การศึกษาเปรียบเทียบระดับความเจ็บปวดและผลแทรกซ้อนการปลูกถ่ายกระดูกจากกระดูกเชิงกรานส่วนหน้าระหว่างด้านในและด้านนอก

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A RANDOMIZED CONTROLLED TRIAL COMPARING THE PAIN AND MORBIDITY OF HARVESTING BONE GRAFT FROM THE INNER AND OUTER CORTEX OF THE ANTERIOR ILIAC CREST

Mr. Tawechai Tejapongvorachai

A Thesis Submitted in Partial Fulfillment of the Requirements
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วัตถุประสงค์ : การศึกษานี้เพื่อเปรียบเทียบระดับความปวดจากการสกัดกระดูกจากกระดูกเชิงกรานเปลือกด้านในกับเปลือกด้านนอก

สถานที่ทำการวิจัย : โรงพยาบาลจุฬาลงกรณ์ กรุงเทพมหานคร

ประชากรที่ทำการศึกษา : ผู้ป่วยในของภาควิชาออร์โธปิดิกส์ ที่จำเป็นต้องรับการผ่าตัดปลูกถ่ายกระดูก และเข้าได้กับเกณฑ์การศึกษาจำนวน 61 คน

ระเบียบวิธีวิจัย : ผู้ป่วยจำนวน 61 คน ที่จำเป็นต้องรับการปลูกถ่ายกระดูก ถูกเลือกสุ่มเพื่อเลือกใช้วิธีสกัดกระดูกจากกระดูกเชิงกรานเปลือกด้านใน หรือจากเปลือกด้านนอก ผู้ป่วยแต่ละคนจะถูกประเมินอาการปวดบริเวณที่สกัดกระดูกไปโดยใช้ pain visual analog scale และติดตามอาการปวดและผลข้างเคียงเป็นเวลา 3 เดือน ระดับความปวดทั้ง 2 กลุ่ม หลังผ่าตัดวันที่ 7, 30, 90 ถูกเปรียบเทียบด้วยวิธีสถิติ repeated measure ANOVA

ผลการวิจัย : ไม่มีความแตกต่างทางสถิติระหว่าง อายุ, เพศ, ขนาดบาดแผล ทางสถิติระหว่าง 2 กลุ่ม ระดับความปวดในกลุ่มที่สกัดกระดูกจากเปลือกด้านใน 30 คน มีค่าเฉลี่ย 40 ในวันที่ 7,12 ในวันที่ 30, และ 5 ในวันที่ 90 ระดับความปวดในกลุ่มที่สกัดกระดูกจากเปลือกด้านนอก 31 คน มีค่าเฉลี่ย 10 ในวันที่ 7, 10 ในวันที่ 30, และ 0 ในวันที่ 90 โดยการใช้วิธีการทางสถิติ repeated measure ANOVA. พบว่าระดับความปวดในกลุ่มที่สกัดกระดูกจากเปลือกด้านนอกน้อยกว่าจากเปลือกด้านในอย่างมีนัยสำคัญ ($P<0.001$) โดยที่ในกลุ่มที่สกัดกระดูกจากเปลือกด้านในมีผลข้างเคียงจากอาการชาหน้าขา 1 ราย ขณะที่กลุ่มที่สกัดกระดูกจากเปลือกด้านนอกไม่มีผลข้างเคียงอื่นๆ เลย

สรุป : การสกัดกระดูกจากกระดูกเชิงกรานเปลือกด้านนอก มีระดับความปวดน้อยกว่าการสกัดกระดูกจากเปลือกด้านใน

ภาควิชา **ออร์โธปิดิกส์** ลายมือชื่อ.....

สาขาวิชา **ออร์โธปิดิกส์** ลายมือชื่ออาจารย์ที่ปรึกษา.....

ปีการศึกษา 2545

4275382430 : MAJOR HEALTH DEVELOPMENT
KEY WORD : iliac / bone graft / randomized

TAWECHAI TEJAPONGVORACHAI : A RANDOMIZED CONTROLLED TRIAL COMPARING THE PAIN AND MORBIDITY OF HARVESTING BONE GRAFT FROM THE INNER AND OUTER CORTEX OF THE ANTERIOR ILIAC CREST. (THESIS ADVISOR : ASSOC. PROF. TAWESIN TANPRAYOON, M.D.,M.Sc., 32 pp. ISBN 974 - 17 - 1600 - 1)

Objectives : This study compared the donor site pain scores between the inner and outer cortex anterior iliac crest bone graft harvesting

Design : A randomized controlled trial

Setting : King Chulalongkorn Memorial Hospital, Bangkok

Participants : 61 patients, inpatient who required iliac bone graft harvesting

Methodology : A consecutive series of 61 patients ; whose anterior iliac bone graft was randomized harvesting from either inner or outer cortex. The patients were evaluated and asked for the donor site pain measured by visual analog scale and were followed up for pain and other donor site morbidity for 90 days. The pain scores of both groups at 7, 30 and 90 days post operatively were then statistically compared by repeated measure ANOVA.

Results : There was no difference in age, sex and wound size between both groups. The median of pain scores of 30 patients with inner cortex anterior iliac bone graft harvesting were 40 at day 7, 12 at day 30, 5 day 90. The pain scores of 31 patients with outer cortex anterior iliac bone graft harvesting were 10 at day 7, 5 at day 30, 0 at day 90. By using the repeated measure ANOVA; it revealed that the pain scores of the outer cortex group were lower than those of the inner cortex group with statistically significant ($P < 0.001$). One case of the lateral cutaneous nerve of thigh was detected in the inner cortex group.

Conclusions : It's indicated that harvesting anterior iliac bone graft from outer cortex caused less pain than inner cortex.

Department	Health Development	Student's signature……
Field of study	Health Development	Advisor's signature……
Academic year	2002	

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CONTENTS

LISTS OF TABLES

CHAPTER I

RATIONALE AND BACKGROUND

Bone grafting is commonly used to augment bone healing in the surgical treatment of a broad spectrum of musculoskeletal disorders.[1] Bone grafts have been used to reconstruct or replace skeletal defects, to augment fracture repair, to strengthen arthrodeses, and to fill defects after the treatment of bone tumors.[1-7] For over 100 years, autologous cancellous bone grafting has been the standard of care.

