side effect that divided in to 2 parts:

1. Side effect evaluated by doctor
2. Side effect evaluated by subject them-self

Table 4.9 Side Effects of Polydioxanone Thread Face Lifting, Doctor Evaluation

	none		**mild**		**moderate**	
	n	**%**	**n**	**%**	**n**	**%**
edema						
week1		-	9	64.29	5	35.71
week4	14	100.00		-		-
week12	14	100.00		-		-
bruising						
week1	1	7.14	9	64.29	4	28.57
week4	14	100.00		-		-
week12	14	100.00		-		-
migration						
week1	12	85.71	2	14.29		-
week4	14	100.00		-		-
week12	14	100.00		-		-
Papule/nodule						
week1	12	85.71	2	14.29		-
week4	13	100.00	1	7.14		-
week12	14	100.00		-		-
infection						
week1	14	100.00		-		-
week4	14	100.00		-		-
week12	14	100.00		-		-

Edema: all patients (100%) have this side effect. 9 patients (64.29%) are mild and 5 patients (35.71%) are moderate degree.

Bruising: nearly hundred percent have this side effect. 9patients (64.29%) are mild, 4 patients (28.57%) are moderate and 1 patient has no bruising (7.14%).

Migration: is refer to one side of the thread was found on skin surface, 2 patients (14.29%) was found and it only mild degree.

Papule/nodule : 2 patients (14.29%) have skin nodule at 1 weeks follow up and degree is mild .at 4 weeks 1 case (7.14%) still has a nodule and not seen in 12 weeks.

Infection: none of the patients (100%) has an infection complication.

Table 4.10 Side Effect of Polydioxanone Thread Face Lifting, Patients' Evaluation

	none		least		little		medium		very		The most	
	n	%	n	%	n	%	n	%	n	%	n	%
Swelling												
week1	-		4	28.57	3	21.43	5	35.71	2	14.29	-	
week4	14	100.00	-		-		-		-		-	
week12	14	100.00	-		-		-		-		-	
Bruising												
week1	1	7.14	2	14.29	3	21.43	5	35.71	3	21.43	-	
week4	13	92.86	1	7.14	-		-		-		-	
week12	14	100.00	-		-		-		-		-	
Migration												
week1	12	85.71	1	7.14	1	7.14	-		-		-	
week4	13	92.86	1	7.14	-		-		-		-	
week12	14	100.00	-		-		-		-		-	
Pimple/lump												
week1	4	28.57	2	14.29	4	28.57	3	21.43	1	7.14	-	
week4	13	92.86	1	7.14	-		-		-		-	
week12	14	100.00	-		-		-		-		-	
Thread palpate												
week1	11	78.57	1	7.14	2	14.29	-		-		-	
week4	13	92.86	1	7.14	-		-		-		-	
week12	14	100.00	-		-		-		-		-	

From Table 4.10 can conclude that:

Swelling: At the 1 week after thread lifting all patients have swollen and the most degree is medium swelling in 5 patients (35.71%), 4 Patients was least degree (28.57%), 3 patients was little degree (21.43%) and 2 patients was very degree (14.29%) respectively . This side effect was not found in 4 and 12 weeks.

Bruising: At 1 week 13 patients had bruising and the most degree is medium in 5 patients (35.71%). Little and very were equally in 3 patients (21.43%) and least was 2 patients (14.29%). 1 patient has not this complication (7.14%). At 4 weeks 1 patient still had abruising (7.14%) and totally not found in 12 weeks.

Migration: Found 2 patients at 1 week. The degree is equally between least and little that 1 patient each degree (7.14%). At 4 weeks 1 patient still migration in least degree (7.14%). At 12 weeks all subjects had not this complication.

Pimple: At 1 week 10 patients have a pimple at their face. Most of them had little degree (28.57%) then medium (21.43%) and least (14.29%) respectively.1 patient (7.14%) has a very degree pimple. At 4 weeks their only 1 case (7.14%) still had a pimple and at 12 weeks it all disappear.

Thread palpating: at 1 weeks 2 patients have little degree (14.29%) and 1 patient has least degree (7.14%). at 4 and 12 weeks none of patients has this complication.

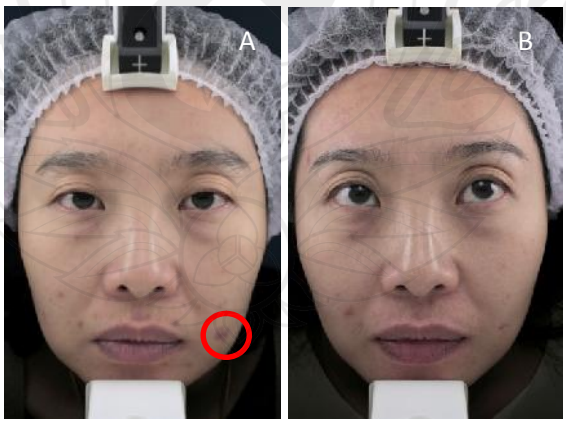


Figure 4.5 Subjects Have One Nodule at Left Cheek After Procedure at 4 Weeks (A) Follow Up and Disappear at 12 Weeks (B) Follow Up

CHAPTER 5

DISCUSSION AND CONCLUSION

5.1 Discussion

This research is study for evaluate effectiveness, satisfaction and side effect of polydioxanone thread for face lifting which compare the result before and after procedure.