Autogenous grafts can be cancellous, nonvascularized cortical, or vascularized cortical: each type has different biologic activities. Ideally, graft substitutes should provide four elements: an osteoconductive matrix, which is a nonviable scaffolding conducive to bone ingrowth; osteoinductive factors, which are the chemical agents that induce the various stages of bone regeneration and repair; osteogenic cells, which have the potential to differentiate and facilitate the various stages of bone regeneration; and structural integrity.[1,3]

Autogenous cancellous bone graft contains three of these components: (1) the hydroxyapatite and collagen are well suited to serve as an osteoconductive framework (2) numerous stromal cells within the lining have osteogenic potential; and (3) the bone graft and the adjacent clot contain a family of growth factors, most notably none morphogenic protein (BMP) and transforming growth factor-beta, which have the ability to induce the regenerative process as well as to augment the process to completion. Autologous cortical bone provides these elements to a more limited extent, but is structure confers strength when needed to fill larger defects.[8]

A number of grafting materials are available as alternatives to autogenous bone graft for a wide range of clinical applications. Allografts can provide structure and osteoconduction; however, they offer limited osteoinduction and no osteoprogeniton; however, they offer limited osteoinduction and on osteoprogenitor cells.[3,6,8] Their indications are similar to those of autologous bone, including repair of nonunions, promotion of arthrodesis, and segmental replacement of long bones,[1-3] However, if the grafting bed is unfavorable (e.g., after infection or if there is poor softtissue coverage), the allograft bone must be augmented with either autograft or another graft substitute that provides growth factors and osteoprogenitor cells. Allograft alone would be contraindicated in treating a 4-cm humeral defect that developed from an infected nonunion. Concerns regarding allografts include fracture, osteointegration, transmission of disease, and infection.[3,6,8]

Ceramics, available in powders, granules, and blocks, are excellent in compression and confer critical structural support. However, they are brittle and have little strength in bending, shear, and tension until incorporated into the existing adjacent bone. Because ceramics are exclusively osteoconductive, they are contraindicated for use by themselves.[9] They must be combined with autograft or have access to a rich bone marrow, but they are effective graft fillers or expanders when patching defects after tumor resection or in a depressed tibial plateau fracture.

Demineralized bone matrix is a limited source of BMP and can be used as an adjunct in the regeneration process. Despite its osteoconductive potential, DBM provides no immediate torque or compressive strength; thus, its use as the sole material would be contraindicated when grafting large cortical segmental defects. Its clinical applications include augmentation of autogenous and allograft bone for repairing fractures, packing cysts, and promoting arthrodesis, and it can be used in both posterolateral lumbar fusions and hip fusions with instrumentation.[6,9,10]

Composite grafts consisting of ceramics, collagen, and bone marrow have been used successfully, but since they are in a form without structure, they must be protected until they have been osteointegrated. They have a role in augmenting limited autogenous bone graft.[11,12]

Bone morphogenic protein is not currently available clinically in a highly purified or recombinant form. The closest alternative is DBM, which is readily available from bone banks. Recombinant BMP is still in clinical trials, but it is accessible to the orthopaedic surgeon in the near future.[1,3,7,8]

When the grafting site is compromised and all three components of osteoconduction, osteoinduction, and osteoprogenitor cells are required, autogenous bone graft is superior.[3,4,6,9,10] Although the other options have some advantages, autologous cortical and cancellous bone are the most commonly used graft materials.[3,4,6,9,10]

The advantages of autologous bone include its osteoinductive and osteoconductive properties.[3,4,6,11-13] Additionally, autologous bone is histocompatible and nonimmunogenic,[4,10,12,14-16] and is usually well incorporated into the graft site. The use of autograft bone also eliminates the potential risk of transplanting infectious disease, as has occurred with allografts.[3,6,8] The disadvantages of autogenous bone graft include limited volume of cancellous bone,[15,19] increased operative time,[1,4] increased blood loss,[1,4] temporary disruption of normal donor site bone structure,[4] and donor site morbidity.[20-25] Although autologous bone can be harvested from the tibia, fibula, olecranon, distal radius, and ribs, the iliac crest remains the most common donor site.[3,4,8,19,24,26]

Postopertively, patients often have more pain from the donor site than from the primary operation. This pain usually resolves over a period of several weeks, but it may

persist and last long. The precise cause of donor site pain remains obscure. It is postulated that it is either periosteal or muscular secondary to the stripping or neurogenic secondary to sensory nerve injury.[19]

Since the inner cortex of iliac bone has loose periosteum, more neural innervation and more chance for neural injuries which can cause neuroma, while the outer cortex has dense periosteum, less neural innervation,[27] these two different bone graft harvesting technique should have different degrees of pain and thus which one has lower pain and less morbidity for the patients?

There is still no comparative study and no universal agreement for this procedure, either the inner or outer cortex harvesting can be used. To better assess the effects and benefits of each procedure and to find out the proper procedure to harvest the anterior iliac crest bone graft. This study is designed to assess the pain outcome of the patients who have undergone the anterior iliac crest bone graft procedures and to document accurately the complication rates associated with this common procedures.

CHAPTER II

LITERATURE REVIEW

The use of bone graft dates back to the work of Ollier and Barth in the 1800s, although in the early 1900s, Axhausen was the first to study its use scientifically.[8,26] Urist.[13] effectively shows the utility of autologous bone, describing its osteoinductive and osteoconductive properties. With inherent advantages over other options, the use of autologous bone from the iliac crest has been commonly used since the turn of the century. However, documented complications in the literature are scant, there is significant morbidity associated with the harvest of bone from the iliac crest. Cockin[21] reviewed 118 cases of iliac crest bone grafts and found minor complaints such as wound pain, wound hypersensitivity, and buttock anesthesia in 6% of cases. He reported a 3.4% incidence of major complications, including meralgia paresthetica, subluxation of the hip after extensive removal of the iliac crest, and 1 case of herniation through the bone graft donor site. Younger and Chapman[28] reported an overall major complication rate of 8.6% after 243 bone grafts from various sites, although 90% were from the iliac crest. Other authors have compared the morbidity of iliac crest harvest with rib grafts or spinous process grafts. Pain is the most frequenlty cited complication of harvesting iliac crest bone grafts. Laurie[24] et al reported that all of their patients had moderate pain that lasted for approximately 6 weeks and that 10% of their patients experienced moderate pain with exercise 2 years or more discomfort lasting for more than 1 year in 36% of their patients in whom an anterior iliac crest bone graft had been harvested. Younger and Chapman[28] reported only a 2.5% incidence of complaints of donor site pain greater than 6 months postoperatively.

Perhaps the most dramatic complication associated with harvesting of iliac crest bone graft is herniation of abdominal contents through the donor defect. This is a rare complication, however, with more than 20 cases reported in several small series and

case reports in the literature. Hernias are associated exclusively with tricortical harvests.[29-38]

Vascular injury involving the superior gluteal artery or 1 of its branches is preventable. The superior gluteal artery is a branch of the internal iliac artery and is in danger as it exits the pelvis to enter the gluteal region through the superior aspect of the sciatic notch.Kurz[23] et al reported 3 cases of superior gluteal artery injury that necessitated bone removal from the sciatic notch to expose the retracted arterial stump. Escalas and Dewald[39] reported the creation of a traumatic arteriovenous fistula and ureteral injury after the inadvertent placement of a Taylor retractor.[23,27,40,41]

Nerve injuries have been associated with harvesting both anterior and posterior iliac crest bones. The lateral femoral cutaneous nerve is a sensory branch of the lumbar plexus, supplying sensation to the lateral aspect of the thigh. It may pass over the crest as much as 2 cm lateral to the anterior superior iliac spine, placing it at risk during anterior iliac crest bone harvest.[25,40]

The ilioinguinal, sciatic, superior gluteal, and femoral nerves are potentially at risk during iliac crest bone graft harvest. Ilioinguinal neuralgia has been reported.[23]

Anterior iliac bone graft harvesting is the one portion that frequently use and the morbidity occur quite obvious as well. Whether inner or outer iliac cortex harvesting will have the less morbidity and less interfere with the function should be considered.

CHAPTER III

RESEARCH DESIGN AND METHODOLOGY

3.1 Research Questions

3.1.1 Primary Research Question

- Does the pain score of the harvesting the anterior iliac bone graft from the inner cortex different from the outer cortex ?

3.1.2 Secondary Research Question

- What is the difference in the complications ? The complications of the interest are those such as nerve or arterial injuries, pelvic fracture, gait disturbances, hematoma, infection, wound breakdown, peritoneal perforation, and hip subluxation.
- What is the difference in the amounts of the pain killer tablet administration ?

3.2 Research Objectives

1. To compare the pain score between the inner and outer cortex harvesting.

2. To find out which methods should be the proper choice for the anterior iliac bone graft harvesting.

3.3 Hypothesis

HO : μ A = μB

H1 : μ A $\neq \mu$B

μ A = mean of pain scores of inner cortex harvesting.

μ B = mean of pain scores of outer cortex harvesting.

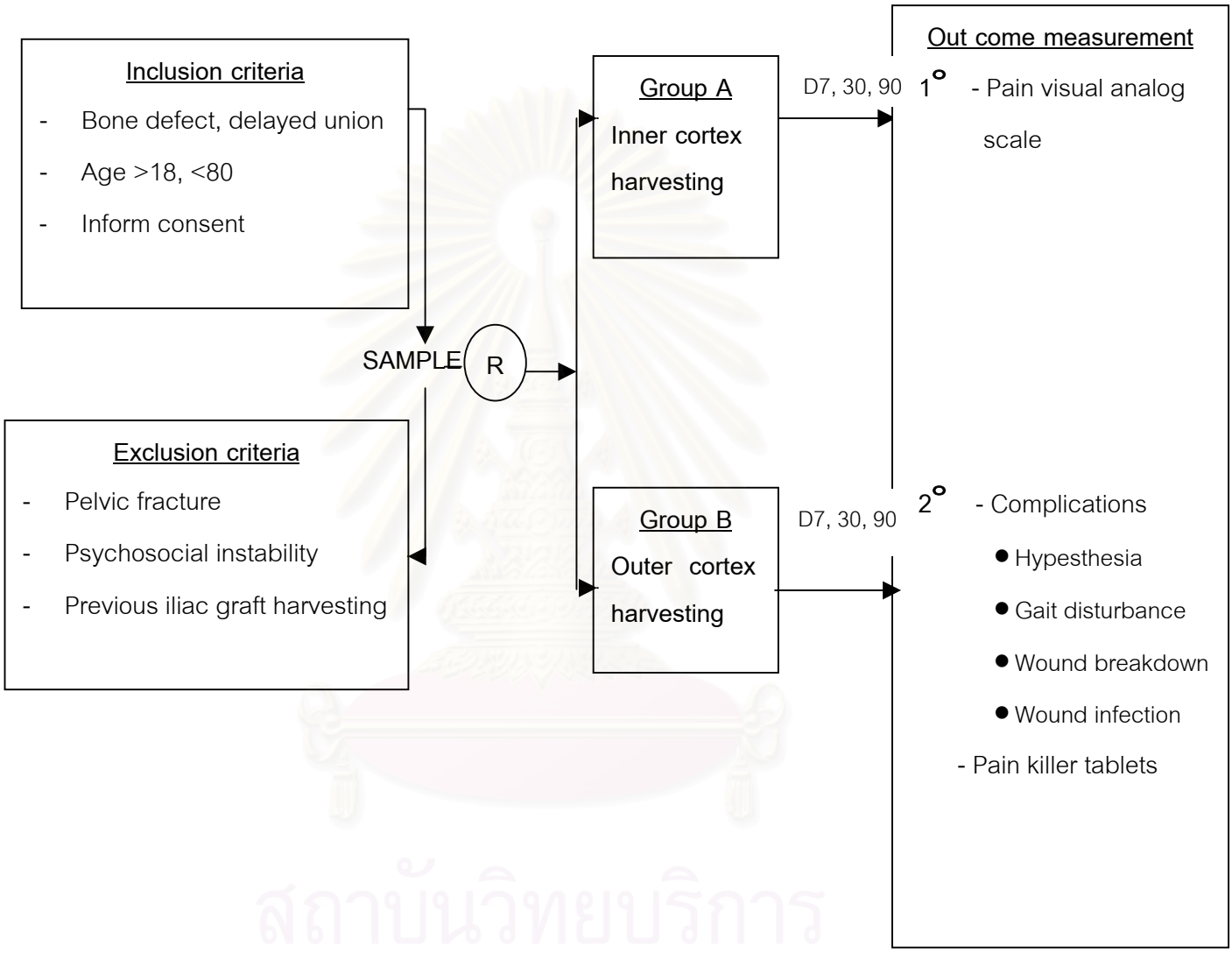
Significant Level 5 %

Power of the test 90 %

Hypothesis testing : unpaired t-test in 2 independent groups

Reject Ho, if P value < 0.05

3.4 Conceptual framework



3.5 Assumption

1. The pain visual analogue score is reliable and sufficient to assess the pain level of the patients with the iliac bone graft harvesting.