They have many methods to treat the sagging face such as surgery, machine device and thread lifting. The treatment of choice is face lift operation but this method has many limitation, side effect and long downtime. Machine devices such as Radiofrequency, Intense focus ultrasound are very expensive and minimal improvement. Threads lifting such as gold thread, Aptos thread and silhouette thread have many side effects due to non-absorbable property.

Now in South Korea, many physician have use an absorbable suture, polydioxanone (PDO), for face lifting by insert a 4–6 centimeters thread into a skin to stimulate collagen production. This method has very popular in Thailand that was used in many hospitals and clinics but they lack of evidence base study to support the effective of this procedure and to determine side effect.

In 2007 Huggins et al., plastic surgeon, was biopsy 22 patients which done the face lift operation. He found that they have a collagen fiber around the suture site at SMAS layer and more prominent in the interstictharea. For the safety of this suture material had many research. In 1984 Chu and Williams have research and conclude that the monofilament suture has less infection rate that polyfilament. In 1984 Henke R was compare the property of the threads that were used in the market between PDO, polyglactin 910 (Vicryl, Ethicon GmbH, Norderstedt, Germany), catgut plain,

and polyester fibers, found that the PDO has less tissue reactivity and more tensile strength than the others.

This research use the polydioxanone thread size 5/0, 6 centimeters long and thread size 7/0, 4 centimeters long insert into the skin, subcutis or SMAS layer, to lift the sagging face for evaluate effectiveness and side effect of this procedures.

5.2 Discussion: General Characteristic

General characteristic of the subjects have detail as follow:

5.2.1 Gender: most of the patients are female.

5.2.2 Age: mean age of the subjects are 41.14 years

5.2.3 Pain score: Mean pain score of the patients are 5 in visual analog scale that mean this procedure has moderate pain for lifting the face and this procedure can done by local anesthesia, no necessary for general anesthesia if patient can tolerate.

5.3 Experimental Discussion

5.3.1 Analysis face lifting outcome by polydioxanone thread compare before and after procedure at various time.

Lifting outcome can first clearly seen at 4 weeks after thread lifting and most lifting effect can see in 12 weeks after procedure and still the lifting effect at 24 weeks

When compare with the previous research. The causes of skin laxity of the face were decrease skin collagen (Ghadially et al., 1995), loss of muscle tones (Dayan et al., 1988), and decrease in subcutaneous fat (Donofrio, 2000) and structural bone change (Shaw et al., 2010). In the past, the method to improvement the skin laxity was face lift operation which have long downtime and a lot of risk. Nowadays many patients favor a noninvasive way that minimal downtime and low risks, to improve the skin laxity such as intense focus ultrasound (Alam, 2010) and Monopolar radiofrequency (Weiss, 2006), both method use a mechanism of inducing collagen production by induce skin injury. For thread lifting, in the past thread was use to hook up the laxity skin such as APTOS

(Sulamanidze et al., 2002), Silhouette Thread (Abraham, DeFatta & Williams, 2009) and Large anchors knot suspension (Eremia & Mark, 2006) which can see the result immediately after the procedure but this research use the thread in different way by induce collagen production which can found around the thread (Huggins et al., 2007) that mean the result must wait collagen to produce to lift up the tissue by wound healing process about 1 week and the collagen strength increase with time (Fonder et al., 2008) this could explain why number of subject improvement increase in 12 weeks and 24 weeks.

5.3.2 Analysis the Skin Elasticity of the Skin Compare Before and After Thread Lifting

The mean skin elasticity decrease after thread lifting was done that may be form skin inflammation by the thread. At 4 week skin elasticity decrease when compare before thread lift but no significant in statistic. At 12 weeks skin elasticity more decrease and statistic significant when compare with before done the procedure that may reflect that in 12 weeks skin may be inflammation more than at 4 weeks which can explain by polydioxanone property in low tissue reactivity (Melton & Hanke, 1996) even though the result between 4 and 12 weeks was not significant in statistic and the skin elasticity return to normal baseline at 24 weeks may be due to the threads were completely absorbed.

5.3.3 Analysis Satisfaction of the Subjects in the Result of Lifting

All patients (100%) have satisfied the result of lifting which done by polydioxanone thread lift procedure. Furthermore they satisfy in the result of their face look smaller and brightener than before done this procedure.

5.3.4 Analysis of the Side Effect

There was no serious adverse effect. By doctor evaluation the major side effect of this method is swelling and bruising which can be found regularly in skin injury and can be found only some area; the most of them were only mild degree swelling and bruising that resolved without sequelae at 1 week. Some of them have thread migration and papule. Thread migration can found only a few thread most of it was seen in forehead area. Two subjects have papule on their skin that was seen at the insertion site. The cause

of papule is the end site of the thread was not into the skin and form the healing process the skin was heal cover the thread and form a papule but for this side effect it resolved by itself overtime from the thread absorption.

For the patients evaluated side effect by them-self. The main side effect were similar that evaluated by doctor that the main side effect were swelling and bruising and only mild degree that completely resolved at 1 weeks and no other serious side effect.

5.4 Related Theory or Previous Research Discussion

In the past, thread was use to suspended or hooked up the soft tissue to correct the ptosis skin. First developed in 1998 by used a non-absorbable suture material (polypropylene) and designed many dent along their length or barbed suture also call APTOS thread (Sulamanidze et al., 2002). This procedure must use a large guide needle to insert the thread in to the skin there for it necessary to inject some local anesthesia because of pain during procedure. Totally number of thread were use 5 to 10 threads each size .this method was simple and short downtime but because of non-absorbable property of the thread when patient have complication such as thread breakage, asymmetry and thread visualization, the thread not resolved by itself and form the pathologic study by Sulamanidze found a fibrous shell around the thread then it was hard to remove the thread, finally they need a surgical procedure to resolve the complication.

Then in 2005 another thread was developed by use a bio-absorbable cones instead of barbed but the thread still use non-absorbable material, polypropylene, in name silhouette thread. This thread need a skin inscision at the temporal area to insert the thread and need to fixed the thread in the temporal fascia (Navarrete, Palao, Torrent, Fuentes & González, 2012). Complication of this method was due to its structure and procedure such as skin dimpling, cone palpable, asymmetry and pain at fixation point. Because of thread was non-absorable property, to resolve the complication must use surgical procedure like an APTOS.

In 2006 Eremia and Mark were invented a suspension suture by 2-0 absorbable material (Maxon or PDS) with a short bit 7–9 mm, 0 thickness in same material. This method use a large needle guide (14 G) therefor they need skin incision to insert the

threads and fixed the thread at the temporal fascia. Due to a large thread and knot of the suture, subjects may have dimple, palpable the thread and lump on their face but the side effect. A few subjects have pain at the temporal area.

This is a novel methods to use a thread for lifting the face by use a small multiple thread insert into the skin in cross technique (reticular pattern) that no skin incision, no skin excision easy to use and minimal downtime can go out to public in 1 weeks.

Table 5.1 Comparison the Difference of Each Thread Lifts Method

Method	Type of thread	Mechanism	Needle size	Thread size	Side effect
Aptos thread (Sulamanidze, et al., 2002).	Non-absorbable (polypropylene)	Hooking	Large	2/0 – 4/0 Depend on area	Ecchymosis Migration Asymmetry Thread visualization Linear hemorrhage Skin retraction
Silhouette lift (Navarrete, et al., 2012)	Thread : Non-absorbable (polypropylene) Cones : Absorbable (polilactic and glycolic acids)	Hooking	Large	2/0	Thread breakage and extrusion Asymmetry Skin dimpling Visible knot Ecchymosis Persistent pain
Suture with large anchor knotted (Eremia & Mark, 2006)	Absorbable (Maxon/PDS)	Hooking	Large 14G /19G	Thread : 2/0 Knot : 0/0	Skin dimpling Palpate and visible Lump Pain at fixation point
Small reticular suture material insertion	Absorbable (PDO)	Collagen induction	Small 25G/27G	5/0 and 6/0	Swelling Bruising Migration Skin nodule

From the table when compare the side effect between this method with other thread lifting procedure. The side effect of this method is very mild that may be the smaller thread and smaller needle than the other. The advantage of this method is the side effect can resolve by itself due to thread absorption while other methods require surgical procedure.

5.5 Conclusion

A polydioxanone thread lift may be a one of alternative choice for non-invasive face lifting because it easy to perform which can be done by topical anesthesia, minimal downtime and little complication. This method effective for improve jawline and marionette line with 100% patient satisfaction but this method is not effective for improve skin elasticity. This method is not appropriate for patient with too much sagging and need to combine with other modality to improve aesthetic outcome.

5.6 Suggestion

5.6.1 Should increase the length of time for evaluate the lasting effect of this procedure, because of polydioxanone thread was completely absorb in 6 month (about 24 weeks).

5.6.2 Should increase in number of subject for more accuracy of statistic because this research two subjects were loss before end the project.