2. The surgeons have the equal skills and same technique in harvesting the graft.

3.6 Operational Definition

3.6.1 Pain visual analogue scale : is the pain measurement, normally used only to rate the overall severity of pain. A visual analogue scale is a line that represents the continuum of the symptom to be rated. The scale contains a straight line 10 cm. Long, is marked at the end of labels that indicate the range of pain being considered. The independent evaluator informed the patients that "zero" score is "no pain" and "100" score is unbearable pain or the most severe pain they had ever experienced, and let the patient marked the score of current pain on the line.

3.6.2 Meralgia paresthetica : is a symptom complex that includes numbness and pain in the anterolateral thigh, which may result from either an entrapment neuropathy or a neuroma of the lateral femoral cutaneous nerve. Variations in the anatomy of the lateral femoral cutaneous nerve about the anterior superior iliac spine may place the nerve at higher risk for damage.

3.6.3 Gait disturbance : is a limp, may cause by the joint or soft tissue pathology around the joint.From the iliac bone graft harvesting, it is due to stripping of the muscles, leading to weakness of the gluteus medius

3.6.4 Infection : is the inflammation with the discharge and culture positive for the organisms.

3.6.5 Wound breakdown : is the disruption of the wound without the sign of the infection.

3.6.6 *Complications* : is all the adverse effects at postoperative and follow up period were counted as complications and were recorded.

3.7 Research Design

- Prospective randomized controlled trial with blinded the patients and pain evaluator. The randomization process ensured that the allocation of the treatment is independent of the characteristics of the patients. It also increased the level of the internal validity of the statistical methods of analysis applied which it was based on the assumption of random samples.

3.8 Population and sample

3.8.1 Target population : All patients that required the anterior iliac bone grafting.

3.8.2 Population sample : All patients that required the anterior iliac bone grafting who come to the service of orthopaedic department of King Chulalongkorn memorial hospital and met the inclusion criteria.

3.8.3 Study population : The study population were the patients who passed the eligibility criteria.

3.9 Eligibility criteria

Inclusion criteria

- Bone defect, delayed union, nonunion that require bone grafting.
- Age more than 18 or less than 80.
- Agree to participate and sign the informed consent.

Exclusion criteria

- Associated pelvic fracture, instability or disease.
- Psychosocial instability.
- Previous bilateral anterior iliac bone graft harvesting.

3.10 Sample Size Estimation

- The main outcome is the mean different of the pain score of 2 independent groups of the bone graft harvesting (inner and outer cortex)

Sample size : n/ group = $\frac{2\ \sigma^2}{d^2} (Z \propto/2 + Z\beta)^2$

$Z\propto/2$ is the value of the standard normal distribution cutting off probability $\propto/2$ in each tail = 1.96 for $\propto$ = 0.05

$Z\beta$ is the value of the standard normal distribution cutting off probability β in the upper tail = 1.28 for 90 % power

σ is the standard deviation of the pain score = 25

d is the difference of the pain score between the inner cortex and outer cortex iliac bone graft harvesting. = 15

$$n/group = \frac{2 \times 25^2 \times (1.96+1.28)^2}{15^2}$$

$$= 58.32$$

3.11 Allocation and Concealment

The patients who met the selection criteria were randomized into either group A or B.

Group A : Inner cortex harvesting

Group B : Outer cortex harvesting

The patients were randomly assigned with equal probability to group A or B in each block of the order which the treatment are assigned in each block randomly. With the sample size of 58 cases/group, We used the block of four which was mostly appropriate for this study. After an eligible patient agreed to participate in the study and had signed the informed consent and preparing for the operation in the operating theater, the surgeon would call the research assistant who handled the randomization, and asked for the selection of the cortex harvesting.

3.12 Blinding

The surgeons knew and chose the site of the iliac cortex to harvest from the research assistant, so we could not blind the surgeon. The patients were not informed as to which arm of the randomized grouping they were in. The evaluators of outcomes were also blinded to the treatment arm.

3.13 Confounding factors

The pain outcome can be interfered by many confounding factors such as age, sex, the underlying disease, the primary trauma, The level of activity that injured to the

graft site in the postoperative period, analgesic drugs and the amount of the bone graft harvesting.

The severity of the primary trauma may affect the pain outcome which can explain by the gate control theory. The problem is how to classify the severity of the primary trauma.

The different amount of the bone graft harvesting may cause the different pain outcome. We can measure the amount of the bone graft by 2 methods, First is measured the volume of the bone graft by filling the chip grafts into the syringe and compress to measure the final volume, second is measured by the weight which the cortical bone is dense and has more weight compare to the cancellous bone. We have found that both measuring methods are not reliable. We have agreed to use the same wound size to have the same soft tissue detachment and the same amount of the bone graft.

The analgesic drugs can interfere with the pain. According to the ethics, the patients are allowed to have only the acetaminophen tablets to control the pain and the amount of the acetaminophen will be recorded for the secondary outcome. The other kinds of analgesic drugs such as herbs, cold tablets might still interfere to our pain outcome.

3.14 Outcome measurement

Evaluation of donor sites.

Donor sites were evaluated using three methods :

1). Examination of the medical record

2). Patient interview with the questionnaire

3). Physical examination the donor-site problems were documented for the ilium.

Primary outcome

1. Pain: The pain visual analogue scale was used. The pain visual analogue scales was proof to be a robust, sensitive, reproducible method of expressing pain severity and results correlate well with other methods of measuring pain.[42] The method is applicable to all patients regardless of language and can be used by children aged 5 or more years. All available patients were asked to complete a postoperative pain questionnaire to assess overall current health states and pain level.

Secondary outcome

2. Complications

The status of wound infection, paresthesia, hematoma and gait disturbances related to the iliac crest donor site were determined.

The pain score and complications were assessed at 1 week, 3 months and 6 months postoperatively.

3. Pain killer tablets

According to the ethics, The patients were allowed to have the pain killer tablets during the postoperative period.

The only pain killer tablets allowed in this study was the acetaminophen. The amounts of acetaminophen were recorded to compare.

3.15 Intervention

Five orthopaedic surgeon with more than two years experience had joined in this study. Each surgeon agreed to use the same surgical technique and the same tools. The iliac bone graft harvesting was quite commonly procedure that there would be not the differences in the surgical results between each surgeon.

- *The inner cortex harvesting*

In supine position, the incision 3-6 cm behind the anterior superior iliac supine was made, after stripping and elevation of the medial periosteum and iliacus muscle. With an osteotome or bone gouge, the cortico-cancellous graft was seperated from the inner table and removed. After haemostasis with the application of gelfoam in the bone cavity, the wound was closed in layers.