5.6.3 Should have a skin biopsy to compare the collagen and process of collagen production by this procedure.

5.6.4 Should be study the appropriate number of thread that effective for face lifting.

5.6.5 Should be further study combine this method with other procedure to increase the effective of lifting effect.

REFERENCES

REFERENCES

Abraham, R. F., DeFatta, R. J. & Williams, E. F. (2009). Thread-lift for facial rejuvenation assessment of long-term results. **Arch Facial PlastSurg, 11**(3), 178-183.

Ahmad, A., Banerjee, S., Wang, Z., Kong, D., Majumdar, A. P. & Sarkar, F. H. (2009). Aging and inflammation: Etiological culprits of cancer. **Curr Aging Sci, 2**(3), 174-186.

Alam, M., White, L. E., Martin, N., Witherspoon, J., Yoo, S. & West, D. P. (2010). Ultrasound tightening of facial and neck skin: A rater-blinded prospective cohort study. **J Am Acad Dermatol, 62**(2), 262-269.

Chantarasak, N. D. & Milner, R. H. (1989). A comparison of scar quality in wounds closed under tension with PGA (Dexon) and Polydioxanone (PDS). **British Journal of Plastic Surgery**, **42**(6), 687-691.

Chu, C. C. & Williams, D. P. (1984). Effects of physical configuration and chemical structure of suture materials on bacterial adhesion: A possible link to wound infection. **Am J Surg, 147**(2), 197-204.

Collins, M. (2010a). **Gold thread lift**. Retrieve June 23, 2012, from http://www.facelift-pedia.com/facelift-blog/gold thread-lift

Collins, M. (2010b). **Silhouette lift**. Retrieve June 23, 2012, from http://www.facelift-pedia.com/facelift-blog/silhouette-lift/silhoulette-lift-3/

Courtney, S., Mcguire, B. S., & Gladstone, H. B. (2009). Novel pretrichial browlift technique and review of methods and complications. **Dermatol Surg 35**(9), 1390-1405.

Dayan, D., Abrahami, I., Buchner, A., Gorsky, M. & Chimovitz, N. (1988). Lipid pigment (lipofuscin) in human perioral muscles with aging. **ExpGerontol, 23**(2), 97-102.

Donofrio, L. M. (2000). Fat distribution: A morphologic study of the aging face. **DermatolSurg, 26**(12), 1107-1112.

Edwards, D. J. & Elson, R. A. (1995). Skin closure using nylon and polydioxanone: A comparison of results. **J R CollSurgEdinb, 40**(5), 342-343.

Elias, P. M. & Ghadially, R. (2002). The aged epidermal permeability barrier: Basis for functional abnormalities. In B. A. Gilchrest (Ed.), **Geriatric dermatology** (vol. 18, pp. 103). Philadelphia: WB Saunders.

Encyclopedia Britannica. (2008). **Muscle system, human: Muscles of facial expression**. Retrieved June 26, 2012, from http://www.britannica.com/EBchecked/topic-art/1346374/119201/Muscle-of-facial-expression

Eremia, S. & Mark, A.W. (2006). Novel face-lift suspension suture and inserting instrument: Use of large anchors knotted into a suture with attached needle and inserting device allowing for single entry point placement of suspension suture. Preliminary report of 20 cases with 6- to 12-month follow-up. **DermatolSurg**, **32**(3), 335-345.

Fonder, M. A., Lazarus, G. S., Cowan, D. A., Aronson-Cook, B., Kohli, A. R. & Mamelak, A. J. (2008). Treating the chronic wound: A practical approach to the care of nonhealing wounds and wound care dressings. **J Am Acad Dermatol**, **58**(2), 185-206.

Ghadially, R., Brown, B. E, Sequeira-Martin, S. M., Feingold, K. R. & Elias, P. M. (1995). The aged epidermal permeability barrier. Structural, functional, and lipid biochemical abnormalities in humans and a senescent murine model. **J Clin Invest, 95**(5), 2281-2290.

Green, J. B., Dover, J. S. & Kaminer, M. S. (2011). Tolerability of a monopolar radiofrequency facial skin tightening procedure: An observational study. **Cosmet Dermatol, 24**, 327-330.

Griffin, R. (2012). **Endotine devices**. Retrieve June 23, 2012, from http://ks.microaire.com/endotine-multipoint-fixation-devices

Huggins, R. J., Freeman, M. E., Kerr, J. B. & Mendelson, B. C. (2007). Histologic and ultrastructural evaluation of sutures used for surgical fixation of the SMAS. **AesthPlastSurg, 31**(6), 719-724.

Kamer, F. M. & Frankel, A. S. (1998). SMAS rhytidectomy versus deep plane rhytidectomy: An objective comparison. **Plast Reconstr Surg**, **102**(3), 878-881.

Laufer, N., Merino, M., Trietsch, H. G. & DeCherney, A. H. (1984). Macroscopic and histologic tissue reaction to polydioxanone, a new, synthetic, monofilament microsuture. **J Reprod Med**, **29**(5), 307-310.

MacLaughlin, J. & Holick, M. F. (1985). Aging decreases the capacity of human skin to produce vitamin D3. **J Clin Invest, 76**(4), 1536-1538.

Marcus, B. C. (2012). Rhytidectomy: Current concepts, controversies and the state of the art. **Current opinion in otolaryngology & head and neck surgery, 20**(4), 262-266.

Melton, J. L. & Hanke, W. C. (1996). Wound closure materials. In G. P. Lask, R. L. Moy (Eds.), **Principles and techniques of cutaneous surgery** (p. 77). New York: McGraw-Hill.

Mitz, V. & Peironye, M. (1976). The superficial musculo-aponeurotic system in the parotid and cheek area. **PlastReconstrSurg, 58**(1), 80.

Moy, R. L., Lee, A. & Zalka, A. (1991). Commonly used suturing techniques in skin surgery. **Am Fam Physician, 44**(5), 1625-1634.

Navarrete, M. L., Palao, R., Torrent, L., Fuentes, J. F. & González, M. (2012). Facial asymmetry correction in facial palsy patients with silhouette sutures. **International Journal of Clinical Medicine, 3**(1), 55-59.

Newman, J. (2006). The safety and efficacy of midface-lifting using an absorbable suspension device (Endotine ST). **Arch Facial PlastSurg, 8**(4), 245-251.

Parara, S. M., Manios, A., de Bree, E., Tosca, A. & Tsiftsis, D. D. (2011). Significant differences in skin irritation by common suture materials assessed by a comparative computerized objective method. **Plast Reconstr Surg, 127**(3), 1191-1198.

Plowden, J., Renshaw-Hoelscher, M., Engleman, C., Katz, J., & Sambhara, S. (2004). Innate immunity in aging: Impact on macrophage function. **Aging Cell, 3**(4), 161-167.

Rohrich, R. J. & Pessa, J. E. (2007). The fat compartment of the face: Anatomy and clinical implications for cosmetic surgery. **Plastic and Reconstructive Surgery, 199**(7), 2219-2227.

Shaw, R. B., Jr., Katzel, E. B., Koltz, P. F., Kahn, D. M., Girotto, J. A. & Langstein, H. N. (2010). Aging of the mandible and its aesthetic implications. **Plastic & Reconstructive Surgery, 125**(1), 332-342.

Sulamanidze, M. A., Fournier, P. F., Paikdze, T. G. & Sulamanidze, G. M. (2002). Removal of facial soft tissue ptosis with special threads. **DermatolSurg**, **28**(5), 367-371.

Sumira, Z. A. (2008). Dermatologic surgery. In P. Brent (Ed.), **Introduction to anatomy and approach** (chapter 243, pp. 2289-2301). New york: McGraw-Hill.

Weiss, R. A., Weiss, M. A., Munavalli, G. & Beasley, K. L. (2006). Monopolar radiofrequency facial tightening: A retrospective analysis of efficacy and safety in over 600 treatments. **J Drugs Dermatol, 5**(8), 707-712.

Wulf, H. C., Sandby-Møller, J., Kobayasi, T. & Gniadecki, R. (2004). Skin aging and natural photoprotection. **Micron, 35**(3), 185-191.

APPENDIX

APPENDIX

RESEARCH RECORD DATA SHEET

การศึกษานำร่องเรื่อง: ประสิทธิผลของการใช้ไหมละลายชนิดโพลี่ไดออกซาโนน (พีดีโอ) ในการยกกระชับใบหน้า

Record number.....

ข้อมูลทั่วไปของผู้ป่วย (Patient demographic information)

เฉพาะเจ้าหน้าที่ (Officer only)

1. วัน เดือน ปี ที่เก็บข้อมูล..... Date
2. ชื่อ นามสกุล..... Name
3. บ้านเลขที่..... Address

   ……

   เบอร์โทรศัพท์..... Tel
4. เพศ ……..1.ชาย .....2. หญิง Sex
5. อายุ .....ปี Age
6. อาชีพ .....1. ข้าราชการ .....2. พนักงาน Occupation

   .....3. แม่บ้าน .....4. นักเรียน/นักศึกษา

   .....5. กิจการส่วนตัว .....6. อื่นๆ
7. โรคประจำตัว.....มี.....ไม่มี Underlying disease

   ถ้ามี ยาที่ทานอยู่..... Drug use
8. ประวัติการทานอาหารเสริม..... Supplement use
9. สูบบุหรี่ หรือไม่ ……สูบ ……ไม่สูบ Smoking
10. ดื่มเครื่องดื่มที่มีแอลกอฮอล์หรือไม่ .....ดื่ม .....ไม่ดื่ม Alcohol drinking

11. ประวัติการรักษาที่เคยได้รับมาก่อน Previous Treatment

.....1.เคย .....2.ไม่เคย

ถ้าเคย ชื่อวิธี..... If yes: Method

ระยะห่างก่อนมาทำการรักษาครั้งนี้..... and time

Experiment record data sheet

1. Clinical evaluation

Patients

name……

Name of evaluator……

Time	Result		
	Worse(-1)	No change(0)	Better (+1)
Week4			
Week12			
Week24			

Name of evaluator ……...