- *The outer cortex harvesting*

Use the same surgical technique as the inner cortex harvesting, except stripping and elevation of the lateral periosteum as well as the muscle.

3.16 Data Management

Data collection

- Zero state and demographic variables were recorded from the in patient and out patient records including name, age, address, operative note, blood loss, scar formation.

- Pain variable which were collected by the pain visual analogue scale

- Complications

All minor and major complications associated with the harvesting of the iliac crest bone graft such as incidence of neural or vascular injuries, infections, hematoma, gait disturbances or wound disruption will be determined and recorded.

- Pain killer tablets

The amounts of the acetaminophen administration in the postoperative period were collected.

Data analysis

Data analysis was evaluated on the intention to treat basis by using SPSS statistical program. (SPSS for Windows Version 10.1, SPSS Inc.)

- The Zero state, demographic variables will be collected by mean, S.D.
- The pain outcome will be analysed by repeated measure ANOVA, as well as 95% confidence internal.
- The complications were analysed by chi square test or Fisher exact test and 95% confidence interval.

3.17 Limitation and Obstacles

- Number of patients

At first, we planned to include King Chulalongkorn and Queen Sawangwattana memorial hospital for gathering the sample which there would be about 40-50 cases/ year of iliac bone graft harvesting in each hospital. Finally, we found that there were so many problems in gathering the cases in Queen Sawangwattana memorial hospital such as the rotating of the doctors were very fast as well as the data collection. So, we excluded the gathering sample there.

- We need a period of 3 months to evaluate and follow up the postoperative pain outcome and other morbidity, which would consume more time for the research.

- The pain outcome may obscure by the underlying disease or trauma that may be difficult to interprete, which can be explained by the gate control theory.

- Randomization is limited to only the patients, we can not random the surgeons as long as our department divided into divisions and perform the operations individually.

3.18 Ethical consideration

Both procedures were standard and believed to have the same bony union outcome. This research proposal was submitted and approved by the Ethics Committee of the Faculty of Medicine, Chulalongkorn University. Every patients was explained about the detail of the study. Patient information forms and informed consent was a prerequisite before the study.

CHAPTER IV

RESULTS

From December 2000 to December 2002,Sixty-one donor sites were evaluated in 61 patient, 30 from the inner iliac cortex and 31 from the outer iliac cortex. The primary traumas consisted of 11 upper extremity fractures, 34 lower extremity fracture, 3 multiple fractures and 13 spine surgery. The analysis was based on the intention to treat analysis.

4.1 Base line data

Table 4.1 : Base line data

	Inner cortex	Outer cortex
Age (mean, SD)	42.27 $\pm$ 14.10	44.26 $\pm$ 16.05
Sex male	20	19
female	10	12
Wound length (cm.)	5.55 $\pm$ 2.94	5.03 $\pm$ 1.25

The base line characteristics of the two groups were comparable. The age was ranged from 19-68 years old in the inner iliac cortex groups and ranged from 18-79 years old in the outer iliac cortex group. The mean wound length was 5.55 cm. in the inner cortex and 5.03 c.m. in the outer cortex. The age, sex and wound length of the inner and outer iliac cortex donor sites were not statistically different.

4.2 Postoperative pain score

Table 4.2 : Descriptive statistics on postoperative pain score

	CORTEX	Median	Min/Max
Day 7	inner	40	5/100
	Outer	10	3/40
Day 30	inner	12	2/75
	Outer	5	0/20
Day 90	inner	5	0/30
	Outer	0	0/20

Table 4.3 : Test of within-subjects effect of post operative pain

Source		Type III Sum of Squares	df	Mean Square	F	Sig.
D	Greenhouse-Geisser	14210.344	1.333	10659.060	82.030	.000
D*CORTEX	Greenhouse-Geisser	2024.144	1.333	1518.294	11.685	.000
D	Greenhouse-Geisser	10047.511	77.324	129.941		

Table 4.4 : Test of Between subjects effect of postoperative pain

(I) D	(J) D	Mean Difference (I-J)	Std. Error	Sig.[a]	95% Confidence Interval for Difference[a]	
					Lower Bound	Upper Bound
1	2	13.317*	1.754	.000	9.806	16.827
1	3	21.567*	2.134	.000	17.295	25.838
2	3	8.250*	1.016	.000	6.217	10.283

Table 4.5 : Acetaminophen administration in each group

		Inner cortex	Outer cortex	Sig.
Analgesics	Day 7	72	20	<0.001
	Day 30	28	2	<0.001
	Day 90	0	0	-

The pain score at 1 week, 30 days, 90 days postoperatively in the outer cortex group was lower than the inner cortex group significantly. The postoperative donor site pain at 3 months persisted in twenty-three patient (76.7 percents) in the inner cortex group and 9 patients (29 percents) in the outer cortex group. There was a significant difference of the pain score at 1 week, 30 days, 90 days postoperatively (within subject factor) $p<0.001$. The acetamenophen usages in the inner cortex groups were more than the outer cortex group significantly. This means the inner cortex group had more postoperative donor site pain even if taking more analgesic pills and lasting more than the outer cortex group.

4.3 Complications

Table 4.6 : Complications

	Inner cortex	Outer cortex	Sig.
Gait disturbance (> 3 Mon)	0	0	-
Hypesthesia of thigh	1/30	0/31	NS
Meralgia paresthesia	0	0	-
Wound breakdown	0	0	-
Wound infection	0	0	-

No patient had a gait disturbance after 3 months. 1 patients (3 percents) in the inner cortex group had hypesthesis or anesthesia over the distributation of the lateral cutaneous nerve of the thigh. There were no cases of meralgia paresthetica, wound break down and wound infection.

All the patients were completed the questionnaires during the admission on the first week and follow up at 1, 3 month. There were no loss of follow-up.

Table 4.7 : A summary of the data and results

		Inner cortex	Outer cortex	Sig.
Age (mean, SD)		42.27 ± 14.10	44.26 ± 16.05	-
Sex (male : female)		20 : 10	19 : 12	-
Wound length		5.55 ± 2.94	5.03 ± 1.25	-
Pain (> 3 Mon)		76.67% (23/30)	29.03% (9/31)	<0.001
Gait disturbance (1 > 3 Mon)		0	0	-
Hypesthesia of thigh		1/30	0/31	NS
Meralgia paresthesia		0	0	-
Wound breakdown		0	0	-
Wound infection		0	0	-
Analgesic	Day 7	72	20	<0.001
	Day 30	28	2	<0.001
	Day 90	0	0	-

Table 4.8 : A summary of the pain score

		Inner cortex	Outer cortex
Mean pain score	Day 7	36.27	15.20
	Day 30	18.43	6.40
	Day 90	6.50	1.83

Repeated measure ANOVA, F = 82.03, df 1.333, p< .001

CHAPTER V

DISCUSSION

Donor-site pain is the most frequent complaint that must be considered when choosing the ilium as a bone graft.[24] The iliac donor site pain persisting for more than 3 months has been reported in up to 15% of the patients and usually has more severe than the pain of the primary operative site. Many patients have persisting pain at their donor site long after their recipient sites have ceased.[41,43,44]

Pain is the subjective symptom and difficult to measure. However, the pain visual analogue scale was accepted for its validity and reliability. In addition, it gives more sensitive and precise measurements than the other descriptive pain scales.[42] Visual analog scale was used to evaluate the postoperative pain at day 7, day 30 and day 90. At that time, the potent analgesics as well as the narcotics would be ceased and allowed the usage of acetaminophen for the pain killer. The scores of the pain visual analogue scale that marked by the patients themselves and the amounts of the acetaminophen would represent their usual pain. The selection bias for the intervention was prevented by the block randomization which the surgeons could not select type of operation by themselves. The measurement bias was prevented by blinding the evaluator about the type of the operation.

In our series, we found the severity; persistence of pain from the outer iliac cortex was less and shorter than the inner iliac cortex harvesting. 23 patients (76.7 percents) reported pain at the inner iliac crest donor site during the first 3 months after surgery comparing to 9 patients (29.0%) of the outer iliac crest donor site. Although the incidence of pain after harvesting decreased with time. This can compare to the report of De Palma,[43] which found the pain and discomfort lasting for more than 1 year in 36% of their patients in whom an anterior crest bone graft had been harvested, while

Arrington[45] reported the persistence of pain in 37.9% of the patient at 6 months after surgery. Our series had the smaller numbers of pain persisting when the outer cortex were harvesting.

Recently, Ahlmann[46] reported fifty eight patients, comparison of anterior and posterior iliac crest bone grafting, a major complication was associated with 8% (five) of the sixty-six anterior sites and 2% (one) of the forty-two posterior sites. The rates of minor complications were 15% (ten) and 0%, respectively. The postoperative pain at the donor site was significantly more severe and of greater duration after the anterior harvests. In this series, the complication rate was lower than those previously reported by the other investigators but was comparable with our results. Murata[47] found the risk of injury to the lateral femoral cutaneous nerve during harvest of iliac bone graft, related to the depth (>30mm.) and width (>45mm.) of the graft, which caused by too much retraction of the periosteum and muscle or injury to the nerve during the nerve cross the iliac crest. Murata[47] also reported 20% of the lateral femoral cutaneous nerve of thigh crossed the superior surface of the ilium instead of passing beneath the inguinal ligament at the anterior superior iliac spine which could cause the nerve at risk for the injury.

Technical modifications to overcome the problem of pain at the donor wound site include the use of anesthetic regimens, a pneumatic gouge to harvest the bone , minimally invasive tools, vertical or oblique incisions to avoid cutting cutaneous nerves, incisions<3cm. dorsal to the anterior superior iliac spine, subperiosteal dissection with careful hemostasis, and a unicortical bone graft harvesting technique.[48-52] In our study, the outer unicortical bone harvesting would be one of the solution to overcome the donor site pain problems.

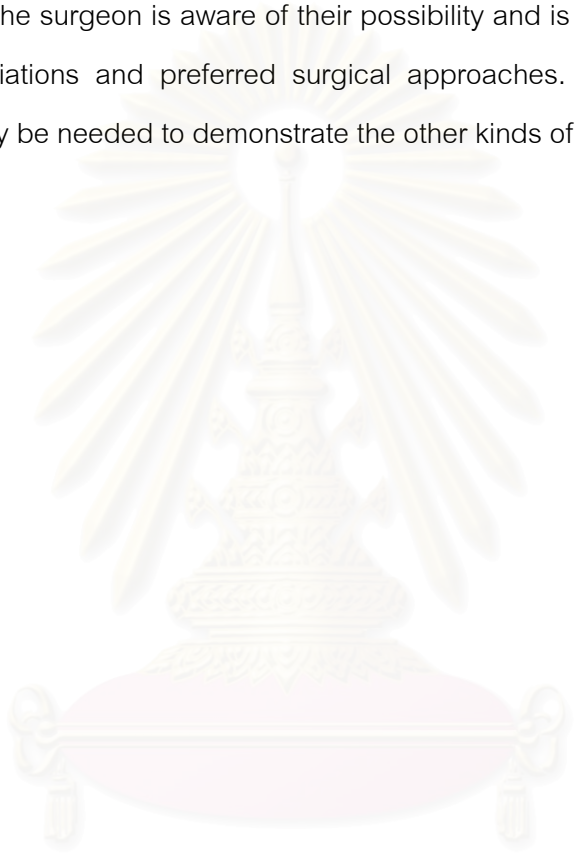
The more severity and persistence of pain from the inner iliac cortex harvesting may originated from the more neural innervation as the lateral femoral cutaneous,

ilioinguinal and iliohypogastric nerve were passed nearby the medial aspect of the ilium. The nerves and their branches may be injured during harvesting. The lateral femoral cutaneous nerve was injuried in one of thirty cases with the inner iliac cortex harvesting. The outer cortex harvesting is safer because it is further from the normal course of the nerve. Besides of the lateral iliac bone graft harvesting, the skin and soft tissue dissection, the amount of the bone graft also affect the magnitude of the pain as we try to control the size of the surgical wound and use the randomization to minimize the effect of the volume of the bone, while we can't limit the amount of the bone graft to be harvested. In addition, the longer follow-up will be necessary to find out the time of pain cessation.

From our series, there were no gait disturbances in either groups at 3 months. The gait disturbances has been reported in up to 3% of patients especially from the outer cortex harvesting.[45] A limp or an abductor lurch due to extensive stripping of the outer table muscles, leading to weakness of the hip abductors, primarily the gluteus medius. This problem was rarely occur for the anterior iliac crest which the lateral iliac cortex harvesting was the attachment of gluteus minimus muscle. Gait problems may be more common when the more posterior crest muscle attachments are affected (quadratus lumborum and erector spinal), as is more often the case in orthopaedic practice where posterior grafts are used.