Time	Result		
	Worse(-1)	No change (0)	Better (+1)
Week4			
Week12			
Week24			

Name of evaluator ……..

Time	Result		
	Worse(-1)	No change (0)	Better (+1)
Week4			
Week12			
Week 24			

Conclusion table

Time	Lifting result			
	Doctor A	Doctor B	Doctor C	Conclusion
Week4				
Week12				
Week24				

2. Pain score during the procedure

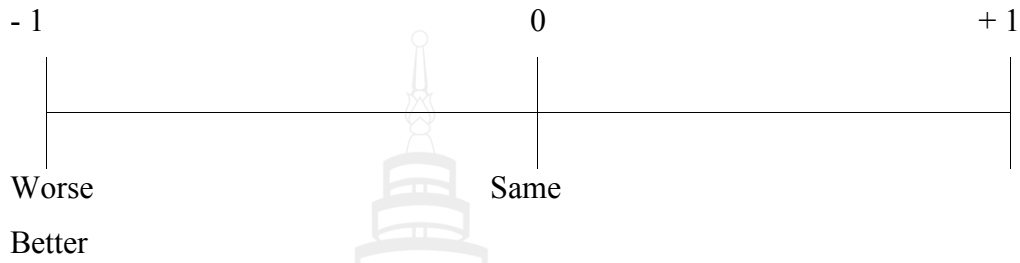
Pain score: Please circle by the real data

No pain Moderate pain Most pian

3. Clinical evaluation by patient

Week……..

Satisfaction**:**Please circle by the real data



*satisfaction is ranging from-1 to+1

-1 = worse, 0 =no change (same), +1 =better

4. Skin elasticity byCutometer MPA 850

	Week			
	0	4	12	24
Skin elasticity score				

Side effect record data sheet

1. การประเมินผลข้างเคียงโดยผู้ป่วย

สัปดาห์ที่……..

….. 1. มี ..... 2. ไม่มี

ผลข้างเคียง	ไม่มีเลย (1)	น้อยมาก (2)	ค่อนข้างน้อย (3)	ปานกลาง (4)	ค่อนข้างมาก (5)	มากที่สุด (6)
บวม						
เขียวช้ำ						
ไหมเหลื่อน						
ตุ่ม						
คลำได้ไหม						

อื่นๆ .....

2. โดยแพทย์ (Physician evaluation)

Week……..

….. 1. Yes ..... 2. No

Adverse effects	Severity		
	Mild	Moderate	Severe
Edema			
Bruising			
Migration			
Granuloma			
Infection			

Other .....

หนังสือให้ความยินยอมเข้าร่วมในโครงการวิจัย

เขียนที่……..……..

วันที่…….……

ข้าพเจ้า……..……อายุ……ปี

อยู่บ้านเลขที่…...…ถนน…….....หมู่ที่…….แขวง/

ตำบล…….……....

เขต/อำเภอ…..……..... จังหวัด…….....

ขอทำหนังสือนี้ให้ไว้ต่อหัวหน้าโครงการวิจัยเพื่อเป็นหลักฐานแสดงว่า

ข้อ 1. ข้าพเจ้าได้รับทราบโครงการวิจัยของนายแพทย์กัลยกฤต อยู่รักษ์ และ อาจารย์นายแพทย์ไพศาล รัมณีย์ธร การศึกษานำร่องเรื่องประสิทธิผลของการใช้ไหมละลายชนิดโพลี่ไดออกซาโนน (พีดีโอ) ในการยกกระชับใบหน้า (The Effectiveness of Polydioxanone (PDO) Thread for Face Lifting: A Pilot Study)

ข้อ 2. ข้าพเจ้ายินยอมเข้าร่วมโครงการวิจัยนี้ด้วยความสมัครใจโดยมิได้มีการบังคับขู่เข็ญหลอกลวงแต่ประการใดและจะให้ความร่วมมือในการวิจัยทุกประการ

ข้อ 3. ข้าพเจ้าได้รับการอธิบายจากผู้วิจัยเกี่ยวกับวัตถุประสงค์ของการวิจัยวิธีการวิจัยประสิทธิผล ความปลอดภัยอาการหรืออันตรายที่อาจเกิดขึ้นรวมทั้งประโยชน์ที่จะได้รับจากการวิจัยโดยละเอียดแล้วจากเอกสารคำอธิบายโครงการวิจัย

ข้อ 4. ข้าพเจ้าได้รับการรับรองจากผู้วิจัยว่าจะเก็บข้อมูลส่วนตัวของข้าพเจ้าเป็นความลับจะเปิดเผยเฉพาะผลสรุปการวิจัยเท่านั้น

ข้อ 5. ข้าพเจ้าได้รับทราบจากผู้วิจัยแล้วว่าหากมีอันตรายใด ๆ **อันเกิดขึ้นจากการวิจัยดังกล่าว**

ข้าพเจ้าจะได้รับการรักษาพยาบาลจากคณะผู้วิจัยโดยไม่คิดค่าใช้จ่ายและจะได้รับค่าชดเชยรายได้ที่สูญเสียไปในระหว่างการรักษาพยาบาลดังกล่าวตลอดจนมีสิทธิ์ได้รับค่าทดแทนความพิการที่อาจเกิดขึ้นจากการวิจัยตามสมควร

ข้อ 6. ข้าพเจ้าได้รับทราบในการติดต่อกับนายแพทย์ กัลยกฤต อยู่รักษ์ หัวหน้าโครงการวิจัยด้วยหมายเลขโทรศัพท์ 084-544-6456 แล้ว

ข้อ 7. ข้าพเจ้าได้รับทราบแล้วว่าข้าพเจ้ามีสิทธิ์จะบอกเลิกการร่วมโครงการวิจัยนี้และการบอกเลิกการร่วมโครงการวิจัยจะไม่มีผลกระทบต่อการดูแลรักษาโรคที่ข้าพเจ้าจะพึงได้รับต่อไป

ข้อ 8. นายแพทย์ กัลยกฤต อยู่รักษ์ หัวหน้าโครงการวิจัยได้อธิบายเกี่ยวกับรายละเอียดต่าง ๆ ของโครงการตลอดจนประโยชน์ของการวิจัยรวมทั้งความเสี่ยงและอันตรายต่าง ๆ ที่อาจจะเกิดขึ้น

ในการเข้าร่วมโครงการนี้ให้ข้าพเจ้าทราบและตกลงรับผิดชอบตามคำรับรองในข้อ 5 ทุกประการ

ข้าพเจ้าได้อ่านและเข้าใจข้อความตามหนังสือนี้โดยตลอดแล้วเห็นว่าถูกต้องตามเจตนา

ของข้าพเจ้าจึงได้ลงลายมือชื่อไว้เป็นสำคัญพร้อมกับหัวหน้าโครงการวิจัยและต่อหน้าพยาน

ลงชื่อ ..... ผู้ยินยอม

(.....)

ลงชื่อ ..... หัวหน้าโครงการวิจัย

(นายแพทย์ กัลยกฤต อยู่รักษ์)

ลงชื่อ ..... พยาน

(.....)

ลงชื่อ ..... พยาน

(.....)

หมายเหตุ

กรณีผู้ยินยอมตนให้ทำวิจัยไม่สามารถอ่านหนังสือได้ให้ผู้วิจัยอ่านข้อความในหนังสือให้ความยินยอมนี้ให้แก่ผู้ยินยอมตนให้ทำวิจัยฟังจนเข้าใจแล้วและให้ผู้ยินยอมตนให้ทำวิจัยลงนามหรือพิมพ์ลายนิ้วหัวแม่มือรับทราบในการให้ความยินยอมดังกล่าวด้วย