Besides of the pain, the other kinds of morbidity seem to be very few. Reported rates of the donor site infection have ranged from 0% to 3% in contemporary series.[27,43] The absence of postoperative infections in our study may be contributed to the facts that all patients were receiving intravenous antibiotics for the treatment of the infection at the time of the bone graft harvest. Hematoma formation has been reported in 1% to 10% of patients following harvesting of iliac bone grafts[21,28], and it has been associated with increased risk for infection. Such a complication had not found in our study, this might be affected by our graft harvesting procedure that were carefully taken and

followed the standard surgical technique, the gelfoam was packed in the donor site as well as the bone wax was used to control active bleeding from the bone, the surgical exposures were limited 3 cm from the anterior superior iliac spine to avoid the nerve injury, not perforate the deeper cortex to avoid the internal structure as well as the proper reapproximation of the periostium and fascia. Most of these complications are avoidable when the surgeon is aware of their possibility and is familiar with the involved anatomy, its variations and preferred surgical approaches. In our study, the more sample sizes may be needed to demonstrate the other kinds of morbidity.



CHAPTER VI

CONCLUSIONS AND RECOMMENDATION

Autologous bone harvested from the ilium is commonly used as a grafting material in surgical reconstructive and arthrodesis procedures to ensure a satisfactory postoperative outcome. However, operative removal of bone from the iliac crest requires an additional surgical procedure with a distinct set of postoperative complications. Most severe complications are rare, but the severity and chronicity of pain at the donor site exceeding three months in duration occurs frequently and can be particularly bothersome to patients.

we have demonstrated that the severity and persistence of pain is greater for the inner iliac cortex harvesting, while the pain from the outer cortex is less and shorter and safe. We recommend the outer iliac cortex harvesting whenever the anterior iliac graft is needed. To avoid the morbidity from the autogenous bone graft, the other bone graft sources, such as allografts or bone substitutes may be used. The bone allograft is still limited since it is not widely available and not safe for the transmitted disease, while the bone substitutes are still very expensive and not available.

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Appendix

Case	Cortex	Age	Sex	Size	D7	D30	D90	P7	P30	P90
1	inner	22.00	male	3.00	43.00	12.00	.00	2.00	.00	.00
2	inner	45.00	male	5.00	5.00	2.00	1.00	.00	.00	.00
3	inner	65.00	female	6.50	50.00	25.00	10.00	4.00	2.00	.00
4	inner	50.00	male	6.00	40.00	30.00	10.00	4.00	4.00	.00
5	inner	19.00	male	5.00	20.00	20.00	5.00	.00	.00	.00
6	inner	68.00	female	6.00	50.00	75.00	30.00	4.00	2.00	.00
7	inner	32.00	male	5.00	30.00	5.00	5.00	4.00	.00	.00
8	inner	33.00	male	7.00	10.00	10.00	5.00	2.00	.00	.00
9	inner	24.00	female	8.00	10.00	2.00	2.00	.00	.00	.00
10	inner	45.00	male	6.00	10.00	10.00	6.00	.00	.00	.00
11	inner	41.00	male	6.00	50.00	20.00	10.00	2.00	.00	.00
12	inner	34.00	male	5.00	10.00	10.00	.00	.00	.00	.00
13	inner	64.00	female	4.00	50.00	30.00	10.00	4.00	2.00	.00
14	inner	28.00	male	4.00	20.00	10.00	10.00	.00	.00	.00
15	inner	46.00	male	6.00	50.00	10.00	5.00	6.00	2.00	.00
16	inner	28.00	male	5.00	20.00	10.00	.00	.00	.00	.00
17	inner	41.00	female	4.00	40.00	15.00	5.00	2.00	.00	.00
18	inner	51.00	male	4.00	50.00	30.00	5.00	6.00	2.00	.00
19	inner	43.00	male	5.00	30.00	20.00	15.00	2.00	2.00	.00
20	inner	31.00	male	5.00	20.00	10.00	.00	.00	.00	.00
21	inner	52.00	female	4.00	70.00	30.00	5.00	4.00	2.00	.00
22	inner	35.00	male	4.00	100.00	40.00	15.00	6.00	2.00	.00
23	inner	65.00	female	6.00	80.00	30.00	12.00	4.00	2.00	.00
24	inner	52.00	female	5.00	40.00	12.00	4.00	2.00	.00	.00
25	inner	34.00	male	5.00	10.00	10.00	.00	2.00	.00	.00
26	inner	64.00	female	4.00	50.00	30.00	10.00	4.00	2.00	.00
27	inner	28.00	male	4.00	20.00	10.00	10.00	.00	.00	.00
28	inner	46.00	male	6.00	50.00	10.00	.00	4.00	2.00	.00
29	inner	28.00	male	5.00	20.00	10.00	.00	.00	.00	.00
30	inner	54.00	female	4.00	40.00	15.00	5.00	4.00	2.00	.00
31	outer	22.00	male	5.00	9.00	5.00	.00	.00	.00	.00
32	outer	24.00	male	4.00	3.00	.00	.00	.00	.00	.00
33	outer	48.00	male	5.50	40.00	20.00	.00	2.00	.00	.00
34	outer	60.00	female	4.50	6.00	3.00	.00	.00	.00	.00
35	outer	24.00	male	5.00	10.00	20.00	20.00	2.00	.00	.00
36	outer	22.00	male	5.00	20.00	3.00	3.00	.00	.00	.00
37	outer	37.00	male	3.00	3.00	.00	.00	.00	.00	.00
38	outer	24.00	female	6.00	8.00	2.00	1.00	.00	.00	.00
39	outer	32.00	male	7.00	7.00	7.00	.00	.00	.00	.00
40	outer	18.00	female	6.00	18.00	10.00	10.00	2.00	.00	.00
41	outer	37.00	male	6.00	10.00	3.00	3.00	.00	.00	.00
42	outer	32.00	male	5.00	15.00	.00	.00	.00	.00	.00
43	outer	58.00	female	5.00	10.00	5.00	4.00	.00	.00	.00
44	outer	41.00	male	6.00	40.00	20.00	5.00	2.00	.00	.00