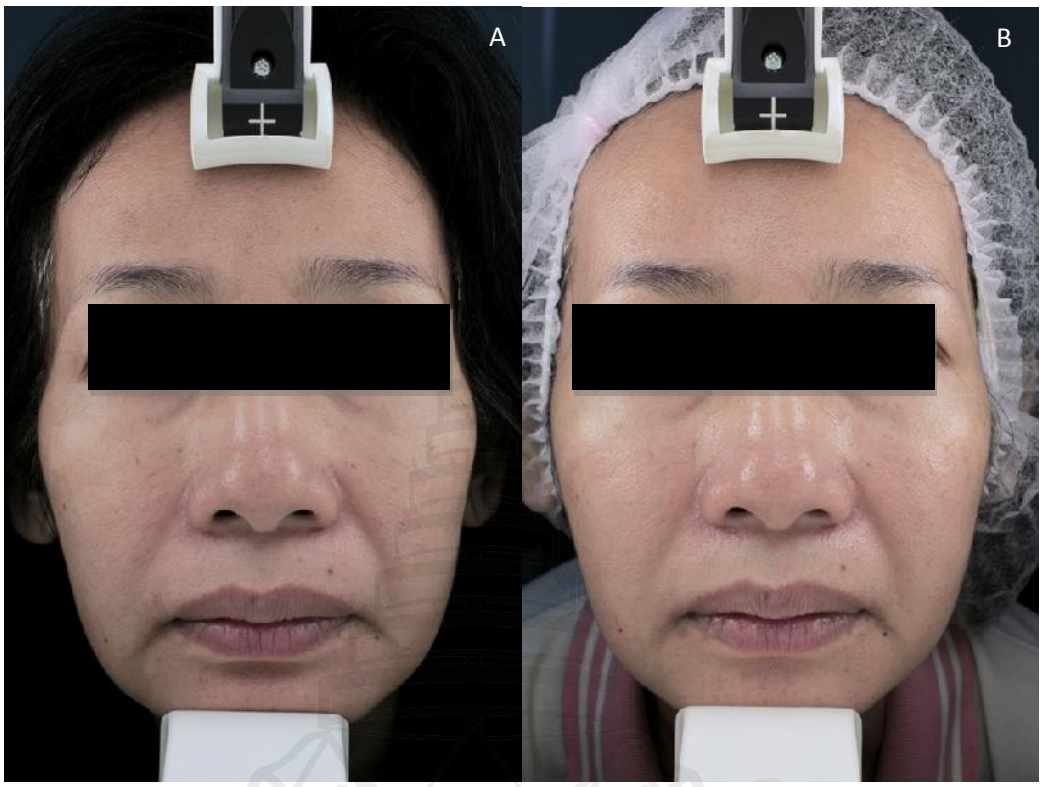


Figure A1 Result of Thread Lifting Compare Between Before Thread Lifting (A) and 12 Weeks (B)

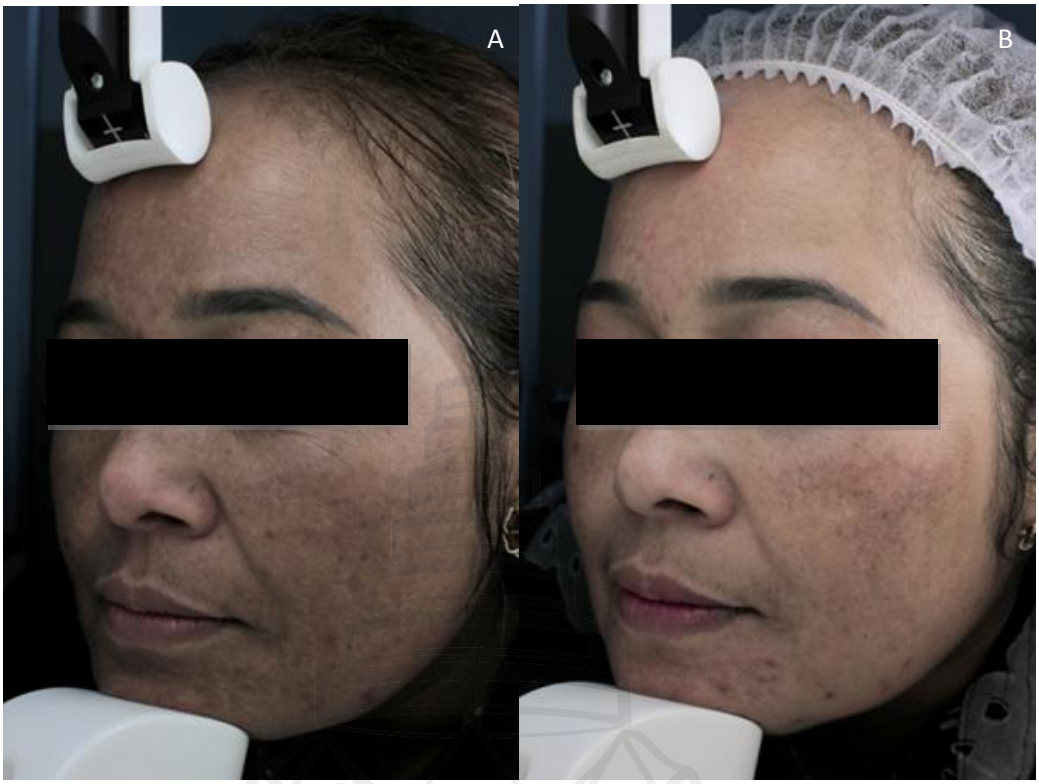


Figure A2 Result of Thread Lifting Compare Between Before Thread Lifting (A) and 12 Weeks (B)

CURRIICULUM VITAE

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NAME	Mr. Kulyakrit Yurugs
DATE OF BIRTH	3 April 1983
ADDRESS	89/28 Samakkee Road, Mueng, Nonthaburi 11000, Thailand

EDUCATION BACKGROUND

2006	Doctor of Medicine Faculty of Medicine Thammasat University, Thailand

WORK EXPERIENCE

2009-2010	Fellowship in surgery: Punyanunthapikku Medical Center, Faculty of Medicine Srinakharinwirot University Nonthaburi
2008-2009	Fellowship in obstetrics and gynecology: Naresuan University Hospital, Faculty of Medicine Naresuan University, Pitsanuloak
2007-2008	Internship & General practitioner: Pootthachinnarat Medical Center, Pitsanuloak