45	outer	62.00	female	4.00	10.00	5.00	.00	.00	.00	.00
46	outer	67.00	female	4.00	5.00	.00	.00	.00	.00	.00
47	outer	60.00	male	6.00	10.00	5.00	.00	.00	.00	.00
48	outer	32.00	male	5.00	5.00	.00	.00	.00	.00	.00
49	outer	54.00	male	4.00	10.00	.00	.00	.00	.00	.00
50	outer	35.00	male	6.00	30.00	10.00	.00	2.00	.00	.00
51	outer	39.00	male	5.00	10.00	7.00	.00	2.00	.00	.00
52	outer	51.00	female	4.00	20.00	5.00	.00	.00	.00	.00
53	outer	64.00	female	4.50	30.00	8.00	.00	2.00	.00	.00
54	outer	36.00	female	4.00	20.00	5.00	.00	.00	.00	.00
55	outer	79.00	male	5.00	25.00	10.00	.00	2.00	.00	.00
56	outer	50.00	male	4.50	10.00	4.00	.00	.00	.00	.00
57	outer	60.00	male	5.00	10.00	5.00	.00	.00	.00	.00
58	outer	42.00	female	4.00	5.00	.00	.00	.00	.00	.00
59	outer	58.00	female	5.00	10.00	5.00	4.00	.00	.00	.00
60	outer	41.00	male	5.00	40.00	20.00	5.00	4.00	.00	.00
61	outer	62.00	female	4.00	10.00	5.00	.00	.00	.00	.00

ใบยินยอมเข้ารับการผ่าตัดปลูกถ่ายกระดูกจากกระดูกเชิงกราน

1. คำชี้แจงเกี่ยวกับโรคที่ผู้ป่วยได้รับการวินิจฉัย

การผ่าตัดปลูกถ่ายกระดูกจากกระดูกเชิงกรานเป็นการผ่าตัดที่ต้องทำกันเป็นประจำ ซึ่งมีข้อบ่งชี้ในกรณีต่าง ๆ ดังนี้คือ การมีช่องว่างของกระดูกจากการทำลายของเนื้องอก การติดเชื้อหรือความผิดปกติโดยกำเนิด, เพื่อเชื่อมกระดูกที่ไม่ติดหรือติดช้ากว่าปกติ เพื่อการเชื่อมข้อต่อที่ไม่ต้องการการเคลื่อนไหวเป็นต้น การผ่าตัดปลูกถ่ายกระดูกจากกระดูกเชิงกรานส่วนหน้า สามารถที่จะผ่าตัดเอาส่วนของกระดูกด้านในหรือด้านนอกก็ได้ โดยทั้ง 2 วิธีถือว่าเป็นวิธีมาตรฐานที่ทั่วโลกยอมรับ

2. คำชี้แจงเกี่ยวกับขั้นตอน, วิธีการและผลข้างเคียง

ในการผ่าตัด ผู้ป่วยจะต้องเตรียมตัวรับการผ่าตัดตามปกติ คืองดน้ำและอาหารหลังเที่ยงคืน แพทย์วิสัญญีอาจจะใช้วิธีฉีดยาชาเข้าไขสันหลังหรือใช้วิธีดมยมสลบ ขึ้นกับบริเวณที่จะปลูกถ่ายกระดูกลงไป การผ่าตัดจะใช้แผลผ่าตัดตามแนวบนของกระดูกเชิงกรานส่วนหน้าโดยอาจจะเป็นด้านขวาหรือซ้ายก็ได้ แผลจะยาวประมาณ 5 เซนติเมตร ใช้เครื่องมือปลอกเยื่อหุ้มกระดูกออกจากกระดูกเชิงกรานด้านในหรือด้านนอก แล้วจึงขูดกระดูกออกมาตามปริมาณที่ต้องใช้ในแต่ละราย หลังการขูดกระดูกจะเย็บแผลปิดด้วยไหมเย็บและตัดไหม ประมาณวันที่ 10 -14 หลังผ่าตัดกระดูกเชิงกรานเป็นบริเวณที่สามารถเอากระดูกออกมาใช้ประโยชน์ได้ โดยไม่มีผลเสียหายมากมายต่อการใช้งานของร่างกาย ผลเสียหรือผลแทรกซ้อนที่อาจจะเกิดจากการผ่าตัดปลูกถ่ายกระดูกเชิงกราน ได้แก่ แผลจากการผ่าตัด การบาดเจ็บต่อเส้นประสาท ผลต่อการเดิน การติดเชื้อ รวมทั้งอาการปวดบริเวณที่ผ่าตัด เป็นต้น อย่างไรก็ดีถ้ามีความผิดปกติที่แผลผ่าตัดให้มาพบแพทย์ได้ที่ห้องตรวจศัลยกรรมออร์โธปิดิกส์ ตึก ภปร. ชั้น 5 รพ.จุฬาลงกรณ์ ยกเว้นวันหยุดราชการให้ไปที่ห้องฉุกเฉิน หรือติดต่อผู้วิจัยได้ที่หมายเลขโทรศัพท์ 02-256-4230, 02-256-4510

3. ประโยชน์ที่ผู้ป่วยจะได้รับ

การศึกษานี้จะเป็นประโยชน์ต่อผู้ป่วยที่ต้องรับการผ่าตัดปลูกถ่ายกระดูกจากกระดูกเชิงกราน ในอันที่จะมีวิธีผ่าตัดมาตรฐานที่ดีที่สุด และมีผลข้างเคียงน้อยที่สุด เพื่อใช้ในการรักษาผู้ป่วยต่อไป

4. **คำชี้แจงเกี่ยวกับสิทธิของผู้ป่วย**

ผลจากการศึกษานี้ จะนำมาใช้ในงานวิจัยของภาควิชาออร์โธปิดิกส์ โรงพยาบาลจุฬาลงกรณ์ ผู้ป่วยจะไม่เสียค่าใช้จ่ายเพิ่มเติมแต่อย่างใด นอกจากนี้ผู้ป่วยมีสิทธิที่จะปฏิเสธการผ่าตัดหรือเลือกวิธีผ่าตัดได้ โดยยังมีสิทธิที่จะได้รับการดูแลจากแพทย์ตามปกติ

5. **คำยินยอมของผู้ป่วย**

ข้าพเจ้าได้อ่านและทำความเข้าใจในข้อความทั้งหมดของใบยินยอมครบถ้วนดีแล้ว ทั้งนี้ข้าพเจ้ายินยอมที่จะเข้ารับการผ่าตัดปลูกถ่ายกระดูกจากกระดูกเชิงกรานส่วนหน้า ด้วยความสมัครใจ โดยไม่มีการบังคับหรือให้อามิสสินจ้างใด ๆ

วันที่……เดือน……พ.ศ……

ผู้ป่วย……..

(……..)

ชื่อพยาน……..

(……)

ผู้ได้รับอนุญาต 1……แพทย์ผ่าตัด

(……..)

ใบอนุญาตประกอบวิชาชีพเวชกรรมเลขที่ ……

2……..แพทย์ผู้วิจัย

(……..)

ใบอนุญาตประกอบวิชาชีพเวชกรรมเลขที่ ……

VITAE

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